CELL THERAPEUTICS INC
Form 424B5
December 21, 2004
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PROSPECTUS SUPPLEMENT

(To Prospectus dated March 22, 2004)

Filed pursuant to Rule 424(b)(5)

Registration No. 333-112681

281,690 Shares of Common Stock

We are offering all of the 281,690 shares of our common stock offered by this prospectus supplement.

Our common stock is quoted on the Nasdaq National Market and on the Nuovo Mercato in Italy under the symbol CTIC. On December 17, 2004, the last reported sale price of our common stock on the Nasdaq National Market was $8.20 per share.

Investing in our common stock involves a high degree of risk. Before buying any shares, you should carefully read the discussion of material risks of investing in our common stock under the heading Risk Factors beginning on page S-12 of this prospectus supplement.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus supplement or the accompanying prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per share	Total
Public offering price of common stock to an institutional investor and total proceeds before other expenses to us	$7.10	$1,999,999

The date of this prospectus supplement is December 21, 2004

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About This Prospectus Supplement

This document is in two parts. The first part is this prospectus supplement, which describes the terms of this offering of common stock and also adds to, updates and changes information contained in the accompanying prospectus and the documents incorporated by reference. The second part is the accompanying prospectus, which gives more general information, some of which may not apply to this offering of common stock. To the extent the information contained in this prospectus supplement differs or varies from the information contained in the accompanying prospectus or any document incorporated by reference, the information in this prospectus supplement shall control.

You should rely only on information contained in or incorporated by reference into this prospectus supplement and the accompanying prospectus. We have not authorized anyone to provide you with information that is different. We are offering to sell and seeking offers to buy shares of common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference herein and therein are accurate only as of their respective dates, regardless of the time of delivery of this prospectus supplement or of any sale of our common stock.

Prospectus Supplement

Base Prospectus

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FORWARD-LOOKING STATEMENTS

Certain statements in this prospectus supplement and the accompanying prospectus and the documents incorporated herein by reference are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended, that involve risks and uncertainties. Any statements contained herein (including without limitation statements to the effect that we estimate, expect, anticipate, plan, believe, project, continue, may, or will or statements concernin opportunity or variations thereof or comparable terminology or the negative thereof) that are not statements of historical fact should be construed as forward-looking statements. These statements are not guarantees of future performance and are subject to certain risks, uncertainties and assumptions that are difficult to predict. Actual results could differ materially and adversely from those anticipated in such forward-looking statement as a result of certain factors, including those described in this prospectus supplement and the accompanying prospectus under Risk factors. Because of these and other factors that may affect our operating results, past performance should not be considered an indicator of future performance and investors should not use historical results to anticipate results or trends in future periods. We undertake no obligation to revise or publicly release the results of any revision to these forward-looking statements.

We have not authorized any person to give any information or to make any representation other than those contained in this prospectus supplement and the accompanying prospectus in connection with this offering. You should not rely on such information or representation. Neither the delivery of this prospectus supplement, or the accompanying prospectus, or any sale made pursuant thereto shall create any implication that the information contained in this prospectus supplement or the accompanying prospectus is correct as of any time subsequent to the date hereof. Neither this prospectus supplement or the accompanying prospectus constitutes an offer to sell no solicitation of an offer to buy any security other than the common stock covered by this prospectus supplement or the accompanying prospectus.

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PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights selected information contained elsewhere or incorporated by reference in this prospectus supplement and the accompanying prospectus. This summary may not contain all the information that you should consider before investing in our common stock. You should read the entire prospectus supplement and the accompanying prospectus carefully before making an investment decision.

Business Overview

We develop, acquire and commercialize novel treatments for cancer. Our goal is to build a leading, vertically-integrated biopharmaceutical company with a diversified portfolio of proprietary cancer drugs. Our research, development, acquisition and in-licensing activities are concentrated on identifying new, less toxic and more effective products to treat cancer. We market TRISENOX, arsenic trioxide injection, for the treatment of relapsed or refractory acute promyelocytic leukemia, or APL, in the U.S. and in the European Union, or EU. We are developing XYOTAX, paclitaxel poliglumex, for the treatment of non-small cell lung cancer, or NSCLC, and ovarian cancer. In July 2004, we completed enrollment in the third of three pivotal phase III trials for XYOTAX, known as STELLAR 2 for the potential single agent use as a second-line treatment of patients with NSCLC. In May 2004, we completed enrollment of the second pivotal trial, known as STELLAR 4, for the potential single agent use as front-line treatment of performance status 2, or PS2, patients with NSCLC. We completed enrollment in November 2003 in the first pivotal trial, known as STELLAR 3, for the potential use in combination with platinum as front-line treatment of PS2 patients with NSCLC. Based on the third-party published survival statistics of PS2 patients, in the beginning of 2004 we had anticipated releasing data from STELLAR 3 in the third quarter of 2004 and had planned to submit a new drug application, or NDA, at the end of 2004. A trial designed to examine the effect of a treatment on patient survival requires a predetermined number of events (deaths) to occur in order to conduct a primary efficacy analysis. However, based on a higher than historically predicted survival rate reported by the data monitoring committee between January and December 2004, we now do not expect to reach the number of events required to conduct the primary analysis in STELLAR 3 until early 2005, thus delaying the potential submission of an NDA until summer 2005. The principal trial investigators and we believe that this higher than anticipated survival rate could be an encouraging trend and potentially indicative of a XYOTAX treatment effect. We also are developing pixantrone, a novel compound for the treatment of non-Hodgkin s lymphoma, or NHL. We have several clinical trials ongoing, including a pivotal phase III trial for the potential treatment of relapsed aggressive NHL. Based on development plans for pixantrone, we expect to have interim data from the phase III trial in late 2005, and if successful, we would submit an NDA for accelerated approval in early 2006. Final results for this trial are expected in the third quarter of 2006 and if successful, we would submit an NDA for full approval for pixantrone at the end of 2006. If we are able to submit for accelerated approval, with acceptance by the FDA, we estimate launch of pixantrone for the potential treatment of aggressive NHL in 2006. If we need full trial results, we estimate launch in 2007. We also are developing CT-2106, polyglutamate camptothecin, which is in a phase II trial for the treatment of colorectal and ovarian cancers and is planned to enter phase II trials for the treatment of small cell lung cancer in 2005.

