CELL THERAPEUTICS INC
Form 10-K/A
April 30, 2003
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K/A

(Mark One)

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

for the fiscal year ended December 31, 2002

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: 0-28386

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 to be registered pursuant to Section 12(b) of the Act: None

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

Common Stock, no par value

(Title of Classes)

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

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes x 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. ¨

The aggregate market value of the voting and non-voting common equity held by nonaffiliates as of December 31, 2002, based on the closing price of such shares on the Nasdaq National Market on June 28, 2002, was approximately $137,774,000. Shares of common stock held by each executive officer and director and by each person known to the Company who beneficially owns more than 5% of the outstanding Common Stock have been excluded in that such persons may under certain circumstances be deemed to be affiliates. This determination of executive officer or affiliate status is not necessarily a conclusive determination for other purposes.

The number of outstanding shares of the registrant s common stock as of March 31, 2003 was 33,136,092.

DOCUMENTS INCORPORATED BY REFERENCE: NONE

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PART I

This Form 10-K/A contains, in addition to historical information, forward-looking statements. These statements relate to our future plans, objectives, expectations, intentions and financial performance, and assumptions that underlie these statements. When used in this Form 10-K/A, terms such as anticipates, believes, continue, could, estimates, expects, intends, may, plans, potential, predicts, should, 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 our 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, Management s Discussion and Analysis of Financial Condition and Results of Operations, and Business and elsewhere in this Form 10-K/A.

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/A 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/A.

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 oncology drugs. Our research and in-licensing activities are concentrated on identifying new, less toxic and more effective ways to treat cancer.

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 Internet 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 (formerly referred to as PG-TXL) are proprietary marks of Cell Therapeutics, Inc. All other product names, trademarks and trade names referred to in this Form 10-K/A are the property of their respective owners.

Our Products

We acquired our lead product called arsenic trioxide, or TRISENOX®, in January 2000. We received Food and Drug Administration, or FDA, approval to market TRISENOX in the U.S. in September 2000, and the European Agency for the Evaluation of Medicinal Products, or EMEA,

approval to market in the European Community, or EU, in March 2002. TRISENOX is marketed for patients with a type of blood cell cancer called acute promyelocytic leukemia, or APL, who have relapsed or failed standard therapies. In its pivotal trial in patients with relapsed or refractory APL, 70% of the 40 patients experienced complete remission following treatment with TRISENOX with 82% achieving a molecular remission. We have received orphan drug designation for TRISENOX from the FDA for APL, multiple myeloma, myelodysplastic syndromes, or MDS, chronic myeloid leukemia, or CML, and acute myeloid leukemia, or AML. In addition, TRISENOX is currently listed in the U.S. Pharmacopeia Oncology Drug Information, or USP DI, under Orphan Product Designation and Approvals in multiple myeloma and MDS. We have also received designation as an orphan medicinal product by

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the EMEA under its orphan drug legislation for APL, MDS, and multiple myeloma. Thirty-four TRISENOX clinical trials studying the drug alone or in combination with other therapies are ongoing. Preliminary data from ongoing clinical trials have shown encouraging responses in patients with multiple myeloma, MDS, CML, prostate cancer, and neuroblastoma.

We are also developing a new way to deliver cancer drugs more selectively to tumor tissue in order to reduce the toxic side effects and improve the anti-tumor activity of existing chemotherapy agents. Our technology links, or conjugates, chemotherapy drugs to biodegradable polymers, including polyglutamate. We believe this technology works by taking advantage of the characteristics of tumor blood vessels to increase the percentage of the drug administered that actually reaches the tumor, which may increase the potency and reduce the side effects of a given dose compared to giving the drug alone. In addition, the conjugates appear to be inactive while circulating in the bloodstream, which may also lower toxicity relative to the drug alone.

Our first application of the polymer technology is XYOTAX, or CT-2103, which is paclitaxel linked to polyglutamate. Paclitaxel is the active ingredient in Taxol®, one of the world s best selling cancer drugs. In animal studies, XYOTAX demonstrated fewer side effects and improved tumor killing-activity when compared to Taxol alone. Six phase I clinical trials, four phase II clinical trials and three phase III clinical trials are currently underway, with three additional trials planned in 2003. We also initiated development of a novel polyglutamate-camptothecin molecule, or PG-CPT, and filed a U.S. investigational new drug application, or IND, in December 2001. We initiated a phase I clinical trial with PG-CPT in the first quarter of 2002, and plan to initiate another trial in the second half of 2003.

We have identified a novel drug target called lysophosphatidic acid acyltransferase, or LPAAT-ß, that when inhibited has been shown to reduce tumor cell growth in preclinical models. We are in the process of identifying a lead candidate for clinical development during 2003.

The Oncology Market

Overview. According to the American Cancer Society, or ACS, cancer is the second leading cause of death in the United States, resulting in over 555,000 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 1.3 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.

Unfortunately, there are significant limitations and complications associated with radiation and chemotherapy 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.

Treatment related toxicities. The majority of current chemotherapy agents kill cancer cells by disrupting the cell division process. Chemotherapy drugs disrupt the process by killing cells once they begin to undergo division and replication. 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 patients quality of life.

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Inability to selectively target tumor tissue. When administered, chemotherapy drugs circulate 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. These toxic effects on normal tissues prevent use of higher, potentially more effective, doses of chemotherapy.

Chemotherapy resistance. Resistance to the cancer killing effects of conventional chemotherapy drugs is a major impediment to effective treatment of cancer. Approximately 70% of all cancer patients undergoing chemotherapy ultimately develop resistance to chemotherapy and die from their disease. Because many chemotherapy drugs 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 not susceptible to the same mechanisms of resistance, could play a very important role in treating resistant tumors.

Strategy

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

We initially develop our cancer drug candidates to treat life threatening types or stages of cancer for which current treatments are inadequate, and that qualify for fast-track designation from the FDA and EMEA. We will also seek to expand the market potential of our products by seeking further approval for other indications in larger cancer patient populations.

We plan to devote a substantial portion of our efforts to develop XYOTAX 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 are applying our patented polymer drug delivery technology to develop a portfolio of improved versions of currently marketed anti-cancer drugs and novel cancer fighting agents to improve their ease of administration, side effect profile and effectiveness.

We plan to continue to in-license or acquire complementary products, technologies, or companies.

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Products in Development

The following table lists active trials (indicated by a status of open), the trials that will be opened to enrollment during the second quarter of 2003 (status 2Q2003) for our products in development, and a phase III trial that will be opened to enrollment during the third quarter of 2003 (status 3Q2003). Also listed are the trials that have recently closed to enrollment but for which clinical trial reports are in progress (status enrollment completed).

Product Candidate	Indication/Intended Use	Phase/Status
TRISENOX®	**HEMATOLOGIC MALIGNANCIES**	
(arsenic trioxide),	**Multiple Myeloma**	
ATO injection	ATO single agent (US)	II / enrollment completed
	ATO single agent (Europe)	II / open
	ATO single agent, twice weekly dosing schedule	II / open
	ATO in combination with dexamethasone	II / open
	ATO in combination with ascorbic acid	I/II / open
	ATO in combination with dexamethasone and ascorbic acid (2 trials)	II / open
	ATO in combination with thalidomide	II / open
	ATO in combination with ascorbic acid prior to autologous stem cell rescue	II / open
	ATO in combination with dexamethasone and ascorbic acid after SCT	II / open
	ATO in combination with dexamethasone post transplant	II / 2Q2003
	ATO in combination with melphalan and ascorbic acid	I/II / 2Q2003
	ATO in combination with dexamethasone and thalidomide	I/II / 2Q2003
	Myelodysplastic Syndromes (MDS)	
	ATO single agent (2 trials, US and Europe)	II / open
	ATO in combination with thalidomide	II / enrollment completed
	ATO in combination with thalidomide	II / open
	ATO single agent (3 trials)	II / open
	ATO in combination with cytarabine	II / open
	ATO in combination with amifostine	I / 2Q2003
	ATO in combination with Ara-C	I/II / 2Q2003
	Acute Promyelocytic Leukemia (APL)	
	ATO in combination with Mylotarg® for injection, salvage treatment	II / enrollment completed
	ATO single agent, APL in molecular relapse (2 trials)	II / open
	ATO in combination with ATRA, de novo APL	II / open
	ATO as consolidation for primary treatment of APL	I / 2Q2003
	Chronic Myeloid Leukemia (CML)	
	ATO single agent in advance phase CML, blast crisis, PH+ ALL	II / open
	ATO in combination with STI-571 (Gleevec) (2 trials)	II/ open
	ATO in combination with STI-571 (Gleevec) (2 trials)	I /II /2Q2003
	Non-Hodgkin s Lymphoma (NHL)	
	ATO in combination with Rituxan®	II / open
	Acute Myeloid Leukemia (AML)	
	ATO in combination with ascorbic acid	II/ open
	ATO in combination with ascorbic acid for non-APL acute myelogenous leukemia	II / open

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Product Candidate	Indication/Intended Use	Phase/Status
	Other Leukemia/Lymphoma	
	ATO in combination with ascorbic acid for relapsed/refractory lymphoid malignancies	II / open
	SOLID TUMORS	
	ATO in neuroblastomas and other solid tumors in pediatric patients	II / open
	Hepatocellular carcinoma	I / open
	Advanced cancer patients with renal dysfunction	I / open
	ATO single agent for metastatic melanoma	II/ open
	ATO in combination with ascorbic acid for metastatic colon cancer refractory to chemotherapy	II / open
	ATO single agent in cutaneous T-cell lymphoma	I / open
	ATO in combination with docetaxel for hormone-refractory prostate cancer	II/ 2Q2003
	ATO single agent for relapsed/refractory metastatic melanoma	II /2Q2003
	ATO in combination with ascorbic acid for hepatocellular carcinoma	II / 2Q2003
	ATO in combination with 5-fluorouracil for gastrointestinal tract tumor	II / 2Q2003
	ATO single agent for advanced carcinoma of the breast	II / 2Q2003
	ATO single agent for advanced non-small cell carcinoma of the lung	II / 2Q2003
	ATO in combination with DTIC for malignant melanoma	I / 2Q2003
XYOTAX (CT-2103)	Advanced solid tumors Dosing every 3 weeks (UK)	I / enrollment completed
	Advanced solid tumors in combination with cisplatin	I / open
	Advanced solid tumors in combination with carboplatin	I / open
	Advanced solid tumors, single agent dosing every week (US)	I / open
	Advanced solid tumors, single agent dosing every 2 weeks (UK)	I / open
	Advanced solid tumors, single agent dosing every 3 weeks (US)	I / open
	Non-small-cell lung cancer salvage, single agent	I / open
	Ovarian front-line dose escalation (GOG)	I/II / 2Q2003
	Ovarian, fallopian tube, peritoneal carcinoma salvage	II / enrollment completed
	Colorectal cancer salvage	II / open
	Non-small-cell lung cancer (high risk patients)	II / open
	Ovarian second relapse (GOG)	II / open
	Ovarian front-line (GOG)	III/ 3Q2003
	Lung cancer, in combination with radiation	I / 2Q2003
	Breast cancer (Cancer Research UK)	II / open
	Non-small-cell lung cancer (second line; multinational)	III / open
	Non-small-cell lung cancer in combination with carboplatin (first line PS=2; multinational)	III / open
	Non-small-cell lung cancer (first line PS=2; multinational)	III / open
PG-CPT (CT-2106)	Advanced solid tumors	I / open

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TRISENOX (arsenic trioxide) injection

We are marketing TRISENOX for the treatment of patients with chemotherapy resistant or relapsed APL. We received FDA approval in this indication in September 2000, and in March 2002, we received EMEA approval in the EU with a subsequent launch in the EU in June 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 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 cancer response rates.

