

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

CELL THERAPEUTICS INC  
Form 10-K/A  
April 30, 2002

=====

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

---

FORM 10-K/A  
(Mark One)

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

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2001

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  
(State or other jurisdiction of  
incorporation or organization)

501 ELLIOTT AVENUE WEST, SUITE 400  
SEATTLE, WA 98119  
(Address of principal executive offices)

91-1533912  
(I.R.S. Employer  
Identification Number)

98119  
(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  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/A.

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

On February 28, 2002, Cell Therapeutics, Inc. had 34,990,992 outstanding shares of Common Stock. Of those, 26,493,979 shares of Common Stock were held by nonaffiliates. The aggregate market value of such Common Stock held by nonaffiliates, based on the closing price of such shares on the Nasdaq National Market on February 28, 2002, was approximately \$585,251,996. 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.

DOCUMENTS INCORPORATED BY REFERENCE: NONE

=====

### 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," or "will" or the negative of those terms or other comparable terms are intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors that may cause industry trends or 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](http://www.cticseattle.com).

"CTI," "CT-2584" and "TRISENOX" are our trademarks. All other product names, trademarks and trade names referred to in this Form 10-K/A are the property of their respective owners.

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

### OUR PRODUCTS

We acquired our lead product called arsenic trioxide, or TRISENOX(R), 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 the EMEA under its

2

recently enacted orphan drug legislation for APL, MDS, and multiple myeloma. Forty-two TRISENOX clinical trials studying the drug alone and in combination with other therapies are ongoing, are planned to begin in the near future, or were recently completed. Twelve of these 42 trials are being done under the sponsorship of the National Cancer Institute, or NCI, in the United States, under a Cooperative Research and Development Agreement, or CRADA, with us. Preliminary data from ongoing clinical trials have shown encouraging responses in patients with multiple myeloma, MDS, CML, lymphoma, prostate cancer, and neuroblastoma. Ten of these studies are being conducted in patients with various solid tumors for which preclinical studies have shown potential activity of TRISENOX. In addition to the 42 current trials, 4 trials in various solid tumors have been approved in concept by the NCI for inclusion in the CRADA program, and 13 trials are planned by independent investigators for the coming year.

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 PG-TXL, or CT-2103, which is paclitaxel linked to polyglutamate. Paclitaxel is the active ingredient in Taxol, the world's best selling cancer drug. In animal studies, PG-TXL demonstrated fewer side effects and improved tumor killing-activity when compared to Taxol alone. The Cancer Research Campaign, or CRC, sponsored a phase I clinical trial of PG-TXL in the United Kingdom for which patient enrollment is complete. Two phase I clinical trials and three phase II clinical trials are currently underway in the U.S. By the end of the second quarter, 4 additional phase I studies investigating various dosing intervals, 5 additional phase II studies in various tumor types, and 2 randomized phase III trials, in non-small-cell lung and first-line ovarian cancer will begin enrolling patients. 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

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

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 2002.

During 2001, we discontinued clinical development of CT-2584, and are investigating the development of a polymer conjugate of this drug candidate, which may make it easier to administer, and potentially more effective.

### 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 550,000 deaths annually. The National Cancer Advisory Board reports that more than 8 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.

3

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
- . 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.

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 90% 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

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

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 PG-TXL 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.

4

- . 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.

### PRODUCTS IN DEVELOPMENT

The following table lists the currently active trials (indicated by a status of "open") and the trials that will be opened to enrollment during the second quarter of 2002 (status "2Q2002") for our products in development. Also listed are the trials that have recently closed to enrollment but for which clinical trial reports are in progress (status "closed").

PRODUCT CANDIDATE	INDICATION/INTENDED USE
TRISENOX(R) (arsenic trioxide), ATO injection	HEMATOLOGIC MALIGNANCIES
	MULTIPLE MYELOMA
	ATO single agent (2 trials, US and Europe)
	ATO single agent, twice weekly dosing schedule
	ATO in combination with dexamethasone
	ATO in combination with ascorbic acid (2 trials, one NCI)
	ATO in combination with dexamethasone and ascorbic acid
	ATO in combination with thalidomide

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

ATO in combination with dexamethasone and ascorbic acid  
 ATO in combination with dexamethasone and ascorbic acid after SCT  
 MYELODYSPLASTIC SYNDROMES (MDS)  
 ATO single agent (2 trials, US and Europe)  
 ATO in combination with thalidomide  
 ATO single agent  
 ATO in combination with cytarabine  
 ATO in combination with growth factors  
 ACUTE PROMYELOCYTIC LEUKEMIA (APL)  
 ATO in combination with Mylotarg, salvage treatment  
 ATO single agent, APL in molecular relapse (2 trials)  
 ATO in combination with ATRA, de novo APL  
 ATO as consolidation in de novo APL following standard induction (NCI)  
 CHRONIC MYELOID LEUKEMIA (CML)  
 ATO in combination with ascorbic acid  
 ATO single agent in patients with rel/ref Ph+ ALL or  
 blast crisis CML (NCI)  
 ATO in combination with STI-571 (Gleevec)  
 ATO in combination with STI-571 (Gleevec)  
 NON-HODGKIN'S LYMPHOMA (NHL)  
 ATO in combination with Rituxan  
 ATO single agent, relapsed/refractory intermediate or high grade NHL

5

PRODUCT CANDIDATE	INDICATION/INTENDED USE
	ACUTE MYELOID LEUKEMIA (AML) Relapsed/refractory AML, secondary leukemia, or pts > 65 yrs of age
	ATO in combination with ascorbic acid
	OTHER LEUKEMIA/LYMPHOMA Pediatric patients with refractory leukemia/lymphoma (NCI) Rel/ref acute lymphoblastic leukemia (NCI) Rel/ref lymphoproliferative disorders (NCI)
	SOLID TUMORS Neuroblastomas and other solid tumors in pediatric patients Advanced cervical carcinoma (NCI) Hormone-refractory prostate cancer (NCI) Urothelial cancer (NCI) Hepatocellular carcinoma Advanced cancer patients with renal dysfunction Malignant melanoma Germ cell tumors Hormone-refractory prostate cancer, in combination with docetaxel Renal cell carcinoma (NCI)
PG-TXL (CT-2103)	Advanced solid tumors - Dosing every 3 weeks (UK) Advanced solid tumors in combination with cisplatin Advanced solid tumors in combination with carboplatin Advanced solid tumors, single agent - dosing every week (US) Advanced solid tumors, single agent - dosing every 2 weeks (UK) Advanced solid tumors, single agent - dosing every 3 weeks (US) Non-small-cell lung cancer salvage, single agent

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

Ovarian front-line dose escalation (GOG)  
Ovarian, fallopian tube, peritoneal carcinoma - salvage  
Colorectal cancer salvage  
Non-small-cell lung cancer (high risk patients)  
Ovarian salvage (GOG)  
Lung cancer, in combination with radiation  
Breast cancer (UK - CRC)  
Kaposi sarcoma, single agent  
Non-small-cell lung cancer (second line; multinational)  
Ovarian cancer (front line; multinational)

---

PG-CPT  
(CT-2106)

Advanced solid tumors

---

6

### 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 marketing authorization in the EU, in the same indication. We anticipate launching TRISENOX in the EU by mid 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(R) in APL and have received U.S. orphan drug designation for TRISENOX for the treatment of multiple myeloma, MDS, CML, and AML. In addition, TRISENOX has received orphan drug designation for the treatment of APL, multiple myeloma, and MDS under the recently enacted 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, Memorial Sloan-Kettering Cancer Center and the Sam Waxman Cancer Foundation that cover methods of treating a variety of cancers and conditions with TRISENOX.

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,

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

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. Up to 10% 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, 9-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 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, an unprecedented 82% were confirmed to

7

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 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 between 40,000 and 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. Fewer than 50% of 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 ASH in December 2000 and 2001, and during a 2001 symposium at the International Myeloma Meeting in Banff. 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



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

condition affecting about 50,000 individuals a year with an annual incidence of 10,000 to 20,000 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. Data from phase I studies suggested that some patients improved after receiving TRISENOX. Several trials to explore the activity of TRISENOX in MDS have been initiated and the early data have shown that some patients had apparent clinical benefit. 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 15,000 individuals in the U.S. and has an annual incidence of 5,000 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 major 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 recent

8

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
- . CML cells are far more sensitive to TRISENOX than are normal blood cells

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 affects 180,000 people in the U.S. and there are 55,000 new cases per year according to the American Cancer Society. Despite new effective therapies, relatively few patients are cured and additional treatments are needed. Data from phase I and phase II studies indicate that TRISENOX can induce remissions in patients with advanced lymphomas. 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 cancer, affect approximately 850,000 patients in the United States,

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

with over 300,000 new cases diagnosed annually. Preclinical tests and preliminary clinical trials results have suggested that TRISENOX may have significant 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 of TRISENOX as a single agent and in combination with standard therapy in patients with solid tumors will begin shortly. Ten trials in various solid tumors are currently underway or are soon to begin.

### 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.

9

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

- . 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
- . broader applicability due to differentiated tumor uptake mechanism
- . 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.

We licensed the worldwide exclusive rights to PG and related polymers and their applications from PG-TXL Company in 1998. The technology was originally developed at the M.D. Anderson Cancer Center. The initial patent, which issued in November 1999, covers PG and related polymers coupled with commonly used

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

cancer drugs such as paclitaxel, docetaxel, etoposide, teniposide, or camptothecins. The patented technology covers formulations of PG-conjugated paclitaxel that also include the use of human serum albumin and conjugation to eptophilones.

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.

PG-TXL (polyglutamate paclitaxel). PG-TXL, or CT-2103, is PG linked to paclitaxel, the active ingredient in Taxol, the world's best selling cancer drug. Taxol is difficult to administer because it must be mixed in 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 requires a minimum of three hours of intravenous infusion. PG-TXL is 80,000 times more water-soluble than paclitaxel, allowing it to be dissolved in 100 mL of dextrose in water and infused over ten minutes. Also, because PG-TXL 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. PG-TXL may also allow delivery of higher doses than can be achieved with the currently marketed version of paclitaxel.

It is estimated that more than 2 million people have breast, ovarian, lung and colon cancer, with more than 500,000 new cases diagnosed each year in the United States. IMS Health reported taxane U.S. sales of approximately \$800 million, and worldwide sales of roughly \$1.3 billion for the year ended September 2001, despite the difficulties associated with their administration and their serious dose-

10

limiting toxicities. The majority of taxane use has been in breast, ovarian and lung cancer indications. Most recently, Taxol received approval as a first-line treatment in node-positive breast cancer, which is expected to add up to an additional 75,000 patients annually eligible for treatment in the U.S.

PG-TXL has been compared to paclitaxel in numerous studies in animals with a variety of different tumors. These studies indicate that PG-TXL 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 (MTD) for PG-TXL is approximately twice that for the approved formulation of paclitaxel.
- . When the MTD of PG-TXL is compared to the MTD of paclitaxel, in over 20 different animal tumor models, PG-TXL 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 PG-TXL to tumor tissue in mice and comparing it to tumors in mice who received the same dose of the approved preparation of paclitaxel showed that 12-fold more paclitaxel was delivered with PG-TXL. Strikingly, more paclitaxel was present in

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

the tumors at the end of one week following PG-TXL administration than was present one day after administration of standard paclitaxel.

- . Because in PG-TXL, paclitaxel is tightly 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 Cremaphor (used in Taxol), which abolishes the requirement for premedications to prevent infusional toxicity. Moreover, little free paclitaxel is present in circulation reducing side effects to normal tissues such as the bone marrow, nervous tissue, and hair follicles.
- . PG-TXL 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; PG-TXL in preclinical studies is effective in tumors that are resistant to standard paclitaxel.

Lastly, PG-TXL is more effective than standard paclitaxel at enhancing the effectiveness of other cancer therapies including chemotherapy and radiation. A recent report shows that in a curative, standard radiation model, PG-TXL was more than 4 times as effective as paclitaxel at enhancing radiation curability. Most importantly, unlike standard paclitaxel, PG-TXL did not sensitize normal organs such as skin, hair follicles, or the GI tract to radiation. A recently approved grant from the National Cancer Institute to the MD Anderson Cancer Center and us will support a clinical trial using PG-TXL in sensitive patients undergoing potentially curative radiation for lung cancer.

We chose to initiate human trials of PG-TXL in the U.K. because of the 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 PG-TXL sponsored by the CRC has completed patient enrollment. Preliminary data presented by the investigator showed that PG-TXL may have a more favorable toxicity profile than expected from equivalent doses of Taxol, while demonstrating evidence of anti-tumor activity, supporting the preclinical evidence that PG-TXL may have applications across a broader variety of types of cancer.

11

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 PG-TXL. Two phase I clinical trials (one in combination with cisplatin and one with carboplatin) and 3 phase II clinical trials are currently underway in the U.S. By the end of the second quarter of 2002, 4 additional phase I studies investigating various dosing intervals, 5 additional phase II studies in various tumor types (non-small-cell lung, ovarian, breast cancers and Kaposi sarcoma), and 2 randomized phase III trials, in non-small-cell lung and first-line ovarian cancer, will begin enrolling patients. Some of these ongoing studies use PG-TXL at doses in excess of the approved dose for Taxol and all use a convenient 10-minute infusion time. Our registration strategy for PG-TXL is to examine its potential safety and efficacy as single agent therapy or in combination with other chemotherapy drugs in solid tumors.

PG-CPT (polyglutamate camptothecin). PG-CPT 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

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

limitations, camptothecins are becoming standard drugs in the treatment of advanced colon, lung and ovarian cancer. Worldwide sales for camptothecins exceeded \$700 million in 2001.

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 2002.

### 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 PG-TXL with Chugai Pharmaceutical Co., Ltd. The aggregate amount of milestone payments we may be required to pay pursuant to the PG-TXL agreement is \$20.5 million, of which \$2.0 million was paid in 2000. These are payable 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. for the development and commercialization of PG-TXL. This agreement grants an exclusive license to Chugai to develop and commercialize PG-TXL 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 milestone payments totaling up to \$16.0 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. 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

12

any, in a given country or fifteen years from the date of the first commercial sale of PG-TXL in such country.

### 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 two issued patents and 21 U.S. and foreign pending patent applications relating to our polymer drug delivery technology. Nine issued U.S. patents cover the chemical entity, pharmaceutical compositions and methods of use of CT-2584 and related compounds. We intend to file additional patent applications when appropriate, with respect to

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

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 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, PG-TXL 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 PG-TXL. Under the supply agreement, we purchased paclitaxel at a pre-determined price and will receive supply over a

multi-year term. 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.

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

### 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 3 regional business directors, 29 field based oncology account managers and 3 medical science liaisons and expect to have a total of 51 field based sales personnel by the end of 2002. We plan to use a combination of our own 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 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.

14

### 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.

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

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 cGMPs, and
- . FDA review and approval of the NDA.

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

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

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. The study protocol and informed consent information for study subjects in clinical trials must also be approved by the Institutional Review Board at 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



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

(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. Once the FDA approves a drug product, we are required to comply with a number of post-approval requirements. For example, holders of an approved NDA are required to report certain adverse reactions to the FDA, and to comply with certain requirements concerning advertising and promotional labeling for their products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. We use and will continue to use third party manufacturers to produce our products in clinical and commercial quantities, and future FDA inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA, including withdrawal of the product from the market.