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XYOTAX and CT-2106 utilize a way to deliver cancer drugs more selectively to tumor tissue intended to reduce toxic side effects and to improve anti-tumor activity of existing, cornerstone cancer drugs, such as Taxol®, one of the world s best selling cancer drugs. Our technology uses a unique biodegradable protein polymer, polyglutamate, linked to a cancer drug which we believe preferentially distributes the drug to tumors. The polymer bound drugs are inactive while circulating in the bloodstream, which may also lower toxicity compared to standard chemotherapy drugs that are active in the bloodstream. In the tumor tissue, the polymer drug is taken up by cells, where naturally occurring enzymes digest the polymer and release the cancer drug. Animal studies and human clinical data indicate that our polyglutamate technology may allow more drug to reach the tumors and thereby provide increased efficacy using the same amount of cancer drug with less toxicity as compared to unlinked cancer drugs.

Our first application of the polyglutamate technology is XYOTAX, which is paclitaxel linked to polyglutamate. Paclitaxel is the active ingredient in Taxol. We are currently conducting three phase III clinical trials in NSCLC, three phase II clinical trials, and eight phase I clinical trials of XYOTAX. On April 1, 2004, we signed a clinical trials agreement with the Gynecologic Oncology Group, or GOG, to perform a phase III trial to compare XYOTAX as monthly maintenance therapy to no maintenance treatment for ovarian cancer patients in complete remission following front-line treatment with carboplatin and paclitaxel. On July 7, 2004 we announced that the GOG submitted an investigational new drug application, or IND, along with the protocol for a special protocol assessment, or SPA, to the Food and Drug Administration, or FDA. In September the GOG had a successful meeting with the FDA regarding the design, endpoints and study conduct of the phase III protocol. We expect the GOG will initiate this trial early in the first quarter of 2005. We estimate that by the end of 2004 more than 2,200 patients will have been treated in the ongoing and completed XYOTAX clinical trials. We believe that these are the largest clinical trials ever conducted in front-line PS2 or second-line NSCLC, or in maintenance therapy for ovarian cancer.

On January 1, 2004, we completed our acquisition of Novuspharma S.p.A., currently CTI (Europe), a public biopharmaceutical company located in Italy. Prior to its spin-out as an independent company in 1998, Novuspharma was the cancer drug development division of Boehringer Mannheim and part of Hoffman-La Roche. This acquisition provided us worldwide rights to pixantrone, approximately $92.5 million of cash and cash equivalents at the time of the acquisition and a high-quality drug discovery organization with an extensive track record in cancer drug development. We believe pixantrone has potentially higher anti-tumor activity and lower cardiac toxicity than marketed anthracyclines. Cardiac toxicity from anthracycline treatment is a serious limitation that can result in life-threatening heart failure and death.

TRISENOX

We market TRISENOX in the U.S. and in the EU for the treatment of patients with APL who have relapsed or not responded to standard therapies. In the pivotal trial in patients with relapsed or refractory APL, 70% of the 40 patients experienced complete remission, or CR, following treatment with TRISENOX, with more than 50% disease-free for more than three years following treatment. Most TRISENOX sales result from use in the treatment of multiple myeloma and myelodysplastic syndromes, or MDS. We have recently refocused our TRISENOX development efforts to approximately 40 clinical and investigator-sponsored trials, with an emphasis on blood-related cancers, including front-line APL and multiple myeloma.

We have received orphan drug designation for TRISENOX from the FDA for APL, multiple myeloma, MDS, chronic myeloid leukemia, or CML, acute myeloid leukemia, or AML, chronic lymphocytic leukemia or CLL, and hepatocellular carcinoma, or HCC, also known as liver cancer. We have also received designation as an orphan medicinal product by the EMEA under its orphan drug legislation for APL, MDS, and multiple myeloma.

In April 2004, the U.S. Patent and Trademark office issued a patent covering TRISENOX injection that extends CTI s market exclusivity in the U.S. for TRISENOX from 2007 to 2018. This extension is eleven years beyond

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the original U.S. orphan drug exclusivity for APL, which currently expires in 2007. We believe further investments in registration-directed trials for various blood-related cancers including front-line APL, multiple myeloma and MDS could accelerate TRISENOX sales growth and increase the drug s commercial potential.

A study published in the April 2004 edition of the Proceedings of the National Academy of Sciences concluded that induction therapy with the combination of arsenic trioxide and ATRA, a vitamin A analogue, for front-line treatment of APL resulted in faster time to achieve CR, significantly greater reduction in leukemia burden and longer lasting remissions than either of the two drugs used alone. Sixty-one newly diagnosed APL patients were randomized into three treatment groups: single agent ATRA, single agent arsenic trioxide, or the combination of the two. All 20 cases in the combination group remained in remission after a median follow up of 18 months, whereas seven of the 37 patients (19%) treated with monotherapy relapsed. Standard treatment for front line APL is ATRA plus an anthracycline cancer drug. This treatment regimen results in a high rate of remission and cure, but also has substantial short- and long-term side effects including neutropenia, infections, an increased lifetime risk for secondary leukemia and MDS and may cause permanent heart damage. We plan to conduct a confirmatory registration-directed clinical trial to determine if TRISENOX can replace anthracycline cancer drug use in the front-line treatment of patients with newly diagnosed APL. This regimen would be the first potentially curative non-cytotoxic non-chemotherapy regimen for this fatal blood cancer. There are approximately 4,000 patients who are treated for newly diagnosed APL in the U.S. and Europe each year.

