

CELL THERAPEUTICS INC  
Form 10-K/A  
April 28, 2006  
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UNITED STATES

**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

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**FORM 10-K/A**

**(AMENDMENT NO. 1)**

(Mark One)

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

For the fiscal year ended December 31, 2005

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 Number)

501 Elliott Avenue West, Suite 400

Seattle, WA 98119

98119

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code: (206) 282-7100

Securities registered pursuant to Section 12(b) of the Act:

None.

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Securities registered pursuant to Section 12(g) of the Act:

Title of each class

Name of each exchange on which registered

**Common Stock, no par value**

**NASDAQ National Market**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer  Accelerated filer  Non-accelerated filer

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

The aggregate market value of the voting and non-voting common equity held by nonaffiliates as of December 31, 2005 was approximately \$181,725,000, based on the closing price of such shares on the NASDAQ National Market on June 30, 2005. Shares of common stock held by each executive officer and director and by each person known to the Company who beneficially owns more than 5% of the outstanding Common Stock have been excluded in that such persons may under certain circumstances be deemed to be affiliates. This determination of executive officer or affiliate status is not necessarily a conclusive determination for other purposes.

The number of outstanding shares of the registrant's common stock as of March 10, 2006 was 101,272,228.

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**DOCUMENTS INCORPORATED BY REFERENCE**

None.

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**EXPLANATORY NOTE**

This Amendment No. 1 on Form 10-K/A ( Form 10-K/A ) to our Annual Report on Form 10-K for the fiscal year ended December 31, 2005, initially filed with the Securities and Exchange Commission ( SEC ) on March 16, 2006 (the Original Filing ), is being filed to include information required by Items 10, 11, 12, 13 and 14 under Part III. This information is being included in this Form 10-K/A because our definitive proxy statement will not be filed within 120 days after the end of our 2005 fiscal year. Reference to our proxy statement on the cover page of this Form 10-K/A has been deleted.

In addition, pursuant to the rules of the SEC, Item 15 of Part IV of the Original Filing has been amended to contain currently-dated certifications from our Chief Executive Officer and Chief Financial Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002. The certifications of our Chief Executive Officer and Chief Financial Officer are attached to this Form 10-K/A as Exhibits 31.1 and 31.2, respectively.

Except for the foregoing amended information, this Form 10-K/A continues to describe conditions as of the date of the Original Filing, and we have not updated the disclosures contained herein to reflect events that occurred at a later date.

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### **Forward Looking Statements**

This Form 10-K and the documents incorporated by reference contain, in addition to historical information, forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act ) and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act ). These statements relate to our future plans, objectives, expectations, intentions and financial performance, and assumptions that underlie these statements. All statements other than statements of historical fact are forward-looking statements for the purposes of these provisions, including:

any projections of future earnings, revenues or other financial items;

any statements of the plans and objectives of management for future operations;

any statements concerning proposed new products or services;

any statements regarding future operations, plans, regulatory filings or approvals;

any statements on plans regarding proposed or potential clinical trials or new drug filing strategies;

any statements concerning proposed new products or services;

any statements regarding pending or future mergers or acquisitions; and

any statement regarding future economic conditions or performance, and any statement of assumption underlying any of the foregoing. When used in this Form 10-K, terms such as anticipates, believes, continue, could, estimates, expects, intends, may, plans, should, or will or the negative of those terms or other comparable terms are intended to identify such forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors that may cause industry trends or actual results, level of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these statements. Our actual results may differ significantly from the results discussed in such forward-looking statements. These factors include, but are not limited to, those listed under Factors Affecting Our Operating Results and Financial Condition, Management's Discussion and Analysis of Financial Condition and Results of Operations, Business and elsewhere in this Form 10-K.

We will not update any of the forward-looking statements after the date of this Form 10-K to conform these statements to actual results or changes in our expectations. Readers are cautioned not to place undue reliance on these forward-looking statements, which apply only as of the date of this Form 10-K.

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**PART I**

**Item 1. Business**

**Overview**

We develop, acquire and commercialize novel treatments for cancer. Our goal is to build a leading biopharmaceutical company with a diversified portfolio of proprietary oncology drugs. Our research, development, acquisition and in-licensing activities concentrate on identifying and developing new, less toxic and more effective ways to treat cancer. We are developing XYOTAX, paclitaxel poliglumex, for the treatment of non-small cell lung cancer, or NSCLC, and ovarian cancer. Our STELLAR 2, 3, and 4, phase III clinical studies for XYOTAX did not meet our primary endpoint of superior overall survival. However, we believe a pooled analysis of STELLAR 3 and 4 demonstrates a statistically significant survival advantage among women receiving XYOTAX when compared to women or men receiving standard chemotherapy. A survival advantage for women over men was also demonstrated in a first-line phase II clinical trial of XYOTAX and carboplatin, known as the PGT202 trial, supporting the potential benefit observed in the STELLAR first-line trials. We believe the lack of safe and effective treatments for women with advanced first-line NSCLC who are performance status 2 represents an unmet medical need. We plan to submit a new drug application, or NDA, with the U.S. Food and Drug Administration, or FDA, for XYOTAX as first-line monotherapy for women with advanced NSCLC who have poor performance status (PS2) based on data from the pooled analysis of our STELLAR 3 and 4 first-line trials and our PGT202 study. To support this application, we have initiated an additional study, known as the PIONEER, or PGT305, study, for XYOTAX as first-line monotherapy in PS2 women with NSCLC, with a target of having interim results available from this study at the time of FDA review of that NDA, as an alternative to waiting for the completion of the study. In Europe, we plan to submit a marketing authorization application, or MAA, based on a non inferior survival and improved side effect profile which we believe was demonstrated in our STELLAR 2, 3, and 4 pivotal trials. We will need additional positive input from the scientific committee of the European Medicines Agency, or EMEA, prior to submitting an MAA on this basis. We are developing pixantrone, a novel anthracycline derivative, for the treatment of non-Hodgkin's lymphoma, or NHL. We are targeting an interim analysis from our ongoing phase III study of pixantrone late in the second quarter of 2006, and depending on the results of this analysis, a second interim analysis may be performed in the second half of 2006. We also are developing CT-2106, polyglutamate camptothecin, which is in the phase II component of a phase I/II trial in combination with 5FU/LV for the treatment of colorectal cancer relapsing following FOLFOX therapy and a phase II trial in ovarian cancer. In the first half of 2005, we commenced a cost savings initiative, including a reduction of workforce, in an effort to conserve capital and focus on programs with the greatest near term commercial potential.

We were incorporated in Washington in 1991. Our principal executive offices are located at 501 Elliott Avenue West, Seattle, Washington 98119. Our telephone number is (206) 282-7100. Our website can be found at [www.cticseattle.com](http://www.cticseattle.com). We make available free of charge on our website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and other filings pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and amendments to such filings, as soon as reasonably practicable after each is electronically filed with, or furnished to, the Securities and Exchange Commission, or the SEC.

CTI and XYOTAX are our proprietary marks. All other product names, trademarks and trade names referred to in this Form 10-K are the property of their respective owners.

**The Oncology Market**

*Overview.* According to the American Cancer Society, or ACS, cancer is the second leading cause of death in the United States, resulting in close to 570,000 deaths annually. The National Cancer Institute estimates that approximately 9.8 million people in the United States with a history of cancer were alive in January 2001, and it is estimated that one in three American women, and one in two American men will develop cancer in their lifetime. Approximately 1.4 million new cases of cancer were expected to be diagnosed in 2005 in the United

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States. The most commonly used methods for treating patients with cancer are surgery, radiation and chemotherapy. Patients usually receive a combination of these treatments depending upon the type and extent of their disease. At the time of diagnosis, 70% of patients have tumors that have already spread to other parts of the body. Therefore, almost all receive systemic therapy such as chemotherapy during the course of their disease.

Despite recent advances in sequencing the human genome and the introduction of new biologic therapies for the treatment of cancer, almost all patients with advanced cancer will receive chemotherapy at some point during the treatment of their disease. Four classes of chemotherapy agents, anthracyclines, camptothecins, platinates and taxanes, account for more than 90% of all chemotherapy usage. Unfortunately, there are significant limitations and complications associated with these agents that result in a high rate of treatment failure. The principal limitations of chemotherapy include:

treatment-related toxicities,

inability to selectively target tumor tissue, and

the development of resistance to the cancer-killing effects of chemotherapy.

We believe developing agents which improve on these cornerstone chemotherapy classes fills a significant unmet need for cancer patients. Our cancer drug development pipeline includes a next-generation drug candidate for each of the four leading classes of chemotherapeutic agents.

*Treatment-related toxicities.* The majority of current chemotherapy agents kill cancer cells by disrupting the cell division and replication process. Although this mechanism often works in cancer cells, which grow rapidly through cell division, non-cancerous cells are also killed because they too undergo routine cell division. This is especially true for cells that line the mouth, stomach and intestines, hair follicles, blood cells and reproductive cells (sperm and ovum). Because the mechanism by which conventional cancer drugs work is not limited to cancer cells, their use is often accompanied by toxicities. These toxicities limit the effectiveness of cancer drugs and seriously impact the patient's quality of life.

*Inability to selectively target tumor tissue.* When administered, chemotherapy circulates through the bloodstream, reaching both tumor and normal tissues. Normal dividing tissues are generally as sensitive as tumor cells to the killing effects of chemotherapy and toxic side effects limit the treatment doses that can be given to patients with cancer.

*Chemotherapy resistance.* Resistance to the cancer killing effects of conventional chemotherapy is a major impediment to continued effective treatment of cancer. Approximately 70% of all cancer patients undergoing chemotherapy ultimately develop resistance to one or more chemotherapy agents and eventually die from their disease. Because many chemotherapies share similar properties, when a tumor develops resistance to a single drug, it may become resistant to many other drugs as well. Drugs that work differently from existing chemotherapies and are less susceptible to the same mechanisms of resistance have consequently begun to play an important role in treating resistant tumors.

## **CTI Strategy**

Our goal is to become a leading cancer drug company. The following are the key elements of our business strategy:

We target development and registration strategies in the United States and Europe that take advantage of the ability to accelerate approval either because there is an unmet medical need, or because our product profiles demonstrate significant improvement in efficacy, toxicity or safety over competitive drugs.

We plan to devote a substantial portion of our efforts to develop XYOTAX and pixantrone.





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We have research and development capabilities focused on continued application of our patented polymer drug delivery technology to expand our portfolio of improved versions of currently marketed anti-cancer drugs. In addition, we are actively investigating approaches to improving current therapeutic agents against validated drug targets in order to discover novel agents with improved side effect and efficacy profiles compared to competitor drugs

We actively explore opportunities to in-license or acquire complementary products, technologies or companies.

### **XYOTAX (paclitaxel poliglumex)**

We are developing XYOTAX, a novel biologically enhanced chemotherapeutic agent which links a widely used anti cancer agent, paclitaxel, to a polyglutamate polymer for the potential treatment of NSCLC and ovarian and other cancers. XYOTAX utilizes a biodegradable polymer to deliver the chemotherapeutic agent paclitaxel preferentially to tumor tissue. By linking paclitaxel to a biodegradable amino acid carrier, the conjugated chemotherapeutic agent is inactive in the bloodstream, sparing normal tissues the toxic side effects of chemotherapy. The chemotherapeutic agent is activated and released once inside a cell, such as a tumor cell. More than 1,700 patients were treated in our three pivotal phase III trials of XYOTAX for the treatment of NSCLC. While each of these trials missed their primary endpoint of superior overall survival, women treated with XYOTAX for newly diagnosed advanced NSCLC had a significant improvement in their overall survival compared to women or men treated with standard chemotherapy. In addition, with single-agent XYOTAX, we observed a significant reduction in most of the severe toxic side effects associated with the standard chemotherapy agents studied in the STELLAR trials.

Taxanes, which include paclitaxel and docetaxel, are one of the best-selling classes of chemotherapies. Paclitaxel, one of two marketed taxanes, is branded as Taxol and is approved for the treatment of NSCLC, ovarian cancer and breast cancer, although it is considered a standard of care in lung and ovarian cancers, where it is most widely used. XYOTAX, a novel biologically enhanced chemotherapeutic links polyglutamate to paclitaxel, the active ingredient in Taxol. Taxol is a formulation of paclitaxel in a mixture of polyethoxylated castor oil (Cremaphor) and ethanol, which is extremely irritating to blood vessels and requires surgical placement of a large catheter for administration. It also can cause severe life threatening allergic reactions that typically requires pre-medications with steroids and antihistamines in addition to a minimum of three hours of intravenous infusion and transportation of patients to and from their treatment location. Unlike formulations of Taxol, XYOTAX uses a biodegradable protein polymer to deliver chemotherapy preferentially to tumor tissue. XYOTAX is approximately 80,000 times more water-soluble than paclitaxel alone, allowing it to be dissolved in a simple water and sugar based solution and infused in the patient over approximately ten to twenty minutes. XYOTAX does not require routine premedication with steroids and antihistamines to prevent severe allergic reactions and patients can drive themselves to and from treatment centers. The distribution and metabolism of XYOTAX to tumor tissue and subsequent release of active paclitaxel chemotherapy appears to be enhanced by estrogen allowing for superior effectiveness in women with pre-menopausal estrogen levels. This gender targeted benefit could also be exploited in post menopausal women or men through estrogen supplementation.

### *XYOTAX for non-small cell lung cancer*

The cancer drug most commonly used to treat NSCLC in the United States is paclitaxel. The ACS estimates that 150,000 new cases of NSCLC will be diagnosed in the United States in 2005 and approximately 128,000 of these patients are expected to receive chemotherapy. Of the estimated 128,000 NSCLC patients who receive chemotherapy, approximately 32,000 are classified as PS2. These patients tolerate chemotherapy poorly and have a significantly shorter median survival than healthier patients. Approximately 40,000 patients in the United States receive second-line treatment for NSCLC annually, for which docetaxel is the most commonly used agent to treat recurrent NSCLC.

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In November 2003, we completed enrollment in our XYOTAX phase III pivotal trial, known as STELLAR 3, for the potential use in combination with platinum as front-line treatment of PS2 patients with NSCLC. In May 2004, we completed enrollment in our second pivotal phase III trial of XYOTAX, known as STELLAR 4, for the potential use as front-line single agent treatment of PS2 patients with NSCLC. In July 2004, we completed enrollment in our third pivotal phase III trial of XYOTAX, known as STELLAR 2, for the potential use as second-line single agent treatment of patients with NSCLC. Each of these studies was designed to demonstrate whether XYOTAX could improve overall survival when compared to standard chemotherapy comparator agents.

In March 2005, we announced that our XYOTAX STELLAR 3 clinical trial study missed its primary endpoint of superior overall survival. XYOTAX had a reduction in certain side effects, including hair loss, muscle and joint pain, and cardiac symptoms. In May 2005, we announced that both the STELLAR 2 and 4 clinical trials missed their primary endpoints of superior overall survival, but had significant reductions in certain severe side effects compared to the comparator agents.

In July 2005, at the 11th World Conference on Lung Cancer, we announced that in a pooled analysis of our STELLAR 3 and 4 pivotal trials the 97 women who received XYOTAX had a significant increase in median and overall survival (9.5 months vs. 7.7 months, hazard ratio 0.70, log rank  $p=0.03$ ) and in 1 year survival (40% vs. 25%,  $p=0.013$ ) compared to 101 women who received comparator control agents. These results pooled data from all women randomized on the STELLAR 3 and 4 trials (a so-called intent to treat analysis). Individually, neither study reached statistical significance for overall survival for women, although a positive trend was observed in both trials, with a strong trend in the STELLAR 4 trial ( $p=0.069$ ). While analysis of survival by gender was pre-specified in the analysis plans for the trials, a gender specific survival advantage for women over men was not a pre-specified endpoint in either trial.

In September 2005, we presented new results from a recently completed phase II clinical trial, known as PGT202, of XYOTAX in the first-line treatment of men and women with advanced NSCLC, which demonstrated a survival advantage for women receiving XYOTAX as first-line therapy for NSCLC when compared to men. In this single arm study, the 35 women who received XYOTAX plus carboplatin had a 36 percent probability of living at least 1 year compared to 16 percent in the 39 men receiving the same regimen. A pooled analysis of the 463 patients treated with XYOTAX in the STELLAR 3, STELLAR 4 and PGT202 trials demonstrated a statistically significant survival advantage for women treated when compared to men, with women having a 39 percent probability of surviving at least 1 year compared to 25 percent for men (hazard ratio 0.63, log rank  $p=0.014$ ).

In February 2006, we presented results that confirm the observation of enhanced efficacy in the presence of estrogen seen in the STELLAR first-line trials. In the three first-line trials of XYOTAX (PGT202, STELLAR 3, and STELLAR 4), women of pre-menopausal age or with normal estrogen levels had the strongest survival advantage over their counterparts. In an analysis of the 113 of 198 women in the pooled STELLAR 3 and 4 trial data who are of pre-menopausal age or normal estrogen level, women treated with XYOTAX had a highly significant prolongation in the 1 year and overall survival estimates compared to women treated with standard chemotherapy, with the XYOTAX patients having a 44% reduction in the overall risk of dying (log rank  $p=0.008$ ) and a 43% 1 year survival estimate compared to 19% for women on standard chemotherapy ( $p=0.003$ ). We believe these data indicate a potential favorable alternative for women with normal estrogen levels who have NSCLC.

In addition, our phase III trials demonstrated that single agent XYOTAX (175-210mg/m<sup>2</sup>) has a significantly reduced incidence of severe side effects, including a reduction in severe neutropenia, febrile neutropenia, infection and anemia when compared to patients receiving standard chemotherapy agents gemcitabine, vinorelbine or docetaxel. XYOTAX also resulted in less severe allergic reactions, hair loss, and requirements for growth factor support (Neupogen®, Neulasta®, Aranesp® and/or Epogen®) than patients receiving standard chemotherapy. However, a higher rate of severe neuropathy (4%) was observed for XYOTAX (175mg/m<sup>2</sup>) compared to comparator agents.

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We plan to submit an MAA in Europe in the second half of 2006, which we do not expect to be limited to women, but which would be on the basis of non-inferior survival with improved side effect and tolerability profile. We believe that the STELLAR 3 and the STELLAR 4 trials demonstrated statistically non-inferior overall survival to comparator control agents (1 year survival 31% vs. 31%,  $p=0.018$  and 26% vs. 26%,  $p=0.039$  for STELLAR 3 and 4, respectively). However, non-inferiority was not a primary endpoint of either trial. While one European regulatory agency agreed to non-inferiority as a potential analysis in support of an MAA filing, one did not. We will require additional positive feedback from the EMEA scientific committee regarding the applicability of a non-inferiority analysis prior to filing.

The FDA has told us that accelerated, sub-part H review and non-inferiority are not possible routes to pursue for regulatory approval in the U.S. However, we believe the potential survival benefit for women is important enough to warrant review and consideration for NDA approval, and that a standard review based on the gender specific survival advantage discussed above is the best available registration route in the U.S. We currently plan to submit an NDA seeking approval for XYOTAX as first-line mono-therapy for PS2 women with advanced NSCLC to the FDA in the second half of 2006. We believe that the modest incremental cost to submit the NDA over the cost of preparing and submitting a MAA is reasonable because if the FDA accepts and reviews the filing, the timing for potential approval for XYOTAX could be accelerated by as much as 18 months over a filing that is based on an additional randomized trial which we just initiated and is known as the PIONEER study. However, as explained below, we believe utilizing current data from pooled analyses of pivotal trials that missed their primary endpoints will make for a challenging FDA review. Because we are fully aware of this challenge, we have initiated the PIONEER study which compares XYOTAX to paclitaxel in the first-line treatment of PS2 women with advanced NSCLC. We intend to have interim data from this trial available at the time of FDA review of our NDA. In addition, we have initiated preclinical studies on the effect of gender/hormonal status on XYOTAX biodistribution, cellular uptake and metabolism to support the hypothesis for survival improvement in women. Without a successful PIONEER trial or positive interim results from PIONEER, we expect a difficult regulatory review from the FDA, which may preclude obtaining approval of our NDA, for a number of reasons: our trials failed to meet their primary endpoints and the FDA has taken the view that it will not favorably review secondary endpoints on data absent achievement of primary endpoints; while gender-specific survival was pre-specified in the analysis plan, the women over men gender-specific survival advantage was not a pre-specified endpoint; and, while the FDA has recently reviewed NDAs based on pooled analyses, none have been approved in the past. We are not pursuing approval from the FDA based on non-inferiority, which is usually the basis for making a comparable survival claim.

In February 2006, we announced that the FDA confirmed that XYOTAX qualifies for fast track designation for the treatment of PS2 women with first-line advanced NSCLC.

### *XYOTAX for ovarian cancer*

The ACS estimated that approximately 22,000 new cases of ovarian cancer would be diagnosed in the United States in 2005. The standard of care for first-line treatment of ovarian cancer is paclitaxel and carboplatin. In April 2004, we announced that we entered into a clinical trials agreement with the Gynecologic Oncology Group, or GOG, to perform a phase III trial of XYOTAX as maintenance therapy in patients with ovarian cancer. In July 2004, the GOG submitted an Investigational New Drug, or IND, along with the protocol for a special protocol assessment, or SPA, to the FDA. The GOG reached agreement with the FDA regarding the SPA in December 2004 and initiated the phase III study March 2005. The primary endpoint of this trial is overall survival. Progression-free survival, safety and side effect profile are secondary endpoints. An interim analysis based on the progression-free survival endpoint is targeted, depending on enrollment rates, at the end of 2007.

### **Pixantrone**

We are developing pixantrone, a novel anthracycline derivative, for the treatment of NHL. In the United States, aggressive NHL affects approximately 160,000 people with approximately 30,000 new cases diagnosed

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per year. The standard of care for first-line treatment of NHL is known as CHOP, which is a combination chemotherapy regimen consisting of cyclophosphamide, doxorubicin (an anthracycline), vincristine and prednisone. CHOP is used either alone or in conjunction with rituximab, and is able to induce complete responses, or CRs, in approximately 70% of patients. However, approximately 30% of patients eventually relapse and many are unable to undergo an additional course of CHOP therapy due to the risk of cardiac toxicity. As a result, chemotherapy regimens that do not include anthracyclines often are used for the second-line treatment of relapsed NHL. There are no drugs approved in the United States for second- or third-line treatment for patients with relapsed aggressive NHL.

Anthracyclines are one of the most potent classes of anti-cancer agents used in first-line treatment of aggressive NHL, leukemia, and breast cancer. For these diseases, anthracycline-containing regimens can often produce long-term cancer remissions and cures. However, the currently marketed anthracyclines can cause severe, permanent and life threatening cardiac toxicity when administered beyond widely recognized cumulative lifetime doses. This toxicity often prevents repeat use of anthracyclines in patients who relapse after first-line anthracycline treatment. In addition, the cardiac toxicity of anthracyclines prevents their use in combination with other drugs, such as trastuzumab, that also can cause cardiac toxicity.

We believe a next-generation anthracycline with better ease of administration, greater anti-tumor activity and less cardiac toxicity could gain a significant share of the anthracycline market. We also believe that such a drug could allow repeat therapy in relapsed patients and could allow combination therapy with a broader range of chemotherapies. Preclinical data and phase I and phase II clinical studies in approximately 300 patients indicate that pixantrone is easy to administer, may exhibit significantly lower potential for cardiac toxicity and may have more potent anti-tumor activity than marketed anthracyclines.

### *Pixantrone for relapsed aggressive non-Hodgkin's lymphoma*

We have several clinical trials ongoing, including a pivotal phase III trial for the treatment of patients with relapsed aggressive NHL, a condition for which there are no chemotherapy drugs approved in the United States. This 320 patient study is an international, randomized trial comparing pixantrone to a single agent of the treating physician's choice. The primary endpoint of the study is complete response rate. We are currently enrolling patients and are targeting an interim analysis late in the second quarter of 2006, and depending on the results of this analysis, a second interim analysis may be performed in the second half of 2006. In July 2004, we announced that the FDA granted fast track designation for pixantrone for the treatment of relapsed aggressive NHL.

In a phase II trial published in the journal *Hematologica* in August 2003, among 33 patients with relapsed aggressive NHL who failed a median of two prior regimens (range 0 to 5), including prior anthracycline therapy, single-agent pixantrone produced an objective tumor response in 9 of 33 patients (27%) with 5 patients (15%) experiencing a CR. Median duration of response was encouraging (~10.5 months) and in one case the response lasted more than 24 months. Pixantrone was well tolerated in this trial with neutropenia being the most relevant hematologic side effect. Cardiac symptoms were infrequent with only three patients experiencing a decrease of more than 10% of the left ventricular ejection fraction, a marker of cardiac function, which was possibly treatment-related. We believe that the low incidence of cardiac toxicity reported in this trial was encouraging because the majority of patients had previously been exposed to anthracycline doses that significantly increased their risk for cardiac toxicity.

We also have reported positive clinical data for pixantrone as a replacement for the standard anthracycline agent doxorubicin as part of the CHOP regimen in patients who previously failed CHOP and other multi-agent regimens. Preliminary results from this phase I/II study of the CHOP-variant regimen, known as CPOP, which replaces doxorubicin with pixantrone, were presented at the 46th Annual Meeting of the American Society of Hematology or ASH in December 2004. The phase I/II experience with the CPOP regimen, in a total of 43 patients evaluable for response, produced a CR in 20 patients (47%), with 10 patients (23%) experiencing a partial response and six patients (14%) achieving stable disease. This corresponds to a major objective response

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rate of 70%. No patients experienced clinically significant cardiac toxicity despite most having previously received a high cumulative dose of doxorubicin, which can cause serious and irreversible heart damage. Based on these positive data, we have initiated a study of CHOP combined with rituximab versus CPOP combined with rituximab for the initial treatment of patients with aggressive NHL.

We also have conducted clinical trials for pixantrone using a variant of the regimen known as ESHAP, which consists of methylprednisolone, etoposide, cisplatin, and cytarabine. The ESHAP-variant, known as the BSHAP regimen, is a non-anthracycline regimen containing pixantrone, developed as a second-line therapy for patients who fail front-line CHOP and who are not able to receive further anthracycline treatment. In this modified regimen, pixantrone replaces etoposide, with a goal to improve efficacy. Results from a phase I/II trial, reported in 2004 at the 40<sup>th</sup> annual meeting of the American Society of Clinical Oncology, or ASCO, showed that among 18 evaluable patients, 11 (61%) achieved an objective tumor response with seven patients (39%) achieving a CR. No clinically significant cardiac events were observed in this trial and no patient experienced a decrease in left ventricular ejection fraction of more than 20%.

*Pixantrone for other indications*

Other clinical data suggest pixantrone may be useful in treating indolent NHL, a less rapidly progressive but ultimately fatal form of NHL. In November 2005, CTI presented results from a multi-center randomized trial, known as PIX302. This trial, evaluating pixantrone plus rituximab versus rituximab alone among patients with relapsed or refractory indolent NHL, was modified and reduced to a study to support registration and market development, as announced in our annual filing on Form 10-K in 2004, as a result of our strategy to conduct a pivotal phase III trial in aggressive NHL, which we believe provides the fastest route to registration for pixantrone. Of the 38 patients evaluable for response, patients receiving the combination of rituximab and pixantrone had an 87 percent overall improvement in time to progression, or TTP, compared to rituximab alone. The median TTP estimate for the pixantrone/rituximab recipients was 13.2 months compared to 8.1 months for rituximab alone (hazard ratio 0.13, log rank  $p < 0.001$ ). The one- and two-year progression-free survival estimates were 66 percent and 44 percent for the pixantrone/rituximab recipients compared to zero percent for the rituximab patients for both measurement intervals ( $p < 0.001$  and 0.003, respectively). The study also demonstrated a significant improvement in major objective responses (? 50 percent shrinkage in tumor size). Seventy-five percent of patients treated with the pixantrone/rituximab combination achieved a major response, with 35 percent achieving a complete response. This compares to 33 percent major response in patients who received rituximab monotherapy, including 11 percent achieving a complete response ( $p = 0.02$ ). The pixantrone-rituximab combination produced a complete response (CR) in seven patients (35%), with eight patients (40%) experiencing a partial response (PR) and four patients (20%) with stable disease (SD). Rituximab monotherapy produced a CR in two patients (11%), PR in four patients (22%) with six patients having SD (33%). This corresponds to a major objective response rate of 75 percent in the combination therapy arm compared to 33 percent in the rituximab group ( $p=0.021$ ). Side effects on pixantrone were generally mild to moderate (grade 1 or 2) with the exception of three cases of serious neutropenia associated with the pixantrone/rituximab arm. The median cumulative dose of pixantrone administered was 1014 mg/m<sup>2</sup>; no cases of treatment-related grade 3 or 4 cardiac toxicity were reported.

A phase I/II study in AML was initiated in the first half of 2005.

In a presentation at ASH 2004, preliminary data from a phase I/II study of pixantrone in combination with fludarabine, dexamethasone and rituximab ( FPD-R ) in the treatment of patients with relapsed/refractory indolent (NHL) were presented. Pixantrone was administered in this variation of the FND-R regimen, where pixantrone replaces the anthracycline derivative mitoxantrone. Preliminary results reveal that of the 22 evaluable patients in this trial, 95% achieved an objective response.

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### *CT-2106 (polyglutamate camptothecin)*

Camptothecins are an important and fast growing class of anti-cancer drugs. However, like taxanes, their full clinical benefit is limited by poor solubility and significant toxicity. Orally delivered analogs, such as topotecan and irinotecan, are soluble but are less effective in combating tumors. Camptothecins are important drugs in the treatment of advanced colon, lung and ovarian cancers. Worldwide sales for camptothecins exceeded \$725.0 million in 2004.

We are developing a novel polyglutamate-camptothecin molecule, CT-2106 with ongoing phase I/II studies in colorectal and ovarian cancers. Linking a camptothecin to the polyglutamate polymer renders CT-2106 water soluble, and animal studies suggest that up to 400% more drug can be administered without an increase in toxicity. CT-2106 as a single-agent and/or in combination with 5FU showed significantly enhanced anti-tumor activity in several animal tumor models. We initiated a phase I clinical study for this product candidate in 2002. To date, we have seen encouraging preliminary safety data in patients with a variety of advanced stage cancers. Neutropenia and thrombocytopenia are the observed dose limiting toxicities. Patients have not experienced severe gastrointestinal or genitourinary toxicity, two side effects common with camptothecin therapy. In April 2004, we initiated a phase I/II clinical trial of CT-2106 in combination with infusional 5 fluorouracil/folinic acid, or 5-FU/FA, in patients with metastatic colorectal cancer who have failed front-line therapy with oxaliplatin. We also initiated a phase II clinical trial of CT-2106 as a single-agent in ovarian cancer at the end of 2004.

We presented preliminary phase I data on CT-2106 at the EORTC-NCI-AACR conference in September 2004. The objectives of the multicenter, open-label study are to determine the maximum tolerated dose, or MTD, and to evaluate the tolerability, safety and pharmacokinetics of CT-2106 when administered to patients with advanced malignancies. Patients received a median of three prior regimens (range 1-4). The data showed that CT-2106 was well tolerated and lacked the severe gastrointestinal side effects, or diarrhea and bladder or hematuria toxicities, which are typical for camptothecins. The dose limiting side effects were neutropenia and thrombocytopenia. Of 24 patients evaluable for efficacy, eight (33%) achieved disease control. One patient with pancreatic cancer that had spread to the lungs exhibited a partial response, another pancreatic patient achieved disease control, two patients with colorectal cancer had stable disease for more than three months, and four patients with NSCLC achieved stable disease, including two who experienced disease control for almost nine months. The MTD of CT-2106 administered every third week has been determined to be 75mg/m<sup>2</sup>.

### **TRISENOX**

On July 18, 2005, we completed the divestiture of TRISENOX and certain proteasome assets to Cephalon Inc. for aggregate consideration of \$71.9 million, net of broker fees. In connection with the divestiture, we were required to repay our royalty obligation to PharmaBio Development, or PharmaBio, and after this repayment, our net proceeds from both transactions were approximately \$32.5 million. The divestiture included all TRISENOX assets, including the capital stock of two of our wholly-owned subsidiaries, Cell Therapeutics (UK) Limited, a United Kingdom corporation, and PolaRx Pharmaceuticals, Inc., a Delaware corporation.

**Table of Contents****CTI s Ongoing Clinical Trials**

The following table lists our active clinical trials (indicated by a status of "open"). Also listed are the trials that have recently closed to enrollment but for which clinical trial reports are in progress (status "enrollment completed").

| <b>Product Candidate</b>                 | <b>Indication/Intended Use</b>  | <b>Phase/Status</b>                                    |
|--|---|--|
| <b>XYOTAX (CT-2103)</b>                  | NSCLC, first-line, PS2, females (PIONEER or PGT305)                                 | III/open   |
|  | NSCLC second-line (STELLAR 2)   | III / enrollment completed                             |
|  | NSCLC in combination with carboplatin, first-line PS2 (STELLAR3)                    | III / enrollment completed                             |
|  | NSCLC first-line PS2 (STELLAR4)   | III / enrollment completed                             |
|  | Ovarian first-line maintenance (GOG0212)  | III / open   |
|  | Ovarian $\geq$ second relapse (GOG186c)   | II / enrollment completed; patient follow up ongoing   |
|  | Ovarian first-line dose escalation (GOG9914)  | I/II / enrollment completed; patient follow up ongoing |
|  | Ovarian first-line in combination with carboplatin (PGT201)                         | II / enrollment completed                              |
|  | NSCLC first-line, combined with carboplatin (PGT202)                                | II / enrollment completed                              |
|  | Combination with cisplatin and radiation for esophageal and gastric cancer (PGT104) | I / open   |
| <b>Pixantrone</b>                        | NSCLC, in combination with radiation (PGT103)                                       | I / enrollment completed                               |
|  | Aggressive NHL, > 3 relapses, single-agent (PIX301)                                 | III / open   |
|  | Relapsed aggressive NHL, BSHAP (AZA-II-02)  | II / closed  |
|  | Aggressive NHL, front-line, CPOP-R (PIX203)   | II / open  |
|  | Relapsed AML, single-agent (PIX109)   | I / open   |
|  | Relapsed indolent NHL, FND-R (AZA-I-06)   | I/II / enrollment completed                            |
| Relapsed aggressive NHL, CPOP (AZA-I-07) | I/II / enrollment completed   |  |

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| <b>Product Candidate</b> | <b>Indication/Intended Use</b>                                    | <b>Phase/Status</b>      |
|--------------------------|---|--------------------------|
| <b>CT-2106</b>           | Advanced solid tumors, single-agent dosing every 3 weeks (CAM101) | I / enrollment completed |
|                          | Advanced solid tumors, single-agent dosing every week (CAM102)    | I / enrollment completed |
|                          | Relapsed ovarian cancer (CAM203)                                  | II / open                |
|                          | Relapsed colorectal cancer (CAM201)                               | II / open                |

**Research and Preclinical Development**

We are also working on a number of drug targets in discovery research. Among these programs are bisplatinum agents, HIF-1 $\alpha$  / p300 inhibitors, and proteasome inhibitors with indirect inhibition properties. We are in the process of continued target validation and lead optimization and may elect to move one or more of these programs into early development in 2006. In addition to discovery research, preclinical activities are focused on product lifecycle management, including the development of alternative dosage forms and routes of administration for existing products in the development pipeline.

Research and development is essential to our business. We spent \$68.8 million, \$101.1 million and \$89.5 million in 2005, 2004 and 2003, respectively, on Company sponsored research and development activities.

**Collaboration and Licensing Arrangements**

*PharmaBio Development* In December 2004, we entered into a six year financing and services agreement with PharmaBio, the strategic partnering group of Quintiles Transnational, Corp., or Quintiles, involving our cancer therapy, TRISENOX. Under the agreement, in return for cash and services, we were required to pay PharmaBio royalties based on a percentage of net sales of TRISENOX in the United States and certain European countries beginning in 2006. The agreement also provided PharmaBio Development with a security interest in TRISENOX related to our royalty payment obligations. In July 2005, the agreement was terminated in connection with the divestiture of TRISENOX to Cephalon and we were required to pay \$39.4 million for the extinguishment of the royalty obligation.

*Nippon Shinyaku Co. Ltd.* In December 2002, we entered into a distribution agreement with Nippon Shinyaku Co. Ltd., or Nippon. This agreement granted certain rights to Nippon to exclusively market and distribute TRISENOX in Japan, South Korea and Taiwan. Under the agreement, we received and recognized as revenue a milestone payment in June 2003 for Nippon's submission of an NDA in Japan. We were also eligible to receive future milestone payments upon attainment of certain regulatory achievements. In October 2004, Nippon received approval from the Japanese Ministry of Health to market TRISENOX for patients with relapsed or refractory acute promyelocytic leukemia, or APL, in Japan. Under the agreement, we received an additional milestone payment from Nippon upon its receipt of approval to market TRISENOX in Japan. In December 2004, Nippon launched TRISENOX for the treatment of relapsed/refractory APL in Japan. Pursuant to a supply agreement we entered into with Nippon, we recorded product sales during 2004 and 2005. Cephalon assumed the agreement with Nippon in connection with the TRISENOX divestiture.

