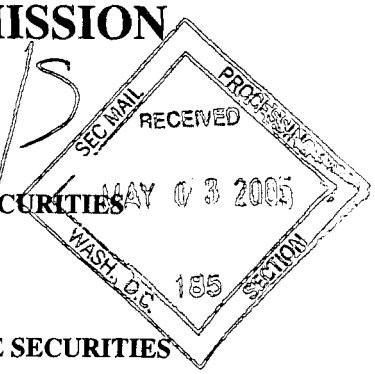
UNITED STATES

'IES AND EXCHANGE COMMISSION

Washington, D.C. 20549



FORM 10-K

(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, 2004

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

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 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 an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes ☒ No ☐

The aggregate market value of the voting and non-voting common equity held by nonaffiliates as of December 31, 2004 was approximately $455,405,000, based on the closing price of such shares on the NASDAQ National Market on June 30, 2004. 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 February 24, 2005 was 64,646,972.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III of this Report, to the extent not set forth herein, will be incorporated herein by reference from the registrant's definitive proxy statement relating to the annual meeting of shareholders to be held in 2005, which definitive proxy statement or amendment to this annual report shall be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year ended December 31, 2004 to which this Report relates.

CELL THERAPEUTICS, INC.

TABLE OF CONTENTS

Forward Looking Statements

This Form 10-K contains, in addition to historical information, forward-looking statements. These statements relate to Cell Therapeutics, Inc. (CTI's) future plans, objectives, expectations, intentions and financial performance, and assumptions that underlie these statements. When used in this Form 10-K, terms such as "anticipates," "believes," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "should," or "will" or the negative of those terms or other comparable terms are intended to identify 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. These factors include those listed under "Factors Affecting Our Operating Results and Financial Condition," "Management's Discussion and Analysis of Consolidated Financial Condition and Results of Operations," and "Business" and elsewhere in this Form 10-K.

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.

PART I

Item 1. Business

Overview

We develop, acquire and commercialize novel treatments for cancer. Our goal is to build a leading, vertically-integrated biopharmaceutical company with a diversified portfolio of proprietary cancer drugs. Our research and in-licensing activities are focused on identifying new, less toxic and more effective ways to treat cancer. We market TRISENOX® (arsenic trioxide) for the treatment of relapsed or refractory acute promyelocytic leukemia, or APL, in the United States and in the European Union, or Europe. We are developing XYOTAX (paclitaxel poliglumex) for the potential treatment of non-small cell lung cancer, or NSCLC, and ovarian cancer. We have completed enrollment of more than 1,700 patients in three pivotal phase III trials of XYOTAX, known as STELLAR 2, 3 and 4, for the treatment of NSCLC. In January 2005, an update on the STELLAR 3 and 4 trials was presented which showed encouraging survival trends. These trends have extended the expected top-line data release in STELLAR 3 to the first half of March 2005. Complete data from STELLAR 3 is expected to be presented at the 2005 Annual Meeting of the American Society of Clinical Oncology, or ASCO. We expect to file a new drug application, or NDA, for XYOTAX based on the data from the STELLAR trials in the third quarter of 2005. We expect to release top-line clinical data from STELLAR 2 and 4 by the end of the second quarter of 2005. In addition, we expect to initiate a phase III trial of XYOTAX in ovarian cancer with the Gynecologic Oncology Group, or GOG, in the first quarter of 2005. We also develop pixantrone, a novel compound in the class of drugs known as anthracyclines, for the potential treatment of non-Hodgkin's lymphoma, or NHL, and have several clinical trials ongoing, including a pivotal phase III trial for the potential treatment of relapsed aggressive NHL. We expect to have interim data from the phase III trial in late 2005, and if successful, we would submit an NDA for accelerated approval in early 2006. Final results for this trial are expected in the third quarter of 2006 and if successful, we would submit an NDA for full approval for pixantrone at the end of 2006. If we are able to submit for accelerated approval, with acceptance by the Food and Drug Administration, or FDA, we estimate launch of pixantrone for the potential treatment of aggressive NHL in 2006. If we need full trial results, we estimate launch in 2007.

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. 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," "TRISENOX" 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 leading cause of death in the United States, among people under the age of 85, resulting in close to 570,000 deaths annually. The National Cancer Advisory Board reports that more than 8.9 million people in the United States have cancer, 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 are diagnosed each year in the United 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 or safety over competitive drugs.
- We plan to devote a substantial portion of our efforts to develop XYOTAX, pixantrone and to further develop and commercialize TRISENOX for additional indications.
- We have developed our own sales and marketing capabilities in the United States and select European territories and may establish collaborations to commercialize our products.
- We have discovery research 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 researching other novel drug targets to discover agents with improved side effect and efficacy profiles compared to competitor drugs.
- We plan to continue to in-license or acquire complementary products, technologies or companies.

TRISENOX (arsenic trioxide)

We acquired our marketed product, TRISENOX, (arsenic trioxide) in January 2000. We market TRISENOX for the treatment of APL patients who have relapsed or failed standard therapies. We received FDA approval to market TRISENOX in the United States in September 2000, and approval from the European Agency for the Evaluation of Medicinal Products or EMEA to market in Europe in March 2002. TRISENOX is a highly purified version of arsenic, a natural element. TRISENOX appears to have multiple targets and mechanisms of antileukemic activity; it degrades a protein that causes abnormal levels of immature white blood cells while simultaneously forcing immature cancer cells to self destruct through a process called programmed cell death or apoptosis. Apoptosis is a normal part of a cell's life cycle. Because cancer is often associated with a malfunction of the normal process of apoptosis, drugs that can induce apoptosis offer the hope of affecting cancer cells more selectively without the typical toxic side effects of conventional treatments. Direct induction of apoptosis represents a relatively new method of killing tumor cells that is different from that of the majority of conventional cancer drugs. As a result, in addition to its use as single-agent therapy, TRISENOX may work well when administered in combination with other cancer therapies to produce more durable response rates.

In April 2004, the U.S. Patent and Trademark office issued a patent covering TRISENOX injection that extends our market exclusivity in the United States for TRISENOX from 2007 to 2018. This extension is eleven years beyond the original U.S. orphan drug exclusivity for APL, which currently expires in 2007. We believe further investments in registration-directed trials for various blood-related cancers including front-line APL, multiple myeloma and myelodysplastic syndrome, or MDS, could accelerate TRISENOX sales growth and increase the drug's commercial potential.

We intend to protect TRISENOX in part through application of orphan drug marketing exclusivity in the United States and Europe. When granted orphan drug status, products usually receive seven years of marketing exclusivity in the United States and ten years in Europe. If a product with an orphan drug designation subsequently receives the first FDA or EMEA approval for the indication for which it has such designation, the product is entitled to orphan drug marketing exclusivity, meaning that the regulatory agency 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 or ten years. We have received U.S. orphan drug marketing exclusivity for TRISENOX in APL and have received U.S. orphan drug designation for TRISENOX for the treatment of multiple myeloma, MDS, chronic myelogenous leukemia, or CML, acute myelogenous leukemia, or AML, chronic lymphocytic leukemia, or CLL and liver cancer. TRISENOX has received orphan drug designation for the treatment of APL, multiple myeloma, and MDS under the European orphan drug regulation.

We commenced sales of TRISENOX in October 2000, and currently market TRISENOX in the United States and Europe. For the year ended December 31, 2004 we recorded $26.6 million in TRISENOX sales, an increase of 20.5% over 2003. Although TRISENOX is approved for patients with a type of blood cell cancer called APL who have relapsed or failed standard therapies, most TRISENOX sales result from treatment of multiple myeloma and MDS. There are more than 15,000 new cases of multiple myeloma diagnosed per year in the United States. We have approximately 40 clinical and investigator-sponsored trials in process for TRISENOX to address a variety of blood-related cancers including, front-line APL, multiple myeloma and MDS.

TRISENOX for Relapsed/Refractory Acute Promyelocytic Leukemia.

APL is a malignant disorder of the white blood cells that can occur across all age groups. Based on ACS data, approximately 1,500 to 2,000 patients are diagnosed with APL each year in the United States, with a similar incidence in Europe. Current treatment for newly diagnosed APL patients includes the use of all-trans retinoic acid, commonly called all-trans retinoic acid, or ATRA, in combination with anthracycline chemotherapy. Between 10% and 15% of patients die during front-line therapy, some patients will have long-term toxicity due to anthracycline treatment, and up to 30% of patients who achieve initial remission will eventually relapse. After relapse, the long-term outlook for these patients is poor.

TRISENOX has been investigated in relapsed and refractory APL patients, previously treated with an anthracycline and retinoid regimen, in two open-label studies. One was a single investigator clinical, or pilot, trial involving 12 patients and the other was a multicenter, nine-institution study, or pivotal, trial of 40 patients. The pilot trial results and accompanying editorial describing the use of TRISENOX to treat patients with relapsed APL were published in the November 5, 1998 issue of *The New England Journal of Medicine*. The results of this study were confirmed by the pivotal trial that was published in September 2001 in *The Journal of Clinical Oncology*. Long-term follow up data were presented at the 8th International Symposium on APL in October 2001. The results demonstrated that among the 85% of patients who achieved a complete remission, 82% were confirmed to have a molecular remission using a highly sensitive molecular test. With a median follow up of 30 months, the overall survival estimate for the 52 patients in the combined pilot and pivotal studies was 66%.

Side effects of TRISENOX noted in these studies were generally manageable, usually did not require interruption of therapy, and most patients were treated as outpatients once the serious symptoms of their APL were resolved. The most common side effects included nausea, cough, fatigue, headache, vomiting, abdominal pain, diarrhea, shortness of breath, leukocytosis (an increase in the number of white blood cells in circulation), hyperglycemia (increased blood sugar), rash, prolongation of the QT interval (an asymptomatic change in electrocardiogram, or EKG), edema (water retention) and dizziness.

TRISENOX for newly diagnosed Acute Promyelocytic Leukemia

A study published in April 2004 in the Proceedings of the National Academy of Sciences concluded that induction therapy with the combination of arsenic trioxide and ATRA, a vitamin A analogue, for front-line treatment of APL resulted in faster time to achieve complete response, or CR, significantly greater reduction in leukemia burden and longer lasting remissions than either of the two drugs used alone. Sixty-one newly diagnosed APL patients were randomized into three treatment groups: single-agent ATRA, single-agent arsenic trioxide or the combination of the two. All 20 cases in the combination group remained in remission after a median follow up of 18 months, whereas seven of the 37 patients (19%) treated with monotherapy relapsed. Standard treatment for front-line APL is ATRA plus an anthracycline cancer drug. This treatment regimen results

in a high rate of remission and cure, but also has substantial short- and long-term side effects including neutropenia, infections, an increased lifetime risk for secondary leukemia and MDS and permanent heart damage. We expect the results of an Intergroup phase II study of TRISENOX to be available in 2005 and these data may provide information for CTI to file a supplemental NDA (sNDA). There are approximately 4,000 patients who are treated for newly diagnosed APL in the United States and Europe each year.

TRISENOX for Multiple Myeloma

Multiple myeloma, an often-fatal malignant disease of the bone marrow, is one of the most common blood cell malignancy. This disease affects nearly 55,000 to 60,000 people in the United States with over 15,000 new cases reported annually. Preliminary reports from a number of exploratory clinical studies and a series of case studies using TRISENOX, alone or in combination with other agents in patients with relapsed and/or refractory myeloma, showed encouraging response rates. In general, the combinations were well tolerated with no reported grade 4 toxicities. We are sponsoring several multicenter trials with TRISENOX used in combination with corticosteroids, ascorbic acid, melphalan, bortezomib or thalidomide for advanced stages of multiple myeloma.

TRISENOX for Myelodysplastic Syndrome

MDS is a preleukemic condition affecting about 36,000 individuals in the United States with an annual incidence of approximately 15,000 patients per year. Many patients who develop MDS progress to develop acute leukemia. There is currently one FDA-approved therapy for MDS known as azacitidine. Recent reports from two phase II clinical studies, and a series of case studies using TRISENOX, alone or in combination with other agents, such as vitamin C or with thalidomide, in high- and low-risk MDS patients showed encouraging responses. Drug-related adverse events generally were manageable and resolved after completion of therapy. Additional trials exploring the activity of TRISENOX, alone or in combination with hypomethylating agents or thalidomide are being or have been initiated. Preliminary data from these trials reported at scientific conferences have been encouraging.

TRISENOX is also being investigated for the potential treatment of other hematologic malignancies including CML and AML. Due to budget restraints, studies in solid tumors have been postponed.

XYOTAX (paclitaxel poliglumex)

We are developing XYOTAX, paclitaxel linked to a polyglutamate polymer, for the potential treatment of NSCLC and ovarian cancer. We have completed enrollment of more than 1,700 patients in three pivotal phase III trials of XYOTAX for the treatment of NSCLC and expect the GOG to initiate a phase III trial of XYOTAX in ovarian cancer in the first quarter of 2005. We believe that XYOTAX may have less severe side effects, including a reduction in severe neutropenia, allergic reactions and hair loss, and superior anti-tumor activity than marketed taxanes. XYOTAX uses a biodegradable protein polymer to deliver the chemotherapy paclitaxel more selectively to tumor tissue.

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 and its widest use is in lung and ovarian cancers. XYOTAX is polyglutamate linked 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 and typically requires a minimum of three hours of intravenous infusion and transportation of patients to and from their treatment location. XYOTAX uses a biodegradable protein polymer to deliver chemotherapy more selectively 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 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. XYOTAX also may allow delivery of higher, better tolerated, cumulative doses than can be achieved with paclitaxel.

It is estimated that in the United States, more than 3.2 million people have lung, ovarian, colon and breast cancer, with more than 550,000 new cases diagnosed each year. IMS Health reported U.S. taxane sales of approximately $0.9 billion, and worldwide sales of roughly $2.5 billion for 2003, despite the difficulties associated with its administration and its serious dose limiting toxicities. The majority of taxane use has been in ovarian and lung cancers.

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 146,000 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. Data from a randomized trial of paclitaxel in NSCLC showed a median survival of approximately 2.4 months in front-line therapy of PS2 patients when administered as a single-agent and 4.7 months when administered in combination with platinum-containing chemotherapy. More recently, a clinical study reported at ASCO in 2004, showed a median survival of 6.1 months, using a slightly lower dose of paclitaxel in combination with carboplatinum. 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.

In the fourth quarter of 2002, we initiated three pivotal phase III clinical trials of XYOTAX, as further described in the following NSCLC pivotal trial table. These trials include two phase III trials of XYOTAX for the front-line treatment of PS2, NSCLC patients, known as STELLAR 3 and 4 and one phase III trial for the second-line treatment of NSCLC patients, known as STELLAR 2. In November 2003, we completed enrollment in STELLAR 3, in May 2004, we completed enrollment in STELLAR 4 and in July 2004, we completed enrollment for STELLAR 2.

XYOTAX Pivotal Trial Design in NSCLC

Trial	Design	Comparator	XYOTAX dose	Primary Endpoint	# of Patients	Status
STELLAR 3 1st line NSCLC, PS2	Superiority	paclitaxel + carboplatin	210 mg/m^2+ carboplatin	Survival	400	Enrollment complete; data expected in 1Q05
STELLAR 4 1st line NSCLC, PS2	Superiority	gemcitabine or vinorelbine	175 mg/m^2	Survival	476	Enrollment complete; data expected in 2Q05
STELLAR 2 2nd line NSCLC	Superiority	docetaxel	210 mg/m^2+ carboplatin 175 mg/m^2 in PS2	Survival	850	Enrollment complete; data expected in 2Q05

STELLAR 3 Update

In February 2005, we announced that we expect to report top-line results from STELLAR 3 in the first half of March 2005. In January 2005, we announced that the required number of events or deaths for data analysis had been reached.

STELLAR 4 Update

In January 2005, we observed that approximately 250 of the 313 events required for primary data analysis for STELLAR 4 had occurred. We expect to release top-line results from this trial by the end of the second quarter of 2005.

In October 2003, following a planned safety analysis by an independent Data Monitoring Committee of our three XYOTAX pivotal trials, we reduced the dose of XYOTAX from 235mg/m^2 to 175mg/m^2 in the STELLAR 4 trial. This change was based on a small percentage of patients in the study who appeared to develop early (first- or second-cycle) neutropenic-related toxicities when compared to the number of patients in the gemcitabine or vinorelbine comparator arm. While the incidence of grade 4 neutropenia observed in our phase II trials of 235mg/m^2 XYOTAX is substantially lower than that reported in the label for the equivalent dose of Taxol (25% vs. 50% respectively), when compared to the approximately 6% incidence of neutropenia reported in the gemcitabine or vinorelbine labels, the observed higher occurrence of early neutropenic events in the XYOTAX arm was not surprising. Since the incidence of neutropenia is low (approximately 2%) at the 175mg/m^2 dose of XYOTAX we believed lowering the dose in STELLAR 4 would prevent an increase in early neutropenic related events relative to the gemcitabine or vinorelbine comparator arm. The 175mg/m^2 dose was well tolerated in prior phase II studies in more than 125 patients and resulted in encouraging duration of median survival in the phase II NSCLC study. All patients enrolled in STELLAR 4 continued their treatment at the lower dose of 175mg/m^2, while the comparator arm dosages continued according to the protocol at their approved marketed dose. The recommendation of the Data Monitoring Committee did not impact the STELLAR 3 trial, which completed enrollment in 2003. With this dose adjustment we do not anticipate any impact on the integrity or utility of our pivotal studies for registration since the single-agent dose of 175mg/m^2 of XYOTAX was standardized across all PS2 patients studied, including PS2 patients in the STELLAR 2 pivotal trial.