Orphan Drug. The FDA may grant orphan drug designation to drugs intended to treat a "rare disease or condition," which generally is a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting an NDA. 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

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

process. If a product which has an orphan drug designation

16

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

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

could be held liable for any damages that result and any such liability could exceed our resources.

17

### EMPLOYEES

As of February 28, 2002, we employed 238 individuals, including 69 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 the Vice Chair of Medical Biochemistry at the University of California, San Diego. He is a noted authority on phospholipases, cell signaling and phospholipid metabolism. Dr. Dennis serves on the Scientific Advisory Board and Management Committee of, and chairs the Management Executive Board of, the Keystone Symposia. He sits on the Editorial Board of the Journal of Cellular Biochemistry and on the Publications Committee of the American Society for Biochemistry and Molecular Biology. He has authored over 185 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. He is currently Professor of Pharmacology and Medicine at Vanderbilt University and is the author of over 170 publications.

The following are our retained Clinical Advisors:

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

E. Donnell 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

18

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.

Karen H. Antman, M.D., is the Chief of the Division of Medical Oncology, College of Physicians & Surgeons of Columbia University. Dr. Antman is an expert in emerging treatment strategies for solid tumors, notably breast cancer and sarcomas. From 1994 to 1995 she served as President of the American Society of Clinical Oncology. Since 1993, Dr. Antman has served on the Sarcoma Committee of the Southwest Oncology Groups, and has been its chairperson since 1995. From 1993 to 1994 she was program committee chair of the American Association for Cancer Research. She is on the editorial board of several prestigious journals, including Associate Editor of The New England Journal of Medicine.

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 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 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, 2001, we had an accumulated deficit of approximately \$290.6 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.

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

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, PG-TXL 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

19

efficacy of the drug 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, PG-TXL 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,

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

- . 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.

20

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.

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

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

yield patentable subject matter. We do not believe that our polymer-drug conjugates will infringe any 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 biotech 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

21

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 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, PG-TXL 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 Memorial Sloan Kettering Cancer Institute, Samuel Waxman Cancer Research Foundation, Beijing Medical University and others, including the intellectual property underlying TRISENOX. We have also in-licensed the intellectual property relating to our polymer drug delivery technology, including PG-TXL. 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 that license. We may not be able to

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

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 PG-TXL and our other products in development, we will need to expand our operations in various areas, including our management, regulatory, clinical, financial

22

and information systems and other elements of our business process infrastructure. We expect to add additional key personnel in these areas in the near future. In addition, if rapid 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.

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



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

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 current and planned operations until 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 and (3) conduct preclinical studies and clinical trials. 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,

23

- . 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 that of ours, historically has been highly volatile, and the market from time to time has experienced significant price and volume

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

fluctuations that are unrelated to the operating performance of such companies. For example, during the twelve months ended December 31, 2001, our stock price has ranged from a low of \$12.50 to a high of \$49.00. 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,

24

- . 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 PG-TXL 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 PG-TXL 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.

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

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. 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, PG-TXL, 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. Because the oncology market is highly concentrated and many prospective clients are unfamiliar with TRISENOX, we will need to continue to expand our sales and marketing infrastructure in order to increase market awareness of this product. We are in the process of expanding our direct sales force, and currently require additional qualified sales personnel. Competition for these individuals is intense, and 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 would need to further expand our marketing and sales force with sufficient technical expertise and distribution capacity. If we are unable to continue to expand our direct sales operations and train new sales personnel as rapidly as necessary, we may not be able to increase market

25

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 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 personnel 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.

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

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.

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.

26

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.

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

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.

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

27

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

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

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 66,000 square feet of space at 201 Elliott Avenue West in Seattle, Washington for our laboratory and administrative operations. The lease expires in January 2003, with two consecutive five-year renewal options 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 executive offices and administrative operations. The lease expires July 2012. To accommodate the operational requirements of Cell Therapeutics (UK) Limited, our wholly-owned, London-based subsidiary, we leased space at 100 Fetter Lane in London, UK and have additional offices at 100 Pall Mall, St. James in London, UK. 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, 2001.

28

## 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
	----	---
2000		
First Quarter .....	\$ 52.00	\$ 5.31
Second Quarter .....	33.50	10.50
Third Quarter .....	68.25	26.38
Fourth Quarter .....	77.25	30.50
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

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

2002

First Quarter (through March 26, 2002)..            27.45                            19.31

On March 26, 2002, the last reported sale price of our common stock on the Nasdaq Market was \$25.05 per share. As of March 26, 2002, there were approximately 278 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 financial condition, results of operations, capital requirements and such other factors as the Board of Directors deems relevant.

29

### 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 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,			
	2001	2000	1999	1998
	(IN THOUSANDS, EXCEPT PER SHARE DATA)			
<b>CONSOLIDATED STATEMENTS OF OPERATIONS DATA:</b>				
<b>Revenues:</b>				
Product sales .....	\$ 6,130	\$ 502	\$ --	\$ --
Collaboration agreements .....	--	--	--	13,200
License revenue .....	106	--	--	--
Total revenues .....	6,236	502	--	13,200
<b>Operating expenses:</b>				
Cost of product sold .....	394	19	--	--
Research and development (1) .....	44,669	26,574	27,682	29,940
General and administrative .....	21,863	14,770	9,788	10,880
Sales and marketing .....	13,405	5,651	--	--
Amortization of purchased intangibles .....	9,390	9,390	--	--
Total operating expenses .....	89,721	56,404	37,470	40,830
Loss from operations .....	(83,485)	(55,902)	(37,470)	(27,630)
<b>Other income (expense):</b>				
Investment income .....	9,200	4,517	1,692	3,090
Interest expense .....	(5,988)	(544)	(502)	(430)
Net loss .....	(80,273)	(51,929)	(36,280)	(24,970)
Preferred stock dividend .....	(1,372)	(508)	(5,201)	--

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

	-----	-----	-----	-----
Net loss applicable to common shareholders ....	\$ (81,645)	\$ (52,437)	\$ (41,481)	\$ (24,97)
	=====	=====	=====	=====
Basic and diluted net loss per common share (2) .....	\$ (2.41)	\$ (2.07)	\$ (2.67)	\$ (1.6)
	=====	=====	=====	=====
Shares used in computation of basic and diluted net loss per common share .....	33,822	25,345	15,552	15,41
	=====	=====	=====	=====

	DECEMBER 31,			
	2001	2000	1999	1998
	----	----	----	----
	(IN THOUSANDS)			
CONSOLIDATED BALANCE SHEETS DATA:				
Cash, cash equivalents, securities available-for-sale and interest receivable...	\$ 259,421	\$ 156,434	\$ 24,248	\$ 47,07
Working capital .....	250,142	146,384	17,705	44,14
Total assets .....	303,750	190,111	30,848	58,15
Convertible subordinated notes .....	175,000	--	--	--
Other long-term obligations, less current portion .....	3,892	1,060	2,653	3,88
Total long-term obligations, less current portion .....	178,892	1,060	2,653	3,88
Accumulated deficit .....	(290,552)	(210,279)	(158,350)	(122,07)
Total shareholders' equity .....	109,557	177,943	20,904	47,16

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

30

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF 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, 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



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

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.

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), and commenced initial product sales for TRISENOX of \$502,000 in the fourth quarter of 2000, and \$6.1 million for the year ended December 31, 2001. As of December 31, 2001, we had incurred aggregate net losses of approximately \$290.6 million since inception. We expect to continue to incur significant additional operating losses over the next several years from our research and development efforts. Operating losses may fluctuate from quarter to quarter as a result of differences in the timing of expenses incurred and revenues recognized.

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. 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.

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 5 million shares of common stock and included assumed net liabilities of \$3.9 million from PolARx. Two additional payouts tied to sales thresholds of \$10 million and \$20 million in any four consecutive quarters, may be payable in tranches of \$4 million and \$5 million at the then fair market value of our stock, at the time such thresholds are 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 at the then fair market value of our common stock or, in certain circumstances, cash. The acquisition was accounted for as a purchase transaction.

In October 2001, we entered into a licensing agreement with Chugai Pharmaceutical Co., Ltd. for the development and commercialization of PG-TXL. This agreement grants an exclusive license to Chugai to develop and commercialize PG-TXL 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 milestone payments totaling up to \$16.0 million upon Chugai's achievement of certain product development milestones, and we are entitled to receive royalties on

31

product sales in the territories covered under the agreement. Chugai has also committed to incur up to \$54 million in development expenditures over the course of the licensing agreement.

We entered into a supply agreement with Natural Pharmaceuticals, Inc. for paclitaxel, a key starting material for our PG-TXL drug candidate. Under the supply agreement, we purchased paclitaxel at a pre-determined price and will receive supply over a multi-year term.

CRITICAL ACCOUNTING POLICIES

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

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 consists of nonrefundable and/or guaranteed technology license fees, collaborative research funding, and various milestone and future product royalty or profit-sharing payments.

Revenue associated with up-front license fees, and research and development funding payments under collaborative agreements is recognized ratably over the relevant periods specified in the agreement, generally the research and development period. Revenue from substantive at-risk milestones and future product royalties is recognized as earned based on the completion of the milestones and product sales, as defined in the respective agreements. Revenue under cost reimbursement contracts 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 returns and discounts. 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 which 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. If the cost of the inventory exceeds the expected market value, provisions are recorded currently for the difference between the cost and the market value. We also record an allowance for excess inventory that may expire and become unsaleable.

32

### Research and Development Expenses

Research and development expenses include related salaries, contractor fees, occupancy costs, utilities, administrative expenses and allocation of corporate costs. Research and development expenses consist of costs incurred for proprietary and collaboration research and development and also include activities such as product registries and investigator sponsored trials. All such costs are charged to research and development expenses as incurred. Costs of materials and other supplies are charged to research and development expense

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

when they have been received.

### 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 loss in shareholders' equity and is reclassified into earnings in the same period during which the hedged transaction affects earnings. The remaining net gain or loss on the derivative in excess of the present value of the expected cash flows of the hedged transaction is recorded in earnings immediately. If a derivative does not qualify for hedge accounting, or a portion of the hedge is deemed ineffective, the change in fair value is recorded in earnings. The swap was perfectly effective at December 31, 2001. We do not enter into forward agreements for trading purposes.

### RESULTS OF OPERATIONS

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 sell TRISENOX primarily to pharmaceutical wholesalers and oncology distributors, who in turn sell TRISENOX primarily to hospitals and clinics. 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.

**License revenue.** In October 2001, we entered into a licensing agreement with Chugai Pharmaceutical Co., Ltd. for the development and commercialization of PG-TXL. 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 the additional product sales in 2001. Further, a reserve for obsolescence of approximately \$96,000 was incurred in 2001. Royalty costs were included in cost of product sold in 2001 and 2000. Prior to FDA approval, the raw material and production costs of TRISENOX were recorded as research and development expense. We expect product costs in the future to continue to approximate a small percentage of revenue.

33

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

	2001	2000
	----	----
Compounds under development		
PG - compounds .....	\$ 20,480	\$ 5,247

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

Trisenox .....	3,244	4,829
Other compounds .....	710	1,111
Operating expenses .....	10,428	6,621
Discovery research	9,807	8,766
	-----	-----
Total research and development expenses..	\$ 44,669	\$ 26,574
	=====	=====

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 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.

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 PG-TXL milestone, an additional \$6.0 million in direct expenses associated with the development of PG-TXL and PG-CPT, the recruitment of additional personnel and related occupancy costs of \$5.0 million to support our expanded development plans for TRISENOX, PG-TXL 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. We anticipate increased research and development expenses in connection with the clinical development plans for TRISENOX, PG-TXL, PG-CPT and our other products.

Our leading drug candidates, PG-TXL 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.

General and administrative. General and administrative expenses increased to approximately \$21.9 million for the year ended December 31, 2001 from approximately \$14.8 million for the year ended December 31, 2000. This increase reflects 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. Corporate

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

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. Offsetting these increases were lower stock-based compensation charges of \$1.8 million. We expect 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.

Sales and marketing. We incurred approximately \$13.4 million of sales and marketing expense for the year ended December 31, 2001 compared to \$5.7 million for the year ended December 31, 2000. This increase is primarily due to higher staffing levels and marketing costs to support the launch of TRISENOX. We expect sales and marketing expenses to continue to increase in 2002.

Amortization of purchased 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 will adopt 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.

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. We are required to pay each Series D preferred stock investor four annual dividend payments notwithstanding any conversion of the preferred stock. 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.

Years ended December 31, 2000 and 1999.

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 initial net product sales of approximately \$502,000 for TRISENOX in the fourth quarter of 2000.

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

Cost of product sold. The cost of product sold during the fourth quarter of 2000 was approximately \$19,000. Prior to FDA approval, the raw material and production costs of TRISENOX were recorded as research and development expense.

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

	2000 ----	1999 ----
Compounds under development		
PG - compounds .....	\$ 5,247	\$ 4,542
Trisenox .....	4,829	--
Other compounds .....	1,111	6,360
Operating expenses .....	6,621	8,488
Discovery research .....	8,766	8,292
	-----	-----
Total research and development expenses .....	\$ 26,574	\$ 27,682
	=====	=====

Research and development expenses decreased to approximately \$26.6 million for the year ended December 31, 2000 from approximately \$27.7 million for the year ended December 31, 1999. The decrease in direct expenses for other compounds and the related decrease in operating expenses are attributed primarily to our discontinuing the development of Lisofylline. These decreases were offset in part by our incurring development expenses associated with TRISENOX (a compound we purchased via the acquisition of PolaRx in January, 2000) and PG-TXL which include a \$2.0 million milestone payment under our license agreement with PG-TXL Company, L.P.

General and administrative. General and administrative expenses increased to approximately \$14.8 million for the year ended December 31, 2000 from approximately \$9.8 million for the year ended December 31, 1999. The increase reflects approximately \$3.3 million in stock-based compensation expense for our consultants and operating expenses associated with supporting our research, development and marketing activities of approximately \$1.7 million.

Sales and marketing. We expensed approximately \$5.7 million in our sales and marketing effort for the year ended December 31, 2000 as we launched TRISENOX in October 2000.

Amortization of purchased intangibles. In January 2000, we acquired PolaRx Biopharmaceuticals, Inc. that 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, 2000 was approximately \$9.4 million.

Investment income. Investment income increased to approximately \$4.5 million for the year ended December 31, 2000 from approximately \$1.7 million for the year ended December 31, 1999. This increase is attributed to higher average cash balances on hand during 2000 because we completed a private placement and secondary offering in 2000 that generated net proceeds of approximately \$164.6 million.

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

Interest expense. Interest expense increased to approximately \$544,000 for the year ended December 31, 2000 from approximately \$502,000 for the year ended December 31, 1999. This increase was due primarily to interest payments made to PolaRx shareholders on notes payable assumed upon the PolaRx acquisition.

36

Preferred stock dividend. We accrued approximately \$508,000 for a preferred stock dividend for the year ended December 31, 2000 in connection with preferred stock issued in November 1999. In 2000, we issued 6,366 shares of common stock valued at approximately \$425,000 in lieu of cash as a payment of our preferred stock dividend obligation.

### LIQUIDITY AND CAPITAL RESOURCES

As of December 31, 2001, we had \$259.4 million in cash, cash equivalents, securities available-for-sale and interest receivable.

Net cash used in operating activities increased to \$61.9 million in 2001, compared to \$36.0 million in 2000 and \$30.0 million in 1999. 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. The increase in net cash used in operating activities in 2000, as compared to 1999, was primarily due to the increase in our net loss.