*Chugai Pharmaceutical Co., Ltd.* In October 2001, we entered into a licensing agreement with Chugai Pharmaceutical Co., Ltd., or Chugai, for the development and commercialization of XYOTAX. This agreement grants an exclusive license to Chugai to develop and commercialize XYOTAX in several Asian markets. Upon execution of the agreement, Chugai paid us an initial payment and we received and recognized as revenue a milestone payment in 2002. We have recently been in discussions with Chugai about the relinquishing by Chugai of its rights to certain Asian markets while retaining our development and commercialization rights of XYOTAX in these territories. In October 2005, we received a letter from Chugai proposing the termination of the License Agreement. The agreement was terminated effective March 2006.



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*PG-TXL Company, L.P.* In June 1998, we entered into an agreement, as amended in February 2006, with PG-TXL Company, L.P. granting us an exclusive worldwide license for the rights to PG-TXL, known as XYOTAX, and to all potential uses of PG-TXL Company's polymer technology. Under the terms of the agreement, we acquired the rights to fund the research, development, manufacture, marketing and sale of anti-cancer drugs developed using this polymer technology. We are obligated to make payments upon the attainment of significant development milestones, as defined in the agreement. We also granted warrants to purchase 350,000 shares of our common stock to PG-TXL Company, L.P., which became exercisable in 2001 upon our entering a licensing agreement for XYOTAX with Chugai Pharmaceutical Co., Ltd. The milestone payments set forth in the agreement may become due upon the achievement of goals, such as trial commencements and completions, filings and regulatory approvals.

### **Patents and Proprietary Rights**

We dedicate significant resources to protecting our intellectual property, which is important to our business. Through our acquisition of PolaRx Biopharmaceuticals, Inc. or PolaRx we obtained rights to four pending patent families that, in the aggregate, cover dosage formulations, methods of administration and methods of use for various forms of arsenic trioxide and related compounds. This portfolio included six issued U.S. patents, and 36 U.S. and foreign pending or issued patent applications directed to TRISENOX. In July 2005, TRISENOX and related assets were sold to Cephalon.

We have exclusive rights to six issued U.S. patents and 126 U.S. and foreign pending or issued patent applications relating to our polymer drug delivery technology. There are six issued U.S. patents, two granted European patents and 72 pending or issued U.S. and foreign patent applications directed to XYOTAX. Of the six issued U.S. patents, two of them and another 20 pending U.S. and foreign patent applications are directed to CT-2106. Additionally, we have four issued U.S. patents and 71 foreign pending and issued patents directed to pixantrone.

We intend to file additional patent applications when appropriate, with respect to improvements in our core technology and to specific products and processes that we develop. Patents may not issue from any present or future applications or, if patents do issue, such patents may not be issued on a timely basis or claims allowed on issued patents may not be sufficient to protect our technology. In addition, the patents issued to us may be challenged, invalidated or circumvented or the rights granted there under may not provide proprietary protection or commercial advantage to us. With respect to such issued U.S. patents or any patents that may issue in the future, they may not effectively protect the technology involved, foreclose the development of competitive products by others or otherwise be commercially valuable.

We have sought and intend to aggressively seek patent protection in the United States, Canada, Mexico, Europe and Japan to protect any products that we may develop. We also intend to seek patent protection or rely upon trade secrets to protect certain of our enabling technologies that will be used in discovering and evaluating new drugs that could become marketable products. However, such steps may not effectively protect the technology involved. To protect any such trade secrets and other proprietary information, we rely on confidentiality and material transfer agreements with our corporate partners, employees, consultants, outside scientific collaborators and sponsored researchers and other advisors. These agreements may be breached, we may not have adequate remedies for breach or our trade secrets may otherwise become known or independently discovered by competitors. We also have our clinical advisors, our consultants and, in most cases, our employees enter into agreements requiring disclosure to us of ideas, developments, discoveries or inventions conceived during employment or consulting and assignment to CTI of proprietary rights to such matters related to our business and technology.

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### **Manufacturing**

We currently use, and expect to continue to be dependent upon, contract manufacturers to manufacture each of our product candidates. We have established a quality control and quality assurance program, including a set of standard operating procedures and specifications, designed to ensure that our products are manufactured in accordance with current Good Manufacturing Procedures, or cGMPs, and other applicable domestic and foreign regulations. We will need to invest in additional manufacturing resources, and may seek to enter into additional collaborative arrangements with other parties that have established manufacturing capabilities. It is likely that we will continue to rely on third-party manufacture of our development and commercial products on a contract basis. Currently, we have agreements with third-party vendors to furnish XYOTAX and pixantrone drug supply for clinical studies. We will be dependent upon these third-parties to supply CTI in a timely manner with products manufactured in compliance with cGMPs or similar standards imposed by foreign regulatory authorities where our products are tested and/or marketed.

In September 2001, we entered into a supply agreement with Natural Pharmaceuticals, Inc. for paclitaxel, a key starting material for XYOTAX. Under the supply agreement, we purchased paclitaxel at a pre-determined price. We have also identified and purchased paclitaxel from two additional suppliers. As we have adequate supply of paclitaxel on hand to support our validation campaigns and clinical activities, we amended our supply agreement in October 2005 and received \$0.8 million to relieve all obligations of undelivered paclitaxel from NPI under this agreement.

### **Competition**

Competition in the pharmaceutical and biotechnology industries is intense. We face competition from a variety of companies focused on developing oncology drugs. We compete with large pharmaceutical companies and with other specialized biotechnology companies, including but not limited to Bristol-Myers Squibb Co., Aventis, Genentech, OSI Pharmaceuticals, Lilly, American Pharmaceutical Partners, Neopharm Inc., and Sonus Pharmaceuticals for XYOTAX. Many of our existing or potential competitors have substantially greater financial, technical and human resources than us and may be better equipped to develop, manufacture and market products. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and established biotechnology companies. Many of these competitors have products that have been approved or are in development and operate large, well-funded research and development programs.

We expect to encounter significant competition for the principal pharmaceutical products we plan to develop. Companies that complete clinical trials, obtain required regulatory approvals and commence commercial sales of their products before us may achieve a significant competitive advantage if their products work through a similar mechanism as our products and if the approved indications are similar. We do not believe competition is as intense among products that treat cancer through novel delivery or therapeutic mechanisms where these mechanisms translate into a clinical advantage in safety and/or efficacy. A number of biotechnology and pharmaceutical companies are developing new products for the treatment of the same diseases being targeted by us. In some instances, such products have already entered late-stage clinical trials or received FDA approval. However, cancer drugs with distinctly different mechanisms of action are often used together in combination for treating cancer, allowing several different products to target the same cancer indication or disease type. Such combination therapy is typically supported by clinical trials that demonstrate the advantage of combination therapy over that of a single-agent treatment.

We believe that our ability to compete successfully will be based on our ability to create and maintain scientifically advanced technology, develop proprietary products, attract and retain scientific personnel, obtain patent or other protection for our products, obtain required regulatory approvals and manufacture and successfully market our products either alone or through outside parties. We will continue to seek licenses with respect to technology related to our field of interest and may face competition with respect to such efforts.

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### **Government Regulation**

The research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing, among other things, of our products are extensively regulated by governmental authorities in the United States and other countries. In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. Failure to comply with applicable U.S. requirements may subject us to administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution.

*Drug Approval Process.* None of our drugs may be marketed in the United States until the drug has received FDA approval. The steps required before a drug may be marketed in the United States include:

preclinical laboratory tests, animal studies and formulation studies;

submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin;

adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for each indication;

submission to the FDA of an NDA;

satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMPs; and

FDA review and approval of the NDA.

Preclinical tests include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. We cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. The study protocol and informed consent information for study subjects in clinical trials must also be approved by an Institutional Review Board for each institution where the trials will be conducted. Study subjects must sign an informed consent form before participating in a clinical trial. Phase I usually involves the initial introduction of the investigational drug into people to evaluate its short-term safety, dosage tolerance, metabolism, pharmacokinetics and pharmacologic actions, and, if possible, to gain an early indication of its effectiveness. Phase II usually involves trials in a limited patient population to (i) evaluate dosage tolerance and appropriate dosage, (ii) identify possible adverse effects and safety risks, and (iii) evaluate preliminarily the efficacy of the drug for specific indications. Phase III trials usually further evaluate clinical efficacy and test further for safety by using the drug in its final form in an expanded patient population. There can be no assurance that phase I, phase II or phase III testing will be completed successfully within any specified period of time, if at all. Furthermore, we or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.



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The FDCA permits the FDA and IND sponsor to agree in writing on the design and size of clinical studies intended to form the primary basis of an effectiveness claim in an NDA application. This process is known as SPA. These agreements may not be changed after the clinical studies begin, except in limited circumstances.

Assuming successful completion of the required clinical testing, the results of the preclinical studies and of the clinical studies, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. The testing and approval process requires substantial time, effort and financial resources. The agencies review the application and may deem it to be inadequate to support the registration, and we cannot be sure that any approval will be granted on a timely basis, if at all. The FDA may also refer the application to the appropriate advisory committee, typically a panel of clinicians, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of the advisory committee.

The FDA has various programs, including fast track, priority review and accelerated approval, that are intended to expedite or simplify the process for reviewing drugs and/or provide for approval on the basis of surrogate endpoints. Generally, drugs that may be eligible for one or more of these programs are those for serious or life threatening conditions, those with the potential to address unmet medical needs and those that provide meaningful benefit over existing treatments. We cannot be sure that any of our drugs will qualify for any of these programs, or that, if a drug does qualify, that the review time will be reduced.

Before approving an NDA, the FDA usually will inspect the facility or the facilities where the drug is manufactured and will not approve the product unless cGMP compliance is satisfactory. If the FDA evaluates the NDA and the manufacturing facilities as acceptable, the FDA may issue an approval letter, or in some cases, an approvable letter followed by an approval letter. Both letters usually contain a number of conditions that must be met in order to secure final approval of the NDA. When and if those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter. The approval letter authorizes commercial marketing of the drug for specific indications. As a condition of NDA approval, the FDA may require post marketing testing and surveillance to monitor the drug's safety or efficacy, or impose other conditions.

After approval, certain changes to the approved product, such as adding new indications, making certain manufacturing changes or making certain additional labeling claims, are subject to further FDA review and approval. Obtaining approval for a new indication generally requires that additional clinical studies be conducted.

*Post-Approval Requirements.* In addition, holders of an approved NDA are required to: (i) report certain adverse reactions to the FDA, (ii) comply with certain requirements concerning advertising and promotional labeling for their products, and (iii) continue to have quality control and manufacturing procedures conform to cGMP after approval. The FDA periodically inspects the sponsor's records related to safety reporting and/or manufacturing facilities; this latter effort includes assessment of compliance with cGMP. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. We use and will continue to use third-party manufacturers to produce our products in clinical and commercial quantities, and future FDA inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal of the product from the market.

*Orphan Drug.* The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition, which generally is a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting an NDA. If the FDA grants orphan drug designation, which it may not, the identity of the therapeutic agent and its potential orphan use are publicly disclosed by the FDA. Orphan drug designation does not convey an advantage in, or shorten the duration of, the review and approval process. If a product which has an orphan drug designation subsequently receives the first

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FDA approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, meaning that the FDA may not approve any other applications to market the same drug for the same indication, except in certain very limited circumstances, for a period of seven years. Orphan drug designation does not prevent competitors from developing or marketing different drugs for that indication.

*Non-U.S. Regulation.* Before our products can be marketed outside of the United States, they are subject to regulatory approval similar to that required in the United States, although the requirements governing the conduct of clinical trials, including additional clinical trials that may be required, product licensing, pricing and reimbursement vary widely from country to country. No action can be taken to market any product in a country until an appropriate application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices may not be approved for such product.

In Europe, marketing authorizations may be submitted at a centralized, a decentralized or national level. The centralized procedure is mandatory for the approval of biotechnology products and provides for the grant of a single marketing authorization that is valid in all European Union members states. As of January 1995, a mutual recognition procedure is available at the request of the applicant for all medicinal products that are not subject to the centralized procedure. There can be no assurance that the chosen regulatory strategy will secure regulatory approvals on a timely basis or at all.

## **Environmental Regulation**

In connection with our research and development activities, we are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. Although we believe that we have complied with these laws, regulations and policies in all material respects and have not been required to take any significant action to correct any noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our research and development involves the controlled use of hazardous materials, including, but not limited to, certain hazardous chemicals and radioactive materials. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources.

## **Employees**

As of December 31, 2005, we employed approximately 214 individuals, including 105 in the United States and 109 in Europe. In the United States, 12 employees hold doctoral degrees while 54 hold doctoral degrees in Europe. Our U.S. employees do not have a collective bargaining agreement. Our European employees are subject to a collective bargaining agreement. We consider our relations with our employees to be good.

Information regarding our executive officers is set forth in Item 10 of this Report, which information is incorporated herein by reference.

## **Item 1a. Risk Factors**

*This annual report on Form 10-K contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks faced by us described below and elsewhere in this annual report on Form 10-K.*

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

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

We were incorporated in 1991 and have incurred a net operating loss every year. As of December 31, 2005, we had an accumulated deficit of approximately \$825.3 million. Effective July 18, 2005, we divested our sole commercial product TRISENOX and we may never become profitable, even if we are able to commercialize other products. We are pursuing regulatory approval for XYOTAX and will need to conduct research, development, testing and regulatory compliance activities expenses for which, together with projected general and administrative expenses, will result in operating losses for the foreseeable future.

*We have a substantial amount of debt.*

As of December 31, 2005, the principal amount on our convertible debt outstanding was over \$230 million. After taking into consideration \$59.0 million of conversions of our 6.75% convertible senior notes as of March 6, 2006, over \$96 million of this debt comes due in 2008 and over \$78 million comes due in 2010. Additionally, our annual interest expense will be over \$9 million. Unless we generate substantial sales from one of our potential products or raise substantial additional capital, we may not be able to repay this debt or the interest, liquidated damages or other payments with respect to our debt. Prior to this debt becoming due, we may engage in one or more restructuring transactions which could involve, among other things, an effective increase in interest rates, alteration of terms or exchanges involving the issuance of additional shares of common stock or other arrangements which may dilute or be adverse to the value of our common stock.

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

We expect that our existing cash, cash equivalents escrow funds and interest receivable will not be sufficient to fund our operations for the next 12 months. Accordingly, we will need to raise additional funds. We are exploring alternatives to raise additional capital through public or private equity financings, partnerships, debt financings, bank borrowings or other sources. In particular, we will need to raise additional funds to complete the PIONEER trial.

If our plans or assumptions change or are inaccurate, it will affect the amount of additional funds we will need to raise. We may raise such capital through public or private equity financings, partnerships, debt financings or restructurings, bank borrowings or other sources. Additional funding may not be available on favorable terms or at all. If adequate funds are not otherwise available, we will further curtail operations significantly, including the delay, modification or cancellation of operations and plans related to XYOTAX, pixantrone and other products we may be developing. To obtain additional funding, we may need to enter into arrangements that require us to relinquish rights to certain technologies, drug candidates, products and/or potential markets. To the extent that additional capital is raised through the sale of equity, or securities convertible into equity, shareholders may experience dilution of their proportionate ownership of us. In addition, the terms of our 6.75% convertible senior notes preclude us from closing certain financings before March 31, 2006.

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

In March 2005, we announced the results of STELLAR 3, and in May 2005, we announced the results of STELLAR 2 and 4, our phase III clinical trials of XYOTAX in non-small cell lung cancer. All three trials did not achieve their primary endpoints of superior overall survival compared to current marketed agents for treating NSCLC. Preclinical and clinical data can be interpreted in different ways, which could delay, limit or preclude regulatory approval. Negative or inconclusive results or adverse medical events during a clinical trial could delay, limit or prevent regulatory approval. Our success depends in large part on obtaining regulatory approval of XYOTAX.

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Without a successful PIONEER trial or positive interim results from the PIONEER trial, we expect a difficult regulatory review from the FDA, which may preclude obtaining approval of our NDA for a number of reasons: our trials failed to meet their primary endpoints and the FDA has taken the view that it will not favorably review secondary endpoints on data absent achievement of primary endpoints; while gender-specific survival was pre-specified in the analysis plan, women over men gender-specific survival was not a pre-specified endpoint; and, while the FDA has recently reviewed NDAs based on pooled analyses, none have been approved in the past. We are not pursuing approval from the FDA based on non-inferiority which is usually the basis for making a comparable survival claim. While we are requesting a pre-NDA meeting with the FDA, our proposed filing strategy for XYOTAX has not been previewed or approved by the FDA, and we expect that obtaining regulatory approval based on our current clinical trial data will be difficult for the reasons stated above in the summary.

We plan to submit an MAA to EMEA based on results of the STELLAR 2, 3 and 4 trials, however a successful regulatory review from the EMEA is also not assured. The EMEA Scientific Advice Working Group will need to agree on the statistical tests and methodologies used to support this non-inferiority endpoint. While one EMEA member country supported using a non-inferiority overall survival endpoint for each of the STELLAR first-line studies, one did not. The EMEA Scientific Advice Working Group may not reach such an agreement and may not support submission to the EMEA for review and potential approval.

*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 countries. Failure to comply with regulatory requirements could result in various adverse consequences, including possible delay in approval or refusal to approve a product, withdrawal of approved products from the market, product seizures, injunctions, monetary penalties, or criminal prosecution.

Our products may not be marketed in the United States until they have been approved by the FDA and may not be marketed in other countries until they have received approval from the appropriate agency. With the exception of TRISENOX, which we recently divested to Cephalon, none of our products have received approval. Obtaining regulatory approval requires substantial time, effort and financial resources, and we may not be able to obtain approval of any of our products on a timely basis, or at all. If our products are not approved in a timely fashion, our business and financial condition may be adversely affected.

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

We believe that while we owned TRISENOX, it was prescribed by physicians largely for uses not approved by the FDA. Although physicians may lawfully prescribe pharmaceutical products, such as TRISENOX, for such off-label uses, promotion by us of such off-label uses is unlawful. Some of our practices intended to make physicians aware of off-label uses of TRISENOX, without engaging in off-label promotion, could nevertheless have been construed as off-label promotion, and it is likely that some instances of off-label promotion occurred in the past. Although we have policies and procedures in place designed to assure ongoing compliance with FDA requirements regarding off-label promotion, some non-compliant actions may nevertheless have occurred. Regulatory authorities could take enforcement action against us if they believe that we promoted TRISENOX for off-label use. The United States Attorney's Office, or USAO, for the Western District of Washington is conducting an investigation into certain of CTI's business practices relating to TRISENOX. USAO's investigation relates to CTI's promotional practices relating to TRISENOX; its reporting of revenue relating to TRISENOX sales; and statements made by CTI representatives, and its expert third party reimbursement



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consultant, relating to the eligibility of TRISENOX for Medicare reimbursement when the drug is used to treat certain off-label indications. USAO has issued subpoenas to third parties relating to its investigation. CTI is fully cooperating with USAO and has not received a subpoena relating to the matter. Management cannot predict whether USAO will bring formal enforcement proceedings (and USAO has not indicated that it will). The Company has been advised that claims associated with the above-referenced as well as related conduct have been filed against the Company under seal on behalf of the Government by a private party. Management cannot provide an estimate of possible loss or range of loss resulting from any such action by USAO or in connection with such lawsuit at this time, however an adverse outcome could have a material adverse effect on our financial position, liquidity, and results of operations.

Additionally, we are subject to numerous regulations and statutes regulating the manner of selling and obtaining reimbursement for our products that receive marketing approval. For example, federal statutes generally prohibit providing certain discounts and payments to physicians to encourage them to prescribe our product. Violations of such regulations or statutes may result in treble damages, criminal or civil penalties, fines or exclusion of CTI or our employees from participation in federal and state healthcare programs. Although we have policies prohibiting violations of relevant regulations and statutes, unauthorized actions of our employees or consultants (including unlawful off-label promotion), or unfavorable interpretations of such regulations or statutes may result in third-parties or regulatory agencies bringing legal proceedings or enforcement actions against us.

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

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

If we are successful in bringing XYOTAX to market, we will face direct competition from oncology-focused multinational corporations. XYOTAX will compete with other taxanes. Many oncology-focused multinational corporations currently market or are developing taxanes, epothilones, and other cytotoxic agents, which inhibit cancer cells by a mechanism similar to taxanes, or similar products including, among others, Bristol-Myers Squibb Co., which markets paclitaxel; Aventis, which markets docetaxel; Genentech and OSI Pharmaceuticals, which market Tarceva ; Genentech, which markets Avastin ; Lilly, which markets Alimta; and American Pharmaceutical Partners, which markets Abraxane . In addition, several companies such as NeoPharm Inc. and Sonus Pharmaceuticals, are also developing taxane re-formulations which could compete with our products.

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

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

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

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

challenging the prices charged for health care products and services,

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

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

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

denying coverage altogether.

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

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

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

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

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

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

fail to receive necessary regulatory approvals,

be difficult to manufacture on a scale necessary for commercialization,

be uneconomical to produce,

fail to achieve market acceptance, or

be precluded from commercialization by proprietary rights of third parties.

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

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

We have licensed intellectual property, including patent applications from The University of Vermont, Hoffman La Roche and others, including the intellectual property relating to pixantrone. We have also in-licensed the intellectual property relating to our drug delivery technology that uses polymers that are linked to drugs, known as polymer-drug conjugates, including XYOTAX and CT-2106. Some of our product development programs depend on our ability to maintain rights under these licenses. Each licensor has the power to terminate its agreement with us if we fail to meet our obligations under these licenses. We may not be able to meet our obligations under these licenses. If we default under any license agreements, we may lose our right to market and sell any products based on the licensed technology.

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

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

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

protect trade secrets, and

prevent others from infringing on our proprietary rights.

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

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

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

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

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

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

*Our dependence on third-party manufacturers means that we do not always have sufficient control over the manufacture of our products.*

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

We will be dependent upon these third-parties to supply us in a timely manner with products manufactured in compliance with cGMPs or similar manufacturing standards imposed by foreign regulatory authorities where our products will be tested and/or marketed. While the FDA and other regulatory authorities maintain oversight for cGMP compliance of drug manufacturers, contract manufacturers may at times violate cGMPs. The FDA and other regulatory authorities may take action against a contract manufacturer who violates cGMPs. One of our products under development, XYOTAX, has a complex manufacturing process, which may prevent us from obtaining a sufficient supply of drug product for the clinical trials and commercial activities currently planned or underway on a timely basis, if at all. The active pharmaceutical ingredient and finished product for pixantrone are both manufactured by a single vendor. If the CT-2106 trials are successful and we need to manufacture additional materials for new clinical trials, we will need to identify and qualify vendors to manufacture and we may not be able to do so in a timely manner, if at all.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We have entered into collaborative arrangements with third-parties to develop and/or commercialize product candidates and are currently seeking additional collaborations. For example, we entered into an agreement with the Gynecologic Oncology Group to perform a phase III trial of XYOTAX in patients with ovarian cancer. Additional collaborations might be necessary in order for us to fund our research and development activities and third-party manufacturing arrangements, seek and obtain regulatory approvals and successfully commercialize our existing and future product candidates. If we fail to enter into additional collaborative arrangements or fail to maintain our existing collaborative arrangements, the number of product candidates from which we could receive future revenues would decline.

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

collaborative arrangements may not be on terms favorable to us;

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

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

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

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

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

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

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

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

## Edgar Filing: CELL THERAPEUTICS INC - Form 10-K/A

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



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

Our stock is traded on the Nuovo Mercato and we are required to also comply with the rules and regulations of CONSOB and Borsa Italiana, which collectively regulate companies listed on Italy's public markets such as the Nuovo Mercato. Conducting our operations in a manner that complies with all applicable laws and rules will require us to devote additional time and resources to regulatory compliance matters. For example, the process of seeking to understand and comply with the laws of each country, including tax, labor and regulatory laws, might require us to incur the expense of engaging additional outside counsel, accountants and other professional advisors and might result in delayed business initiatives as we seek to ensure that each new initiative will comply with all regulatory regimes.

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

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

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

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

tariffs, customs, duties and other trade barriers; and

capital controls, terrorism and other political risks.

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

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

successfully commercializing products under development;

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

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

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

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

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

## Edgar Filing: CELL THERAPEUTICS INC - Form 10-K/A

Our business exposes us to potential product liability risks inherent in the testing, manufacturing and marketing of human pharmaceutical products, and we may not be able to avoid significant product liability exposure. While we have insurance covering product use in our clinical trials, it is possible that we will not be able to maintain such insurance on acceptable terms or that any insurance obtained will provide adequate

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coverage against potential liabilities. Our inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or limit the commercialization of any products we develop. A successful product liability claim in excess of our insurance coverage could exceed our net worth.

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

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

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

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

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

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

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

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

The market price for securities of biopharmaceutical and biotechnology companies, including ours, historically has been highly volatile, and the market from time to time has experienced significant price and volume fluctuations that are unrelated to the operating performance of such companies. For example, during the twelve month period ended December 31, 2005, our stock price ranged from a low of \$1.97 to a high of \$10.85. 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;

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

our quarterly operating results;

developments or disputes concerning patent or other proprietary rights;

developments in our relationships with collaborative partners;

acquisitions or divestitures;

litigation and government proceedings;

adverse legislation, including changes in governmental regulation;

third-party reimbursement policies;

changes in securities analysts' recommendations;

changes in health care policies and practices;

economic and other external factors; and

general market conditions.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted. In the case of our company, beginning in March 2005, several class action lawsuits were instituted against CTI, James Bianco and Max Link and a derivative action lawsuit was filed against CTI's full board of directors. See the section under the heading "Legal Proceedings." As a result of these lawsuits, we could incur substantial legal fees and our management's attention and resources could be diverted from operating our business as we respond to the litigation.

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

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

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

elimination of cumulative voting in the election of directors;

procedures for advance notification of shareholder nominations and proposals;

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

the ability of our board of directors to issue up to 10,000,000 shares of preferred stock without shareholder approval upon the terms and conditions and with the rights, privileges and preferences as the board of directors may determine; and

a shareholder rights plan.

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

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

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**Item 2. Properties**

We lease approximately 68,000 square feet of lab and office space at 201 Elliott Avenue West in Seattle, Washington. The lease expires in January 2008, with one five-year renewal option at the then prevailing market rent. As of December 31, 2005, we had entered into subleases for approximately 21,000 square feet of this space with the subleases expiring in January 2008 and have vacated the remaining space. We also lease approximately 76,984 square feet of space at 501 Elliott Avenue West in Seattle, Washington under an amended lease for our executive offices and administrative operations. The lease expires in July 2012. Cell Therapeutics Europe S.r.l., or CTI (Europe), acquired through the merger with Novuspharma at the beginning of 2004, leases approximately 75,000 square feet of office and laboratory space in Bresso (Milan), Italy. The office and laboratory leases expire in June 2007. To accommodate the operational requirements of our wholly-owned subsidiaries, Cell Therapeutics (UK) Limited and Cell Therapeutics Corporate Development, Inc., we leased additional space in London, UK and Hillsboro, Oregon, respectively. In 2005, our UK lease was terminated in connection with the sale of TRISENOX to Cephalon and our Cell Therapeutics Corporate Development, Inc. lease was terminated in connection with the termination of our aircraft lease. We believe our existing and planned facilities are adequate to meet our present requirements. We anticipate that additional space will be available, when needed, on commercially reasonable terms.

**Item 3. Legal Proceedings**

On February 10, 2004, Micromet AG, or Micromet, a Munich, Germany-based company, filed complaints against CTI in the federal district court for the Western District in the State of Washington, asserting that CTI (Europe), formerly known as Novuspharma S.p.A., had purportedly breached a contract with Micromet for the development of MT-201, a fully human antibody targeting the EP-CAM molecule. The claims allege that CTI (Europe) failed to pay for certain milestones and development expenses owed under the contract. On February 23, 2004, CTI answered the complaint, denying the substance of the allegations, and filed counterclaims for breach of contract and for rescission of the contract based on Micromet's misrepresentations and failures to disclose material information including preclinical tests which were determined to be invalid. Management believes that Micromet's complaint is without merit and intends to vigorously defend against the Micromet action, as well as to seek recovery based upon its counterclaims. Management believes the ultimate outcome will not have a material adverse impact on the Company's financial condition or results of operations. No estimate of possible loss or range of loss resulting from the lawsuit can be made at this time.

Beginning in March 2005, a number of purported shareholder class actions, alleging violations of federal securities laws, were filed against CTI, Jim Bianco and Max Link. These actions have been consolidated in the United States District Court for the Western District of Washington. On November 7, 2005, the plaintiffs filed a Consolidated and Amended Class Action Complaint against CTI, James Bianco and Jack Singer. The Consolidated and Amended Complaint asserts claims arising under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder on behalf of a class of purchasers of common stock during the period from November 14, 2003 to March 7, 2005, or the Class Period. Plaintiffs allege that the defendants violated federal securities laws by, among other things, making false statements of material facts and/or omitting to state material facts to make the statements not misleading in connection with the results of the Company's STELLAR clinical trials for its drug XYOTAX. On January 6, 2006, CTI filed a motion to dismiss this class action complaint, to which the plaintiffs filed an opposition on February 21, 2006. No estimate of possible loss or range of loss resulting from the lawsuit can be made at this time. Management believes that the allegations in the foregoing actions are without merit and intend to defend the actions vigorously.

On May 9, 2005, Terence Fernandes, a shareholder of CTI, filed a complaint in the Superior Court of the State of Washington, King County on behalf of CTI against members of CTI's board of directors. The shareholder derivative action alleges breaches of fiduciary duties, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment since June 7, 2004. The case now resides in the United States District Court for the Western District of Washington. On December 7, 2005, plaintiff filed an amended complaint and

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defendants filed a motion to dismiss on February 6, 2006, to which the plaintiffs filed an opposition on March 10, 2006. The ultimate outcome of this matter is uncertain.

The United States Attorney's Office, or USAO, for the Western District of Washington is conducting an investigation into certain of CTI's business practices relating to TRISENOX. USAO's investigation relates to CTI's promotional practices relating to TRISENOX; its reporting of revenue relating to TRISENOX sales; and statements made by CTI representatives, and its expert third party reimbursement consultant, relating to the eligibility of TRISENOX for Medicare reimbursement when the drug is used to treat certain off-label indications. USAO has issued subpoenas to third parties relating to its investigation. CTI is fully cooperating with USAO and has not received a subpoena relating to the matter. Management cannot predict whether USAO will bring formal enforcement proceedings (and USAO has not indicated that it will). The Company has been advised that claims associated with the above-referenced as well as related conduct have been filed against the Company under seal on behalf of the Government by a private party. Management cannot provide an estimate of possible loss or range of loss resulting from any such action by USAO or in connection with such lawsuit at this time, however an adverse outcome could have a material adverse effect on our financial position, liquidity, and results of operations.

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

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

No matters were submitted to a vote of security holders during the fourth quarter of the year ended December 31, 2005.

**Table of Contents****PART II****Item 5. Market for Registrant's Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities**

Our common stock is traded on the Nasdaq National Market under the symbol CTIC, and effective January 2, 2004, we commenced the trading of our common stock on the Nuovo Mercato in Italy, also under the ticker symbol CTIC. The following table sets forth, for the periods indicated, the high and low reported sales prices per share of the common stock, as reported on the Nasdaq National Market, our principal trading market.

|                | <b>High</b> | <b>Low</b> |
|----------------|-------------|------------|
| <b>2004</b>    |             |            |
| First Quarter  | 10.25       | 7.80       |
| Second Quarter | 9.43        | 6.75       |
| Third Quarter  | 7.43        | 4.55       |
| Fourth Quarter | 8.62        | 5.69       |
| <b>2005</b>    |             |            |
| First Quarter  | 10.85       | 3.49       |
| Second Quarter | 4.05        | 2.47       |
| Third Quarter  | 3.49        | 1.97       |
| Fourth Quarter | 2.83        | 2.10       |

On March 10, 2006, the last reported sale price of our common stock on the Nasdaq Market was \$1.88 per share. As of March 10, 2006, there were approximately 275 shareholders of record of our common stock.

**Dividend Policy**

We have not declared or paid any cash dividends on our capital stock since our inception. We currently intend to retain all of our cash and any future earnings to finance the growth and development of our business and therefore do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay cash dividends will be at the discretion of the Board of Directors and will be dependent upon our consolidated financial condition, results of operations, capital requirements and such other factors as the Board of Directors deems relevant.

**Sales of Unregistered Securities**

Not Applicable.



**Table of Contents****Equity Compensation Plan Information**

The following table gives information about our common stock that may be issued upon the exercise of options, warrants and rights under all of our existing compensation plans as of December 31, 2005, including the 2003 Equity Incentive Plan, Novuspharma S.p.A. Stock Option Plan, 1994 Equity Incentive Plan and the 1996 Employee Stock Purchase Plan.

| <b>Plan Category</b>                            | <b>(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights</b> | <b>(b) Weighted Average Exercise Price of Outstanding Options, Warrants, and Rights</b> | <b>(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))</b> | <b>(d) Total of Securities Reflected in Columns (a) and (c)</b> |
|---|--|---|--|---|
| Plans Approved by Shareholders                  | 5,959,985(1)   | \$ 11.05  | 946,765(2)   | 6,906,750   |
| Plans Not Approved by Shareholders              | 903,665(3)   | \$ 10.21  | None   | 903,665   |
| Plan Not Approved by Shareholders (Novuspharma) | 154,800(4)   | \$ 7.17   | 192,200  | 347,000   |

- (1) Consists of the 2003 Equity Incentive Plan and the 1994 Equity Incentive Plan.
- (2) Consists of 701,806 shares available for future issuance under the 2003 Equity Incentive Plan and 244,959 shares available for future issuance under the 1996 Employee Stock Purchase Plan.
- (3) Consists of warrants to purchase 350,000 shares issued to the initial purchaser in connection with our 6.75% convertible senior notes, warrants to purchase 350,000 shares and 103,665 restricted share rights issued in connection with a license agreement with PG-TXL Company, L.P., and warrants to purchase 100,000 shares issued in connection with a research services agreement with The Hope Heart Institute.
- (4) Consists of the Novuspharma S.p.A. Stock Option Plan adopted in connection with the merger between CTI and Novuspharma.

**License Agreement with PG-TXL Company, L.P.**

In 1998, we issued fully-vested warrants to purchase 350,000 shares of our common stock in connection with a license agreement with PG-TXL Company, L.P. These warrants expire in 2008 and have an exercise price of \$20.00. We also issued 103,665 restricted share rights to non-employees for which ownership vests upon the achievement of clinical trial milestones. Upon entering into an amendment to the PG-TXL License Agreement in February 2006, we issued 87,999 shares of common stock upon the exercise of these restricted share rights.

**Warrants Issued to Placement Agents and Underwriters**

In 2000, we completed a \$40.0 million private placement of common stock. In connection with the offering, we issued fully-vested warrants to purchase 170,000 shares of common stock with an exercise price of \$13.20 to a placement agent and finder. These warrants expired in August 2005.

In November 2005, we completed the issuance of \$82 million of 6.75% convertible senior notes. In connection with this offering, we issued fully-vested warrants to purchase 350,000 shares of common stock within five years at an exercise price of \$3.50 per share to the initial purchaser of these notes. As of December 31, 2005, all warrants were still outstanding.

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### **Research Services Agreement with The Hope Heart Institute**

In 2002, we entered into an agreement with The Hope Heart Institute for research services, which we terminated in 2004. In connection with this agreement, we issued 100,000 fully-vested warrants to purchase shares of common stock at an exercise price of \$10.00. These warrants expire in 2007, and no warrants have been exercised.

### **Warrants Issued in Conjunction with the Conversion and Placement Agreement**

In conjunction with issuance of our 6.75% convertible senior notes, or 6.75% notes, we entered into a Conversion and Placement Agreement, or CAP agreement, with two existing holders of approximately \$38.4 million of our convertible senior subordinated notes. In exchange for the conversion of these notes and the purchase of our 6.75% notes, we issued 6,500,000 zero strike price warrants. No warrants had been exercised as of December 31, 2005.

### **Cell Therapeutics, Inc. Novuspharma S.p.A. Stock Option Plan**

In December 2003, the Board of Directors approved the assumption and amendment and restatement of the Cell Therapeutics, Inc. Novuspharma S.p.A. Stock Option Plan, or Plan, in connection with the merger between CTI and Novuspharma. The Plan provides for the grant of nonqualified stock options and restricted stock to certain of our officers, employees, members of our Board of Directors and consultants. The plan administrator determines, on a grant-by-grant basis, what terms and conditions apply to options and restricted stock granted under the Plan (including vesting restrictions). The Plan permits options to be exercised with cash or certain other legal forms of consideration. In the event of our change of control (including our merger with or into another corporation or our sale of substantially all of our assets), the Plan provides that we may determine, in our discretion, that each optionee may vest in his or her option or restricted stock award with respect to any or all of the shares subject to the award (including shares that were unvested prior to the change of control) and that such awards may otherwise be assumed or substituted for by the successor corporation. There are 350,000 shares of common stock reserved under the Plan, and 192,200 shares remain available for future issuance.