We intend to protect TRISENOX by obtaining orphan drug marketing exclusivity in the U.S. and Europe. When granted orphan drug status, products usually receive seven years of marketing exclusivity in the U.S. and ten years in the EU. 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, CML, and AML. TRISENOX has received orphan drug designation for the treatment of APL, multiple myeloma, and MDS under the European orphan drug regulation. We also plan to pursue orphan designation for other indications. In addition, we have exclusive rights to several patent applications filed by PolaRx Biopharmaceuticals, Inc., or PolaRx, and The Memorial Sloan-Kettering Cancer Center that are directed to methods of treating a variety of cancers and conditions with TRISENOX, and a patent application from the Samuel Waxman Cancer Research Foundation that is directed to certain formulations of arsenic trioxide.

TRISENOX for 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 the EU. Current treatment for newly diagnosed APL patients includes the use of all-trans retinoic acid, commonly called ATRA, in combination with anthracycline chemotherapy. Between 10% to 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 from the multicenter study were presented at the 8th International Symposium on APL in Rome, Italy. 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 these two studies is 66%.

Side effects of TRISENOX noted in these studies were generally manageable, and most patients were treated as outpatients once the serious symptoms of their APL were resolved. The most common side effects

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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 Multiple Myeloma. Multiple myeloma is a malignant disease of the bone marrow that is invariably fatal. According to the Multiple Myeloma Research Foundation, multiple myeloma is the second most common blood cell malignancy, affecting nearly 50,000 people in the United States with over 14,000 new cases reported annually. The disease is initially treated with oral chemotherapy drugs. Once the disease can no longer be controlled with oral drugs, treatments include high dose corticosteroids, high dose chemotherapy, a combination of high dose chemotherapy and stem cell transplants, and recently thalidomide. Approximately 50% of myeloma patients respond to these treatments.

Preclinical studies have suggested that TRISENOX may be able to kill multiple myeloma cells taken from chemotherapy-resistant patients and that the killing may be enhanced when TRISENOX is combined with vitamin C (ascorbic acid), corticosteroids, or other agents used to treat myeloma. Preliminary reports from three clinical studies using TRISENOX in patients with myeloma who had failed multiple prior therapies showed encouraging responses as reported at the American Society of Hematology, or ASH, in December 2002. We are sponsoring several multicenter trials with TRISENOX used either as a single agent or in combination with corticosteroids, ascorbic acid, or thalidomide for advanced stages of multiple myeloma. TRISENOX has received orphan drug designation from the FDA and the EMEA for this indication.

TRISENOX for Myelodysplastic Syndrome, or MDS. MDS is a preleukemic condition affecting about 35,000 individuals a year with an annual incidence of 15,000 patients a year. Many patients who develop MDS progress to develop acute leukemia. All patients have a progressive decline in their ability to make blood cells, ultimately resulting in anemia requiring red blood cell transfusions, a low white blood cell count placing them at risk for infections, and a low platelet count making them prone to bleeding. There is no specific approved therapy for this disorder except supportive care and the use of growth factors such as Procrit and Leukine. Reports from three clinical studies using TRISENOX in high and low-risk myelodysplastic syndrome patients showed encouraging responses as reported at ASH in December 2002. Additional trials exploring the activity of TRISENOX, alone or in combination with growth factors, thalidomide and Ara-C have been initiated, and preliminary data is encouraging. Orphan drug designation has been received from both the FDA and the EMEA.

TRISENOX for Chronic Myeloid Leukemia, or CML. CML is a form of leukemia affecting approximately 16,000 individuals in the U.S. and has an annual incidence of 4,000 patients per year. It is caused by a highly specific chromosomal rearrangement that produces an abnormal fusion gene called the bcr-abl (this is similar to the cause of APL, which results from a different chromosomal rearrangement). A dramatic advance was recently made in the treatment of CML with the approval of Gleevec, a new drug that specifically targets and inactivates the bcr-abl gene product. Gleevec can induce durable clinical remissions in a very high percentage of patients with early stage CML. Although it is active in patients with later stages of the disease, termed accelerated phase or blast crisis, the remissions are short-lived as resistance to Gleevec develops. There is a need to identify drugs that will enhance the efficacy of Gleevec in advanced stages of CML and in particular, prevent the emergence of resistance. Two publications indicate that TRISENOX may be the ideal agent to use with Gleevec for the following reasons:

- It is active in CML by itself producing complete remissions in 74% of newly diagnosed CML patients in a study from China;
- It causes degradation of the bcr-abl and therefore works in concert with Gleevec against the direct cause of the disease and prevents the emergence of resistance to Gleevec; and
- CML cells are far more sensitive to TRISENOX than are normal blood cells.

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Trials exploring the use of TRISENOX in conjunction with Gleevec in both early and later stages of CML are in progress or are about to begin.

TRISENOX for Other Hematologic Malignancies. A number of other cancers of blood and lymphatic organs are under study including lymphomas and leukemias. Non-Hodgkin s lymphoma has affected more than 300,000 people in the U.S. and there are 54,000 new cases per year according to the American Cancer Society. Despite new effective therapies, relatively few patients are cured and additional treatments are needed. Studies are currently in progress to evaluate the activity of TRISENOX as a single agent and in combination with standard therapies for lymphoma.

TRISENOX for Solid Tumors. Solid tumors include malignancies that develop in various tissues throughout the body, as opposed to hematologic cancers described above. Genitourinary cancers, such as cervical, renal cell, bladder and prostate, have affected approximately three million patients in the United States, with over 370,000 new cases diagnosed annually. Preclinical data and preliminary clinical trial results have suggested that TRISENOX may have anti-tumor activity in a number of solid tumors including cancers of the ovary, prostate, bladder, liver, lung and melanoma. Early data from phase I and II studies show evidence for clinical activity in prostate cancer and neuroblastoma. A number of other studies looking at TRISENOX as a single agent and in combination with standard therapy in patients with solid tumors are either underway or planned.

Polyglutamate Drug Delivery Technology

We are also developing a new way to deliver cancer drugs more selectively to tumor tissue with the goal of reducing the toxic side effects and improving the anti-tumor activity of existing chemotherapy agents. Our technology links cancer drugs to proprietary polymers, such as polyglutamate. Polyglutamate, which we call PG, is a biodegradable polymer of glutamic acid, a naturally occurring amino acid. To build PG we link glutamic acid molecules together to an optimal size. We believe the polymer technology takes advantage of a well-described difference between tumor blood vessels and blood vessels in normal tissues. The blood vessels in tumor tissues are more porous than those in normal tissues, and they are therefore more permeable to large molecules, such as our polymers, that are within a specific size range. As the polymer, carrying its tumor-killing drug, circulates in the bloodstream and passes through the tumor blood vessels, it becomes trapped in the tumor tissue allowing a significantly greater percentage of the anti-cancer drug to accumulate in tumor tissue compared to normal tissue. The toxicity of the chemotherapy drug to normal tissues also may be reduced because the drug appears to be inactive as long as it is bound to the polymer. Once the polymer backbone is digested in the tumor, the cancer-killing drug is released directly into the cancer tissues.

Based on observations from preclinical animal studies, along with early clinical trial data from phase I and phase II studies, we believe that our polymer-chemotherapy drug conjugates may be able to achieve a number of benefits over existing chemotherapy drugs, including:

- more drug reaches the tumor,
- increased efficacy using the same amount of active drug,
- ability to use higher doses of the active drug,

less toxicity at the same or higher doses of active drug, and

potential to overcome resistance to the underlying chemotherapy drug.

In addition, we believe that linking our polymers to existing drugs will yield patentable subject matter and that our polymer-drug conjugates will not infringe any third party patents covering the underlying drug. However, there can be no assurance that we will receive a patent for our polymer conjugates or that we will not be challenged by the holder of a patent covering the underlying drug.

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We licensed the worldwide exclusive rights to PG and related polymers with their applications to anticancer drugs from PG-TXL Company, L.P. in 1998. This technology was originally developed at the M.D. Anderson Cancer Center. The initial patent, which issued in November 1999, covers compositions of PG and related polymers coupled with commonly used cancer drugs such as paclitaxel, docetaxel, etoposide, teniposide, or camptothecins. The patented technology also covers formulations of PG-conjugated paclitaxel that also include the use of human serum albumin and conjugation to epothilones.

Our strategy is to use this novel polymer technology to build a portfolio of potentially safer and more effective versions of well-known anti-cancer agents. We believe that our polymer drug development program may lower the risks inherent in developing new drugs because we are linking polymers to well defined and widely used chemotherapy drugs. We are initially focusing our development efforts on applying PG to two of the fastest growing classes of anticancer drugs, taxanes and camptothecins.

XYOTAX (paclitaxel poliglutamex). XYOTAX, or CT-2103, is PG linked to paclitaxel, the active ingredient in Taxol, one of the world s best selling cancer drugs. Taxol is difficult to administer because it is formulated in Cremophor, a mixture of castor oil and ethanol, which is extremely irritating to blood vessels and requires surgical placement of a large catheter for administration. It also may cause allergic reactions, and typically requires a minimum of three hours of intravenous infusion. XYOTAX is 80,000 times more water-soluble than paclitaxel, allowing it to be dissolved in 100 mL of a simple water and sugar based solution and infused over ten minutes. Also, because XYOTAX is water-soluble, its administration does not require routine premedication with steroids and antihistamines to prevent severe allergic reactions; such premedication can be reserved for those patients who show signs of sensitivity during treatment. XYOTAX may also allow delivery of higher doses than can be achieved with paclitaxel.