STELLAR 2 Update

In January 2005, we updated our progress on STELLAR 2, stating that we have observed 578 out of the 635 events required for primary data analysis. We expect to release top-line results for STELLAR 2 by the end of the second quarter of 2005.

XYOTAX phase II data in non-small cell lung cancer

At the 12th European Conference on Clinical Oncology (ECCO 12) meeting in September 2003, we reported data on a phase II study of XYOTAX (175 mg/m^2) in the front-line treatment of advanced NSCLC patients who were either over 70 years old and/or PS2. In the study, 28 patients were treated with XYOTAX every 21 days. Using standard response evaluation criteria in solid tumors or RECIST criteria to assess efficacy, 18 patients (64%) achieved disease control, with two patients (7%) achieving a partial remission and 16 patients (57%) having stable disease. XYOTAX therapy was well tolerated with 50% of patients receiving four or more cycles of therapy and 21% of patients receiving six or more cycles and 7% receiving eight cycles. No alopecia or hypersensitivity reactions, which are common with standard paclitaxel formulations, were reported. Only one patient experienced grade 4 neutropenia and four patients reported grade 3 neuropathy, which occurred mostly in patients with concomitant progressive disease and significant disease-related comorbid conditions. A median survival time of 5.4 months among PS2 patients was observed, which compares favorably to the 2.4 months reported in a separate randomized trial of standard paclitaxel (225 mg/m^2).

XYOTAX for ovarian cancer

Ovarian cancer is diagnosed in approximately 22,000 women per year in the United States. The standard of care for front-line treatment of ovarian cancer is paclitaxel and carboplatin. On April 1, 2004, we announced that we signed a clinical trials agreement with the GOG to perform a phase III trial comparing XYOTAX as maintenance therapy, administered monthly for 12 months, to no maintenance treatment, for ovarian cancer patients who have achieved a CR following front-line treatment with carboplatin and paclitaxel. On July 7, 2004 we announced that the GOG submitted an investigational new drug or IND along with the protocol for a special protocol assessment, or SPA, to the FDA. In September 2004, the GOG had a successful SPA meeting with the FDA regarding the design, endpoints and study conduct of the XYOTAX phase III protocol. We expect the GOG to initiate this trial in the first quarter of 2005. The primary endpoints of this study will be overall survival, with progression-free survival, or PFS, safety and side effect profile as secondary endpoints. An assessment of PFS may provide the basis for an accelerated approval. We also are conducting two other phase II clinical trials of XYOTAX in ovarian cancer.

Pixantrone

We are developing pixantrone in a phase III clinical trial for the potential treatment of relapsed aggressive NHL. In the United States, aggressive NHL affects approximately 215,000 people with approximately 30,000 new cases diagnosed per year. The standard of care for front-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 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 for second- or third-line treatment for patients in the United States with relapsed aggressive NHL.

Anthracyclines are one of the most potent classes of anti-cancer agents used in front-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 front-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 more than 220 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 are conducting three ongoing clinical trials, including one pivotal phase III trial for pixantrone. In the first quarter of 2004, we met with the FDA and discussed the design for our pivotal clinical trial of single-agent pixantrone in the treatment of third-line relapsed aggressive NHL. We initiated this pivotal trial of pixantrone for relapsed aggressive NHL in approximately 320 patients. On July 12, 2004, we announced that the FDA granted fast track designation for pixantrone for the potential treatment of relapsed aggressive NHL on the basis that relapsed aggressive NHL in the third-line or subsequent recurrence is a life threatening disease and responses had been noted in phase II pixantrone trials in patients with relapsed, aggressive NHL. We expect to have interim data from the phase III trial in late 2005 and if successful we intend to file an NDA for pixantrone in early 2006.

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 or more prior regimens 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 frequently reported 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 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. In this trial, 11 of 18 (61%) evaluable patients achieved an objective tumor response with six patients (33%) 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

A phase I/II study in AML is planned in 2005. Other clinical data suggest pixantrone may be useful in treating indolent NHL a less rapidly progressive but ultimately fatal form of NHL. 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.

Due to cost cutting measures, a planned clinical trial of pixantrone for the potential treatment of multiple sclerosis, or MS, will not be initiated at this time.

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 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 oxaliplatinum. 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 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, two of those patients experienced disease control for almost nine months. The MTD of CT-2106 administered every third week has been determined to be 75mg/m^2.

CTI's Ongoing Clinical Trials

The following table lists our active clinical trials (indicated by a status of "open") and the trials that will be opened to enrollment during 2005 ("05"). Also listed are the trials that have recently closed to enrollment but for which clinical trial reports are in progress (status "enrollment completed"). In addition to clinical trials that are part of our registration strategy, we also assist clinical investigators who request our help for their independent investigations that advance clinical knowledge of the use of our products. Certain studies conducted independently from CTI or, Investigator-Sponsored Trials, also are included in the table below and are indicated by an "*".

Product Candidate	Indication/Intended Use	Phase/Status
TRISENOX® (arsenic trioxide), ATO injection	**HEMATOLOGIC MALIGNANCIES**	
	Multiple Myeloma	
	Single-agent (Europe)	II /enrollment completed
	Combination with ascorbic acid and dexamethasone following high dose chemotherapy and autologous stem cell transplant*	II / open
	Combination with thalidomide in refractory MM*	II / open
	Combination with ascorbic acid prior to high dose chemotherapy with autologous stem cell rescue for stage II/III MM*	II / open
	Combination with dexamethasone after stem cell transplant*	II / open
	Combination with melphalan and ascorbic acid in relapsed/refractory MM*	II / open
	Combination with ascorbic acid and dexamethasone (Europe)*	II / open

Product Candidate	Indication/Intended Use	Phase/Status
	Myelodysplastic Syndromes	
	Single-agent (2 trials, U.S. and Europe)*	II / enrollment completed
	Single-agent, followed by combination with thalidomide for non-responders*	II / completed
	Single-agent (5 trials)*	II / open
	Combination with cytarabine*	I/II / open
	Combination with Ara-C*	I/II / open
	Combination with amifostine*	II / open
	Acute Promyelocytic Leukemia	
	Single-agent, APL in molecular relapse*	II / open
	Combination with ATRA, de novo APL*	II / open
	Consolidation for primary treatment of APL*	II / open
	Other Leukemia/Lymphoma	
	Combination with Gleevec for CML (3 trials)*	I/II / open
	Combination with ascorbic acid for non-APL AML*	II / open
	Combination with ascorbic acid for relapsed/refractory lymphoid malignancies*	II / open
	Single-agent in cutaneous T-cell lymphoma*	II / open
	SOLID TUMORS	
	Single-agent for neuroblastoma solid tumors in pediatric patients*	II / open
	Combination with radiosurgery/radiotherapy for malignant glioma (2 trials)*	I/II / open
XYOTAX (CT-2103)	Non-small-cell lung cancer (second-line; "STELLAR 2")	III / enrollment completed
	Non-small-cell lung cancer in combination with carboplatin (front-line PS2; "STELLAR3")	III / enrollment completed
	Non-small-cell lung cancer (front-line PS2; "STELLAR4")	III / enrollment completed
	Ovarian front-line maintenance (GOG) (0212)	III / 1Q05 start
	Ovarian ≥ second relapse (GOG) (186c)	II / open
	Ovarian front-line dose escalation (GOG) (9914)	I/II / open
	Ovarian 1st line in combination with carboplatin (201)	II / enrollment completed
	Advanced solid tumors in combination with cisplatin (1055)	I / open
	Advanced solid tumors, single-agent—dosing every week (U.S.) (102)	I / open
	Advanced solid tumors, single-agent—dosing every 3 weeks (U.S.) (1052)	I / enrollment completed
	NSCLC first-line, combined with carboplatin (202)	II / enrollment completed
	NSCLC salvage, single-agent (105)	I / enrollment completed
	Advanced solid tumors combined with carboplatin (1072)	I / enrollment completed
	Combination with cisplatin and radiation for esophageal and gastric cancer (104)	I / open
	Lung cancer, in combination with radiation (103)	I / open

Product Candidate	Indication/Intended Use	Phase/Status
Pixantrone	Aggressive NHL, > 3 relapses, single-agent (301)	III / open
	Relapsed aggressive NHL, BSHAP (II-02)	II / open
	Aggressive NHL, front-line, CPOP-R (II-03)	II / 05
	Relapsed AML, single-agent (I-09)	I / 05
	Relapsed indolent NHL, FND-R (I-06)	I/II / enrollment completed
	Relapsed aggressive NHL, CPOP (I-07)	I/II / open
CT-2106	Advanced solid tumors, single-agent—dosing every 3 weeks (101)	I / enrollment completed
	Advanced solid tumors, single-agent—dosing every week (102)	I / 05
	Relapsed ovarian cancer (203)	II / open
	Relapsed colorectal cancer (201)	II / open

Discovery Research

We are also working on a number of drug targets in discovery research. Among these programs are bisplatinum agents, HIF-1 alpha:p300, proteasome inhibition, a novel enzymatic drug target called lysophosphatidic acid acyltransferase or LPAAT-ß and other cytotoxic and/or antiangiogenic targets. 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 life cycle management, including the development of alternative dosage forms and routes of administration for TRISENOX and existing products in the development pipeline.

Research and development is essential to our business. We spent $101.1 million, $89.5 million and $58.8 million in 2004, 2003 and 2002, 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 Development, the strategic partnering group of Quintiles Transnational, Corp. (Quintiles) involving our cancer therapy, TRISENOX. Under the agreement, PharmaBio Development provided us cash and services. In return, we will pay PharmaBio Development royalties based on a percentage of net sales of TRISENOX in the United States and certain European countries beginning in 2006. The agreement also provides PharmaBio Development with a security interest in TRISENOX related to our royalty payment obligations. The royalty payments from us are subject to certain annual minimum and maximum amounts.

Nippon Shinyaku Co. Ltd. In December 2002, we entered into a distribution agreement with Nippon Shinyaku Co. Ltd., or Nippon. This agreement grants 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 are 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 APL in Japan. Under the agreement, we received an additional milestone payment from Nippon Shinyaku 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.

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 may also receive future milestone payments upon Chugai's achievement of certain product development milestones. We are also entitled to receive royalties on product sales in the territories covered under the agreement. Chugai has also committed to development expenditures over the course of the licensing agreement. The agreement will terminate on a country-by-country basis upon the earlier to occur of the expiration of the applicable patent rights, if any, in a given country or fifteen years from the date of the first commercial sale of XYOTAX in such country.

PG-TXL Company, L.P. In June 1998, we entered into an agreement with PG-TXL Company, L.P. granting us an exclusive worldwide license for the rights to PG-TXL 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 includes one issued U.S. patent, three allowed U.S. patent applications and 35 U.S. and foreign pending patent applications directed to TRISENOX.

We have exclusive rights to five issued U.S. patents and 101 U.S. and foreign pending patent applications relating to our polymer drug delivery technology. There are five issued U.S. patents, an allowed European patent application and 28 pending U.S. and foreign patent applications directed to XYOTAX. Of the five issued U.S. patents, two of them and another 18 pending U.S. and foreign patent applications are directed to CT-2106. Additionally, we have four issued U.S. patents and 57 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.

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 TRISENOX, XYOTAX, pixantrone and CT-2106 drug supply for clinical studies and in the case of TRISENOX, for commercial market demand.

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 and expect to receive supply through August 2005. We have also identified and purchased paclitaxel from an additional supplier. 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.

Sales and Marketing

We have developed an experienced sales and marketing infrastructure in the United States to commercialize our portfolio of oncology products. The oncology market is highly concentrated. It is comprised primarily of the approximately 8,500 physicians who order the vast majority of cancer therapeutics, but we sell TRISENOX primarily to pharmaceutical wholesalers and oncology distributors, who in turn sell TRISENOX primarily to hospitals and clinics. We currently market TRISENOX with our direct sales force in the United States consisting of 2 senior directors, four regional business directors, 30 field based oncology account managers and 1 market development manager. An additional two medical science liaisons managers and eight medical science liaisons provide scientific support in the field.

In February 2004, we announced a significant expansion of our European commercial operations by hiring additional sales personnel. We have one Director of Sales and 15 field-based country managers and hospital sales representatives in the major market countries selling TRISENOX. We believe this experienced sales force will increase European sales of TRISENOX as well as aid in the promotion of any additional commercial products that we may acquire or develop internally.

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, American Pharmaceutical Partners, Neopharm Inc., and Sonus Pharmaceuticals for XYOTAX; Celgene Corporation, Millennium Pharmaceuticals, Inc., Pharmion Corporation and SuperGen Corporation for TRISENOX. 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.

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 the 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.

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 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 postmarketing 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. For example, before we can market TRISENOX for additional indications, we must obtain additional

approvals from the FDA. Obtaining approval for a new indication generally requires that additional clinical studies be conducted. We cannot be sure that any additional approval for new indications for TRISENOX will be approved on a timely basis, or at all.

Post-Approval Requirements. TRISENOX was approved by the FDA under its accelerated approval process in September 2000. In order to secure this approval, we committed to completing several post-approval requirements, including the conduct of additional clinical studies. Should we fail to fulfill these obligations, the FDA may withdraw approval of TRISENOX. 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.

TRISENOX was also approved in Europe by way of the centralized process and marketing authorization was granted by the EMEA "under exceptional circumstances." We have agreed to fulfill several post-approval commitments regarding TRISENOX. In addition, reporting of adverse reactions, compliance with certain requirements concerning advertising and promotional labeling and adherence to cGMP in the area of production and quality control is also required. Not completing these commitments or maintaining adherence to cGMP may result in similar actions as those described above for FDA, including withdrawal of TRISENOX.

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 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.

We have obtained orphan drug market exclusivity from the FDA for TRISENOX to treat patients with drug resistant or relapsed APL. We have also received orphan drug designation for TRISENOX for the treatment of patients with refractory multiple myeloma and MDS, CML, AML, CLL and HCC. However, TRISENOX may not receive an orphan drug marketing exclusivity for any of these indications, or any of our other drug products may not receive orphan drug exclusivity for any indication. Also, it is possible that our competitors could obtain approval, and attendant orphan drug exclusivity, for products that would preclude CTI from marketing our products for specified indications for some time.

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, 2004, we employed approximately 402 individuals, including 277 in the United States and 125 in Europe. In the United States, 84 employees hold doctoral or other advanced degrees while 69 hold doctoral or other advanced 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.

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.

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, 2004, we had an accumulated deficit of approximately $722.8 million. We may never become profitable, even if we are able to commercialize additional products. We will need to conduct significant research, development, testing and regulatory compliance activities that, together with projected general and administrative expenses, we expect

will result in substantial increasing operating losses for at least the next 18 months, assuming a successful launch of XYOTAX in 2006. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

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

We have only one product, TRISENOX, for relapsed or refractory APL that has received marketing approval to date. Our leading drug candidates, TRISENOX for other indications, XYOTAX, pixantrone and CT-2106, are currently in clinical trials and may not be successful. Even if our drugs progress successfully through initial human testing, they may fail in later stages of development. Many drugs in human clinical trials fail to demonstrate the desired safety and efficacy characteristics. 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. For example, in our first phase III human trial for lisofylline, completed in March 1998, we failed to meet our two primary endpoints, or goals, even though we met our endpoints in two earlier phase II trials for lisofylline. Many of our drug candidates are still in research and pre-clinical 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 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.

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

We expect that our existing capital resources, including the proceeds from our December 2004 offering, will enable us to maintain our currently planned operations through the third quarter of 2005 and at least through 2005 if our XYOTAX trials are not successful; however, to fully fund ongoing and planned activities, especially if one of our XYOTAX pivotal trials is successful, we will need to raise additional funds. From time to time we may receive certain grants and subsidized loans from the Italian government and Europe through our Italian subsidiary. However, to date such grants have not been significant, and we may not receive such funding in the future because the grants and subsidiaries are awarded at the discretion of relevant authorities.

If our plans or assumptions change or are inaccurate, it will affect the amount of additional funds we will need to raise to continue the development of our technologies and complete the commercialization of products, if any, resulting from our technologies. We may raise such capital through public or private equity financings, partnerships, debt financings, 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 may curtail operations significantly, including the delay, modification or cancellation of research and development programs aimed at bringing new products to market. To obtain additional funding, we may need to enter into arrangements that require us to relinquish rights to certain technologies, drug candidates, products and/or potential markets. To the extent that additional capital is raised through the sale of equity, or securities convertible into equity, shareholders may experience dilution of their proportionate ownership of us.

We may 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 pre-clinical development phase to enter the human clinical testing phase. Authorized pre-clinical 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 pre-clinical 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 future clinical trial results. In addition, we or regulatory authorities may suspend clinical trials at any time on the basis that the participants are being exposed to unacceptable health risks or for other reasons. Completion of clinical trials depends on, among other things, the number of patients available for enrollment in a particular trial, which is a function of many factors, including the number of patients with the relevant conditions, the nature of the clinical testing, the proximity of patients to clinical testing centers, the eligibility criteria for tests as well as competition with other clinical testing programs involving the same patient profile but different treatments.

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

If we fail to commence or complete, need to perform more or larger clinical trials than planned or experience delays in any of our present or planned clinical trials, including the phase III clinical trials of XYOTAX, the phase II clinical trials of TRISENOX and the phase II and phase III clinical trials of pixantrone, 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.

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. With the exception of TRISENOX for patients with APL who have relapsed or failed standard therapies, all of our compounds currently are in research or development, and none has been submitted for marketing approval.