**Table of Contents****Item 6. Selected Consolidated Financial Data**

The data set forth below should be read in conjunction with Item 7. Management's Discussion and Analysis of Consolidated Financial Condition and Results of Operations and the Consolidated Financial Statements and Notes thereto appearing at Item 8 of this report.

|   | Year ended December 31,               |                     |                     |                    |                    |
|---|---------------------------------------|---------------------|---------------------|--------------------|--------------------|
|   | 2005                                  | 2004                | 2003                | 2002               | 2001               |
|   | (In thousands, except per share data) |                     |                     |                    |                    |
| <b>Consolidated Statements of Operations Data:</b>                        |                                       |                     |                     |                    |                    |
| Revenues:   |                                       |                     |                     |                    |                    |
| Product sales   | \$ 14,599                             | \$ 26,626           | \$ 22,105           | \$ 11,393          | \$ 6,130           |
| License and contract revenue  | 1,493                                 | 2,968               | 2,660               | 5,503              | 106                |
| <b>Total revenues</b>   | <b>16,092</b>                         | <b>29,594</b>       | <b>24,765</b>       | <b>16,896</b>      | <b>6,236</b>       |
| Operating expenses:   |                                       |                     |                     |                    |                    |
| Cost of product sold  | 518                                   | 1,104               | 840                 | 423                | 394                |
| Research and development(1)   | 68,767                                | 101,127             | 89,534              | 58,759             | 44,669             |
| Selling, general and administrative                                       | 61,717                                | 78,522              | 55,641              | 49,800             | 35,268             |
| Acquired in-process research and development(2)                           |                                       | 87,375              |                     |                    |                    |
| Amortization of purchased intangibles                                     | 1,254                                 | 2,294               | 1,335               | 6,701              | 9,390              |
| Restructuring charges and related asset impairments(3)                    | 12,780                                |                     |                     |                    |                    |
| Gain on divestiture of TRISENOX(4)  | (71,211)                              |                     |                     |                    |                    |
| <b>Total operating expenses</b>   | <b>73,825</b>                         | <b>270,422</b>      | <b>147,350</b>      | <b>115,683</b>     | <b>89,721</b>      |
| <b>Loss from operations</b>   | <b>(57,733)</b>                       | <b>(240,828)</b>    | <b>(122,585)</b>    | <b>(98,787)</b>    | <b>(83,485)</b>    |
| Other income (expense):   |                                       |                     |                     |                    |                    |
| Investment and other income   | 2,824                                 | 1,636               | 1,880               | 4,819              | 9,200              |
| Interest expense  | (17,559)                              | (10,988)            | (9,326)             | (11,240)           | (5,988)            |
| Foreign exchange gain (loss)  | 8                                     | (2,118)             |                     |                    |                    |
| Debt conversion expense   | (23,608)                              |                     |                     |                    |                    |
| Loss on extinguishment of royalty obligation                              | (6,437)                               |                     |                     |                    |                    |
| Gain on exchange of convertible subordinated notes                        |                                       |                     |                     | 55,305             |                    |
| <b>Net loss</b>   | <b>(102,505)</b>                      | <b>(252,298)</b>    | <b>(130,031)</b>    | <b>(49,903)</b>    | <b>(80,273)</b>    |
| Preferred stock dividend  |                                       |                     |                     |                    | (1,372)            |
| <b>Net loss</b>   | <b>\$ (102,505)</b>                   | <b>\$ (252,298)</b> | <b>\$ (130,031)</b> | <b>\$ (49,903)</b> | <b>\$ (81,645)</b> |
| <b>Basic and diluted net loss per share(5)</b>                            | <b>\$ (1.59)</b>                      | <b>\$ (4.67)</b>    | <b>\$ (3.89)</b>    | <b>\$ (1.48)</b>   | <b>\$ (2.41)</b>   |
| <b>Shares used in calculation of basic and diluted net loss per share</b> | <b>64,553</b>                         | <b>54,052</b>       | <b>33,418</b>       | <b>33,763</b>      | <b>33,822</b>      |

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|  | 2005      | 2004       | December 31,<br>2003<br>(In thousands) | 2002       | 2001       |
|--|-----------|------------|--|------------|------------|
| <b>Consolidated Balance Sheets Data:</b>   |           |            |  |            |            |
| Cash and cash equivalents, securities available-for-sale and interest receivable | \$ 69,067 | \$ 116,020 | \$ 92,838                              | \$ 142,157 | \$ 259,421 |
| Restricted cash(6)   | 25,596    |            |  |            |            |
| Working capital  | 76,288    | 93,813     | 71,898                                 | 129,849    | 250,142    |
| Total assets   | 155,440   | 184,996    | 146,090                                | 186,780    | 303,750    |
| 6.75% Convertible senior notes(7)  | 79,046    |            |  |            |            |
| 5.75% Convertible senior subordinated notes(8)                                   | 66,929    | 85,459     | 85,459                                 | 85,460     |            |
| 4.0% Convertible senior subordinated notes(9)                                    | 55,150    | 75,000     | 75,000                                 |            |            |
| 5.75% Convertible subordinated notes(10)   | 29,640    | 29,640     | 29,640                                 | 29,640     | 175,000    |
| Royalty obligation   |           | 25,123     |  |            |            |
| Other long-term obligations, less current portion                                | 7,326     | 6,363      | 5,012                                  | 6,704      | 3,892      |
| Accumulated deficit  | (825,289) | (722,784)  | (470,486)                              | (340,455)  | (290,552)  |
| Total shareholders' equity (deficit)   | (107,097) | (70,708)   | (82,542)                               | 43,483     | 109,557    |

- (1) Amount in 2001 includes an equity-based expense of \$9.2 million related to the issuance of warrants to purchase 350,000 shares of common stock for the achievement of a XYOTAX milestone.
- (2) Amount represents the value of Novuspharma's research and development projects and technologies which had no alternative use and which had not reached technological feasibility as of January 1, 2004, the effective date of the merger between CTI and Novuspharma.
- (3) Amount represents costs related to our 2005 restructuring activities which includes excess facilities charges of \$7.1 million, employee separation costs of \$3.5 million, lease termination payments of \$1.2 million and restructuring related asset impairment charges of \$1.0 million.
- (4) Amount represents the gain recognized on the divestiture of TRISENOX and certain proteasome assets to Cephalon as well as transition services provided to Cephalon related to TRISENOX and proteasome assets.
- (5) See Notes 1 and 14 of Notes to Consolidated Financial Statements for a description of the computation of the number of shares and net loss per share.
- (6) Amount represents approximately \$24.6 million held in escrow to fund potential redemptions of up to 30% of the aggregate amount of our 6.75% convertible senior notes and approximately \$1.0 million held in connection with the liquidation of Cell Therapeutics (Ireland) Holding Limited.
- (7) The 6.75% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 380.37 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of approximately \$2.63 per share.
- (8) The 5.75% convertible senior subordinated notes are convertible into shares of CTI common stock at a conversion rate of 100 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of \$10.00 per share.
- (9) The 4.0% convertible senior subordinated notes are convertible into shares of CTI common stock at a conversion rate of 74.0741 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of approximately \$13.50 per share.
- (10) The 5.75% convertible subordinated notes are convertible into shares of CTI common stock at a conversion rate of 29.4118 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of approximately \$34.00 per share.

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### **Item 7. Management's Discussion and Analysis of Consolidated Financial Condition and Results of Operations**

The following discussion should be read in conjunction with the Selected Consolidated Financial Data and the Consolidated Financial Statements and the related Notes included in Items 6 and 8 of this Form 10-K. The following discussion contains forward-looking statements that involve risks and uncertainties. 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 risks and uncertainties, including, but not limited to, those discussed below and elsewhere in this Form 10-K, particularly in Factors Affecting Our Operating Results and Financial Condition, that could cause actual results to differ significantly from those projected. Although we believe that expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. We will not update any of the forward-looking statements after the date of this Form 10-K to conform these statements to actual results or changes in our expectations. Readers are cautioned not to place undue reliance on these forward-looking statements, which apply only as of the date of this Form 10-K.

#### **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 cancer drugs. Our research and in-licensing activities are concentrated on identifying new, less toxic and more effective ways to treat cancer. As of December 31, 2005, we had incurred aggregate net losses of approximately \$825.3 million since inception. We expect to continue to incur additional operating losses for at least the next several years.

On January 1, 2004, we completed our merger with Novuspharma S.p.A., a public biopharmaceutical company located in Italy, currently Cell Therapeutics Europe S.r.l., or CTI (Europe). This provided us with worldwide rights to pixantrone, approximately \$92.5 million of cash and cash equivalents upon closing of the acquisition, and a drug discovery organization and staff with an extensive track record in cancer drug development. The merger, including the addition of pixantrone to our pipeline, is consistent with our strategy of growth by strategic acquisition and our goal to develop improved cancer therapies.

On July 18, 2005, we completed the divestiture of TRISENOX<sup>®</sup> (arsenic trioxide), an anti-cancer compound, and certain proteasome assets to Cephalon Inc., or Cephalon. Per the divestiture agreement, we also provided transition services to Cephalon related to the TRISENOX and proteasome assets for approximately six months subsequent to the closing date. Proceeds from the divestiture, net of broker fees, were approximately \$71.9 million which includes proceeds received from transition services provided. In connection with the divestiture, we were required to repay our royalty obligation to PharmaBio Development, Inc., or PharmaBio, and after this repayment our net proceeds from both transactions were approximately \$32.5 million. In addition, in the future we may potentially receive up to an additional \$100 million if Cephalon is successful in achieving certain sales and development milestones, although achievement of such milestones is uncertain. As TRISENOX was our only commercial product, we no longer have revenues from product sales.

#### ***TRISENOX***

In January 2000, we acquired the rights to TRISENOX from PolaRx Biopharmaceuticals, Inc., or PolaRx, and subsequently submitted an application for and received approval to market from the FDA and EMEA. In connection with the TRISENOX divestiture which was completed in July 2005, Cephalon assumed any liabilities for future milestone payments to PolaRx.

In December 2002, we entered into a distribution agreement with Nippon Shinyaku Co. Ltd., or Nippon. This agreement grants an exclusive license to Nippon to market and distribute TRISENOX injection in Japan, South Korea and Taiwan. In October 2004, Nippon received approval from the Japanese Ministry of Health, or

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JMH, to market TRISENOX for patients with relapsed or refractory acute promyelocytic leukemia, or APL, in Japan. In December 2004, Nippon launched TRISENOX for the treatment of relapsed/refractory APL in Japan. Cephalon assumed the agreement with Nippon in connection with the TRISENOX divestiture.

In December 2004, we entered into a royalty interest financing arrangement with PharmaBio for \$25.0 million in financing and \$5.0 million in services to be provided by PharmaBio and its affiliates and paid by PharmaBio.

On July 18, 2005, we completed the divestiture of TRISENOX and certain proteasome assets to Cephalon. In connection with the divestiture, we made a payment to PharmaBio of \$39.4 million from the proceeds received from the transaction, terminating our obligations under the financing agreement with PharmaBio. PharmaBio's obligation to provide to us the remainder of the \$5.0 million in services survived the termination of our obligations, of which \$3.4 million is remaining as of December 31, 2005.

## **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 consolidated financial statements. We evaluate our estimates and judgments on an on-going basis and base our estimates on historical experience and on assumptions that we believe to be reasonable under the circumstances. Our experience and assumptions form the basis for our judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may vary from what we anticipate and different assumptions or estimates about the future could change our reported results. We believe the following accounting policies are the most critical to us, in that they are important to the portrayal of our consolidated financial statements and require our most difficult, subjective or complex judgments in the preparation of our consolidated financial statements.

### *Product Sales*

We recognized revenue from product sales when there was persuasive evidence that an arrangement existed, title had passed and delivery had occurred, the price was fixed and determinable, and collectability was reasonably assured. As we sold our only commercial product, TRISENOX, to Cephalon on July 18, 2005, there are no product sales subsequent to this date. Product sales were generally recorded upon shipment net of an allowance for estimated returns and discounts. Customers were able to return damaged or expired inventory for up to one year after the expiration date. In estimating returns, we analyzed historical returns and sales patterns. To arrive at the accrual for product returns, we matched the returns to the corresponding production batch to assess the historical trend for returns. Based on this analysis, the estimated return percentage was applied to the current period sales. Allowances for returns, discounts and bad debts were netted against accounts receivable. If customers had product acceptance rights or product return rights, and we were unable to reasonably estimate returns related to that customer or market, we deferred revenue recognition until such rights had expired. We do not expect additional product sales revenues until another commercial product is approved or acquired.

### *License and Contract Revenue*

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

Revenue associated with up-front license fees and research and development funding payments under collaborative agreements is recognized ratably over the relevant periods specified in the agreement, generally the research and development period. If the time period is not defined in the agreement, we calculate the revenue recognition period based on our current estimate of the research and development period considering experience

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with similar projects, level of effort and the stage of development. Should there be a change in our estimate of the research and development period, we will revise the term over which the initial payment is recognized. Revenue from substantive at-risk milestones and future product royalties is recognized as earned based on the completion of the milestones and product sales, as defined in the respective agreements. Revenue under cost reimbursement contracts and research grants is recognized as the related costs are incurred. Payments received in advance of recognition as revenue are recorded as deferred revenue.

We evaluate multiple element arrangements pursuant to Emerging Issues Task Force, or EITF, 00-21, *Revenue Arrangements with Multiple Deliverables*. For multiple element arrangements that have continuing performance obligations, we recognize contract, milestone or license fees together with any up-front payments over the term of the arrangement as we complete our performance obligation, unless the delivered technology has stand alone value to the customer and there is objective, reliable evidence of fair value of the undelivered element in the arrangement. Additionally, pursuant to the guidance of Securities and Exchange Commission Staff Accounting Bulletin 104, or SAB 104, unless evidence suggests otherwise, revenue from consideration received is recognized on a straight-line basis over the expected term of the arrangement.

### *Research and Development Expenses*

Research and development expenses include salaries and benefits, clinical trial and clinical manufacturing costs, contract and other outside service fees, and facilities and overhead costs related to our research and development efforts. Research and development expenses also consist of costs incurred for proprietary and collaboration research and development and include activities such as product registries and investigator-sponsored trials. Research and development costs are expensed as incurred. Generally, in instances where we enter into agreements with third parties for research, clinical trial, and related manufacturing costs, costs are expensed upon the earlier of when non-refundable amounts are due or as services are performed unless there is an alternative future use of the funds in other research and development projects. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments, and payments upon the completion of milestones or receipt of deliverables.

### *Impairment of Long-lived Assets*

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

### *Valuation of Goodwill*

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

### *Derivatives Embedded in Certain Debt Securities*

We evaluate financial instruments for freestanding or embedded derivatives in accordance with SFAS 133, *Accounting for Derivative Instruments and Hedging Activities*, and related guidance. Derivative instruments are recorded at fair value with changes in value recognized in the period of change.

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Our 6.75% convertible senior notes, or 6.75% notes, contain a feature providing for payments in cash or common stock to be made in the event of conversions of the debt to common stock. In general, this feature calls for make-whole payments equal to the interest on the debt over its term less any amounts paid prior to the date of conversion.

This feature represents an embedded derivative which is required to be accounted for separately from the related debt securities. The estimated fair value of this feature is calculated based on a discounted cash flow model. Changes in the estimated fair value of the liability are included in *other income* and will be required until the feature expires or all of the notes are converted.

### *Purchase price allocation*

The purchase price for Novuspharma S.p.A. was allocated to the tangible and identifiable intangible assets acquired and liabilities assumed based on their estimated fair values at the acquisition date of January 1, 2004. An independent third-party valuation firm was engaged to assist in determining the fair values of in-process research and development and identifiable intangible assets. Such a valuation requires significant estimates and assumptions including but not limited to: determining the timing and expected costs to complete the in-process projects, projecting regulatory approvals, estimating future cash flows from product sales resulting from in-process projects, and developing appropriate discount rates and probability rates by project. We believe the fair values assigned to the assets acquired and liabilities assumed are based on reasonable assumptions. However, these assumptions may be inaccurate, and unanticipated events and circumstances may occur.

### *Restructuring Charges*

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

## **Results of Operations**

*Years ended December 31, 2005 and 2004.*

*Product sales.* TRISENOX was, prior to its divestiture to Cephalon in July 2005, our pharmaceutical grade arsenic product approved by the FDA, EMEA, and the JMH to treat patients with relapsed or refractory APL. We recorded net product sales of approximately \$14.6 million and \$26.6 million for TRISENOX for the year ended December 31, 2005 and 2004, respectively. The decrease in net sales is due to the divestiture of TRISENOX to Cephalon resulting in no TRISENOX sales subsequent to July 18, 2005.

*License and contract revenue.* Upon execution of the Chugai agreement in October 2001, we received a \$3.0 million initial payment, which we recorded as deferred revenue and which was being recognized as revenue over the estimated development period of approximately seven years on a straight-line basis. As of December 31, 2005, we recognized the remaining deferred revenue related to this initial payment in anticipation of the termination of our agreement with Chugai which occurred in March 2006. In connection with the Nippon agreement, we received \$750,000 payment which was recorded as deferred revenue and which was recognized as revenue over the performance period which ended during the fourth quarter 2004.

For the year ended December 31, 2005, we recognized approximately \$1.5 million of license and contract revenue consisting primarily of the remaining deferred revenue balance related to the initial payment from Chugai. For the year ended December 31, 2004, we recognized approximately \$1.9 million of license and contract revenue, of which \$0.8 million related to cost reimbursements for development expenses received from



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Chugai in 2004, \$0.6 million related to the amortization of the initial payments from Chugai and Nippon, and \$0.5 million related to a milestone payment from Nippon for obtaining an MAA approval for relapsed APL. We also recognized \$1.1 million in grant income received for research and development activities in 2004.

*Cost of product sold.* The cost of product sold during the year ended December 31, 2005 and 2004 was approximately \$0.5 million and \$1.1 million, respectively. Our gross margins have remained relatively consistent. Cost of product sold consists primarily of manufacturing costs, royalties paid on product sales, and allowances for excess inventory that may expire and become unsaleable. Due to the divestiture of TRISENOX to Cephalon, there was no cost of product sold subsequent to July 18, 2005.

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

|   | 2005          | 2004           |
|---|---------------|----------------|
| Compounds under development:                |               |                |
| XYOTAX                                      | \$ 18,251     | \$ 41,638      |
| Pixantrone                                  | 6,634         | 6,835          |
| TRISENOX                                    | 3,682         | 7,208          |
| Other compounds                             | 2,019         | 1,301          |
| Operating expenses                          | 31,394        | 33,076         |
| Discovery research                          | 6,787         | 11,069         |
| <br>Total research and development expenses | <br>\$ 68,767 | <br>\$ 101,127 |

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 new drug applications or similar regulatory filings to the FDA, EMEA or other regulatory agencies outside the United States and Europe. Operating costs include our personnel and occupancy expenses associated with developing these compounds. Discovery research costs include primarily personnel, occupancy and laboratory expenses associated with the discovery and identification of new drug targets and lead compounds. We do not allocate operating costs to the individual compounds under development as our accounting system does not track these costs by individual compound. As a result, we are not able to capture the total cost of each compound. Direct external costs incurred to date for XYOTAX, TRISENOX and pixantrone are approximately \$167.7 million, \$29.1 million and \$13.5 million, respectively. Costs for pixantrone prior to our merger with Novuspharma in January 2004 are excluded from this amount.

Research and development expenses decreased to approximately \$68.8 million for the year ended December 31, 2005, from approximately \$101.1 million for the year ended December 31, 2004. Costs for our XYOTAX program decreased primarily due to an \$18.6 million decrease in our Phase III trial costs attributable to the winding down of our STELLAR trials, a \$2.1 million decrease related to the near completion of two phase II clinical trials, a \$1.4 million reduction in our manufacturing costs associated with the completion of our STELLAR trials and a \$1.2 million decrease in preclinical expenses related to fewer development activities with Chugai in 2005. TRISENOX costs decreased due to the divestiture of TRISENOX to Cephalon. Costs for other compounds increased primarily due to costs for two Phase II clinical trials for CT-2106 that initiated enrollment in the fourth quarter of 2004. Operating costs decreased primarily due to a reduction in our headcount resulting from our restructuring activities in 2005. Discovery research costs decreased primarily as a result of decreased personnel and other costs due to a reduction in programs.

Our lead drug candidates, XYOTAX and pixantrone are currently in clinical trials. Many drugs in human clinical trials fail to demonstrate the desired safety and efficacy characteristics. Even if our drugs progress successfully through initial human testing, they may fail in later stages of development. A number of companies

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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 pre-clinical and clinical testing. We or regulatory authorities may suspend clinical trials at any time on the basis that the participants are being exposed to unacceptable health risks. Completion of clinical trials depends on, among other things, the number of patients available for enrollment in a particular trial, which is a function of many factors, including the availability and proximity of patients with the relevant condition. We rely on third parties to conduct clinical trials, which may result in delays or failure to complete trials if the third parties fail to perform or meet applicable standards. Many of our drug candidates are still in research and preclinical development, which means that they have not yet been tested on humans. We will need to commit significant time and resources to develop these and additional product candidates.

Our products will be successful only if:

our product candidates are developed to a stage that will enable us to commercialize 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.

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

Because of these risks and uncertainties, we cannot accurately predict when or whether we will successfully complete the development of our product candidates or the ultimate product development cost. We reported XYOTAX STELLAR 3 clinical trial results in March 2005 and STELLAR 2 and 4 results in May 2005, all of which missed their primary endpoints of superior overall survival. We are targeting submission of an NDA for XYOTAX in the second half of 2006, and depending on the duration of the review cycle and timing of interim results of the PIONEER trial, a U.S. XYOTAX approval is targeted in late 2007 with launch shortly thereafter. Approval in the EU would be targeted approximately 15 months following the submission of an MAA, which is targeted in the second half of 2006.

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

*Selling, general and administrative expenses.* Selling, general and administrative expenses decreased to approximately \$61.7 million for the year ended December 31, 2005, from approximately \$78.5 million for the year ended December 31, 2004. This decrease is primarily attributed to an \$11.3 million decrease in our sales and marketing expenses related to reduced commercialization efforts and headcount due to the divestiture of TRISENOX to Cephalon in the third quarter of 2005, a \$2.7 million decrease in corporate development expenses including a \$1.1 million decrease in aircraft operating costs due to increased charter income in 2005 and the termination of our aircraft operating lease in the fourth quarter of 2005, and a \$2.3 million decrease in stock-based compensation charges. Corporate development expenses include certain legal expenses, business development activities, charitable contributions, costs related to operating our aircraft, and our corporate communications programs.

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We expect selling, general and administrative expenses to decrease in 2006 due to the divestiture of TRISENOX to Cephalon as well as the termination of our aircraft lease. In the event that we are able to move forward with the commercialization of XYOTAX, our sales and marketing expenses would then increase. Further, due to the variable accounting treatment of certain stock options and restricted stock awards, fluctuation in quoted prices for our common stock may result in unpredictable and potentially significant charges or credits to our stock-based compensation expense.

*Acquired in-process research and development.* Acquired in-process research and development relates to a one-time non-cash charge recorded in connection with our acquisition of Novuspharma in January 2004. The \$87.4 million charge for the year ended December 31, 2004 represents the estimated fair value of purchased technology that had not reached technological feasibility at the effective time of the merger.

*Amortization of purchased intangibles.* Amortization for the year ended December 31, 2005 decreased to approximately \$1.3 million from approximately \$2.3 million for the year ended December 31, 2004, due to patents that became fully amortized in December 2004, offset in part by a \$0.3 million write-down of our assembled workforce asset resulting from non-restructuring related voluntary terminations during 2005 of certain Italian employees who had been included in the original valuation of this asset.

*Restructuring charges and related asset impairments.* In 2005, we announced plans to reduce our workforce through selected layoffs of employees as part of our cost savings initiative in an effort to reduce costs and conserve capital in anticipation of an NDA filing and potential launch of XYOTAX. In conjunction with our workforce reduction, we vacated a portion of our laboratory and office facilities. Restructuring activities and asset impairments for the year ended December 31, 2005 include \$7.1 million related to excess facilities charges, \$3.5 million due to a reduction in workforce in both our U.S. and Italian operations, \$1.2 million related to the termination of our aircraft operating lease, \$0.8 million in write-downs of tangible assets, consisting primarily of lab equipment in the U.S. that will cease to be used as we consolidate our research operations with CTI (Europe), and a \$0.2 million write-down of our workforce intangible asset for restructuring related employee terminations in Italy.

*Gain on divestiture of TRISENOX.* The gain of \$71.2 million for the year ended December 31, 2005 relates to the gain recognized, net of broker fees, on the divestiture of TRISENOX and certain proteasome assets to Cephalon as well as transition services provided to Cephalon related to TRISENOX and proteasome assets for a period of approximately six months subsequent to the date of closing.

*Investment and other income.* Investment and other income increased to approximately \$2.8 million for the year ended December 31, 2005 from approximately \$1.6 million for the year ended December 31, 2004. This increase is primarily due to receipt of a \$0.7 million vendor settlement in 2005 and an increase in our investment income due to increased interest rates on our securities available-for sale for the year ended December 31, 2005 compared to the year ended December 31, 2004.

*Interest expense.* Interest expense increased to approximately \$17.6 million for the year ended December 31, 2005 from approximately \$11.0 million for the year ended December 31, 2004. The increase is due to interest in 2005 of \$2.7 million on the \$25.0 million royalty interest financing arrangement entered into with PharmaBio in December 2004 and terminated in July 2005 in connection with the divestiture of TRISENOX to Cephalon. The increase was also due to a \$1.2 million liquidated damages accrual made in connection with the Conversion and Placement agreement entered into in conjunction with the November 2005 issuance of our 6.75% notes, an increase in the amortization of debt issuance costs of \$1.0 million, \$0.7 of which is due to the conversion of a portion of our 5.75% and 4% convertible senior subordinated notes and \$0.3 million of which is due to new debt issuance costs related to our 6.75% notes, a \$1.0 million make-whole interest payment related to the conversion of \$3.0 million in principal of our 6.75% notes, interest expense of \$0.8 million on our 6.75% notes and \$0.3 million of accretion of the debt discount on our 6.75% notes. These increases were offset by a decrease in interest expense of \$0.3 million on our 5.75% and 4% convertible senior subordinated notes due to the conversion of a portion of these notes in November 2005.

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*Foreign exchange loss.* There was no significant foreign currency exchange activity for the year ended December 31, 2005. The exchange loss for the year ended December 31, 2004 of approximately \$2.1 million is due to a fluctuation in foreign currency exchange rates, primarily related to U.S. dollar investments held by CTI (Europe).

*Debt conversion expense.* Debt conversion expense resulted from a conversion inducement consisting of 3.4 million shares and 6.5 million zero strike warrants valued at \$23.6 million to effect the conversion of \$38.4 million of convertible senior subordinated notes.

*Loss on extinguishment of royalty obligation.* The loss on extinguishment of royalty obligation for the year ended December 31, 2005 relates to the repayment of our royalty obligation to PharmaBio as a result of the divestiture of TRISENOX.

*Years ended December 31, 2004 and 2003.*

*Product sales.* We recorded net product sales of approximately \$26.6 million and \$22.1 million for TRISENOX for the years ended December 31, 2004 and 2003, respectively. The increase in net sales during 2004 is primarily due to an increase in demand for our product and a full year's activity with a dedicated commercial sales team in Europe, sales under our agreement with Nippon Shinyaku, and an increase in sales price in the United States. Additionally, we recorded a \$1.3 million adjustment to decrease our sales reserve to reflect a lower than expected estimated weighted average return rate for our remaining open production batches and a lower than expected actual return rate on our most recently closed production batch.

The demand for our product during the first part of 2004 was affected by a technical error made by the Center for Medicare Services, or CMS, stating a payment rate of \$2.81/mg for TRISENOX when administered in a physician's office versus the correct rate of \$32.94/mg. This error delayed physicians and patients from receiving accurate approved reimbursement information for the product until the correct payment rate was published in early February 2004. We also had additional wholesaler purchases in the fourth quarter of 2003 that were generated from an anticipated price increase which occurred in December 2003. This additional wholesaler inventory and CMS error resulted in lower sales in the first part of 2004.

*License and contract revenue.* For the year ended December 31, 2004, we recognized approximately \$1.9 million of license and contract revenue, of which \$0.8 million related to cost reimbursements for development expenses received from Chugai in 2004, \$0.6 million related to the amortization of the initial payments from Chugai and Nippon, and \$0.5 million related to a milestone payment from Nippon for obtaining an MAA approval for relapsed APL. In addition to license revenue, we recognized \$1.1 million in grant income received for research and development activities. For the year ended December 31, 2003, we recognized approximately \$2.7 million of license and contract revenue, of which \$1.2 million related to cost reimbursements for development expenses received from Chugai in 2003, \$1.0 million related to the amortization of the initial payments from Chugai and Nippon, and \$0.5 million related to a milestone payment received from Nippon in 2003 for their submission of an NDA in Japan.

*Cost of product sold.* The cost of product sold during the year ended December 31, 2004 and 2003 was approximately \$1.1 million and \$0.8 million, respectively. Our gross margins have remained relatively consistent. Cost of product sold consists primarily of manufacturing costs, royalties paid on product sales, and allowances for excess inventory that may expire and become unsaleable.

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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):

|   | 2004           | 2003          |
|---|----------------|---------------|
| Compounds under development:                |                |               |
| XYOTAX                                      | \$ 41,638      | \$ 52,888     |
| TRISENOX                                    | 7,208          | 4,862         |
| pixantrone                                  | 6,835          |               |
| Other compounds                             | 1,301          | 1,655         |
| Operating expenses                          | 33,076         | 18,699        |
| Discovery research                          | 11,069         | 11,430        |
| <br>Total research and development expenses | <br>\$ 101,127 | <br>\$ 89,534 |

Research and development expenses increased to approximately \$101.1 million for the year ended December 31, 2004 from approximately \$89.5 million for the year ended December 31, 2003. This increase is primarily related to higher operating expenses and pixantrone direct project expenses associated with our acquired CTI (Europe) operations, offset in part by a decrease in expenses related to XYOTAX development. Costs for our XYOTAX program decreased by approximately \$11.3 million primarily due to a decrease in manufacturing and clinical trial expenses, including a \$4.4 million decrease related to advanced purchases of comparator drugs in 2003 which were used primarily for our phase III clinical trials, a decrease in clinical trial costs and preclinical activities of \$4.2 million due to the near completion of the phase III studies and a \$3.5 million decrease in manufacturing expenses related to lower levels of drug production offset by an increase of approximately \$1.1 million in regulatory activities to support our anticipated filing of an NDA for XYOTAX in 2005. TRISENOX costs increased approximately \$2.3 million primarily as a result of an increase in investigator-sponsored trials, as well as filing fees and consulting costs related to registrations with regulatory agencies. Costs incurred for pixantrone resulted from our acquisition of pixantrone through the merger with Novuspharma in January of 2004. The increase in operating expenses is primarily related to costs associated with CTI (Europe) operations as well as increased personnel and occupancy costs. Costs for discovery research decreased primarily as a result of the dissolution of PanGenex during the first quarter of 2004, offset by approximately \$1.7 million in discovery research costs incurred by CTI (Europe).

*Selling, general and administrative expenses.* Selling, general and administrative expenses increased to approximately \$78.5 million for the year ended December 31, 2004, from approximately \$55.6 million for the year ended December 31, 2003. This increase is attributable to additional sales and marketing costs of \$7.7 million related to our expanded commercialization efforts of TRISENOX in both the United States and Europe and marketing research costs for XYOTAX as we prepare for potential commercial development, approximately \$6.5 million of costs related to our CTI (Europe) operations, approximately \$3.4 million in stock-based compensation charges, approximately \$2.7 million of additional operating, personnel and occupancy costs associated mainly with supporting our research, development and marketing activities, approximately \$2.0 million in increased financial consulting and advisory services primarily related to Sarbanes-Oxley compliance work and the re-audit of Novuspharma's historical financials as well as tax related valuation services and approximately \$0.5 million in increased corporate development expenses. Corporate development expenses include certain legal expenses, certain business development activities, costs related to operating our aircraft, and our corporate communications program.

*Acquired in-process research and development.* Acquired in-process research and development relates to a one-time non-cash charge recorded in connection with our acquisition of Novuspharma in January 2004. The \$87.4 million charge for the year ended December 31, 2004 represents the estimated fair value of purchased technology that had not reached technological feasibility at the effective time of the merger.

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*Amortization of purchased intangibles.* Amortization increased to approximately \$2.3 million for the year ended December 31, 2004 from approximately \$1.3 million for the year ended December 31, 2003, due to amortization of assembled workforce acquired as part of the acquisition of Novuspharma in January 2004.

*Investment and other income.* Investment income decreased to approximately \$1.6 million for the year ended December 31, 2004 from approximately \$1.9 million for the year ended December 31, 2003. This decrease is attributed primarily to a lower average securities available-for-sale balance compared to the prior year.

*Interest expense.* Interest expense increased to approximately \$11.0 million for the year ended December 31, 2004 from approximately \$9.3 million for the year ended December 31, 2003. The increase is primarily due to the issuance of \$75.0 million of our 4% convertible senior subordinated notes in June 2003 which were outstanding during the entire year in 2004.

*Foreign exchange loss.* The exchange loss for the year ended December 31, 2004 is due to a fluctuation in foreign currency exchange rates. There were no significant foreign currency transaction gains or losses during year ended December 31, 2003.

## **Liquidity and Capital Resources**

As of December 31, 2005, we had approximately \$94.7 million in cash and cash equivalents, restricted cash, securities available-for-sale and interest receivable.

Net cash used in operating activities totaled approximately \$125.2 million in 2005, compared to approximately \$148.2 million in 2004 and \$107.1 million in 2003. The decrease in net cash used in operating activities during the year ended December 31, 2005, as compared to the same period in 2004, was primarily due to the decrease in our net loss, excluding a gain on the divestiture of TRISENOX to Cephalon, a non-cash charge for our debt conversion expense, a charge in 2005 related to the loss on extinguishment of our royalty obligation with PharmaBio and a non-cash charge in 2004 related to acquired in-process research and development resulting from our merger with Novuspharma. The increase in net cash used in operating activities in 2004 as compared to 2003, was primarily due to the increase in our net loss, excluding a non-cash charge related to acquired in-process research and development resulting from our merger with Novuspharma, and cash used to reduce accounts payable and accrued expenses in 2004, partially offset by increases in 2004 in non-cash expenses including depreciation and amortization and equity-based compensation.

Net cash provided by investing activities totaled approximately \$60.3 million in 2005, \$154.4 million in 2004, and \$24.9 million in 2003. The decrease in net cash provided by investing activities in 2005, as compared to 2004, was due to cash acquired through our merger with Novuspharma in January 2004 and greater proceeds in 2004 from sales and maturities of securities available-for-sale in excess of purchases of such securities partially offset by proceeds from the divestiture of TRISENOX in 2005. The increase in net cash provided by investing activities in 2004, as compared to 2003, was primarily due to an increase in cash acquired through our merger with Novuspharma in January 2004 and from proceeds from sales and maturities of securities available-for-sale in excess of purchases of such securities.

Net cash provided by financing activities totaled approximately \$12.1 million in 2005, \$88.9 million in 2004 and \$72.7 million in 2003. The net cash provided by financing activities during 2005 was primarily due to net proceeds of \$77.7 million from the issuance of our 6.75% convertible senior notes, or 6.75% notes, offset by \$24.6 million of restricted cash that must be held in escrow until April 30, 2006 to fund potential redemption of a portion of these notes. As of March 6, 2006, \$59.0 million of the 6.75% notes had been converted into 22.4 million shares of common stock resulting in make-whole interest payments of \$19.9 million. Based on these conversions, \$17.7 million of the redemption right was forfeited. These amounts were also partially offset by the repayment of \$39.4 million for our royalty obligation with PharmaBio. The net cash provided by financing activities during 2004 was primarily due to the issuance of approximately 12.9 million shares of our common

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stock in August and December resulting in net proceeds of \$63.8 million as well as proceeds from the royalty interest financing arrangement with PharmaBio totaling \$25.0 million. The net cash provided by financing activities during 2003 was primarily due to the issuance of 4% convertible senior subordinated notes resulting in net proceeds of \$72.1 million.

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

The financial statements have been prepared on the basis of a going concern which contemplates realization of assets and satisfaction of liabilities in the normal course of business. We expect that our existing cash, cash equivalents, restricted cash and interest receivable will not be sufficient to fund our operations for the next 12 months. Accordingly, we will need to raise additional funds during 2006 and are currently exploring alternative sources of equity or debt financing. Additional funding may not be available on favorable terms or at all. If we are unable to raise additional capital in the near term, we have developed a plan to further curtail operations significantly, by delaying, modifying, or canceling selected aspects of research and development programs related to XYOTAX, pixantrone and other products we may be developing. The plan contains reductions in operating expenditures related to certain research and development and general and administrative activities including compensation and benefits, corporate costs and clinical trial costs, which are designed to allow the company to continue to operate on a going concern basis.

Periodically, we may receive certain grants and subsidized loans from the Italian government and the EU through CTI (Europe). However, to date such grants have not been significant and we may not receive such funding because the grants and subsidies are awarded at the discretion of the relevant authorities. In addition, our future capital requirements will depend on many factors, including:

results of our clinical trials;

success in acquiring or divesting products, technologies or businesses;

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

competitive market developments.