It is estimated that more than 3.8 million people have breast, ovarian, lung and colon cancer, with more than 550,000 new cases diagnosed each year in the United States. IMS Health reported taxane U.S. sales of approximately $934 million, and worldwide sales of roughly $1.7 billion for 2002, despite the difficulties associated with their administration and their serious dose-limiting toxicities. The majority of taxane use has been in breast, ovarian and lung cancer indications.

XYOTAX has been compared to paclitaxel in numerous studies in animals with a variety of different tumors. These studies indicate that XYOTAX has a unique profile resulting in better tolerability and efficacy, both when used by itself as a single agent or in combination with other chemotherapy, radiation therapy, or therapeutic monoclonal antibodies. Specifically:

- The maximum tolerated dose, or MTD, for XYOTAX is approximately twice that for the approved formulation of paclitaxel.

- When the MTD of XYOTAX is compared to the MTD of paclitaxel, in over 20 different animal tumor models, XYOTAX was invariably more effective and in a number of models was curative. Cures were never observed with paclitaxel in these models.

- Examination of the distribution of XYOTAX to tumor tissue in mice and comparing it to tumors in mice who received the equivalent dose of the approved preparation of paclitaxel showed that 12-fold more paclitaxel was delivered with XYOTAX. Strikingly, more paclitaxel was present in the tumors at the end of one week following XYOTAX administration than was present one day after administration of standard paclitaxel.

- Because in XYOTAX, paclitaxel is directly bound to PG backbone, it is both highly water soluble and inactive until released. Therefore, it can be delivered without toxic solubilizing agents such as Cremophor (used in Taxol), which minimizes the requirement

for premedications to prevent infusional hypersensitivity. Moreover, little free paclitaxel is present in circulation, potentially reducing side effects to normal tissues such as the bone marrow, nervous tissue, and hair follicles.

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XYOTAX is engulfed by tumor cells instead of passively diffusing into them. Because of this, it bypasses a common mechanism of paclitaxel resistance associated with a cell membrane pump known as the multi-drug resistance pump, or MDR; XYOTAX in preclinical studies is effective in tumors that are resistant to standard paclitaxel.

Lastly, based on additional preclinical data, XYOTAX is more effective than standard paclitaxel at enhancing the effectiveness of other cancer therapies including chemotherapy and radiation. A recent report in the International Journal of Radiation Oncology Biology-Physics shows that in a curative, standard radiation model, XYOTAX selectively improved tumor response to radiation by up to eightfold after single-dose or fractionated irradiation. Most importantly, unlike standard paclitaxel, XYOTAX did not sensitize normal organs such as skin, hair follicles, or the gastrointestinal tract to radiation. A grant from the National Cancer Institute to the MD Anderson Cancer Center and us will support a clinical trial using XYOTAX in sensitive patients undergoing potentially curative radiation for lung cancer.

We chose to initiate clinical trials of XYOTAX in the U.K. because of the Cancer Research Campaign s, or CRC s, experience with polymer drug conjugates and because of the ability to perform trials in patients who had not received a taxane. The phase I clinical trial of XYOTAX sponsored by the CRC has completed patient enrollment. Preliminary data presented by the investigators showed that XYOTAX may have a more favorable toxicity profile than expected from equivalent doses of Taxol, while demonstrating evidence of anti-tumor activity across a variety of types of cancer.

Based on the preliminary data generated in the phase I CRC trial, and following discussions with a number of opinion leaders and cooperative groups, we initiated an aggressive development program for XYOTAX in the US and other countries. Six phase I clinical trials, four phase II clinical trials, and three phase III clinical trials are currently underway, with three additional trials planned this year. Some of these ongoing studies use XYOTAX at doses in excess of the approved dose for Taxol and all are scheduled to use a convenient 10-minute infusion time. Our registration strategy for XYOTAX is to examine its potential safety and efficacy as single agent therapy or in combination with other chemotherapy drugs in solid tumors. The phase III trials in non-small-cell lung cancer patients are intended to more fully characterize the safety and efficacy of XYOTAX. Based upon a successful conclusion to these trials, we anticipate submitting a New Drug Application, or NDA, in the second half of 2004.

In 2002, we announced that the Gynecologic Oncology Group, or GOG, plans to conduct a phase III trial of XYOTAX in front-line treatment of ovarian cancer. This trial is expected to begin in the third quarter of 2003. We had initiated a XYOTAX phase III ovarian clinical trial in July 2002, but have since closed this trial as a result of the GOG s decision to conduct the trial for us.

PG-CPT (polyglutamate camptothecin). PG-CPT, or CT-2106, is a camptothecin linked to PG. Camptothecins are an important and rapidly growing class of anti-cancer drugs. However, like taxanes, their full clinical benefit is limited by poor solubility and significant toxicity. To avert solubility limitations, oral analogs such as Hycamtin and Camptosar were developed. However, conversion to oral dosage forms has been accompanied by a reduction in anti-tumor potency. Despite these limitations, camptothecins are becoming standard drugs in the treatment of advanced colon, lung and ovarian cancer. Worldwide sales for camptothecins exceeded $970 million in 2002.

Linking a camptothecin to PG renders it water soluble, and animal studies suggest that it permits up to 400% more drug to be administered without an increase in toxicity. PG-CPT showed significantly enhanced anti-tumor activity in animal models of lung, colon and breast cancer, with up to 500% improvement over the free drug. We have optimized a polyglutamate camptothecin for clinical development and filed an IND in December 2001. A phase I clinical trial of PG-CPT in patients with advanced cancers was initiated in the first quarter of 2002, and we plan to initiate another trial in the second half of 2003.

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Collaboration and Licensing Arrangements

PG-TXL Company, L.P. On June 30, 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 upon our entering a licensing agreement for CT-2103 with Chugai Pharmaceutical Co., Ltd. We made payments of $3.0 million during 2002 and a $2.0 million payment in 2000. The aggregate amount of future milestone payments we may be required to pay pursuant to the PG-TXL agreement is $15.5 million. These additional payments may become due upon future milestones, such as trial commencements and completions, filings and regulatory approvals.

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 a $3.0 million initial payment. Under the agreement, we may also receive future milestone payments totaling up to $13.0 million upon Chugai s achievement of certain product development milestones, and we are entitled to receive royalties on product sales in the territories covered under the agreement. We received a $3.0 million milestone payment and approximately $1.9 million in development expenditure reimbursements from Chugai during 2002. Chugai has also committed up to $54 million in 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.

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 (arsenic trioxide) injection in Japan, South Korea, and Taiwan. Upon execution of the agreement, Nippon paid us a $750,000 initial payment. Under the agreement, we may also receive future milestone payments totaling up to $4.0 million upon attainment of certain regulatory achievements.

Patents and Proprietary Rights

We dedicate significant resources to protecting our intellectual property. Through our acquisition of PolaRx, we obtained rights to four pending patent applications that, in the aggregate, cover dosage formulations, methods of administration and methods of use for various forms of arsenic trioxide and related compounds. We have exclusive rights to three issued U.S. patents and 21 U.S. and foreign pending patent applications relating to our polymer drug delivery technology. 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 thereunder 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

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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 members of our Scientific Advisory Board, 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 us 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. These manufacturers may not meet our requirements for quality, quantity or timeliness.

We will need to develop additional manufacturing resources, and may seek to enter into additional collaborative arrangements with other parties that have established manufacturing capabilities or may elect to have a third party manufacture our products on a contract basis. We have agreements with third party vendors to furnish TRISENOX, XYOTAX and PG-CPT 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 will receive supply through early 2004. We will be dependent upon these third parties to supply us 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. Contract manufacturers may violate cGMPs, and the FDA has recently intensified its oversight of drug manufacturers. The FDA may take action against a contract manufacturer who violates cGMPs. Such actions may include requiring the contract manufacturer to cease its manufacturing activities.

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 are marketing TRISENOX with our direct sales force in the U.S. consisting of one national account manager, five regional business directors, and 39 field based oncology account managers. We are using a combination of our own regional sales personnel and contract sales personnel to support the commercialization outside of the U.S.

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. 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 significant 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

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commercial sales of their products before their competitors may achieve a significant competitive advantage if their products work through a similar mechanism as our products. Accordingly, we do not believe competition is as intense among products that treat cancer through novel delivery or therapeutic mechanisms. 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.

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 the 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 U.S. until the drug has received FDA approval. The steps required before a drug may be marketed in the U.S. include:

- preclinical laboratory tests, animal studies, and formulation studies,
- submission to the FDA of an investigational new drug application, or 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.

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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, the Company 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.

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.

Before approving an NDA, the FDA usually will inspect the facility or the facilities at which 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, manufacturing changes, or additional labeling claims are subject to further FDA review and approval.

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

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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. After the FDA grants orphan drug designation, 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 an 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, and AML. 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 us from marketing our products for specified indications for some time.

Non-United States 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.

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Employees

As of February 28, 2003, we employed 286 individuals, including 83 holding doctoral or other advanced degrees. Our employees do not have a collective bargaining agreement. We consider our relations with our employees to be good.

Scientific Advisory Board and Clinical Advisors

We have a Scientific Advisory Board that consists of recognized scientists with expertise in the fields of immunology, cell and molecular biology, and synthetic and medical chemistry. Our Scientific Advisory Board meets with our management and key scientific employees on a semi-annual basis and in smaller groups or individually from time to time on an informal basis. The members assist us in identifying scientific and product development opportunities, reviewing with management the progress of our specific projects and recruiting and evaluating our scientific staff. We also have clinical advisors that assist us from time to time on clinical matters.

The following are members of our Scientific Advisory Board:

Lewis Cantley, Ph.D., is a noted authority in cellular biochemical signaling pathways that employ phosphatidyl inositol and its metabolites and is the discoverer of one of the most critical enzymes in those pathways, the PI3 Kinase. He is currently Professor of Cell Biology at Harvard Medical School and Chief of the Division of Signal Transduction in the Department of Medicine, Beth Israel Hospital, Boston and the author of over 180 publications.