Prior to commercialization, each product candidate requires significant additional research, development and pre-clinical 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 pre-clinical testing or clinical trials,
- fail to receive necessary regulatory approvals,
- be difficult to manufacture on a scale necessary for commercialization,

- be uneconomical to produce,
- fail to achieve market acceptance, or
- be precluded from commercialization by proprietary rights of third-parties.

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

If any of our license agreements for intellectual property underlying TRISENOX, 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 Memorial Sloan-Kettering Cancer Center, Samuel Waxman Cancer Research Foundation, Daopei Lu, M.D. of the Beijing Medical University, The University of Vermont, Hoffman La Roche and others, including the intellectual property relating to TRISENOX, other arsenic applications or 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.

We are subject to extensive government regulation, including the requirement of approval before our products may be marketed and regulation regarding the promotion of Trisenox.

Regulatory agencies have approved only one of our products, TRISENOX, for sale in the United States and Europe, to treat patients with a type of blood cancer called APL who have relapsed or failed standard therapies. Before we can market TRISENOX for other indications in the United States or Europe, we must obtain additional FDA approval and/or approval of the EMEA. Our other products are in development, and will have to be approved by the FDA before they can be marketed in the United States and by the EMEA before they can be marketed in Europe. Obtaining FDA or other regulatory approval requires substantial time, effort and financial resources, and we may not obtain approval on a timely basis, if at all. If the FDA and/or the EMEA do not approve our developmental products and any additional indications for marketed products in a timely fashion, or do not approve them at all, or withdraw the approval or otherwise restrict the marketing of our only approved product, TRISENOX, our business and financial condition may be adversely affected.

In addition, we and our currently marketed product and our product candidates are subject to comprehensive regulation by the FDA and the EMEA. Regulation by the FDA and EMEA begins before approval for marketing is granted and continues during the life of each product. For example, TRISENOX was approved for its current indication by the FDA following fast track review process and by the EMEA "under exceptional circumstances," and we committed to completing several post-approval requirements to both the FDA and the EMEA, including the conduct of additional clinical studies. If we fail to fulfill these obligations, the FDA or EMEA may withdraw approval of TRISENOX. In addition, the FDA and other regulatory authorities regulate, for example, research and development, including pre-clinical and clinical testing, safety, effectiveness, manufacturing, labeling, advertising, promotion, export and marketing of our products. Manufacturing processes must conform to 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 TRISENOX is 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 be construed as off-label promotion, and it is likely that some instances of off-label promotion occurred in the past. We are in discussions with the U.S. Attorney for the Western District of Washington in connection with previous promotional practices. 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 occur. Regulatory authorities could take enforcement action against us if they believe that we are promoting, or have promoted, TRISENOX for off-label use. Failure to comply with regulatory requirements, including off-label promotion of TRISENOX or other products approved for marketing, could result in various adverse consequences, including possible delay in approval or refusal to approve a product, recalls, seizures, withdrawal of an approved product from the market and/or the imposition of civil or criminal sanctions.

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.

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 have entered into an agreement with Chugai Pharmaceutical Co., Ltd. to develop and commercialize XYOTAX in several Asian markets. Additional collaborations might be necessary in order for us to fund our research and development activities and third-party manufacturing arrangements, seek and obtain regulatory approvals and successfully commercialize our existing and future product candidates. If we fail to enter into additional collaborative arrangements or fail to maintain our existing collaborative arrangements, the number of product candidates from which we could receive future revenues would decline.

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

- collaborative arrangements may not be on terms favorable to us;
- disagreements with partners may result in delays in the development and marketing of products, termination of our collaboration agreements or time consuming and expensive legal action;
- we cannot control the amount and timing of resources partners devote to product candidates or their prioritization of product candidates and partners may not allocate sufficient funds or resources to the development, promotion or marketing of our products, or may not perform their obligations as expected;
- partners may choose to develop, independently or with other companies, alternative products or treatments, including products or treatments which compete with ours;
- agreements with partners may expire or be terminated without renewal, or partners may breach collaboration agreements with us;
- business combinations or significant changes in a partner's business strategy might adversely affect that partner's willingness or ability to complete its obligations to us; and
- the terms and conditions of the relevant agreements may no longer be suitable.

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

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

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

We may face difficulties in achieving acceptance of our products in the market if we do not continue to expand our sales and marketing infrastructure.

We currently are marketing TRISENOX with our direct sales force. Competition for these individuals is intense, and in the event we need additional sales personnel, we may not be able to hire individuals with the experience required or number of sales personnel we need. In addition, if we market and sell products other than TRISENOX, we may need to further expand our marketing and sales force with sufficient technical expertise and distribution capacity. If we are unable to expand our direct sales operations and train new sales personnel as rapidly as necessary, we may not be able to increase market awareness and sales of our products, which may prevent us from growing our revenues and achieving and maintaining profitability.

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

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

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

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

The patent position of biopharmaceutical firms generally is highly uncertain and involves complex legal and factual questions. The U.S. Patent and Trademark Office has not established a consistent policy regarding the breadth of claims that it will allow in biotechnology patents. If it allows broad claims, the number and cost of patent interference proceedings in the United States and the risk of infringement litigation may increase. If it allows narrow claims, the risk of infringement may decrease, but the value of our rights under our patents, licenses and patent applications may also decrease. Patent applications in which we have rights may never issue as patents and the claims of any issued patents may not afford meaningful protection for our technologies or products. We currently have patent properties directed to all approved uses for TRISENOX, however, we have no patent claims covering the composition itself. 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 our TRISENOX orphan drug designations in the United States or Europe, which are designations for products meeting criteria based on the size of the potential U.S. or European patient population for a drug, respectively, and which entitle that drug to seven years of exclusive rights in the United States market or ten years in the European market, as applicable. Costly litigation might also be necessary to protect a patent position or to determine the scope and validity of third-party proprietary rights, and we may not have the required resources to pursue any such litigation or to protect our patent rights. Any adverse outcome in litigation with respect to the infringement or validity of any patents owned by third-parties could subject us to significant liabilities to third-parties, require disputed rights to be licensed from third-parties or require us to cease using a product or technology.

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

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

We attempt to monitor the 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.

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 TRISENOX, XYOTAX and pixantrone.

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 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. We purchase the majority of the paclitaxel we need from a single vendor and this vendor is behind in its delivery schedule of paclitaxel to us. As a result, we may need to obtain paclitaxel from another vendor, which we may not be able to obtain on a timely basis or under acceptable terms. We also 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 facilities for the current Good Manufacturing Practice, or cGMP, manufacture of any of our development or commercial products. In addition, TRISENOX, our first commercial product, is currently manufactured primarily by two vendors. In 2002, we began the process of qualifying an additional supplier for our finished product manufacturing for TRISENOX. This additional supplier received FDA approval to manufacture TRISENOX in June 2003. Because we do not directly control our suppliers, these vendors may not be able to provide us with finished product when we need it. Plans are in place to develop additional manufacturing resources, such as entering into collaborative arrangements with other parties that have established manufacturing capabilities or electing to have other additional third-parties manufacture our products on a contract basis.

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 current manufacturer for TRISENOX was inspected by the FDA and follow up discussions are ongoing between the manufacturer and the FDA. As a result, the FDA could, among other things, shut down the operations of the manufacturer or disallow the manufacturer to ship product it currently holds. Either outcome could materially affect our operations. Another 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.

As a result of our merger with Novuspharma, we are required to comply with the regulatory structure of Italy, which could result in administrative challenges.

As a result of our merger with Novuspharma, our operations now need to comply not only with applicable laws of and rules of the United States, including Washington law and the rules and regulations of the Securities and Exchange Commission and the Nasdaq National Market, but also the European Union legal system and the Republic of Italy, including 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.

As a result of our merger with Novuspharma, we are subject to additional legal duties, additional operational challenges and additional political and economic risks related to our operations in Italy.

As a result of our merger with Novuspharma, 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 while effectively marketing our approved product (TRISENOX);
- successfully commercializing products under development and increasing revenues from TRISENOX;
- 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 uniform standards, controls, procedures and policies relating to financial reporting and employment related matters 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.

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 are increasingly attempting to contain healthcare costs by:

- challenging the prices charged for healthcare 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. The Medicare Prescription Drug Improvement, and Modernization Act (MMA), enacted last December, will affect reimbursement and purchases of prescription drugs, including cancer drugs. Implementation of the MMA and yet to be issued regulation could have an adverse impact on sales of prescription drugs. While we cannot predict whether any other legislative or regulatory proposals will be adopted, the adoption of other proposals could make it difficult or impossible to sell our products. TRISENOX has been reimbursed by third-party payors, but there is no guarantee this reimbursement will continue.

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 our markets. 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, 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™; Lilly, which markets Alimta® and American Pharmaceutical Partners, which recently received approval and expects to begin marketing for its Abraxane product). In addition, several companies, NeoPharm Inc. and Sonus Pharmaceuticals, are also developing novel taxanes and formulations which could compete with our products.
- In the hematology market, we hope to receive approval to market TRISENOX in more indications other than relapsed or refractory APL. We will face competition from a number of biopharmaceutical companies, including:
- Celgene Corporation, which currently sells thalidomide for the treatment of multiple myeloma, a cancer of the bone marrow. Celgene is also developing Revlimid in MDS with an expected NDA submission in the first quarter of 2005 for that indication;
- Millennium Pharmaceuticals, Inc., which launched Velcade® in 2003 for treatment of multiple myeloma;
- Pharmion Corporation, which has signed an agreement with Celgene to expand internationally the marketing of thalidomide and received approval for Vidaza™ for treatment of MDS, also known as 'smoldering' leukemia or preleukemia, which are a group of diseases in which the bone marrow does not function normally and insufficient numbers of mature blood cells are in circulation; and
- MGI Pharma, which is developing decitabine, which has been accepted for a rolling NDA submission by the FDA in MDS.
- 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, to be less expensive, to have fewer side effects or to 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.

If we lose our key personnel or we are unable to attract and retain additional personnel, we may be unable to pursue collaborations or develop our own products.

We are highly dependent on James A. Bianco, M.D., our president and chief executive officer, Jack W. Singer, M.D., our chief medical officer and Silvano Spinelli, our executive vice president of development and

managing director of European operations. The loss of any one of these principal members of our scientific or management staff, or failure to attract or retain other key scientific employees, could prevent us from pursuing collaborations or developing and commercializing our products and core technologies. Recruiting and retaining qualified scientific personnel to perform research and development work are critical to our success. There is intense competition for qualified scientists and managerial personnel from numerous pharmaceutical and biotechnology companies, as well as from academic and government organizations, research institutions and other entities. In addition, we will rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development strategy. All of our consultants and advisors will be employed by other employers or are self-employed, and will have commitments to or consulting or advisory contracts with other entities that may limit their availability to us.

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

As a result of our merger with Novuspharma and our consequent operations in Italy, we are exposed to risks associated with foreign currency transactions insofar as we might desire to 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, as a result of our merger with Novuspharma, we are exposed to risks associated with the translation of Novuspharma's euro-denominated financial results and balance sheet 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.

Our limited operating experience may cause us difficulty in managing our growth and could seriously harm our business.

As a result of additional trials for TRISENOX for indications other than relapsed or refractory APL and clinical trials currently underway for XYOTAX, pixantrone and our other products in development, we have expanded our operations in various areas, including our management, regulatory, clinical, financial and information systems and other elements of our business process infrastructure. We may need to add additional key personnel in these areas. In addition, as growth occurs, it may strain our operational, managerial and financial resources. We may not be able to increase revenues or control costs unless we continue to improve our operational, financial, regulatory and managerial systems and processes, and expand, train and manage our work force.

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

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

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

Our research and development activities involve the controlled use of hazardous materials, chemicals and various radioactive compounds. We are subject to federal, state, local and international 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.

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 common stock 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 year ended December 31, 2004, our stock price ranged from a low of $4.55 to a high of $10.25. 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 common stock include:

- announcements of technological innovations or new commercial therapeutic products by us, our collaborative partners or our present or potential competitors;
- our quarterly operating results;
- announcements by us or others of results of pre-clinical testing and clinical trials;
- developments or disputes concerning patent or other proprietary rights;
- developments in our relationships with collaborative partners;
- our success in integrating the business and operations of Novuspharma;
- acquisitions;
- litigation and government proceedings;
- adverse legislation, including changes in governmental regulation and the status of our regulatory approvals or applications;
- third-party reimbursement policies;
- changes in securities analysts' recommendations;
- changes in healthcare 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. If a securities class action suit is filed against us, we would incur substantial legal fees and our management's attention and resources would be diverted from operating our business in order to 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.

Item 2. Properties

We lease approximately 68,000 square feet of space at 201 Elliott Avenue West in Seattle, Washington for our laboratory and administrative operations. The lease expires in January 2008, with one five-year renewal option at the then prevailing market rent. We also lease approximately 110,000 square feet of space at 501 Elliott Avenue West in Seattle, Washington for our executive offices and administrative operations. The lease expires in July 2012. 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 and December 2008, respectively. 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. 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 German company, filed a complaint against us in federal district court in Washington, asserting that CTI (Europe), formerly known as Novuspharma S.p.A., had purportedly breached a contract with Micromet for the development of a drug candidate known as MT-201. The alleged breach is based on the assertion that CTI (Europe) failed to pay for certain milestones and development expenses owed under the contract. On February 23, 2004, we answered the complaint, denying the substance of the allegations, and filing counterclaims for breach of contract and for rescission of the contract based on

Micromet's misrepresentations and failures to disclose material information. We believe that Micromet's complaint is without merit and intend to vigorously defend against the Micromet action, as well as to seek recovery based upon our counterclaims. No estimate of possible loss or range of loss resulting from the lawsuit can be made at this time.

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, 2004.

PART II

Item 5. Market for Registrant's Common Equity and Related Shareholder Matters

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.

	High	Low
2003		
First Quarter	$ 8.89	$5.18
Second Quarter	15.70	7.76
Third Quarter	13.76	9.35
Fourth Quarter	12.49	7.49
2004		
First Quarter	10.25	7.80
Second Quarter	9.43	6.75
Third Quarter	7.43	4.55
Fourth Quarter	8.62	5.69
2005		
First Quarter (through February 24, 2005)	10.85	7.50

On February 24, 2005, the last reported sale price of our common stock on the Nasdaq Market was $10.22 per share. As of February 24, 2005, there were approximately 229 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

None.

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, 2004, including the 2003 Equity Incentive Plan, Novuspharma S.p.A. Stock Option Plan, 1994 Equity Incentive Plan and the 1996 Employee Stock Purchase Plan.

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(b) Weighted Average Exercise Price of Outstanding Options, Warrants, and Rights	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))	(d) Total of Securities Reflected in Columns (a) and (c)
Plans Approved by Shareholders	5,728,969(1)	$15.12	4,310,490(2)	10,039,459
Plans Not Approved by Shareholders	662,790(3)	$14.39	None	662,790
Plan Not Approved by Shareholders (Novuspharma)	230,100(4)	$ 9.13	119,900	350,000

(1) Consists of the 2003 Equity Incentive Plan and the 1994 Equity Incentive Plan.

(2) Consists of 4,031,133 shares available for future issuance under the 2003 Equity Incentive Plan and 279,357 shares available for future issuance under the 1996 Employee Stock Purchase Plan.

(3) Consists of 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., warrants to purchase 109,125 shares issued to a placement agent in connection with private placement of our stock, 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 future events. No warrants have been exercised.

Warrants Issued to Placement Agent

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 to a placement agent and finder. These warrants expire in February 2005, and have an exercise price of $13.20. As of December 31, 2004, there were 109,125 warrants outstanding.

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.

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 119,900 shares remain for future issuance.

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,				
	2004	2003	2002	2001	2000
	(In thousands, except per share data)				
Consolidated Statements of Operations Data:					
Revenues:					
Product sales	$ 26,626	$ 22,105	$ 11,393	$ 6,130	$ 502
License and contract revenue	2,968	2,660	5,503	106	—
Total revenues	29,594	24,765	16,896	6,236	502
Operating expenses:					
Cost of product sold	1,104	840	423	394	19
Research and development(1)	101,127	89,534	58,759	44,669	26,574
Selling, general and administrative	78,522	55,641	49,800	35,268	20,421
Acquired in-process research and development(2)	87,375	—	—	—	—
Amortization of purchased intangibles	2,294	1,335	6,701	9,390	9,390
Total operating expenses	270,422	147,350	115,683	89,721	56,404
Loss from operations	(240,828)	(122,585)	(98,787)	(83,485)	(55,902)
Other income (expense):					
Investment and other income	1,636	1,880	4,819	9,200	4,517
Interest expense	(10,988)	(9,326)	(11,240)	(5,988)	(544)
Foreign exchange loss	(2,118)	—	—	—	—
Gain on exchange of convertible subordinated notes	—	—	55,305	—	—
Net loss	(252,298)	(130,031)	(49,903)	(80,273)	(51,929)
Preferred stock dividend	—	—	—	(1,372)	(508)
Net loss	$(252,298)	$(130,031)	$(49,903)	$(81,645)	$(52,437)
Basic and diluted net loss per share(3)	$ (4.67)	$ (3.89)	$ (1.48)	$ (2.41)	$ (2.07)
Shares used in calculation of basic and diluted net loss per share	54,052	33,418	33,763	33,822	25,345

	December 31,				
	2004	2003	2002	2001	2000
			(In thousands)		
Consolidated Balance Sheets Data:					
Cash, cash equivalents, securities available-for-sale and interest receivable	$ 116,020	$ 92,838	$ 142,157	$ 259,421	$ 156,434
Working capital	93,813	71,898	129,849	250,142	146,384
Total assets	184,996	146,090	186,780	303,750	190,111
5.75% Convertible senior subordinated notes(4)	85,459	85,459	85,460	—	—
4.0% Convertible senior subordinated notes(5)	75,000	75,000	—	—	—
5.75% Convertible subordinated notes(6)	29,640	29,640	29,640	175,000	—
Royalty obligation	25,123	—	—	—	—
Other long-term obligations, less current portion	6,363	5,012	6,704	3,892	1,060
Accumulated deficit	(722,784)	(470,486)	(340,455)	(290,552)	(210,279)
Total shareholders' equity (deficit)	(70,708)	(82,542)	43,483	109,557	177,943

(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) See Notes 1 and 13 of Notes to Consolidated Financial Statements for a description of the computation of the number of shares and net loss per share.