Future capital requirements will also depend on the extent to which we acquire or invest in businesses, products and technologies. 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 December 31, 2005 (in thousands):

| Contractual Obligations                        | Payments Due by Period |           |            |            |               |
|--|------------------------|-----------|------------|------------|---------------|
|  | Total                  | 1 Year    | 2-3 Years  | 4-5 Years  | After 5 Years |
| 6.75% Convertible senior notes(1)              | \$ 79,000              | \$ 6,900  | \$         | \$ 72,100  | \$            |
| 5.75% Convertible senior subordinated notes(2) | 66,929                 |           | 66,929     |            |               |
| 4.0% Convertible senior subordinated notes(3)  | 55,150                 |           |            | 55,150     |               |
| 5.75% Convertible subordinated notes(4)        | 29,640                 |           | 29,640     |            |               |
| Interest on convertible notes(5)               | 49,305                 | 13,091    | 23,155     | 13,059     |               |
| Operating leases:                              |                        |           |            |            |               |
| Facilities                                     | 33,705                 | 8,500     | 11,617     | 7,551      | 6,037         |
| Long term obligations(6)                       | 2,543                  | 127       | 618        | 796        | 1,002         |
|  | \$ 316,272             | \$ 28,618 | \$ 131,959 | \$ 148,656 | \$ 7,039      |

- (1) The 6.75% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 380.37 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of approximately \$2.63 per share.
- (2) The 5.75% convertible senior subordinated notes are convertible into shares of CTI common stock at a conversion rate of 100 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of \$10.00 per share.
- (3) The 4.0% convertible senior subordinated notes are convertible into shares of CTI common stock at a conversion rate of 74.0741 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of approximately \$13.50 per share.
- (4) The 5.75% convertible subordinated notes are convertible into shares of CTI common stock at a conversion rate of 29.4118 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of approximately \$34.00 per share.
- (5) As of March 6, 2006, we have made \$19.9 million in make-whole interest payments related to the early conversions of \$59.0 million of our 6.75% convertible senior notes.
- (6) Long-term debt does not include \$6.3 million related to excess facilities charges and \$1.3 million recorded as a long-term obligation for benefits owed to our Italian employees pursuant to Italian Law. The timing of the payments related to this obligation is unknown as the benefit is paid upon an employees' separation from the Company.

The remaining amount of milestone payments we may be required to pay pursuant to the amended agreement with PG-TXL Company L.P. is \$14.9 million, \$5.4 million of which may be triggered in 2007 if we are successful with our current plans for registrations with the FDA and EMEA.

**Impact of Inflation**

In the opinion of management, inflation has not had a material effect on our operations including selling prices, capital expenditures and operating expenses.

**Recent Accounting Pronouncements**

In December 2004, the Financial Accounting Standards Board, or FASB, issued SFAS, 123R, *Share-Based Payment (Revised 2004)*, which requires companies to recognize in the income statement the fair value of all employee share-based payments, including grants of employee stock options as well as compensatory employee



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stock purchase plans. In March 2005, the Securities and Exchange Commission, or SEC, issued Staff Accounting Bulletin, or SAB, No. 107 which expresses views of the SEC staff regarding the interaction between SFAS 123R and certain SEC rules and regulations. In April 2005, the SEC issued a press release that amends the required adoption date of SFAS 123R as no later than the first fiscal year beginning after June 15, 2005, which will be effective for us January 1, 2006. We will implement SFAS 123R in the first quarter of 2006 and intend to use the modified prospective method. We expect the adoption to result in the recognition of stock-based compensation expense of between \$2.3 million and \$2.7 million for stock options granted prior to January 1, 2006 plus the expense related to stock options granted during 2006. The expense for stock options granted during 2006 cannot be determined at this time due to the uncertainty of our stock price, the related Black-Scholes fair value and the timing of future grants.

In May 2005, the FASB issued SFAS 154, *Accounting Changes and Error Corrections*, which replaces Accounting Principles Board, or APB, Opinion 20, *Accounting Changes* and SFAS 3, *Reporting Accounting Changes in Interim Financial Statements* and changes the requirements of the accounting for and reporting of a change in accounting principle. SFAS 154 also carries forward the guidance in APB 20 regarding reporting a correction of an error and a change in accounting estimate. The provisions of this statement are applicable for accounting changes and error corrections made in fiscal years beginning after December 15, 2005. We do not expect the provisions of this statement to have a material impact on our financial position, results of operations or cash flows.

In June 2005, the Emerging Issues Task Force, or EITF, reached a consensus on Issue 05-6, *Determining the Amortization Period for Leasehold Improvements*, which requires that leasehold improvements acquired in a business combination or purchased subsequent to the inception of a lease be amortized over the lesser of the useful life of the assets or a lease term that includes renewals that are reasonably assured at the date of the business combination or purchase. EITF 05-6 is effective for periods beginning after July 1, 2005. We do not expect the provisions of this consensus to have a material impact on our financial position, results of operations or cash flows.

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**Item 7a. Quantitative and Qualitative Disclosures about Market Risk**

*Interest Rate Market Risk*

We are exposed to market risk related to changes in interest rates that could adversely affect the value of our investments. We maintain a short-term investment portfolio consisting of interest bearing securities with an average maturity of less than one year. These securities are classified as available-for-sale. These securities are interest bearing and thus subject to interest rate risk and will fall in value if market interest rates increase. Since we generally hold our fixed income investments until maturity, we do not expect our operating results or cash flows to be affected to any significant degree by a sudden change in market interest rates related to our securities portfolio. The fair value of our securities available-for-sale at December 31, 2005 and 2004 was \$18.9 million and \$10.8 million, respectively. A one percent change in interest rates would not significantly impact the fair value of our securities available-for-sale as of December 31, 2005.

*Foreign Exchange Market Risk*

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

We have foreign exchange risk related to euro-denominated cash, cash equivalents and interest receivable ( foreign funds ). Based on the balance of foreign funds at December 31, 2005 of \$12.9 million, an assumed 5%, 10% and 20% negative currency movement would result in fair value declines of \$0.6 million, \$1.3 million and \$2.6 million, respectively.

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**Item 8. Consolidated Financial Statements and Supplementary Data**

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**Management's Report on Internal Control over Financial Reporting**

Management of Cell Therapeutics, Inc., together with its consolidated subsidiaries (the Company), is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is a process designed under the supervision of the Company's principal executive and principal financial officers to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the Company's financial statements for external reporting purposes in accordance with U.S. generally accepted accounting principles.

As of the end of the Company's 2005 fiscal year, management conducted an assessment of the effectiveness of the Company's internal control over financial reporting based on the framework established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this assessment, management has determined that the Company's internal control over financial reporting as of December 31, 2005 is effective.

The Company's internal control over financial reporting includes policies and procedures that pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and dispositions of assets; provide reasonable assurances that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America and that receipts and expenditures are being made only in accordance with authorizations of management and the directors of the Company; and provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on our financial statements.

The registered independent public accounting firm of Stonefield Josephson, Inc., as auditors of the Company's consolidated financial statements, has issued an attestation report on management's assessment of the Company's internal control over financial reporting.

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Board of Directors and Shareholders

Cell Therapeutics, Inc.

We have audited management's assessment, included in the accompanying Management's Report on Internal Control over Financial Reporting, that Cell Therapeutics, Inc. maintained effective internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Cell Therapeutics, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with accounting principles generally accepted in the United States of America, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that Cell Therapeutics, Inc. maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on the COSO criteria. Also in our opinion, Cell Therapeutics, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on the COSO criteria.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet of Cell Therapeutics, Inc. as of December 31, 2005, and the related statements of operations, shareholders' equity (deficit) and other comprehensive loss, and cash flows for the year then ended and our report dated March 14, 2006 expressed an unqualified opinion on those financial statements.

/s/ Stonefield Josephson, Inc.

Stonefield Josephson, Inc.

Los Angeles, CA

March 14, 2006

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Board of Directors and Shareholders

Cell Therapeutics, Inc.

We have audited the accompanying consolidated balance sheet of Cell Therapeutics, Inc. as of December 31, 2005, and the related consolidated statements of operations, shareholders' equity (deficit) and other comprehensive loss, and cash flows for the year then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Cell Therapeutics, Inc. as of December 31, 2005, and the results of their operations and their cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

Our audit was conducted for the purpose of forming an opinion on the basic consolidated financial statements taken as a whole. The financial statement schedule listed in the index at Item 15(a) is presented for purposes of additional analysis and is not a required part of the basic consolidated financial statements. This schedule has been subjected to the auditing procedures applied in the audit of the 2005 basic consolidated financial statements and, in our opinion, is fairly stated in all material respects in relation to the basic consolidated financial statements taken as a whole.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of Cell Therapeutics, Inc.'s internal control over financial reporting as of December 31, 2005, based on the criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 14, 2006 expressed an unqualified opinion thereon.

/s/ Stonefield Josephson, Inc.

Stonefield Josephson, Inc.

Los Angeles, Ca

March 14, 2006

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**REPORT OF GRANT THORNTON LLP,  
INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Board of Directors and Shareholders

Cell Therapeutics, Inc.

We have audited the accompanying consolidated balance sheet of Cell Therapeutics, Inc. as of December 31, 2004, and the related consolidated statements of operations, shareholders' equity (deficit), and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Cell Therapeutics, Inc. as of December 31, 2004, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

Our audit was conducted for the purpose of forming an opinion on the basic financial statements taken as a whole. The financial statement schedule listed in the index at Item 15(a) is presented for purposes of additional analysis and is not a required part of the 2004 basic financial statements. This schedule has been subjected to the auditing procedures applied in the audit of the basic financial statements and, in our opinion, is fairly stated in all material respects in relation to the basic financial statements taken as a whole.

/s/ GRANT THORNTON LLP

Seattle, WA

February 28, 2005

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**REPORT OF ERNST & YOUNG LLP,  
INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Shareholders

Cell Therapeutics, Inc.

We have audited the accompanying consolidated statements of operations, shareholders' equity (deficit), and cash flows of Cell Therapeutics, Inc. for the year ended December 31, 2003. Our audit also included the financial statement schedule listed in the Index at Item 15(a)(ii) for the year ended December 31, 2003. These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated results of operations and cash flows of Cell Therapeutics, Inc. for the year ended December 31, 2003, in conformity with accounting principles generally accepted in the United States. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

/s/ Ernst & Young LLP

Seattle, Washington

February 6, 2004



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

|  | December 31,<br>2005 | December 31,<br>2004 |
|--|----------------------|----------------------|
| <b>ASSETS</b>  |                      |                      |
| Current assets:  |                      |                      |
| Cash and cash equivalents  | \$ 50,022            | \$ 105,033           |
| Restricted cash  | 25,596               |                      |
| Securities available-for-sale  | 18,858               | 10,840               |
| Interest receivable  | 187                  | 147                  |
| Accounts receivable  | 2,306                | 879                  |
| Inventory  |                      | 920                  |
| Prepaid expenses and other current assets  | 10,107               | 10,113               |
| <b>Total current assets</b>  | <b>107,076</b>       | <b>127,932</b>       |
| Property and equipment, net  | 12,278               | 22,360               |
| Goodwill   | 17,064               | 17,064               |
| Other intangibles, net   | 2,239                | 4,175                |
| Other assets   | 16,783               | 13,465               |
| <b>Total assets</b>  | <b>\$ 155,440</b>    | <b>\$ 184,996</b>    |
| <b>LIABILITIES AND SHAREHOLDERS DEFICIT</b>  |                      |                      |
| Current liabilities:   |                      |                      |
| Accounts payable   | \$ 3,370             | \$ 7,309             |
| Accrued expenses   | 17,558               | 25,020               |
| Current portion of deferred revenue  | 80                   | 408                  |
| Current portion of long-term obligations   | 2,880                | 1,382                |
| Current portion of convertible senior notes  | 6,900                |                      |
| <b>Total current liabilities</b>   | <b>30,788</b>        | <b>34,119</b>        |
| Deferred revenue, less current portion   | 558                  | 1,310                |
| Other long-term obligations, less current portion  | 7,326                | 5,053                |
| Royalty obligation   |                      | 25,123               |
| Convertible senior notes   | 72,146               |                      |
| Convertible senior subordinated notes  | 122,079              | 160,459              |
| Convertible subordinated notes   | 29,640               | 29,640               |
| Commitments and contingencies  |                      |                      |
| Shareholders' deficit:   |                      |                      |
| Preferred stock, no par value:   |                      |                      |
| Authorized shares 10,000,000   |                      |                      |
| Series C, 100,000 shares designated, none issued or outstanding  |                      |                      |
| Common stock, no par value:  |                      |                      |
| Authorized shares 200,000,000  |                      |                      |
| Issued and outstanding shares 73,421,721 and 63,862,658 at December 31, 2005 and December 31, 2004, respectively | 721,544              | 652,773              |
| Deferred stock-based compensation  | (1,669)              | (2,736)              |
| Accumulated other comprehensive income (loss)  | (1,683)              | 2,039                |
| Accumulated deficit  | (825,289)            | (722,784)            |

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|   |            |            |
|---|------------|------------|
| Total shareholders' deficit                 | (107,097)  | (70,708)   |
| Total liabilities and shareholders' deficit | \$ 155,440 | \$ 184,996 |

See accompanying notes.

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

|  | Year Ended December 31, |                     |                     |
|--|-------------------------|---------------------|---------------------|
|  | 2005                    | 2004                | 2003                |
| <b>Revenues:</b>   |                         |                     |                     |
| Product sales  | \$ 14,599               | \$ 26,626           | \$ 22,105           |
| License and contract revenue                                       | 1,493                   | 2,968               | 2,660               |
| <b>Total revenues</b>  | <b>16,092</b>           | <b>29,594</b>       | <b>24,765</b>       |
| <b>Operating expenses:</b>   |                         |                     |                     |
| Cost of product sold   | 518                     | 1,104               | 840                 |
| Research and development   | 68,767                  | 101,127             | 89,534              |
| Selling, general and administrative                                | 61,717                  | 78,522              | 55,641              |
| Acquired in-process research and development                       |                         | 87,375              |                     |
| Amortization of purchased intangibles                              | 1,254                   | 2,294               | 1,335               |
| Restructuring charges and related asset impairments                | 12,780                  |                     |                     |
| Gain on divestiture of TRISENOX                                    | (71,211)                |                     |                     |
| <b>Total operating expenses</b>                                    | <b>73,825</b>           | <b>270,422</b>      | <b>147,350</b>      |
| Loss from operations   | (57,733)                | (240,828)           | (122,585)           |
| <b>Other income (expense):</b>                                     |                         |                     |                     |
| Investment and other income  | 2,824                   | 1,636               | 1,880               |
| Interest expense   | (17,559)                | (10,988)            | (9,326)             |
| Foreign exchange gain (loss)                                       | 8                       | (2,118)             |                     |
| Debt conversion expense  | (23,608)                |                     |                     |
| Loss on extinguishment of royalty obligation                       | (6,437)                 |                     |                     |
| <b>Other expense, net</b>  | <b>(44,772)</b>         | <b>(11,470)</b>     | <b>(7,446)</b>      |
| <b>Net loss</b>  | <b>\$ (102,505)</b>     | <b>\$ (252,298)</b> | <b>\$ (130,031)</b> |
| <b>Basic and diluted net loss per share</b>                        | <b>\$ (1.59)</b>        | <b>\$ (4.67)</b>    | <b>\$ (3.89)</b>    |
| Shares used in calculation of basic and diluted net loss per share | 64,553                  | 54,052              | 33,418              |

See accompanying notes.

**Table of Contents****CELL THERAPEUTICS, INC.****CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY (DEFICIT) AND OTHER COMPREHENSIVE LOSS**

(In thousands)

|   | Common Stock |            | Deferred<br>Stock-based<br>Compensation | Accumulated<br>Deficit | Accumulated<br>Other<br>Comprehensive<br>Income/(Loss) | Total<br>Shareholders<br>Equity<br>(Deficit) |
|---|--------------|------------|---|------------------------|--|--|
|   | Shares       | Amount     |   |                        |  |  |
| Balance at December 31, 2002  | 33,054       | \$ 384,994 | \$                                      | \$ (340,455)           | \$ (1,056)   | \$ 43,483                                    |
| Conversion of senior subordinated notes to common stock   |              | 1          |   |                        |  | 1  |
| Conversion of warrants to common stock  | 134          |            |   |                        |  |  |
| Preferred stock dividend  | 44           | 500        |   |                        |  | 500  |
| Proceeds from stock options exercised and stock sold via employee stock purchase plan                   | 603          | 2,303      |   |                        |  | 2,303  |
| Deferred compensation   | 504          | 6,581      | (6,581)                                 |                        |  |  |
| Amortization of deferred compensation of restricted stock   |              |            | 625                                     |                        |  | 625  |
| Equity-based compensation expense   |              | 371        |   |                        |  | 371  |
| Comprehensive loss:   |              |            |   |                        |  |  |
| Unrealized losses on securities available-for-sale  |              |            |   |                        | (175)  | (175)  |
| Unrealized gains on interest rate swap  |              |            |   |                        | 381  | 381  |
| Net loss for the year ended December 31, 2003   |              |            |   | (130,031)              |  | (130,031)                                    |
| Comprehensive loss  |              |            |   |                        |  | (129,825)                                    |
| Balance at December 31, 2003  | 34,339       | 394,750    | (5,956)                                 | (470,486)              | (850)  | (82,542)                                     |
| Issuance of common stock for the acquisition of Novuspharma   | 15,629       | 189,760    |   |                        |  | 189,760                                      |
| Conversion of warrants to common stock  | 22           |            |   |                        |  |  |
| Proceeds from issuance of common stock, net   | 12,936       | 63,846     |   |                        |  | 63,846                                       |
| Proceeds from stock options exercised and stock sold via employee stock purchase plan                   | 595          | 2,220      |   |                        |  | 2,220  |
| Deferred compensation   | 315          | 990        | (990)                                   |                        |  |  |
| Amortization of deferred compensation of restricted stock   |              |            | 4,210                                   |                        |  | 4,210  |
| Equity-based compensation expense   | 27           | 1,207      |   |                        |  | 1,207  |
| Comprehensive loss:   |              |            |   |                        |  |  |
| Foreign currency translation gain   |              |            |   |                        | 2,511  | 2,511  |
| Unrealized gains on securities available-for-sale   |              |            |   |                        | 4  | 4  |
| Unrealized gains on interest rate swap  |              |            |   |                        | 374  | 374  |
| Net loss for the year ended December 31, 2004   |              |            |   | (252,298)              |  | (252,298)                                    |
| Comprehensive loss  |              |            |   |                        |  | (249,409)                                    |
| Balance at December 31, 2004  | 63,863       | 652,773    | (2,736)                                 | (722,784)              | 2,039  | (70,708)                                     |
| Conversion of convertible senior subordinated notes to common stock                                     | 3,323        | 39,047     |   |                        |  | 39,047                                       |
| Equity instruments issued to induce conversion of convertible senior subordinated notes to common stock | 3,378        | 23,608     |   |                        |  | 23,608                                       |
| Issuance of warrants to underwriter of convertible senior notes   |              | 564        |   |                        |  | 564  |
| Conversion of convertible senior notes to common stock  | 1,141        | 3,000      |   |                        |  | 3,000  |
| Proceeds from stock options exercised and stock sold via employee stock purchase plan                   | 81           | 238        |   |                        |  | 238  |
| Deferred compensation   | 1,641        | 2,186      | (2,186)                                 |                        |  |  |
| Amortization of deferred compensation of restricted stock   |              |            | 3,253                                   |                        |  | 3,253  |
| Equity-based compensation expense   | (5)          | (49)       |   |                        |  | (49)   |
| Conversion of restricted share rights to common stock   |              | 177        |   |                        |  | 177  |
| Comprehensive loss:   |              |            |   |                        |  |  |
| Foreign currency translation loss   |              |            |   |                        | (4,174)  | (4,174)                                      |
| Unrealized gains on securities available-for-sale   |              |            |   |                        | 16   | 16   |
| Unrealized gains on interest rate swap  |              |            |   |                        | 436  | 436  |

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|   |        |            |    |         |              |    |         |                  |
|---|--------|------------|----|---------|--------------|----|---------|------------------|
| Net loss for the year ended December 31, 2005 |        |            |    |         | (102,505)    |    |         | (102,505)        |
| <b>Comprehensive loss</b>                     |        |            |    |         |              |    |         | <b>(106,227)</b> |
| Balance at December 31, 2005                  | 73,422 | \$ 721,544 | \$ | (1,669) | \$ (825,289) | \$ | (1,683) | \$ (107,097)     |

See accompanying notes.

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

|   | Year Ended December 31, |                  |                  |
|---|-------------------------|------------------|------------------|
|   | 2005                    | 2004             | 2003             |
| <b>Operating activities</b>   |                         |                  |                  |
| Net loss  | \$ (102,505)            | \$ (252,298)     | \$ (130,031)     |
| Adjustments to reconcile net loss to net cash used in operating activities: |                         |                  |                  |
| Depreciation and amortization   | 9,975                   | 10,311           | 4,868            |
| Acquired in-process research and development                                |                         | 87,375           |                  |
| Equity-based compensation expense   | 3,381                   | 5,417            | 996              |
| Loss on disposition of property and equipment                               | 157                     | 505              | 113              |
| Asset impairments   | 3,020                   |                  |                  |
| Debt conversion expense   | 23,608                  |                  |                  |
| Gain on divestiture of Trisenox   | (71,211)                |                  |                  |
| Loss on extinguishment of royalty obligation                                | 6,437                   |                  |                  |
| Amortization of investment premium  | 303                     | 1,123            | 3,572            |
| Noncash other income  | (236)                   |                  |                  |
| Noncash interest expense  | 2,930                   | 1,091            | 758              |
| Noncash rent expense  | 180                     | 415              | 1,170            |
| Loss on sale of investment securities                                       | 14                      | 29               | 13               |
| Changes in operating assets and liabilities:                                |                         |                  |                  |
| Restricted cash   | (1,045)                 |                  |                  |
| Interest receivable   | (40)                    | 1,109            | 644              |
| Accounts receivable, net  | (894)                   | (221)            | 170              |
| Inventory   | 4                       | 88               | (130)            |
| Prepaid expenses and other current assets                                   | 1,971                   | (1,068)          | 64               |
| Other assets  | (1,452)                 | 2,734            | 1,573            |
| Accounts payable  | (3,451)                 | (1,651)          | 1,587            |
| Accrued expenses  | (5,181)                 | (2,292)          | 8,507            |
| Deferred revenue  | (1,081)                 | (819)            | (1,018)          |
| Excess facilities obligations   | 6,334                   |                  |                  |
| Other long-term obligations   | 3,550                   |                  |                  |
| <b>Total adjustments</b>  | <b>(22,727)</b>         | <b>104,146</b>   | <b>22,887</b>    |
| <b>Net cash used in operating activities</b>                                | <b>(125,232)</b>        | <b>(148,152)</b> | <b>(107,144)</b> |
| <b>Investing activities</b>   |                         |                  |                  |
| Net proceeds from sale of Trisenox  | 70,417                  |                  |                  |
| Purchases of securities available-for-sale                                  | (46,827)                | (59,011)         | (167,433)        |
| Proceeds from sales of securities available-for-sale                        | 15,815                  | 50,830           | 27,403           |
| Proceeds from maturities of securities available-for-sale                   | 22,693                  | 79,333           | 175,437          |
| Purchases of property and equipment   | (2,016)                 | (4,632)          | (3,335)          |
| Sale of property and equipment  | 253                     |                  |                  |
| Additional consideration related to PolaRx acquisition                      |                         | (4,969)          | (3,981)          |
| Repayment of notes receivable from officers                                 |                         | 3,500            |                  |
| Net cash acquired in (paid for) the Novuspharma merger                      |                         | 89,391           | (3,160)          |
| <b>Net cash provided by investing activities</b>                            | <b>60,335</b>           | <b>154,442</b>   | <b>24,931</b>    |



**Table of Contents****CELL THERAPEUTICS, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued)**

(In thousands)

|   | Year Ended December 31, |            |          |
|---|-------------------------|------------|----------|
|   | 2005                    | 2004       | 2003     |
| <b>Financing activities</b>   |                         |            |          |
| Proceeds from issuance of convertible senior notes, net   | 77,704                  |            |          |
| Restricted cash from issuance of senior convertible notes                                       | (24,600)                |            |          |
| Proceeds from issuance of common stock, net   |                         | 63,846     |          |
| Proceeds from royalty based financing   |                         | 25,000     |          |
| Repayment of royalty obligation   | (39,388)                |            |          |
| Proceeds from issuance of convertible senior subordinated notes, net                            |                         |            | 72,143   |
| Proceeds from common stock options exercised and stock sold via employee stock purchase plan    | 238                     | 2,220      | 2,303    |
| Repayment of long-term obligations  | (1,805)                 | (2,172)    | (1,741)  |
| Net cash provided by financing activities   | 12,149                  | 88,894     | 72,705   |
| Effect of exchange rate changes on cash and cash equivalents                                    | (2,263)                 | 1,411      |          |
| Net increase (decrease) in cash and cash equivalents  | (55,011)                | 96,595     | (9,508)  |
| Cash and cash equivalents at beginning of period  | 105,033                 | 8,438      | 17,946   |
| Cash and cash equivalents at end of period  | \$ 50,022               | \$ 105,033 | \$ 8,438 |
| <b>Supplemental disclosure of cash flow information</b>   |                         |            |          |
| Cash paid during the period for interest  | \$ 12,640               | \$ 9,823   | \$ 8,439 |
| Cash paid for taxes   | \$                      | \$         | \$       |
| <b>Supplemental disclosure of non cash financing and investing activities</b>                   |                         |            |          |
| Conversion of convertible senior subordinated notes to common stock, including accrued interest | \$ 39,047               | \$         | \$       |
| Conversion of convertible senior notes to common stock  | \$ 3,000                | \$         | \$       |
| Issuance of warrants to underwriter of convertible senior notes                                 | \$ 564                  | \$         | \$       |
| Common stock issued for acquisition of Novuspharma  | \$                      | \$ 189,760 | \$       |
| Issuance of common stock for payment of preferred stock dividend                                | \$                      | \$         | \$ 500   |

See accompanying notes.





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**CELL THERAPEUTICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**December 31, 2005**

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

*Description of Business*

Cell Therapeutics, Inc., or CTI or the Company, focuses on the discovery, development, acquisition and commercialization of drugs for the treatment of cancer. Our principal business strategy is to focus our activities on cancer therapeutics, an area that represents a large market opportunity that is not adequately served by existing therapies. Our operations are primarily conducted in the United States and Italy.

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 and may take many years and involve expenditure of substantial resources.

We operate in one business segment. On July 18, 2005, we completed the divestiture of TRISENOX<sup>®</sup> (arsenic trioxide), an anti-cancer compound, and certain proteasome assets to Cephalon Inc., or Cephalon, for aggregate consideration of approximately \$71.9 million, net of broker fees. In addition, we provided transition services related to TRISENOX and proteasome assets for approximately six months subsequent to the closing date. In connection with the divestiture, we were required to repay our royalty obligation to PharmaBio Development, or PharmaBio, and after this repayment, our net proceeds from both transactions were approximately \$32.5 million. In addition, in the future we may potentially receive up to an additional \$100 million if Cephalon is successful in achieving certain sales and development milestones, although achievement of such milestones is uncertain. Because TRISENOX was our only commercial product, we have had no revenues from product sales subsequent to its divestiture.

*Principles of Consolidation*

The consolidated financial statements include the accounts of Cell Therapeutics, Inc., its wholly owned subsidiaries which include Cell Therapeutics Europe S.r.l., CTI Technologies, Inc., PolaRx Biopharmaceuticals, Inc., or PolaRx, CTI Corporate Development, Inc., Cell Therapeutics (UK) Limited, and Cell Therapeutics (Ireland) Holding Limited, and its majority owned subsidiary (PanGenex, Inc.) which was dissolved in 2004. Cell Therapeutics (UK) Limited and PolaRx were sold to Cephalon in connection with the divestiture of TRISENOX in July 2005. All intercompany transactions and balances are eliminated in consolidation.

*Use of Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America (US GAAP) requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. For example, estimates included our liability for excess facilities, the fair value of our derivatives, and prior to the divestiture of TRISENOX to Cephalon our sales return reserve, inventory obsolescence reserve, and our estimate of royalty and interest payments in connection with our royalty obligation. Actual results could differ from those estimates.

*Cash and Cash Equivalents*

We consider all highly liquid debt instruments with maturities of three months or less at the time acquired to be cash equivalents. Cash equivalents represent short-term investments consisting of investment-grade corporate and government obligations, carried at cost, which approximates market value.

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**CELL THERAPEUTICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Restricted Cash*

As of December 31, 2005 restricted cash included \$24.6 million held in escrow through April 30, 2006 to fund potential redemptions of up to 30% of our 6.75% convertible senior notes (see Note 6, *Long-Term Obligations*). In March 2006, we amended our Paying Agent Agreement to allow for the release of the funds held in escrow when the conversions of the notes occur. As of March 6, 2006, \$59.0 million of the notes had converted and accordingly, \$17.7 million had been released from escrow. We also have restricted cash of \$1.0 million held in connection with the liquidation of Cell Therapeutics (Ireland) Holding Limited, of which \$0.8 million became unrestricted in February 2006.

*Securities Available-for-Sale*

Management determines the appropriate classification of debt securities at the time of purchase. Management currently classifies our investment portfolio as available-for-sale which consists of U.S. government and corporate obligations with maturities of up to one year and carries the securities at fair value based on quoted market prices with unrealized gains and losses included in accumulated other comprehensive income or loss. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Interest on securities available-for-sale and amortization and accretion of premiums and discounts are included in investment income. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities, if any, are included in investment income. The cost of securities sold is based on the specific identification method.

*Liquidity*

*Cash and cash equivalents, restricted cash, securities available for sale and interest receivable* are approximately \$94.7 million as of December 31, 2005 which includes \$24.6 million held in escrow until April 30, 2006 to fund potential redemptions of a portion of our 6.75% convertible senior notes (see Note 6, *Long-Term Obligations*).

The financial statements have been prepared on the basis of a going concern which contemplates realization of assets and satisfaction of liabilities in the normal course of business. We expect that our existing cash, cash equivalents, restricted cash and interest receivable will not be sufficient to fund our operations for the next 12 months. Accordingly, we will need to raise additional funds during 2006 and are currently exploring alternative sources of equity or debt financing. Additional funding may not be available on favorable terms or at all. If we are unable to raise additional capital in the near term, we have developed a plan to further curtail operations significantly, by delaying, modifying, or canceling selected aspects of research and development programs related to XYOTAX, pixantrone and other products we may be developing. The plan contains reductions in operating expenditures related to certain research and development and general and administrative activities including compensation and benefits, corporate costs and clinical trial costs, which are designed to allow the company to continue to operate on a going concern basis.

*Certain Concentrations*

We are exposed to risks associated with foreign currency transactions to use U.S. dollars to make contract payments denominated in euros or vice versa. As the net positions of our unhedged foreign currency transactions fluctuate, our earnings might be negatively affected. In addition, we are exposed to risks associated with the translation of euro-denominated financial results and amounts into U.S. dollars. We currently do not utilize forward exchange contracts or any type of hedging instruments to hedge foreign exchange risk as we believe our overall exposure is relatively limited.

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**CELL THERAPEUTICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

We are subject to concentration of credit risk primarily from our cash investments. Under our investment guidelines, credit risk is managed by diversification of the investment portfolio and by the purchase of investment-grade securities. Prior to the divestiture of TRISENOX, we did not require collateral or other security to support credit sales, but provided an allowance for bad debts when warranted.

If we are unable to obtain sufficient quantities of needed starting materials for the manufacture of our products in development from existing suppliers, or if we were unable to source these materials and services from other suppliers and manufacturers, certain research and development and sales activities may be delayed.

We are exposed to certain labor risk related to our European employees, who represent 51% of our total employees as of December 31, 2005, and who are subject to a collective bargaining agreement as well as to local regulations governing employment.

*Product Sales*

We recognized revenue from product sales when there was persuasive evidence that an arrangement existed, title had passed and delivery had occurred, the price was fixed and determinable, and collectability was reasonably assured. As we sold our only commercial product, TRISENOX, to Cephalon on July 18, 2005, there are no product sales subsequent to this date. Product sales were generally recorded upon shipment net of an allowance for returns and discounts. Customers were able to return damaged or expired inventory for up to one year after the expiration date. In estimating returns, we analyzed historical returns and sales patterns. To arrive at the accrual for product returns, we matched the returns to the corresponding production batch to assess the historical trend for returns. Based on this analysis, the estimated return percentage was applied to current period sales. If customers had product acceptance rights or return rights, and we were unable to reasonably estimate returns related to that customer or market, we deferred revenue recognition until such rights had expired. Allowances for returns, discounts and bad debts, which were netted against accounts receivable, totaled approximately \$1.4 million at December 31, 2004. There was no allowance for returns, discount and bad debts at December 31, 2005 as all trade receivables were sold in connection with the divestiture of TRISENOX to Cephalon.

During 2004, we recorded a \$1.3 million adjustment to decrease our sales reserve to reflect a lower than expected estimated weighted average return rate for our remaining open production batches and a lower than expected actual return rate on our most recently closed production batches.

*License and Contract Revenue*

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

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

**Table of Contents****CELL THERAPEUTICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

contracts and research grants is recognized as the related costs are incurred. Payments received in advance of recognition as revenue are recorded as deferred revenue.

We evaluate multiple element arrangements pursuant to Emerging Issues Task Force, or EITF, 00-21, *Revenue Arrangements with Multiple Deliverables* for multiple element arrangements that have continuing performance obligations, we recognize contract, milestone or license fees together with any up-front payments over the term of the arrangement as we complete our performance obligation, unless the delivered technology has stand alone value to the customer and there is objective, reliable evidence of fair value of the undelivered element in the arrangement. Additionally, pursuant to the guidance of Securities and Exchange Commission Staff Accounting Bulletin 104, or SAB 104, unless evidence suggests otherwise, revenue from consideration received is recognized on a straight-line basis over the expected term of the arrangement.

*Cost of Product Sold*

Cost of product sold consists of the cost of TRISENOX sold to our customers, including allowances for excess inventory that may expire and become unsaleable. Royalties paid on product sales, as well as shipping and handling costs are also included in cost of product sold. As we sold our only commercial product, TRISENOX, to Cephalon on July 18, 2005, there is no cost of product sold subsequent to this date.

*Accounts Receivable*

Due to the sale of TRISENOX to Cephalon in July, 2005, our accounts receivable balance did not include any trade receivables related to TRISENOX as of December 31, 2005. This balance consists primarily of receivables from Cephalon for transition services provided as well as receivables from fixed asset sales. The balance as of December 31, 2004 primarily relates to trade receivables from the sale of TRISENOX, net of our allowance for doubtful accounts.

*Inventory*

Finished goods inventory consisted of our marketed pharmaceutical drug, TRISENOX. All inventory was sold in connection with the completion of the divestiture of TRISENOX to Cephalon. Prior to the divestiture, inventory was stated at the lower of cost or market. Cost was determined using a weighted-average method. If the cost of the inventory exceeded the expected market value, provisions were recorded for the difference between the cost and the net realizable value. When required, an allowance for excess inventory that would have expired and become unsaleable was recorded. The components of inventory are as follows as of December 31, 2004 (in thousands):

|                 |               |
|-----------------|---------------|
| Work in process | \$ 529        |
| Finished goods  | 391           |
|                 | <b>\$ 920</b> |

*Research and Development Expenses*

Research and development expenses include related salaries and benefits, clinical trial and related manufacturing costs, contract and other outside service fees, and facilities and overhead costs related to our research and development efforts. Research and development expenses also consist of costs incurred for proprietary and collaboration research and development and include activities such as product registries and investigator-sponsored trials. Research and development costs are expensed as incurred. Generally, in instances

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**CELL THERAPEUTICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

*Acquired in-process research and development*

Costs to acquire in-process research and development, or IPRD, projects and technologies which had no alternative future use and which had not reached technological feasibility as of January 1, 2004, the date of our merger with Novuspharma, were expensed as incurred.

*Value Added Tax Receivable*

Our European subsidiaries are subject to Value Added Tax, or VAT, which is usually applied to all goods and services purchased and sold throughout Europe. The VAT receivable is approximately \$8.9 million and \$8.8 million as of December 31, 2005 and December 31, 2004, respectively, of which \$8.3 million and \$8.1 million is included in *other assets* and \$0.6 million and \$0.7 million is included in *prepaid expenses and other current assets* as of December 31, 2005 and December 31, 2004, respectively. This receivable balance relates to our Italian operations and typically has a three year collection period. We review our VAT receivable balance for impairment whenever events or changes in circumstances indicate the carrying amount might not be recoverable.

*Property and Equipment*

Property and equipment, including assets pledged as security in financing agreements, are carried at cost, less accumulated depreciation and amortization. Leasehold improvements are amortized over the lesser of the useful life or the term of the applicable lease using the straight-line method. Depreciation commences at the time assets are placed in service and is calculated using the straight-line method over the estimated useful lives of the assets ranging from three to five years.

*Impairment of Long-lived Assets*

We review our long-lived assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Each impairment test is based on a comparison of the undiscounted future cash flows to the recorded value of the asset. If an impairment is indicated, the asset is written down to its estimated fair value based on quoted fair market values. During 2005 we recorded a charge of approximately \$1.0 million for asset impairments associated with our restructuring activities (see Note 7, *Restructuring Activities*).

*Goodwill and Intangible Assets*

Intangible assets consist of acquisition-related intangible assets. Intangible assets with finite lives are carried at cost less accumulated amortization. Amortization is computed using the straight-line method over the estimated useful lives of the respective assets, which is approximately five years.

Goodwill is not amortized but is tested for impairment at least annually, or more frequently if indicators of impairment are present. If goodwill is impaired it is written down; however, no impairment of goodwill has been found to date.