Multiple myeloma, an often-fatal malignant disease of the bone marrow, is the second most common blood cell malignancy. This disease affects nearly 50,000 people in the U.S. with over 15,000 new cases reported annually. Preliminary reports from a number of exploratory clinical studies and a series of case studies using TRISENOX, alone or in combination with other agents in patients with relapsed and/or refractory myeloma, showed encouraging high response rates. In general, the combinations were well tolerated with no reported grade 4 toxicities. We are sponsoring several multicenter trials with TRISENOX used in combination with corticosteroids, ascorbic acid, melphalan, bortezomib or thalidomide for advanced stages of multiple myeloma.

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

XYOTAX

We are developing XYOTAX, which is paclitaxel linked to polyglutamate, for the treatment of NSCLC and ovarian cancer. In July 2004, we completed enrollment in the last of three pivotal phase III trials for the treatment of NSCLC. In November 2003, we completed enrollment in our first pivotal phase III trial of XYOTAX, in combination with carboplatinum, known as STELLAR 3, for the front-line treatment of PS2 patients with NSCLC. In May 2004, we completed enrollment in our second pivotal phase III trial of XYOTAX, known as STELLAR 4, for the front-line treatment of PS2 patients with NSCLC. Based on our phase I and II data from over 400 patients and dosing and survival trends in the ongoing phase III trials, we believe that XYOTAX may have less severe side effects, including a reduction in severe neutropenia, allergic reactions and hair loss, and superior anti-tumor activity than marketed taxanes.

Lung cancer is the most common cause of cancer death in the U.S. and Europe. The ACS estimates that 139,000 new cases of NSCLC will be diagnosed in the U.S. in 2004 and approximately 106,000 patients are expected to

be treated with cancer drugs. The ACS also estimates that ovarian cancer is diagnosed in approximately 26,000 women per year in the U.S. and almost all of the patients are expected to be treated with cancer drugs.

Taxanes, which include paclitaxel and docetaxel, are one of the best-selling classes of chemotherapy drugs. IMS Health reported U.S. taxane sales for 2003 of approximately $900 million, and worldwide sales of roughly $2.5 billion, despite the difficulties associated with their administration and their serious dose-limiting toxicities. The majority of paclitaxel use is in the treatment of ovarian and lung cancers. Paclitaxel, one of two marketed taxanes, is branded as Taxol and is considered a standard of care in the front-line treatment of NSCLC and ovarian cancer.

Taxol is a formulation of paclitaxel in a mixture of polyethoxylated castor oil (Cremaphor) and ethanol, which is extremely irritating to blood vessels and requires surgical placement of a large catheter for administration. It also can cause severe life-threatening allergic reactions, and typically requires a minimum of three hours of intravenous infusion and transportation of patients to and from their treatment location. XYOTAX is approximately 80,000 times more water-soluble than paclitaxel alone, allowing it to be dissolved in a simple water and sugar-based solution and infused in the patient over approximately ten minutes. XYOTAX does not require routine premedication with steroids and antihistamines to prevent severe allergic reactions and patients can drive themselves to and from treatment centers. XYOTAX also may allow delivery of higher, better tolerated, cumulative doses than can be achieved with paclitaxel.

The cancer drug most commonly used to treat NSCLC in the U.S. is paclitaxel. Of the estimated 106,000 NSCLC patients who receive chemotherapy, approximately 30,000 are classified as PS2. These patients tolerate chemotherapy poorly and have a significantly shorter median survival than healthier patients. Data from a randomized trial of paclitaxel in NSCLC showed a median survival of approximately 2.4 months in front-line therapy of PS2 patients when administered as a single agent and 4.7 months when administered in combination with platinum-containing chemotherapy drugs. Approximately 55,000 patients in the U.S. receive second-line treatment for lung cancer annually, for which docetaxel is the most commonly used agent to treat recurrent NSCLC.

In the fourth quarter of 2002, we initiated three pivotal phase III clinical trials of XYOTAX. These trials include two phase III trials of XYOTAX for the front-line treatment of PS2, NSCLC patients and one phase III trial for the second-line treatment of NSCLC. In November 2003, we completed enrollment in one of the pivotal clinical trials, STELLAR 3, approximately six weeks ahead of schedule. In May 2004, we completed enrollment in our second pivotal phase III trial of XYOTAX, known as STELLAR 4, for the potential use as front-line treatment of PS2 patients with NSCLC. In July 2004, we completed enrollment for STELLAR 2, the final pivotal XYOTAX lung cancer trials. We anticipate releasing clinical data from STELLAR 3 and potentially STELLAR 4 in early 2005 and releasing clinical data from STELLAR 2 by mid-2005. We believe that a positive trial with respect to efficacy will provide the basis for approval for the front-line treatment of PS2, NSCLC patients and/or second-line treatment of NSCLC.

At the ECCO 12 (European Cancer Conference) meeting in September 2003, we reported data on a phase II study of XYOTAX (175 mg/m^2) in the front-line treatment of advanced NSCLC patients who were either over 70 years old and/or PS2. In the study, 28 patients were treated with XYOTAX every 21 days. Using standard RECIST criteria to assess efficacy, 18 patients (64%) achieved disease control, with two patients (7%) achieving a partial remission and 16 patients (57%) having stable disease. XYOTAX therapy was well tolerated with 50% of patients receiving four or more cycles of therapy and almost 30% of patients receiving six or more cycles. No alopecia or hypersensitivity reactions, which are common with standard paclitaxel formulations, were reported. Only one patient experienced grade 4 neutropenia and four patients reported grade 3 neuropathy, which occurred mostly in patients with concomitant progressive disease and significant disease-related comorbid conditions. We observed a median survival time of 5.4 months among PS2 patients, which compares favorably to the 2.4 months reported in a separate randomized trial of standard paclitaxel (225 mg/m^2).