(4) 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.

(5) 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.

(6) 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.

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, vertically-integrated 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, 2004, we had incurred aggregate net losses of approximately $722.8 million since inception. Assuming a successful launch of XYOTAX in 2006, we would expect to continue to incur significant additional operating losses for at least the next 18 months from our research and development efforts.

On January 1, 2004, we completed our merger with Novuspharma S.p.A., currently CTI Europe S.r.l., or CTI (Europe), a public biopharmaceutical company located in Italy. We issued 15,629,138 shares of CTI common stock in exchange for all of the outstanding shares of Novuspharma. The total cost of the merger was approximately $196.1 million. This provided us with worldwide rights to pixantrone, approximately $92.5 million of cash and cash equivalents upon closing of the acquisition, and a high-quality drug discovery organization and staff with an extensive track record in cancer drug development. The merger and addition of pixantrone to the pipeline are consistent with our strategy of growth by strategic acquisition and our goal to develop improved cancer therapies.

XYOTAX

In June 1998, we entered into an agreement with PG-TXL Company, L.P., or PG-TXL, and scientists at The University of Texas M. D. Anderson Cancer Center, granting us an exclusive worldwide license to the rights to paclitaxel poliglumex and to all potential uses of PG-TXL's polymer technology. Paclitaxel poliglumex is paclitaxel linked to polyglutamate, and is branded as XYOTAX™. Under the terms of the agreement, we will fund the research, development, manufacture, marketing and sale of drugs developed using PG-TXL's polymer technology. As of December 31, 2004, we have made $5.0 million in milestone payments upon the attainment of significant achievements and are obligated to make additional future milestone payments of up to $15.5 million, $4.0 million of which will be triggered in 2005 if we successfully complete one of our phase III clinical trials. We are also obligated to make royalty payments on net product sales as defined in the agreement.

In September 2001, we entered into a supply agreement with Natural Pharmaceuticals, Inc., or NPI, for paclitaxel, a key starting material for our XYOTAX drug candidate. Under the supply agreement, we prepaid for paclitaxel. NPI is behind in its delivery of paclitaxel to us although we expect to receive delivery through August 2005. NPI has provided a security deposit in escrow in an amount equal to the undelivered paclitaxel, to be reduced as the deliveries are received. We are also purchasing paclitaxel supply from an additional supplier. We may need to obtain paclitaxel from other sources, which we may not be able to receive on a timely basis, if at all.

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 made a $3.0 million initial payment, which has been recorded as deferred revenue and is being recognized as license revenue over the development period of approximately seven years on a straight-line basis. Under the agreement, we received and recognized as revenue a $3.0 million milestone payment during 2002 resulting from the filing of the first investigational new drug application, or IND, in Japan. We may also receive future milestone payments totaling up to $13.0 million upon Chugai's achievement of certain milestones, and we are entitled to receive royalties on product sales in the territories covered under the agreement. Chugai has also committed to incur up to $54.0 million in development expenditures over the course of the licensing agreement. As of December 31, 2004, we have received approximately $3.8 million in development expenditure reimbursements from Chugai.

In 2002, we initiated a XYOTAX phase III clinical trial for second-line treatment of non-small cell lung cancer, or NSCLC, and two additional phase III trials of XYOTAX in the front-line treatment of poor performance status, or PS2, patients with NSCLC.

In June 2003, we received fast track designation from the Federal Drug Administration, or FDA, for our XYOTAX pivotal trials in PS2 patients with advanced NSCLC.

In November 2003, we completed enrollment in one of our XYOTAX phase III pivotal trials, known as STELLAR 3, for the potential use in combination with platinum as front-line treatment of PS2 patients with NSCLC. We reached the number of events required to perform the primary efficacy analysis of the STELLAR 3 trial in January 2005. We expect to report top-line results in the first half of March 2005. As a result, our revised target for submission of a new drug application, or NDA, for XYOTAX is the third quarter of 2005 with an expected XYOTAX launch in 2006.

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 in patients with ovarian cancer. In July 2004, the GOG submitted an IND along with the protocol for a special protocol assessment, or SPA, to the FDA. The trial is expected to begin in the first quarter of 2005.

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. We expect to report results from this trial in the second quarter of 2005.

In July 2004, we completed enrollment in our third and final pivotal phase III trial of XYOTAX, known as STELLAR 2, for the potential use as second-line single agent treatment of patients with NSCLC. We expect to report results from this trial in the second quarter of 2005.

TRISENOX

In January 2000, we entered a Merger Agreement to acquire PolaRx Biopharmaceuticals, Inc., or PolaRx, a biopharmaceutical company that owned the rights to TRISENOX (arsenic trioxide), an anti-cancer compound for which we submitted and received approval to market from the FDA and EMEA. The acquisition was accounted for as a purchase transaction. Under the terms of the Merger Agreement, we have made additional contingent payments to former PolaRx stockholders of approximately $4.0 million for meeting a $10.0 million TRISENOX sales threshold in 2002 and approximately $5.0 million for achieving a $20.0 million TRISENOX sales threshold in 2003. Under the Merger Agreement, we are also required to make an additional payout of a 2% royalty on total net sales of arsenic products, payable in cash or common stock at the then fair market of our stock, for any calendar year during which sales of TRISENOX exceed $40.0 million.

In September 2000, we received marketing approval of our NDA by the FDA for TRISENOX and sales of TRISENOX in the United States commenced in October 2000. In March 2002, we received approval from the EMEA to market TRISENOX in the European Union, or EU, and we commenced the launch and sale of TRISENOX in the EU during the second quarter of 2002.

We have recorded cumulative net product sales for TRISENOX of approximately $66.8 million through December 31, 2004. TRISENOX is manufactured primarily by two vendors and sold through our direct sales force.

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. Upon execution of the agreement, Nippon paid us a $750,000 initial payment, which was recorded as deferred revenue and which is being recognized as revenue over the performance period of approximately two years on a straight-line basis. Under the agreement, we received and recognized as revenue a $0.5 million milestone payment in 2003 related to Nippon's submission of an NDA in Japan. In October 2004, Nippon received approval from the Japanese Ministry of Health, or JMH, to market TRISENOX for patients with relapsed or refractory acute promyelocytic leukemia, or APL, in Japan. Under the agreement, we received an additional $0.5 million 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. We may also receive additional future milestone payments totaling up to $3.0 million upon attainment of certain milestones.

In April 2004, the U.S. Patent and Trademark office issued a patent directed to TRISENOX injection that extends our market exclusivity in the United States for the drug from 2007 to 2018. This extension is eleven years beyond the original orphan drug exclusivity for APL that currently expires in 2007.

In December 2004, we entered into a royalty interest financing arrangement with PharmaBio Development, Inc. (PharmaBio) for $25.0 million in financing and $5.0 million in clinical and other services to be provided by PharmaBio and its affiliates and paid by PharmaBio. From 2006 through 2010, PharmaBio is entitled to receive a royalty based on a percentage of TRISENOX annual net sales in the United States and select countries in the European Union as set forth in the arrangement. Our royalty obligation under the arrangement ranges from $53.0 million to $69.0 million depending on our achievement of TRISENOX sales targets and certain other factors.

In 2004, we refocused our TRISENOX development efforts to approximately 40 company-sponsored and investigator-sponsored trials, with an emphasis on blood-related cancers, including front-line APL, multiple myeloma and myelodysplastic syndrome.

PIXANTRONE

We acquired pixantrone, a novel compound, for the potential treatment of non-Hodgkin's lymphoma, or NHL, through our merger with Novuspharma S.p.A. in January 2004. We are developing pixantrone and have several clinical trials ongoing, including a pivotal phase III trial for the potential treatment of relapsed aggressive NHL. Based on development plans for pixantrone, we expect to have interim data from the phase III trial in late 2005, and if successful, we would submit an NDA for accelerated approval in early 2006. Final results for this trial are expected in the third quarter of 2006 and if successful, we would submit an NDA for full approval for pixantrone at the end of 2006. If we are able to submit for accelerated approval, with acceptance by the FDA, we estimate launch of pixantrone for the potential treatment of aggressive NHL in 2006. If we need full trial results, we estimate launch in 2007. If this launch is successful, significant cash inflows are expected in 2007.

In July 2004, we announced that the FDA granted fast track designation for pixantrone for the potential treatment of relapsed aggressive NHL on the basis that relapsed aggressive NHL in third-line or subsequent recurrence is a life threatening disease and responses have been noted in phase II trials with patients with relapsed, aggressive NHL.

OTHER COMPOUNDS

We are developing a novel polyglutamate-camptothecin molecule, or CT-2106. We filed an IND in December 2001 for this compound and initiated a phase I clinical study in the first quarter of 2002. 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 oxaliplatinum. Additionally, we initiated a phase II clinical trial of CT-2106 in ovarian cancer at the end of 2004.

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 recognize revenue from product sales when there is persuasive evidence that an arrangement exists, title has passed and delivery has occurred, the price is fixed and determinable, and collectibility is reasonably assured. Product sales are recorded net of an allowance for estimated returns and discounts. Customers may return damaged or expired inventory up to twelve months after the expiration date. In estimating returns, we analyze historical returns, sales patterns, estimated inventory on hand at the distributors and the remaining shelf life of that inventory. To arrive at the accrual for product returns, we match the returns to the corresponding production batch to assess the historical trend for returns. Based on this analysis, the estimated return percentage is applied to current period sales. Allowances for returns, discounts and bad debts are netted against accounts receivable. If customers have product acceptance rights or product return rights, and if we are unable to reasonably estimate returns in a particular market, we defer revenue until such rights have expired.

License and Contract Revenue

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

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

We evaluate multiple element arrangements pursuant to Emerging Issues Task Force (EITF) 00-21, *Revenue Arrangements with Multiple Deliverables*. Pursuant to EITF 00-21, in multiple element arrangements where we have continuing performance obligations, contract, milestone and license fees are recognized 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 (SAB 104), unless evidence suggests otherwise, revenue from consideration received is recognized on a straight-line basis over the expected term of the arrangement.

Inventory

Inventory is stated at the lower of cost or market. Cost is determined using a weighted-average method. Finished goods inventory consists of our FDA and EMEA approved pharmaceutical drug, TRISENOX. We also record an allowance for inventory that may expire and become unsaleable due to the expiration of shelf life. In estimating inventory obsolescence reserves, we analyze (i) the shelf life and the expiration date, (ii) sales forecasts and (iii) inventory levels compared to forecasted usage. Judgment is required in determining whether the forecasted sales and usage information is sufficiently reliable to enable us to estimate inventory obsolescence reserve.

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. In instances where we enter into agreements with third parties for research, clinical trial, and related clinical trial manufacturing costs, costs are expensed upon the earlier of when non-refundable amounts are due or as services are performed. 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.

Derivative Financial Instruments

We are subject to risks associated with fluctuations in the LIBOR interest rate from lease payments on our leased aircraft. Our policy is to hedge a portion of these forecasted transactions through an interest rate swap agreement. This swap agreement has been designated as a cash flow hedge. The portion of the net gain or loss on the derivative instrument that is effective as a hedge is reported as a component of accumulated other comprehensive income or loss in shareholders' deficit and is reclassified into earnings in the same period during which the hedged transaction affects earnings. The remaining net gain or loss on the derivative in excess of the present value of the expected cash flows of the hedged transaction is recorded in earnings immediately. If a derivative does not qualify for hedge accounting, or a portion of the hedge is deemed ineffective, the change in fair value is recorded in earnings. The swap was perfectly effective at December 31, 2004 and 2003. We do not enter into forward agreements for trading purposes.

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.

Royalty Obligation

We recognize interest expense on our $25.0 million royalty obligation using the effective interest method. The imputed interest rate is determined based on our estimate as to total royalty and interest payments due under the arrangement which vary depending on whether we reach certain TRISENOX targets and certain other factors as described in the agreement. We will reassess the imputed interest rate as circumstances change.

Results of Operations

Years ended December 31, 2004 and 2003.

Product sales. TRISENOX is our pharmaceutical grade arsenic product that has been approved by the FDA, EMEA and the JMH to treat patients with relapsed or refractory APL. 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. We expect a slight increase in net sales for 2005 due to increases in sales in Europe and Asia.

License and contract revenue. In October 2001, we entered into a licensing agreement with Chugai for the development and commercialization of XYOTAX. Upon execution of the agreement, Chugai made a $3.0 million initial payment, which we recorded as deferred revenue and which is being recognized as revenue over the estimated development period of approximately seven years on a straight-line basis. In December 2002, we entered into a distribution agreement with Nippon for the distribution and commercialization of TRISENOX. We received $750,000 upon execution of the agreement which was recorded as deferred revenue and which was recognized as revenue over the performance period of approximately two years on a straight-line basis.

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 a Marketing Authorization Application, or 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. We expect product costs in the future to continue to approximate a small percentage of product sales.

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
Total research and development expenses	$101,127	$89,534

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 $149.4 million, $25.4 million and $6.8 million, respectively. Costs for pixantrone incurred prior to our merger with Novuspharma in January 2004 are excluded from this amount.

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).

Our lead drug candidates, XYOTAX, pixantrone and TRISENOX for indications other than relapsed or refractory APL, are currently in clinical trials. Many drugs in human clinical trials fail to demonstrate the desired safety and efficacy characteristics. Even if our drugs progress successfully through initial human testing, they may fail in later stages of development. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in advanced clinical trials, even after reporting promising results in earlier trials. Regulatory agencies, including the FDA and EMEA, regulate many aspects of a product candidate's life cycle, including research and development and 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. Based on our current development plans, we expect to report top-line results for XYOTAX for the potential treatment of NSCLC in the first half of March 2005, intend to submit an NDA in the third quarter of 2005 and expect to launch XYOTAX in 2006. If this launch is successful, we would expect to receive significant cash inflows in 2006 from this compound. Based on development plans for pixantrone, we expect to have interim data from the phase III trial in late 2005, and if successful, we would submit an NDA for accelerated approval in early 2006. Final results for this trial are expected in the third quarter of 2006 and if successful, we would submit an NDA for full approval for pixantrone at the end of 2006. If we are able to submit for accelerated approval, with acceptance by the FDA, we estimate launch of pixantrone for the potential treatment of aggressive NHL in 2006. If we need full trial results, we estimate launch in 2007. If this launch is successful, significant cash inflows are expected in 2007.

With the exception of TRISENOX, we anticipate that we will not generate revenue from the sale of commercial drugs for approximately 18 months, 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 equity financings, collaborations, milestones and licensing opportunities from current or future collaborators.

Selling, general and administrative expenses. Selling, general and administrative expenses increased to approximately $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.

We expect selling, general and administrative expenses to increase during 2005 as a result of our expanded research, development and commercialization efforts. In the event that we are able to move forward with the commercialization of XYOTAX, our sales and marketing expenses may increase significantly. 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.

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. This balance 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 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. We recognize foreign currency exchange gains and losses primarily due to the fluctuation in the value of the U.S. dollar versus the euro, and to a lesser extent, versus other currencies. 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.

Income Taxes

As of December 31, 2004, we had net operating loss carryforwards of approximately $498.4 million, of which $47.7 million relates to stock option deductions, and research credit carryforwards of approximately $16.6 million. The carryforwards begin to expire in 2007. Utilization of stock option deductions will not result in a reduction of tax expense.

Due to rounds of equity financings, 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 $413.2 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.

Years ended December 31, 2003 and 2002.

Product sales. We recorded net product sales of approximately $22.1 million and $11.4 million for TRISENOX for the years ended December 31, 2003 and 2002, respectively. The increase in net sales is primarily due to greater demand for our product in 2003. An increase in net sales in the fourth quarter was due to both an increase in product demand and additional wholesaler purchases resulting from an anticipated price increase that occurred in December 2003.

License and contract revenue. 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. For the year ended December 31, 2002, we recognized $5.5 million of license and contract revenue, of which $3.0 million related to a milestone payment and $1.9 million for cost reimbursements for development expenses received from Chugai in 2002, and $0.5 million related to the amortization of the initial payments from Chugai and Nippon.

Cost of product sold. The cost of product sold during the year ended December 31, 2003 and 2002 was approximately $0.8 million and $0.4 million, respectively. Our gross margins remained consistent during this period. Cost of product sold consists primarily of manufacturing costs, allowances for excess inventory that may expire and become unsaleable, and royalties paid on product sales.