We expect net cash used in operating activities to increase in 2002. The extent of cash flow used in operating activities will be significantly affected by our expanded development plans for TRISENOX, PG-TXL, and PG-CPT.

Net cash used in investing activities totaled \$92.7 million in 2001, compared to \$113.9 million in 2000 and net cash provided of \$22.9 million in 1999. The decrease 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. The increase in net cash used in investing activities in 2000, as compared to net cash provided by investing activities in 1999, was primarily due to a net increase in purchases of securities available-for-sale.

Net cash provided by financing activities increased to approximately \$169.6 million in 2001, compared to \$168.0 million in 2000 and \$8.4 million in 1999. In 2001, we received net proceeds of \$168.0 million from the issuance of 5.75% convertible subordinated notes as compared to two equity offerings in 2000 that provided \$164.6 million in net proceeds. These notes are due June 15, 2008 with interest payable semi-annually in June and December. Financing activities in 1999 included \$9.3 million from the sale of Series D preferred stock.

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 current and planned operations through at least mid 2004. Our future capital requirements will depend on many factors, including:

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

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

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

37

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, 2001 (in thousands):

CONTRACTUAL OBLIGATIONS	PAYMENTS DUE BY PERIOD				Af Y
	Total	1 Year	2-3 Years	4-5 Years	
Long Term Debt .....	\$ 3,572	\$ 2,051	\$ 1,521	\$ --	\$
Operating Leases:					
Aircraft .....	18,630	1,927	3,854	3,854	
Facilities .....	47,450	4,653	7,851	8,167	
Convertible Subordinated Notes....	175,000	--	--	--	
Interest on Convertible					
Subordinated Notes. ....	55,344	10,063	20,125	20,125	
.....	299,996	18,694	33,351	32,146	
Preferred Stock Dividends					
Payable in Cash or Stock ....	1,000	500	500	--	
.....	\$ 300,996	\$ 19,194	\$ 33,851	\$ 32,146	\$

The remaining amount of milestone payments we may be required to pay pursuant to the PG-TXL agreement is \$18.5 million.

### INCOME TAXES

As of December 31, 2001, we had available for Federal income tax purposes net operating loss carryforwards of approximately \$302.5 million, of which \$41.7 million relates to stock option deductions, and research and development credit carryforwards of approximately \$9.8 million. 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.

### RECENT ACCOUNTING PRONOUNCEMENTS



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

In June 2001, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards No. 141 Business Combinations, and No. 142, Goodwill and Other Intangible Assets, effective for fiscal years beginning after December 15, 2001. Under the new rules, goodwill and intangible assets deemed to have indefinite lives will no longer be amortized but will be subject to an annual impairment test in accordance with the Statement. Other intangible assets will continue to be amortized over their useful lives. We will apply the new rules on accounting for goodwill and other intangible assets beginning in the first quarter of 2002. We had previously expected to record amortization expense of \$2.7 million during 2002 related to goodwill that will not be amortized due to the adoption of the new statement. We are evaluating the impact of the impairment rules, if any, on our earnings and financial position.

38

In October 2001, FASB issued Statement of Financial Accounting Standards No. 144, Accounting for Impairment or Disposal of Long-Lived Assets, effective for fiscal years beginning after December 15, 2001, with transition provisions for certain matters. The FASB's new rules on asset impairment supersedes FASB Statement No. 121, Accounting for Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of, and provides a single accounting model for long-lived assets to be disposed of. We will evaluate the effect of the implementation of the impairment rules, if any, on our earnings and financial position.

### 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, 2001 was \$217.3 million. For each one percent change in interest rates, the fair value of our securities available-for-sale would change by approximately \$217,000.

We may manage our interest rate market risk, when deemed appropriate, through the use of derivative financial instruments. Derivative financial instruments are viewed as risk management tools and are not used for speculative or trading purposes. In 2001, we entered into a long-term operating lease that had a variable rent component that was based on LIBOR. In connection with this lease, we entered into an interest rate swap agreement to limit our interest rate exposure. This swap agreement has been designated as a cash flow hedge. The portion of the net gain or loss on the derivative instrument that is effective as a hedge is reported as a component of accumulated other comprehensive loss in shareholders' equity. As of December 31, 2001, the fair value of the interest rate swap was \$301,000.

#### Foreign Exchange Market Risk

We have operated primarily in the United States and all 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

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

foreign exchange contracts to hedge any exposure to foreign currency rate fluctuations because such exposure is immaterial.

39

### ITEM 8. CONSOLIDATED FINANCIAL STATEMENTS

#### INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	Page
	----
Report of Ernst & Young LLP, Independent Auditors .....	41
Consolidated Balance Sheets .....	42
Consolidated Statements of Operations .....	43
Consolidated Statements of Shareholders' Equity .....	44
Consolidated Statements of Cash Flows .....	45
Notes to Consolidated Financial Statements .....	46

40

#### 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, 2001 and 2000, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2001. Our audits also included the financial statement schedule listed in the Index at Item 14(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, 2001 and 2000, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2001, 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.

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

Ernst & Young LLP

Seattle, Washington  
February 8, 2002

41

CELL THERAPEUTICS, INC.  
CONSOLIDATED BALANCE SHEETS  
(IN THOUSANDS, EXCEPT SHARE AMOUNTS)

	DECEMBER 31, 2001
	-----
ASSETS	
Current assets:	
Cash and cash equivalents	\$ 38,688
Securities available-for-sale	217,255
Interest receivable	3,478
Accounts receivable, net of allowance of \$389 and \$67 at December 31, 2001 and December 31, 2000, respectively	1,453
Inventory	973
Prepaid expenses and other current assets	3,596
	-----
Total current assets	265,443
Property and equipment, net	8,395
Goodwill, net	8,064
Other intangibles, net	9,371
Other assets and deferred charges	12,477
	-----
Total assets	\$ 303,750 =====
LIABILITIES AND SHAREHOLDERS' EQUITY	
Current liabilities:	
Accounts payable	\$ 1,206
Accrued expenses	11,521
Current portion of deferred revenue	523
Current portion of long-term obligations	2,051
	-----
Total current liabilities	15,301
Convertible subordinated notes	175,000
Deferred revenue, less current portion	2,371
Other long-term obligations, less current portion	1,521
Commitments	
Shareholders' equity:	
Preferred Stock, no par value:	
Authorized shares - 10,000,000	
Series A and B, 161,118.645 shares designated, none issued or outstanding	--
Series D, designated, issued and outstanding shares - none at December 31, 2001 (2,425 at December 31, 2000)	--
Common Stock, no par value:	
Authorized shares - 100,000,000	
Issued and outstanding shares - 34,981,763 and 33,562,627 at December 31, 2001 and December 31, 2000, respectively	399,649

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

Notes receivable from officers	(225)
Accumulated other comprehensive income	685
Accumulated deficit	(290,552)
	-----
Total shareholders' equity	109,557
	-----
Total liabilities and shareholders' equity	\$ 303,750
	=====

See accompanying notes.

42

CELL THERAPEUTICS, INC.  
CONSOLIDATED STATEMENTS OF OPERATIONS  
(IN THOUSANDS, EXCEPT PER SHARE AMOUNTS)

	YEAR ENDED DECEMBER 31,		
	2001	2000	1999
	-----	-----	-----
Revenues:			
Product sales	\$ 6,130	\$ 502	\$ --
License revenue	106	--	--
	-----	-----	-----
Total revenues	6,236	502	--
	-----	-----	-----
Operating expenses:			
Cost of product sold	394	19	--
Research and development	44,669	26,574	27,682
General and administrative	21,863	14,770	9,788
Sales and marketing	13,405	5,651	--
Amortization of purchased intangibles	9,390	9,390	--
	-----	-----	-----
Total operating expenses	89,721	56,404	37,470
	-----	-----	-----
Loss from operations	(83,485)	(55,902)	(37,470)
Other income (expense):			
Investment income	9,200	4,517	1,692
Interest expense	(5,988)	(544)	(502)
	-----	-----	-----
Net other income (expense)	3,212	3,973	1,190
	-----	-----	-----
Net loss	(80,273)	(51,929)	(36,280)
Preferred stock dividend	(1,372)	(508)	(5,201)
	-----	-----	-----
Net loss applicable to common shareholders	\$ (81,645)	\$ (52,437)	\$ (41,481)
	=====	=====	=====
Basic and diluted net loss per common share	(\$ 2.41)	(\$ 2.07)	(\$ 2.67)
	=====	=====	=====
Shares used in calculation of basic and diluted net loss per common share	33,822	25,345	15,552
	=====	=====	=====

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

See accompanying notes.

43

CELL THERAPEUTICS, INC.  
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY  
(IN THOUSANDS)

	PREFERRED STOCK		COMMON STOCK		NOTES	RECEIVABLE	ACCUM
	SERIES D				FROM	DEF	
	SHARES	AMOUNT	SHARES	AMOUNT	OFFICERS	DEF	
Balance at January 1, 1999	-	\$ -	15,535	\$169,619	\$ (380)	\$ (1)	
Net proceeds from the issuance of Series D convertible preferred stock and warrants to acquire common stock net of offering costs of \$755 (including warrants issued to placement agent valued at \$100)	10	6,228	-	3,117	-	-	
Preferred stock dividend	-	-	-	(44)	-	-	
Proceeds from stock options exercised and stock awards, and stock sold via employee stock purchase plan	-	-	61	131	-	-	
Equity-based compensation expense	-	-	-	569	-	-	
Reclass to current asset for former officer	-	-	-	-	50	-	
Comprehensive loss:							
Unrealized losses on securities available-for-sale	-	-	-	-	-	-	
Net loss for the year ended December 31, 1999	-	-	-	-	-	-	
Comprehensive loss	-	-	-	-	-	-	
Balance at December 31, 1999	10	6,228	15,596	173,392	(330)	(1)	
PolarX acquisition	-	-	5,000	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	-	-	
Net proceeds from the issuance of common stock via follow-on public offering, net of offering costs of \$9,302	-	-	3,600	127,498	-	-	
Preferred stock dividend	-	-	6	(83)	-	-	
Proceeds from stock warrants exercised	-	-	1,291	2,876	-	-	
Proceeds from stock options exercised and stock awards, and stock sold via employee stock purchase plan	-	-	1,234	4,257	-	-	
Equity-based compensation expense	-	-	-	5,716	-	-	
Reclass to current asset for former officer	-	-	-	-	75	-	
Comprehensive loss:							

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

Unrealized gains on securities available-for-sale	-	-	-	-	-	-
Net loss for the year ended December 31, 2000	-	-	-	-	-	(
Comprehensive loss	-	-	-	-	-	-
Balance at December 31, 2000	2	1,510	33,563	386,895	(255)	(2
Conversion of preferred stock to common stock	2	(1,510)	1,121	1,510		
Preferred stock dividend	-	-	21	(872)	-	
Proceeds from stock warrants exercised	-	-	20	264	-	
Proceeds from stock options exercised and stock awards, and stock sold via employee stock purchase plan	-	-	347	1,489	-	
Rescission of option exercises	-	-	(91)	(266)	-	
Equity-based expense related to warrants vesting	-	-	-	9,212	-	
Equity-based compensation expense	-	-	-	1,400	-	
Reclass to current asset for former officer	-	-	-	-	30	
Donation of common stock	-	-	1	17	-	
Comprehensive loss:						
Unrealized gains on securities available-for-sale	-	-	-	-	-	-
Unrealized gains on interest rate swap	-	-	-	-	-	-
Net loss for the year ended December 31, 2001	-	-	-	-	-	(
Comprehensive loss	-	-	-	-	-	-
Balance at December 31, 2001	-	\$ -	34,982	\$399,649	\$ (225)	\$ (2

See accompanying notes.

44

CELL THERAPEUTICS, INC.  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
(In thousands)

	Year Ended D	
	2001	200
	-----	-----
OPERATING ACTIVITIES		
Net loss applicable to common shareholders	\$ (81,645)	\$ (52
Adjustments to reconcile net loss applicable to common shareholders to net cash used in operating activities:		
Preferred stock dividend	1,372	
Depreciation and amortization	11,197	11
Noncash rent benefit	(115)	
Equity-based expense related to warrants vesting	9,212	

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

Equity-based compensation expense	1,417	5
Loss on disposition of property and equipment	-	
Amortization of investment (discount) and premium	1,040	
Loss (gain) on sale of investment securities	(26)	
Changes in assets and liabilities:		
Interest receivable	(1,952)	(1)
Accounts receivables, net	(1,344)	
Inventory	(806)	
Prepaid expenses and other current assets	(2,537)	
Other assets and deferred charges	(3,599)	
Accounts payable	93	
Accrued expenses	2,907	1
Deferred revenue	2,894	
Total adjustments	19,753	16
Net cash used in operating activities	(61,892)	(36)
INVESTING ACTIVITIES		
Purchases of securities available-for-sale	(297,471)	(148)
Proceeds from sales of securities available-for-sale	35,183	2
Proceeds from maturities of securities available-for-sale	175,503	33
Purchases of property and equipment	(5,938)	
PolaRx acquisition, net of cash acquired	-	
Net cash provided by (used in) investing activities	(92,723)	(113)
FINANCING ACTIVITIES		
Proceeds from issuance of convertible subordinated notes, net	167,954	
Sale of common stock, net of offering costs	-	164
Sale of preferred stock via private placement, net of offering costs	-	
Proceeds from common stock options exercised	977	4
Rescission of stock options exercised	(266)	
Proceeds from common stock warrants exercised	264	2
Proceeds from employee stock purchase plan	512	
Repayment of notes payable	-	(2)
Repayment of long-term obligations	(1,425)	(1)
Proceeds from the issuance of long-term obligations	1,552	
Net cash provided by financing activities	169,568	167
Net increase in cash and cash equivalents	14,953	18
Cash and cash equivalents at beginning of year	23,735	5
Cash and cash equivalents at end of year	\$ 38,688	\$ 23
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Conversion of Series D preferred stock into common stock	\$ 1,510	\$ 4
Common Stock issued in PolaRx acquisition	\$ -	\$ 31
Cash paid during the period for interest obligations	\$ 4,987	\$
Issuance of common stock for payment of preferred stock dividend	\$ 500	\$

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

See accompanying notes.

45

## CELL THERAPEUTICS, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2001

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

##### Description of Business

Cell Therapeutics, Inc. focuses on the discovery, development, and commercialization of drugs for the treatment of cancer. Our principal business strategy is to focus our activities on cancer therapeutics, an area that represents a large market opportunity that is not adequately served by existing therapies. We commenced operations February 1992.

We operate in a highly regulated and competitive environment. The manufacturing and marketing of pharmaceutical products require approval from, and are subject to, ongoing oversight by the Food and Drug Administration in the United States and by comparable agencies in other countries. Obtaining approval for a new therapeutic product is never certain and may take several years and involve expenditure of substantial resources. Competition in researching, developing, and marketing pharmaceutical products is intense. Any of the technologies covering our existing products under development could become obsolete or diminished in value by discoveries and developments of other organizations. We operate in one business segment.

The market for our current pharmaceutical product is primarily the United States. Sales are primarily to pharmaceutical wholesalers. During 2001, approximately 92% of our product sales were made to three of these wholesalers, and during 2000, approximately 83% of sales were made to four of these wholesalers. We obtain our product from one supplier.