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On April 1, 2004, we announced that we signed a clinical trials agreement with the GOG to perform a phase III trial to compare XYOTAX as maintenance therapy, administered monthly for 12 months, to no maintenance treatment, for ovarian cancer patients who have achieved a CR following front-line treatment with carboplatin and paclitaxel. On July 7, 2004 we announced that the GOG submitted an IND along with the protocol for an SPA to the FDA. In September 2004 the GOG had a successful SPA meeting with the FDA regarding the design, endpoints and study conduct of its XYOTAX phase III protocol. We expect the GOG will begin this trial early in the first quarter of 2005. The planned primary endpoints of this study will be progression free survival and overall survival compared to no maintenance treatment. We also are currently conducting three other phase II clinical trials of XYOTAX in ovarian cancer.

Pixantrone

We are developing pixantrone for the potential treatment of aggressive, relapsed NHL. In the U.S., aggressive NHL affects approximately 160,000 people with approximately 30,000 new cases diagnosed per year. The standard of care for front-line treatment of NHL is known as CHOP, which is a combination chemotherapy regimen consisting of cyclophosphamide, doxorubicin (an anthracycline), vincristine and prednisone. CHOP is used either alone or in conjunction with Rituxan, and is able to induce CRs in up to half of patients. However, approximately 60% of patients eventually relapse and many are unable to undergo an additional course of CHOP therapy due to the risk of cardiac toxicity. As a result, chemotherapy regimens that do not include anthracyclines often are used for the second-line treatment of relapsed NHL. There are no drugs approved for second- or third-line treatment for the 73,000 patients in the U.S. with relapsed aggressive NHL.

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

We believe a next-generation anthracycline with better ease of administration, greater anti-tumor activity and less cardiac toxicity could gain a significant share of the anthracycline market. We also believe that such a drug could allow repeat therapy in relapsed patients and could allow combination therapy with a broader range of chemotherapy drugs. Preclinical data and phase I and phase II clinical studies in over 220 patients indicate that pixantrone is easy to administer, may exhibit significantly lower potential for cardiac toxicity and may have more potent anti-tumor activity than marketed anthracyclines.

We currently are conducting five clinical trials, including one pivotal phase III trial for pixantrone. In the first quarter of 2004, we met with the FDA and discussed the design for our pivotal clinical trial of single-agent pixantrone in the treatment of third-line relapsed aggressive NHL. We initiated this pivotal trial of pixantrone for relapsed NHL in approximately 320 patients. On July 12, 2004 we announced that the FDA granted fast track designation for pixantrone for the potential treatment of relapsed aggressive NHL on the basis that relapsed aggressive NHL in the third-line or subsegment recurrence is a life threatening disease and responses have been noted in phase II trials with patients with relapsed, aggressive NHL. We expect to have interim data from the phase III trial late in the second half of 2005 and if successful we intend to file an NDA for pixantrone in early 2006.

In a phase II trial published in the journal Hematologica in August 2003, among 33 patients with relapsed aggressive NHL who failed a median of two or more prior regimens including prior anthracycline therapy, single-agent pixantrone produced an objective tumor response in 9 of 33 patients (27%) with 5 patients (15%) experiencing a complete response. Median duration of response was encouraging (~10.5 months) and in one case lasting more than 24 months. Pixantrone was well tolerated in this trial with neutropenia being the most

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frequently reported side effect. Cardiac symptoms were infrequent with only three patients experiencing a decrease of more than 10% of the left ventricular ejection fraction, a marker of cardiac function, which was possibly treatment-related. We believe that the low incidence of cardiac toxicity reported in this trial was encouraging because the majority of patients had previously been exposed to anthracycline doses that significantly increased their risk for cardiac toxicity.

We also have reported positive clinical data for pixantrone as a replacement for the standard anthracycline agent doxorubicin as part of the CHOP regimen in patients who previously failed CHOP and other multiagent regimens. Preliminary results from this trial, which were presented at the 2003 American Society of Hematology, or ASH, meeting, revealed that of the 22 patients evaluable for a response, 13 patients (59%) had a complete response, with four patients experiencing a partial response, for an overall response rate of 77%. We believe these data compare favorably to the approximately 50% complete response rate typically seen in front-line CHOP therapy for aggressive NHL, and less than 10-37% CR rate seen with other chemotherapy regimens for the second-line treatment of the disease. Cardiac side effects were infrequent. The low rate of cardiac events is very encouraging, considering the patients age and their level of pre-treatment with the traditional anthracyclines. A phase II study at the highest dose level studied is ongoing in up to 30 additional patients.

Sales and Marketing

We have developed an experienced sales and marketing infrastructure in the U.S. and the EU to commercialize our portfolio of cancer products. We currently are marketing TRISENOX with our direct sales force in the U.S., which consists of 38 field based sales personnel. An additional nine medical science liaisons provide scientific support in the field.

In February 2004, we announced a significant expansion of our European commercial operations by hiring additional sales personnel. We have established a 16 person TRISENOX sales force, consisting of country managers and hospital specialists in Western Europe. We believe this experienced sales force will increase European sales of TRISENOX as well as aid in the promotion of any additional commercial products that we may acquire or develop internally.