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

	2003	2002
Compounds under development:		
XYOTAX	$52,888	$26,193
TRISENOX	4,862	5,225
Other compounds	1,655	2,804
Operating expenses	18,699	14,099
Discovery research	11,430	10,438
Total research and development expenses	$89,534	$58,759

Research and development expenses increased to approximately $89.5 million for the year ended December 31, 2003, from approximately $58.8 million for the year ended December 31, 2002. Costs for our XYOTAX program increased primarily due to increased clinical and manufacturing costs of approximately $27.8 million associated with the set up, initiation and execution of our three phase III clinical trials and other clinical trials. These manufacturing costs were offset in part by a $2.0 million charge for a payment related to the achievement of contractual milestones associated with the completion of a phase II trial and the filing of the first IND application in Japan during the year ended December 31, 2002. TRISENOX costs decreased primarily as a result of a reduction in manufacturing and clinical costs of approximately $1.0 million offset in part by an increase in investigator sponsored trial expenses of approximately $0.6 million. Costs incurred for other compounds decreased primarily due to a $1.0 million milestone payment made in 2002 for the commencement of our phase I clinical trial for CT-2106. Operating expenses increased by approximately $4.6 million primarily due to additional personnel and occupancy costs related to our expanded development plans for XYOTAX, TRISENOX and CT-2106, including employee termination benefits of $0.6 million resulting from a reduction in workforce associated with our merger with Novuspharma. Costs for discovery research increased primarily as a result of $0.9 million in employee termination benefits and $0.8 million in additional occupancy costs. These costs were offset in part by a $0.5 million charge related to the fair value of warrants issued to the Hope Heart Institute in connection with a Sponsored Research Agreement entered into in November 2002 and a $0.4 million decrease in personnel costs.

Selling, general and administrative expenses. Selling, general and administrative expenses increased to approximately $55.6 million for the year ended December 31, 2003, from approximately $49.8 million for the year ended December 31, 2002. This increase is primarily attributed to approximately $4.6 million of additional sales and marketing costs mainly related to TRISENOX as well as increased marketing costs associated with product awareness and medical education for XYOTAX, approximately $3.2 million of additional personnel, operating and occupancy costs associated with supporting our research, development and marketing activities and an increase of approximately $0.6 million in stock-based compensation charges. These costs were offset in part by reductions of approximately $1.4 million in our corporate communications program and approximately $1.6 million in maintenance and operating costs of our leased aircraft.

Amortization of purchased intangibles. Amortization for the year ended December 31, 2003 decreased to approximately $1.3 million from approximately $6.7 million for the year ended December 31, 2003, due to a marketing intangible asset that became fully amortized in December 2002.

Investment and other income. Investment income decreased to approximately $1.9 million for the year ended December 31, 2003 from approximately $4.8 million for the year ended December 31, 2002. This decrease is attributed to lower average cash balances and lower prevailing interest rates on our securities available-for-sale during the year ended December 31, 2003 compared with the year ended December 31, 2002, offset by a reduction of investment premium amortization of approximately $1.0 million.

Interest expense. Interest expense decreased to approximately $9.3 million for the year ended December 31, 2003 from approximately $11.2 million for the year ended December 31, 2002. In December 2002, we completed an exchange offer for our 5.75% convertible subordinated notes, in which approximately $145.4 million of our 5.75% convertible subordinated notes were tendered in exchange for approximately $85.5 million of our new 5.75% convertible senior subordinated notes. The decrease in interest expense is attributable to the reduction of debt resulting from this exchange and was partially offset by an increase in interest expense due to the issuance of $75.0 million principal amount of our 4% convertible senior subordinated notes in June 2003.

Liquidity and Capital Resources

As of December 31, 2004, we had approximately $116.0 million in cash, cash equivalents, securities available-for-sale and interest receivable.

Net cash used in operating activities increased to approximately $148.2 million in 2004, compared to approximately $107.1 million in 2003 and $88.9 million in 2002. 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. The increase in net cash used in operating activities in 2003 as compared to 2002, was primarily due to the increase in our net loss offset in part by an increase in accrued expenses and other obligations.

If our XYOTAX clinical trials are successful, we would expect the amount of net cash used in operating activities in 2005 to be higher than 2004 due to the completion of the trials, pre-commercialization costs and our effort towards filing an NDA, as well as our continued progress in our phase III clinical trials for pixantrone and phase II clinical studies for CT-2106. If our XYOTAX clinical trials are unsuccessful, we would expect the amount of cash used in operating activities in 2005 to be considerably less than 2004 as we would not be incurring further significant costs related to the development of XYOTAX. However, we would still incur costs related to our phase III clinical trials for pixantrone and phase II clinical studies for CT-2106. Additionally, the extent of cash flow used in operating activities will be significantly affected by our ability to in-license or acquire rights to other products and maintain TRISENOX sales.

Net cash provided by investing activities totaled approximately $154.4 million in 2004, $24.9 million in 2003, and $80.6 million in 2002. 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 maturity of securities available-for-sale in excess of purchases of such securities. The decrease in net cash provided by investing activities in 2003, as compared to 2002, was primarily due to a decrease in proceeds from sales and maturities of securities available-for-sale partially offset by a decrease in purchases of securities available-for-sale.

Net cash provided by financing activities totaled approximately $88.9 million in 2004 and $72.7 million in 2003, and net cash used in financing activities totaled approximately $12.5 million in 2002. The net cash provided by financing activities during 2004 was primarily due to the issuance of approximately 12.9 million shares of our common 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. The net cash used in financing activities during 2002 was due primarily to the repurchase of our common stock for $16.4 million.

We identified and implemented a number of certain program deferrals in an effort to reduce and conserve capital in anticipation of an NDA filing for XYOTAX in 2005 and a potential XYOTAX launch in 2006. These program deferrals included delaying some clinical trials and deferring initiation of other clinical studies that do not significantly affect the registration timeline for XYOTAX or the phase III timing of pixantrone.

Assuming a successful launch of XYOTAX in 2006, we would expect to generate losses from operations for at least the next 18 months due to substantial additional research and development costs, including costs related to clinical trials and increased sales and marketing expenditures. We expect that our existing capital resources, including proceeds from our recent common stock offerings, and taking into account the deferrals discussed above, will enable us to maintain our current operations through the third quarter of 2005; however, to fully fund ongoing and planned activities, especially if one of our XYOTAX pivotal trials is successful, we believe we will need to raise additional funds through equity financings, partnerships or other sources.

If our XYOTAX trials are not successful, we would expect to generate losses from operations for at least two years due to research and development costs related to clinical trials for pixantrone and CT-2106; however, we would expect costs associated with XYOTAX to significantly decrease. We expect that our existing capital resources, including proceeds from our recent common stock offerings, and taking into account the deferrals discussed above, would enable us to maintain operations through at least 2005.

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 of our sales and marketing efforts;
- success in acquiring complementary 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. If we should require additional financing, such financing may not be available when needed or, if available, we may not be able to obtain it on terms favorable to us or to our shareholders. Insufficient funds may require us to delay, scale back or eliminate some or all of our research and development programs, or may adversely affect our ability to operate as a going concern. If additional funds are raised by issuing equity securities, substantial dilution to existing shareholders may result.

The following table includes information relating to our contractual obligations as of December 31, 2004 (in thousands):

Contractual Obligations	Payments Due by Period				
	Total	1 Year	2-3 Years	4-5 Years	After 5 Years
5.75% Convertible senior subordinated notes(1)	$ 85,459	$ —	$ —	$ 85,459	$ —
4.0% Convertible senior subordinated notes(2)	75,000	—	—	—	75,000
5.75% Convertible subordinated notes(3)	29,640	—	—	29,640	—
Interest on convertible and convertible senior subordinated notes	39,370	9,618	19,237	9,015	1,500
Royalty obligation(4)	53,000	—	23,000	20,500	9,500
Operating leases:					
Facilities	49,373	9,227	17,877	9,619	12,650
Aircraft	13,811	1,927	3,854	3,854	4,176
Long term debt(5)	4,331	1,382	866	683	1,400
Payment related to PolaRx acquisition	50	50	—	—	—
	$350,034	$22,204	$64,834	$158,770	$104,226

(1) 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.
(2) 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.
(3) 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.
(4) The minimum royalty payment due pursuant to the royalty interest financing arrangement with PharmaBio Development, Inc. Our maximum royalty payment under the arrangement is $69.0 million.
(5) Long-term debt does not include $0.4 million recorded as interest rate swap and $1.7 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 agreement with PG-TXL Company L.P. is $15.5 million, $4.0 million of which will be triggered in 2005 if we successfully complete one of our phase III clinical trials. We may also be required to make an additional payout in future years to former PolaRx stockholders based on a 2% royalty on total net sales of arsenic products, payable in cash or common stock at the then fair market value of our stock, related to the PolaRx acquisition contingent upon achieving sales of TRISENOX in excess of $40 million for any calendar year.

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 March 2004, the FASB issued EITF Issue No. 03-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*. EITF 03-1 includes new guidance for evaluating and recording impairment losses on debt and equity investments, as well as new disclosure requirements for investments that are deemed to be temporarily impaired. In September 2004, the FASB issued FASB Staff Position EITF 03-1-1, which delays the effective date until additional guidance is issued for the application of the recognition and measurement provisions of EITF 03-1 to investments in securities that are impaired; however, the disclosure requirements are effective for annual periods ending after June 15, 2004. Although we will continue to evaluate the application of EITF 03-1, management does not currently believe adoption will have a material impact on our results of operations or financial position.

In December 2004, the FASB issued FAS 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, for interim periods beginning after June 15, 2005 and will become effective for the Company for the quarter ending September 30, 2005. Accordingly, SFAS 123R eliminates the ability to account for share-based compensation using APB 25, and the pro forma disclosures previously permitted under SFAS 123 no longer will be an alternative to financial statement recognition. Although we have not yet determined whether the adoption of SFAS 123R will result in amounts that are similar to the current pro forma disclosures under SFAS 123, we are evaluating the requirements under SFAS 123R including the valuation methods and support for the assumptions that underlie the valuation of the awards, as well as the transition methods (modified prospective transition method or the modified retrospective transition method) and expect the adoption to have a significant impact on our consolidated statements of operations and net loss per share.

Item 7a. Quantitative and Qualitative Disclosure 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. Because we have the ability to 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, 2004 and 2003 was $10.8 million and $83.1 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, 2004.

We may manage our interest rate market risk, when deemed appropriate, through the use of derivative financial instruments. Derivative financial instruments are viewed as risk management tools and are not used for speculative or trading purposes. In 2001, we entered into a long-term operating lease that had a variable rent component that was based on LIBOR. In connection with this lease, we entered into an interest rate swap agreement to limit our interest rate exposure. This swap agreement has been designated as a cash flow hedge. The portion of the net gain or loss on the derivative instrument that is effective as a hedge is reported as a component of accumulated other comprehensive loss in shareholders' deficit. As of December 31, 2004 and 2003, the fair value of the interest rate swap was a liability of $0.4 million and $0.8 million, respectively.

Foreign Exchange Market Risk

As a result of our acquisition of Novuspharma, we are exposed to risks associated with foreign currency transactions insofar as we might desire 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 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, 2004 of $16.9 million, an assumed 5%, 10% and 20% negative currency movement would result in fair value declines of $0.8 million, $1.7 million and $3.4 million, respectively.

Item 8. Consolidated Financial Statements and Supplementary Data

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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 2004 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, 2004 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 Grant Thornton LLP, 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.

REPORT OF GRANT THORNTON LLP, 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, 2004, 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, 2004, 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, 2004, 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, 2004, and the related statements of operations, shareholders' equity (deficit), and cash flows for the year then ended and our report dated February 28, 2005 expressed an unqualified opinion on those financial statements.

/s/ GRANT THORNTON LLP

Seattle, WA
February 28, 2005

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 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.

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, 2004, 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 February 28, 2005 expressed an unqualified opinion thereon.

/s/ GRANT THORNTON LLP

Seattle, WA
February 28, 2005

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 balance sheet of Cell Therapeutics, Inc. as of December 31, 2003 and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the two years in the period ended December 31, 2003. Our audits also included the financial statement schedule listed in the Index at Item 15(a) for the years ended December 31, 2002 and 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 audits.

We conducted our audits 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 audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Cell Therapeutics, Inc. at December 31, 2003 and the consolidated results of its operations and its cash flows for each of the two years in the period ended December 31, 2003, in conformity with accounting principles generally accepted in the United States. Also, in our opinion, the related financial statement schedule for the years ended December 31, 2002 and 2003, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

ERNST & YOUNG LLP

Seattle, Washington
February 6, 2004

CELL THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS
(In thousands, except share amounts)

	December 31, 2004	December 31, 2003
ASSETS		
Current assets:		
Cash and cash equivalents	$ 105,033	$ 8,438
Securities available-for-sale	10,840	83,144
Interest receivable	147	1,256
Accounts receivable, net	879	1,980
Inventory	920	1,008
Note receivable from officer	—	3,500
Prepaid expenses and other current assets	10,113	6,093
Total current assets	127,932	105,419
Property and equipment, net	22,360	11,341
Goodwill	17,064	17,064
Other intangibles, net	4,175	1,335
Other assets	13,465	10,931
Total assets	$ 184,996	$ 146,090
LIABILITIES AND SHAREHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 7,309	$ 4,031
Accrued expenses	24,970	21,940
Accrued liability related to PolaRx acquisition	50	5,019
Current portion of deferred revenue	408	765
Current portion of long-term obligations	1,382	1,766
Total current liabilities	34,119	33,521
Deferred revenue, less current portion	1,310	1,310
Other long-term obligations, less current portion	5,053	3,702
Royalty obligation	25,123	—
Convertible senior subordinated notes	160,459	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—63,862,658 and 34,339,040 at December 31, 2004 and December 31, 2003, respectively	652,773	394,750
Deferred stock-based compensation	(2,736)	(5,956)
Accumulated other comprehensive income (loss)	2,039	(850)
Accumulated deficit	(722,784)	(470,486)
Total shareholders' deficit	(70,708)	(82,542)
Total liabilities and shareholders' deficit	$ 184,996	$ 146,090

See accompanying notes.

CELL THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)

	Year Ended December 31,		
	2004	2003	2002
Revenues:			
Product sales	$ 26,626	$ 22,105	$ 11,393
License and contract revenue	2,968	2,660	5,503
Total revenues	29,594	24,765	16,896
Operating expenses:			
Cost of product sold	1,104	840	423
Research and development	101,127	89,534	58,759
Selling, general and administrative	78,522	55,641	49,800
Acquired in-process research and development	87,375	—	—
Amortization of purchased intangibles	2,294	1,335	6,701
Total operating expenses	270,422	147,350	115,683
Loss from operations	(240,828)	(122,585)	(98,787)
Other income (expense):			
Investment and other income	1,636	1,880	4,819
Interest expense	(10,988)	(9,326)	(11,240)
Foreign exchange loss	(2,118)	—	—
Gain on exchange of convertible subordinated notes	—	—	55,305
Other income (expense), net	(11,470)	(7,446)	48,884
Net loss	$(252,298)	$(130,031)	$ (49,903)
Basic and diluted net loss per share	$ (4.67)	$ (3.89)	$ (1.48)
Shares used in calculation of basic and diluted net loss per share	54,052	33,418	33,763

See accompanying notes.

CELL THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)
(In thousands)

	Common Stock		Deferred Stock-based	Notes Receivable from		Accumulated Other	Total Shareholders'
	Shares	Amount	Compensation	Officers	Accumulated Deficit	Comprehensive Income/(Loss)	Equity (Deficit)
Balance at January 1, 2002	34,982	$399,649	$ —	$(225)	$(290,552)	$ 685	$ 109,557
Preferred stock dividend	113	500	—	—	—	—	500
Proceeds from stock options exercised and stock sold via employee stock purchase plan	413	1,253	—	—	—	—	1,253
Equity-based compensation expense	147	11	—	—	—	—	11
Repurchase of common stock	(2,601)	(16,419)	—	—	—	—	(16,419)
Repayment of notes receivable from officers	—	—	—	225	—	—	225
Comprehensive loss:							
Unrealized losses on securities available-for-sale	—	—	—	—	—	(249)	(249)
Unrealized loss on interest rate swap	—	—	—	—	—	(1,492)	(1,492)
Net loss for the year ended December 31, 2002	—	—	—	—	(49,903)	—	(49,903)
Comprehensive loss							(51,644)
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 gain 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 gain 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)

See accompanying notes.

CELL THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Year Ended December 31,		
	2004	2003	2002
Operating activities			
Net loss	$(252,298)	$(130,031)	$ (49,903)
Adjustments to reconcile net loss to net cash used in operating activities:			
Acquired in-process research and development	87,375	—	—
Depreciation and amortization	10,311	4,868	9,703
Equity-based compensation expense	5,417	996	11
Amortization of investment premium	1,123	3,572	4,537
Noncash interest expense	1,091	758	992
Noncash rent expense (benefit)	415	1,170	(115)
Loss on disposition of property and equipment	505	113	—
Loss (gain) on sale of investment securities	29	13	(15)
Gain on exchange of convertible subordinated notes	—	—	(55,305)
Changes in operating assets and liabilities:			
Interest receivable	1,109	644	1,578
Accounts receivable, net	(221)	170	(697)
Inventory	88	(130)	95
Prepaid expenses and other current assets	(1,068)	64	(2,561)
Other assets and deferred charges	2,734	1,573	1,038
Accounts payable	(1,651)	1,587	1,238
Accrued expenses and other obligations	(2,292)	8,507	275
Deferred revenue	(819)	(1,018)	199
Total adjustments	104,146	22,887	(39,027)
Net cash used in operating activities	(148,152)	(107,144)	(88,930)
Investing activities			
Purchases of securities available-for-sale	(59,011)	(167,433)	(287,516)
Proceeds from sales of securities available-for-sale	50,830	27,403	111,554
Proceeds from maturities of securities available-for-sale	79,333	175,437	266,134
Purchases of property and equipment	(4,632)	(3,335)	(6,259)
Additional consideration related to PolaRx acquisition	(4,969)	(3,981)	—
Issuance of note receivable to officer	—	—	(3,500)
Repayment of notes receivable from officers	3,500	—	225
Net cash acquired in (paid for) the Novuspharma merger	89,391	(3,160)	—
Net cash provided by investing activities	154,442	24,931	80,638
Financing activities			
Proceeds from issuance of common stock, net	63,846	—	—
Proceeds from royalty based financing	25,000	—	—
Proceeds from issuance of convertible subordinated notes, net	—	72,143	—
Repurchase of common stock	—	—	(16,419)
Proceeds from common stock options exercised and stock sold via employee stock purchase plan	2,220	2,303	1,253
Repayment of long-term obligations	(2,172)	(1,741)	(1,781)
Proceeds from the issuance of long-term obligations	—	—	4,497
Net cash provided by (used in) financing activities	88,894	72,705	(12,450)
Effect of exchange rate changes on cash and cash equivalents	1,411	—	—
Net increase (decrease) in cash and cash equivalents	96,595	(9,508)	(20,742)
Cash and cash equivalents at beginning of period	8,438	17,946	38,688
Cash and cash equivalents at end of period	$ 105,033	$ 8,438	$ 17,946
Supplemental disclosure of cash and noncash flow information			
Cash paid during the period for interest	$ 9,823	$ 8,439	$ 10,469
Common stock issued for acquisition of Novuspharma	$ 189,760	$ —	$ —
Reduction upon exchange of outstanding convertible notes	$ —	$ —	$ 59,900
Issuance of common stock for payment of preferred stock dividend	$ —	$ 500	$ 500

See accompanying notes.