##### Principles of Consolidation

The consolidated financial statements include the accounts of Cell Therapeutics, Inc., its wholly owned subsidiaries (CTI Technologies, Inc., PolaRx Biopharmaceuticals, Inc., CTI Corporate Development, Inc. and Cell Therapeutics (UK) Limited), and its majority owned subsidiary (PanGenex, Inc.). All intercompany transactions and balances are eliminated in consolidation.

##### Cash and Cash Equivalents

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

##### Securities Available-for-Sale

Management determines the appropriate classification of debt securities at the time of purchase. Management currently classifies our investment portfolio as available-for-sale and carries the securities at fair value based on quoted market prices with unrealized gains and losses included in accumulated other



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

comprehensive income and loss. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion is included in investment income. Realized gains and losses and declines in value judged to be other than

46

### CELL THERAPEUTICS, INC.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS-(CONTINUED)

temporary on available-for-sale securities are included in investment income. The cost of securities sold is based on the specific identification method. Interest on securities classified as available-for-sale is included in investment income.

#### Certain Concentrations

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

We entered into a supply agreement with our sole supplier of paclitaxel, a key starting material for our PG-TXL drug candidate. We also have an agreement with a contract manufacturer for TRISENOX, our current commercial product. If we are unable to obtain sufficient quantities from these suppliers, and if we were unable to source these materials and services from other suppliers and manufacturers, certain research and development and sales activities may be delayed.

#### 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 consists of nonrefundable and/or guaranteed technology license fees, collaborative research funding, and various milestone and future product royalty or profit-sharing payments.

Revenue associated with up-front license fees, and research and development funding payments under collaborative agreements is recognized ratably over the relevant periods specified in the agreement, generally the research and development period. Revenue from substantive at-risk milestones and future product royalties is recognized as earned based on the completion of the milestones and product sales, as defined in the respective agreements. Revenue under cost reimbursement contracts 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 returns and discounts. Allowances for discounts, returns and bad debts, which are netted against accounts receivable, totaled approximately \$389,000 and \$67,000 for the years ended December 31, 2001 and 2000, respectively.

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

## Cost of Product Sold

Cost of product sold consists primarily of the cost of product sold to our customers, including allowances for excess inventory that may expire and become unsaleable. Royalties paid on product sales, as well as shipping and handling costs are also included.

47

## CELL THERAPEUTICS, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS-(Continued)

#### 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. If the cost of the inventory exceeds the expected market value, provisions are recorded currently for the difference between the cost and the market value. We also record an allowance for excess inventory that may expire and become unsaleable. The components of inventories are as follows as of December 31 (in thousands):

	2001	2000
Work in process .....	\$ 813	\$ --
Finished goods .....	160	167
	-----	-----
	\$ 973	\$ 167
	=====	=====

#### Research and Development Expenses

Research and development expenses include related salaries, contractor fees, occupancy costs, utilities, administrative expenses and allocation of corporate costs. Research and development expenses consist of costs incurred for proprietary and collaboration research and development and also include activities such as product registries and investigator sponsored trials. All such costs are charged to research and development expenses as incurred.

#### Property and Equipment

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

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

#### Intangible Assets

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

Intangible assets consist of goodwill and other acquisition-related intangible assets acquired in 2000. The assets are amortized using the straight-line method over their estimated useful lives, ranging from three to five years. We periodically perform reviews to evaluate the recoverability of goodwill and other intangibles and take into account events or circumstances that warrant revised estimates of useful lives or that indicate an impairment exists. In the event that the sum of future undiscounted cash flows is less than recorded book value, the carrying amount will be reduced to its fair value.

48

### CELL THERAPEUTICS, INC.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS-(CONTINUED)

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

	2001	2000
	-----	-----
Goodwill .....	\$ 13,440	\$ 13,440
Marketing intangible asset .....	16,100	16,100
Other intangibles .....	6,674	6,674
	-----	-----
	36,214	36,214
Less: accumulated amortization ....	18,779	9,389
	-----	-----
	\$ 17,435	\$ 26,825
	=====	=====

#### Stock-Based Compensation

In accordance with Statement of Financial Accounting Standards No. 123, Accounting for Stock-Based Compensation (SFAS 123), we elected to continue to account for stock-based compensation using the intrinsic value method prescribed in Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees and related interpretations. Accordingly, compensation cost for stock options is measured as the excess, if any, of the market price of our common stock at the date of grant over the stock option exercise price. Any deferred compensation is recognized on a graded vesting method. Under our plan, stock options are generally granted at fair market value.

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

#### Advertising Costs

The costs of advertising are expensed as incurred. We incurred advertising costs of \$839,000 and \$469,000 in 2001 and 2000, respectively. There were no material advertising costs in 1999.

#### Net Loss per Share

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

Basic net loss per share is calculated based on the net loss applicable to common shareholders divided by the weighted average number of common shares outstanding for the period excluding any dilutive effects of options, warrants and convertible securities. Diluted earnings per share, if separately presented, would assume the conversion of all dilutive convertible securities, such as convertible subordinated debt and convertible preferred stock using the if-converted method, and would assume the exercise of other dilutive securities, such as option and warrants, using the treasury stock method. Due to our history of losses, all such securities have been anti-dilutive.

### 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

49

## CELL THERAPEUTICS, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS-(CONTINUED)

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 and is reclassified into earnings in the same period during which the hedged transaction affects earnings. The remaining net gain or loss on the derivative in excess of the present value of the expected cash flows of the hedged transaction is recorded in earnings immediately. If a derivative does not qualify for hedge accounting, or a portion of the hedge is deemed ineffective, the change in fair value is recorded in earnings. The swap was perfectly effective at December 31, 2001. We do not enter any forward agreements for trading purposes.

### Other Financial Instruments

At December 31, 2001 and 2000, the carrying value of financial instruments such as receivables and payables, approximated their fair values based on the short-term maturities of these instruments. Additionally, the carrying value of long-term liabilities and convertible subordinated notes approximated fair values because the underlying interest rates reflect market rates at the balance sheet dates.

### Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

### New Accounting Pronouncements

During July 2001, the FASB issued SFAS 141, Business Combinations, and SFAS 142, Goodwill and Other Intangible Assets. SFAS 141 prohibits the use of the pooling-of-interests method for business combinations initiated after June 30, 2001. SFAS 141, which also includes the criteria for the recognition of intangible assets separately from goodwill, is effective for any business combination accounted for by the purchase method that is completed after June

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

30, 2001. Under SFAS 142, goodwill will no longer be amortized over its expected useful life, but rather, will be assessed for impairment on an annual basis. Separately identifiable intangible assets that do not have an indefinite life will continue to be amortized. We recorded goodwill in conjunction with our acquisition of PolaRx in 2000. We will apply the new rules on accounting for goodwill and other intangible assets beginning in the first quarter of 2002. We will perform the first of the required impairment tests of goodwill as of January 1, 2002. We do not expect the impact of these tests to be material to our net loss or financial position. The effect of discontinuing the amortization of goodwill is expected to result in a decrease in our net loss of \$2.7 million in 2002.

During August 2001, the FASB issued SFAS 144, Accounting for the Impairment or Disposal of Long-Lived Assets. SFAS 144 is applicable to financial statements issued for fiscal years beginning after December 15, 2001. SFAS 144 supersedes SFAS 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of, and provides a single accounting model for long-lived assets to be disposed of. We do not anticipate that the adoption of this statement will have a material effect on our consolidated results of operations or financial position.

50

CELL THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS-(CONTINUED)

Reclassifications

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

Comprehensive Loss

SFAS 130, Reporting Comprehensive Income, includes unrealized gains and losses on our securities available-for-sale and interest rate swap agreement, designated as a cash flow hedge, to be included in other comprehensive loss.

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

	2001	2000
	-----	-----
Net unrealized gains on securities available-for-sale .....	\$ 384	\$ 72
Net unrealized gains on interest rate swap ..	301	--
	-----	-----
	\$ 685	\$ 72
	=====	=====

2. SECURITIES AVAILABLE-FOR-SALE

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

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

	2001		
	AMORTIZED COST	GROSS UNREALIZED GAINS	GROSS UNREALIZED LOSSES
U.S. government obligations .....	\$ 37,108	\$ 46	\$ --
Municipal government obligations .....	24,071	17	(13)
Corporate obligations .....	155,692	376	(42)
	-----	-----	-----
	\$ 216,871	\$ 439	\$ (55)
	=====	=====	=====

	2001		
	AMORTIZED COST	GROSS UNREALIZED GAINS	GROSS UNREALIZED LOSSES
U.S. government obligations .....	\$ 20,078	\$ 14	\$ --
Municipal government obligations .....	4,050	16	--
Corporate obligations .....	106,972	56	(14)
	-----	-----	-----
	\$ 131,100	\$ 86	\$ (14)
	=====	=====	=====

As of December 31, 2001 and 2000, all securities available-for-sale had contractual maturities of less than one year. Gross realized gains and losses to date have not been material.

51

CELL THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS-(CONTINUED)

3. PROPERTY AND EQUIPMENT

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

	2001	2000
	-----	-----
Leasehold improvements .....	\$ 6,369	\$ 4,5
Lab equipment .....	7,947	6,0
Furniture and office equipment .....	9,126	6,8
	-----	-----
	23,442	17,5
Less: accumulated depreciation and amortization .....	(15,047)	(13,2)

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

\$	8,395	\$	4,2
=====	=====	=====	=====

Depreciation expense of \$1.8 million, \$1.7 million, and \$1.8 million was recognized during 2001, 2000, and 1999, respectively.

4. ACCRUED LIABILITIES

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

	2001	2000
	----	----
Employee compensation and related expenses .....	\$ 3,430	\$ 3,033
Accrued manufacturing expenses .....	1,675	627
Accrued clinical development .....	1,558	700
Insurance financing and accrued interest expense .....	1,052	358
Accrued corporate development and sales and marketing expenses .....	772	818
Accrued other research and development expenses .....	588	719
Other .....	2,446	2,112
	\$ 11,521	\$ 8,367

5. CONTRACTUAL ARRANGEMENTS AND COMMITMENTS

License Agreement

We have an agreement with the Fred Hutchinson Cancer Research Center (FHCRC) under the terms of which we received worldwide licenses and options to technology, or technology claimed, for five U.S. patent applications. We are obligated to pay royalties on revenues resulting from future sales of products employing the technology and on revenues received from sublicenses for the technology, with minimum annual royalties of \$50,000 prior to, and \$100,000 after, the first commercial sale of such products. The agreements are for a term equal to the later of March 2007 or the expiration of the last issued patent included within the licensed technology, unless terminated earlier for certain specified events, including our failure to take reasonable efforts to engage in research and development with respect to the licensed technology. We recognized research and development expense of \$50,000 in 2001, 2000 and 1999 related to this agreement.

Lease Agreements

Facilities

-----

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

We have executed noncancelable operating leases for office and laboratory space that expire in 2003, with two five-year renewal options at the then-current market rates. The lessor provided approximately \$575,000 for leasehold improvements and rent concessions, which is being amortized over the initial lease term. In 2001, we executed an operating lease for additional office space expiring in July 2012. Rent expense amounted to \$2.9 million, \$1.2 million, and \$1.4 million, for the years ended December 31, 2001, 2000, and 1999, respectively.

### Aircraft

-----

In 2001, we entered into an operating lease agreement for use of an aircraft. Terms of the lease include current monthly rental payments of approximately \$70,000. Effective March 1, 2002, our monthly rental payments will be the sum of \$161,000 plus an incremental rent adjustment, which is based on the value of the aircraft and will vary depending on the prevailing applicable LIBOR rate. After one year, we may cancel this agreement if certain conditions are met and six months notice is provided. The lease expires in August 2011 with provision for renewal and we are responsible for all maintenance and insurance costs for the aircraft. Rent expense amounted to \$294,000 for the year ended December 31, 2001.

In connection with this aircraft lease, we entered into an interest rate swap agreement that effectively locks in the effect of the incremental rate adjustment for the first 78 payments. Under the swap agreement, we will receive a variable amount based on the monthly LIBOR rate and we will pay a fixed rate payment based on a rate of 4.78%. The swap agreement's notional amount matches the incremental rent value of the aircraft. The other party to the swap agreement is an affiliate of the lessor; therefore, we do not believe we have any counterparty risk related to the interest rate swap. At December 31, 2001, the fair value of the swap was \$301,000, which is recorded in long-term other assets and other comprehensive income, and we believe it is 100% effective. As a result of the above transactions, the effective interest rate on this lease is 6.49%.

### Future Minimum Lease Payments

-----

Future minimum lease commitments for operating leases at December 31, 2001 are as follows (in thousands):

2002 .....	\$	6,580
2003 .....		5,854
2004 .....		5,852
2005 .....		5,955
2006 .....		6,066
Thereafter .....		35,773
		-----
	\$	66,080
		=====



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

In September 2001, we entered into a supply agreement with Natural Pharmaceuticals, Inc. for paclitaxel, a key starting material for our PG-TXL drug candidate. Under the supply agreement, we purchased paclitaxel at a pre-determined price and will receive supply over a multi-year term. At December 31, 2001, we had recorded a \$5.7 million prepayment relating to this agreement, of which \$3.8 million is classified as noncurrent.

### 6. CONVERTIBLE SUBORDINATED NOTES

In June 2001, we issued \$150.0 million principal amount of 5.75% convertible subordinated notes due June 15, 2008 with interest payable semi-annually in June and December. In September 2001, we issued an additional \$25.0 million principal amount of these notes. This additional issuance resulted from the exercise of an over-allotment option that we had granted to the initial purchasers. Net proceeds to us were approximately \$168.0 million, after deducting expenses and underwriters' discounts and commissions. We recorded issuance costs related to the notes of approximately \$7.0 million. These issuance costs are recorded in other assets and are being amortized to interest expense over the seven-year life of the notes.

The notes are convertible, at the option of the holder, into shares of our common stock at any time prior to maturity or redemption at a conversion rate of 29.4118 shares per each \$1,000 principal note, subject to adjustment in certain circumstances. This is equivalent to a conversion price of approximately \$34.00 per share. Under certain conditions, we may be able to redeem the notes by making an additional payment of \$172.50 per \$1,000 note, less any interest paid on the notes before June 21, 2004. Thereafter, we can redeem the notes at specified redemption prices ranging from 103.286% to 100% of the principal amount. The redemption prices will vary depending on the year redeemed.

### 7. OTHER LONG-TERM OBLIGATIONS

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

	2001	
	-----	-----
Master financing agreement, due October 2004, monthly payments of \$48, including interest at 7.1% .....	\$ 1,489	\$
Master financing agreement, due September 2002, monthly payments of \$60, including interest at 12.4% .....	680	
Master financing agreement, due December 2002, monthly payments of \$18, including interest at 12.4% .....	255	
Master financing agreement, due December 2001, monthly payments of \$44, including interest at 12.5% .....	--	
Accrued preferred stock dividend .....	1,000	
Deferred rent and other long-term obligations .....	148	
	-----	-----
	3,572	
Less current portion .....	(2,051)	
	-----	-----
	\$ 1,521	\$
	=====	=====

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

CELL THERAPEUTICS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS-(CONTINUED)

For each borrowing, we granted the lender a security interest in specified fixed assets. Maturities of the long-term obligations listed above at December 31, 2001 are as follows (in thousands):

Years Ending December 31,	
-----	
2002 .....	\$ 2,051
2003 .....	1,045
2004 .....	476
	-----
	\$ 3,572
	=====

As of December 31, 2001, we drew down \$1.6 million on an approximate \$6.0 million line of credit for purchases of equipment. All draw-downs will be secured by the equipment purchased, and will be repaid monthly over a period ranging from three to four years. The interest rate will be calculated at each draw-down and will be based on the three or five year U.S. treasury rate, determined by the loan term, plus approximately 4%.