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Changes in the net carrying amount of goodwill in 2003, 2004 and 2005 are as follows (in thousands):

|                                 |           |
|---------------------------------|-----------|
| Balance as of January 1, 2003   | \$ 12,064 |
| Additional goodwill in 2003     | 5,000     |
| Balance as of December 31, 2003 | 17,064    |
| Additional goodwill in 2004     |           |
| Balance as of December 31, 2004 | 17,064    |
| Additional goodwill in 2005     |           |
| Balance as of December 31, 2005 | \$ 17,064 |

During 2003, we recorded as goodwill an additional \$5.0 million related to contingent consideration that became due and payable in connection with our 2000 acquisition of PolaRx, (see Note 18, *Acquisition of PolaRx Biopharmaceuticals, Inc.*).

Other intangible assets are composed of the following as of December 31 (in thousands):

|                                | <b>Gross<br/>Carrying<br/>Amount</b> | <b>2005<br/>Accumulated<br/>Amortization</b> | <b>Net<br/>Carrying<br/>Amount</b> |
|--------------------------------|--------------------------------------|--|------------------------------------|
| Assembled workforce            | \$ 4,566                             | \$ (2,327)                                   | \$ 2,239                           |
|                                |                                      |  |                                    |
|                                | <b>Gross<br/>Carrying<br/>Amount</b> | <b>2004<br/>Accumulated<br/>Amortization</b> | <b>Net<br/>Carrying<br/>Amount</b> |
| Patents and other intangibles  | \$ 6,674                             | \$ (6,674)                                   | \$                                 |
| Assembled workforce            | 5,219                                | (1,044)                                      | 4,175                              |
| Total other intangibles assets | \$ 11,893                            | \$ (7,718)                                   | \$ 4,175                           |

The changes in the value of intangible assets is as follows:

|                               |          |    |
|-------------------------------|----------|----|
| Balance as of January 1, 2003 | \$ 2,670 | \$ |
| Amortization                  | (1,335)  |    |

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|  |         |          |
|--|---------|----------|
| Balance as of January 1, 2004              | 1,335   |          |
| Increase due to acquisition of Novuspharma |         | 4,868    |
| Amortization                               | (1,335) | (959)    |
| Increase due to exchange rate              |         | 266      |
| Balance as of December 31, 2004            |         | 4,175    |
| Impairment                                 |         | (232)    |
| Amortization                               |         | (1,254)  |
| Decrease due to exchange rate              |         | (450)    |
| Balance as of December 31, 2005            | \$      | \$ 2,239 |



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**CELL THERAPEUTICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In 2004 we recorded an intangible asset related to the assembled workforce acquired in our acquisition of Novuspharma. In 2005, *restructuring charges and related asset impairments* includes an impairment charge of \$0.2 million due to the termination of certain Italian employees included in the original valuation of this asset. We expect amortization expense on assembled workforce to be approximately \$0.8 million for each of the next three years, at which time it will be fully amortized.

*Royalty Obligation*

Our royalty obligation to PharmaBio was recorded as debt as we had significant continuing involvement in the generation of cash flows due to PharmaBio. The obligation was accreted using the effective interest method and an imputed interest rate that was based on our estimates of total royalty and interest payments due under the arrangement. The amount of royalty and interest payments varied depending on whether we reached certain TRISENOX targets and certain other factors as described in the agreement. We reassessed the imputed interest rate as circumstances changed. We extinguished the royalty obligation in July 2005 (see Note 9, *Extinguishment of PharmaBio Royalty Obligation*).

*Stock-Based Compensation*

In accordance with Statement of Financial Accounting Standards, or SFAS, 123, *Accounting for Stock-Based Compensation*, as amended by SFAS 148, *Accounting for Stock-Based Compensation-Transition and Disclosure*, we elected to continue to account for stock-based compensation using the intrinsic value method prescribed in Accounting Principles Board, or APB, Opinion 25, *Accounting for Stock Issued to Employees*, and related interpretations. Generally, compensation cost for employee stock options is measured as the excess, if any, of the market price of our common stock at the date of grant over the stock option exercise price. Any deferred compensation is recognized on a graded vesting method. Under our plan, stock options are generally granted at fair market value.

On December 16, 2004, the FASB issued FASB Statement No. 123 (revised 2004), *Share-Based Payment*, known as SFAS 123(R), which is a revision of SFAS No. 123. SFAS 123(R) supersedes APB Opinion No. 25 and amends FASB Statement No. 95, *Statement of Cash Flows*. Generally, the approach in SFAS 123(R) is similar to the approach described in SFAS No. 123. However, SFAS 123(R) requires all share-based payments to employees, including grants of employee stock options, to be recognized in the statements of operations based on their fair value. Pro forma disclosure is no longer an alternative upon adopting SFAS 123(R).

We adopted SFAS 123(R) on January 1, 2006. SFAS 123(R) permits public companies to adopt its requirements using one of two methods:

A modified prospective method in which compensation cost is recognized beginning with the effective date (a) based on the requirements of SFAS 123(R) for all share-based payments granted after the effective date and (b) based on the requirements of SFAS 123 for all awards granted to employees prior to the effective date of SFAS 123(R) that remain unvested on the effective date.

A modified retrospective method which includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under SFAS 123 for purposes of pro forma disclosures for either (a) all prior periods presented or (b) prior interim period of the year of adoption.

We will implement SFAS 123(R) in the first quarter of 2006 and intend to use the modified prospective method. We expect the adoption to result in the recognition of stock-based compensation expense of between \$2.3 and \$2.7 million for stock options granted prior to January 1, 2006 plus the expense related to stock options granted during 2006. The expense for stock options granted during 2006 cannot be determined at this time due to

**Table of Contents****CELL THERAPEUTICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

the uncertainty of our stock price, the related Black-Scholes fair value and the timing of future grants. We will also continue to incur stock-based compensation charges related to restricted stock grants.

If we elected to recognize compensation cost based on the fair value at grant date of the options granted as prescribed by SFAS 123, net loss and basic and diluted net loss per share would have been adjusted, or increased, as follows for the years ended December 31 (in thousands, except per share amounts):

|   | 2005         | 2004         | 2003         |
|---|--------------|--------------|--------------|
| Net loss:   |              |              |              |
| As reported   | \$ (102,505) | \$ (252,298) | \$ (130,031) |
| Add: Stock-based employee compensation included in reported net loss  | 3,253        | 5,342        | 663          |
| Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards | (5,684)      | (11,397)     | (11,992)     |
| As adjusted   | \$ (104,936) | \$ (258,353) | \$ (141,360) |
| Basic and diluted net loss per share:   |              |              |              |
| As reported   | \$ (1.59)    | \$ (4.67)    | \$ (3.89)    |
| As adjusted   | \$ (1.63)    | \$ (4.78)    | \$ (4.23)    |

Stock compensation expense for options granted to non-employees has been determined in accordance with SFAS 123 and the Emerging Issues Task Force, or EITF, consensus in Issue No. 96-18, *Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, at the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured. The fair value of options granted to non-employees is periodically remeasured as the underlying options vest.

*Advertising Costs*

The costs of advertising are expensed as incurred. We incurred advertising costs of \$1.8 million, \$1.8 million, and \$0.7 million in 2005, 2004, and 2003 respectively.

*Net Loss per Share*

Basic net loss per share is calculated based on the net loss divided by the weighted average number of shares outstanding for the period excluding any dilutive effects of options, warrants, unvested restricted stock awards and convertible securities. Diluted earnings per share assumes the conversion of all dilutive convertible securities, such as convertible subordinated debt using the if-converted method, and assumes the exercise or vesting of other dilutive securities, such as options, warrants and restricted stock using the treasury stock method.

*Derivatives Embedded in Certain Debt Securities*

We evaluate financial instruments for freestanding or embedded derivatives in accordance with SFAS 133, *Accounting for Derivative Instruments and Hedging Activities*, and related guidance. Derivative instruments are recorded at fair value with changes in value recognized in the period of change.

*Other Financial Instruments*

At December 31, 2005 and 2004, the carrying value of financial instruments such as receivables and payables approximated their fair values based on the short-term maturities of these instruments. The carrying value of other



**Table of Contents****CELL THERAPEUTICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

long-term liabilities approximated fair values because the underlying interest rates approximate market rates at the balance sheet dates. We believe the carrying value of our royalty obligation approximated its fair value at December 31, 2004 as the arrangement was entered into on an arms length basis during December 2004.

Based on their respective trading prices, the fair values of our convertible senior notes, convertible senior subordinated notes and convertible subordinated notes are as follows as of December 31 (in thousands):

|   | 2005      | 2004      |
|---|-----------|-----------|
| 6.75% convertible senior notes common shareholders              | \$ 79,000 | \$        |
| 5.75% convertible senior subordinated notes common shareholders | \$ 43,504 | \$ 87,800 |
| 4.0% convertible senior subordinated notes                      | \$ 25,369 | \$ 73,100 |
| 5.75% convertible subordinated notes                            | \$ 14,524 | \$ 26,100 |

*Foreign Currency Translation*

For our operations that have a functional currency other than the U.S. dollar, gains and losses resulting from the translation of the functional currency into U.S. dollars for financial statement presentation are not included in determining net loss but are accumulated in the cumulative foreign currency translation adjustment account as a separate component of shareholders' deficit in accordance with SFAS 52, *Foreign Currency Translation*. We had a loss from foreign currency translation of \$4.2 million for the year ended December 31, 2005 and a gain of \$2.5 million for the year ended December 31, 2004.

*Comprehensive Loss*

Comprehensive loss is comprised of net loss and other comprehensive income or loss. SFAS 130, *Reporting Comprehensive Income*, provides for unrealized gains and losses on our securities available-for-sale and interest rate swap agreement, designated as a cash flow hedge, to be included in other comprehensive income or loss. Also included are net exchange gains or losses resulting from the translation of assets and liabilities of foreign subsidiaries. Total comprehensive loss was \$106.2 million, \$249.4 million and \$129.8 million as of December 31, 2005, 2004 and 2003, respectively.

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

|  | 2005       | 2004     |
|--|------------|----------|
| Foreign currency translation adjustment              | \$ (1,663) | \$ 2,511 |
| Net unrealized loss on interest rate swap            |            | (436)    |
| Net unrealized loss on securities available-for-sale | (20)       | (36)     |
| Total other comprehensive income (loss)              | \$ (1,683) | \$ 2,039 |

*Recently Issued Accounting Pronouncements*

In December 2004, the Financial Accounting Standards Board, or FASB, issued SFAS 123R, *Share-Based Payment (Revised 2004)*, which requires companies to recognize in the income statement the fair value of all employee share-based payments, including grants of employee stock options as well as compensatory employee stock purchase plans. In March 2005, the Securities and Exchange Commission, or SEC, issued Staff Accounting Bulletin, or SAB, No. 107 which expresses views of the SEC staff regarding the interaction between SFAS 123R



**Table of Contents****CELL THERAPEUTICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

and certain SEC rules and regulations. In April 2005, the SEC issued a press release that amends the required adoption date of SFAS 123R as no later than the first fiscal year beginning after June 15, 2005, which will be effective for us January 1, 2006. We will implement SFAS 123R in the first quarter of 2006 and intend to use the modified prospective method. We expect the adoption to result in the recognition of stock-based compensation expense of between \$2.3 million and \$2.7 million for stock options granted prior to January 1, 2006 plus the expense related to stock options granted during 2006. The expense for stock options granted during 2006 cannot be determined at this time due to the uncertainty of our stock price, the related Black-Scholes fair value and the timing of future grants.

In May 2005, the FASB issued SFAS 154, *Accounting Changes and Error Corrections*, or SFAS 154, which replaces APB Opinion 20, *Accounting Changes*, or APB 20, and SFAS 3, *Reporting Accounting Changes in Interim Financial Statements* and changes the requirements of the accounting for and reporting of a change in accounting principle. SFAS 154 also carries forward the guidance in APB 20 regarding reporting a correction of an error and a change in accounting estimate. The provisions of this statement are applicable for accounting changes and error corrections made in fiscal years beginning after December 15, 2005. We do not expect the provisions of this statement to have a material impact on our financial position, results of operations or cash flows.

In June 2005, the EITF reached a consensus on Issue 05-6, *Determining the Amortization Period for Leasehold Improvements*, which requires that leasehold improvements acquired in a business combination or purchased subsequent to the inception of a lease be amortized over the lesser of the useful life of the assets or a lease term that includes renewals that are reasonably assured at the date of the business combination or purchase. EITF 05-6 is effective for periods beginning after July 1, 2005. We do not expect the provisions of this consensus to have a material impact on our financial position, results of operations or cash flows.

*Reclassifications*

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

**2. Securities Available-for-Sale**

Securities available-for-sale consist of the following debt securities as of December 31 (in thousands):

|                             | 2005              |                              |                               |               |
|-----------------------------|-------------------|------------------------------|-------------------------------|---------------|
|                             | Amortized<br>Cost | Gross<br>Unrealized<br>Gains | Gross<br>Unrealized<br>Losses | Fair<br>Value |
| Corporate obligations       | \$ 16,525         | \$                           | \$ (18)                       | \$ 16,507     |
| U.S. government obligations | 2,353             |                              | (2)                           | 2,351         |
|                             | \$ 18,878         | \$                           | \$ (20)                       | \$ 18,858     |

|                             | 2004              |                              |                               |               |
|-----------------------------|-------------------|------------------------------|-------------------------------|---------------|
|                             | Amortized<br>Cost | Gross<br>Unrealized<br>Gains | Gross<br>Unrealized<br>Losses | Fair<br>Value |
| Corporate obligations       | \$ 8,714          | \$                           | \$ (31)                       | \$ 8,683      |
| U.S. government obligations | 2,162             |                              | (5)                           | 2,157         |
|                             | \$ 10,876         | \$                           | \$ (36)                       | \$ 10,840     |



**Table of Contents****CELL THERAPEUTICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

As of December 31, 2005, and 2004, all securities available-for-sale had contractual maturities of less than one year. Gross realized gains and losses to date have not been material.

**3. Property and Equipment**

Property and equipment are composed of the following as of December 31 (in thousands):

|   | <b>2005</b> | <b>2004</b> |
|---|-------------|-------------|
| Leasehold improvements                          | \$ 12,694   | \$ 12,753   |
| Lab equipment                                   | 5,483       | 11,394      |
| Furniture and office equipment                  | 17,122      | 18,617      |
|   | 35,299      | 42,764      |
| Less: accumulated depreciation and amortization | (23,021)    | (20,404)    |
|   | \$ 12,278   | \$ 22,360   |

Depreciation expense of \$8.9 million, \$8.0 million, and \$3.5 million was recognized during 2005, 2004, and 2003, respectively. We also recorded fixed asset impairments of \$0.8 million during 2005 related to our restructuring activities (see Note 7, *Restructuring Activities*).

**4. Accrued Liabilities**

Accrued liabilities consist of the following as of December 31 (in thousands):

|   | <b>2005</b> | <b>2004</b> |
|---|-------------|-------------|
| Employee compensation and related expenses            | \$ 6,566    | \$ 7,606    |
| Clinical development and regulatory expense           | 3,616       | 6,404       |
| Manufacturing expense                                 | 1,387       | 3,870       |
| Corporate development and sales and marketing expense | 983         | 2,066       |
| Other research and development expenses               | 963         | 1,575       |
| Insurance financing and accrued interest expense      | 2,391       | 294         |
| Other   | 1,652       | 3,205       |
|   | \$ 17,558   | \$ 25,020   |

**5. Contractual Arrangements and Commitments***Lease Agreements*Facilities

We lease our office and laboratory space under operating leases. Leases for our corporate office space contain an annual escalation clause of approximately 3%; the related rent expenses are recognized on a straight-line basis over the term of the respective lease. In connection with a lease agreement, we have a \$0.7 million irrevocable, unconditional standby letter of credit which is secured by a certificate of deposit classified



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in our consolidated balance sheet in *other assets* as of December 31, 2005 and 2004. Rent expense amounted to approximately \$7.3 million, \$7.8 million, and \$6.8 million, for the years ended December 31, 2005, 2004 and 2003, respectively.

**Table of Contents****CELL THERAPEUTICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

During 2004 and 2005, we entered into sublease agreements to sublet a portion of our facilities considered to be in excess of current requirements. Total sublease rental income for fiscal years 2005 and 2004 was \$0.2 million and \$21,000, respectively, recorded as an offset to lease expense. Total future sublease income to be recognized over the term of our existing subleases is approximately \$1.0 million.

Aircraft

In 2001, we entered into an operating lease agreement for use of an aircraft. Terms of the lease included monthly rental payments of \$161,000 plus an incremental rent adjustment, which was based on the value of the aircraft and varied depending on the prevailing applicable LIBOR rate. This lease was terminated in November 2005. Rent expense related to the aircraft amounted to \$1.9 million, \$2.3 million, and \$2.4 million for the years ended December 31, 2005, 2004 and 2003, respectively. In 2005 we also made a \$1.2 million payment in connection with the early termination of the lease which is included in *restructuring charges and related asset impairments* (see Note 7, *Restructuring Activities*).

In connection with this aircraft lease, we entered into an interest rate swap agreement that effectively locked in the effect of the incremental rate adjustment for the first 78 payments. Under the swap agreement, we received a variable amount based on the monthly LIBOR rate and we paid a fixed rate payment based on a rate of 4.78%. In connection with the termination of the aircraft lease, the swap agreement was also terminated in November 2005 and we made a payment of approximately \$50,000, the fair value of the swap liability at the time of termination. At December 31, 2004, the fair value of the swap was a liability of \$0.4 million which was recorded in *other long-term obligations and accumulated other comprehensive income (loss)*. This swap was 100% effective.

Capital Leases

In connection with our merger with Novuspharma, we assumed two capital lease agreements to finance lab equipment. These capital leases have terms of 47 months at interest rates of 5.1% and 5.4%. The gross amount of assets under capital lease obligations was approximately \$0.6 million and \$0.7 million as of December 31, 2005 and 2004, respectively. The related accumulated depreciation was approximately \$0.2 million and \$0.1 million as of December 31, 2005 and 2004, respectively.

Future Minimum Lease Payments

Future minimum lease commitments for noncancelable operating and capital leases at December 31, 2005 are as follows (in thousands):

|  | <b>Capital<br/>Leases</b> | <b>Operating<br/>Leases</b> |
|--|---------------------------|-----------------------------|
| 2006   | \$ 122                    | \$ 8,500                    |
| 2007   | 72                        | 7,634                       |
| 2008   | 44                        | 3,983                       |
| 2009   |                           | 3,739                       |
| 2010   |                           | 3,812                       |
| Thereafter                                   |                           | 6,037                       |
| <b>Total minimum lease commitments</b>       | <b>\$ 238</b>             | <b>\$ 33,705</b>            |
| Less interest                                | (12)                      |                             |
| <b>Present value of lease obligation</b>     | <b>226</b>                |                             |
| Less current portion of long-term obligation | (114)                     |                             |
| <b>Long-term obligation</b>                  | <b>\$ 112</b>             |                             |



**Table of Contents****CELL THERAPEUTICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

As of December 31, 2005, we recorded a liability of approximately \$6.3 million in charges for excess facilities under our current operating leases in accordance with SFAS 146, *Accounting for Costs Associated with Exit and Disposal Activities*. These charges included lease commitments, net of estimated sublease income (see Note 7, *Restructuring Activities*).

*Paclitaxel Supply*

In September 2001, we entered into a purchase agreement with Natural Pharmaceuticals, Inc., or NPI, to purchase \$6.0 million of paclitaxel, a starting material for XYOTAX, which was to be delivered by NPI over several years. This material was intended to be used primarily for research and development activities. We paid for the entire purchase upon execution of the agreement in 2001 and recorded the amount as a prepaid asset. We also entered into a security agreement with NPI to collateralize our prepayment with the value of the NPI-owned yew trees from which paclitaxel is derived. Based on the original terms of the agreement, NPI fell behind on its delivery of paclitaxel, and in October 2004, we received a revised delivery schedule from NPI that detailed new delivery dates through August 2005 for the remaining paclitaxel. In 2004, we terminated our interest in the yew trees, so that NPI could sell the raw materials and deposit the funds in escrow in an amount equal to the value of the undelivered paclitaxel, to be reduced as future deliveries were made.

As we had adequate supply of paclitaxel on hand to support our validation campaigns and clinical activities, we amended our supply agreement with NPI in October 2005. Under the amended agreement we received \$0.8 million, the value of the remaining undelivered paclitaxel, to relieve all obligations of undelivered paclitaxel from NPI. In addition, the agreement grants NPI the exclusive right to purchase up to 5 kilograms of our paclitaxel supply at our original cost through September 1, 2006.

As of December 31, 2004, our prepaid asset related to the undelivered paclitaxel was approximately \$2.1 million, all of which was classified as current. There was no prepaid asset as of December 31, 2005 as we received cash in lieu of all remaining undelivered amounts based on the amended agreement. As of December 31, 2005 and 2004, we also had paclitaxel supply of \$2.3 million and \$2.5 million, respectively, which has been capitalized and is included in *prepaid expenses and other current assets*. These costs have been capitalized since there is a ready market for this ingredient. The paclitaxel supply was adjusted during the second quarter of 2005 to reflect a \$1.7 million write-down to its estimated re-sale value based on current prices obtained from an external vendor.

**6. Long-Term Obligations***Convertible subordinated notes*

In June and September 2001, we issued a total of \$175.0 million principal amount of 5.75% convertible subordinated notes due June 15, 2008 with interest payable semi-annually in June and December. Net proceeds to us were approximately \$168.0 million, after deducting expenses and the initial purchaser's discounts and commissions. We recorded issuance costs related to the notes of approximately \$7.0 million. Issuance costs are recorded in *other assets* and amortized to interest expense over the life of the notes using the effective interest method.

The notes are convertible, at the option of the holder, into shares of our common stock at any time prior to maturity or redemption at a conversion rate of 29.4118 shares per each \$1,000 principal note, subject to adjustment in certain circumstances. This is equivalent to a conversion price of \$34.00 per share. We can redeem the notes at specified redemption prices ranging from 103.286% to 100% of the principal amount. The redemption prices will vary depending on the year redeemed. The holder may elect to convert their notes prior to any such redemption.

**Table of Contents****CELL THERAPEUTICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In December 2002, we completed an exchange offer for the 5.75% convertible subordinated notes, in which approximately \$145.4 million of our convertible subordinated notes were tendered in exchange for approximately \$85.5 million of our new convertible senior subordinated notes. We recognized a net gain of \$55.3 million on the early extinguishment of these notes. This net gain is based on the carrying value of the exchanged notes less the fair value of the new notes, net of issuance costs of \$4.6 million attributable to the exchanged notes. As of December 31, 2005, we had \$29.6 million convertible subordinated notes outstanding.

*Convertible senior subordinated notes*

In connection with the exchange of convertible subordinated notes, we issued \$85.5 million of 5.75% convertible senior subordinated notes and recorded additional issuance costs of approximately \$2.1 million, which are recorded in *other assets* and are being amortized to interest expense using the effective interest method, over the remaining life of the notes. The terms of the new notes are similar to the convertible subordinated notes except for the conversion price and provisional redemption provision. The conversion rate for these notes is 100 shares per \$1,000 principal note; this is equivalent to a conversion price of \$10.00 per share. We can redeem the notes at specified redemption prices ranging from 103.286% to 100% of the principal amount. The redemption prices will vary depending on the year redeemed. The holder may elect to convert their notes prior to any such redemption. As of December 31, 2005, we had \$66.9 million of 5.75% convertible senior subordinated notes outstanding (see Conversion and Placement Agreement below).

In June 2003, we issued \$75.0 million principal amount of 4.0% convertible senior subordinated notes due July 1, 2010 with interest payable semi-annually in January and July. Net proceeds to us were approximately \$72.1 million, after deducting expenses and the initial purchaser's discounts and commissions. We recorded issuance costs related to the notes of approximately \$2.9 million. These issuance costs are recorded as *other assets* and are being amortized to interest expense using the effective interest method, over the seven-year life of the notes.

The notes are convertible, at the option of the holder, into shares of our common stock at any time prior to maturity, redemption or repurchase at an initial conversion rate of 74.0741 shares of common stock per \$1,000 principal amount of notes, which is subject to adjustment in certain circumstances. This conversion rate is equivalent to a conversion price of approximately \$13.50 per share. Prior to maturity, we may redeem the notes upon certain conditions, the most significant of which is that the closing price of our common stock must exceed 150% of the conversion price for at least 20 trading days within a period of 30 consecutive trading days. Upon such redemption, we would make an additional payment of \$280.00 per \$1,000 note, less any interest previously paid on the notes. The holder may elect to convert their notes prior to any such redemption. As of December 31, 2005, we had \$55.2 million of 4.0% convertible senior subordinated notes outstanding (see Conversion and Placement Agreement below).

*Conversion and Placement Agreement*

In November 2005, in conjunction with issuance of the 6.75% convertible senior notes discussed below, we entered into a Conversion and Placement Agreement, or CAP agreement, with two existing holders of approximately \$18.5 million of our outstanding 5.75% Convertible Senior Subordinated Notes, or 5.75% notes, and approximately \$19.9 million of our 4% Convertible Senior Subordinated Notes, or 4% notes. Pursuant to the original terms of the agreement, the CAP holders agreed to exercise their right to convert their 5.75% notes and 4% notes into approximately 3.3 million shares of our common stock. In connection with the conversion, we also issued to the CAP holders a \$23.6 million conversion inducement which consisted of 3.4 million shares of common stock and 6.5 million shares issuable upon exercise of zero strike price warrants. The shares and warrants were valued based on the trading price of our common stock on the effective date of the agreement. The conversion inducement was recorded as *debt conversion expense*.

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**CELL THERAPEUTICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Under the terms of this agreement we were required to file a resale registration statement with respect to these shares which was required to be declared effective by November 30, 2005. We filed the resale registration statement on November 30, 2005, however it was not declared effective until December 2005 and as a result, we were required to make a liquidated damages payment of approximately \$1.2 million which is included in *interest expense* for the year ended December 31, 2005.

*Convertible senior notes*

In November 2005, we completed the issuance of \$82 million of 6.75% convertible senior notes due October 31, 2010 with interest payable semi-annually in April and October. Net proceeds to us were approximately \$77.7 million, after deducting expenses and the initial purchaser's discounts and commissions. We recorded issuance costs related to the notes of approximately \$4.9 million which includes approximately \$0.6 million related to the Black-Scholes estimated fair value of warrants issued to the initial purchaser of the notes. These issuance costs are recorded in *other assets* and are being amortized to interest expense using the effective interest method over the five-year life of the notes.

The notes are convertible, at the option of the holder, into shares of our common stock at any time prior to maturity, redemption or repurchase at an initial conversion rate of 380.37 shares of common stock per \$1,000 principal amount of the notes, which is subject to adjustment in certain circumstances. This conversion rate is equivalent to a conversion price of approximately \$2.63 per share. We also issued warrants to purchase 350,000 shares of common stock within five years at an exercise price of \$3.50 per share to the initial purchaser of these notes. On April 30, 2006, holders of the notes have the right to cause us to redeem in cash up to 30% of the aggregate amount of the notes, or approximately \$24.6 million, on a pro-rata basis, excluding any accrued and unpaid interest. We must hold this amount in escrow through April 30, 2006 in order to fund any such redemptions. We have the option to redeem all of the notes if the closing price per share of our common stock has exceeded 125% of the conversion price then in effect for at least 20 trading days within any 30-consecutive trading day period. The redemption price will be par including accrued and unpaid interest up to but not including the redemption date. Upon any conversion of the notes, we will pay the holder of the notes a make-whole interest payment equal to \$337.50 per \$1,000 principal amount of the notes so converted, less any interest paid on such notes prior to the conversion date. Under this agreement we must also file a shelf registration statement within 45 days of the initial issuance of the notes which must be effective within 90 days of issuance in order to avoid liquidating damages penalties of additional interest of 0.25% for any period for which the registration statement is not effective until such time that the shares are tradable which is approximately two years. A shelf registration statement was declared effective on January 8, 2006, prior to the 90<sup>th</sup> day following the initial issuance of the notes as per the terms of the agreement.

As of March 6, 2006, \$59.0 million of the 6.75% notes had been converted into 22.4 million shares of common stock resulting in make-whole interest payments of \$19.9 million. Based on these conversions, \$17.7 million of the redemption right was forfeited.

Under the terms of the convertible debt we are restricted from issuing additional convertible debt or preferred equity securities until March 31, 2006. Thereafter, we are restricted from issuing convertible debt with a maturity date earlier than that of the 6.75% convertible debt or October 31, 2010.

As of December 31, 2005, we had \$79.0 million of 6.75% convertible senior notes outstanding.

*Embedded Features*

We recorded a derivative liability related to our 6.75% convertible senior notes. The interest make-whole provision, included in the note indenture and described above, represents an embedded derivative which is

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**CELL THERAPEUTICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

required to be accounted for separate from the underlying 6.75% senior notes. At the issuance of the 6.75% senior notes, the interest make-whole feature was estimated to have a fair value of approximately \$4.5 million and the initial recorded value of the 6.75% senior notes was reduced by this allocation. The resulting discount to the notes will be accreted over the life of the notes as additional interest expense using the effective interest method, of which \$0.3 million was recorded for the year ended December 31, 2005. The estimated fair value of the derivative liability will be adjusted quarterly for changes in the estimated market value. Changes in the estimated fair value for the year ended December 31, 2005 were \$0.2 million and included in *other income*. At December 31, 2005, the fair value of the derivative was \$4.3 million and was recorded in *convertible senior notes*.

Our evaluation of the embedded make-whole feature was made in accordance with SFAS 133. We determined that the make-whole provision meets the definition of an embedded derivative because 1) the economic characteristics of the make-whole provision are not clearly and closely related to those of the host instrument because they could at least double the investor's rate of return and result in a rate of return that is at least twice that of a market rate of return for a similar instrument, 2) the host convertible debt instrument is not remeasured at fair value and 3) if the make-whole provision were a separate instrument with the same terms it would meet the definition of a derivative.

We determined that the conversion feature in the notes did not result in a beneficial conversion feature based on the guidance in EITF-007, *Application of Issue No. 98-5 to Certain Convertible Instruments*.

We determined that the maximum amount of payment under the liquidated damages provision related to the 6.75% convertible senior notes is less than the difference between registered and unregistered shares. In accordance with guidance in EITF 00-19, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*, and EITF 05-4, *The Effect of a Liquidated Damages Clause on a Freestanding Financial Instrument Subject to EITF Issue No. 00-19, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*, we evaluated the effect of the liquidated damages provision under the EITF's view A which requires that the registration rights agreement be combined with the related convertible debt instrument. Because the amount of the liquidated damages is less than a reasonable discount on unregistered shares, we determined that delivery of unregistered shares plus the penalty is an economic alternative to the issuance of registered shares and therefore the debt conversion feature will not be accounted for as a derivative.

**Table of Contents****CELL THERAPEUTICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)***Other long-term obligations*

Other long-term obligations consist of the following as of December 31 (in thousands):

|   | 2005     | 2004     |
|---|----------|----------|
| Master equipment financing agreement, due May 2006, monthly payments of \$51, including interest at 8.0%  | \$       | \$ 611   |
| Master equipment financing agreement, due December 2006, monthly payments of \$35, including interest at 7.0%   |          | 522      |
| Master equipment financing agreement, due October 2006, monthly payments of \$35, including interest at 7.1%  |          | 479      |
| Capital lease equipment financing agreement, due February 2008, monthly payments of \$6, including interest at 5.1%   | 177      | 272      |
| Capital lease equipment financing agreement, due March 2006, monthly payments of \$6, including interest at 5.4% monthly payments of \$48, including interest at 7.1% | 49       | 134      |
| Excess facilities liability   | 6,334    |          |
| Accrued rent  | 1,774    | 1,594    |
| Employee defined benefit plan (see Note 12, <i>Employee Benefit Plans</i> )   | 1,329    | 1,668    |
| European public loans   | 475      | 542      |
| Interest rate swap related to aircraft  |          | 436      |
| Other long-term obligations   | 68       | 177      |
|   | 10,206   | 6,435    |
| Less current portion  | (2,880)  | (1,382)  |
|   | \$ 7,326 | \$ 5,053 |

For each equipment financing, we granted the lender a security interest in specified fixed assets. The net book value of these assets at December 31, 2004 was approximately \$2.9 million. There was no equipment financing outstanding as of December 31, 2005 as the remaining portion of the related obligation was paid down during the fourth quarter of 2005.

Maturities of the convertible senior, convertible senior subordinated, and convertible subordinated notes as well as other long-term obligations listed above, excluding the employee defined benefit plan at December 31, 2005 are as follows (in thousands):

| <b>Years Ending December 31,</b> |            |
|----------------------------------|------------|
| 2006                             | \$ 9,780   |
| 2007                             | 2,574      |
| 2008                             | 97,357     |
| 2009                             | 606        |
| 2010                             | 127,942    |
| Thereafter                       | 1,337      |
|                                  | \$ 239,596 |





**Table of Contents****CELL THERAPEUTICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)****7. Restructuring Activities**

In June 2005, we announced a plan to reduce our U.S. workforce as part of our cost savings initiative in an effort to reduce costs and conserve capital in anticipation of a new drug application, or NDA, and potential launch of XYOTAX. Additionally, in October 2005, we announced a planned reduction in our EU workforce. In conjunction with our workforce reduction we vacated a portion of our laboratory and office facilities. Additionally, we terminated our aircraft lease in November 2005 under a plan approved based on our restructuring activities and efforts to reduce costs. For the year ended December 31, 2005, restructuring and related asset impairment charges totaled approximately \$12.8 million which is comprised of the following:

|   |                  |
|---|------------------|
| Excess facilities charges                                       | \$ 7,092         |
| Employee separation cost  | 3,478            |
| Aircraft lease termination payment                              | 1,170            |
| Asset Impairments   | 1,040            |
| <b>Total restructuring and related asset impairment charges</b> | <b>\$ 12,780</b> |

*Excess Facilities Charges*

Charges for excess facilities relate to our lease obligation for excess laboratory and office space in the U.S. that we have vacated as a result of the restructuring plan. Pursuant to SFAS 146, we recorded restructuring charges when we ceased using this space. For the year ended December 31, 2005 total restructuring charges related to this vacated space was approximately \$7.1 million. The charge is calculated as the present value of total lease commitments, net of estimated sublease income. During the year ended December 31, 2005 we made lease payments of approximately \$0.8 million and our ending lease obligation as of December 31, 2005 was approximately \$6.3 million. We will periodically evaluate our existing needs, the current and estimated future values of our subleases, and other future commitments to determine whether we should record additional excess facilities charges or adjustments to such charges.

*Employee Separation Costs*

As of December 31, 2005, a total of 66 U.S. and 24 EU employees have been terminated or received notice of termination as a result of our restructuring activities. Employee separation costs associated with the layoffs consist primarily of one-time termination benefits, principally severance payments, recognized in accordance with SFAS 146. During 2005 we recorded approximately \$3.5 million in employee termination benefits and made cash payments of approximately \$1.5 million. As of December 31, 2005, we had an accrual related to termination benefits of approximately \$2.0 million.

*Aircraft Lease Termination Payment*

In 2001, we entered into an operating lease agreement for use of an aircraft which was terminated in November 2005. As part of the termination, we negotiated and paid a settlement amount of approximately \$1.2 million to fulfill the termination penalty per the lease agreement.

*Restructuring Related Asset Impairments*

Impairment charges recorded pursuant to SFAS 144, *Accounting for the Impairment or Disposal of Long Lived Assets*, or SFAS 144, primarily include laboratory equipment, computers, and furniture and fixtures which are unlikely to be utilized due to our vacated lab and office space as well as employee terminations and



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accordingly, have been written down to estimated fair market value primarily based on quoted market prices obtained from external sources. We recorded a loss of approximately \$1.0 million for restructuring related asset impairments for the year ended December 31, 2005.

**8. Divestiture of TRISENOX and Certain Proteasome Assets**

On July 18, 2005, we divested TRISENOX and certain proteasome asset to Cephalon. In addition, we provided transition services related to TRISENOX and proteasome assets for approximately six months subsequent to the closing date. We received aggregate consideration of \$71.9 million for the assets and transition services, net of broker fees. As part of the transaction Cephalon purchased the capital stock of two wholly-owned subsidiaries, Cell Therapeutics (UK) Limited and PolaRx and assumed certain liabilities. In connection with the divestiture, we were required to repay our royalty obligation to PharmaBio (see Note 9, *Extinguishment of PharmaBio Royalty Obligation*) and, after this repayment, our net proceeds from both transactions were approximately \$32.5 million. In addition, we may receive up to an additional \$100 million in payments upon achievement by Cephalon of specified sales and development milestones. However, achievement of such milestones is uncertain.

Pursuant to the terms of the acquisition agreement, we provided transition services to Cephalon related to the TRISENOX and proteasome assets for a period of up to six months subsequent to the closing date. We consider the multiple deliverables under the agreement to be one unit of accounting as defined in EITF 00-21, *Revenue Arrangements with Multiple Deliverables*, because we do not have evidence of the fair value of the undelivered service elements. Based upon the requirements in Staff Accounting Bulletin 104, *Revenue Recognition*, we deferred the proceeds received from the divestiture and recognized the gain ratably over the transition service period. As of December 31, 2005, all revenue related to the acquisition agreement was recognized, including approximately \$3.8 million for transition services of which \$1.4 million was included in *accounts receivable*.