Our Strategy

Our goal is to become a leading pharmaceutical company focused on discovering, developing and commercializing innovative cancer treatments. The key elements of our business strategy are:

- To target development and registration strategies in the U.S. or Europe that take advantage of the ability to expedite approval either because there is an unmet medical need or because our product profiles demonstrate significant improvement in efficacy or safety over competitive drugs.

- To devote a substantial portion of our efforts to develop XYOTAX, pixantrone and to further develop and commercialize TRISENOX for additional indications.

- To develop further our sales and marketing capabilities in the U.S. and select European territories and possibly establish collaborations to commercialize our products.

To continue to focus our discovery research on application of our patented polymer drug delivery technology in order to expand our portfolio of improved versions of currently marketed anti-cancer drugs and to continue to identify novel drug targets that will enable us to develop product candidates with improved side effect and efficacy profiles as compared to existing cancer drugs.

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

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Our Current Product Development Pipeline

The following table lists our active trials (indicated by a status of open) and the trials that will be opened to enrollment during each of the second half of 2004 (2H04) and during 2005 (05). Also listed are the trials that have recently closed to enrollment but for which clinical trial reports are in progress (status enrollment completed). In addition to clinical trials that are part of our registration strategy, we also assist clinical investigators who request our help for their independent investigations that advance clinical knowledge of the use of our products. Certain Investigator-Sponsored Trials (studies conducted independent of us) also are included in the table below and are indicated by an * . We have deferred some of our previously planned clinical trials in order to reduce our aggregate expenditures on our clinical trial program and to focus on our currently ongoing clinical trials.

Product Candidate/ Clinical Indication	Phase/Status
TRISENOX	
Multiple Myeloma (MM)	
Single agent (two trials)	II / enrollment completed
Single agent, twice weekly dosing schedule	II / enrollment completed
Combination with ascorbic acid and dexamethasone following high dose chemotherapy and autologous stem cell transplant*	II / open
Combination with thalidomide in refractory MM*	II / open
Combination with ascorbic acid prior to high dose chemotherapy with autologous stem cell rescue for stage II/III MM*	II / open
Combination with dexamethasone after stem cell transplant*	II / open
Combination with melphalan and ascorbic acid in relapsed/refractory MM*	II / open
Combination with ascorbic acid and dexamethasone*	II / open
Myelodysplastic Syndromes (MDS)	
Single agent (2 trials)	II / enrollment completed
Single agent, followed by combination with thalidomide for non-responders*	II / open
Single agent (5 trials)*	I/II / open
Combination with cytarabine*	I/II / open
Combination with Ara-C*	I/II / open
Combination with amifostine*	II / open
Acute Promyelocytic Leukemia (APL)	
Single agent, APL in molecular relapse*	II / open
Combination with ATRA, de novo APL*	II / open
Consolidation for primary treatment of APL*	II / open
Other Leukemia/Lymphoma	
Comination with Gleevec for CML (3 trials)*	I/II / open
Combination with ascorbic acid for non-APL AML*	II / open
Combination with ascorbic acid for relapsed/refractory lymphoid malignancies*	II / open
Single agent in cutaneous T-cell lymphoma*	II / open
Solid Tumors	
Single agent for neuroblastoma solid tumors in pediatric patients*	II / open
Combination with radiosurgery/radiotherapy for malignant glioma (2 trials)*	I/II / open

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Product Candidate/ Clinical Indication	Phase/Status
XYOTAX	
NSCLC (second-line; STELLAR 2)	III / enrollment completed
NSCLC in combination with carboplatin (front-line PS2; STELLAR3)	III / enrollment completed
NSCLC (front-line PS2; STELLAR4)	III / enrollment completed
Ovarian front-line maintenance (GOG) (0212)	III / 2H04
Ovarian second relapse (GOG) (186c)	II / open
Ovarian front-line dose escalation (GOG) (9914)	I/II / open
Ovarian first-line in combination with carboplatin (201)	II / open
Advanced solid tumors in combination with cisplatin (1055)	I / open
Advanced solid tumors, single agent dosing every week (102)	I / open
Advanced solid tumors, single agent dosing every 3 weeks (1052)	I / enrollment completed
NSCLC first-line, combined with carboplatin (202)	II /open
NSCLC salvage, single agent (105)	I / open
Advanced solid tumors combined with carboplatin (1072)	I / enrollment completed
Combination with cisplatin and radiation for esophageal and gastric cancer (104)	I / open
Lung cancer, in combination with radiation (103)	I / open
Pixantrone	
Aggressive NHL ≥3 relapses, single agent (301)	III / open
Relapsed aggressive NHL, BSHAP (II-02)	II / open
Aggressive NHL, front-line, CPOP-R (II-03)	II / 05
Relapsed AML, single agent (I-09)	I / 05
Relapsed indolent NHL, FND-R (I-06)	I/II / enrollment completed
Relapsed aggressive NHL, BSHAP	I / enrollment completed
Relapsed aggressive NHL, CPOP (I-07)	I/II / open
CT-2106	
Advanced solid tumors, single agent dosing every 3 weeks (101)	I / enrollment completed
Advanced solid tumors, single agent dosing every week (102)	I / 05
Small cell lung cancer (202)	II / 05
Relapsed ovarian cancer (203)	II / open
Relapsed colorectal cancer (201)	II / open

Corporate Information

We were incorporated in Washington in 1991. Our principal executive office is located at 501 Elliott Avenue West, Suite 400, Seattle, Washington 98119. Our telephone number is (206) 282-7100. Our world wide web address is http://www.cticseattle.com. Information on our web site does not constitute part of this prospectus supplement.