### 8. CAPITAL STOCK

In November 1999, we completed a \$10 million private placement of 10,000 shares of Series D convertible preferred stock (Series D) and warrants to acquire 1,523,810 shares of common stock, resulting in net proceeds of \$9.3 million. Each share of Series D was convertible into 462.427 shares of common stock. The warrants were valued at \$3.0 million, have exercise prices of \$2.625 per share of common stock and expire in November 2004. We also issued warrants to purchase 50,000 shares of common stock to the placement agent of the Series D. These warrants expire in 2004, and have exercise prices of \$2.38. All warrants were valued using the Black-Scholes pricing model with input assumptions for volatility, risk-free interest rate, dividends, and life of 1.01, 5.5%, none, and five years, respectively. During 2001 and 2000, 2,425 shares of Series D were converted into 1,121,386 shares of common stock, and 7,575 shares of Series D were converted into 3,502,890 shares of common stock, respectively. As of December 31, 2001, all preferred stock had been converted into common stock. No warrants were exercised during 2001, and 1,164,286 warrants were exercised and converted into 1,137,805 shares of common stock during 2000. There were 409,524 warrants outstanding as of December 31, 2001.

Investors of the Series D are entitled to receive cumulative dividends at a rate per share of 5% per annum payable on each September 30, commencing September 30, 2000. At our option, subject to certain restrictions and penalties, dividends may be paid in cash or in shares of our common stock. We are to pay each Series D investor four annual dividends notwithstanding any conversion. We paid dividends with 20,785 and 6,366 shares of our common stock in 2001 and 2000, respectively. We recorded \$1.0 million and \$128,000 as a preferred stock dividend payable as of December 31, 2001 and 2000, respectively.

On the date of the preferred stock issuance, the effective conversion price of the preferred stock (after allocating the portion of the proceeds to the common stock warrants based on the relative fair values) was at a discount to the price of the common stock into which the preferred stock is convertible. In accordance with EITF 98-5 Convertible Securities with Beneficial Conversion Features, the discount was recorded as a preferred stock dividend valued at \$5.2 million.

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

In February 2000, we completed a \$40 million private placement of 3,333,334 shares of common stock at an offering price of \$12 per share, resulting in net proceeds of approximately \$37.1 million. In

CELL THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS-(CONTINUED)

connection with the offering, we issued 170,000 warrants to purchase shares of common stock to a placement agent. The warrants are exercisable at a price of \$13.20 per share and expire in February 2005. The shares of common stock issued and issuable upon the exercise of the warrants have certain registration rights. During 2001 and 2000, 20,000 warrants were exercised and converted into 20,000 shares of common stock, and 40,875 warrants were exercised and converted into 38,721 shares of common stock, respectively. There were 109,125 and 129,125 such warrants outstanding as of December 31, 2001 and 2000, respectively.

In September 2000, we completed a public offering of 3.6 million shares of our common stock at \$38 per share, which generated net proceeds of \$127.5 million.

Common Stock Reserved

A summary of common stock reserved for issuance is as follows as of December 31, 2001:

Convertible subordinated notes .....	5,147,065
Equity incentive plan .....	5,020,316
Common stock warrants .....	868,649
Restricted share rights .....	103,665
Employee stock purchase plan .....	90,701
	-----
	11,230,396
	=====

9. STOCK OPTIONS AND WARRANTS

Stock Options

The 1994 Equity Incentive Plan (the 1994 Plan) provides for (a) the grant of incentive stock options (with terms not to exceed ten years), nonstatutory stock options and stock appreciation rights, (b) the award of stock bonuses, (c) the sale of stock, and (d) any other equity-based or equity-related awards which the Plan Administrator determines to be consistent with the purpose of the 1994 Plan. Option-vesting schedules are specified by the Plan Administrator. The 1994 Plan also provides for the automatic grant of nonstatutory options to non-employee directors.

CELL THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS-(CONTINUED)

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

	SHARES UNDER OPTION	EX
	-----	---
Balance January 1, 1999 (57,477 exercisable) .....	2,508,827	
Granted .....	1,198,459	
Canceled .....	(517,718)	
Exercised .....	(4,932)	
	-----	
Balance December 31, 1999 (1,666,822 exercisable)	3,184,636	
Granted .....		
At fair value .....	1,179,654	
At prices below fair value .....	52,600	
Canceled .....	(173,784)	
Exercised .....	(1,214,001)	
	-----	
Balance December 31, 2000 (1,097,625 exercisable)	3,029,105	
Granted .....	1,583,129	
Canceled .....	(40,478)	
Exercised .....	(324,182)	
Rescinded .....	91,384	
	-----	
Balance December 31, 2001 (1,812,564 exercisable)	4,338,958	
	=====	

RANGE OF EXERCISE PRICES	OPTIONS OUTSTANDING			EXERCISABLE (WITHO
	NUMBER OUTSTANDING 12/31/01	WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE	WEIGHTED AVERAGE EXERCISE PRICE	NUMBER EXERCISABL
-----	-----	-----	-----	-----
\$ 2.00 - \$11.09 .....	1,610,202	7.07 Years	\$ 2.98	1,418,604
\$ 14.72 - \$24.55 .....	664,548	9.46 Years	\$ 23.88	28,810
\$ 24.81 - \$30.06 .....	1,272,403	9.47 Years	\$ 27.40	100,760
\$ 39.56 - \$47.28 .....	791,805	8.89 Years	\$ 42.67	264,390
	-----			-----
\$ 2.00 - \$47.28 .....	4,338,958	8.47 Years	\$ 20.59	1,812,564
	=====			=====

The weighted average fair value of options granted during 2001 was \$19.66, during 2000 was \$33.23 and \$41.20 for those issued at fair value and in-the-money, respectively, and during 1999 was \$1.94. As of December 31, 2001, 479,627 shares of common stock were available for future grants.

SFAS 123 encourages, but does not require, entities to adopt the fair value method of accounting for their stock-based compensation plans. Under this method, compensation cost for stock-based compensation plans is measured at the grant date based on the fair value of the award and is recognized over the vesting period. Fair value is determined using a Black-Scholes option pricing

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

model that takes into account (1) the stock price at the grant date, (2) the exercise price, (3) an assumed four and a half-year expected life in 2001 and 2000, and an assumed two-year expected life in 1999, (4) no expected dividends, (5) a risk-free interest rate of 4.5%, 6.0%, and 5.5% in 2001, 2000, and 1999, respectively, and (6) a volatility factor of 1.062, 1.095, and 1.006, in 2001, 2000, and 1999, respectively. In accordance

57

### CELL THERAPEUTICS, INC.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS-(Continued)

with the provisions of SFAS 123, we apply Accounting Principles Board Opinion No. 25 and related interpretations in accounting for our stock option plans and, accordingly, do not recognize compensation cost for options granted with exercise prices equal to or greater than fair value. If we elected to recognize compensation cost based on the fair value of the options granted at grant date as prescribed by SFAS 123, net loss applicable to common shareholders and basic and diluted net loss and basic and diluted net loss per share would have been adjusted (increased) as follows for the years ended December 31 (in thousands, except per share amounts):

	2001 ----	2000 ----	
Net loss applicable to common shareholders:			
As reported .....	\$ (81,645)	\$ (52,437)	\$
As adjusted .....	(104,152)	(56,894)	
Basic and diluted net loss per share:			
As reported .....	\$ (2.41)	\$ (2.07)	\$
As adjusted .....	\$ (3.08)	\$ (2.24)	\$

During the year ended December 31, 2000, in connection with the grant of certain options to employees, we recorded deferred stock compensation (included in deferred charges) of \$800,000, representing the difference between the exercise price and the fair value of our common stock on the measurement date, of which \$145,000 and \$366,000 was expensed during 2001 and 2000, respectively.

In accordance with EITF 96-18, we consider all equity instruments issued to non-employees to be accounted for as fair value equity instruments. The value of the instrument is amortized to expense over the vesting period with final valuation measured on the vesting date. At December 31, 2001 and 2000, options to acquire 153,674 and 224,332 shares of common stock, respectively, are considered fair value options. We recognized non-employee equity-based compensation related expense of \$1,639,000, \$2,674,000, and \$569,000, during 2001, 2000, and 1999, respectively.

We also issued 103,665 restricted share rights to non-employees in 1998 for which ownership vests upon the achievement of a future event (see Note 13). Compensation related to these rights will be measured as the event becomes probable with final valuation on the vesting date.

In December 1999, the Compensation Committee of the Board of Directors authorized the issuance of 243,903 restricted share rights valued at \$746,000 to executive officers and certain employees. The rights vest in December 2002. During 2001 and 2000, 13,947 and 28,225 restricted share rights were canceled,

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

respectively, due to employee terminations. The share value was recorded as deferred compensation (included in deferred charges on the balance sheet), and is being amortized over the three year vesting period. We recognized compensation related expense of \$206,000 and \$220,000 during 2001 and 2000, respectively. In May 2001, the Compensation Committee of the Board of Directors approved the rescission of certain stock option exercises that two officers and a consultant had made in January 2001. In exchange for the return of 91,384 shares of our common stock, we reinstated their original option grant and returned to them the related exercise price of \$266,000. These options are now subject to variable stock compensation accounting.

58

### CELL THERAPEUTICS, INC.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS-(Continued)

##### Warrants

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 became exercisable only upon the occurrence of certain exercise events. In October 2001, we entered into a licensing agreement with Chugai Pharmaceutical Co, Ltd., allowing them to develop PG-TXL within certain territories. The signing of this agreement qualified as an exercise event, and these warrants became exercisable at an exercise price of \$20. We recorded related expense of \$9.2 million as research and development expense in the fourth quarter of 2001 based upon the fair value of the warrants on the date of the event. The warrants expire in November 2008.

In 1999, we entered into an agreement with two consulting companies to develop and execute a communication plan. In connection with this agreement, we granted warrants to purchase 150,000 shares of common stock to the consultants, whereby each warrant entitled the holder to purchase one share of our common stock at strike prices ranging from \$3.00 to \$18.00 per share. Except for those warrants with a strike price of \$3.00 per share which vested immediately (valued at \$37,500, in accordance with EITF 96-18), the warrants vested when the closing price for our common stock equaled or exceeded its strike price for a specified period of time. During 2000, all of the warrants vested and we recognized compensation expense of \$2.2 million. All the warrants were exercised by the consultants, and converted into 114,308 shares of common stock during 2000.

##### Employee Stock Purchase Plan

We maintain an Employee Stock Purchase Plan (the Purchase Plan), under which eligible employees may purchase a limited number of shares of our common stock at 85% of the lower of the subscription date fair market value and the purchase date fair market value. There are two six-month offerings per year. Under the Purchase Plan, we issued 23,567 and 19,666 shares to employees in 2001 and 2000, respectively. There is a balance of 90,701 shares reserved for future purchases at December 31, 2001.

#### 10. NET LOSS PER SHARE

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

Year ended December 31,

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

	2001 ----	2000 ----	1999 ----
Net loss applicable to common shareholders (A).....	\$ (81,645) =====	\$ (52,437) =====	\$ (41,488) =====
Weighted average common stock outstanding (B) .....	33,822 =====	25,345 =====	15,550 =====
Loss per share:			
Basic and diluted (A/B) .....	\$ (2.41) =====	\$ (2.07) =====	\$ (2.63) =====

As of December 31, 2001, 2000, and 1999, options, warrants and convertible preferred stock aggregating 5,313,003, 5,358,484, and 9,986,388 common equivalent shares, respectively, were not included in the calculation of diluted net loss per share as they are anti-dilutive.

59

CELL THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS-(Continued)

11. INCOME TAXES

As of December 31, 2001, we had net operating loss carryforwards of approximately \$302.5 million (of which \$41.7 million relates to stock option deductions) and research and development credit carryforwards of approximately \$9.8 million. The carryforwards begin to expire in the year 2007. Due to rounds of equity financings (and other ownership changes as defined in Section 382 of the Internal Revenue Code of 1986, as amended (the Code) see Notes 8 and 14), we incurred "ownership changes" pursuant to the Code, as amended. Accordingly, our use of the net operating loss carryforwards is limited to approximately \$6.7 million annually for losses incurred prior to March 26, 1997 and may be subject to additional limitations thereafter. To the extent that any single-year loss is not utilized to the full amount of the limitation, such unused loss is carried over to subsequent years until the earlier of its utilization or the expiration of the relevant carryforward period.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. We recognized a valuation allowance equal to the deferred tax assets due to the uncertainty of realizing the benefits of the assets. Our valuation allowance increased \$25,406,000, \$29,900,000, and \$13,609,000, during 2001, 2000, and 1999, respectively.

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

	2001 ----	2000 ----
Deferred tax assets:		
Net operating loss carryforwards .....	\$ 102,837	\$ 80,267

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

Research and development tax credit		
carryforwards .....	9,768	7,753
Accruals on financial statements in excess of		
tax returns .....	303	148
Charitable contributions carryforward .....	572	139
Depreciation in financial statements in		
excess of tax .....	649	529
Other .....	62	--
	-----	-----
Gross deferred tax assets .....	114,191	88,836
Less valuation allowance .....	(114,191)	(88,785)
	-----	-----
Gross deferred tax liability: .....	--	51
Accruals on tax returns in excess of financial		
statements .....	--	(51)
	-----	-----
Net deferred tax .....	\$ --	\$ --
	=====	=====

### 12. CONSULTING AND EMPLOYMENT AGREEMENTS

#### Corporate Officers

Loans to executive officers totaling \$225,000 and \$255,000 were outstanding as of December 31, 2001 and 2000, respectively. Each of the full-recourse notes has a term of four years and bears interest at approximately 5%. The full balance of principal and accumulated interest is due at maturity. Although

60

### CELL THERAPEUTICS, INC.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS-(CONTINUED)

not required by the terms of these loans, the executives used the funds to purchase shares of our common stock on the open market.

We have severance agreements with certain of our officers having terms between twelve and eighteen months.

#### Advisory Boards

We have entered into consulting agreements with the members of our Scientific and Clinical Advisory Boards ("Advisory Boards") providing for the periodic issuance of common stock and options to purchase common stock, and consulting fees. One agreement has an annual retainer of \$10,000. The remaining advisory board members are paid consulting fees on a per diem basis. The consulting agreements with members of the Advisory Boards are cancelable upon 30 days notice. We issued 5,712 and 49,276 stock options to members of our Advisory Boards in 2000 and 1999, respectively. No stock options were issued to these members in 2001. All options held by advisory board members are accounted for at fair value in accordance with EITF 96-18. Compensation related expense for options issued to advisory board members recognized in 2001, 2000, and 1999 was \$8,000, \$1,248,000, and \$156,000, respectively.

#### Consultants

We issued stock options to other consultants for various services. All options held by consultants are accounted for at fair value in accordance with



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

EITF 96-18. Related compensation expense recognized in 2001, 2000, and 1999 was \$1,639,000, \$1,426,000, and \$256,000, respectively.

### Related Party Disclosure

In 1999, we entered into an agreement with a clinical medical consultant who is the spouse of one of our executive officers. No services were rendered during 2001. We paid the clinical medical consultant approximately \$77,450 and \$107,000 during 2000 and 1999, respectively, in fees for services rendered.