All of our product revenue to date related to sales of TRISENOX. Subsequent to the transaction date, there was no product revenue or cost generating activities related to TRISENOX except for revenue provided under the transition services agreement with Cephalon, costs related to providing such services, and certain other non-cancelable obligations that were not assumed by Cephalon.

The following table summarizes the carrying amounts of the major classes of assets and liabilities included as part of the disposal group related to the divestiture (in thousands):

|                                  |                 |
|----------------------------------|-----------------|
| <b>Disposed Assets:</b>          |                 |
| Accounts receivable, net         | \$ 1,404        |
| Inventory                        | 916             |
| Prepays                          | 60              |
| <b>Total</b>                     | <b>\$ 2,380</b> |
| <br><b>Disposed Liabilities:</b> |                 |
| Accrued liabilities              | \$ 1,738        |
| <b>Total</b>                     | <b>\$ 1,738</b> |

We determined that the TRISENOX and proteasome compound asset group met the criteria to be accounted for as a disposed asset, however, as we cannot clearly distinguish the cash flows related to TRISENOX, it did not



**Table of Contents****CELL THERAPEUTICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

meet the criteria to be considered a component of an entity as defined in SFAS 144. Accordingly, results of operations related to the asset groups are reported in continuing operations.

In January 2000, we acquired the rights to TRISENOX through our acquisition of PolaRx which resulted in the recording of goodwill. SFAS 142, *Accounting for Intangible Assets*, requires that when a reporting unit that constitutes a business is to be disposed of, goodwill related to this reporting unit should be allocated to the carrying amount of the business sold. In our divestiture of TRISENOX to Cephalon, we retained key systems, processes and expertise required to support TRISENOX, therefore, the assets divested were not considered a business in accordance with EITF Issue 98-3, *Determining Whether a Nonmonetary Transaction Involves Receipt of Productive Assets or of a Business* and, accordingly, we did not allocate a portion of our goodwill to these assets.

**9. Extinguishment of PharmaBio Royalty Obligation**

In December 2004, we entered into a financing and services agreement with PharmaBio. In return for cash and services, we were required to pay PharmaBio royalties based on a percentage of net sales of TRISENOX. As a result of the divestiture of TRISENOX, we were required to repay this royalty obligation to PharmaBio. Originally, the agreement stipulated that upon a divestiture of TRISENOX in 2005, a \$40 million termination payment would be held in escrow until December 31, 2005. In July 2005, the agreement was amended to allow for the immediate repayment of the \$40 million termination payment reduced by the interest we would have earned had the funds been placed in escrow. The aggregate termination payment of \$39.4 million was made on July 18, 2005. A \$6.4 million loss on the extinguishment of this royalty obligation was recognized for the year December 31, 2005 determined as follows (in thousands):

|  |             |
|--|-------------|
| Termination payment to PharmaBio                 | \$ (39,388) |
| Extinguishment of royalty obligation             | 28,859      |
| Prepaid service commitment (as of July 18, 2005) | 4,092       |
| Loss on extinguishment of royalty obligation     | \$ (6,437)  |

Under the agreement, we were entitled to receive \$5.0 million in services from PharmaBio and its affiliates (the Prepaid Service Commitment) which may be used through December 31, 2010, approximately \$0.9 million of which had been used as of the repayment date. As of December 31, 2005, we have used approximately \$1.6 million under the service commitment and have \$3.4 million remaining, of which \$2.9 is recorded in *prepaid expenses and other current assets* and \$0.5 million is included in *other assets*.

**10. Capital Stock**

In November 1999, we completed a \$10 million private placement of shares of Series D convertible preferred stock, or Series D, and warrants to acquire shares of common stock with exercise prices of \$2.38 or \$2.625 per share of common stock. Each share of Series D was convertible into 462.427 shares of common stock, and all shares had been converted as of December 31, 2001. Warrants totaling 35,000 and 165,000 were exercised on a net basis and 22,364 and 133,839 shares of common stock were issued during 2004 and 2003, respectively. The remaining warrants expired in November 2004.

Investors of the Series D shares were entitled to receive four annual dividends at a rate per share of 5% per year payable on each September 30, commencing September 30, 2000 regardless of whether the shares had been converted or not. We paid dividends with 44,165 shares of our common stock in 2003. There is no future dividend obligation.

**Table of Contents****CELL THERAPEUTICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In February 2000, we completed a \$40 million private placement of shares of common stock. In connection with the offering, we issued warrants to purchase 170,000 shares of common stock to a placement agent. The warrants are exercisable at a price of \$13.20 per share. The shares of common stock issued and issuable upon the exercise of the warrants have certain registration rights. No warrants were exercised during 2005, 2004 or 2003. All remaining unexercised warrants expired in August 2005.

In August 2004, we received approximately \$49.2 million in gross proceeds from a public offering of 10,350,000 shares of our common stock, including 9,000,000 shares initially sold and an additional 1,350,000 following the underwriter's exercise of their over-allotment option. These shares were sold under a shelf registration statement filed in February 2004 at a public offering price of \$4.75 per share. We incurred approximately \$3.5 million in expenses, including underwriters' discounts and commissions related to this offering.

In December 2004, we received approximately \$18.4 million in gross proceeds from a direct registered offering of 2,585,915 shares of our common stock to several institutional investors. These shares were sold under the same shelf registration statement filed in February 2004 at a price of \$7.10 per share. We incurred expenses of approximately \$0.1 million related to this offering.

In connection with the CAP agreement entered into in November 2005, we issued 3,323,370 shares of common stock upon conversion of a portion of our 5.75% and 4.0% convertible senior subordinated notes based on the conversion terms of the notes as well as an additional 3,377,932 shares of common stock and 6,500,000 zero strike price warrants.

In December 2005, we issued 1,141,110 shares upon conversion of \$3.0 million of our convertible senior notes.

*Common Stock Reserved*

A summary of common stock reserved for issuance is as follows as of December 31, 2005:

|                                       |            |
|---------------------------------------|------------|
| Convertible senior notes              | 42,921,323 |
| Convertible senior subordinated notes | 10,778,088 |
| Convertible subordinated notes        | 871,765    |
| Equity incentive plans                | 7,008,791  |
| Common stock warrants                 | 7,300,000  |
| Employee stock purchase plan          | 244,959    |
| Restricted share rights               | 103,665    |
|                                       | 69,228,591 |

The shares reserved for issuance under our convertible senior notes include shares to be issued to satisfy make-whole interest payments due upon conversion of the notes.

**11. Stock Options, Restricted Stock, Warrants and Employee Stock Purchase Plan***Stock Options*

During 2003, shareholders approved the 2003 Equity Incentive Plan, or 2003 Plan, which replaced the 1994 Equity Incentive Plan, or 1994 Plan. The 1994 Plan has since been terminated, except with respect to outstanding awards previously granted thereunder. The 2003 Plan provides for (a) the grant of nonqualified and/or incentive





**Table of Contents****CELL THERAPEUTICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

stock options, stock appreciation rights and restricted stock, (b) annual, automatic, non-discretionary grants of non-qualified stock options and restricted stock to non-employee members of our board of directors and (c) the award of stock-based performance bonuses. There are 6,443,289 shares authorized under the 2003 Plan including the authorization for issuance of an additional 5,000,000 shares of common stock as set forth in an August 2004 amendment to the 2003 Plan approved by our shareholders at our 2004 Annual Meeting of Shareholders and 293,289 shares which had been reserved but not granted under the 1994 Plan.

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

The Plans are administered by the Compensation Committee of the Board of Directors which has the discretion to determine which employees, consultants and directors shall be granted options. The options are typically exercisable ratably over a four-year period commencing one year from the date of grant, and expire not more than 10 years from the date of grant. As of December 31, 2005, 894,006 shares of common stock were available for future grants.

|   | <b>Shares<br/>Under<br/>Option</b> | <b>Weighted<br/>Average<br/>Exercise<br/>Price Per<br/>Share</b> |
|---|------------------------------------|--|
| Balance January 1, 2003 (2,655,159 exercisable)   | 5,714,295                          | 16.21  |
| Granted   | 1,403,425                          | 8.14   |
| Canceled  | (687,135)                          | 16.02  |
| Exercised   | (521,470)                          | 3.33   |
| Balance December 31, 2003 (3,314,006 exercisable) | 5,909,115                          | 15.45  |
| Granted   | 1,260,384                          | 7.63   |
| Canceled  | (680,889)                          | 15.25  |
| Exercised   | (529,541)                          | 3.43   |
| Balance December 31, 2004 (3,764,175 exercisable) | 5,959,069                          | 14.89  |
| Granted   | 2,948,647                          | 4.13   |
| Canceled  | (2,748,226)                        | 12.31  |
| Exercised   | (44,705)                           | 7.75   |
| Balance December 31, 2005 (3,619,426 exercisable) | 6,114,785                          | \$ 10.95   |

The weighted average exercise price of shares exercisable at December 31, 2005, 2004 and 2003 was \$15.61, \$18.74 and \$18.87, respectively.

**Table of Contents****CELL THERAPEUTICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following table summarizes information about common stock options outstanding at December 31, 2005:

| Range of Exercise Prices | Options Outstanding |   |                                 | Exercisable Options Outstanding (Without Restriction) |                                 |
|--------------------------|---------------------|---|---------------------------------|---|---------------------------------|
|                          | Number Outstanding  | Weighted Average Remaining Contractual Life | Weighted Average Exercise Price | Number Exercisable                                    | Weighted Average Exercise Price |
| \$ 2.10 \$ 2.78          | 1,619,050           | 9.67 Years                                  | \$ 2.47                         | 207,050   | \$ 2.73                         |
| \$ 2.90 \$ 3.49          | 1,233,320           | 6.40 Years                                  | \$ 3.04                         | 895,943   | \$ 3.10                         |
| \$ 3.59 \$ 9.50          | 1,605,052           | 7.76 Years                                  | \$ 7.74                         | 1,095,692   | \$ 7.98                         |
| \$ 9.76 \$26.21          | 597,644             | 7.41 Years                                  | \$ 15.77                        | 361,022   | \$ 19.49                        |
| \$27.30 \$47.28          | 1,059,719           | 5.33 Years                                  | \$ 35.26                        | 1,059,719   | \$ 35.26                        |
| \$ 2.10 \$47.28          | 6,114,785           | 7.54 Years                                  | \$ 10.95                        | 3,619,426   | \$ 15.61                        |

The weighted average fair value of options granted was \$2.72, \$5.41 and \$5.85 during 2005, 2004, and 2003, respectively. Fair value is determined using a Black-Scholes option pricing model that takes into account the stock price at the grant date, the exercise price, as well as the following weighted average assumptions:

|                           | 2005 | 2004 | 2003 |
|---------------------------|------|------|------|
| Risk-free interest rate   | 4.1% | 3.6% | 3.2% |
| Expected life (in years)  | 3.5  | 4.5  | 4.5  |
| Expected price volatility | 0.90 | 0.98 | 1.02 |
| Expected dividend yield   |      |      |      |

In 2004, we recorded \$1.1 million in equity-based compensation expense resulting from an award modification accounted for in accordance with FIN 44, *Accounting for Certain Transactions Involving Stock Compensation*, using the intrinsic value method. The award modification resulted in the recognition of expense related to 193,558 options granted in prior years and 26,667 restricted shares issued in 2004.

In May 2001, the Compensation Committee of the Board of Directors approved the rescission of certain stock option exercises that two officers and a consultant had made in January 2001. In exchange for the return of 91,384 shares of our common stock, we reinstated their original option grant and returned to them the related aggregate exercise price of \$0.3 million. These options are subject to variable stock compensation accounting until the earlier of the expiration of the option grants or the end of the tax year in which the options are exercised. As of December 31, 2005, 19,170 options are still subject to variable stock compensation accounting.

In accordance with EITF 96-18, all equity instruments issued to non-employees are accounted for at the estimated fair value of the equity instruments. The value of the instrument is amortized to expense over the vesting period with final valuation measured on the vesting date. At December 31, 2005, 2004 and 2003, options to acquire 50,368, 107,537 and 132,000 shares of common stock, respectively, were accounted for based on their estimated fair values. We reversed previously recorded stock compensation expense of \$49,000 in 2005 and recorded compensation expense related to the issuance of these stock options of approximately \$76,000 and \$0.4 million in 2004 and 2003, respectively.

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**CELL THERAPEUTICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Restricted Stock*

We issued 2,292,291, 345,082 and 504,200 shares of restricted common stock in 2005, 2004 and 2003, respectively. Additionally, 654,743 and 30,450 shares of restricted stock were cancelled during 2005 and 2004, respectively. The weighted average fair value of restricted shares issued during 2005, 2004 and 2003 was \$4.90, \$7.79 and \$9.86, respectively.

Deferred stock-based compensation recorded for the restricted share grants for the years ended December 31, 2005, 2004 and 2003 was approximately \$4.4 million, \$1.4 million and \$6.6 million respectively, which generally represents the fair value of our stock issued on the date of grant. We reversed deferred stock-based compensation of \$2.2 million and \$0.4 million in 2005 and 2004, respectively, related to cancellations of restricted shares. During 2005, 2004 and 2003, we recognized total compensation expense related to the issuance of restricted stock of approximately \$3.3 million, \$4.2 million and \$0.6 million, respectively.

We also issued 103,665 restricted share rights to non-employees in 1998 for which ownership vests upon the achievement of clinical trial milestones (see Note 16, *Significant Agreements*). Upon entering into an amendment to the PG-TXL License Agreement in February 2006, we issued 87,999 shares of common stock upon the exercise of these restricted share rights and recorded a research and development expense of approximately \$0.2 million as of December 31, 2005.

*Warrants*

In 1998, we issued contingently exercisable warrants to purchase 350,000 shares of our common stock in connection with a license agreement with PG-TXL Company, L.P. at a per share exercise price of \$20.00. The warrants expire in November 2008. In October 2001, we entered into a licensing agreement with Chugai Pharmaceutical Co, Ltd., or Chugai, allowing them to develop XYOTAX within certain territories. The signing of this agreement qualified as an exercise event, and the PG-TXL warrants became exercisable at an exercise price of \$20.00. No warrants have been exercised.

In 2002, we entered into an agreement with The Hope Heart Institute for research services. In connection with this agreement, we issued fully-vested warrants to purchase 100,000 shares of common stock at an exercise price of \$10.00 per share. The warrants expire in November 2007. Phillip M. Nudelman, Ph.D., is the chairman of our board of directors, and a member of our audit, compensation, and nominating and governance committees, and President, Chief Executive Officer and a member of the board of directors of the Hope Heart Institute (see Note 17, *Related Party Transactions*). No warrants have been exercised.

In connection with our November 2005 convertible senior notes offering, we issued warrants to purchase 350,000 shares of common stock within five years at an exercise price of \$3.50 per share to the initial purchaser of these notes. The estimated fair value of the warrants of approximately \$0.6 million was capitalized as a debt issuance cost and is being amortized over the life of the convertible senior notes of five years.

In connection with the CAP agreement, in November 2005 we issued 6.5 million zero strike price warrants as well as 3.4 million shares to two investors of our 6.75% convertible senior notes for an inducement to convert \$38.4 million of our outstanding convertible senior subordinated notes. The conversion inducement was recorded as a debt conversion expense. (see Note 6, *Long-Term Obligations*). These warrants expire in October 2010. As of December 31, 2005, no warrants have been exercised.

**Table of Contents****CELL THERAPEUTICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)***Employee Stock Purchase Plan*

We maintain an Employee Stock Purchase Plan, or the Purchase Plan, under which eligible employees may purchase a limited number of shares of our common stock at 85% of the lower of the subscription date fair market value and the purchase date fair market value. There are two six-month offerings per year. Under the Purchase Plan, we issued 34,398, 64,361 and 76,390 shares to employees in 2005, 2004 and 2003, respectively. There is a balance of 244,959 shares reserved for future purchases at December 31, 2005.

**12. Employee Benefit Plans**

CTI's U.S. employees participate in the Cell Therapeutics, Inc. 401(k) Plan whereby eligible employees may defer up to 80% of their compensation, up to the annual maximum allowed by the Internal Revenue Service. We may make a discretionary matching contributions based on certain plan provisions. We made contributions of approximately \$0.2 million and \$0.3 million during the years ended December 31, 2005 and 2004, respectively. We did not make any contributions during the year ended December 31, 2003.

In connection with our merger with Novuspharma, on January 1, 2004, we assumed a defined benefit plan and related obligation for benefits owed to our Italian employees who, pursuant to Italian law, are entitled to a lump sum payment upon separation from the Company. Related costs are accrued over the employees' service periods based on compensation and years of service. In accordance with EITF 88-1, *Determination of Vested Benefit Obligation for a Defined Benefit Pension Plan*, we have elected to carry the obligation under the plan at the amount of the vested benefit obligation which is defined as the actuarial present value of the vested benefit to which the employee is entitled if the employee separates immediately. Benefits of approximately \$0.6 million and \$0.2 million were paid to employees who separated from the Company during 2005 and 2004, respectively. For the years ended December 31, 2005 and 2004, the vested benefit obligation was approximately \$1.3 million and \$1.7 million, respectively and was included in *other long-term obligations*.

**13. Segment Information and Other Data**

We consider our operations to be a single operating segment, focused in the development, acquisition and commercialization of novel treatments for cancer. Financial results of this reportable segment are presented in the accompanying consolidated financial statements.

During the years ended December 31, 2005, 2004 and 2003, TRISENOX product sales from major customers as a percentage of total product sales were as follows:

|            | 2005 | 2004 | 2003 |
|------------|------|------|------|
| Customer A | 32%  | 35%  | 35%  |
| Customer B | 21%  | 24%  | 30%  |
| Customer C | 22%  | 20%  | 24%  |

The following table depicts revenues attributed to external customers based the following geographic locations (in thousands):

|               | Year Ended December 31, |           |           |
|---------------|-------------------------|-----------|-----------|
|               | 2005                    | 2004      | 2003      |
| North America | \$ 11,413               | \$ 22,501 | \$ 20,525 |
| Europe        | 1,932                   | 4,427     | 1,580     |
| Asia          | 2,747                   | 2,666     | 2,660     |
|               | \$ 16,092               | \$ 29,594 | \$ 24,765 |



**Table of Contents****CELL THERAPEUTICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The following table depicts long-lived assets based on the following geographic locations (in thousands):

|               | Year Ended<br>December 31, |           |
|---------------|----------------------------|-----------|
|               | 2005                       | 2004      |
| United States | \$ 29,882                  | \$ 33,065 |
| Europe        | 18,482                     | 23,999    |
|               | \$ 48,364                  | \$ 57,064 |

**14. Net Loss Per Share**

Basic and diluted net loss per share is calculated using the weighted average number of shares outstanding as follows (in thousands, except per share amounts):

|  | Year Ended December 31, |              |              |
|--|-------------------------|--------------|--------------|
|  | 2005                    | 2004         | 2003         |
| Net loss   | \$ (102,505)            | \$ (252,298) | \$ (130,031) |
| Basic and diluted:   |                         |              |              |
| Weighted average shares outstanding                                | 66,116                  | 54,795       | 33,515       |
| Less weighted-average restricted shares outstanding                | (1,563)                 | (743)        | (97)         |
| Shares used in calculation of basic and diluted net loss per share | 64,553                  | 54,052       | 33,418       |
| Net loss per share:  |                         |              |              |
| Basic and diluted  | \$ (1.59)               | \$ (4.67)    | \$ (3.89)    |

As of December 31, 2005, 2004 and 2003, options, warrants, unvested restricted share awards and rights and convertible debt aggregating 56,825,236, 22,235,863 and 22,089,328, common equivalent shares, respectively, prior to the application of the treasury stock method for options and warrants, were not included in the calculation of diluted net loss per share as they are anti-dilutive.

**15. Income Taxes**

As of December 31, 2005, we had net operating loss carryforwards of approximately \$407.9 million, of which \$55.4 million relates to stock option deductions, and research credit carryforwards of approximately \$16.9 million. The carryforwards begin to expire in 2007.

Due to our equity financing transactions, and other ownership changes as defined in Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, we incurred ownership changes pursuant to the Code. Accordingly, our use of net operating loss carryforwards is limited to approximately \$12.7 million annually for losses incurred prior to August 2, 2004 (which aggregate approximately \$360.0 million). Additionally, all losses incurred prior to March 27, 1997 (which aggregate \$75.5 million) are subject to an annual limitation of approximately \$4.2 million. All losses may also be subject to future ownership change limitations. To the extent that any single-year loss is not utilized to the full amount of the limitation, such unused loss is carried over to subsequent years until the earlier of its utilization or the expiration of the relevant carryforward period, which is generally 15-20 years. Approximately \$9.7 million of the losses incurred prior to March 27, 1997 will expire unused.



**Table of Contents****CELL THERAPEUTICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Deferred income taxes reflect the net tax effects of temporary differences between the carrying values of assets and liabilities for financial reporting purposes and income tax reporting. We recognized a valuation allowance equal to the deferred tax assets due to the uncertainty of realizing the benefits of the assets. Our valuation allowance increased \$29.6 million, \$52.7 million, and \$43.0 million during 2005, 2004 and 2003, respectively.

Significant components of our deferred tax assets and liabilities as of December 31 are as follows (in thousands):

|  | 2005       | 2004       |
|--|------------|------------|
| Deferred tax assets:                                 |            |            |
| Net operating loss carryforwards                     | \$ 138,677 | \$ 169,458 |
| Capitalized research and development                 | 64,218     | 39,343     |
| Intangible asset                                     | 26,453     |            |
| Research and development tax credit carryforwards    | 16,932     | 16,584     |
| Debt issuance costs                                  | 7,110      |            |
| Warrants issued                                      | 3,319      | 3,306      |
| Capital loss carryforward                            |            | 2,931      |
| Lease liability and building impairments             | 2,417      |            |
| Charitable contributions carryforward                | 2,058      | 2,020      |
| Other deferred tax assets                            | 4,166      | 3,146      |
|  |            |            |
| Gross deferred tax assets                            | 265,350    | 236,788    |
| Less valuation allowance                             | (262,668)  | (233,036)  |
|  |            |            |
|  | 2,682      | 3,752      |
| Deferred tax liabilities:                            |            |            |
| GAAP adjustments on Novuspharma merger               | (1,995)    | (3,093)    |
| Deductions for tax in excess of financial statements | (687)      | (659)      |
|  |            |            |
| Gross deferred tax liabilities                       | (2,682)    | (3,752)    |
| Net deferred tax assets                              | \$         | \$         |

The reconciliation between our effective tax rate and the income tax rate as of December 31 are as follows:

|                                      | 2005  | 2004  | 2003  |
|--------------------------------------|-------|-------|-------|
| Federal income tax rate              | (34%) | (34%) | (34%) |
| Research and development tax credits | (1)   | (1)   | (3)   |
| Permanent difference IPRD            |       | 12    |       |
| Permanent difference other           | 1     | 1     | 1     |
| Valuation allowance                  | 30    | 21    | 33    |
| Other                                | 4     | 1     | 3     |
|                                      |       |       |       |
| Net effective tax rate               | %     | %     | %     |

**16. Significant Agreements**



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*PG-TXL Company, L.P.*: In 1998, we entered into an agreement with PG-TXL Company, L.P., as amended in February 2006, granting us an exclusive worldwide license for the rights to polyglutamic acid paclitaxel, a water soluble form of the cancer drug Taxol, and to all potential uses of PG-TXL Company, L.P.'s polymer technology. Under the terms of the agreement, we acquired the rights to the research, development, manufacture, marketing and sale of anti-cancer drugs developed using this polymer technology.

**Table of Contents****CELL THERAPEUTICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

We made \$3.0 million in milestone payments during 2002 to PG-TXL Company L.P. As of December 31, 2005 we accrued a \$0.6 milestone payment related to the amended license agreement. In addition, we will be obligated to make future payments upon the achievement of certain milestones as defined in the agreement of up to \$14.9 million, \$5.4 million of which may be triggered in 2007 if we are successful with our current plans for registrations of XYOTAX with the FDA and EMEA. We also granted warrants to purchase 350,000 shares of our common stock to PG-TXL Company, L.P., which became exercisable upon our entering a licensing agreement for XYOTAX with Chugai Pharmaceutical Co., Ltd (see Note 11, *Stock Options, Restricted Stock, Warrants and Employee Stock Purchase Plan*).

We also entered into Signing Bonus and Restricted Stock and Share Grant Agreements and Consulting Agreements with certain individuals affiliated with PG-TXL Company, L.P., or the PG-TXL Affiliates. The Company also granted 103,665 restricted share rights to the PG-TXL Affiliates, 87,999 of which vested and were issued in February 2006 in connection with the amendment to the License Agreement. As of December 31, 2005, we recorded approximately \$0.2 million in research and development expense related to the vesting of these restricted share rights. The remaining restricted share rights vest upon certain performance conditions which include successfully completing a phase III clinical trial of a licensed product and receiving regulatory approval of an NDA by the FDA. We will begin to record compensation expense at the time the vesting of the share rights become probable. Our obligation to pay consulting fees ended in 2002.

*Chugai Pharmaceutical Co., Ltd.:* In October 2001, we entered into a licensing agreement with Chugai for the development and commercialization of XYOTAX. This agreement grants an exclusive license to Chugai to develop and commercialize XYOTAX in several Asian markets. We have recently been in discussions with Chugai about the return of its rights to certain Asian markets while retaining our development and commercialization rights of XYOTAX in these territories. In October 2005, we received a letter from Chugai proposing the termination of the License Agreement. This agreement was terminated effective March 2006. Upon execution of the agreement, Chugai paid us a \$3.0 million initial payment, which we recorded as deferred revenue and which was being recognized as revenue over the estimated development period of approximately seven years on a straight-line basis; we recognized \$0.4 million and \$0.5 million of revenue during 2004 and 2003. Due to the planned termination of the agreement and the resulting discontinuation of development activities, we recognized the remaining deferred revenue of \$1.4 million during 2005 as there is no additional planned development period. We also received and recognized as revenue approximately \$0.8 million, and \$1.1 million in development expenditure reimbursements from Chugai during 2004, and 2003 respectively, as well as a \$3.0 million milestone payment in 2002.

*Nippon Shinyaku Co., Ltd.:* In December 2002, we entered into a distribution agreement with Nippon Shinyaku Co., Ltd., or Nippon. This agreement grants an exclusive license to Nippon to market and distribute TRISENOX in Japan, South Korea and Taiwan. Upon execution of the agreement, Nippon paid us a \$750,000 initial payment, which was recorded as deferred revenue and was recognized as revenue over the performance period of approximately two years on a straight-line basis. We recognized \$0.2 million and \$0.5 million of revenue during 2004 and 2003, respectively. As of December 31, 2004 all deferred revenue related to the initial payment had been recognized. We also received and recognized as revenue \$0.5 million milestone payments in 2004 and 2003 related to Nippon's receipt of marketing approval and submission of an NDA in Japan, respectively. In December 2004, Nippon launched TRISENOX for the treatment of relapsed/refractory APL in Japan. Pursuant to a supply agreement we entered into with Nippon, we recorded \$1.3 million and \$0.8 million in product sales during 2005 and 2004, respectively. Cephalon assumed the agreement with Nippon in connection with the TRISENOX divestiture in July 2005.

*Other Significant Agreements:* We have several agreements with clinical research organizations, third party manufacturers, and distributors which have a duration greater than one year for the development of our products.

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**CELL THERAPEUTICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**17. Related Party Transactions**

In the case of termination, we have severance agreements with our executive officers that provide benefits for eighteen to twenty-four months.

On April 8, 2002, before the passage of the Sarbanes Oxley Act of 2002, we extended a loan of \$3.5 million to Dr. James A. Bianco, our president and chief executive officer, which bore interest at the six-month LIBOR rate plus 2.25%, adjusted semi-annually, and was due on April 8, 2004. Dr. Bianco paid accrued interest on the loan through October 2003. Prior to April 8, 2004, Dr. Bianco informed the board that he would not be able to repay this loan, including accrued interest, in full when due on April 8, 2004. On April 8, 2004, in accordance with the terms of the original loan agreement, the interest rate on the loan increased by an additional 3%. On October 22, 2004, Dr. Bianco paid the loan and all outstanding accrued interest in full.

In November 2002, we entered into a two-year Sponsored Research Agreement with the Hope Heart Institute, a non-profit corporation, to perform research specified by us and reviewed by a joint research committee comprised of individuals from our company and from the Hope Heart Institute. In addition to monthly payments, we granted a fully vested warrant to the Hope Heart Institute to purchase 100,000 shares of our common stock at a purchase price of \$10.00 per share (see Note 11, *Stock Options, Restricted Stock, Warrants and Employee Stock Purchase Plan*). Phillip M. Nudelman, Ph.D., is the chairman of our board of directors, and a member of our audit, compensation, and nominating and governance committees, and President, Chief Executive Officer and a member of the board of directors of the Hope Heart Institute. Jack W. Singer, M.D., who is a member of our board of directors and our Executive Vice President, Chief Medical Officer, was a member of the Scientific Advisory Board of the Hope Heart Institute in 2002. During 2004 and 2003, we made payments to the Hope Heart Institute of \$45,000 and \$181,000 for research related expenses. We also made charitable contributions of \$24,000, \$11,000 and \$45,000 in 2005, 2004 and 2003, respectively. In 2004, we terminated the Sponsored Research Agreement.

In December 2004, we entered into a licensing agreement with DiaKine Therapeutics, Inc., or DiaKine, for the development and commercialization of Lisofylline. We received an upfront payment of \$250,000 in 2004 and additional payments of \$427,000 in 2005. These payments were recorded as deferred revenue and are being recognized as revenue over the estimated development term in the agreement of December 31, 2013. Jack W. Singer, M.D., is a member of the board of Directors for DiaKine.

**18. Acquisition of PolaRx Biopharmaceuticals, Inc.**

On January 7, 2000, we entered into a Merger Agreement to acquire PolaRx, a biopharmaceutical company that owned the rights to TRISENOX, an anti-cancer compound for which we submitted and received approval for an NDA with the FDA. The acquisition was accounted for as a purchase transaction. Under the terms of the Merger Agreement, we made additional contingent payments of \$5.0 million for achieving a \$20.0 million sales threshold in 2003 and \$4.0 million for meeting a \$10 million TRISENOX sales threshold in 2002 which were recorded as additional goodwill. PolaRx was sold in connection with the divestiture of TRISENOX to Cephalon in July 2005.

**19. PanGenex, Inc.**

In June 2000, we founded PanGenex, Inc., or PanGenex, a majority-owned subsidiary focused on identifying novel drug development targets using the recently completed human genome sequence database. We provided funds and administrative services to support PanGenex's research and development efforts totaling \$0.3 million and \$3.1 million during 2004 and 2003, respectively. In January 2004, PanGenex's board of directors and shareholders approved the termination of its development program and the dissolution of the company.

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**CELL THERAPEUTICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**20. Legal Proceedings**

On February 10, 2004, Micromet AG, or Micromet, a Munich, Germany-based company, filed complaints against CTI in the federal district court for the Western District in the State of Washington, asserting that CTI (Europe), formerly known as Novuspharma S.p.A., had purportedly breached a contract with Micromet for the development of MT-201, a fully human antibody targeting the EP-CAM molecule. The claims allege that CTI (Europe) failed to pay for certain milestones and development expenses owed under the contract. On February 23, 2004, CTI answered the complaint, denying the substance of the allegations, and filed counterclaims for breach of contract and for rescission of the contract based on Micromet's misrepresentations and failures to disclose material information which includes preclinical tests which were determined to be invalid. Management believes that Micromet's complaint is without merit and intends to vigorously defend against the Micromet action, as well as to seek recovery based upon its counterclaims. Management believes the ultimate outcome will not have a material adverse impact on the Company's financial condition or results of operations. No estimate of possible loss or range of loss resulting from the lawsuit can be made at this time.

Beginning in March 2005, a number of purported shareholder class actions, alleging violations of federal securities laws, were filed against CTI, Jim Bianco and Max Link. These actions have been consolidated in the United States District Court for the Western District of Washington. On November 7, 2005, the plaintiffs filed a Consolidated and Amended Class Action Complaint against CTI, James Bianco and Jack Singer. The Consolidated and Amended Complaint asserts claims arising under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder on behalf of a class of purchasers of common stock during the period from November 14, 2003 to March 7, 2005, or the Class Period. Plaintiffs allege that the defendants violated federal securities laws by, among other things, making false statements of material facts and/or omitting to state material facts to make the statements not misleading in connection with the results of the Company's STELLAR clinical trials for its drug XYOTAX. On January 6, 2006, CTI filed a motion to dismiss this class action complaint, to which the plaintiffs filed an opposition on February 21, 2006. No estimate of possible loss or range of loss resulting from the lawsuit can be made at this time. Management believes that the allegations in the foregoing actions are without merit and intend to defend the actions vigorously.

On May 9, 2005, Terence Fernandes, a shareholder of CTI, filed a complaint in the Superior Court of the State of Washington, King County on behalf of CTI against members of CTI's board of directors. The shareholder derivative action alleges breaches of fiduciary duties, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment since June 7, 2004. The case now resides in the United States District Court for the Western District of Washington. On December 7, 2005, the plaintiff filed an amended complaint and defendants filed a motion to dismiss on February 6, 2006, to which the plaintiffs filed an opposition on March 10, 2006. The ultimate outcome of this matter is uncertain.

The United States Attorney's Office, or USAO, for the Western District of Washington is conducting an investigation into certain of CTI's business practices relating to TRISENOX. USAO's investigation relates to CTI's promotional practices relating to TRISENOX; its reporting of revenue relating to TRISENOX sales; and statements made by CTI representatives, and its expert third party reimbursement consultant, relating to the eligibility of TRISENOX for Medicare reimbursement when the drug is used to treat certain off-label indications. USAO has issued subpoenas to third parties relating to its investigation. CTI is fully cooperating with USAO and has not received a subpoena relating to the matter. Management cannot predict whether USAO will bring formal enforcement proceedings (and USAO has not indicated that it will). The Company has been advised that claims associated with the above-referenced as well as related conduct have been filed against the Company under seal on behalf of the Government by a private party. Management cannot provide an estimate of possible loss or range of loss resulting from any such action by USAO or in connection with such lawsuit at this time. However, an adverse outcome could have a material adverse effect on our financial position, liquidity, and results of operations.

**Table of Contents****CELL THERAPEUTICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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.

**21. Subsequent Events**

As of March 6, 2006, holders of our 6.75% convertible senior notes due 2010 had exercised their right to convert \$59.0 million aggregate principal amount of such notes into 22,441,825 shares of our common stock. In connection with such conversions, we paid to the holders interest make-whole payments totaling \$19.9 million pursuant to the terms of the indenture governing the notes. Additionally, these conversions resulted in \$17.7 million of the note holders redemption right under the original terms of the agreement to be forfeited.

As of February 2006, 6,500,000 shares have been issued in connection with the exercise of zero strike price warrants issued under the CAP agreement.

**22. Unaudited Quarterly Data**

The following table presents summarized unaudited quarterly financial data (in thousands, except per share data):

|                                      | <b>First<br/>Quarter</b> | <b>Second<br/>Quarter</b> | <b>Third<br/>Quarter</b> | <b>Fourth<br/>Quarter</b> |
|--------------------------------------|--------------------------|---------------------------|--------------------------|---------------------------|
| <b>2005</b>                          |                          |                           |                          |                           |
| Revenues                             | \$ 6,140                 | \$ 7,468                  | \$ 1,291                 | \$ 1,193                  |
| Gross profit                         | 5,894                    | 7,256                     | 1,231                    | 1,193                     |
| Operating income (expenses)          | (41,888)                 | (40,254)                  | (713)(ii)                | 9,030(ii)                 |
| Net loss                             | (39,132)                 | (36,175)                  | (8,504)                  | (18,694)                  |
| Net loss per share basic and diluted | (0.62)                   | (0.57)                    | (0.13)                   | (0.27)                    |
| <b>2004</b>                          |                          |                           |                          |                           |
| Revenues                             | \$ 4,495                 | \$ 8,300                  | \$ 8,669                 | \$ 8,130                  |
| Gross profit                         | 4,343                    | 8,024                     | 8,239                    | 7,884                     |
| Operating expenses                   | (138,227)(i)             | (44,016)                  | (40,152)                 | (48,027)                  |
| Net loss                             | (136,395)                | (37,457)                  | (34,909)                 | (43,537)                  |
| Net loss per share basic and diluted | (2.75)                   | (0.75)                    | (0.62)                   | (0.72)                    |

- (i) In the first quarter of 2004, we recorded an \$88.5 million charge to operations for acquired IPRD expenses related to the merger of Novuspharma.
- (ii) In the third and fourth quarters of 2005, we recognized the gain on divestiture of TRISENOX of \$30.5 million and \$40.7 million, respectively.

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**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

No disclosure required pursuant to Item 304 of Regulation S-K.

**Item 9A. Controls and Procedures**

(a) Evaluation of Disclosure Controls and Procedures

We carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, as of the end of the period covered by this report. Based upon that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective in timely alerting them to material information relating to us (including our consolidated subsidiaries) required to be included in our periodic SEC filings.

Management's annual report on internal control over financial reporting and the attestation report of the Company's independent registered public accounting firm are set forth in part II, Item 8 of the Annual Report on Form 10-K.

(b) Changes in Internal Controls

During our fourth fiscal quarter, there were no significant changes in our internal controls or in other factors that have materially affected or are reasonably likely to materially affect our internal controls.