Edward A. Dennis, Ph.D., is Professor and Vice Chair for Medical Biochemistry and former Chair of the Department of Chemistry and Biochemistry at the University of California, San Diego. He is a noted authority on phospholipases, cell signaling and phospholipid metabolism. Dr. Dennis serves as Chair of the Board of Directors and President of the Keystone Symposia on Cell and Molecular Biology. He has served as President of the Association of Medical and Graduate Departments of Biochemistry and as Chair of the Publications Committee and of the Meetings Committee of the American Society for Biochemistry and Molecular Biology. In 2000, he was the recipient of the prestigious Avanti Award for research in lipid enzymology. In July 2003, he will become editor of the Journal of Lipid Research. He has over 250 publications and numerous patents in the lipid area.

Mike Gelb, Ph.D., is Professor of Chemistry and Adjunct Professor of Biochemistry at the University of Washington. He has developed techniques for structure-based drug design and clinical assays of enzymes to identify genetic defects. He is a noted authority on lipid enzymes. Dr. Gelb is the recipient of the Pfizer Award in Enzyme Chemistry and the ICI Pharmaceuticals Award for Excellence in Chemistry and the author of more than 200 manuscripts.

Edwin Krebs, M.D., is a Professor Emeritus, Department of Pharmacology and Biochemistry, at the University of Washington in Seattle and a Senior Investigator Emeritus at the Howard Hughes Medical Institute. He is a recognized authority on mechanisms of action of second messengers, including protein kinases and phosphorylation reactions. He is the recipient of numerous awards and honors and has authored 297 manuscripts. In 1992, Dr. Krebs was awarded the Nobel Prize in Physiology of Medicine for his work on second messenger pathways.

L. Jackson Roberts, II, M.D., is an internationally recognized authority on the oxidative metabolism of polyunsaturated fatty acids. He is known for having identified PGD2 on the major mast cell lipid mediator and, more recently, for having originated the field of studying non enzymatically generated prostanoids, including the isprostanes and neuroprostanes, and newly discovered products of lipid peroxidation, isofurans. He is currently Professor of Pharmacology and Medicine at Vanderbilt University and is the author of over 283 publications.

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Julian Simon, Ph.D., is an Associate Member, Clinical Research and Human Biology Divisions, at the Fred Hutchinson Cancer Research Center in Seattle and is Affiliate Associate Professor of Chemistry at the University of Washington. He is a member of the Experimental Therapeutics Study Section and Special Emphasis Panel of the National Cancer Institute. His research is focused on application of chemical genetics to the discovery of mechanistically novel anticancer agents.

The following are our retained Clinical Advisors:

E. Donnall Thomas, M.D., is the former Associate Director of Clinical Research and presently a Professor Emeritus at the Fred Hutchinson Cancer Research Center, of which he was a founding member. His research has spanned a wide array of fields from radiation biology to developmental immunology, and from cancer causing genes to gene transfer therapies. For his pioneering work in bone marrow transplant, Dr. Thomas was awarded the Nobel Prize for Medicine in 1990. Among the other honors awarded to Dr. Thomas in recognition of his medical research are the American Cancer Society Award for Distinguished Service in Basic Research and the Kettering Prize of the General Motors Cancer Research Foundation. He is a member of the U.S. Academy of Sciences.

Steven Soignet, M.D., is the Vice President and co-founder of the Arcus Group, a healthcare information consulting company. He held a faculty appointment in the Developmental Chemotherapy Service, Memorial Sloan-Kettering Cancer Center, and in the Department of Medicine, Cornell University Medical Center. Dr. Soignet s research primarily has focused on early phase clinical drug development in both hematologic and solid tumors. He is a member of the American College of Physicians, the American Association of Cancer Research, the American Society of Hematology, and the American Society of Clinical Oncology.

In addition to selected retained experts, an Ad Hoc advisory board approach has been taken by us to avail ourselves to the broadest expertise in a given oncologic disease. We have convened disease specific advisory boards in the U.S. as well as in Europe to take advantage of the differences in clinical practice as well as regulatory requirements between these different territories. This allows us to plan for registration of our drugs in multiple markets.

Factors Affecting Our Operating Results

This amended annual report on Form 10-K /A 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 amended annual report on Form 10-K/A.

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

We were incorporated in 1991 and have incurred a net operating loss every year. As of December 31, 2002, we had an accumulated deficit of approximately $340.5 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 several years. 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 additional revenue.

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 and PG-CPT, are currently in clinical trials. These clinical trials of the drug candidates involve the testing of potential therapeutic agents, or effective treatments, in humans in three phases to determine the safety and efficacy of the drug

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candidates necessary for an approved drug. 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. 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. As a result, we are no longer developing lisofylline as a potential product. In addition, 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. The clinical trials of TRISENOX, XYOTAX and PG-CPT or any of our future drug candidates may not be successful.

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. We are dependent on the successful completion of clinical trials and obtaining regulatory approval 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.

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 relapsed or refractory APL, all of our compounds currently are in research or development, and none has been submitted for marketing approval. Our other compounds may not enter human clinical trials on a timely basis, if at all, and we may not develop any product candidates suitable for commercialization. Prior to commercialization, each product candidate will require significant additional research, development and preclinical testing and extensive clinical investigation before submission of any regulatory application for marketing approval. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons. Potential products may:

- be found ineffective or cause harmful side effects during preclinical testing or clinical trials,
- fail to receive necessary regulatory approvals,
- be difficult to manufacture on a large scale,
- be uneconomical to produce,
- fail to achieve market acceptance, or
- be precluded from commercialization by proprietary rights of third parties.

Our product development efforts or our collaborative partners efforts may not be successfully completed and we may not obtain required regulatory approvals. Any products, if introduced, may not be successfully marketed nor achieve customer acceptance.

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

We base many of our product candidates upon novel delivery technologies that we are using to discover and develop drugs for the treatment of cancer. This technology has not been proven. Furthermore, preclinical results in animal studies may not predict outcome in human clinical trials. Our product candidates may not be proven safe or effective. If this technology does not work, our drug candidates may not develop into commercial products.

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We may not complete our clinical trials in the time expected, which could delay or prevent the commercialization of our products.

Although for planning purposes we forecast the commencement and completion of clinical trials, the actual timing of these events can vary dramatically due to factors such as delays, scheduling conflicts with participating clinicians and clinical institutions and the rate of patient enrollment. Clinical trials involving our product candidates may not commence nor be completed as forecasted. We have limited experience in conducting clinical trials. In certain circumstances we rely on academic institutions or clinical research organizations to conduct, supervise or monitor some or all aspects of clinical trials involving our products. In addition, certain clinical trials for our products will be conducted by government-sponsored agencies and consequently will be dependent on governmental participation and funding. We will have less control over the timing and other aspects of these clinical trials than if we conducted them entirely on our own. These trials may not commence or be completed as we expect. They may not be conducted successfully. Failure to commence or complete, or delays in, any of our planned clinical trials could delay or prevent the commercialization of our products and harm our business.

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

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

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

protect trade secrets, and

prevent others from infringing on our proprietary rights.

In particular we believe that linking our polymers to existing drugs may yield patentable subject matter. We do not believe that our polymer-drug conjugates will infringe any valid third-party patents covering the underlying drug. However, we may not receive a patent for our polymer conjugates and we may be challenged by the holder of a patent covering the underlying drug.

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 U.S. and the risk of infringement litigation may increase. If it allows narrow claims, the risk of infringement may decrease, but the value of our rights under our patents, licenses and patent applications may also decrease.

Patent applications in which we have rights may never issue as patents and the claims of any issued patents may not afford meaningful protection for our technologies or products. In addition, patents issued to us or our licensors may be challenged and subsequently narrowed, invalidated or circumvented. Litigation, interference proceedings or other governmental proceedings that we may become involved in with respect to our proprietary technologies or the proprietary technology of others could result in substantial cost to us. Patent litigation is widespread in the biotechnology industry, and any patent litigation could harm our business. Costly litigation might be necessary to protect our

orphan drug designations or patent position or to determine the scope and validity of third party proprietary rights, and we may not have the required resources to pursue such litigation or to protect our patent rights. An adverse outcome in litigation with respect to the validity of any of our patents 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

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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.

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

Patents issued to third parties may cover our products as ultimately developed. We may need to acquire licenses to these patents or challenge the validity of these patents. We may not be able to license any patent rights on acceptable terms or successfully challenge such patents. The need to do so will depend on the scope and validity of these patents and ultimately on the final design or formulation of the products and services that we develop.

We have licensed intellectual property, including patent applications from The Memorial Sloan Kettering Cancer Center, Samuel Waxman Cancer Research Foundation, Beijing Medical University and others, including the intellectual property directed to arsenic drugs and TRISENOX. We have also in-licensed the intellectual property relating to our polymer drug delivery technology, including XYOTAX. 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 those licenses. We may not be able to meet our obligations under these licenses. If we default under any of these license agreements, we may lose our right to market and sell any products based on the licensed technology.

Our products could infringe on the intellectual property rights of others, which may cause us to engage in costly litigation and, if we are not successful, could cause us to pay substantial damages and prohibit us from selling our products.

Although we attempt to monitor the patent filings of our competitors in an effort to guide the design and development of our products to avoid infringement, third parties may challenge the patents that have been issued or licensed to us. We may have to pay substantial damages, possibly including treble damages, for past infringement 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. Even if infringement claims against us are without merit, defending a lawsuit takes significant time, may be expensive and may divert management attention from other business concerns.

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 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 will 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.

If we fail to keep pace with rapid technological change in the biotechnology and pharmaceutical industries, our products could become obsolete.

Biotechnology and related pharmaceutical technology have undergone and are subject to rapid and significant change. We expect that the technologies associated with biotechnology research and development will continue to develop rapidly. Our future will depend in large part on our ability to maintain a competitive position with respect to these technologies. Any compounds, products or processes that we develop may become obsolete before we recover any expenses incurred in connection with developing these products.

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

The biotechnology and pharmaceutical industries are intensely competitive. We have numerous competitors in the United States and elsewhere. Our competitors include major, multinational pharmaceutical and chemical companies, specialized biotechnology firms and universities and other research institutions. Many of these competitors have greater financial and other resources, larger research and development staffs and more effective marketing and manufacturing organizations, than we do. In addition, academic and government institutions have become increasingly aware of the commercial value of their research findings. These institutions are now more likely to enter into exclusive licensing agreements with commercial enterprises, including our competitors, to market commercial products.