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. Sales of TRISENOX® (arsenic trioxide), or TRISENOX are primarily to pharmaceutical wholesalers who distribute the drug in the United States. We purchase the raw material from two suppliers, and we currently have two vendors approved by regulatory agencies to manufacture the finished product for TRISENOX.

Principles of Consolidation

The consolidated financial statements include the accounts of Cell Therapeutics, Inc., its wholly owned subsidiaries (Cell Therapeutics Europe S.r.l., CTI Technologies, Inc., PolaRx Biopharmaceuticals, Inc., 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. 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, our estimates include 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.

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.

Certain Concentrations

We are exposed to risks associated with foreign currency transactions insofar as we might desire 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 accounts 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.

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. We do not require collateral or other security to support credit sales, but provide an allowance for bad debts when warranted.

We entered into a supply agreement with our primary supplier of paclitaxel, a key starting material for our XYOTAX drug candidate. We have also identified and purchased paclitaxel from an additional supplier. We have agreements with two contract manufacturers for TRISENOX, our current commercial product. If we are unable to obtain sufficient quantities from these suppliers, and 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 31% of our total employees as of December 31, 2004, and who are subject to a collective bargaining agreement as well as to local regulations governing employment.

Liquidity

If our XYOTAX clinical trials are not successful, we will discontinue XYOTAX development and significantly decrease our XYOTAX development and selling, general and administrative expenses accordingly, which will enable us to maintain our operations through 2005; however, if one of our XYOTAX clinical Phase III trials is successful we plan to raise additional funds for our ongoing and planned activities.

If our plans or assumptions change or are inaccurate, it will affect the amount of additional funds we will need to raise to continue the development of our technologies and complete the commercialization of products, if any, resulting from our technologies. We may raise such capital through public or private equity financings, partnerships, debt financings, 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 may curtail operations significantly, including the delay, modification or cancellation of research and development programs aimed at bringing new products to market.

Product Sales

We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, title has passed and delivery has occurred, the price is fixed and determinable, and collectibility is reasonably assured.

Product sales are generally recorded upon shipment net of an allowance for returns and discounts. Customers may return damaged or expired inventory up to one year after the expiration date. In estimating returns, we analyze historical returns, sales patterns, estimated inventory on hand at the distributors and the remaining shelf life of that inventory. To arrive at the accrual for product returns, we match the returns to the corresponding production batch to assess the historical trend for returns. Based on this analysis, the estimated return percentage is applied to current period sales. If customers have product acceptance rights or return rights, and we are unable to reasonably estimate returns related to that customer or market, we defer revenue until such rights have expired. Allowances for returns, discounts and bad debts, which are netted against accounts receivable, totaled approximately $1.4 million and $2.1 million for the years ended December 31, 2004 and 2003, respectively.

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 Agreement Revenues

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. 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 are recognized as the related costs are incurred. Payments received in advance of recognition as revenue are recorded as deferred revenue.

Cost of Product Sold

Cost of product sold consists primarily of the cost of product 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.

Inventory

Inventory is stated at the lower of cost or market. Cost is determined using a weighted-average method. Finished goods inventory consists of our FDA and EMEA approved pharmaceutical drug, TRISENOX. If the cost of the inventory exceeds the expected market value, provisions are recorded for the difference between the cost and the net realizable value. When required, an allowance for excess inventory that may expire and become unsaleable is recorded. The components of inventories are as follows as of December 31 (in thousands):

	2004	2003
Work in process	$529	$ 759
Finished goods	391	249
	$920	$1,008

Research and Development Expenses

Research and development expenses include related salaries and benefits, clinical trial and related clinical trial manufacturing costs, contract and other outside service fees, and facilities and overhead costs. Research and development expenses consist of costs incurred for proprietary and collaboration research and development and also include activities such as product registries and investigator-sponsored trials. Research and development costs are expensed as incurred. In instances where we enter into agreements with third parties for research, clinical trial, and related clinical trial manufacturing costs, costs are expensed upon the earlier of when non-refundable amounts are due or as services are performed. 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 have no alternative future use and which have not reached technological feasibility at the date of our merger with Novuspharma, S.p.A. are expensed as incurred (see Note 2, "Merger with Novuspharma, S.p.A.").

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 $8.8 million as of December 31, 2004, of which $8.1 million is included in other assets and $0.7 million is included in prepaid expenses and other current assets. This receivable balance primarily relates to our Italian operations which typically has a three year collection period. We will 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.

We perform reviews of our long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount might not be recoverable. We do not perform a periodic assessment of assets for impairment in the absence of such information or indicators. To date, there has been no material impairment of long-lived assets.

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. Purchased intangible assets other than goodwill are amortized over their useful lives unless these lives are determined to be indefinite.

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.

Changes in the net carrying amount of goodwill in 2002, 2003 and 2004 are as follows (in thousands):

Balance as of January 1, 2002	$ 8,064
Additional goodwill in 2002	4,000
Balance as of December 31, 2002	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

During 2003 and 2002, we recorded as goodwill an additional $5.0 million and $4.0 million, respectively, related to contingent consideration that became due and payable in connection with our 2000 acquisition of PolaRx Biopharmaceuticals, Inc., or PolaRx, (see Note 17).

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

	2004		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Patents and other intangibles	$ 6,674	$(6,674)	$ —
Assembled workforce	5,219	(1,044)	4,175
Other intangibles assets	$11,893	$(7,718)	$4,175

	2003		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
Patents and other intangibles	$ 6,674	$(5,339)	$1,335

Amortization expense of our other intangible assets is as follows (in thousands):

	Year Ended December 31,		
	2004	2003	2002
Patents and other intangibles	$1,335	$1,335	$1,334
Assembled workforce	959	—	—
Marketing intangible asset	—	—	5,367
	$2,294	$1,335	$6,701

We expect amortization expense on assembled workforce to be approximately $1.0 million for each of the next four years, at which time it will be fully amortized.

Royalty Obligation

Our $25.0 million royalty obligation with PharmaBio Development, Inc., or PharmaBio, was recorded as debt as we have significant continuing involvement in the generation of cash flows due to PharmaBio. Royalty

payments made to PharmBio will reduce the future obligation. The obligation will be amortized under the effective interest method using an imputed interest rate that is based on our estimates of total royalty and interest payments due under the arrangement. The amount of royalty and interest payments will vary depending on whether we reach certain TRISENOX targets and certain other factors as described in the agreement. We will reassess the imputed interest rate as circumstances change.

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 Opinion, or APB, 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.

In accordance with the provisions of SFAS 123, we apply APB 25 and related interpretations in accounting for our stock option plans and, accordingly, do not recognize compensation cost for options granted with exercise prices equal to or greater than fair value. 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):

	2004	2003	2002
Net loss:			
As reported	$(252,298)	$(130,031)	$(49,903)
Add: Stock-based employee compensation included in reported net loss	5,342	663	59
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	(11,397)	(11,992)	(21,404)
As adjusted	$(258,353)	$(141,360)	$(71,248)
Basic and diluted net loss per share:			
As reported	$ (4.67)	$ (3.89)	$ (1.48)
As adjusted	$ (4.78)	$ (4.23)	$ (2.11)

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, $0.7 million, and $0.9 million in 2004, 2003 and 2002, 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.

Derivative Financial Instruments

We account for derivative financial instruments under SFAS 133, *Accounting for Derivative Instruments and Hedging Activities*, as amended. We are subject to risks associated with fluctuations in the LIBOR interest rate from lease payments on our aircraft. Our policy is to hedge a portion of these forecasted transactions through an interest rate swap agreement. This swap agreement has been designated as a cash flow hedge. The portion of the net gain or loss on a derivative instrument that is effective as a hedge is reported as a component of accumulated other comprehensive income or loss in shareholders' deficit and is reclassified into earnings in the same period during which the hedged transaction affects earnings. The remaining net gain or loss on a derivative in excess of the present value of the expected cash flows of the hedged transaction is recorded in earnings immediately. If a derivative does not qualify for hedge accounting, or a portion of the hedge is deemed ineffective, the change in fair value is recorded in earnings. The swap was perfectly effective at December 31, 2004 and 2003. We do not enter into forward agreements for trading purposes.

Other Financial Instruments

At December 31, 2004 and 2003, 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 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 subordinated notes and convertible subordinated notes are as follows as of December 31 (in thousands):

	2004	2003
5.75% convertible senior subordinated notes	$87,800	$87,600
4.0% convertible senior subordinated notes	$73,100	$70,100
5.75% convertible subordinated notes	$26,100	$24,500

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. Total gain from foreign currency translation was $2.5 million as of December 31, 2004.

Comprehensive Income (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 $249.4 million, $129.8 million and $51.6 million as of December 31, 2004, 2003 and 2002, respectively.

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

	2004	2003
Foreign currency translation adjustment	$2,511	$ —
Net unrealized loss on interest rate swap	(436)	(810)
Net unrealized losses on securities available-for-sale	(36)	(40)
	$2,039	$(850)

Recently Issued Accounting Pronouncements

In March 2004, the FASB issued EITF Issue No. 03-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*. EITF 03-1 includes new guidance for evaluating and recording impairment losses on debt and equity investments, as well as new disclosure requirements for investments that are deemed to be temporarily impaired. In September 2004, the FASB issued FASB Staff Position EITF 03-1-1, which delays the effective date until additional guidance is issued for the application of the recognition and measurement provisions of EITF 03-1 to investments in securities that are impaired; however, the disclosure requirements are effective for annual periods ending after June 15, 2004. Although we will continue to evaluate the application of EITF 03-1, management does not currently believe adoption will have a material impact on our results of operations or financial position.

In December 2004, the FASB issued FAS 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, for interim periods beginning after June 15, 2005 and will become effective for the Company for the quarter ending September 30, 2005. Accordingly, SFAS 123R eliminates the ability to account for share-based compensation using APB 25, and the pro forma disclosures previously permitted under SFAS 123 no longer will be an alternative to financial statement recognition. See "Stock-Based Compensation" above for the pro forma net loss and net loss per share amounts, for the years ended 2004, 2003 and 2002, as if we had used a fair-value-based method similar to the methods required under SFAS 123R to measure compensation expense for employee stock incentive awards. Although we have not yet determined whether the adoption of SFAS 123R will result in amounts that are similar to the current pro forma disclosures under SFAS 123, we are evaluating the requirements under SFAS 123R including the valuation methods and support for the assumptions that underlie the valuation of the awards, as well as the transition methods (modified prospective transition method or the modified retrospective transition method) and expect the adoption to have a significant impact on our consolidated statements of operations and net loss per share.

2. Merger with Novuspharma, S.p.A.

On January 1, 2004, we completed the merger of Novuspharma, an Italian biopharmaceutical company focused on oncology, into CTI ("the Merger"). Novuspharma's development strategy focused on the treatment of cancer, both by modifying existing chemotherapies to make them more effective and less toxic and by developing novel therapeutics for treatment of the disease. Following completion of the merger, Novuspharma's assets and liabilities were contributed to CTI (Europe).

As a closing condition to the merger, we applied and received approval for the listing of CTI common stock on the Nuovo Mercato (a segment of the Italian stock exchange) in Italy and began trading on this exchange under the ticker symbol "CTIC" effective January 2, 2004.

At the time of the merger, approximately 15,629,000 shares of CTI common stock were issued for all outstanding Novuspharma shares. The total cost of the merger was approximately $196.1 million, based on a fair value of CTI common stock of $12.14, the average price of our common stock during a seven-day period beginning three trading days before and ending three trading days after the public announcement of the merger (June 12, 13, 16, 17, 18, 19 and 20, 2003) and related transaction costs.

The total purchase price of the merger is as follows (in thousands):

Total value of CTI common stock	$189,760
Estimated direct transaction costs	6,344
Total estimated purchase price	$196,104

As an asset purchase, the total purchase price as shown in the table above was allocated to Novuspharma's net tangible and intangible assets, including IPRD, based initially on their fair values as of January 1, 2004. These fair values were determined through a valuation performed by an independent third party. The purchase price in excess of these estimated fair values in the amount of $51.5 million was then allocated on a pro rata basis to IPRD and to non-monetary long-lived assets. During the second and fourth quarters of 2004, certain adjustments to the fair value of assets acquired were made resulting in an adjustment to the original excess purchase price allocation to IPRD and non-monetary long-lived assets. IPRD represents the value of Novuspharma's research and development projects in progress and was charged to operations upon the closing of the merger in accordance with SFAS 2, *Accounting for Research and Development Costs*. Other identified intangible assets arising from the merger totaled $4.9 million and represent assembled workforce. This amount was determined by assigning value to Novuspharma's skilled assembled workforce based on a replacement cost approach. These intangible assets have an estimated useful life of five years and will be reviewed for impairment on at least an annual basis. No goodwill was recognized as a result of the Novuspharma transaction. Novuspharma's results of operations are included in CTI's statement of operations from January 1, 2004.

The allocation of the estimated purchase price was as follows (in thousands):

Cash and cash equivalents	$ 92,491
Accounts receivable	2,595
Prepaid expenses and other current assets	154
Property and equipment	14,025
Other intangible assets	4,857
Other assets	7,286
Accounts payable and accrued expenses	(9,949)
Deferred revenue	(469)
Current portion of long-term obligations	(132)
Other long-term obligations, less current portion	(2,129)
Acquired in-process research and development	87,375
Total	$196,104

In-process research and development

Acquired IPRD was evaluated utilizing the present value of the estimated after-tax cash flows expected to be generated by purchased technology, which, at the effective time of the Merger, had not reached technological feasibility. The cash flow projections for revenues are based on estimates of growth rates and the aggregate size of the respective market for each product, probability of technical success given the stage of development at the time of acquisition, royalty rates based on an assessment of industry market rates, product sales cycles, and the

estimated life of a product's underlying technology. The projections for revenues include assumptions that significant cash flows from product revenue would commence in 2006. Estimated operating expenses and income taxes are deducted from estimated revenue projections to arrive at estimated after-tax cash flows. Projected operating expenses include cost of goods sold, general and administrative expenses, and research and development costs. The rate utilized to discount projected cash flows was 30%, and was based on the relative risk of each in-process technology and was based primarily on risk adjusted rates of return for research and development and our weighted average cost of capital at the time of the Merger.

Acquired IPRD of approximately $87.4 million represents the values determined by our management to be attributable to the IPRD assets associated with the technology acquired in the Merger as follows (in thousands):

BBR 2778 (NHL)	$80,541
BBR 2778 (MS)	6,834
	$87,375

As of January 1, 2004, pixantrone, also known as BBR 2778, was in Phase III clinical trials in indolent non-Hodgkin's lymphoma, or NHL, in Phase II clinical trials in aggressive NHL, and was expected to enter clinical trials in multiple sclerosis, or MS, during the first half of 2004. The trial for indolent NHL was modified and reduced to a registration supporting study and has been subsequently discontinued based on our strategy to conduct a pivotal phase III trial in aggressive NHL. Additionally, the planned MS trial has not been initiated due to the priority placed on the registration trials. Pixantrone produced positive results in terms of efficacy and safety in preclinical trials and in Phase I and II trials. In preclinical studies, pixantrone has shown notable activity in animal models of cancer, particularly in models of blood-born tumors such as lymphoma. For purposes of the valuation, Novuspharma estimated its future research and development costs for pixantrone to be approximately $35.8 million through the launch year. Additionally, Novuspharma expected to file a new drug application with the FDA for pixantrone in 2005, at the earliest, with an estimated launch of pixantrone for aggressive NHL in 2006, with additional revenues for pixantrone in indolent NHL and MS. However, significant risk remains relative to the uncertainties inherent in clinical trials and in ultimately obtaining regulatory approval.

The values associated with these programs represent values ascribed by CTI's management, based on the discounted cash flows currently expected from the technologies acquired and a pro rata allocation of the purchase price in excess of the estimated fair values of non-monetary assets acquired. The estimated cash flows include the estimated development costs and estimated product launch dates referred to above with estimated lives of these products ranging from twelve to fourteen years after approval. If these projects are not successfully developed, our business, results of operations and financial condition may be adversely affected. As of the date of the Merger, we concluded that once completed, the technologies under development can only be economically used for their specific and intended purposes and that the in-process technology has no alternative future use after taking into consideration the overall objectives of the project, progress toward the objectives, and uniqueness of developments to these objectives.