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THE OFFERING

Common stock we are offering	281,690 shares
Common stock to be outstanding immediately after the offering	61,492,266 shares
Nasdaq National Market symbol	CTIC
Use of proceeds after expenses	For expansion of commercial activities, clinical development of our existing product candidates; potential acquisitions of products, technologies or businesses; product manufacturing; and other general corporate purposes, including working capital. See Use of Proceeds.
Risk Factors	See Risk Factors beginning on page S-12 of this prospectus supplement for a discussion of factors you should carefully consider before deciding to invest in shares of our common stock.

The number of shares of our common stock to be outstanding after this offering is based on 61,210,576 shares of common stock outstanding as of December 17, 2004 and excludes:

- 5,938,978 shares of common stock subject to outstanding options as of December 17, 2004 under our stock option plans at a weighted average exercise price of $14.91 per share;
- 4,193,937 shares of common stock reserved for future stock option grants and restricted stock awards as of December 17, 2004 under our stock option plans;
- 313,545 shares of common stock reserved for issuance as of December 17, 2004 under our employee stock purchase plan; and
- 564,125 shares of our common stock subject to warrants outstanding as of December 17, 2004 at a weighted average exercise price of $16.76 per share.
- 2,304,225 shares of our common stock offered pursuant to a prospectus supplement dated December 20, 2004.

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SUMMARY CONSOLIDATED FINANCIAL DATA

The summary financial data presented below is derived from the audited financial statement of Cell Therapeutics, Inc. and our subsidiaries incorporated by reference in this prospectus supplement and accompanying prospectus. The summary consolidated financial data set forth below is qualified in its entirety by, and should be read in conjunction with, the consolidated financial statements and notes thereto and Management s discussion and analysis of financial condition and results of operations incorporated by reference in this prospectus supplement and the accompanying prospectus. The as adjusted balance sheet data gives effect to the issuance and sale by us of 281,690 shares of our common stock in this offering at a public offering price of $7.10 per share, after deducting estimated offering expenses payable by us.

	Fiscal years ended December 31,			Nine months ended September 30,	
Consolidated Statements of Operations Data:	**2001**	**2002**	**2003**	**2003**	**2004** (unaudited)
	(in thousands, except per share data)				
Revenues:					
Product sales	$ 6,130	$ 11,393	$ 22,105	$ 15,501	$ 20,224
License and contract revenue	106	5,503	2,660	2,048	1,240
Total revenues	6,236	16,896	24,765	17,549	21,464
Operating expenses:					
Cost of product sold	394	423	840	619	858
Research and development(1)	44,669	58,759	89,534	65,123	73,287
Selling, general and administrative	35,268	49,800	55,641	39,099	58,414
Acquired in-process research and development					88,120
Amortization of purchased intangibles	9,390	6,701	1,335	1,001	1,716
Total operating expenses	89,721	115,683	147,350	105,842	222,395
Loss from operations	(83,485)	(98,787)	(122,585)	(88,293)	(200,931)
Other income (expense):					
Investment and other income	9,200	4,819	1,880	1,496	1,255
Interest and other expense	(5,988)	(11,240)	(9,326)	(6,567)	(8,148)
Foreign exchange loss					(937)
Gain on exchange of convertible subordinated notes		55,305			
Net loss	(80,273)	(49,903)	(130,031)	$ (93,364)	$ (208,761)
Preferred stock dividend	(1,372)				
Net loss applicable to common shareholders	$ (81,645)	$ (49,903)	$ (130,031)	$ (93,364)	$ (208,761)
Basic and diluted net loss per common share	$ (2.41)	$ (1.48)	$ (3.89)	$ (2.80)	$ (4.03)
Shares used in computation of basic and diluted net loss per common share	33,822	33,763	33,418	33,297	51,820

See footnotes on next page.

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	September 30, 2004	
Consolidated Balance Sheet Data:	**Actual**	**As adjusted**
	(in thousands, unaudited)	
Cash, cash equivalents, securities available-for-sale and interest receivable	$ 103,248	$ 105,243
Working capital	86,749	88,744
Total assets	174,168	176,163
5.75% Convertible senior subordinated notes(2)	85,459	85,459
4.0% Convertible senior subordinated notes(3)	75,000	75,000
5.75% Convertible subordinated notes(4)	29,640	29,640
Other long-term obligations, less current portion	6,283	6,283
Accumulated deficit	(679,247)	(679,247)
Total shareholders deficit	(51,719)	(49,724)

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

(2) *The 5.75% convertible senior subordinated notes are due June 15, 2008 and are convertible into shares of our common stock at a conversion rate of 100 shares of common stock per $1,000 principal amount of the notes, which is equivalent to an initial conversion price of $10.00 per share.*

(3) *The 4.0% convertible senior subordinated notes are due July 1, 2010 and are convertible into shares of our common stock at a conversion rate of 74.0741 shares of common stock per $1,000 principal amount of the notes, which is equivalent to an initial conversion price of approximately $13.50 per share.*

(4) *The 5.75% convertible subordinated notes are due June 15, 2008 and are convertible into shares of our common stock at a conversion rate of 29.4118 shares of common stock per $1,000 principal amount of the notes, which is equivalent to an initial conversion price of approximately $34.00 per share.*

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RISK FACTORS

Investing in our common stock involves a high degree of risk. In addition to the other information included or incorporated by reference in this prospectus supplement and the accompanying prospectus, you should carefully consider the risks described below before purchasing our common stock. If any of the following risks actually occur, our business, financial condition and results of operations could materially suffer. As a result, the trading price of our common stock could decline, and you might lose all or part of your investment.