**Item 9B. Other Information**

None.

**Table of Contents****PART III****Item 10. Directors and Executive Officers of the Registrant  
Directors**

The following table sets forth certain information with respect to our directors:

| Name                                    | Age as of<br>March 31,<br>2006 | Director<br>Since | Class | Term Expiration     |
|---|--------------------------------|-------------------|-------|---------------------|
| James A. Bianco, M.D.                   | 49                             | 1991              | II    | 2008 Annual Meeting |
| John H. Bauer (3)                       | 65                             | 2005              | I     | 2006 Annual Meeting |
| Vartan Gregorian, Ph.D (2)(3)(4)        | 71                             | 2001              | II    | 2008 Annual Meeting |
| Mary O. Munding, Dr. PH (2)(4)          | 68                             | 1997              | III   | 2006 Annual Meeting |
| Phillip M. Nudelman, Ph.D. (1)(2)(3)(4) | 70                             | 1994              | I     | 2007 Annual Meeting |
| Jack W. Singer, M.D.                    | 63                             | 1991              | III   | 2006 Annual Meeting |

- (1) Chairman of the board of directors.
- (2) Member of the compensation committee.
- (3) Member of the audit committee.
- (4) Member of the nominating and governance committee.

**Dr. Bianco** is our principal founder and has been our president and chief executive officer since February 1992 and one of our directors since our inception in September 1991. Prior to founding CTI, Dr. Bianco was an assistant professor of medicine at the University of Washington, Seattle, and an assistant member in the clinical research division of the Fred Hutchinson Cancer Research Center. From 1990 to 1992, Dr. Bianco was the director of the Bone Marrow Transplant Program at the Veterans Administration Medical Center in Seattle. Dr. Bianco currently serves on the board of directors of Jose Carreras International Leukemia Foundation, Fred Hutchinson Business Alliance, Arts Fund, Seattle Police Foundation and Marsha Rivkin Center for Ovarian Cancer Research. Dr. Bianco received his B.S. degree in biology and physics from New York University and his M.D. from Mount Sinai School of Medicine. Dr. Bianco is the brother of Louis A. Bianco, our executive vice president, finance and administration.

**Mr. Bauer** was appointed to our board of directors in October 2005. Mr. Bauer was formerly Executive Vice President for Nintendo of America Inc. from 1994 to 2003. While at Nintendo of America Inc., he had direct responsibility for all administrative and finance functions. He is currently serving as a consultant to Nintendo of America Inc. In addition, he serves as an executive advisor and chief financial officer at DigiPen Institute of Technology. From 1979 to 1994 he worked for Coopers & Lybrand, including serving as the business assurance (audit) practice Partner. He was also a member of Coopers & Lybrand's Firm Council, the senior policy making and governing board for the firm.

**Dr. Gregorian** has been one of our directors since December 2001. He is the twelfth president of Carnegie Corporation of New York, a grant-making institution founded by Andrew Carnegie in 1911. Prior to his current position, which he assumed in June 1997, Dr. Gregorian served for eight years as Brown University's sixteenth president. He was awarded a Ph.D. in history and humanities from Stanford University. A Phi Beta Kappa and a Ford Foundation Foreign Area Training Fellow, he is a recipient of numerous fellowships, including those from the John Simon Guggenheim Foundation, the American Council of Learned Societies, the Social Science Research Council and the American Philosophical Society.

**Dr. Munding** has been one of our directors since April 1997. Since 1986, she has been a dean and professor at the Columbia University School of Nursing, and an associate dean on the faculty of medicine at Columbia University. Dr. Munding currently serves on the board of directors of United Health Group and Gentiva Health Services. Dr. Munding received her doctorate of public health from Columbia's School of Public Health.

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**Dr. Nudelman** has been one of our directors since March 1994. Since May 2000, he has been the president and chief executive officer of The Hope Heart Institute. From 1998 to 2000, he was the chairman of the board of Kaiser/Group Health. From 1990 to 2000, Dr. Nudelman was the president and chief executive officer of Group Health Cooperative of Puget Sound, a health maintenance organization. Dr. Nudelman received his B.S. degree in microbiology, zoology and pharmacy from the University of Washington, and holds an M.B.A. and a Ph.D. in health systems management from Pacific Western University.

**Dr. Singer** is one of our founders and directors and currently serves as our executive vice president, chief medical officer. Dr. Singer has been one of our directors since our inception in September 1991. He also serves on the board of directors of DiaKine Therapeutics, Inc. From July 1995 to January 2004, Dr. Singer was our executive vice president, research program chairman and from April 1992 to July 1995, he served as our executive vice president, research and development. Prior to joining us, Dr. Singer was a professor of medicine at the University of Washington and a full member of the Fred Hutchinson Cancer Research Center. From 1975 to 1992, Dr. Singer was the chief of medical oncology at the Veterans Administration Medical Center in Seattle. Dr. Singer received his M.D. from State University of New York, Downstate Medical College.

**Executive Officers**

The following table provides certain information with respect to our executive officers:

| Name                      | Age as of      |   |
|---------------------------|----------------|---|
|                           | March 31, 2006 | Position  |
| James A. Bianco, M.D.     | 49             | President, Chief Executive Officer, Director                          |
| Alberto Bernareggi, Ph.D. | 49             | Managing Director, Cell Therapeutics Europe S.r.l.                    |
| Louis A. Bianco           | 53             | Executive Vice President, Finance and Administration                  |
| Jade Brown                | 37             | Executive Vice President, Chief Business Officer                      |
| Jack W. Singer, M.D.      | 63             | Executive Vice President, Chief Medical Officer, Director             |
| Scott C. Stromatt, M.D.   | 48             | Executive Vice President, Clinical Development and Regulatory Affairs |

For biographical information for all our directors, including biographical information concerning Drs. Bianco and Singer who are each directors of CTI as well as executive officers, please see the discussion under the heading Directors.

**Mr. Bianco** is one of our founders and has been our executive vice president, finance and administration since February 1, 1992, and was a director from our inception in September 1991 to April 1992 and from April 1993 to April 1995. From January 1989 through January 1992, Mr. Bianco was a vice president at Deutsche Bank Capital Corporation in charge of risk management. Mr. Bianco is a Certified Public Accountant and received his M.B.A. from New York University. Mr. Bianco and Dr. Bianco are brothers.

**Dr. Bernareggi** was named managing director, Cell Therapeutics Europe S.r.l in September 2005. A co-founder of Novuspharma, Dr. Bernareggi joined CTI as Senior Director of Preclinical Development as part of the acquisition of our acquisition of Novuspharma in January 2004. Dr. Bernareggi has more than 23 years of experience in scientific and management roles in research and development at pharmaceutical and biotech companies, including Marion-Merrell-Dow, Boehringer Mannheim, and Roche. Dr. Bernareggi has authored more than 75 peer-reviewed manuscripts and is a contract Professor of Medicinal Chemistry at the University of Milan.

**Mr. Brown** was promoted to executive vice president and chief business officer in August 2005. Prior to joining us, Mr. Brown was vice president of business development & marketing at Natestch Pharmaceuticals. Additionally, he was employed at Eli Lilly and Company for 12 years where he held a number of leadership positions in business development and commercialization, ultimately serving as the Brand Director in the



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Women's Health Division. Mr. Brown received his M.B.A from Harvard University Graduate School of Business and his B.S. Degree from Indiana University.

*Dr. Stromatt* was promoted to executive vice president, clinical development and regulatory affairs in August 2005, and has managed CTI's global clinical research programs and related functional areas since 2003. Prior to joining us, Dr. Stromatt was vice president clinical research and chief medical officer for Northwest Biotherapeutics and, prior to that, was an analyst focused on public and private biotechnology, pharmaceutical, and medical device companies. Dr. Stromatt earned his MD from the University of Chicago and received his MBA from the University of Colorado.

### **Litigation Involving Directors, Officers and Affiliates**

Cell Therapeutics, Inc., James A. Bianco, M.D., president, chief executive officer and director, and Jack W. Singer, M.D., chief medical officer, are defendants in a consolidated shareholder class action alleging violations of federal securities laws. A number of securities lawsuits were filed beginning in March 2005 and have been consolidated in the United States District Court for the Western District of Washington. A Consolidated and Amended Complaint filed in November 2005 asserts claims arising under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder on behalf of a class of purchasers of common stock during the period from November 14, 2003 to March 7, 2005, or the Class Period. The Consolidated and Amended Complaint alleges generally that the defendants knowingly or recklessly made false or misleading statements during the Class Period concerning its Phase III XYOTAX clinical trial. On January 6, 2006, CTI filed a motion to dismiss this class action complaint to which the plaintiffs filed an opposition on February 21, 2006. The defendants believe that the allegations in the foregoing actions are without merit and intend to defend the actions vigorously.

On May 9, 2005, a shareholder of CTI filed a complaint in the Superior Court of the State of Washington, King County on behalf of CTI against members of CTI's board of directors. The shareholder derivative action alleges breaches of fiduciary duties, abuse of control, gross mismanagement, waste of corporate assets and unjust enrichment since June 7, 2004. The case now resides in the United States District Court for the Western District of Washington. On December 7, 2005, the plaintiff filed an amended complaint and defendants filed a motion to dismiss on February 6, 2006, to which the plaintiffs filed an opposition on March 10, 2006.

### **Audit Committee Financial Expert**

The Company's board of directors has determined that Audit Committee member John Bauer is an audit committee financial expert as defined by Item 401(h) of Regulations S-K of the Securities Exchange Act of 1934, as amended, or Exchange Act, and is independent within the meaning of Item 7(d)(3)(iv) of Schedule 14A of the Exchange Act.

### **Audit Committee**

The Company has an Audit Committee established in accordance with Section 3(a)(58)(A) of the Exchange Act. John Bauer, Vartan Gregorian and Phil Nudelman are the members of the Company's Audit Committee.

### **Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our executive officers and directors, and persons who own more than ten percent of a registered class of our equity securities, to file with the Securities and Exchange Commission reports of ownership and reports of changes in ownership of common stock and our other equity securities. Executive officers, directors and greater than ten percent shareholders are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file.

We prepare Section 16(a) forms on behalf of our executive officers and directors based on the information provided by them. Based solely on review of this information or written representations from reporting persons

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that no other reports were required, we believe that, during the 2005 fiscal year, all Section 16(a) filing requirements applicable to our executive officers, directors and greater than ten percent beneficial owners complied with Section 16(a), except in October 2005, a Form 4 for John H. Bauer was not timely filed due to an inadvertent administrative error.

**Code of Ethics**

The Company has adopted a code of ethics for its senior executive and financial officers (including its principal executive officer and principal financial officer), as well as a code of ethics applicable to all employees and directors. Both codes of ethics are available on the Company's website at [http://www.cticseattle.com/investors\\_management.htm](http://www.cticseattle.com/investors_management.htm). Shareholders may request a free copy of the codes of ethics from:

Cell Therapeutics, Inc.

Attention: Investor Relations

501 Elliott Avenue West, Suite 400

Seattle, WA 98119

(206) 282-7100

Any waivers of the Company's code of ethics will be posted on its website, at <http://www.cticseattle.com>.

**Corporate Governance Guidelines**

The Company has adopted Corporate Governance Guidelines, which are available on the Company's website at [http://www.cticseattle.com/investors\\_management.htm](http://www.cticseattle.com/investors_management.htm). Shareholders may request a free copy of the Corporate Governance Guidelines at the address and phone numbers set forth above.

**Item 11. Executive Compensation**

The following table sets forth all compensation earned in the years ended December 31, 2005, 2004, and 2003 by our chief executive officer and our four other most highly compensated executive officers as of December 31, 2005, who we will collectively refer to as the named executive officers.

**Summary Compensation Table**

| Name and Principal Position                                    | Year | Annual Compensation |            |                                   | Long-Term Compensation Awards   |                                   | All Other Compensation (\$) |
|--|------|---------------------|------------|-----------------------------------|---------------------------------|-----------------------------------|-----------------------------|
|  |      | Salary (\$)         | Bonus (\$) | Other Annual Compensation (\$)(1) | Restricted Stock Awards (\$)(2) | Securities Underlying Options (#) |                             |
| James A. Bianco, M.D.<br>President and Chief Executive Officer | 2005 | 650,000             | 240,000    | 114,385(3)                        | 2,212,000                       | 250,000                           | 43,588(4)                   |
|  | 2004 | 460,297             | 306,832    | 162,518(3)                        | 139,000                         |                                   | 43,588(4)                   |
| Louis A. Bianco<br>Executive Officer                           | 2005 | 330,000             | 99,000     | 10,030(5)                         | 1,002,800                       | 270,000                           | 7,326(6)                    |
|  | 2004 | 300,120             | 120,048    | 5,959(5)                          | 104,250                         |                                   | 7,326(6)                    |
| Executive Vice President,                                      | 2003 | 300,120             | 81,997     | 5,550(5)                          | 751,800                         | 60,000                            | 2,349(6)                    |

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Finance and Administration

|            |      |         |        |        |         |         |        |
|------------|------|---------|--------|--------|---------|---------|--------|
| Jade Brown | 2005 | 245,288 | 84,000 | 345(5) | 291,890 | 185,278 | 441(7) |
|            | 2004 |         |        |        |         |         |        |

Executive Vice President,

Chief Business Officer 2003

|                      |      |         |         |           |           |         |           |
|----------------------|------|---------|---------|-----------|-----------|---------|-----------|
| Jack W. Singer, M.D. | 2005 | 340,000 | 102,000 | 17,290(5) | 1,002,800 | 270,000 | 30,234(8) |
|                      | 2004 | 309,747 | 95,253  | 21,551(5) | 104,250   |         | 30,086(8) |

Executive Vice President,

Chief Medical Officer 2003 302,000 106,703 25,583(5) 751,800 75,000 37,510(8)

|                      |      |         |        |  |         |         |        |
|----------------------|------|---------|--------|--|---------|---------|--------|
| Scott Stromatt, M.D. | 2005 | 288,750 | 87,450 |  | 244,800 | 190,000 | 810(7) |
|                      | 2004 |         |        |  |         |         |        |

Executive Vice President, 2003

Clinical Development

and Regulatory Affairs

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- (1) Other annual compensation in the form of perquisites and other personal benefits has been omitted where the aggregate amount of the perquisites and other personal benefits constituted the lesser of \$50,000 or 10% of the total annual salary and bonus for the named executive officer for the applicable year.
- (2) The amounts shown in this column represent the dollar value of the grant of restricted stock based on the closing price of our common stock on the date of issuance and will accrue any future dividends declared. Restricted stock granted in 2005 includes contingent awards that vest upon the achievement of certain performance goals. During 2005, 450,000 of these awards were granted to Dr. Bianco, 200,000 of which are contingent on shareholder approval, and 100,000 of these awards were granted to each of Mr. Bianco and Dr. Singer. The vesting terms of the awards shown in this column are included in the Restricted Stock Awards Not Yet Vested table below.
- (3) In 2005, 2004, and 2003, other annual compensation for Dr. Bianco represents perquisites, including the following: (i) travel and entertainment expenses reimbursed by the Company, including the aggregate incremental cost of using our aircraft for personal use (the aircraft was disposed of in November 2005), of \$80,138, \$101,721 and \$42,769 and (ii) tax reimbursements of \$28,075, \$53,446 and \$60,128; respectively. The Jobs Creation Act of 2004 does not permit a deduction for the company for any amount not included in compensation of the individuals utilizing the aircraft for non-business use. To the extent non-business use was not included in the aforementioned compensation, the company forewent the deduction for these amounts in determining taxable income. Although we are not able to currently use these foregone tax deductions given our net loss position, the company would have otherwise utilized these expenditures to offset future revenue in determining taxable income. Protective services were provided for Dr. Bianco and his family as part of the Company's corporate security program, which was cancelled in August 2005. The approximate costs of the Company's corporate security program totaled \$216,000, \$1,242,201 and \$939,537 for 2005, 2004 and 2003, respectively. The Company did not consider the cost of providing protective services to Dr. Bianco and his family to be compensatory and therefore such costs are not reflected in the above table.
- (4) All other compensation for Dr. Bianco for 2005, 2004 and 2003 includes the following: (i) a premium payment of \$24,810, \$24,810 and \$34,310 for life insurance required by the terms of Dr. Bianco's employment; (ii) reimbursement of a disability insurance premium of \$5,577, \$5,578 and \$0; and (iii) reimbursement of a health insurance premium of \$13,200, \$13,200 and \$22,000, respectively.
- (5) Other annual compensation consists of tax reimbursements.
- (6) In 2005, 2004 and 2003, all other compensation for Mr. Bianco includes the following: (i) reimbursement for long-term disability insurance premiums of \$4,977, \$4,977 and \$0; and (ii) a premium payment of \$2,349 for life insurance in each of the three years; respectively.
- (7) All other compensation includes a premium payment for life insurance.
- (8) In 2005, 2004 and 2003, all other compensation for Dr. Singer includes the following: (i) reimbursement for long-term disability insurance premiums of \$6,870, \$6,870 and \$0; (ii) premium payments of \$3,564, \$3,416 and \$3,564 for life insurance; and (iii) reimbursement of a health insurance premium of \$19,800, \$19,800 and \$33,946; respectively.

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The following table provides additional detail regarding Restricted Stock Awards presented in the Summary Compensation table above which were unvested as of December 31, 2005.

**Restricted Stock Awards Not Yet Vested**

| Name                    | Grant Date         | Vesting Date | Initial Grant Amount | Initial Price | Initial Value | Remaining Shares  | Current Value (a)   |
|-------------------------|--------------------|--------------|----------------------|---------------|---------------|-------------------|---------------------|
| James A. Bianco, M.D.   | December 14, 2005  | (b)          | 250,000              | \$ 2.36       | \$ 590,000    | 250,000           | \$ 545,000          |
|                         | January 10, 2005   | (c)          | 200,000              | 8.11          | 1,622,000     | 200,000           | 436,000             |
|                         | May 21, 2004       | (d)          | 20,000               | 6.95          | 139,000       | 6,667             | 14,534              |
|                         | January 1, 2004    | (e)          | 110,000              | 8.67          | 953,700       | 27,500            | 59,950              |
|                         | December 11, 2003  | (f)          | 145,000              | 8.10          | 1,174,500     | 48,333            | 105,366             |
|                         |                    |              |                      |               |               | <b>Total</b>      | <b>\$ 1,160,850</b> |
| Louis A. Bianco         | December 14, 2005  | (e)          | 30,000               | \$ 2.36       | \$ 70,800     | 30,000            | \$ 65,400           |
|                         | January 28, 2005   | (g)          | 100,000              | 9.32          | 932,000       | 100,000           | 218,000             |
|                         | May 21, 2004       | (d)          | 15,000               | 6.95          | 104,250       | 5,000             | 10,900              |
|                         | January 1, 2004    | (e)          | 40,000               | 8.67          | 346,800       | 10,000            | 21,800              |
|                         | December 11, 2003  | (f)          | 50,000               | 8.10          | 405,000       | 16,666            | 36,332              |
|                         |                    |              |                      |               | <b>Total</b>  | <b>\$ 352,432</b> |                     |
| Jade Brown              | December 14, 2005  | (e)          | 50,000               | \$ 2.36       | \$ 118,000    | 50,000            | \$ 109,000          |
|                         | June 16, 2005      | (h)          | 56,000               | 2.90          | 162,400       | 37,333            | 81,386              |
|                         | February 28, 2005  | (i)          | 1,163                | 9.88          | 11,490        | 1,163             | 2,535               |
|                         | September 29, 2004 | (j)          | 6,000                | 7.10          | 42,600        | 3,000             | 6,540               |
|                         |                    |              |                      |               | <b>Total</b>  | <b>\$ 199,461</b> |                     |
| Jack W. Singer, M.D.    | December 14, 2005  | (e)          | 30,000               | \$ 2.36       | \$ 70,800     | 30,000            | \$ 65,400           |
|                         | January 28, 2005   | (g)          | 100,000              | 9.32          | 932,000       | 100,000           | 218,000             |
|                         | May 21, 2004       | (d)          | 15,000               | 6.95          | 104,250       | 5,000             | 10,900              |
|                         | January 1, 2004    | (e)          | 40,000               | 8.67          | 346,800       | 10,000            | 21,800              |
|                         | December 11, 2003  | (f)          | 50,000               | 8.10          | 405,000       | 16,666            | 36,332              |
|                         |                    |              |                      |               | <b>Total</b>  | <b>\$ 352,432</b> |                     |
| Scott C. Stromatt, M.D. | December 14, 2005  | (e)          | 30,000               | \$ 2.36       | \$ 70,800     | 30,000            | \$ 65,400           |
|                         | June 16, 2005      | (h)          | 60,000               | 2.90          | 174,000       | 40,000            | 87,200              |
|                         | August 26, 2003    | (k)          | 10,000               | 10.21         | 102,100       | 5,000             | 10,900              |
|                         |                    |              |                      |               | <b>Total</b>  | <b>\$ 163,500</b> |                     |

- (a) Determined based on the closing price of our common stock (\$2.18) on December 31, 2005.
- (b) 50% of the restricted stock award vests when we close a material partnership deal with a pharmaceutical company for XYOTAX and 50% of the restricted stock award vests when we file an NDA with the FDA related to the approval of XYOTAX if either such event occurs on or before December 14, 2008.
- (c) Restricted stock award is subject to shareholder approval. Award vests when we receive an NDA approval for XYOTAX or pixantrone from the FDA, if the approval is obtained on or before January 1, 2007.
- (d) Restricted stock award vests at a rate of 33 1/3% on each of December 11, 2004, 2005 and 2006.
- (e) Restricted stock award vests over two years with 25% vesting six months from the date of grant, 25% vesting one year from the date of grant, 25% vesting 18 months from the date of grant and 25% vesting two years from the date of grant.
- (f) Restricted stock award vests over three years with 1/3 of the shares vesting one year from the date of grant, 1/3 of the shares vesting two years from the date of grant and 1/3 of the shares vesting three years from the date of grant.
- (g) Restricted stock award vests upon the date that we receive approval for an NDA for XYOTAX from the FDA, if the approval is obtained on or before January 1, 2007.



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- (h) Restricted stock award vests over 18 months with 1/3 of the shares vesting six months from the date of grant, 1/3 of the shares vesting one year from the date of grant and 1/3 of the shares vesting 18 months from the date of grant.
- (i) Restricted stock award vests on May 16, 2007.
- (j) 50% of restricted stock award vests on March 26, 2005 and 50% vests on March 26, 2006.
- (k) Restricted stock award vests over four years with 25% of the shares vesting one year from the date of grant, 25% vesting two years from the date of grant, 25% vesting three years from the date of grant and 25% vesting four years from the date of grant.

The following table provides the number of options granted to each of the named executive officers during the year ended December 31, 2005 and the potential realizable value of such grants. No stock appreciation rights were granted to such individuals for the 2005 fiscal year.

**Options Granted in Last Fiscal Year**

| Name                  | Number of Securities Underlying Options Granted (1) | Individual Grants  |                        |                     | Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term (4) |          |
|-----------------------|---|--|------------------------|---------------------|--|----------|
|                       |   | Percent of Total Options Granted to Employees in Fiscal Year (2) | Exercise Price (\$/Sh) | Expiration Date (3) | 5% (\$)  | 10% (\$) |
| James A. Bianco, M.D. | 250,000   | 8.7%   | 2.36                   | 12/14/2015          | 371,048  | 940,308  |
| Louis A. Bianco       | 150,000   | 5.2%   | 2.78                   | 7/14/2015           | 262,249  | 664,591  |
|                       | 120,000   | 4.2%   | 2.36                   | 12/14/2015          | 178,103  | 451,348  |
| Jade Brown            | 6,278   | 0.2%   | 9.88                   | 2/28/2015           | 39,008   | 98,854   |
|                       | 150,000   | 5.2%   | 2.36                   | 12/14/2015          | 222,629  | 564,185  |
|                       | 29,000  | 1.0%   | 2.90                   | 6/16/2015           | 52,890   | 134,034  |
| Jack W. Singer, M.D.  | 150,000   | 5.2%   | 2.78                   | 7/14/2015           | 262,249  | 664,591  |
|                       | 120,000   | 4.2%   | 2.36                   | 12/14/2015          | 178,103  | 451,348  |
| Scott Stromatt, M.D.  | 40,000  | 1.4%   | 2.90                   | 6/16/2015           | 72,952   | 184,874  |
|                       | 150,000   | 5.2%   | 2.36                   | 12/14/2015          | 222,629  | 564,185  |

- (1) Options granted under our 2003 Equity Incentive Plan and Novuspharma Plan typically have a ten-year term and have an exercise price equal to the fair market value on the date of grant; options granted under our 2003 Equity Incentive Plan and Novuspharma Plan have various vesting terms.
- (2) During the fiscal year ended December 31, 2005, options to purchase an aggregate of 2,875,754 shares of our common stock were granted to employees.
- (3) Options may terminate before their expiration dates if the optionee's status as an employee is terminated, or upon the optionee's death.
- (4) Potential realizable value is based on the assumption that the common stock appreciates at the annual rates shown (compounded annually) from the date of grant until the expiration of the option term. These assumed rates of appreciation are mandated by the rules of the SEC and do not represent our estimate or projection of the future common stock price. There can be no assurance that any of the values reflected in this table will be achieved.

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The following table provides the fiscal year-end number and value of unexercised options for each of the named executive officers. None of the named executive officers held any stock appreciation rights at the end of the 2005 fiscal year.

**Aggregated Option Exercises in Last Fiscal Year and Fiscal Year-End Option Values**

| Name                  | Shares<br>Acquired On<br>Exercise (#) | Value<br>Realized<br>(\$ (1)) | Number of Securities<br>Underlying Unexercised<br>Options at |               | Value of Unexercised<br>In-the-Money Options at<br>Fiscal Year-End (\$) (2) |               |
|-----------------------|---------------------------------------|-------------------------------|--|---------------|---|---------------|
|                       |                                       |                               | Fiscal Year End (#)<br>Exercisable                           | Unexercisable | Exercisable   | Unexercisable |
| James A. Bianco, M.D. |                                       |                               | 1,098,739  | 291,666       |   |               |
| Louis A. Bianco       |                                       |                               | 317,517  | 290,000       |   |               |
| Jade Brown            |                                       |                               | 19,236   | 190,042       |   |               |
| Jack W. Singer, M.D.  | 15,000                                | 106,135                       | 410,190  | 295,000       |   |               |
| Scott Stromatt, M.D.  |                                       |                               | 53,750   | 203,750       |   |               |

- (1) Calculated based on the fair market value of the purchased shares on the exercise date less the option exercise price paid for such shares.  
(2) Calculated by determining the difference between the fair market value of the securities underlying the options at December 31, 2005 and the exercise price of the options.

**Employment, severance and/or change of control agreements**

Dr. Bianco, president and chief executive officer, entered into an employment agreement with us effective January 1, 2005, superseding the agreement he had with us effective December 31, 2002. The employment agreement provides for an employment term commencing on January 1, 2005 and ending on December 31, 2008 (the Term). At the end of the Term, the employment agreement will renew automatically for a period of three (3) years thereafter subject to any mutually agreed upon changes or amendments unless Dr. Bianco or the Company gives 120 days notice of intention not to renew the Employment Agreement. The employment agreement entitles Dr. Bianco to an annual base salary of \$650,000 a year, and eligibility to receive an annual bonus to be determined by the Company's compensation committee, with a target bonus opportunity to be not less than 50% of base salary. Pursuant to the terms of the employment agreement, Dr. Bianco was granted 200,000 restricted shares of our common stock which shall vest on the date we receive a new drug application approval for XYOTAX or pixantrone from the Food and Drug Administration, provided that Dr. Bianco has continued employment with us through the vesting date, and that such vesting date occurs prior to January 1, 2007. Vesting will be accelerated if Dr. Bianco resigns for good reason, is terminated without cause, or upon a change of control prior to January 1, 2007. Pursuant to the employment agreement, if Dr. Bianco is terminated without cause or if he resigns for good reason, he will receive (i) at his choice either (x) a lump sum payment representing two years of his salary based on a 6% discount factor, or (y) continuing payments of severance pay at a rate equal to his monthly base salary rate, as then in effect, plus his most recent annual cash bonus continuation, for a period of eighteen (18) months from the date of such termination, (ii) full vesting of outstanding unvested stock options which shall become exercisable for a period of two (2) years following the date on which they vest, subject to the terms of the applicable award agreements, and full vesting of outstanding unvested or restricted stock, (iii) continuation of health benefits for the severance period not to exceed two (2) years following termination, and (iv) all accrued but unused vacation. In the event of a change of control and Dr. Bianco is terminated without cause or resigns for good reason, Dr. Bianco will receive the following severance benefits: (i) a lump sum payment equal to two years of his base salary plus his most recent annual cash bonus, (ii) full vesting of outstanding unvested stock options which shall become exercisable for a period of two (2) years following the date on which they vest, and full vesting of outstanding unvested or restricted stock (iii) continuation of health benefits for two (2) years, and (iv) all accrued but unused vacation. The employment agreement restricts Dr. Bianco from competing with us for the term of the severance payment period following



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the termination of his employment with us. In addition, the severance payments are conditioned upon Dr. Bianco not competing with us and not soliciting our employees. The agreement further provides that, if any payments are subject to the excise tax on parachute payments, we will make a gross up payment in an amount that covers the excise tax due plus the excise and income taxes payable on the gross up payment.

Mr. Bianco, Mr. Brown, Dr. Singer and Dr. Stromatt entered into severance agreements with us, effective as of April 12, 2005 for Mr. Bianco and Dr. Singer and effective as of September 15, 2005 for Mr. Brown and Dr. Stromatt, pursuant to which, in the event that the executive is discharged from employment by us without cause or resigns for good reason (including upon a change of control), he will be entitled to receive (i) acceleration of all then existing unvested stock based compensation (options will remain exercisable for 21 months following the severance date), (ii) severance pay based on the executive's base salary in effect immediately prior to the severance date for a period of eighteen months, (iii) bonus pay equal to the greater of the average of the three prior years bonuses or 30% of base salary, (iv) continuation of or reimbursement for certain health benefits for a period of up to eighteen months, (v) all accrued but unused vacation and certain other benefits for a severance period of eighteen months. The agreements further provide that, if any payments are subject to the excise tax on parachute payments, we will make a gross up payment in an amount that covers the excise tax due plus the excise and income taxes payable on the gross up payment. The severance payments are conditioned upon the executive not breaching his inventions and proprietary information agreement with us. Under the terms of the severance benefits agreement, the executive is not entitled to severance benefits if employment is terminated for cause, as a result of his death or disability or due to his own resignation without good reason. For Mr. Bianco and Dr. Singer, these severance agreements replace severance agreements entered into with us effective September 23, 1997 and February 1, 1998, respectively.

Inventions and proprietary information agreements restrict Dr. Singer from competing with us for two years after the termination of his employment with us.

### **Italian Law and National Collective Bargaining Agreements**

Many material terms of our Italian executives' employment are mandated by Italian law and national collective bargaining agreements. In Italy, collective bargaining agreements are much more prevalent than in the United States and are negotiated at a national level beyond the control of any particular employer between the unions of a particular business sector (mechanical, commerce, banks, chemical, etc.) and the employers' association in the applicable sector.

In particular, our employment relationships with our Italian executives are regulated by Italy's National Collective Agreement for the Executives in the Industrial Sector of May 23, 2000, as amended, which provides, among other things:

executives are entitled to minimum gross monthly salary related to length of service;

executives' yearly salaries are paid in 13 installments;

executives are not subject to working time schedules or overtime rules;

executives are entitled to 35 days of holiday per year;

for justified reasons, executives are entitled to an unpaid leave period;

in case of illness, the executives are entitled to maintain their job position for a period of up to 12 months during which they will receive their full salary (with the cost being fully borne by the employer);

executives are entitled to mandatory paid maternity leave;

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executives are entitled to insurance coverage for on- and off-duty accidents; and

executives are entitled to indemnification for any civil and criminal liabilities incurred by the executives in the performance of their employment activities.

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Finally, the Italian National Collective Agreement regulates the severance benefits we would be required to pay upon any termination by us of the employment of our officers in Italy. The severance amount varies based upon whether the termination is for cause, for justified reasons or for no justified reason, as generally described below:

**Terminations for Cause.** If we were to dismiss an executive in Italy for cause, he would not be entitled to any notice period or indemnity in lieu of the notice period, but he would be entitled to receive the severance compensation (so-called TFR). We would have cause to terminate an executive's employment, under Article 2119 of the Italian civil code, following any serious event that makes the continuation of the employment relationship impossible, even on a temporary basis. Events such as theft, riots and serious insubordination are generally considered cause for termination in Italy.

**Terminations for Justified Reasons.** If we were to terminate the employment of any executive in Italy, other than for cause, the executive would be entitled to a notice period. The notice period is equal to eight months for executives having a seniority of up to two years, and it is increased in proportion to seniority up to a maximum of 12 months for executives having more than 10 years of seniority. If we were to terminate an executive's employment for justified reasons without providing the required notice, he would be entitled to the indemnity in lieu of the notice period equal to the salary he would have received during the notice period, in addition to the severance compensation. The average amount of the bonuses paid to him during the prior three years and the value of his fringe benefits, including stock options under certain circumstances, would be taken into account when calculating this indemnity. Under Article 2118 of the Italian civil code, the following events are generally considered to provide a justified reason for terminating an executive's employment: failure of the executive to comply with material management directions; a restructuring or reorganization of the company; a complete closing of the company; or the closing of the office to which the executive is assigned.

**Unlawful Terminations.** If we were to terminate the employment of any executive in Italy without cause or justified reasons, the executive might challenge the dismissal in court. If the termination of the employment relationship is deemed unlawful by the court, the executive may be awarded damages in the form of an indemnity (to be paid in addition to the indemnity in lieu of the notice period and the severance compensation) ranging from a minimum amount equal to the notice indemnity due to the executive, plus two months' salary up to a maximum amount equal to 22 months' salary. The amount of damages may automatically be increased by a sum ranging between two and seven months' salary if the executive's age is between 46 and 56 years. An executive is never entitled to reinstatement, regardless of the cause of termination.

**Table of Contents****Non-Employee Director Compensation**

Directors who are also our employees are not paid an annual retainer, nor are they compensated for serving on the board. Information regarding compensation otherwise received by our directors who are also executive officers is provided under the heading Compensation of Executive Officers. As increased by our board of directors effective for meetings after February 17, 2006, subject to shareholder approval, our non-employee directors are paid meeting fees as follows:

|                               | Annual Cash   | Meeting Fees (\$) |           | Telephone Meeting Fees (\$) |           |
|-------------------------------|---------------|-------------------|-----------|-----------------------------|-----------|
|                               | Retainer (\$) | Board             | Committee | Board                       | Committee |
| Board Member                  | 25,000(1)     | 1,500             |           | 1,000                       |           |
| Chairman of the Board         | Plus 22,000   | 1,500             |           | 1,000                       |           |
| Audit Committee Member        | Plus 1,000    |                   | 500       |                             | 500       |
| Audit Committee Chair         | Plus 7,500(2) |                   | 500       |                             | 500       |
| Compensation Committee Member | Plus 1,000    |                   | 500       |                             | 500       |
| Compensation Committee Chair  | Plus 5,000(2) |                   | 500       |                             | 500       |
| Other Board Committee Member  | Plus 1,000    |                   | 500       |                             | 500       |
| Other Board Committee Chair   | Plus 2,500(2) |                   | 500       |                             | 500       |

(1) Prior to February 17, 2006, members of the board of directors were paid an annual cash retainer of \$18,000.

(2) Prior to February 17, 2006, the chairperson of a committee of the board of directors was paid an annual cash retainer of \$1,000.

In addition, all non-employee directors are reimbursed for their expenses incurred in attending board meetings.

During 2005, pursuant to our 2003 Equity Incentive Plan, each non-employee director also received one of the following fully-vested option grants:

| Grant Type                                    | Option Grants |
|---|---------------|
| Initial Grant Upon Appointment Directors (1)  | 15,000        |
| Annual Grant Continuing Directors             | 12,000        |
| Annual Grant Continuing Chairman of the Board | 15,000        |

(1) After February 17, 2006, and subject to shareholder approval, new non-employee directors receive options to purchase 24,000 shares of our common stock on the date such director first becomes a non-employee director, which options become vested after one year provided that such director remains an eligible non-employee director on such anniversary.

Each of these options granted during 2005 had an exercise price that ranged from \$2.43 to \$8.14 and was equal to 100% of the fair market value on the date of grant. These options have a term of ten years measured from the grant date, subject to early termination if the optionee ceases serving as a director.

During 2005, pursuant to our 2003 Equity Incentive Plan, each non-employee director also received one of the following restricted stock awards, such restricted stock awards becoming fully-vested on the one year anniversary of the grant date.

| Award Type                               | Restricted Stock |
|--|------------------|
| Initial Award Upon Appointment Directors | 2,500            |
| Annual Award Continuing Directors        | 2,500            |

We provide liability insurance for our officers and directors. Our current coverage is through various underwriters, and extends until October 9, 2006 at an annual cost of approximately \$2.1 million.



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The following table provides the actual compensation received by our non-employee directors over the course of the last fiscal year.