Our competitors may succeed in developing or licensing technologies and drugs that are more effective or less costly than any we are developing. Our competitors may succeed in obtaining FDA or other regulatory approvals for drug candidates before we do. In particular, we face direct competition from many companies focusing on delivery technologies. Drugs resulting from our research and development efforts, if approved for sale, may not compete successfully with our competitors existing products or products under development.

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 and the interest earned thereon will enable us to maintain our planned operations through at least mid 2004. Beyond that time, if our capital resources are insufficient to meet future capital requirements, we will have to raise additional funds to continue the development of our technologies and complete the commercialization of products, if any, resulting from our technologies. We will require substantial funds to: (1) continue our research and development programs, (2) in-license or acquire additional technologies, (3) conduct preclinical studies and clinical trials and (4) launch new drug products. We may need to raise additional capital to fund our operations repeatedly. We may raise such capital through public or private equity financings, partnerships, debt financings, bank borrowings, or other sources. Our capital requirements will depend upon numerous factors, including the following:

- the establishment of additional collaborations,
- the development of competing technologies or products,
- changing market conditions,
- the cost of protecting our intellectual property rights,
- the purchase of capital equipment,
- the progress of our drug discovery and development programs, the progress of our collaborations and receipt of any option/license, milestone and royalty payment resulting from those collaborations, and
- in-licensing and acquisition opportunities.

Additional funding may not be available on favorable terms or at all. If adequate funds are not otherwise available, we may curtail operations significantly. 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, you may experience dilution of your proportionate ownership of the company.

Our stock price is extremely volatile, which may affect our ability to raise capital in the future.

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

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volume fluctuations that are unrelated to the operating performance of such companies. For example, during the twelve months ended December 31, 2002, our stock price has ranged from a low of $2.68 to a high of $27.45. Fluctuations in the trading price or liquidity of our common stock may adversely affect our ability to raise capital through future equity financings.

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 preclinical testing and clinical trials,
- developments or disputes concerning patent or other proprietary rights,
- developments in our relationships with collaborative partners,
- acquisitions,
- litigation,
- 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 health care policies and practices,
- economic and other external factors, and
- general market conditions.

In the past, following periods of volatility in the market price of a company s securities, securities class action litigation has often been instituted. 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.

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

Paclitaxel is derived from certain varieties of yew trees. Supply of yew trees is tightly controlled by a limited number of companies. We cannot be sure that we will be able to continue to purchase the materials necessary to produce XYOTAX in adequate volume and quality. We purchase the majority of the paclitaxel we need from a single vendor. Should the paclitaxel purchased from this source prove to be insufficient in quantity or quality, or should this relationship terminate, there can be no assurance that we will be able to enter into a similar agreement with an alternate source.

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

We currently do not have internal facilities for the manufacture of any of our products for clinical evaluation or commercial production. In addition, TRISENOX, our first commercial product, is currently manufactured by a single vendor. In 2002, we began the process of transitioning our finished product manufacturing for TRISENOX to a new additional supplier. We believe that this additional supplier will receive FDA approval to manufacture

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TRISENOX in the second half of 2003. If this approval is not received and we are unable to obtain supply from our current vendor, we may not have sufficient supply to meet our future sales demand. We will need to develop additional manufacturing resources, enter into collaborative arrangements with other parties that have established manufacturing capabilities or elect to have other third parties manufacture our products on a contract basis. We are dependent on such collaborators or third parties to supply us in a timely way with products manufactured in compliance with standards imposed by the FDA and foreign regulatory authorities. The manufacturing facilities of contract manufacturers may not comply with applicable manufacturing regulations of the FDA nor meet our requirements for quality, quantity or timeliness. Another of our products under development, XYOTAX, is complex to manufacture, which may prevent us from obtaining a sufficient supply for the increased clinical trials that are currently planned or underway.

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 the experience required and 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 lose our key personnel or 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 Dr. James A. Bianco, our Chief Executive Officer, and Dr. Jack W. Singer, our Executive Vice President, Research Program Chairman. The loss 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 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 rely on consultants and advisors, including our scientific and clinical advisors, to assist us in formulating our research and development strategy. All of our consultants and advisors are employed by other employers or are self-employed, and have commitments to or consulting or advisory contracts with other entities that may limit their availability to us.

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

The FDA has approved only one of our products, TRISENOX, for sale in the United States, for relapsed or refractory APL. Before we can market TRISENOX for other indications, we must obtain FDA approval. Our other products are in development, and will have to be approved by the FDA before they can be marketed in the United States. If the FDA does not approve our products and any additional indications for marketed products in a timely fashion, or does not approve them at all, our business and financial condition may be adversely affected.

In addition, we and our products are subject to comprehensive regulation by the FDA both before and after products are approved for marketing. The FDA regulates, for example, research and development, including preclinical and clinical testing, safety, effectiveness, manufacturing, labeling, advertising, promotion, export, and marketing of our products. Our failure to comply with regulatory requirements may result in various adverse consequences including FDA delay in approving or refusal to approve a product, recalls, withdrawal of an approved product

from the market, and/or the imposition of civil or criminal sanctions.

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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.

Uncertainty regarding third party reimbursement and health care cost containment initiatives may limit our returns.

The ongoing efforts of governmental and third party payors to contain or reduce the cost of health care will affect our ability to commercialize our products successfully. Governmental and other third party payors are increasingly attempting to contain health care costs by:

- challenging the prices charged for health care products and services,
- limiting both coverage and the amount of reimbursement for new therapeutic products,
- denying or limiting coverage for products that are approved by the FDA but are considered experimental or investigational by third-party payors, and
- 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.

In addition, the trend toward managed health care 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.

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. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the adoption of such 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.

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

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

Certain of our research and development activities involve animal testing. Such activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas. 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.

Because our charter documents contain certain anti-takeover provisions and we have a rights plan, it may be more difficult for a third party to acquire us, and the rights of some shareholders could be adversely affected.

Our Restated Articles of Incorporation and Bylaws contain provisions that may make it more difficult for a third party to acquire or make a bid for us. These provisions could limit the price that certain investors might be willing to pay in the future for shares of our common stock. In addition, shares of our preferred stock may be issued in the future without further shareholder approval and upon such terms and conditions and having such rights, privileges and preferences, as the board of directors may determine. The rights of the holders of common stock will be subject to, and may be adversely affected by, the rights of any holders of preferred stock that may be issued in the future. The issuance of preferred stock, while providing desirable flexibility in connection with possible acquisitions and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from acquiring, a majority of our outstanding voting stock. We have no present plans to issue any additional shares of preferred stock. In addition, we have adopted a shareholder rights plan that, along with certain provisions of our Restated Articles of Incorporation, may have the effect of discouraging certain transactions involving a change of control of the company.

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 a 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. 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 currently anticipate that additional space will be available to us, when needed, on commercially reasonable terms.

Item 3. Legal Proceedings

We are not a party to any material legal proceedings.

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, 2002.

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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. 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.

	High	Low
2001		
First Quarter	49.00	12.50
Second Quarter	34.81	14.50
Third Quarter	32.63	20.18
Fourth Quarter	34.70	22.50
2002		
First Quarter	27.45	19.31
Second Quarter	25.50	4.57
Third Quarter	5.89	2.68
Fourth Quarter	9.85	3.85
2003		
First Quarter (through March 24, 2003)	8.89	5.18

On March 24, 2003, the last reported sale price of our common stock on the Nasdaq Market was $8.73 per share. As of March 24, 2003, there were approximately 264 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.

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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, 2002, including the 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	5,714,295(1)	$ 16.21	945,690(2)	6,659,985
Plans Not Approved by Shareholders	702,790(3)	$ 15.41	None	702,790

(1) Consists of the 1994 Equity Incentive Plan.
(2) Consists of 775,582 shares available for future issuance under the 1994 Equity Incentive Plan and 170,108 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 149,125 shares issued to placement agents in connection with private placements of our stock, and warrants to purchase 100,000 shares issued in connection with a research services agreement with The Hope Heart Institute.

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

In 1998, we issued 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.

Warrants Issued to Placement Agents

In 1999, we completed a $10 million private placement of 10,000 shares of Series D convertible preferred stock and warrants to acquire 1,523,810 shares of common stock. In connection with the offering, we issued warrants to purchase shares of common stock to a placement

agent. These warrants expire in 2004, and have an exercise price of $2.38.

In 2000, we completed a $40 million private placement of 3,333,334 shares of common stock. In connection with the offering, we issued warrants to purchase shares of common stock to a placement agent and finder. These warrants expire in 2005, and have an exercise price of $13.20.

Research Services Agreement with The Hope Heart Institute

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 shares of common stock at an exercise price of $10.00. These warrants expire in 2007.

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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,				
	2002	2001	2000	1999	1998
	(In thousands, except per share data)				
Consolidated Statements of Operations Data:					
Revenues:					
Product sales	$ 11,393	$ 6,130	$ 502	$	$
License and contract revenue	5,503	106			13,200
Total revenues	16,896	6,236	502		13,200
Operating expenses:					
Cost of product sold	423	394	19		
Research and development(1)	58,759	44,669	26,574	27,682	29,942
Selling, general and administrative	49,800	35,268	20,421	9,788	10,889
Amortization of purchased intangibles	6,701	9,390	9,390		
Total operating expenses	115,683	89,721	56,404	37,470	40,831
Loss from operations	(98,787)	(83,485)	(55,902)	(37,470)	(27,631)
Other income (expense):					
Investment income	4,819	9,200	4,517	1,692	3,094
Interest expense	(11,240)	(5,988)	(544)	(502)	(435)
Gain on exchange of convertible subordinated notes	55,305				
Net loss	(49,903)	(80,273)	(51,929)	(36,280)	(24,972)
Preferred stock dividend		(1,372)	(508)	(5,201)	
Net loss applicable to common shareholders	$ (49,903)	$ (81,645)	$ (52,437)	$ (41,481)	$ (24,972)
Basic and diluted net loss per common share(2)	$ (1.48)	$ (2.41)	$ (2.07)	$ (2.67)	$ (1.62)
Shares used in computation of basic and diluted net loss per common share	33,763	33,822	25,345	15,552	15,410

	December 31,				
	2002	2001	2000	1999	1998
	(In thousands)				

Consolidated Balance Sheets Data:					
Cash, cash equivalents, securities available-for-sale and interest receivable	$ 142,157	$ 259,421	$ 156,434	$ 24,248	$ 47,072
Working capital	129,849	250,142	146,384	17,705	44,143
Total assets	186,780	303,750	190,111	30,848	58,156
Convertible senior subordinated notes	85,500				
Convertible subordinated notes	29,600	175,000			
Other long-term obligations, less current portion	6,704	3,892	1,060	2,653	3,888
Total long-term obligations, less current portion	121,804	178,892	1,060	2,653	3,888
Accumulated deficit	(340,455)	(290,552)	(210,279)	(158,350)	(122,070)
Total shareholders equity	43,483	109,557	177,943	20,904	47,165

(1) Amount in 2001 includes an equity-based expense of $9.2 million related to the issuance of 350,000 warrants for the achievement of a XYOTAX milestone.