Unaudited Pro forma results of operations

The following table sets forth the pro forma combined historical results of operations of CTI and Novuspharma for the year end December 31, 2003 as if the Merger occurred on January 1, 2003 (in thousands, except for per share amounts):

Revenues	$ 28,142
Net loss	$(255,836)
Basic and diluted net loss per share	$ (5.22)

The unaudited pro forma combined financial data is not intended to represent or be indicative of our consolidated results of operations that would have been reported had the merger been completed as of the dates presented, and should not be taken as representative of our future consolidated results of operation. The pro forma results include the effect of the charge for IPRD of $87.4 million.

Since the merger was effective January 1, 2004, the results of operations for 2004 reflect a full year of activity for CTI (Europe) which includes an $87.4 million IPRD charge.

3. Securities Available-for-Sale

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

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

	2003			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government obligations	$36,614	$ 3	$(11)	$36,606
Corporate obligations	34,452	1	(36)	34,417
Municipal government obligations	12,118	5	(2)	12,121
	$83,184	$ 9	$(49)	$83,144

As of December 31, 2004, $10.8 million of securities available-for-sale had contractual maturities of less than one year. As of December 31, 2003, $82.1 million of securities available-for-sale had contractual maturities of less than one year, while $1.0 million had contractual maturities over one year. Gross realized gains and losses to date have not been material.

4. Property and Equipment

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

	2004	2003
Leasehold improvements	$ 12,753	$ 8,911
Lab equipment	11,394	6,340
Furniture and office equipment	18,617	10,173
	42,764	25,424
Less: accumulated depreciation and amortization	(20,404)	(14,083)
	$ 22,360	$ 11,341

Depreciation expense of $8.0 million, $3.5 million, and $3.0 million was recognized during 2004, 2003, and 2002, respectively.

5. Accrued Liabilities

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

	2004	2003
Employee compensation and related expenses	$ 7,606	$ 5,121
Clinical development and regulatory activities	6,404	6,878
Manufacturing expenses	3,870	1,776
Corporate development and sales and marketing expenses	2,066	1,300
Other research and development expenses	1,575	1,701
Insurance financing and accrued interest expense	294	294
Novuspharma acquisition costs	84	1,742
Research and development services provided by Novuspharma	—	1,163
Other	3,071	1,965
	$24,970	$21,940

At December 31, 2004 and 2003, we also accrued a $50,000 and $5.0 million liability, respectively, related to our acquisition of PolaRx in 2000 (see Note 17).

6. 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% and 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 in our consolidated balance sheet in other assets as of December 31, 2004 and 2003. Rent expense amounted to approximately $7.8 million, $6.8 million, and $4.7 million for the years ended December 31, 2004, 2003 and 2002, respectively.

Aircraft

In 2001, we entered into an operating lease agreement for use of an aircraft. Terms of the lease include current monthly rental payments of $161,000 plus an incremental rent adjustment, which is based on the value of the aircraft and will vary depending on the prevailing applicable LIBOR rate. We may cancel this agreement if certain conditions are met and six months notice is provided. The lease expires in February 2012 with provision for renewal and we are responsible for all maintenance and insurance costs for the aircraft. Rent expense related to the aircraft amounted to $2.3 million, $2.4 million, and $2.6 million for the years ended December 31, 2004, 2003 and 2002, respectively.

In connection with this aircraft lease, we entered into an interest rate swap agreement that effectively locks in the effect of the incremental rate adjustment for the first 78 payments. The swap agreement expires in September 2008. Under the swap agreement, we will receive a variable amount based on the monthly LIBOR rate and we will pay a fixed rate payment based on a rate of 4.78%. The swap agreement's notional amount of approximately $13.6 million as of December 31, 2004 matches the incremental rent value of the aircraft. The other party to the swap agreement is an affiliate of the lessor; therefore, we do not believe we have any counterparty risk related to the interest rate swap. At December 31, 2004 and 2003, the fair value of the swap was a liability of $0.4 million and $0.8 million, respectively, which is recorded in long-term other liabilities and other comprehensive income (loss). This swap is 100% effective.

Capital Leases

In connection with our merger with Novuspharma, we assumed two short-term capital lease agreements to finance mass-spectrometum equipment. These capital leases both have a term of 47 months at interest rates that range from 5.1% to 5.4%. Assets under the capital lease obligation and accumulated depreciation totaled approximately $0.7 million and $0.1 million, respectively, as of December 31, 2004.

Future Minimum Lease Payments

Future minimum lease commitments for noncancelable operating and capital leases at December 31, 2004 are as follows (in thousands):

	Capital Leases	Operating Leases
2005	$ 165	$11,154
2006	139	11,212
2007	83	10,519
2008	50	6,846
2009	—	6,627
Thereafter	—	16,826
Total minimum lease commitments	$ 437	$63,184
Less interest	(31)	
Present value of lease obligation	406	
Less current portion of long-term obligation	(148)	
Long-term obligation	$ 258	

During 2004, we entered into a sublease agreement to sublease a portion of our facilities considered to be in excess of current requirements. Total sublease rental income for fiscal year 2004 was $21,000 and offset lease expense. Total future lease income to be recognized under our existing sublease is $0.4 million.

Paclitaxel Supply

In September 2001, we entered into a purchase agreement with Natural Pharmaceuticals, Inc., or NPI, to purchase $6.0 million of paclitaxel which was to be delivered by NPI over several years. 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 the deliveries are received. As of December 31, 2004 and 2003, our prepaid asset related to the undelivered paclitaxel was approximately $2.1 million and $3.7 million, respectively, all of which was classified as current. As of December 31, 2004, we also have paclitaxel supply of $2.5 million 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 active pharmaceutical ingredient.

7. Long-Term Obligations

Convertible subordinated notes

In June 2001, we issued $150.0 million principal amount of 5.75% convertible subordinated notes due June 15, 2008 with interest payable semi-annually in June and December. In September 2001, we issued an additional $25.0 million principal amount of these notes. This additional issuance resulted from the exercise of an over-allotment option that we had granted to the initial purchasers. Net proceeds to us were approximately $168.0 million, after deducting expenses and underwriters' 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.

In December 2002, we completed an exchange offer for our 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 debt issue costs of $4.6 million attributable to the exchanged notes. As of December 31, 2004, we had $29.6 million convertible subordinated notes outstanding.

Convertible senior subordinated notes

In connection with the exchange, 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, 2004, we had $85.5 million of 5.75% convertible senior subordinated notes outstanding.

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 underwriters' 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, 2004, we had $75.0 million of 4.0% convertible senior subordinated notes outstanding.

Other long-term obligations

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

	2004	2003
Master equipment financing agreement, due May 2006, monthly payments of $51, including interest at 8.0%	$ 611	$ 1,146
Master equipment financing agreement, due December 2006, monthly payments of $35, including interest at 7.0%	522	893
Master equipment financing agreement, due October 2006, monthly payments of $35, including interest at 7.1%	479	847
Master equipment financing agreement, due October 2004, monthly payments of $48, including interest at 7.1%	—	469
Capital lease equipment financing agreement, due February 2008, monthly payments of $7, including interest at 5.1%	272	—
Capital lease equipment financing agreement, due March 2006, monthly payments of $7, including interest at 5.4%	134	—
Employee defined benefit plan (see Note 11)	1,668	—
Accrued rent	1,594	1,179
European public loans	542	—
Interest rate swap related to aircraft	436	810
Other long-term obligations	177	124
	6,435	5,468
Less current portion	(1,382)	(1,766)
	$ 5,053	$ 3,702

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.

Maturities of the convertible subordinated and convertible senior subordinated notes as well as other long-term obligations listed above, excluding the interest rate swap and employee defined benefit plan at December 31, 2004 are as follows (in thousands):

Years Ending December 31,	
2005	$ 1,382
2006	589
2007	277
2008	115,427
2009	355
Thereafter	76,400
	$194,430

8. Royalty Obligation

In December 2004, we entered into a royalty interest financing arrangement, or Arrangement, with PharmaBio for $25.0 million in financing and up to $5.0 million in clinical and other services to be provided by PharmaBio and its affiliates and paid by PharmaBio. Interest expense on the financing is calculated using the effective interest method which results in an imputed interest rate of approximately 18% as of December 31, 2004. Future amounts due under the arrangement are estimated based on our ability to meet certain TRISENOX sales milestones and other factors and will be reviewed periodically in order to assess whether this imputed interest rate should be updated.

From January 1, 2006 through December 31, 2010, PharmaBio is entitled to receive a royalty based on a percentage of TRISENOX annual net sales in the United States, the European Union and certain other territories set forth in the Arrangement. The cumulative royalty payments to PharmaBio may not be less than $53.0 million, nor exceed $69.0 million. If sales royalty payments to PharmaBio do not meet certain targets, we will pay PharmaBio minimum annual payments beginning in 2006 of (in thousands):

Years Ending December 31,	
2006	10,600
2007	12,400
2008	11,500
2009	9,000
Thereafter	9,500
	$53,000

Under the arrangement, we have committed to certain development and commercialization efforts which if not met, would increase our minimum royalty obligation from $53.0 million to $58.0 million, with the additional $5.0 million due in 2010. Additionally, we pledged to PharmaBio 100% and 65% of the capital stock of PolaRx Biopharmaceuticals, Inc., and Cell Therapeutics (UK) Limited, respectively, both wholly owned subsidiaries of Cell Therapeutics, Inc. We also granted PharmaBio a security interest in the assets related to TRISENOX, including the intellectual property, as well as accounts receivable, inventory and marketing materials. Accordingly, we must retain the primary responsibility for regulatory compliance, marketing and promotion of TRISENOX in the United States and the European Union. If we do not retain this primary responsibility, or upon a change in the control of Cell Therapeutics, Inc., we will owe a termination payment of not less than $40.0 million less any royalties or true-up payments made as of the date of the event.

We may also be required to repay the remaining balance under the minimum payment obligation of $53.0 million upon certain events of default, including: (1) failure to repay amounts due under the arrangement, (2) certain settlements or violations of law, (3) suspensions, fines, or infractions relating to the sale of TRISENOX, (4) loss of our rights to specific licenses securing the financing arrangement, (5) uncured breaches of certain provisions of the Arrangement, (6) an event of default triggering repayment of any other debt obligation of $15.0 million or more, (7) bankruptcy proceedings, or (8) failure of related agreements to remain in full force and effect.

9. 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, 165,000 and 204,524 were exercised on a net basis and 22,364, 133,839 and 146,978 shares of common stock were issued during 2004, 2003 and 2002, 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 and 113,630 shares of our common stock in 2003 and 2002, respectively. There is no future dividend obligation.

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 and expire in February 2005. The shares of common stock issued and issuable upon the exercise of the warrants have certain registration rights. No warrants were exercised during 2004, 2003 or 2002. There are warrants to purchase 109,125 shares of common stock outstanding as of December 31, 2004.

In May 2002, our Board of Directors authorized a stock repurchase program for up to three million shares of our common stock. Repurchases were made in the open market at the discretion of our management. In 2002, approximately 2.6 million shares were repurchased and retired for a total cost of $16.4 million. No shares were repurchased in 2004 or 2003.

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.

Common Stock Reserved

A summary of common stock reserved for issuance is as follows as of December 31, 2004:

Convertible senior subordinated notes	14,101,458
Convertible subordinated notes	871,765
Equity incentive plans	10,110,102
Common stock warrants	559,125
Employee stock purchase plan	279,357
Restricted share rights	103,665
	26,025,472

10. 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 stock options, stock appreciation rights and restricted stock, (b) annual, automatic, non-discretionary grants of non-qualified stock options to non-employee members of the Company's 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, 2004, 4,151,033 shares of common stock were available for future grants.

	Shares Under Option	Weighted Average Exercise Price Per Share
Balance January 1, 2002 (1,812,564 exercisable)	4,338,958	$20.59
Granted	1,871,789	6.62
Canceled	(349,544)	24.74
Exercised	(146,908)	2.99
Balance December 31, 2002 (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

The weighted average exercise price of shares exercisable at December 31, 2004, 2003 and 2002 was $18.74, $18.87 and $16.19, respectively.

The following table summarizes information about common stock options outstanding at December 31, 2004:

	Options Outstanding			Exercisable Options Outstanding (Without Restriction)	
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$ 2.00 – $ 4.60	1,230,762	5.80 Years	$ 3.47	1,080,200	$ 3.31
$ 4.94 – $ 7.10	1,228,935	8.51 Years	$ 6.88	201,401	$ 6.66
$ 7.63 – $ 9.50	1,248,444	8.61 Years	$ 8.69	581,902	$ 8.94
$ 9.76 – $23.38	411,542	8.34 Years	$11.84	134,192	$14.50
$24.55 – $47.28	1,839,386	6.34 Years	$32.77	1,766,480	$33.09
$ 2.00 – $47.28	5,959,069	7.29 Years	$14.89	3,764,175	$18.74

The weighted average fair value of options granted during 2004 was $5.41, during 2003 was $5.85, and during 2002 was $4.90. Fair value is determined using a Black-Scholes option pricing model that takes into account (1) the stock price at the grant date, (2) the exercise price, (3) an assumed four and a half-year expected life (4) no expected dividends, (5) a risk-free interest rate of 3.6%, 3.2% and 3.0%, in 2004, 2003 and 2002, respectively, and (6) a volatility factor of 0.98, 1.02 and 1.05, in 2004, 2003 and 2002, respectively.

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 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, 2004, 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, 2004, 2003 and 2002, options to acquire 107,537, 132,000 and 90,508 shares of common stock, respectively, were accounted for based on their estimated fair values. Compensation expense related to the issuance of these stock options in 2004 and 2003 was approximately $76,000 and $0.4 million, respectively, and reversed previously recorded non-employee equity-based compensation expense was $0.2 million in 2002.

Restricted Stock

We issued 345,082 and 504,200 shares of restricted common stock in 2004 and 2003, respectively. Of the restricted shares issued in 2004, 231,000 shares had been granted by our Compensation Committee of the Board of Directors in 2003 but were not issued until the occurrence of certain 2004 events. These shares were subject to variable stock compensation accounting treatment from the date of grant until issuance. Additionally, 30,450

shares of restricted stock were cancelled during 2004. The weighted average fair value of restricted shares issued during 2004 and 2003 was $7.79 and $9.86, respectively.

Deferred stock-based compensation recorded for the restricted share grants for the years ended December 31, 2004 and 2003 was approximately $1.0 million and $6.6 million respectively, which generally represents the fair value of the Company's stock issued on the date of grant. The deferred stock-based compensation recorded in 2004 includes $0.5 million in promises to issue 55,000 restricted shares of common stock to certain Italian employees. Such value is recognized as an expense over the vesting periods of six months to four years. During 2004 and 2003, we recognized total compensation expense related to the issuance of restricted stock of approximately $4.2 million and $0.6 million, respectively.

In December 2002, restricted share rights granted to executive officers and certain employees by the Compensation Committee in December 1999 vested, and we issued 142,433 shares of our common stock, recognizing $0.2 million of compensation related expense. At the election of certain right holders, 39,298 shares of our common stock were utilized to pay the holders minimum withholding tax liability.

We also issued 103,665 restricted share rights to non-employees in 1998 for which ownership vests upon the achievement of a future event (see Note 15). Compensation related to these rights will be measured as the event becomes probable with final valuation on the vesting date.

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. We recorded related expense of $0.5 million during 2002 based upon the fair value of the warrants on the date of the event. Phillip M. Nudelman, Ph.D., is a member of our board of directors, audit committee and our nominating and governance committee, and President, Chief Executive Officer and a member of the board of directors of the Hope Heart Institute (see Note 16). No warrants have been exercised.

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 64,361, 76,390 and 120,593 shares to employees in 2004, 2003 and 2002, respectively. There is a balance of 279,357 shares reserved for future purchases at December 31, 2004.

11. 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 $0.3 million and $0.2 million during the years ended December 31, 2004 and 2002, 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 $0.2 million were paid to employees who separated from the Company during 2004. The vested benefit obligation was approximately $1.7 million and was included in other long-term obligations for the year ended December 31, 2004.

12. 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, 2004, 2003 and 2002, TRISENOX product sales from major customers as a percentage of total product sales were as follows:

	2004	2003	2002
Customer A	35%	35%	37%
Customer B	24%	30%	29%
Customer C	20%	24%	22%

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

	Year Ended December 31,		
	2004	2003	2002
North America	$22,501	$20,525	$10,930
Europe	4,427	1,580	463
Asia	2,666	2,660	5,503
	$29,594	$24,765	$16,896

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

	Year Ended December 31,	
	2004	2003
United States	$33,065	$40,633
Europe	23,999	38
	$57,064	$40,671

13. 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,		
	2004	2003	2002
Net loss	$(252,298)	$(130,031)	$(49,903)
Basic and diluted:			
Weighted average shares outstanding	54,795	33,515	33,763
Less weighted-average unvested restricted shares outstanding	(743)	(97)	—
Shares used in calculation of basic and diluted net loss per share	54,052	33,418	33,763
Net loss per share:			
Basic and diluted	$ (4.67)	$ (3.89)	$ (1.48)

As of December 31, 2004, 2003 and 2002, options, warrants, unvested restricted share awards and rights and convertible debt aggregating 22,235,863, 22,089,328 and 15,999,850, 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.