### 13. SIGNIFICANT AGREEMENTS

#### Other Agreements

Chugai Pharmaceutical Co., Ltd.: In October 2001, we entered into a licensing agreement with Chugai Pharmaceutical Co., Ltd. for the development and commercialization of PG-TXL. This agreement grants an exclusive license to Chugai to develop and commercialize PG-TXL in several Asian markets. Upon execution of the agreement, Chugai paid us a \$3.0 million initial payment, which we recorded as deferred revenue and which is being recognized as revenue over the development period on a straight-line basis. We recognized \$106,000 of revenue during 2001. Under the agreement, we may also receive milestone payments totaling up to \$16.0 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. Chugai has also committed to incur up to \$54 million in development expenditures over the course of the licensing agreement. The agreement will terminate on a country-by-country basis

61

#### CELL THERAPEUTICS, INC.

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS-(CONTINUED)

upon the earlier to occur of the expiration of the applicable patent rights in a given country or fifteen years from the date of the first commercial sale of PG-TXL in such country.

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

We will be obligated to make future milestone payments upon the attainment of significant achievements, as defined in the agreement of up to \$20.5 million. We made a \$2 million milestone payment to PG-TXL Company L.P. in 2000. 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 PG-TXL with Chugai Pharmaceutical Co., Ltd (see Note 9). We are obligated to meet certain development requirements by June 30, 2002 to maintain exclusive license rights.

We also entered into Signing Bonus and Restricted Stock and Share Grant Agreements and Consulting Agreements with certain individuals affiliated with PG-TXL Company, L.P. (the PG-TXL Affiliates). Under the terms of these agreements, we issued 51,835 restricted shares of common stock. These shares vested in November 1999 upon the issuance of a patent, whereupon we recorded an expense of \$91,000 in accordance with EITF 96-18. The Company also granted

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

103,665 restricted share rights to the PG-TXL Affiliates, which also vest upon certain performance conditions. These performance conditions include successfully completing a phase III clinical trial of a licensed product and receiving regulatory approval of an NDA by the FDA. We will begin to record compensation expense at the time the vesting of the share rights become probable. We paid consulting fees to the PG-TXL Affiliates of \$75,000, \$111,000 and \$343,000 in 2001, 2000 and 1999, respectively.

### 14. ACQUISITION OF POLARX BIOPHARMACEUTICALS, INC.

On January 7, 2000, we acquired PolaRx Biopharmaceuticals, Inc. (PolaRx), a biopharmaceutical company that owns the rights to TRISENOX (arsenic trioxide, ATO), an anti-cancer compound for which we submitted and received approval for a New Drug Application with the FDA. Under the terms of the Agreement and Plan of Merger and Reorganization, dated January 7, 2000, (the Agreement), we assumed PolaRx's liabilities and commitments. PolaRx's shareholders received 5 million shares of our common stock. The aggregate consideration of \$36.2 million consisted of the 5 million shares of common stock valued at \$31.4 million, assumed net liabilities of \$3.9 million and transaction costs of approximately \$0.9 million.

We are also required to make contingent payments of up to \$9.0 million and future royalties if certain milestones and target net sales specified in the merger agreement are attained. Any additional or contingent payments made to PolaRx shareholders will be considered additional purchase price and will be capitalized as additional goodwill. The acquisition was accounted for as a purchase transaction and PolaRx operating results are included in our operating results from the date of acquisition. The aggregate purchase price of approximately \$36.2 million, which was valued by an outside independent party, was allocated, based on the fair value on the acquisition date, to marketing intangible assets (\$16.1 million), patented technology (\$6.7 million) and goodwill (\$13.4 million). The intangible assets are amortized

62

CELL THERAPEUTICS, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS-(CONTINUED)

over their estimated useful lives of three to five years. Notes payable aggregating \$2,673,000 were assumed in connection with the PolaRx acquisition. The notes carried interest rates of 9% to 15% and became due and were paid between March and November 2000. We also assumed and paid a fee of \$750,000 to a placement agent in connection with the acquisition.

The marketing of a commercial product bridges the gap in our pipeline of products and creates an opportunity to access a broader market segment with a relatively non-controversial and accepted product. The value of this marketing strategy is related to the acquisition of successfully completed clinical trial studies that included bioanalytical and statistical data, analyses and reports which have enabled the subsequent timely filing of a New Drug Application. The timely filing of the New Drug Application greatly enhances our relative competitive market position. The value of the preclinical and clinical research acquired together with the Orphan Drug Designation by the FDA accelerates the potential for regulatory approval and commercialization of a marketable product. The fair value of the marketing intangibles was determined by the replacement cost approach, which seeks to measure the future benefits of ownership by quantifying the amount of money that would be required to replace the future service capability of the subject intangible property. Replacement cost was the total cost to create a successful marketing strategy and included an examination

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

of the substantial research and development cost savings we achieved through the acquisition of PolaRx.

Through the purchase of PolaRx, we also acquired a patent for the treatment of primary and metastatic neoplastic diseases using arsenic compounds. By forecasting the incremental revenues and net incomes expected by the utilization of this patent in the areas of Acute Promyelocytic Leukemia (APL) and Multiple Myeloma over an expected five year period, it is possible to separate the value attributable to the patent by utilizing an income approach. The fair value of the patented technology was determined by discounting the forecasted earnings streams to each application at 30% over the anticipated revenue life of five years, which produced net present values of \$2,018,000 and \$4,594,000 for the APL and Multiple Myeloma indications, respectively.

The pro forma consolidated financial information for the year ended December 31, 1999, determined as if the acquisition had occurred on January 1, 1999, would have resulted in no revenues, a net loss applicable to common shareholders of \$53,570,000 and basic and diluted net loss per common share of \$2.61. Pro forma information for the period ended December 31, 2000 has not been included as the transaction was consummated on January 7, 2000, which is near the beginning of the period. This unaudited pro forma information is presented for illustrative purposes only and is not necessarily indicative of the results that would have been achieved had we and PolaRx been combined during the specified period.

### 15. PANGENEX, INC.

In June 2000, we founded PanGenex, Inc. (PanGenex), a majority-owned subsidiary focused on identifying novel drug development targets using the recently completed human genome sequence database. We provided funds and administrative services totaling \$2,457,000 and \$568,000 to support PanGenex's research and development efforts during 2001 and 2000, respectively. Minority interests are not reflected in the balance sheet as all losses of the entity are funded by us with no obligation of reimbursement by the minority shareholders.

63

## CELL THERAPEUTICS, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS-(CONTINUED)

### 16. UNAUDITED QUARTERLY DATA

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

	FIRST QUARTER	SECOND QUARTER	THIRD QUARTER	FOUR QUAR
	-----	-----	-----	-----
2001				
Revenues .....	\$ 929	\$ 1,886	\$ 1,004	\$ 2,
Gross profit .....	879	1,803	846	2,
Operating expenses .....	14,777	19,257	22,493	33,
Net loss .....	(11,580)	(15,866)	(21,340)	(31,
Net loss applicable to common shares .....	(11,705)	(15,992)	(21,461)	(32,
Net loss per common share-basic and diluted .....	(0.35)	(0.47)	(0.64)	(0

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

2000

Revenues .....	\$	--	\$	--	\$	--	\$
Gross profit .....		--		--		--	
Operating expenses .....		11,355		12,392		14,618	18,
Net loss .....		(11,069)		(11,832)		(13,980)	(15,
Net loss applicable to common shares .....		(11,195)		(11,958)		(14,108)	(15,
Net loss per common share-basic and diluted .....		(0.58)		(0.49)		(0.55)	(0

ITEM 9. CHANGES IN DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

64

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

DIRECTORS

NAME	AGE AS OF 5/01/02	DIRECTOR
James A. Bianco, M.D.(2)	45	199
Jack L. Bowman(3)(4)	69	199
Vartan Gregorian, Ph.D.	68	200
Wilfred E. Jaeger, M.D.(3)(4)	46	199
Max E. Link, Ph.D.(1)(2)	61	199
Mary O. Munding, DrPH(3)	65	199
Phillip M. Nudelman, Ph.D.(2)(4)	66	199
Jack W. Singer, M.D.	59	199

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

Dr. Bianco is our principal founder and has been our president and chief executive officer since February 1992 and one of our directors since our inception in September 1991. Prior to joining us, Dr. Bianco was an assistant professor of medicine at the University of Washington, Seattle, and an assistant member in the clinical research division of the Fred Hutchinson Cancer Research Center, the world's largest bone marrow transplant center. From 1990 to 1992, Dr. Bianco was the director of the Bone Marrow Transplant Program at the Veterans Administration Medical Center in Seattle. Dr. Bianco received his B.S. degree in biology and physics from New York University and his M.D. from Mount Sinai School of Medicine. Dr. Bianco is the brother of Louis A. Bianco, our executive vice president, finance and administration.

Mr. Bowman has been one of our directors since April 1995. From 1987 until January 1994, Mr. Bowman was a company group chairman at Johnson &

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

Johnson, having primary responsibility for a group of companies in the diagnostic, blood glucose monitoring and pharmaceutical businesses. From 1980 to 1987, Mr. Bowman held various positions at American Cyanamid Company, most recently as executive vice president. Mr. Bowman was a member of the board of trustees of The Johns Hopkins University and serves on the board of directors of NeoRx Corporation, Cellegy Pharmaceuticals, Inc., Targeted Genetics Corporation, Celgene Corporation, Osiris Therapeutics, and Reliant Pharmaceuticals.

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

Dr. Jaeger has been one of our directors since September 1992. Dr. Jaeger is a founding general partner of Three Arch Partners, a venture capital firm which focuses on health care investments. Prior to

joining Three Arch Partners in 1993, he was a partner at Collinson Howe Venture Partners, formerly

65

Schroeder Venture Advisors and the Phoenix Partners. Dr. Jaeger is also a director of numerous other healthcare companies. Dr. Jaeger received his M.D. from the University of British Columbia in Vancouver, B.C., Canada.

Dr. Link joined the board of directors in July 1995 as its vice chairman and has served as chairman of the board of directors since January 1996. In addition, Dr. Link has held a number of executive positions with pharmaceutical and healthcare companies. Most recently, he served as chief executive officer of Corange, Limited from May 1993 until June 1994. Prior to joining Corange, Dr. Link served in a number of positions within Sandoz Pharma Ltd., including chief executive officer from 1990 until April 1992, and chairman from April 1992 until May 1993. Dr. Link currently serves on the board of directors of Alexion Pharmaceuticals, Inc., Access Pharmaceuticals, CytRx Corporation, Discovery Labs, Human Genome Sciences, Inc., Protein Design Labs, Inc., Celsion Corporation, and Osiris Therapeutics. Dr. Link received his Ph.D. in economics from the University of St. Gallen.

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

Dr. Nudelman has been one of our directors since March 1994. Since May 2000, he has been the president and chief executive officer of The Hope Heart Institute. From 1998 to 2000, he was the chairman of the board of Kaiser/Group Health. From 1990 to 2000, Dr. Nudelman was the president and chief executive officer of Group Health Cooperative of Puget Sound, a health maintenance organization. Dr. Nudelman serves on the board of directors of SpaceLabs Medical, Inc., Personal Path Systems, and Cytran Ltd. Dr. Nudelman received his B.S. degree in microbiology, zoology and pharmacy from the University of

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

Washington, and holds an M.B.A. and a Ph.D. in health systems management from Pacific Western University.

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

66

### EXECUTIVE OFFICERS

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

NAME	AGE AS OF 5/01/02	POSITION
James A. Bianco, M.D.	45	President, Chief Executive Officer
Louis A. Bianco	49	Executive Vice President, Finance and Administration
James Canfield	44	Executive Vice President, Chief Administrative Officer
Edward F. Kenney	57	Executive Vice President, Chief Operating Officer
Michael B. Mumford	45	Executive Vice President, Manufacturing
Carolyn M. Paradise, M.D.	57	Executive Vice President, Chief Medical Officer
Jack W. Singer, M.D.	59	Executive Vice President, Research and Development

See "Directors and Executive Officers of the Registrant - Directors" for biographical information concerning Drs. Bianco and Singer.

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

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

Mr. Kenney has been our executive vice president, chief operating officer since January 1999. From February 1997 to September 1998 he was vice president of marketing and sales at CellPro Incorporated. From 1987 to 1996 he served in various sales, marketing and business development positions at Cetus Corporation and Chiron Corporation, which merged in 1991. From 1991 to 1996, Mr. Kenney was

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

a marketing manager in the cardiovascular therapy area at Boehringer Ingelheim, and from 1978 to 1986, he served in various sales, marketing and business development capacities at Bristol-Myers Corporation. Mr. Kenney received his M.S. degree in Natural Resources from Ohio State University.

Mr. Mumford has been our executive vice president, manufacturing operations since August 2001. From 1987 through 2001, Mr. Mumford held several positions at Immunex Corporation serving as the vice president of business and alliance management from June 2000 through August 2001 and vice president of manufacturing from January 1992 to June 2000. From 1981 to 1987, he held various development and manufacturing positions at Genentech, Inc. Mr. Mumford received his M.S. degree in Microbiology from the University of Oklahoma.

Ms. Paradise has been our executive vice president, chief medical officer since September 2001. From May 2000 to September 2001, she served as our vice president of clinical development and from November 1997 to April 2000, as our head of medical affairs. Ms. Paradise has also been a key member of our project review board. From 1994 to 1998, she served as the assistant clinical professor in the

67

department of medical oncology at UCSF Cancer Center and from 1992 to 1997, was vice president of clinical development at Chiron Technologies. She also was the director of clinical research oncology at Sterling Winthrop Pharmaceutical from 1991 to 1992 and has held several pharmaceutical/biotechnology related positions since 1977. Ms. Paradise received her B.A. degree from Hunter College and her M.D. from Free University of Brussels, Belgium.

### SECTION 16(A) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our executive officers and directors, and persons who own more than ten percent of a registered class of our equity securities, to file with the Securities and Exchange Commission reports of ownership and changes in ownership of common stock and other of our equity securities. Executive officers, directors and greater than ten percent shareholders are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file. We prepare Section 16(a) forms on behalf of our executive officers and directors based on the information provided by them. Based solely on review of this information, or written representations from reporting persons that no other reports were required, we believe that, during the 2001 fiscal year, all Section 16(a) filing requirements applicable to our executive officers, directors and greater than ten percent beneficial owners were complied with, other than the filings of a Form 4 for each of James A. Bianco, Louis A. Bianco, and Jack W. Singer, which were filed one day late.

### ITEM 11. EXECUTIVE COMPENSATION

#### DIRECTOR COMPENSATION

Directors who are also our employees are not paid an annual retainer, nor are they compensated for serving on the board. Non-employee directors are paid \$2,000 per meeting of the board, up to a maximum of \$10,000 per director each calendar year, and \$1,000 per meeting of a board committee, up to a maximum of \$5,000 per director each calendar year. All directors are reimbursed for their expenses incurred in attending board meetings. In 2001, pursuant to the Automatic Option Grant Program in effect for the directors under our 1994 Stock Option Plan, each non-employee director also received a fully-vested option grant for 15,000 shares upon appointment to the board, and a fully-vested option

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

grant for 5,000 shares annually after the commencement of his or her service as a director. Each of these options has an exercise price equal to 100% of the fair market value on the grant date in 2001 and a term of ten years measured from the grant date, subject to early termination if the optionee stops serving as a director.