Factors Affecting Our Operating Results and Financial Condition

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

We were incorporated in 1991 and have incurred a net operating loss every year. As of September 30, 2004, we had an accumulated deficit of approximately $679.2 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 eighteen months, assuming a successful launch of XYOTAX in 2006. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

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

We have only one product, TRISENOX, for relapsed or refractory APL that has received marketing approval to date. Our leading drug candidates, TRISENOX for other indications, XYOTAX, pixantrone and CT-2106, are currently in clinical trials and may not be successful. Even if our drugs progress successfully through initial human testing, they may fail in later stages of development. Many drugs in human clinical trials fail to demonstrate the desired safety and efficacy characteristics. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in advanced clinical trials, even after reporting promising results in earlier trials. For example, in our first phase III human trial for lisofylline, completed in March 1998, we failed to meet our two primary endpoints, or goals, even though we met our endpoints in two earlier phase II trials for lisofylline. Many of our drug candidates are still in research and pre-clinical development, which means that they have not yet been tested on humans. We will need to commit significant time and resources to develop these and additional product candidates. Our product candidates will be successful only if:

- our product candidates are developed to a stage that will enable us to commercialize them or sell related marketing rights to pharmaceutical companies;
- we are able to commercialize product candidates in clinical development or sell the marketing rights to third parties; and
- our product candidates, if developed, are approved by the regulatory authorities.

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

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

We expect that our existing capital resources, including the proceeds from our recent offering, will enable us to maintain our currently planned operations through the first half of 2005; however, to fully fund ongoing and planned activities, especially if one of our XYOTAX pivotal trials is successful, we will need to raise additional

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funds. We expect to receive certain grants and subsidized loans from the Italian government and the EU through our Italian branch. However, we may not receive the relevant funding because the grants and subsidiaries are awarded at the discretion of relevant authorities.

If our plans or assumptions change or are inaccurate, it will affect the amount of additional funds we will need to raise to continue the development of our technologies and complete the commercialization of products, if any, resulting from our technologies. We may raise such capital through public or private equity financings, partnerships, debt financings, bank borrowings or other sources. Additional funding may not be available on favorable terms or at all. If adequate funds are not otherwise available, we may curtail operations significantly, including the delay, modification or cancellation of research and development programs aimed at bringing new products to market. To obtain additional funding, we may need to enter into arrangements that require us to relinquish rights to certain technologies, drug candidates, products and/or potential markets. To the extent that additional capital is raised through the sale of equity, or securities convertible into equity, you may experience dilution of your proportionate ownership of us.

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

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

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

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

If we fail to commence or complete, or experience delays in any of our present or planned clinical trials, including the Phase III clinical trials of XYOTAX, the Phase II clinical trials of TRISENOX and the Phase II and Phase III clinical trials of pixantrone, our ability to conduct our business as planned could be harmed. Our development costs may increase if we experience any future delays in our clinical trials for XYOTAX, TRISENOX, pixantrone or our other product candidates or if we need to perform more or larger clinical trials than planned. If delays or costs are significant, our financial results and our ability to commercialize our product candidates may be adversely affected.

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

Since our inception in 1991, we have dedicated substantially all of our resources to the research and development of our technologies and related compounds. With the exception of TRISENOX for patients with APL who have relapsed or failed standard therapies, all of our compounds currently are in research or development, and none has been submitted for marketing approval.

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

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

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

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

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

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

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

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approve our developmental products and any additional indications for marketed products in a timely fashion, or do not approve them at all, or withdraw the approval or otherwise restrict the marketing of our sole approved product, TRISENOX, our business and financial condition may be adversely affected.

In addition, we and our currently marketed product and our product candidates are subject to comprehensive regulation by the FDA and the EMEA. Regulation by the FDA and EMEA begins before approval for marketing is granted and continues during the life of each product. For example, TRISENOX was approved for its current indication by the FDA following fast track review process and by the EMEA under exceptional circumstances, and we committed to completing several post-approval requirements to both the FDA and the EMEA, including the conduct of additional clinical studies. If we fail to fulfill these obligations, the FDA or EMEA may withdraw approval of TRISENOX. In addition, the FDA and other regulatory authorities regulate, for example, research and development, including pre-clinical and clinical testing, safety, effectiveness, manufacturing, labeling, advertising, promotion, export, and marketing of our products. Manufacturing processes must conform to cGMPs. The FDA and other regulatory authorities periodically inspect manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort to maintain compliance.

We believe that TRISENOX is prescribed by physicians largely for uses not approved by the FDA. Although physicians may lawfully prescribe pharmaceutical products, such as TRISENOX, for such off-label uses, promotion by us of such off-label uses is unlawful. Some of our practices intended to make physicians aware of off-label uses of TRISENOX, without engaging in off-label promotion, could nevertheless be construed as off-label promotion and it is likely that some instances of off-label promotion occurred in the past. Although we have policies and procedures in place designed to assure ongoing compliance with FDA requirements regarding off-label promotion, some non-compliant actions may nevertheless occur. Regulatory authorities could take enforcement action against us if they believe that we are promoting, or have promoted, TRISENOX for off-label use. Failure to comply with regulatory requirements, including off-label promotion of TRISENOX or other products approved for marketing, could result in various adverse consequences, including possible delay in approval or refusal to approve a product, recalls, seizures, withdrawal of an approved product from the market, and/or the imposition of civil or criminal sanctions.

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

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

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

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

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

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

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

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

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

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

necessary, we may not be able to increase market awareness and sales of our products, which may prevent us from growing our revenues and achieving and maintaining profitability.

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

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

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

protect trade secrets; and

prevent others from infringing on our proprietary rights.