14. Income Taxes

As of December 31, 2004, we had net operating loss carryforwards of approximately $498.4 million, of which $47.7 million relates to stock option deductions, and research credit carryforwards of approximately $16.6 million. The carryforwards begin to expire in 2007.

Due to rounds of equity financings, 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 $413.2 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.

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 $52.7 million, $43.0 million, and $18.8 million during 2004, 2003 and 2002, respectively.

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

	2004	2003
Deferred tax assets:		
Net operating loss carryforwards	$ 169,458	$ 159,014
Capitalized research and development	39,343	—
Research and development tax credit carryforwards	16,584	15,164
Warrants issued	3,306	3,306
Capital loss carryforward	2,931	—
Charitable contributions carryforward	2,020	1,382
Other deferred tax assets	3,146	2,390
Gross deferred tax assets	236,788	181,256
Less valuation allowance	(233,036)	(180,317)
	3,752	939
Deferred tax liabilities:		
GAAP adjustments on Novuspharma merger	(3,093)	—
Deductions for tax in excess of financial statements	(659)	(939)
Gross deferred tax liabilities	(3,752)	(939)
Net deferred tax assets	$ —	$ —

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

	2004	2003	2002
Federal income tax rate	(34%)	(34%)	(34%)
Research and development tax credits	(1)	(3)	(4)
Permanent difference – IPRD	12	—	—
Permanent differences – other	1	1	—
Valuation allowance	21	33	38
Other	1	3	—
Net deferred tax assets	— %	— %	— %

15. Significant Agreements

PG-TXL Company, L.P.: In 1998, we entered into an agreement with PG-TXL Company, L.P. 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 fund the research, development, manufacture, marketing and sale of anti-cancer drugs developed using this polymer technology.

We made $3.0 million in milestone payments during 2002 to PG-TXL Company L.P. In addition, we will be obligated to make future payments upon the achievement of certain milestones as defined in the agreement of up to $15.5 million, $4.0 million of which will be triggered in 2005 if we successfully complete one of our phase III clinical trials. 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 10).

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, which also vest upon certain performance conditions. These performance conditions include successfully completing a phase III clinical trial of a licensed product and receiving regulatory approval of a New Drug Application, or NDA, by the FDA. Data from our XYOTAX STELLAR 3 clinical trial is expected to be released in the first half of March 2005 and if successful, 51,833 restricted share rights will vest. 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. Upon execution of the agreement, Chugai paid us a $3.0 million initial payment, which we recorded as deferred revenue and which is being recognized as revenue over the estimated development period of approximately seven years on a straight-line basis. We recognized $0.4 million, $0.5 million and $0.5 million of revenue during 2004, 2003 and 2002, respectively. Under the agreement, we may also receive future payments totaling up to $13.0 million upon Chugai's achievement of certain milestones, and we are entitled to receive royalties on product sales in the territories covered under the agreement. Chugai has also committed to incur up to $54 million in development expenditures over the course of the licensing agreement. We received and recognized as revenue approximately $0.8 million, $1.1 million, and $1.9 million in development expenditure reimbursements from Chugai during 2004, 2003, and 2002 respectively, as well as a $3.0 million milestone payment in 2002. The agreement will terminate on a country-by-country basis upon the earlier to occur of the expiration of the applicable patent rights in a given country or fifteen years from the date of the first commercial sale of XYOTAX in such country.

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 (arsenic trioxide) injection 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 which is being recognized as revenue over the performance period of approximately two years on a straight-line basis. We recognized $0.2 million, $0.5 million, and $21,000 of revenue during 2004, 2003, and 2002, respectively. 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. We are also entitled to receive future payments totaling up to $3.0 million upon Nippon's achievement of certain milestones. 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 $0.8 million in product sales during 2004.

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.

16. Related Party Transactions

In the case of termination, we have severance agreements with our executive officers that provide benefits for either twelve or thirty-six months.

On April 8, 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. This loan was a full-recourse loan and was secured by a second mortgage on certain property owned by Dr. Bianco, as well as 255,381 shares of our common stock owned by Dr. Bianco. Dr. Bianco

paid accrued interest on his $3.5 million loan through October 2003. The loan to Dr. Bianco was made by CTI before the passage of the Sarbanes-Oxley Act of 2002. Prior to April 8, 2004, Dr. Bianco informed the board that he would not be able to pay 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 10). Phillip M. Nudelman, Ph.D., is a member of our board of directors, audit committee and our nominating and governance committee, 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, and $11,000 and $45,000 in charitable contributions, respectively. We also made charitable contributions during 2002 of $55,000. In 2004, we terminated the Sponsored Research Agreement with 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, which is included in deferred revenue as of December 31, 2004. Jack W. Singer, M.D., is a member of the board of Directors for DiaKine.

17. Acquisition of PolaRx Biopharmaceuticals, Inc.

On January 7, 2000, we entered into a Merger Agreement to acquire PolaRx Biopharmaceuticals, Inc., or PolaRx, a biopharmaceutical company that owned the rights to TRISENOX, an anti-cancer compound for which we submitted and received approval for a New Drug Application with the FDA. The acquisition was accounted for as a purchase transaction. Under the terms of the Merger Agreement, we have made an additional contingent payment of approximately $4.0 million for meeting a $10 million TRISENOX sales threshold in 2002. We also recorded $5.0 million in additional goodwill and an accrued liability during the fourth quarter of 2003 in connection with achieving a $20.0 million sales threshold during the year, which was paid out during the first half of 2004. We are also required to make an additional payout of a 2% royalty on net sales of arsenic products, payable in cash or common stock at the then fair market of our stock, for any calendar year that sales of TRISENOX exceed $40 million.

18. 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 during 2004, $3.1 million during 2003 and $2.5 million during 2002. In January 2004, PanGenex's board of directors and shareholders approved the termination of its development program and the dissolution of the company.

19. Restructuring Activities

In 2003, we implemented plans to reduce our workforce to eliminate areas of redundancy and capitalize on synergies and efficiencies expected to be created by the merger with Novuspharma. As of December 31, 2004, a total of 44 employees had been terminated or received notice of termination. Employee separation costs associated with the reorganization consist primarily of one-time termination benefits, principally severance payments and for certain key employees include retention bonuses and are recognized in accordance with SFAS No. 146, *Accounting for Costs Associated with Exit and Disposal Activities*. During the year ended December 31, 2003 we recorded approximately $1.5 million in research and development expenses for employee termination benefits related to terminated employees, approximately $0.6 million of which was paid out during 2003 with approximately $0.9 million accrued at December 31, 2003. To date, we have recorded approximately $1.5 million in research and development expenses for employee termination benefits related to terminated employees, of which approximately $31,000 was incurred during 2004. We expect to incur additional employee termination benefit expenses of approximately $33,000 during early 2005.

The following table summarizes the changes in the liability for employee separation costs for the year ended December 31, 2004 (in thousands):

Balance at January 1, 2004	$ 874
Additional charges	240
Adjustments	(209)
Cash payments	(819)
Balance December 31, 2004	$ 86

20. Legal Proceedings

On February 10, 2004, Micromet AG, or Micromet, a Munich, Germany-based company, filed a complaint against CTI in federal district court 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.

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

In January 2005, we issued 500,000 shares of contingent restricted stock to certain executives which would vest upon the date that we receive FDA approval for an NDA for XYOTAX if the approval is obtained prior to January 1, 2007. We also issued 200,000 shares of contingent restricted stock to an executive which would vest upon the date that we receive FDA approval for an NDA for XYOTAX or pixantrone if the approval is obtained prior to January 1, 2007. Compensation expense related to these awards would be recognized when achievement of the milestones becomes probable based on the then fair value of the underlying common stock.

22. Unaudited Quarterly Data

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

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
2004				
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)
2003				
Revenues	$ 4,881	$ 6,129	$ 6,539	$ 7,216
Gross profit	4,735	5,877	6,318	6,995
Operating expenses	34,116	35,418	36,308	41,508
Net loss	(30,469)	(30,776)	(32,119)	(36,667)
Net loss per share—basic and diluted	(0.92)	(0.93)	(0.96)	(1.09)

(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.

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.

PART III

Item 10. Directors and Executive Officers of the Registrant

Executive Officers

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

Name	Age as of 12/31/04	Position
James A. Bianco, M.D.	48	President, Chief Executive Officer
Stephen J. Aselage	53	Executive Vice President, Global Commercial Operations
Louis A. Bianco	52	Executive Vice President, Finance and Administration
James Canfield	47	Executive Vice President, Chief Administrative Officer
Richard E. Leigh, Jr.	45	Executive Vice President, General Counsel
Jack W. Singer, M.D.	63	Executive Vice President, Chief Medical Officer
Silvano Spinelli	52	Executive Vice President of Development and Managing Director of European Operations

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 joining us, 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, the world's largest bone marrow transplant 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 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. Aselage has been our executive vice president, global commercial operations since February 2004. From February 1999 to January 2004 he was senior vice president, North American sales and marketing at Sangstat, which was acquired by Genzyme in December 2003. He received his B.S. in biology from the University of Notre Dame.

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.

Mr. Canfield has been our executive vice president, chief administrative officer since December 2001. From May 2001 to December 2001, Mr. Canfield served as our vice president, human resource development and administrative services. From September 1999 to May 2001, Mr. Canfield was a senior consultant at Cobus Group and from April 1996 to August 1999, served as the head of human resources at Sonus Pharmaceuticals, Inc. Additionally, he has held senior human resource positions at Northern Automotive Corporation and Lucky Stores. Mr. Canfield received his B.S. Degree in human resources management from Kennedy Western University.

Mr. Leigh has been our executive vice president, general counsel since August 2004. From December 2000 to July 2004, Mr. Leigh served as vice president and general counsel at Vulcan Inc., and from August 1997 to November 2000, was vice president and general counsel for the NFL's Seattle Seahawks. In addition, from October 1989 to August 1997, he spent eight years as a corporate attorney with the Seattle law firm of Foster Pepper & Shefelman, PLLC. Mr. Leigh received his B.A. at Brown University in Providence, Rhode Island, his M.A. in International Politics from The Johns Hopkins University School of Advanced International Studies in Washington, D.C., and a J.D. from Columbia University School of Law in New York.

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. 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.

Mr. Spinelli was a founder of Novuspharma, which we recently acquired, and was Novuspharma's chief executive officer and managing director since January 1, 1999. He has been our managing director of European operations and one of our directors since January 2004. He joined Novuspharma in 1999 after having worked for Boehringer Mannheim Italia S.p.A. since 1980, holding a number of positions, which culminated in his appointment as R&D director in 1995. Prior to joining Boehringer Mannheim, Mr. Spinelli was assistant to the professor of quantitative analysis at the University of Pisa and responsible for the Chemical Synthesis Laboratory at Unibos Company. Mr. Spinelli received his degree in chemistry in 1976 from the University of Pisa.

Audit Committee Financial Expert

The Company's board of directors has determined that Audit Committee member Max Link 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 if 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 Fluke, Jr., Max Link and Phil Nudelman are the members of the Company's Audit Committee.

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. 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 codes of ethics required to be disclosed will be posted on its website, at http://www.ctiseattle.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. Shareholders may request a free copy of the Corporate Governance Guidelines at the address and phone numbers set forth above.

The information required by Part III, Item 10, to the extent not set forth herein, will be incorporated herein by reference from the registrant's definitive proxy statement relating to the 2005 annual meeting of shareholders,

which definitive proxy statement or amendment to this annual report shall be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this Report relates.

Item 11. Executive Compensation

The information required by Part III, Item 11, will be incorporated herein by reference from the registrant's definitive proxy statement relating to the 2005 annual meeting of shareholders, which definitive proxy statement or amendment to this annual report shall be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this Report relates.

Item 12. Security Ownership of Certain Beneficial Owners and Management

The information required by Part III, Item 12, will be incorporated herein by reference from the registrant's definitive proxy statement relating to the 2005 annual meeting of shareholders, which definitive proxy statement or amendment to this annual report shall be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this Report relates.

Item 13. Certain Relationships and Related Transactions

The information required by Part III, Item 13, will be incorporated herein by reference from the registrant's definitive proxy statement relating to the 2005 annual meeting of shareholders, which definitive proxy statement or amendment to this annual report shall be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this Report relates.

Item 14. Principal Accounting Fees and Services

The information required by Part III, Item 14, will be incorporated herein by reference from the registrant's definitive proxy statement relating to the 2005 annual meeting of shareholders, which definitive proxy statement or amendment to this annual report shall be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this Report relates.

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 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

Exhibit Number	Description
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 Amended and 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(7)	Indenture between the Registrant and State Street Bank and Trust Company of California, N.A., as trustee dated June 13, 2001.
4.3(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.
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 Cell Therapeutics, Inc. and U.S. Bank National Association and trustee, dated June 23, 2003.
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.

Exhibit Number	Description
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(2)*	Form of Strategic Management Team Severance Agreement.
10.12(22)*	Severance Agreement dated September 29, 2004 between the Registrant and Richard E. Leigh, Jr.
10.13(9)*	Form of Indemnification Agreement.
10.14(11)*	1994 Equity Incentive Plan, as amended.
10.15(20)*	1996 Employee Stock Purchase Plan, as amended.
10.16(20)*	2003 Equity Incentive Plan.
10.17(19)*	Cell Therapeutics, Inc. Novuspharma S.p.A. Stock Option Plan.
10.18*	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.
10.19*	Form of Notice of Grant of Stock Options and Option Agreement for option grants under the Registrant's 2003 Equity Incentive Plan, as amended.
10.20*	Form of Nonqualified Stock Option Agreement for option grants under the Registrant's Novuspharma S.p.A. Stock Option Plan.
10.21(5)†	License Agreement dated as of November 13, 1998, by and between PG-TXL Company, L.P. and the Registrant.
10.22(8)†	Paclitaxel Purchase Agreement dated as of September 28, 2001, between Natural Pharmaceuticals, Inc. and the Registrant.
10.23(8)†	License Agreement dated as of October 19, 2001, between Chugai Pharmaceutical Co., Ltd. and the Registrant.
10.24(9)	ISDA Master Agreement dated as of January 25, 2002, between Citibank N.A. and the Registrant.
10.25(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.
10.26†	Financing Agreement dated December 21, 2004, between the Registrant PolaRx Biopharmaceuticals, Inc., a wholly owned subsidiary of the Registrant, and PharmaBio Development, Inc.
10.27(23)	Security Agreement dated December 21, 2004 among the Registrant, PolaRx Biopharmaceuticals, Inc., a wholly owned subsidiary of the Registrant, and PharmaBio Development, Inc.
10.28(23)	Guaranty Agreement dated December 21, 2004 between PolaRx Biopharmaceuticals, Inc., a wholly owned subsidiary of the Registrant, and PharmaBio Development, Inc.

Exhibit Number	Description
10.29(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.
10.30(23)	Joint Press Release dated December 21, 2004 between PolaRx Biopharmaceuticals, Inc., a wholly owned subsidiary of the Registrant, and PharmaBio Development, Inc.
12.1	Statement Re: Computation of Ratio of Earnings to Fixed Charges.
21.1	Subsidiaries of the Registrant.
23.1	Consent of Grant Thornton LLP, Independent Registered Public Accounting Firm.
23.2	Consent of Ernst & Young LLP, Independent Registered Public Accounting Firm.
24.1	Power of Attorney. Contained in the signature page of this Annual Report on Form 10-K and incorporated herein by reference.
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.

* 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.

(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.

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 March 3, 2005.

Cell Therapeutics, Inc.

By: /s/ James A. Bianco

James A. Bianco, M.D.
President and Chief Executive Officer

POWER OF ATTORNEY

KNOW BY ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints James A. Bianco and Louis A. Bianco, and each of them his attorney-in-fact, with the power of substitution, for him in any and all capacities, to sign any amendment of post-effective amendment to this Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that said attorney-in-fact, or his substitute or substitutes, may do or cause to be done by virtue hereof.

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/ Max E. Link **Max E. Link, Ph.D.**	Chairman of the Board and Director	March 3, 2005
/s/ James A. Bianco **James A. Bianco**	President, Chief Executive Officer and Director (Principal Executive Officer)	March 3, 2005
/s/ Louis A. Bianco **Louis A. Bianco**	Executive Vice President, Finance and Administration (Principal Financial Officer and Principal Accounting Officer)	March 3, 2005
/s/ Jack W. Singer **Jack W. Singer M.D.**	Director	March 3, 2005
/s/ John M. Fluke, Jr. **John M. Fluke, Jr.**	Director	March 3, 2005
/s/ Vartan Gregorian **Vartan Gregorian, Ph.D.**	Director	March 3, 2005
/s/ Mary O. Mundinger **Mary O. Mundinger**	Director	March 3, 2005
/s/ Phillip M. Nudelman **Phillip M. Nudelman**	Director	March 3, 2005
/s/ Erich Platzer **Erich Platzer, M.D.**	Director	March 3, 2005
/s/ Silvano Spinelli **Silvano Spinelli**	Director	March 3, 2005

SCHEDULE II

CELL THERAPEUTICS, INC.

VALUATION AND QUALIFYING ACCOUNTS
YEARS ENDED DECEMBER 31, 2004, 2003 and 2002
(in thousands)

	Balance at Beginning of Period	Additions Charged to Expense	Deductions	Balance at End of Period
Year ended December 31, 2004:				
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
Year ended December 31, 2003:				
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
Year ended December 31, 2002:				
Allowance for sales returns	$ 296	$ 592	$ (157)	$ 731
Allowance for doubtful accounts and discounts	93	265	(231)	127
Reserve for excess inventory that may expire or become unsaleable	96	(9)	(87)	—
	$ 485	$ 848	$ (475)	$ 858