68

COMPENSATION OF EXECUTIVE OFFICERS

The following table sets forth all compensation earned in the years ended December 31, 2001, 2000 and 1999 by our chief executive officer and the four other most highly compensated executive officers who were serving as executive officers at December 31, 2001, who we will collectively refer to as the named executive officers:

SUMMARY COMPENSATION TABLE

NAME AND PRINCIPAL POSITION	YEAR	ANNUAL COMPENSATION		LONG-TERM COMPENSATION AWARDS	
		SALARY (\$)	BONUS (\$)	OTHER ANNUAL COMPENSATION (\$)	RESTRICTED STOCK AWARDS (\$)
James A. Bianco, M.D. .... President and Chief Executive Officer	2001	433,008	222,013	88,589 (4)	--
	2000	433,125	293,101	66,394 (6)	--
	1999	433,224	50,000	101,885 (8)	108,412
Louis A. Bianco ..... Executive Vice President, Finance and Administration	2001	300,120	48,874	--	--
	2000	300,120	60,000	--	--
	1999	300,120	--	--	54,252
Edward F. Kenney ..... Executive Vice President, Chief Operating Officer	2001	246,000	66,420	--	--
	2000	225,000	100,000	--	--
	1999	211,442	--	--	56,304
Carolyn M. Paradise, M.D. ... Executive Vice President, Chief Medical Officer	2001	238,152	66,103	--	--
Jack W. Singer, M.D. .... Executive Vice President, Research Program Chairman	2001	260,016	70,204	--	--
	2000	260,016	70,000	--	--
	1999	260,016	--	--	65,067

- (1) Other annual compensation in the form of perquisites and other personal benefits has been omitted where the aggregate amount of the perquisites and other personal benefits constituted the lesser of \$50,000 or 10% of the total annual salary and bonus for the named executive officer for the applicable year.
- (2) All restricted stock grants were made on December 22, 1999 under the 1994 Equity Incentive Plan. The aggregate number of shares held by the named executive officers at the end of 2001 (and their market value as of December 31, 2001) were: Dr. Bianco, 35,394 (\$108,412); Dr. Singer, 21,243 (\$65,067); Mr. Bianco, 17,712 (\$54,252); Mr. Kenney, 18,382 (\$56,304); and Ms. Paradise, 10,000 (\$30,630). All of these grants vest 100% on the third anniversary of the grant date.
- (3) None of the named executive officers held any stock appreciation rights.
- (4) Other annual compensation for Dr. Bianco represents perquisites, including



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

- \$51,685 in tax reimbursements.
- (5) All other compensation for Dr. Bianco includes the following: (i) a premium payment of \$40,000 for life insurance required by the terms of Dr. Bianco's employment, and (ii) reimbursement of long-term disability insurance premiums of \$9,304.
  - (6) Other annual compensation for Dr. Bianco represents perquisites, including \$38,772 in tax reimbursements and \$19,416 in business travel reimbursements.
  - (7) All other compensation for Dr. Bianco includes the following: (i) a premium payment of \$40,000 for life insurance required by the terms of Dr. Bianco's employment, and (ii) reimbursement of long-term disability insurance premiums of \$9,461.
  - (8) Other annual compensation for Dr. Bianco represents perquisites, including \$34,166 in tax reimbursements for certain perquisites, and \$61,304 in tax reimbursement with respect to loan forgiveness described in Note 9.
  - (9) All other compensation for Dr. Bianco includes the following: (i) loan forgiveness of \$88,036 pursuant to the terms of Dr. Bianco's employment agreement, (ii) a premium payment of \$40,000 for life insurance required by the terms of Dr. Bianco's employment, (iii) reimbursement of long-term disability insurance premiums of \$9,461, and (iv) travel and expense reimbursements totaling \$3,900.
  - (10) All other compensation for Mr. Bianco includes reimbursement for long-term disability insurance premiums.
  - (11) All other compensation for Mr. Bianco includes the following: (i) reimbursement for long-term disability insurance premiums of \$8,443, and (ii) a premium payment of \$2,178 for life insurance.
  - (12) All other compensation for Mr. Bianco includes the following: (i) reimbursement for long-term disability insurance premiums of \$8,499, and (ii) a premium payment of \$1,929 for life insurance.
  - (13) All other compensation for Dr. Singer includes reimbursement for long-term disability insurance premiums.

69

The following table sets forth for each of the named executive officers the number of options granted during the year ended December 31, 2001 and the potential realizable value of such grants. No stock appreciation rights were granted to such individuals for the 2001 fiscal year.

OPTIONS GRANTED IN LAST FISCAL YEAR

NAME	INDIVIDUAL GRANTS				POTENTIAL VALUE OF ANNUAL GRANTS AT EXPIRATION DATE
	NUMBER OF UNDERLYING OPTIONS GRANTED (1)	% OF TOTAL OPTIONS GRANTED TO EMPLOYEES IN FISCAL YEAR (%)	EXERCISE PRICE (\$/SH) (2)	EXPIRATION DATE	
James A. Bianco, M.D.....	250,000	16.5%	\$27.30	11/30/11	\$4,200,000
Louis A. Bianco.....	75,000	4.9	27.30	11/30/11	1,200,000
Edward F. Kenney.....	75,000	4.9	27.30	11/30/11	1,200,000
Carolyn M. Paradise, M.D.....	20,000	1.3	24.55	7/6/11	300,000
Carolyn M. Paradise, M.D.....	55,000	3.6	27.30	11/30/11	900,000
Jack W. Singer, M.D.....	75,000	4.9	27.30	11/30/11	1,200,000

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

- (1) Options were granted under the 1994 plan.
- (2) Stock options were granted at an exercise price equal to 100% of the estimated fair value of the common stock, as determined by the board of directors on the date of grant, pursuant to the terms of the 1994 plan.
- (3) Potential realizable value is based on the assumption that the common stock appreciates at the annual rates shown (compounded annually) from the date of grant until the expiration of the option term. These assumed rates of appreciation are mandated by the rules of the SEC and do not represent our estimate or projection of the future common stock price. There can be no assurance that any of the values reflected in this table will be achieved.

The following table sets forth for each of the named executive officers, the fiscal year-end number and value of unexercised options. None of the named executive officers held any stock appreciation rights at the end of the 2001 fiscal year.

### AGGREGATED OPTION EXERCISES IN LATEST FISCAL YEAR AND FISCAL YEAR-END OP

NAME	SHARES		NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS AT		
	ACQUIRED ON EXERCISE (#)	VALUE REALIZED (\$)	FISCAL YEAR END (#)		EX
-----	-----	-----	-----	-----	-----
James A. Bianco, M.D.	--	\$ --	372,291 (2)	33,333	\$
Louis A. Bianco	--	--	146,647 (3)	11,666	
Edward F. Kenney	--	--	90,005	44,995	
Carolyn M. Paradise, M.D.	--	--	33,074	9,030	
Jack W. Singer, M.D.	10,000	267,792	111,198	13,333	

(1) This amount is the aggregate number of in-the-money options multiplied by the difference between the last reported sale price of the common stock on the Nasdaq National Market on December 31, 2001 and the exercise price for that option.

(2) Includes 38,048 options exercised and rescinded by Dr. Bianco in 2001.

(3) Includes 43,336 options exercised and rescinded by Mr. Bianco in 2001.

#### EMPLOYMENT AGREEMENTS

Dr. Bianco, president and chief executive officer, entered into an employment agreement with us effective July 4, 2000. The agreement provides that, in the event that Dr. Bianco's employment is involuntarily terminated, the severance benefits are equal to: eighteen months base salary, immediate vesting of all of Dr. Bianco's stock options and restricted shares, payment for life insurance and accrued but unused vacation. The employment agreement restricts Dr. Bianco from competing with us for the term of the severance payment period following the termination of his employment with us. In addition, the severance payments are conditioned upon Dr. Bianco not soliciting our employees. The agreement also provides that, in the event a change of control (as defined in

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

the employment agreement) occurs, then all of Dr. Bianco's stock options and restricted shares will immediately become vested. It further provides that, if any payments are subject to the excise tax on parachute payments, we will make a gross up payment in an amount that covers the excise tax due plus the excise and income taxes payable on the gross up payment.

Each of Jack W. Singer, Louis A. Bianco, and Edward F. Kenney has entered into a severance agreement with us effective September 23, 1997, February 1, 1998, and January 22, 1999, respectively. The agreements provide that, in the event any of the foregoing named executive officers is terminated by us without cause or resigns for good reason, including a change in title in connection with a change in control in the cases of Dr. Singer and Mr. Bianco: (1) we will pay the base salary for one year from the severance date (2) we will pay accrued but unused vacation through the severance date, (3) we will continue to pay benefits for one year from the severance date, and (4) all stock options will become immediately vested. Inventions and proprietary information agreements restrict Dr. Singer from competing with us for two years after the termination of his employment with us.

### COMPENSATION COMMITTEE REPORT ON EXECUTIVE COMPENSATION

The compensation committee of the board of directors is composed of directors who are not our employees. The compensation committee is responsible for establishing and administering our executive compensation arrangements, including the compensation of the chief executive officer and our other executive officers and key employees, subject to ratification by the board. The compensation committee also administers the 1994 plan and the 1996 employee stock purchase plan and makes all stock option grants under the 1994 plan to our executive officers.

### GENERAL COMPENSATION POLICY

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

71

- . Offer a total compensation program that takes into consideration the compensation practices of a specifically identified peer group of companies with which we compete for executive talent.
- . Integrate each executive officer's compensation package with annual and long-term corporate objectives and focus the officer's attention on the attainment of those objectives.
- . Encourage the creation of shareholder value through the achievement of strategic corporate objectives.
- . Provide annual variable incentive awards that take into account our performance relative to corporate objectives and the individual executive officer's contributions.
- . Align the financial interests of executive officers with those of shareholders by providing significant equity-based, long-term

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

incentives.

### COMPENSATION COMPONENTS AND PROCESS

The compensation committee has developed a compensation policy that is designed to attract and retain qualified key executive officers critical to our success.

Accordingly, the compensation committee makes its decisions based upon the attainment of corporate-wide, team and individual performances. These performances are evaluated in terms of the achievement of strategic and business plan goals, including long-term goals tied to the expansion of our core technology and innovative product development, the discovery of new drug candidates and the development of our organizational infrastructure.

In establishing the compensation package of our executive officers, the compensation committee has adopted a "total pay" philosophy which includes three major components: (1) base salary set at levels that are commensurate with those of comparable positions at other pharmaceutical or biotechnology companies; (2) annual bonuses and stock option grants tied to the achievement of strategic corporate and team objectives and individual performance; and (3) long-term, stock-based incentive awards intended to strengthen the mutuality of interests between the executive officers and our shareholders.

The compensation committee determines the compensation levels for the executive officers with the assistance of an independent consulting firm that furnishes the compensation committee with executive compensation data drawn from several nationally recognized surveys of companies within the biotechnology and pharmaceutical industries. On the basis of those surveys, the compensation committee has identified a peer group of companies with which we compete for executive talent and which have a total capitalization and head count similar to ours and are at approximately the same stage of commercialization, which we will refer to as the peer companies.

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

**Base Salary.** The base salary for each executive officer is set at a level considered appropriate for comparable positions at the peer companies. The compensation committee's policy is to target base salary

72

levels at the market average level of base salary in effect for comparable positions at the peer companies. Executive officers who attain the core competencies required of their positions are paid at that level. The compensation committee makes its base salary determinations in accordance with the market average level in effect for comparable positions at the peer companies, competitive market forces and the evaluation of performance and core competency provided for each executive officer by the chief executive officer.

**Variable Incentive Awards.** To reinforce the attainment of our goals, the compensation committee believes that a substantial portion of the annual compensation of each executive officer should be in the form of variable incentive pay. The annual incentive payment for each executive officer is

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

determined on the basis of the achievement of the corporate objectives established for the fiscal year and the Committee's evaluation of the officer's performance both on an individual and team basis. For the 2001 fiscal year, the corporate performance objectives were tied to the following measures of success: (1) expand the commercial projects for TRISENOX revenue growth targeting break even operating unit by 2003; (2) enhance our drug candidate portfolio; (3) optimize the development and commercial potential for PG-TXL; and (4) secure adequate operating capital.

Long-Term, Equity-Based Incentive Awards. The goal of our long-term equity-based incentive awards is to align the interests of executive officers with the shareholders and to provide each executive officer with a significant incentive to perform his or her management duties from the perspective of an owner with an equity stake in the business. Such incentive is provided through stock option grants made under the 1994 plan. The size of the option grant to each executive officer is set at a level which the compensation committee feels is appropriate to create a meaningful opportunity for stock ownership based upon the executive officer's current position with us, internal comparability with stock option grants made to our other executives, the executive officer's current level of performance and his or her potential for future responsibility and promotion over the option term. The compensation committee also takes into account comparable equity incentives provided to individuals in similar positions in the biotechnology and pharmaceutical industries, as reflected in external surveys, and the number of unvested options held by the executive officer at the time of the new grant. The compensation committee has established certain general guidelines by which it seeks to target a fixed number of unvested option shares for each executive officer based upon his or her current position with us and his or her potential for in-house growth (i.e., future responsibilities and possible promotions over the option term). However, the compensation committee does not strictly adhere to these guidelines in making stock option grants, and the relative weight that is given to the various factors varies from individual to individual, as the circumstances warrant.

During fiscal 2001, the compensation committee awarded the executive officers named in this proxy statement, new stock options for an aggregate of 550,000 shares of common stock. Each grant allows the officer to acquire the shares underlying the stock option at a fixed price per share (the market price on the grant date) over a ten-year period of time. Specifically, the options vest in periodic installments over a three-year period, contingent upon the executive officer's continued employment with us. Accordingly, the option will provide a return only if the officer remains with us and then only if the market price appreciates over the option term.

### COMPENSATION OF THE CHIEF EXECUTIVE OFFICER

The base salary of our chief executive officer, James A. Bianco, M.D., is reviewed annually by the compensation committee and was \$433,008 for the 2001 fiscal year, which equates to a 0% increase over fiscal year 2000. Such salary level was established on the basis of the base salary levels in effect for

chief executive officers at the other biotechnology and pharmaceutical companies comprising the peer companies. This salary level for Dr. Bianco brings him to 8% above the average of the salary levels in effect for the chief executive officers of the peer companies. The compensation committee granted Dr. Bianco bonuses of \$222,013 during 2001. This amount is 51% of base pay, and is above peer data suggesting that short term incentive target grants are approximately 40% of base pay.

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

Dr. Bianco was also awarded stock options for 250,000 shares of common stock at an exercise price of \$27.30 per share. The grant reflected the compensation committee's continuing policy to maintain his option holdings at a level consistent with that for other chief executive officers of comparable commercial companies in the pharmaceutical industry and to subject a portion of his overall compensation each year to the market performance of our common stock. Accordingly, the stock option grants will be of no value to Dr. Bianco unless there is appreciation in the value of our common stock over the option term.

### COMPLIANCE WITH INTERNAL REVENUE CODE SECTION 162(M)

As a result of Section 162(m) of the Internal Revenue Code, which was enacted into law in 1993, we will not be allowed a federal income tax deduction for compensation paid to certain officers, to the extent that compensation exceeds one (1) million dollars per officer in any one year. This limitation will apply to all compensation that is not considered to be performance based. Compensation that does qualify as performance-based compensation will not have to be taken into account for purposes of this limitation. Our 1994 plan has been structured so any compensation deemed paid in connection with the exercise of stock options granted under that plan with an exercise price equal to the market price of the option shares on the grant date will qualify as performance-based compensation. The cash compensation paid to our executive officers during fiscal 2001 did not exceed the one (1) million dollar limit per officer.