**2005 Non-Employee Director Compensation**

| Name                      | Annual Retainer | Board of Directors Meeting Fees | Committee Meeting Fees | Option Grants | Restricted Stock Grants |
|---------------------------|-----------------|---------------------------------|------------------------|---------------|-------------------------|
| John H. Bauer (1)         | \$ 5,000        | \$ 2,500                        | \$ 1,000               | 15,000        | 2,500                   |
| John M. Fluke, Jr. (2)    | 14,672          | 14,500                          | 6,000                  |               |                         |
| Vartan Gregorian, Ph.D    | 19,750          | 18,000                          | 7,000                  | 12,000        | 2,500                   |
| Max E. Link, Ph.D (3)     | 33,250          | 17,500                          | 9,000                  | 15,000        | 2,500                   |
| Mary O. Mundinger, Dr. PH | 20,250          | 21,000                          | 8,000                  | 10,000        |                         |
| Phillip M. Nudelman, Ph.D | 28,500          | 21,500                          | 12,000                 | 10,000        |                         |
| Erich Platzer, M.D. (2)   | 12,500          | 12,000                          | 500                    | 10,000        |                         |

- (1) Joined the board of directors on October 17, 2005.
- (2) Resigned from the board of directors on August 19, 2005.
- (3) Resigned from the board of directors on September 30, 2005.

**Compensation Committee Report on Executive Compensation**

The current compensation committee consists of only non-employee directors, who are appointed by the board of directors, and all of whom meet the requirements of independence as set forth in the rules and regulations promulgated by the Securities and Exchange Commission and the Nasdaq Stock Market listing standards. We are responsible for establishing and administering CTI's executive compensation arrangements. We also administer the 2003 and 1994 Equity Incentive Plans, the Novuspharma Plan and the 1996 Employee Stock Purchase Plan and make all stock option grants under the 2003 Equity Incentive Plan and the Novuspharma Plan to CTI's executive officers. The current compensation committee consists of Dr. Mary O. Mundinger, Dr. Phillip M. Nudelman, and Dr. Vartan Gregorian and has served as such since September of 2005; prior to that time for the calendar year 2005 the compensation committee consisted of Drs. Mundinger and Gregorian and Dr. Max Link, and was chaired by Dr. Link.

**General Compensation Policy**

We operate in the extremely competitive and rapidly changing biotechnology industry. We believe that the compensation programs for the company's executive officers should be designed to attract, retain and motivate talented executives responsible for the success of the company and should be determined within a competitive framework and based on the achievement of strategic corporate objectives and individual performance and teamwork. Within this overall philosophy, our objectives are to:

Offer a total compensation program that takes into consideration the compensation practices of a peer group of companies with which CTI competes for executive talent.

Integrate each executive officer's compensation package with annual and long-term corporate objectives and focus the officer's attention on the attainment of those objectives.

Promote the creation of shareholder value through the achievement of strategic corporate objectives.

Provide annual variable incentive awards that take into account CTI's performance relative to corporate objectives and the individual executive officer's contributions.

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Align the financial interests of executive officers with those of shareholders by providing significant equity-based, long-term incentives.

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**Compensation Components and Process**

We have endeavored to apply a compensation philosophy that is designed to attract and retain qualified key executive officers critical to CTI's success taking into account the company's current profile and challenges.

We make decisions based upon the attainment of corporate-wide, team and individual performance objectives and based on the formulation of new corporate objectives and the formulation and implementation of those objectives in response to negative events, such as the failure of a clinical trial or similar setback. However, we determine compensation amounts relying foremost upon our judgment about each individual evaluated after taking into account the analysis of an independent consulting firm and the chief executive officer with respect to all executive officers other than the chief executive officer, and not based upon a rigid set of guidelines or formulas.

In establishing the compensation package of CTI's executive officers, we adopted a total pay philosophy which includes three major components: (1) base salary set at levels that are commensurate with those of comparable positions at other pharmaceutical or biotechnology companies; (2) annual bonuses and stock option grants tied to the achievement of strategic corporate and team objectives and individual performance; and (3) long-term, stock-based incentive awards intended to strengthen the mutuality of interests between the executive officers and our shareholders. In the case of CTI's chief executive officer, his base salary is set pursuant to a written employment agreement entered into on January 1, 2005 and approved by the prior compensation committee.

As referenced above, an independent consulting firm furnishes the compensation committee with executive compensation data drawn from several nationally recognized surveys of companies within the biotechnology and pharmaceutical industries. On the basis of those surveys, we identified a peer group of companies with which CTI competes for executive talent, which we will refer to as the peer companies.

The positions of CTI's chief executive officer and the other executive officers were compared with those of their counterparts at the peer companies, and the market compensation levels for comparable positions were examined to compare base salary, target incentives, and total cash compensation. In addition, the practices of the peer companies concerning stock option grants and restricted stock grants were also reviewed and compared.

*Base Salary.* The base salary for each executive officer is set at a level considered appropriate for comparable positions at the peer companies. We make base salary determinations in accordance with the range in effect for comparable positions at the peer companies, competitive market forces and our evaluation of performance of the chief executive officer and the evaluation of performance provided to us for each executive officer by the chief executive officer. In January of 2005, the company and Dr. Bianco entered into a four-year employment agreement which establishes by contract a base salary of \$650,000 for Dr. Bianco for the calendar year 2005. This agreement was approved by the prior compensation committee and ratified by the board of directors of CTI as formulated in January of 2005. Accordingly, we did not review or make market compensation comparisons with respect to the chief executive officer's base salary because it is governed by a written binding contract between the company and Dr. Bianco.

*Variable Incentive Awards.* To reinforce the attainment of CTI's goals, we believe that a substantial portion of the annual compensation of each executive officer should be in the form of variable incentive pay or bonuses generally tied to the achievement of corporate and individual targets. Given the industry in which the company operates and the rapid changes that can occur throughout a given year in corporate objectives, this process is necessarily dynamic and not static. For the calendar year 2005, the determination of the appropriate amount of variable compensation was especially challenging. In the spring and early summer it became clear that the major corporate objective established at the outset of 2005, the filing of an NDA with respect to XYOTAX, would not be met because our STELLAR 2, 3 and 4 phase III trials did not achieve their primary endpoints. This led to other corporate challenges and a split on appropriate strategy and leadership at the board level. As such, management's



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variable compensation in 2005 was tied to significant efforts to formulate a viable registration strategy for XYOTAX, and making appropriate and expeditious reductions in operating expenses while increasing its liquidity and cash reserves. In the second half of the year the company dramatically reduced its headcount and burn-rate, sold TRISENOX to Cephalon for aggregate consideration of \$71.9 million and used \$39.4 million of those proceeds to retire CTI's debt owed to Pharmabio Development, Inc. The company also sold \$82 million of 6.75% convertible senior notes, which, after taking into account offering expenses and assuming the conversion of all notes and required make-whole interest payments added approximately \$49.5 million of cash to the company. As of March 31, 2006, approximately \$62.8 million of the 6.75% convertible senior notes had been converted.

*Long-Term, Equity-Based Incentive Awards.* The goal of CTI's long-term equity-based incentive awards is to align the interests of CTI's executive officers with the shareholders and to provide each executive officer with a significant incentive to perform his management duties from the perspective of an owner with an equity stake in the business. This incentive is provided through stock option and restricted stock grants made under the 2003 Equity Incentive Plan and the Novuspharma Plan. The size of the stock option and restricted stock grants to each executive officer is set at a level we feel is appropriate to create a meaningful opportunity for stock ownership based upon the executive officer's current position with CTI, internal comparability with stock option and restricted stock grants made to CTI's other executives, the executive officer's current level of performance and his potential for future responsibility and promotion over the option term. We also take into account comparable equity incentives provided to individuals in similar positions in the biotechnology and pharmaceutical industries, as reflected in external surveys, and the number of unvested options held by the executive officer at the time of the new grant. We have established certain general guidelines by which we seek to target a fixed number of unvested option shares for each executive officer based upon his current position with CTI and his potential for in-house growth (i.e., future responsibilities and possible promotions over the option term). However, we do not strictly adhere to these guidelines in making stock option and restricted stock grants, and the relative weight that is given to the various factors varies from individual to individual, as the circumstances warrant.

During fiscal 2005, we awarded CTI's executive officers named in this proxy statement, new stock options for an aggregate of 1,251,278 shares of common stock. Each grant allows the officer to acquire the shares underlying the stock option at a fixed price per share (the market price or fair market value on the grant date) over a ten-year period of time. Specifically, the options vest in periodic installments over one-year to three-year periods, contingent upon the executive officer's continued employment with CTI. Accordingly, the option will provide a return only if the officer remains with CTI and then only if the market price appreciates over the option term. During 2005, we also authorized the issuance of 907,163 shares of restricted stock to executive officers named in this proxy statement which included 257,163 shares of time-based restricted stock and 650,000 shares of contingent restricted stock. Time-based restricted stock awards vest in periodic installments over one-year to four-year periods contingent upon the executive officer's continued employment with CTI. The contingent grants are performance-based and vest upon the achievement of certain business objectives, which include (1) 200,000 shares awarded to certain executive officers which vest upon an NDA approval for XYOTAX from the FDA prior to January 1, 2007, (2) 200,000 shares awarded to our Chief Executive Officer which are subject to shareholder approval and vest upon an NDA approval for XYOTAX or pixantrone from the FDA prior to January 1, 2007, and (3) 250,000 shares awarded to the Chief Executive Officer, 50% of which vests upon the closure of a material partnership deal for XYOTAX and 50% of which vests upon the filing of an NDA with the FDA related to the approval of XYOTAX, either of which must occur prior to December 14, 2008. As discussed above, 2005 was a challenging year; yet it is clear to the compensation committee that the best current prospect of creating shareholder value is dependent on the success of XYOTAX, and the retention of a core group of dedicated executives to stay with the company to continue the development of XYOTAX. All restricted stock grants were made to further this objective and 650,000 of those are directly contingent upon XYOTAX's success.

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**Compensation of the Chief Executive Officer**

As stated above, the annual base salary for our Chief Executive Officer, James A. Bianco, M.D., was set pursuant to the terms of an employment agreement entered into with Dr. Bianco in January 2005 and approved by the prior compensation committee.

Dr. Bianco was also awarded (1) options to purchase 250,000 shares of common stock at an exercise price of \$2.36 per share and (2) 450,000 shares of performance-based contingent restricted stock, 200,000 of which are subject to shareholder approval, and which vest as described above primarily based on whether XYOTAX is successful. The grants reflected our intention to subject a portion of Dr. Bianco's overall compensation to the market performance of CTI's common stock and to the success of XYOTAX as measured by regulatory approval or third-party validation. The stock option awards will be of little or no value to Dr. Bianco unless there is appreciation in the value of CTI's common stock over the option term. The contingent restricted stock awards will be of no value to Dr. Bianco unless the performance criteria are attained.

**Compliance with Internal Revenue Code Section 162(m)**

As a result of Section 162(m) of the Internal Revenue Code, which was enacted into law in 1993, CTI will not be allowed a federal income tax deduction for compensation paid to certain officers, to the extent that compensation exceeds one (1) million dollars per officer in any one year. This limitation will apply to all compensation that is not considered to be performance-based within the meaning of Section 162(m). Compensation that does qualify as performance-based compensation will not have to be taken into account for purposes of this limitation. Any compensation deemed paid in connection with the exercise of stock options granted under CTI's 2003 Equity Incentive Plan and CTI's 1994 Equity Incentive Plan with an exercise price not less than the market price of the option shares on the grant date is intended to qualify as performance-based compensation for this purpose. In addition, under CTI's 2003 Equity Incentive Plan, the compensation committee may grant restricted stock awards that are structured to qualify as performance-based compensation for this purpose. While the compensation committee intends to structure performance-related awards in a way that will preserve the maximum deductibility of compensation awards, the compensation committee may from time to time approve awards which would not result in qualification of those awards as performance-based compensation under Section 162(m) and could result in a loss of tax deductions.

The compensation paid to our Chief Executive Officer during fiscal 2005 that was not performance-based under Section 162(m) exceeded the one (1) million dollar limit per officer by approximately \$485,000. CTI will not be able to take a federal income tax deduction for this excess amount. We feel for the reasons stated above that arrangements entered into with Dr. Bianco were appropriate in the circumstances; as of December 31, 2005 the company has approximately \$408 million in loss carryforwards and had never earned a profit so that the loss of the deduction has no current economic impact.

**COMPENSATION COMMITTEE**

Mary O. Munding, Dr. PH (Chair)

Vartan Gregorian, Ph.D.

Phillip M. Nudelman, Ph.D.

**Table of Contents****Stock Performance Graph**

|                             | <b>3/31/01</b> | <b>6/30/01</b> | <b>9/30/01</b> | <b>12/31/01</b> |
|-----------------------------|----------------|----------------|----------------|-----------------|
| Cell Therapeutics, Inc.     | \$ 39.81       | \$ 61.34       | \$ 53.37       | \$ 53.57        |
| Nasdaq Stock Index (U.S.)   | \$ 74.65       | \$ 87.98       | \$ 61.04       | \$ 79.35        |
| Nasdaq Pharmaceutical Index | \$ 74.05       | \$ 91.99       | \$ 74.16       | \$ 85.22        |
|                             | <b>3/31/02</b> | <b>6/30/02</b> | <b>9/30/02</b> | <b>12/31/02</b> |
| Cell Therapeutics, Inc.     | \$ 55.10       | \$ 12.09       | \$ 9.76        | \$ 16.13        |
| Nasdaq Stock Index (U.S.)   | \$ 75.30       | \$ 60.02       | \$ 48.16       | \$ 54.94        |
| Nasdaq Pharmaceutical Index | \$ 76.20       | \$ 54.03       | \$ 49.80       | \$ 55.04        |
|                             | <b>3/31/03</b> | <b>6/30/03</b> | <b>9/30/03</b> | <b>12/31/03</b> |
| Cell Therapeutics, Inc.     | \$ 18.40       | \$ 21.66       | \$ 25.12       | \$ 19.24        |
| Nasdaq Stock Index (U.S.)   | \$ 55.23       | \$ 66.59       | \$ 73.32       | \$ 82.09        |
| Nasdaq Pharmaceutical Index | \$ 59.59       | \$ 74.74       | \$ 78.92       | \$ 80.68        |
|                             | <b>3/31/04</b> | <b>6/30/04</b> | <b>9/30/04</b> | <b>12/31/04</b> |
| Cell Therapeutics, Inc.     | \$ 18.77       | \$ 16.36       | \$ 15.22       | \$ 18.06        |
| Nasdaq Stock Index (U.S.)   | \$ 81.50       | \$ 83.92       | \$ 77.88       | \$ 89.32        |
| Nasdaq Pharmaceutical Index | \$ 84.20       | \$ 83.29       | \$ 79.66       | \$ 85.91        |
|                             | <b>3/31/05</b> | <b>6/30/05</b> | <b>9/30/05</b> | <b>12/31/05</b> |
| Cell Therapeutics, Inc.     | \$ 7.97        | \$ 6.01        | \$ 6.35        | \$ 4.84         |
| Nasdaq Stock Index (U.S.)   | \$ 82.05       | \$ 84.83       | \$ 88.88       | \$ 91.21        |
| Nasdaq Pharmaceutical Index | \$ 75.45       | \$ 79.02       | \$ 92.89       | \$ 94.60        |

**Table of Contents****Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters**

The following table provides certain information regarding beneficial ownership of common stock as of March 15, 2006 by (1) each shareholder known by us to be the beneficial owner of more than 5% of our outstanding shares of common stock, (2) each of our directors and nominees for director, (3) each of our executive officers named in the Summary Compensation Table and (4) all directors and executive officers as a group:

| Name and Address of Beneficial Owner (1)                            | Number of<br>Shares<br>Beneficially<br>Owned (2) | Shares<br>Subject to<br>Options | Percentage<br>Ownership (2) |
|---|--|---------------------------------|-----------------------------|
| James A. Bianco, M.D.** (3)   | 1,982,308  | 1,098,739                       | 1.9%                        |
| John H. Bauer** (4)   | 17,500   | 15,000                          | *                           |
| Louis A. Bianco (5)   | 639,956  | 367,517                         | *                           |
| Jade Brown (6)  | 118,732  | 27,236                          | *                           |
| Vartan Gregorian, Ph.D.**   | 59,500   | 52,000                          | *                           |
| Mary O. Mundinger, Dr. PH**   | 51,650   | 50,000                          | *                           |
| Phillip M. Nudelman, Ph.D.**  | 94,811   | 44,906                          | *                           |
| Jack W. Singer, M.D.** (5)  | 916,480  | 460,190                         | *                           |
| Scott C. Stromatt, M.D (7)  | 142,083  | 67,083                          | *                           |
| All directors and executive officers as a group (10 persons) (8)(9) | 4,034,520  | 2,194,171                       | 3.9%                        |

\* Less than 1%

\*\* Denotes director of CTI

- (1) The address of the individuals listed is 501 Elliott Avenue West, Suite 400, Seattle, Washington 98119.
- (2) Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission ( SEC ) and generally includes voting or investment power with respect to securities. This table is based upon information supplied by officers, directors, Schedules 13D, 13G and 13F and Forms 3 and 4 filed with the SEC. Shares of common stock subject to options or warrants currently exercisable or convertible, or exercisable or convertible within 60 days of March 15, 2006, are deemed outstanding for computing the percentage of the person holding the option or warrant but are not deemed outstanding for computing the percentage of any other person. Except as indicated in the footnotes to this table and pursuant to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock beneficially owned.
- (3) Number of shares beneficially owned includes 505,000 shares of unvested restricted stock, of which 450,000 shares have contingent vesting terms and 200,000 shares are subject to shareholder approval. Of these contingent shares, 200,000 shares would vest upon the date that we receive a new drug application, or NDA, approval for XYOTAX or pixantrone from the Food and Drug Administration, or FDA, if the approval is obtained prior to January 1, 2007. Additionally, 125,000 shares will vest upon the closing of a material partnership deal with a pharmaceutical company and 125,000 shares will vest upon the filing of an NDA with the FDA related to the approval of XYOTAX, if either such event occurs on or before December 14, 2008.
- (4) Mr. Bauer joined our board of directors effective October 17, 2005.
- (5) Number of shares beneficially owned includes 151,666 shares of unvested restricted stock, of which 100,000 shares are contingent and would vest upon the date that we receive approval for an NDA for XYOTAX from the FDA if the approval is obtained prior to January 1, 2007.
- (6) Number of shares beneficially owned includes 91,496 shares of unvested restricted stock.
- (7) Number of shares beneficially owned includes 75,000 shares of unvested restricted stock.
- (8) Number of shares beneficially owned includes 974,828 shares of unvested restricted stock for all executive officers as a group, of which 650,000 shares are contingent and would vest as described in the above footnotes.
- (9) Does not include shares owned by directors and executive officers who served as directors and executive officers during all or part of the 2005 fiscal year but were not serving in that capacity as of March 15, 2006.

**Table of Contents****Item 13. Certain Relationships and Related Transactions**

In November 2002, we entered into a two-year Sponsored Research Agreement with the Hope Heart Institute, a non-profit corporation, to perform research specified by us and reviewed by a joint research committee comprised of individuals from our company and from the Hope Heart Institute. In addition to monthly payments, we granted a fully vested warrant to the Hope Heart Institute to purchase 100,000 shares of our common stock at a purchase price of \$10.00 per share. Dr. Nudelman is the President, Chief Executive Officer and a member of the board of directors of The Hope Heart Institute. Dr. Singer was a member of the Scientific Advisory Board of The Hope Heart Institute in 2002. In 2004, we terminated the Sponsored Research Agreement with the Hope Heart Institute. During 2005, we made charitable contributions of \$24,000 to the Hope Heart Institute.

In December 2004, we entered into a licensing agreement with DiaKine Therapeutics, Inc., or DiaKine, for the development and commercialization of Lisofylline. We received an upfront payment of \$250,000 in 2004 and additional payments of \$427,000 in 2005. As part of the agreement, Jack W. Singer, M.D., agreed to join the board of directors of DiaKine. Dr. Singer is not currently compensated for his service on the DiaKine board of directors.

**Item 14. Principal Accounting Fees and Services**

The following table provides the aggregate fees billed for professional services rendered by our principal accountants during each of the past two fiscal years ended December 31:

| Services Rendered      | Ernst & Young LLP |            | Grant Thornton LLP |            | Stonefield Josephson, Inc. |      |
|------------------------|-------------------|------------|--------------------|------------|----------------------------|------|
|                        | 2005              | 2004       | 2005               | 2004       | 2005                       | 2004 |
| Audit Fees (1)         | \$                | \$ 318,000 | \$ 212,325         | \$ 555,000 | \$ 1,051,000               | \$   |
| Audit-Related Fees (2) |                   | 233,000    |                    |            |                            |      |
| Tax Fees (3)           |                   | 46,000     | 7,014              |            |                            |      |
| All Other Fees (4)     |                   |            |                    |            |                            |      |

- (1) *Audit Fees.* This category includes fees for professional services provided in conjunction with the audit of our financial statements and with the audit of management's assessment of internal control over financial reporting and the effectiveness of internal control over financial reporting, review of our quarterly financial statements, assistance and review of documents filed with the SEC, consents, and comfort letters and attestation services provided in connection with statutory and other regulatory filings and engagements.
- (2) *Audit Related Fees.* This category includes fees for assurance and related professional services associated with due diligence related to mergers and acquisitions, consultation on accounting standards or transactions, internal control reviews and assistance with internal control reporting requirements, services related to the audit of employee benefit plans, and other attestation services not required by statute or regulation.
- (3) *Tax Services.* This category includes fees for professional services provided related to tax compliance, tax planning and tax advice.
- (4) *Other Services.* There were no other fees for services not included above.

**Pre-Approval Policy**

Pursuant to our Audit and Non-Audit Services Pre-Approval Policy, which is approved by the Audit Committee on an annual basis, the audit committee pre-approves all auditing services and non-audit services to be performed by our independent auditors. The audit committee also pre-approves all associated fees, except for de minimus amounts for non-audit services, which are approved by the audit committee prior to the completion of the audit.

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**PART IV**

**Item 15. Exhibits, Financial Statement Schedules**

(a) Financial Statements and Financial Statement Schedules

(i) Financial Statements

Management's Report on Internal Control over Financial Reporting

Reports of Stonefield Josephson, Inc. Independent Registered Public Accounting Firm

Report of Grant Thornton LLP. Independent Registered Public Accounting Firm

Report of Ernst & Young LLP. Independent Registered Public Accounting Firm

Consolidated Balance Sheets

Consolidated Statements of Operations

Consolidated Statements of Shareholders' Equity (Deficit)

Consolidated Statements of Cash Flows

Notes to Consolidated Financial Statements

(ii) Financial Statement Schedules

II Valuation and Qualifying Accounts

All other schedules have been omitted since they are either not required, are not applicable, or the required information is shown in the financial statements or related notes.

(i) Exhibits

| <b>Exhibit Number</b> | <b>Description</b>   |
|-----------------------|--|
| 2.1(6)                | Agreement and Plan of Reorganization between PolaRx Biopharmaceuticals, Inc., the Registrant and PolaRx Biopharmaceuticals Acquisition Corp., dated January 7, 2000.   |
| 2.2(13)               | Amendment No. 1 to Agreement and Plan of Reorganization between PolaRx Biopharmaceuticals, Inc., the Registrant and David M. Tanen as PolaRx Representative, dated March 6, 2003.  |
| 2.3(14)               | Agreement and Plan of Merger by and between Cell Therapeutics, Inc. and Novuspharma, S.p.A., dated as of June 16, 2003.  |
| 3.1(20)               | Registrant's Restated Articles of Incorporation.   |
| 3.2(15)               | Registrant's Amended and Restated Bylaws.  |
| 4.1(4)                | Form of Rights Agreement dated as of November 11, 1996, between the Registrant and Harris Trust Company of California, which includes the Form of Rights Certificate as Exhibit A, the Summary of Rights to Purchase Preferred Stock as Exhibit B and the Form of Certificate of Designation of the Series C Preferred Stock as Exhibit C. |
| 4.2(12)               | First Amendment to Rights Agreement dated as of November 20, 2002, between the Registrant, Harris Trust Company of California and Computershare Investor Services, LLC.  |

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- 4.3(7) Indenture between the Registrant and State Street Bank and Trust Company of California, N.A., as trustee dated June 13, 2001.
- 4.4(13) Indenture between the Registrant and State Street Bank and Trust Company of California, N.A., as trustee dated December 20, 2002.
- 4.5(18) Indenture between the Registrant and U.S. Bank National Association as trustee, dated June 23, 2003.
- 4.6(28) Indenture between the Registrant and U.S. Bank National Association as trustee, dated November 4, 2005.

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| <b>Exhibit Number</b> | <b>Description</b>   |
|-----------------------|--|
| 10.1(3)               | Lease Agreement between David A. Sabey and Sandra L. Sabey and the Registrant, dated March 27, 1992, as amended March 31, 1993 and October 13, 1993. |
| 10.2(1)               | Assignment of Lease between Manlove Travel and the Registrant, dated April 23, 1993.   |
| 10.3(2)               | Letter Agreement between David A. Sabey, Sandra L. Sabey and the Registrant, dated as of September 6, 1996, amending the Assignment of Lease.        |
| 10.4(2)               | Third Amendment to Lease Agreement between David A. Sabey and Sandra L. Sabey and the Registrant, dated as of September 10, 1996.                    |
| 10.5(10)              | Sublease Agreement between F5 Networks, Inc. and the Registrant, dated March 30, 2001, as amended April 13, 2001.                                    |
| 10.6(8)               | Amended Equipment Leasing Agreement dated as of September 1, 2001, between Citiflight, Inc. And the Registrant.                                      |
| 10.7(13)              | Lease agreement between Elliott Park LLC and the Registrant, dated August 20, 2002.  |
| 10.8(24)*             | Employment Agreement between the Registrant and James A. Bianco, dated as of January 1, 2005.  |
| 10.9(16)*             | Employment Agreement between the Registrant and Silvano Spinelli, dated as of June 16, 2003.   |
| 10.10(18)*            | Employment Agreement between the Registrant and Cesare Parachini, dated as of June 16, 2003.   |
| 10.11(25)*            | Form of Strategic Management Team Severance Agreement.   |
| 10.12(22)*            | Severance Agreement between the Registrant and Richard E. Leigh, Jr, dated September 29, 2004.   |
| 10.13(27)*            | Severance Agreement and General Release by and between the Registrant and Stephen A. Aselage, dated June 28, 2005.                                   |
| 10.14(9)*             | Form of Indemnification Agreement.   |
| 10.15(11)*            | 1994 Equity Incentive Plan, as amended.  |
| 10.16(20)*            | 1996 Employee Stock Purchase Plan, as amended.   |
| 10.17(20)*            | 2003 Equity Incentive Plan.  |
| 10.18(19)*            | Cell Therapeutics, Inc. Novuspharma S.p.A. Stock Option Plan   |
| 10.19(30)*            | Form of Notice of Grant of Award and Award Agreement for grants of restricted stock under the Registrant s 2003 Equity Incentive Plan, as amended.   |
| 10.20(30)*            | Form of Notice of Grant of Stock Options and Option Agreement for option grants under the Registrant s 2003 Equity Incentive Plan, as amended.       |
| 10.21(30)*            | Form of Nonqualified Stock Option Agreement for option grants under the Registrant s Novuspharma S.p.A. Stock Option Plan.                           |
| 10.22(5)              | License Agreement dated as of November 13, 1998, by and between PG-TXL Company, L.P. and the Registrant.   |
| 10.23(29)             | Amendment No. 1 to the License Agreement, dated as of February 1, 2006, by and between the Registrant and PG-TXL Company, L.P.                       |
| 10.24(8)              | Paclitaxel Purchase Agreement dated as of September 28, 2001, between Natural Pharmaceuticals, Inc. and the Registrant.                              |
| 10.25(8)              | License Agreement dated as of October 19, 2001, between Chugai Pharmaceutical Co., Ltd. and the Registrant.  |
| 10.26(31)             | Termination Agreement dated March 14, 2006, between Chugai Pharmaceutical Co., Ltd. and the Registrant.  |
| 10.27(9)              | ISDA Master Agreement dated as of January 25, 2002, between Citibank N.A. and the Registrant.  |



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| <b>Exhibit Number</b> | <b>Description</b>  |
|-----------------------|---|
| 10.28(18)             | Registration Rights Agreement dated June 23, 2003, by and among Cell Therapeutics, Inc., CIBC World Markets Corp. and U.S. Bancorp Piper Jaffray Inc.                                     |
| 10.29(30)             | Financing Agreement dated December 21, 2004, between the Registrant PolaRx Biopharmaceuticals, Inc., a wholly owned subsidiary of the Registrant, and PharmaBio Development, Inc.         |
| 10.30(23)             | Security Agreement dated December 21, 2004, among the Registrant PolaRx Biopharmaceuticals, Inc., a wholly owned subsidiary of the Registrant, and PharmaBio Development, Inc.            |
| 10.31(23)             | Guaranty Agreement dated December 21, 2004, between PolaRx Biopharmaceuticals, Inc., a wholly owned subsidiary of the Registrant, and PharmaBio Development, Inc.                         |
| 10.32(23)             | Registration Rights Agreement dated December 21, 2004, among the Registrant PolaRx Biopharmaceuticals, Inc., a wholly owned subsidiary of the Registrant, and PharmaBio Development, Inc. |
| 10.33(23)             | Joint Press Release dated December 21, 2004, between PolaRx Biopharmaceuticals, Inc., a wholly owned subsidiary of the Registrant, and PharmaBio Development, Inc.                        |
| 10.34(26)             | Acquisition Agreement by and among the Registrant, Cell Technologies, Inc. and Cephalon, Inc., dated June 10, 2005.   |
| 12.1#                 | Statement Re: Computation of Ratio of Earnings to Fixed Charges.  |
| 21.1#                 | Subsidiaries of the Registrant.   |
| 23.1#                 | Consent of Stonefield Josephson, Inc., Independent Registered Public Accounting Firm  |
| 23.2#                 | Consent of Grant Thornton LLP, Independent Registered Public Accounting Firm.   |
| 23.3#                 | Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.  |
| 24.1#                 | Power of Attorney. (See page 114 of the Registrant's Annual Report on Form 10-K for the year ended December 31, 2005).  |
| 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.   |

# Previously filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 2005, filed on March 16, 2006.

\* Indicates management contract or compensatory plan or arrangement.

Portions of these exhibits have been omitted pursuant to a request for confidential treatment.

- (1) Incorporated by reference to exhibits to the Registrant's Registration Statement on Form S-1 (No. 33-4154), filed on April 26, 1996.
- (2) Incorporated by reference to the Registrant's Registration Statement on Form S-1 (No. 333-20855).
- (3) Incorporated by reference to exhibits to the Registrant's Registration Statement on Form 10, filed on April 29, 1996.
- (4) Incorporated by reference to exhibits to the Registrant's Registration Statement on Form 8-A, filed on November 15, 1996.
- (5) Incorporated by reference to exhibits to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1998, filed on March 31, 1999.
- (6) Incorporated by reference to exhibits to the Registrant's Current Report on Form 8-K, filed on January 25, 2000.
- (7) Incorporated by reference to exhibits to the Registrant's Current Report on Form 8-K, filed on June 13, 2001.

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- (8) Incorporated by reference to exhibits to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001, filed on November 14, 2001.
- (9) Incorporated by reference to exhibits to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2001, filed on March 29, 2002.
- (10) Incorporated by reference to exhibits to the Registrant's amended Annual Report on Form 10-K/A for the year ended December 31, 2001, filed on April 30, 2002.
- (11) Incorporated by reference to exhibits to the Registrant's Registration Statement on Form S-8, filed on July 24, 2002.
- (12) Incorporated by reference to exhibits to the Registrant's Form 8A/A, filed on January 10, 2003.
- (13) Incorporated by reference to exhibits to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002, filed on March 27, 2003.
- (14) Incorporated by reference to exhibits to the Registrant's Current Report on Form 8-K, filed on June 17, 2003.
- (15) Incorporated by reference to appendix H to the Registrant's Registration Statement on Form S-4 (No. 333-106906).
- (16) Incorporated by reference to exhibit 10.23 to the Registrant's Registration Statement on Form S-4, filed on July 9, 2003 (No. 333-106906).
- (17) Incorporated by reference to exhibit 10.24 to the Registrant's Registration Statement on Form S-4, filed on July 9, 2003 (No. 333-106906).
- (18) Incorporated by reference to exhibits to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2003, filed on August 6, 2003.
- (19) Incorporated by reference to exhibits to the Registrant's Registration Statement on Form S-8, filed on February 13, 2004.
- (20) Incorporated by reference to exhibits to the Registrant's Current Report on Form 8-K filed June 4, 2004.
- (21) Incorporated by reference to exhibits to the Registrant's Registration Statement on Form S-8, filed on August 6, 2004.
- (22) Incorporated by reference to exhibits to the Registrant's Current Report on Form 8-K filed October 4, 2004.
- (23) Incorporated by reference to exhibits to the Registrant's Current Report on Form 8-K, filed on December 23, 2004.
- (24) Incorporated by reference to exhibits to the Registrant's Current Report on Form 8-K, filed on January 6, 2005.
- (25) Incorporated by reference to exhibits to the Registrant's Current Report on Form 8-K, filed on April 18, 2005.
- (26) Incorporated by reference to exhibits to the Registrant's Current Report on Form 8-K, filed on June 14, 2005.
- (27) Incorporated by reference to exhibits to the Registrant's Current Report on Form 8-K, filed on June 29, 2005.
- (28) Incorporated by reference to exhibits to the Registrant's Current Report on Form 8-K, filed on November 10, 2005.
- (29) Incorporated by reference to exhibits to the Registrant's Current Report on Form 8-K, filed on February 14, 2006.
- (30) Incorporated by reference to exhibits to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2004, filed on March 4, 2005.

**Table of Contents****SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) 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, in the City of Seattle, State of Washington, on April 27, 2006.

Cell Therapeutics, Inc.

By: /s/ James A. Bianco  
**James A. Bianco, M.D.**

President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

| Signature                      | Title   | Date           |
|--------------------------------|---|----------------|
| /s/ Phillip M. Nudelman*       | Chairman of the Board and Director  | April 27, 2006 |
| <b>Phillip M. Nudelman</b>     |   |                |
| /s/ James A. Bianco            | President, Chief Executive Officer and Director (Principal Executive Officer)                                       | April 27, 2006 |
| <b>James A. Bianco</b>         |   |                |
| /s/ Louis A. Bianco            | Executive Vice President, Finance and Administration (Principal Financial Officer and Principal Accounting Officer) | April 27, 2006 |
| <b>Louis A. Bianco</b>         |   |                |
| /s/ John H. Bauer*             | Director  | April 27, 2006 |
| <b>John H. Bauer</b>           |   |                |
| /s/ Vartan Gregorian*          | Director  | April 27, 2006 |
| <b>Vartan Gregorian, Ph.D.</b> |   |                |
| /s/ Mary O. Mundinger*         | Director  | April 27, 2006 |
| <b>Mary O. Mundinger</b>       |   |                |
| /s/ Jack W. Singer*            | Director  | April 27, 2006 |
| <b>Jack W. Singer M.D.</b>     |   |                |

\*By: /s/ James A. Bianco  
**James A. Bianco, M.D., as**  
**Attorney-in-fact**



**Table of Contents****SCHEDULE II****CELL THERAPEUTICS, INC.****VALUATION AND QUALIFYING ACCOUNTS****YEARS ENDED DECEMBER 31, 2005, 2004 and 2003**

(in thousands)

|   | <b>Balance at<br/>Beginning<br/>of Period</b> | <b>Additions<br/>Charged to<br/>Expense</b> | <b>Deductions</b> | <b>Balance at<br/>End of<br/>Period</b> |
|---|---|---|-------------------|---|
| <b>Year ended December 31, 2005:</b>                              |   |   |                   |   |
| Allowance for sales returns                                       | \$ 1,406                                      | \$ 201                                      | \$ (1,607)(1)     | \$                                      |
| Allowance for doubtful accounts and discounts                     | 36  | 234   | (270)(2)          |   |
| Reserve for excess inventory that may expire or become unsaleable | 51  | 1   | (52)(3)           |   |
|   | \$ 1,493                                      | \$ 436                                      | \$ (1,929)        | \$                                      |
| <b>Year ended December 31, 2004:</b>                              |   |   |                   |   |
| Allowance for sales returns                                       | \$ 2,029                                      | \$ 60                                       | \$ (683)          | \$ 1,406                                |
| Allowance for doubtful accounts and discounts                     | 88  | 442   | (494)             | 36                                      |
| Reserve for excess inventory that may expire or become unsaleable | 76  | 57  | (82)              | 51                                      |
|   | \$ 2,193                                      | \$ 559                                      | \$ (1,259)        | \$ 1,493                                |
| <b>Year ended December 31, 2003:</b>                              |   |   |                   |   |
| Allowance for sales returns                                       | \$ 731  | \$ 1,391                                    | \$ (93)           | \$ 2,029                                |
| Allowance for doubtful accounts and discounts                     | 127   | 422   | (461)             | 88                                      |
| Reserve for excess inventory that may expire or become unsaleable |   | 131   | (55)              | 76                                      |
|   | \$ 858  | \$ 1,944                                    | \$ (609)          | \$ 2,193                                |

(1) Approximately \$1,572,000 was included in the asset disposal group related to the divestiture of TRISENOX to Cephalon.

(2) Approximately \$51,000 was included in the asset disposal group related to the divestiture of TRISENOX to Cephalon.

(3) This balance was included in the asset disposal group related to the divestiture of TRISENOX to Cephalon.