(2) See Notes 1 and 10 of Notes to Consolidated Financial Statements for a description of the computation of the number of shares and net loss per common share.

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

The following discussion should be read in conjunction with the Selected Financial Data and the Consolidated Financial Statements and the related Notes included in Items 6 and 8 of this Form 10-K/A. The following discussion contains forward-looking statements that involve risks and uncertainties. Such statements, which include statements concerning 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/A, particularly in Factors Affecting Our Operating Results, that could cause actual results to differ significantly from those projected.

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 oncology 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, 2002, we had incurred aggregate net losses of approximately $340.5 million since inception. We expect to continue to incur significant additional operating losses over the next several years from our research and development efforts.

XYOTAX

In June 1998, we entered into an agreement with PG-TXL Company, L.P. and scientists at the M.D. Anderson Cancer Center, granting us an exclusive worldwide license to the rights to PG-TXL, and to all potential uses of PG-TXL s polymer technology. PG-TXL 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. We will be obligated to make future milestone payments upon the attainment of significant achievements, as defined in the agreement, of up to $15.5 million, and royalty payments on net product sales. As of December 31, 2002, we have made $5.0 million in milestone payments.

In September 2001, we entered into a supply agreement with Natural Pharmaceuticals, Inc. for paclitaxel, a key starting material for our XYOTAX drug candidate. Under the supply agreement, we purchased paclitaxel at a pre-determined price and will receive supply through early 2004.

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 a $3.0 million initial payment, which has been recorded as deferred revenue and is being recognized as license revenue over the development period on a straight-line basis. Under the agreement, we may also receive future milestone payments totaling up to $13.0 million upon Chugai s achievement of certain product development milestones, and we are entitled to receive royalties on product sales in the territories covered under the agreement. We received and recognized as revenue a $3.0 million milestone payment and approximately $1.9 million in development expenditure reimbursements from Chugai during 2002. Chugai has also committed to incur up to $54.0 million in development expenditures over the course of the licensing agreement. During 2002, we initiated a XYOTAX phase III clinical trial for second-line treatment of non-small cell lung cancer, and two additional phase III trials of XYOTAX in the front line treatment of poor performance status patients with non-small cell lung cancer.

In November 2002, we announced that the Gynecologic Oncology Group, or GOG, plans to conduct a phase III trial of XYOTAX in front-line treatment of ovarian cancer. This trial is expected to begin in late 2003. We had initiated a XYOTAX phase III ovarian clinical trial in July 2002, but have since closed this trial as a result of the GOG s decision to conduct the trial for us.

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TRISENOX

In January 2000, we acquired TRISENOX upon our acquisition of PolaRx Biopharmaceuticals, Inc., or PolaRx, a single product company that owned the rights to TRISENOX. The aggregate purchase price of approximately $36.2 million consisted primarily of five million shares of common stock and included assumed net liabilities of $3.9 million from PolaRx. In connection with the achievement of a $10 million sales threshold, we recorded $4.0 million in additional goodwill and a current liability as of December 31, 2002, which we will pay in cash in 2003. An additional $5.0 million payout tied to a sales threshold of $20 million in any four consecutive quarters is payable in cash or common stock with a market value of $5 million, within thirty days following the end of the first calendar quarter after the end of the previous four calendar quarter period in which such threshold is achieved. For any calendar year that sales of TRISENOX exceed $40 million, PolaRx shareholders will receive a 2% royalty on total net sales for that year payable in cash or common stock at the then fair market value of our common stock, payable within thirty days following the end of the calendar year. The acquisition was accounted for as a purchase transaction. Any additional or contingent payments made to PolaRx shareholders will be considered additional purchase price and will be capitalized as additional goodwill.

In September 2000, we received approval of our New Drug Application, or NDA, by the Food and Drug Administration, or FDA, for TRISENOX (arsenic trioxide), commenced sales in October 2000 and have recorded cumulative net product sales for TRISENOX of approximately $18.0 million through December of 2002. In March 2002, we received from the European Agency for the Evaluation of Medicinal Products, or EMEA, approval to market TRISENOX in the European Community, or EU. We commenced the launch and sale of TRISENOX in the EU during the second quarter of 2002. TRISENOX is manufactured primarily by a single vendor 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 (arsenic trioxide) injection in Japan, South Korea, and Taiwan. Upon execution of the agreement, Nippon paid us a $750,000 initial payment, which we recorded as deferred revenue and which is being recognized as revenue over the performance period on a straight-line basis. Under the agreement, we may also receive future milestone payments totaling up to $4.0 million upon attainment of certain achievements.

Other Compounds

We are developing a novel polyglutamate-camptothecin molecule, or PG-CPT. We filed a U.S. investigational new drug application, or IND, in December 2001 for this compound, and initiated a phase I clinical study in the first quarter of 2002.

We have identified a novel drug target called lysophosphatidic acid acyltransferase, or LPAAT-ß, that when inhibited has been shown to reduce tumor cell growth in preclinical models. We are in the process of identifying a lead candidate for clinical development during 2003.

Critical Accounting Policies

In December 2001, the SEC requested that all registrants discuss their most *critical accounting policies* in management s discussion and analysis of financial condition and results of operations. The SEC indicated that a *critical accounting policy* is one which is both important to the

portrayal of the company s financial condition and results and requires management s most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. While our significant accounting policies are more fully described in Note 1 to our consolidated financial statements included in this report, we believe the following accounting policies to be critical:

License Agreement Revenues

We may generate revenue from technology licenses, collaborative research and development arrangements, and cost reimbursement contracts. Revenue under technology licenses and collaborative agreements typically

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

Product Sales

We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, 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 based on historical experience. In estimating returns, we analyze historical returns, sales patterns, current inventory on hand at the distributors and the remaining shelf life of that inventory. In arriving 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 discounts, returns and bad debts are netted against accounts receivable.

Inventory

Inventory is stated at the lower of cost or market. Cost is determined using a weighted-average approach that approximates the first-in first-out method. Finished goods inventory consists of our FDA-approved pharmaceutical drug, TRISENOX. Prior to FDA approval, the raw material and production costs of TRISENOX were recorded as research and development expense. 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 related salaries and benefits, clinical trial and related clinical 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 investigator and company sponsored clinical trials, production of clinical supplies and regulatory costs associated with product registries. Research and development costs are expensed as incurred. In instances where we enter into agreements with third parties for research and/or clinical trial activities, costs are expensed upon the earlier of when amounts are due or when services are performed.

Derivative Financial Instruments

Effective at the beginning of fiscal 2001, we adopted 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 the derivative instrument that is effective as a hedge is reported as a component of accumulated other comprehensive income or loss in shareholders equity and is reclassified into earnings in the

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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, 2002 and 2001. We do not enter into forward agreements for trading purposes.

Results of Operations

Years ended December 31, 2002 and 2001.

Product sales. TRISENOX is our pharmaceutical grade arsenic product that has been approved by the FDA to treat patients with relapsed or refractory acute promyelocytic leukemia. We recorded net product sales of approximately $11.4 million and $6.1 million for TRISENOX for the years ended December 31, 2002 and 2001, respectively. The increase in net sales is primarily due to greater demand for our product in 2002. We expect our net sales to increase in 2003.

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 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 six years on a straight-line basis. In December 2002, we entered into a distribution agreement with Nippon Shinyaku Co., Ltd., or Nippon, for the distribution and commercialization of TRISENOX. We received $750,000 upon execution of the agreement which we recorded as deferred revenue and which is being recognized as revenue on a straight-line basis over the estimated time to receive marketing authorization application approval. For the year ended December 31, 2002, we recognized approximately $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, 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, 2002 and 2001 was approximately $423,000 and $394,000, respectively. Our gross margins have improved mainly due to lower charges for excess inventory in 2002. 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. We expect product costs in the future to continue to approximate a small percentage of revenue.

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

	2002	2001
Compounds under development:		
XYOTAX	$ 26,193	$ 18,345
TRISENOX	5,225	3,244
Other compounds	2,804	2,845
Operating expenses	14,099	10,428
Discovery research	10,438	9,807

Total research and development expenses	$ 58,759	$ 44,669

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 to the FDA or similar regulatory filings with agencies outside the U.S. Operating costs include our

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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.

Research and development expenses increased to approximately $58.8 million for the year ended December 31, 2002, from approximately $44.7 million for the year ended December 31, 2001. Costs for our XYOTAX program increased primarily due to approximately $11.9 million of clinical and manufacturing costs associated with the set up and initiation of phase III clinical trials as well as several other clinical trials, approximately $3.3 million of preclinical and quality assurance development costs related to our agreement with Chugai and $2.0 million in milestone payments to PG-TXL Company, L.P. for completion of our phase II clinical trial and the filing of the first IND application in Japan. These increases were offset in part by a $9.2 million decrease in an equity-based development expense related to the vesting of 350,000 warrants upon the achievement of a milestone in 2001. TRISENOX costs increased due to approximately $2.5 million of medical affairs, manufacturing, quality assurance and clinical expenses associated with ongoing clinical trials offset by reduced costs of approximately $.9 million of regulatory and preclinical expenses. Costs incurred for other compounds in 2002 included a $1.0 million milestone payment for the commencement of our phase I clinical trial for PG-CPT, offset by lower expenses due to the discontinued clinical development of CT-2584 during 2001. We also incurred additional personnel and operating expenses of approximately $3.7 million related to our expanded development plans for XYOTAX, TRISENOX and PG-CPT. We anticipate increased research and development expenses in connection with our clinical development plans for XYOTAX and our other products.

Our leading drug candidates, XYOTAX and TRISENOX for indications other than relapsed or refractory acute promyelocytic leukemia, 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. 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. We are dependent on the successful completion of clinical trials and obtaining regulatory approval 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. Because of these risks and uncertainties, we cannot predict when or whether we will successfully complete the development of our product candidates or the ultimate product development cost.