#### COMPENSATION COMMITTEE

Jack L. Bowman  
Wilfred E. Jaeger, M.D.  
Mary Munding, DrPH

#### COMPENSATION COMMITTEE INTERLOCKS AND INSIDER PARTICIPATION

During the last completed fiscal year, the compensation committee consisted of Mr. Bowman and Drs. Jaeger and Munding. None of these individuals was at any time during the last completed fiscal year, or at any other time, one of our officers or employees.

74

#### ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information regarding beneficial ownership of common stock, as of March 31, 2002, by (1) each shareholder known by us to be the beneficial owner of more than 5% of our outstanding shares of common stock, (2) each of our directors and nominees for director, (3) each of our executive officers named in the Summary Compensation Table herein, and (4) all directors and executive officers as a group:

NAME AND ADDRESS OF BENEFICIAL OWNER (1)	NUMBER OF SHARES BENEFICIALLY OWNED (2)	SHARES SUBJECT TO OPTIONS	PERCENTAGE OWNED
Lindsay A. Rosenwald and The Aries Master Funds (3) . . . . . c/o Paramount Capital Asset Management, Inc. 787 Seventh Avenue, 48th Floor	3,483,491	--	9.9%

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

New York, NY 10019			
Essex Woodlands Health Ventures Fund IV, L.P. (4) .....	1,965,816	--	5.6%
15001 Walden Road, Suite 101			
Montgomery, TX 77356			
Janus Capital Corporation (5) .....	2,515,370	--	7.2%
100 Fillmore Street			
Denver, CO 90206			
James A. Bianco, M.D.** .....	759,610	472,291	2.1%
Jack L. Bowman** .....	27,383	27,383	*
Vartan Gregorian, Ph.D.** .....	15,000	15,000	*
Wilfred E. Jaeger, M.D.** .....	8,240	8,240	*
Max E. Link, Ph.D.** .....	10,000	10,000	*
Mary O. Munding, DrPH** .....	20,000	20,000	*
Phillip M. Nudelman, Ph.D.** .....	36,811	36,811	*
Jack W. Singer, M.D.** .....	357,779	134,532	1.0%
Louis A. Bianco .....	188,190	166,647	*
Edward F. Kenney .....	156,668	156,668	*
Carolyn M. Paradise, M.D. ....	37,551	37,324	*
All directors and executive officers as a group			
(13 persons) .....	1,625,232	1,092,896	4.5%

\* Less than 1%

\*\* Denotes director of the Company

- (1) The address of the individuals listed is 501 Elliott Avenue West, Suite 400, Seattle, Washington 98119.
- (2) Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission and generally includes voting or investment power with respect to securities. This table is based upon information supplied by officers, directors, and Schedules 13D and 13G filed with the SEC. Shares of common stock subject to options or warrants currently exercisable or convertible, or exercisable or convertible within 60 days of March 31, 2002, are deemed outstanding for computing the percentage of the person holding the option or warrant but are not deemed outstanding for computing the percentage of any other person. Except as indicated in the footnotes to this table and pursuant to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock beneficially owned.
- (3) Includes (a) warrants to purchase 35,000 shares of common stock, and 1,544,510 shares of common stock held by Lindsay A. Rosenwald, M.D., (b) warrants to purchase 257,219 shares of common stock, and 1,007,481

shares of common stock held by The Aries Master Fund, a Cayman Island exempted company, (c) warrants to purchase 104,229 shares of common stock, and 405,866 shares of common stock held by Aries Domestic Fund L.P., (d) warrants to purchase 8,076 shares of common stock, and 121,110 shares of common stock, held by Aries Domestic Fund II, L.P. Paramount Capital Asset Management, Inc. is the general partner of each of the Aries Domestic Funds and the investment manager of The Aries Master Fund. Dr. Rosenwald is the chairman and sole shareholder of Paramount Capital Asset Management.

- (4) Consists of 1,965,816 shares of common stock beneficially owned by Essex Woodlands Health Ventures Fund IV, L.P. Mr. Martin P. Sutter is the managing director of Essex Woodlands Health Ventures Fund IV, L.P.
- (5) Janus Capital Corporation has sole power to vote and dispose of 2,515,370 shares. Mr. Thomas H. Bailey, the president and chairman of the board of Janus Capital Corporation, has sole power to vote and dispose of 2,515,370

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

shares. Also, Janus Global Life Sciences Fund has sole power to vote and dispose of 1,773,055 shares.

### 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, 2001, 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)
Equity Compensation Plans Approved by Shareholders	4,540,689	\$19.67	570,328	

### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

On December 16, 1998, in lieu of cash bonuses, we extended loans at 4.97% annual interest to the following executive officers: Dr. Bianco, \$100,000 and Dr. Singer, \$75,000. The promissory notes provide for a single payment of principal and interest on December 16, 2002. The largest balances outstanding on the loans during 2001 were \$115,663 and \$86,747, respectively. The amounts outstanding at March 31, 2002 were \$117,317 and \$87,987, respectively.

On April 8, 2002, we extended a loan of \$3.5 million to Dr. Bianco. The loan is a full-recourse loan and is secured by a mortgage on certain property owned by Dr. Bianco, as well as 255,381 shares of Cell Therapeutics, Inc. common stock owned by Dr. Bianco. The loan bears interest at the six-month LIBOR rate plus 2.25%, adjusted semi-annually (4.55% at April 8, 2002). Interest is due on October 8th and April 8th of each year that the loan is outstanding and principal is due April 8, 2004.

76

### Stock Performance Graph

[GRAPH]

	3/21/1997 -----	3/31/1997 -----	6/30/1997 -----	9/30/1997 -----	12/31/1997 -----
Cell Therapeutics, Inc	\$ 100.00	\$ 97.56	\$ 108.54	\$ 145.12	\$ 165.8
Nasdaq Stock Index (U.S.)	\$ 100.00	\$ 97.51	\$ 115.38	\$ 134.88	\$ 126.2
Nasdaq Pharmaceutical Index	\$ 100.00	\$ 93.41	\$ 100.51	\$ 112.78	\$ 101.4



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

	9/30/1998	12/31/1998	3/31/1999	6/30/1999	9/30/1999
	-----	-----	-----	-----	-----
Cell Therapeutics, Inc	\$ 20.73	\$ 29.27	\$ 34.15	\$ 24.09	\$ 21.00
Nasdaq Stock Index (U.S.)	\$ 137.04	\$ 178.07	\$ 199.70	\$ 218.41	\$ 223.00
Nasdaq Pharmaceutical Index	\$ 96.98	\$ 128.74	\$ 141.16	\$ 144.09	\$ 165.00

  

	6/30/2000	9/30/2000	12/31/2000	3/31/2001	6/30/2001
	-----	-----	-----	-----	-----
Cell Therapeutics, Inc	\$ 298.78	\$ 650.61	\$ 439.63	\$ 175.02	\$ 269.60
Nasdaq Stock Index (U.S.)	\$ 322.96	\$ 297.19	\$ 199.00	\$ 148.55	\$ 175.00
Nasdaq Pharmaceutical Index	\$ 330.89	\$ 363.34	\$ 302.78	\$ 224.21	\$ 278.50

The stock performance graph depicts the cumulative total return on our common stock compared to the current total return for the Nasdaq Stock Index (U.S.) and the Nasdaq Pharmaceutical Index. The graph assumes an investment of \$100 on March 21, 1997, when our stock was first traded in a public market. Reinvestment of dividends, if any, is assumed in all cases.

77

PART IV

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

(a) Financial Statements and Financial Statement Schedules

(i) Financial Statements

Report of Ernst & Young LLP, Independent Auditors  
 Consolidated Balance Sheets  
 Consolidated Statements of Operations  
 Consolidated Statements of Shareholders' Equity  
 Consolidated Statements of Cash Flows  
 Notes to Consolidated Financial Statements

(ii) Financial Statement Schedules

II--Valuation and Qualifying Accounts

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

(iii) Exhibits

EXHIBIT NUMBER	DESCRIPTION
-----	-----
2.1(12)	Agreement and Plan of Reorganization between PolARx Biopharmaceuticals, Inc., the Registrant and PolARx Biopharmaceuticals Acquisition Corp., dated January 7, 2000.
3.1(1)	Registrant's Restated Articles of Incorporation.

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

- 3.2(2) Registrant's Articles of Amendment to Restated Articles of Incorporation of Cell Therapeutics, Inc. Effecting a Reverse Stock Split.
- 3.3(3) Registrant's Articles of Amendment to Restated Articles of Incorporation of Undesignating Series A and Series B Preferred Stock.
- 3.4(4) Registrant's Restated Bylaws.
- 4.1(5) Form of Rights Agreement dated as of November 11, 1996, between the Registrant and Harris Trust Company of California, which includes the Form of Rights Certificate as Exhibit A, the Summary of Rights to Purchase Preferred Stock as Exhibit B and the Form of Certificate of Designation of the Series C Preferred Stock as Exhibit C.
- 10.1(6) Lease Agreement between David A. Sabey and Sandra L. Sabey and the Registrant, dated March 27, 1992, as amended March 31, 1993 and October 13, 1993.
- 10.2(2) Third Amendment to Lease Agreement between David A. Sabey and Sandra L. Sabey and the Registrant, dated as of September 10, 1996.
- 10.3(1) Assignment of Lease between Manlove Travel and the Registrant, dated April 23, 1993.
- 10.4(2) Letter Agreement between David A. Sabey, Sandra L. Sabey and the Registrant, dated as of September 6, 1996, amending the Assignment of Lease.

78

EXHIBIT NUMBER	DESCRIPTION
10.5(13)*	Employment Agreement between the Registrant and James A. Bianco, dated as of July 4, 2000.
10.6(6)*	Employment Agreement between the Registrant and Louis A. Bianco, dated as of February 1, 1992, as amended May 27, 1994.
10.7(7)*	Employment Agreement between the Registrant and Jack W. Singer, dated September 23, 1997.
10.8(2)*	Form of Strategic Management Team Severance Agreement.
10.9(1)*	1994 Equity Incentive Plan, as amended.
10.10(1)*	1996 Employee Stock Purchase Plan.
10.11(6)+	Collaboration Agreement by and between BioChem Therapeutic Inc. and the Registrant, dated March 7, 1995, as amended November 30, 1995 and December 6, 1995.
10.12(6)+	Supply Agreement by and between BioChem Therapeutic Inc. and the Registrant, dated March 7, 1995.
10.13(7)	Master Loan and Security Agreement between the Company and the Transamerica Business Credit Corporation, dated as of December

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

9, 1997.

- 10.14(10)+ License Agreement dated as of November 13, 1998, by and between PG- TXL Company, L.P. and the Registrant.
- 10.15(10) Form of Promissory Note (executed on December 12, 1998), between the Registrant and each of the following persons: James A. Bianco, Jack W. Singer, and Louis A. Bianco.
- 10.16(14) Amended Equipment Leasing Agreement dated as of September 1, 2001, between Citiflight, Inc. and the Registrant.
- 10.17(14)+ Paclitaxel Purchase Agreement dated as of September 28, 2001, between Natural Pharmaceuticals, Inc. and the Registrant.
- 10.18(14)+ License Agreement dated as of October 19, 2001, between Chugai Pharmaceutical Co., Ltd. and the Registrant.
- 10.19(15)\* Form of Indemnification Agreement
- 10.20(15) ISDA Master Agreement dated as of January 25, 2002, between Citibank N.A. and the Registrant
- 10.21 Sublease Agreement between F5 Networks, Inc. and the Registrant, dated March 30, 2001, as amended April 13, 2001
- 10.22(16) Loan Agreement by and between James A. Bianco and the Registrant, dated April 8, 2002.
- 21.1# Subsidiaries of the Registrant.
- 23.1 Consent of Ernst & Young LLP, Independent Auditors.

79

EXHIBIT NUMBER -----	DESCRIPTION -----
24.1#	Power of Attorney (see page 70 of the Registrant's Annual report on Form 10-K for the year ended December 31, 2001).

# Previously filed.

\* Indicates management contract or compensatory plan or arrangement.

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

(1) Incorporated by reference to exhibits to the Registrant's Registration Statement on Form S-1 (No. 33-4154).

(2) Incorporated by reference to the Registrant's Registration Statement on Form S-1 (No. 333-20855).

(3) Incorporated by reference to the Registrant's Registration Statement on Form S-3 (No. 333-36603).

(4) Incorporated by reference to exhibits to the Registrant's Quarterly Report

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

on Form 10-Q for the quarter ended September 30, 1996.

- (5) Incorporated by reference to exhibits to the Registrant's Registration Statement on Form 8-A.
- (6) Incorporated by reference to exhibits to the Registrant's Registration Statement on Form 10.
- (7) Incorporated by reference to exhibits to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1997.
- (8) Incorporated by reference to exhibits to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1998.
- (9) Incorporated by reference to exhibits to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1996.
- (10) Filed with the Registrant's Annual Report on Form 10-K for the year ended December 31, 1998.
- (11) Incorporated by reference to exhibits to the Registrant's Form 10-Q for the quarter ended September 30, 1997.
- (12) Incorporated by reference to exhibits to the Registrant's Form 8-K, filed on January 25, 2000.
- (13) Incorporated by reference to exhibits to the Registrant's amended Annual Report on Form 10-K/A for the year ended December 31, 2000.
- (14) Incorporated by reference to exhibits to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2001.
- (15) Incorporated by reference to exhibits to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2001.
- (16) Incorporated by reference to exhibits to the Registrant's Form 8-K, filed on April 12, 2002.

(b) Reports on Form 8-K

There were no reports on Form 8-K filed by us during the quarter ended December 31, 2001.

80

### SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Amended Report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Seattle, State of Washington, on April 29, 2002.

Cell Therapeutics, Inc.

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

-----  
JAMES A. BIANCO, M.D.  
President and Chief Executive  
Officer

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

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

SIGNATURE	TITLE
----- * ----- MAX E. LINK, PH.D.	----- Chairman of the Board and Director
/s/ James A. Bianco, M.D. ----- JAMES A. BIANCO, M.D.	President, Chief Executive Officer and Director (Principal Executive Officer)
/s/ Louis A. Bianco ----- LOUIS A. BIANCO	Executive Vice President, Finance and Administration (Principal Financial Officer and Principal Accounting Officer)
* ----- JACK W. SINGER M.D.	Director
* ----- JACK L. BOWMAN	Director
* ----- VARTAN GREGORIAN, PH.D.	Director
* ----- WILFRED E. JAEGER, M.D.	Director
* ----- MARY O. MUNDINGER, DRPH	Director
* ----- PHILLIP M. NUDELMAN, PH.D.	Director
*By: /s/ James A. Bianco, M.D. ----- JAMES A. BIANCO, M.D.	

(Attorney-in-Fact)

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

VALUATION AND QUALIFYING ACCOUNTS  
 YEARS ENDED DECEMBER 31, 2001 and 2000  
 (IN THOUSANDS)

	BALANCE AT BEGINNING OF PERIOD	ADDITIONS CHARGED TO EXPENSE	DED
	-----	-----	-----
Year ended December 31, 2000 Reserve for sales returns and allowances	\$ --	\$ 67	\$
Year ended December 31, 2001 Reserve for sales returns and allowances	\$ 67	\$ 322	\$
Year ended December 31, 2001 Reserve for excess inventory that may expire and become unsaleable	\$ --	\$ 96	\$