Selling, general and administrative expenses. Selling, general and administrative expenses increased to approximately $49.8 million for the year ended December 31, 2002, from approximately $35.3 million for the year ended December 31, 2001. This increase is primarily attributed to approximately $5.9 million of additional personnel, operating and occupancy costs associated with supporting our research, development and marketing activities and our expanded corporate communication program, $5.6 million of lease, maintenance and operating costs for our leased aircraft, $4.8 million of additional sales personnel and marketing costs for TRISENOX, offset in part by an approximate $1.8 million reduction in stock-based compensation. We expect selling, general and administrative expenses to increase in the future to support our expected increase in research, development and commercialization efforts. Additionally, due to the variable accounting treatment of certain stock options, fluctuations in quoted prices for our common stock may result in unpredictable and potentially significant charges or credits to our stock-based compensation.

Amortization of acquisition related intangibles. In January 2000, we acquired PolaRx Biopharmaceuticals, Inc., which was accounted for using the purchase method of accounting. Our intangible assets are amortized over their remaining lives, estimated to be three to five years. Amortization for the year ended December 31, 2002 was approximately $6.7 million compared to approximately $9.4 million for the year ended December 31, 2001.

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This $2.7 million decrease is due to our adoption of SFAS 142, *Goodwill and Other Intangible Assets*, which we adopted January 1, 2002. Upon adoption, we performed the following steps:

On January 1, 2002, we ceased amortization of the net goodwill balance of $8.1 million. Accordingly, there are no charges for the amortization of goodwill in 2002 or thereafter;

We completed our transitional goodwill impairment test and based on our analysis, determined that no goodwill impairment had occurred as of January 1, 2002. In addition, we will be required to perform an annual impairment test, which we will perform in the fourth quarter of each year. During the fourth quarter of 2002, we completed our annual impairment test and determined that our goodwill had not been impaired;

The net book value of goodwill will be reviewed for impairment annually and whenever there is an indication that the value of the goodwill may be impaired. Any resulting impairment will be recorded in the income statement in the period it is identified and quantified;

Other intangibles resulting from the acquisition will continue to be amortized. The net book value of these intangibles at December 31, 2002 was approximately $2.7 million.

Investment income. Investment income decreased to approximately $4.8 million for the year ended December 31, 2002 from approximately $9.2 million for the year ended December 31, 2001. This decrease is attributed primarily to lower prevailing interest rates on our securities available-for-sale during the year ended December 31, 2002.

Interest expense. Interest expense increased to approximately $11.2 million for the year ended December 31, 2002 from approximately $6.0 million for the year ended December 31, 2001. The increase is attributable to the interest associated with the $175.0 million of 5.75% convertible subordinated notes issued in the second and third quarters of 2001.

Gain on exchange of convertible notes. 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 fair value of the new notes less debt issue costs of $4.6 million attributable to the exchanged notes. As of December 31, 2002, we had $29.6 million of original convertible subordinated notes outstanding, and $85.5 million of new convertible senior subordinated notes outstanding.

Income Taxes

As of December 31, 2002, we had available for Federal income tax purposes net operating loss carryforwards of approximately $345.1 million, of which $44.2 million relates to stock option deductions, and approximately $11.4 million relates to research and development credit carryforwards. These carryforwards begin to expire in 2007. Our ability to utilize these net operating loss and research and development credit carryforwards is subject to annual limitations of $6.7 million for losses incurred prior to March 26, 1997 and may be subject to additional limitations thereafter pursuant to the change in ownership rules under Section 382 of the Internal Revenue Code of 1986.

Years ended December 31, 2001 and 2000.

Product sales. In October 2000, we launched TRISENOX, a pharmaceutical grade arsenic product that has been approved by the FDA to treat patients with relapsed or refractory acute promyelocytic leukemia. We recorded net product sales of approximately $6.1 million for TRISENOX for the year ended December 31, 2001 compared to the initial net product sales of approximately $502,000 for TRISENOX in the fourth quarter of 2000.

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License and contract revenue. In October 2001, we entered into a licensing agreement with Chugai Pharmaceutical Co., Ltd. for the development and commercialization of XYOTAX. 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 development period on a straight-line basis. We recognized $106,000 of revenue during 2001.

Cost of product sold. The cost of product sold for the year ended December 31, 2001 was approximately $394,000 compared to $19,000 for the fourth quarter of 2000. This increase was primarily due to increased sales of TRISENOX. Further, a reserve for obsolescence of approximately $96,000 was incurred in 2001. Cost of product sold consists primarily of manufacturing costs, allowance 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):

	2001	2000
Compounds under development:		
XYOTAX	$ 18,345	$ 5,247
TRISENOX	3,244	4,829
Other compounds	2,845	1,111
Operating expenses	10,428	6,621
Discovery research	9,807	8,766
Total research and development expenses	$ 44,669	$ 26,574

Research and development expenses increased to approximately $44.7 million for the year ended December 31, 2001 from approximately $26.6 million for the year ended December 31, 2000. This increase is primarily due to an equity-based expense of $9.2 million related to the vesting of 350,000 warrants upon the achievement of a XYOTAX milestone, an additional $6.0 million in direct expenses associated with the development of XYOTAX and PG-CPT and the recruitment of additional personnel and related occupancy costs of $5.0 million to support our expanded development plans for TRISENOX, XYOTAX and PG-CPT. This increase was offset in part by a reduction of stock-based compensation of $1.4 million and regulatory costs for TRISENOX of $1.1 million.

Selling, general and administrative. Selling, general and administrative expenses increased to approximately $35.3 million for the year ended December 31, 2001 from approximately $20.4 million for the year ended December 31, 2000. This increase is primarily attributed to approximately $7.8 million of additional sales personnel and marketing costs for TRISENOX, higher corporate resource development costs of approximately $4.9 million and additional general operating expenses associated with supporting our research, development and marketing activities of approximately $4.0 million, offset in part by an approximate $1.8 million reduction in stock-based compensation. Corporate resource development costs include our business development activities related to our continued pursuit to in-license or acquire complementary products or technologies, or companies, costs related to operating our aircraft, and our corporate communication programs.

Amortization of acquisition related intangibles. In January 2000, we acquired PolaRx Biopharmaceuticals, Inc. which was accounted for using the purchase method of accounting. We recorded acquired intangible assets for marketing, patents and goodwill aggregating $36.2 million. These intangible assets are amortized over their remaining lives, estimated to be three to five years. The amortization for the year ended

December 31, 2001 and 2000 was approximately $9.4 million. Effective January 1, 2002, we adopted SFAS 142 *Goodwill and Other Intangible Assets*. In accordance with this statement, goodwill will no longer be amortized and will be periodically tested for impairment.

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Investment income. Investment income increased to approximately $9.2 million for the year ended December 31, 2001 from approximately $4.5 million for the year ended December 31, 2000. This increase is attributed to higher average cash balances on hand during 2001 because we completed a secondary offering in September 2000, which generated net proceeds of $127.5 million and we completed a convertible debt offering in September 2001, which generated net proceeds of $168.0 million.

Interest expense. Interest expense increased to approximately $6.0 million for the year ended December 31, 2001 from approximately $544,000 for the year ended December 31, 2000. The increase is attributable to the interest associated with the $175.0 million of 5.75% convertible subordinated notes issued in 2001.

Preferred stock dividend. We accrued approximately $1.4 million and $508,000 for a preferred stock dividend for the years ended December 31, 2001 and 2000, respectively, in connection with preferred stock issued in November 1999. In 2001, we automatically converted any remaining preferred stock to common stock. In connection with this conversion, we accrued all future dividend payments due to these investors resulting in an increase of approximately $0.9 million in the preferred stock dividend for the year ended December 31, 2001. In 2001, we issued 20,785 shares of common stock valued at approximately $500,000 in lieu of cash as a payment of our preferred stock dividend obligation.

Liquidity and Capital Resources

As of December 31, 2002, we had $142.2 million in cash, cash equivalents, securities available-for-sale and interest receivable.

Net cash used in operating activities increased to $88.9 million in 2002, compared to $61.9 million in 2001 and $36.0 million in 2000. The increase in net cash used in operating activities in 2002 as compared to 2001, was primarily due to the increase in our operating expenses. The increase in net cash used in operating activities in 2001, as compared to 2000, was primarily due to the increase in our net loss, offset in part by an increase in equity-based compensation.

We expect the amount of net cash used in operating activities in 2003 to be consistent with the amount of net cash used in 2002. The extent of cash flow used in operating activities will be significantly affected by our expanded development plans for XYOTAX and our ability to offset the related development expenses by licensing XYOTAX in Europe.

Net cash provided by investing activities totaled $80.6 million in 2002, compared to net cash used of $92.7 million in 2001 and $113.9 million in 2000. The increase in net cash provided by investing activities in 2002, as compared to 2001, was primarily due to an increase in proceeds from sales and maturities of securities available-for-sale. The increase in net cash used in investing activities in 2001, as compared to 2000, was primarily due to a lower level of net additional investments in securities available-for-sale during 2001.

Net cash used in financing activities totaled approximately $12.5 million in 2002, compared to net cash provided by financing activities of approximately $169.6 million in 2001 and $168.0 million in 2000. The net cash used in financing activities during 2002 was due primarily to the repurchase of our common stock for $16.4 million. The net cash provided by financing activities during 2001 was primarily due to the issuance of 5.75% convertible subordinated notes resulting in net proceeds of $167.9 million. During 2000, there were two equity offerings that provided $164.6 million in net proceeds. 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. As a result of the exchange offer, we reduced our related annual cash interest payments by approximately $3.4 million.

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We expect to generate losses from operations for several years 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 will enable us to maintain our planned operations through at least mid 2004. Our future capital requirements will depend on many factors, including:

- success of our sales and marketing efforts,
- success in licensing XYOTAX in Europe,
- progress in and scope of our research and development activities,
- competitive market developments, and
- success in acquiring complementary products, technologies or businesses.

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 due to unanticipated developments, additional financing may not be available when needed or, if available, we may not be able to obtain this financing 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, 2002 (in thousands):

Contractual Obligations	Payments Due by Period				
	Total	1 Year	2-3 Years	4-5 Years	After 5 Years
Convertible senior subordinated notes.	$ 85,500	$	$	$	$ 85,500
Convertible subordinated notes.	29,600				29,600
Interest on convertible and convertible senior subordinated notes.	36,106	6,618	13,236	13,236	3,016
Operating leases:					
Aircraft	16,702	1,927	3,854	3,854	7,067
Facilities	58,064	6,779	14,082	14,872	22,331
Long term debt	5,673	2,250	2,981	441	1
Payment related to PolaRx acquisition	4,000	4,000			
	$ 235,645	$ 21,574	$ 34,153	$ 32,403	$ 147,515

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. We may also be required to make a $5.0 million cash and/or stock payment related to the PolaRx acquisition in 2004 contingent upon achievement of certain sales thresholds.

Recent Accounting Pronouncements

In April 2002, the Financial Accounting Standards Board, or FASB, issued SFAS 145, *Rescission of FASB Statements No. 4, 44, and 64, Amendment of FASB Statement No. 13, and Technical Corrections,* which rescinded SFAS 4 and SFAS 64. These former standards had required that certain gains and losses from extinguishment of debt be aggregated and, if material, classified as an extraordinary item in the income statement, net of related income tax effect. SFAS 145 requires that such gains are not reflected as an extraordinary item. The provisions of SFAS 145 are effective for fiscal years beginning after May 15, 2002, with early adoption encouraged. The Company applied the provisions of SFAS 145 in the year ended December 31, 2002.

In June 2002, the FASB, issued Statement of Financial Accounting Standards, or SFAS, 146, *Accounting for Costs Associated with Exit or Disposal Activities,* which addresses accounting for restructuring, discontinued

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operation, plant closing, or other exit or disposal activity. SFAS 146 requires companies to recognize costs associated with exit or disposal activities when they are incurred rather than at the date of a commitment to an exit or disposal plan. SFAS 146 is to be applied prospectively to exit or disposal activities initiated after December 31, 2002. The adoption of SFAS 146 is not expected to have a material impact on our consolidated financial position and results of operations.

In November 2002, the FASB issued FIN 45, Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others, an interpretation of FASB Statements No. 5, 57 and 107 and Rescission of FASB Interpretation No. 34. FIN 45 clarifies the requirements of SFAS 5, Accounting for Contingencies, relating to the guarantor s accounting for, and disclosure of, the issuance of certain types of guarantees. The disclosure provisions of FIN 45 are effective for financial statements of periods ending after December 15, 2002. However, the provisions for initial recognition and measurement are effective on a prospective basis for guarantees that are issued or modified after December 31, 2002. The adoption of FIN 45 is not expected to have a material impact on our consolidated financial position and results of operations.

In December 2002, the FASB issued SFAS 148, *Accounting for Stock-Based Compensation Transition and Disclosure.* This Statement amends SFAS 123, *Stock-Based Compensation,* to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, this Statement amends the disclosure requirements of SFAS 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The disclosure provisions of this Standard are effective for fiscal years ending after December 15, 2002 and have been incorporated into these financial statements and accompanying footnotes.

In January 2003, the FASB issued FIN 46, *Consolidation of Variable Interest Entities*. FIN 46 clarifies the application of Accounting Research Bulletin No. 51, *Consolidated Financial Statements*, to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support from other parties. FIN 46 applies immediately to variable interest entities created after January 31, 2003, and to variable interest entities in which an enterprise obtains an interest after that date. It applies in the first fiscal year or interim period beginning after June 15, 2003, to variable interest entities in which an enterprise holds a variable interest that it acquired before February 1, 2003. FIN 46 applies to public enterprises as of the beginning of the applicable interim or annual period. The adoption of FIN 46 is not expected to have a material impact on our consolidated financial position and results of operations.

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, 2002 and 2001 was $122.3 million and $217.0 million, respectively. For each one percent change in interest rates, the fair value of our securities available-for-sale would change by approximately $1.2 million and $2.2 million as of December 31, 2002 and 2001, respectively.

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

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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 equity. As of December 31, 2002, the fair value of the interest rate swap was a liability of $1.2 million.

Foreign Exchange Market Risk

We have operated primarily in the United States and revenues to date have been primarily in U.S. dollars. Accordingly, we do not have material exposure to foreign currency rate fluctuations. We have not entered into any foreign exchange contracts to hedge any exposure to foreign currency rate fluctuations because such exposure is immaterial.

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Item 8. Consolidated Financial Statements and Supplementary Data

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REPORT OF ERNST & YOUNG LLP, INDEPENDENT AUDITORS

The Board of Directors and Shareholders

Cell Therapeutics, Inc.

We have audited the accompanying consolidated balance sheets of Cell Therapeutics, Inc. as of December 31, 2002 and 2001, and the related consolidated statements of operations, shareholders equity, and cash flows for each of the three years in the period ended December 31, 2002. Our audits also included the financial statement schedule listed in the Index at Item 15(a). 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 auditing standards generally accepted in the 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 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, 2002 and 2001, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2002, in conformity with accounting principles generally accepted in the United States. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

As discussed in Note 1 to the consolidated financial statements, in 2002 the Company changed its method of accounting for goodwill and other intangibles in connection with the adoption of Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets.

ERNST & YOUNG LLP

Seattle, Washington

January 31, 2003

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CELL THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share amounts)

	December 31, 2002	December 31, 2001
ASSETS		
Current assets:		
Cash and cash equivalents	$ 17,946	$ 38,688
Securities available-for-sale	122,311	217,255
Interest receivable	1,900	3,478
Accounts receivable, net	2,150	1,453
Inventory	878	973
Prepaid expenses and other current assets	6,157	3,596
Total current assets	151,342	265,443
Property and equipment, net	11,652	8,395
Note receivable from officer	3,500	
Goodwill, net	12,064	8,064
Other intangibles, net	2,670	9,371
Other assets and deferred charges	5,552	12,477
Total assets	$ 186,780	$ 303,750
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 2,444	$ 1,206
Accrued expenses	11,796	11,521
Accrued liability related to PolaRx acquisition	4,000	
Current portion of deferred revenue	1,003	523
Current portion of long-term obligations	2,250	2,051
Total current liabilities	21,493	15,301
Convertible senior subordinated notes	85,500	
Convertible subordinated notes	29,600	175,000
Deferred revenue, less current portion	2,090	2,371
Other long-term obligations, less current portion	4,614	1,521
Commitments		
Shareholders equity:		
Preferred Stock, no par value:		
Authorized shares 10,000,000		
Series C, 100,000 shares designated, none issued or outstanding		
Series D, 10,000 shares designated, none issued or outstanding		
Common Stock, no par value:		
Authorized shares 100,000,000		
Issued and outstanding shares 33,054,176 and 34,981,763 at December 31, 2002 and December 31, 2001, respectively	384,994	399,649

Notes receivable from officers		(225)
Accumulated other comprehensive income (loss)	(1,056)	685
Accumulated deficit	(340,455)	(290,552)
Total shareholders equity	43,483	109,557
Total liabilities and shareholders equity	$ 186,780	$ 303,750

See accompanying notes.

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CELL THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

	Year Ended December 31,		
	2002	2001	2000
Revenues:			
Product sales	$ 11,393	$ 6,130	$ 502
License and contract revenue	5,503	106	
Total revenues	16,896	6,236	502
Operating expenses:			
Cost of product sold	423	394	19
Research and development	58,759	44,669	26,574
Selling, general and administrative	49,800	35,268	20,421
Amortization of purchased intangibles	6,701	9,390	9,390
Total operating expenses	115,683	89,721	56,404
Loss from operations	(98,787)	(83,485)	(55,902)
Other income (expense):			
Investment income	4,819	9,200	4,517
Interest expense	(11,240)	(5,988)	(544)
Gain on exchange of convertible subordinated notes	55,305		
Other income, net	48,884	3,212	3,973
Net loss	(49,903)	(80,273)	(51,929)
Preferred stock dividend		(1,372)	(508)
Net loss applicable to common shareholders	$ (49,903)	$ (81,645)	$ (52,437)
Basic and diluted net loss per common share	$ (1.48)	$ (2.41)	$ (2.07)
Shares used in calculation of basic and diluted net loss per common share	33,763	33,822	25,345

See accompanying notes.

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CELL THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY

(In thousands)

	Preferred Stock Series D		Common Stock		Notes Receivable from	Accumulated	Accumulated Other Comprehensive	Total Shareholders
	Shares	Amount	Shares	Amount	Officers	Deficit	Income/(Loss)	Equity
Balance at January 1, 2000	10	$ 6,228	15,596	$ 173,392	$ (330)	$ (158,350)	$ (36)	$ 20,904
PolaRx acquisition			5,000	31,401				31,401
Conversion of preferred stock to common stock	(8)	(4,718)	3,503	4,718				
Net proceeds from the issuance of common stock, net of offering costs of $4,461 (including warrants issued to placement agent valued at $1,581)			3,333	37,120				37,120
Net proceeds from the issuance of common stock via follow-on public offering, net of offering costs of $9,302			3,600	127,498				127,498
Preferred stock dividend			6	(83)				(83)
Proceeds from stock warrants exercised			1,291	2,876				2,876
Proceeds from stock options exercised and stock sold via employee stock purchase plan			1,234	4,257				4,257
Equity-based compensation expense				5,716				5,716
Reclass to current asset for former officer					75			75
Comprehensive loss:								
Unrealized gains on securities available-for-sale							108	108
Net loss for the year ended December 31, 2000						(51,929)		(51,929)
Comprehensive loss								(51,821)
Balance at December 31, 2000	2	1,510	33,563	386,895	(255)	(210,279)	72	177,943
Conversion of preferred stock to common stock	(2)	(1,510)	1,121	1,510				
Preferred stock dividend			21	(872)				(872)
Proceeds from stock warrants exercised			20	264				264
Proceeds from stock options exercised and stock sold via employee stock purchase plan			347	1,489				1,489
Rescission of option exercises			(91)	(266)				(266)
Equity-based expense related to warrants vesting				9,212				9,212
Equity-based compensation expense				1,400				1,400
Reclass to current asset for former officer					30			30
Donation of common stock			1	17				17

Comprehensive loss:							
Unrealized gains on securities available-for-sale						312	312
Unrealized gains on interest rate swap						301	301
Net loss for the year ended December 31, 2001					(80,273)		(80,273)
Comprehensive loss							(79,660)
Balance at December 31, 2001		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 losses 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

See accompanying notes.

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CELL THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,		
	2002	**2001**	**2000**
Operating activities			
Net loss applicable to common shareholders	$ (49,903)	$ (81,645)	$ (52,437)
Adjustments to reconcile net loss applicable to common shareholders to net cash used in operating activities:			
Depreciation and amortization	9,703	11,197	11,115
Amortization (accretion) of investment premium (discou			