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When polymers are linked, or conjugated, to drugs, the results are referred to as polymer-drug conjugates. We are developing drug delivery technology that links chemotherapy drugs to biodegradable polymers. For example, XYOTAX is paclitaxel, the active ingredient in Taxol®, one of the world s best selling cancer drugs, linked to polyglutamate. We may not receive a patent for our polymer-drug 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 United States Patent and Trademark Office has not established a consistent policy regarding the breadth of claims that it will allow in biotechnology patents. If it allows broad claims, the number and cost of patent interference proceedings in the United States and the risk of infringement litigation may increase. If it allows narrow claims, the risk of infringement may decrease, but the value of our rights under our patents, licenses and patent applications may also decrease. Patent applications in which we have rights may never issue as patents and the claims of any issued patents may not afford meaningful protection for our technologies or products. We currently have patent properties directed to all approved uses for TRISENOX, however, we have no patent claims covering the composition itself. In addition, patents issued to us or our licensors may be challenged and subsequently narrowed, invalidated or circumvented. Litigation, interference proceedings or other governmental proceedings that we may become involved in with respect to our proprietary technologies or the proprietary technology of others could result in substantial cost to us. Patent litigation is widespread in the biotechnology industry, and any patent litigation could harm our business. Costly litigation might be necessary to protect our orphan drug designations in the United States or EU, which are designations for products meeting criteria based on the size of the potential United States or EU patient population for a drug, respectively, and which entitle that drug to seven years of exclusive rights in the United States market or ten years in the EU market, as applicable, or to protect a patent position or to determine the scope and validity of third party proprietary rights, and we may not have the required resources to pursue any such litigation or to protect our patent rights. Any adverse outcome in litigation with respect to the infringement or validity of any patents owned by third parties could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using a product or technology.

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

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

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

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

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

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

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

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

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

We do not currently have internal facilities for the current Good Manufacturing Practice, or cGMP, manufacture of any of our development or commercial products. In addition, TRISENOX, our first commercial product, is currently manufactured primarily by a single vendor. In 2002, we began the process of qualifying an additional supplier for our finished product manufacturing for TRISENOX. This additional supplier received FDA approval to manufacture TRISENOX in June 2003. Because we do not directly control our suppliers, these vendors may not be able to provide us with finished product when we need it. Plans are in place to develop additional manufacturing resources, such as entering into collaborative arrangements with other parties that have established manufacturing capabilities or electing to have other additional third parties manufacture our products on a contract basis.

We will be dependent upon these third parties to supply us in a timely manner with products manufactured in compliance with cGMPs or similar manufacturing standards imposed by foreign regulatory authorities where our products will be tested and/or marketed. While the FDA and other regulatory authorities maintain oversight for cGMP compliance of drug manufacturers, contract manufacturers may at times violate cGMPs. The FDA and other regulatory authorities may take action against a contract manufacturer who violates cGMPs. Our current manufacturer for TRISENOX was inspected by the FDA and follow-up discussions are ongoing between the manufacturer and the FDA. As a result, the FDA could, among other things, shut down the operations of the manufacturer or disallow the manufacturer to ship product it currently holds. Either outcome could materially affect our operations. Another one of our products under development, XYOTAX, has a complex manufacturing process, which may prevent us from obtaining a sufficient supply of drug product for the clinical trials and commercial activities currently planned or underway on a timely basis, if at all.

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

As a result of our merger with Novuspharma, our operations now need to comply not only with applicable laws of and rules of the United States, including Washington law and the rules and regulations of the Securities and Exchange Commission and the Nasdaq National Market, but also the EU legal system and the Republic of Italy, including the rules and regulations of CONSOB and Borsa Italiana, which collectively regulate

companies listed on Italy s public markets such as the Nuovo Mercato. Conducting our operations in a manner that complies with all applicable laws and rules will require us to devote additional time and resources to regulatory compliance matters. For example, the process of seeking to understand and comply with the laws of each country, including

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tax, labor and regulatory laws, might require us to incur the expense of engaging additional outside counsel, accountants and other professional advisors and might result in delayed business initiatives as we seek to ensure that each new initiative will comply with all regulatory regimes.

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

As a result of our merger with Novuspharma, a portion of our business is based in Italy. We are subject to duties and risks arising from doing business in Italy, such as:

- Italian employment law, including collective bargaining agreements negotiated at the national level and over which we have no control;
- EU data protection regulations, under which we will be unable to send private personal data, including many employment records and some clinical trial data, from our Italian offices to our United States offices until our United States offices self-certify their adherence to the safe harbor framework established by the United States Department of Commerce in consultation with the European Commission;
- tariffs, customs, duties and other trade barriers; and
- capital controls, terrorism and other political risks.

These risks related to doing business in Italy could harm the results of our operations.

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 may 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;

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

denying coverage altogether.

The trend toward managed 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. In addition, in almost all European markets, pricing and choice of prescription pharmaceuticals are subject to governmental control. Therefore, the price of our products and their reimbursement in Europe will be determined by national regulatory authorities.

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

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

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

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

If we are successful in bringing XYOTAX to market, we will face direct competition from oncology-focused multinational corporations. XYOTAX will compete with other taxanes. Many oncology-focused multinational corporations currently market or are developing taxanes, epothilones, which inhibit cancer cells by a mechanism similar to taxanes, or similar products (including, among others, Bristol-Myers Squibb Co., which markets paclitaxel, one of the best-selling cancer drugs, and Aventis, which markets docetaxel). In addition, several companies, including American Pharmaceutical Partners, NeoPharm Inc. and Sonus Pharmaceuticals are also developing novel taxanes and formulations which could compete with our products.

In the hematology market, we hope to receive approval to market TRISENOX in more indications than currently authorized. We will face competition from a number of biopharmaceutical companies, including:

Celgene Corporation, which currently sells thalidomide used in the treatment of multiple myeloma, a cancer of the bone marrow, and is developing IMiDs;

Millennium Pharmaceuticals, Inc., which launched Velcade® in 2003 for treatment of multiple myeloma;

Pharmion Corporation, which has signed an agreement with Celgene to expand internationally the marketing of thalidomide and received approval for Vidaza for treatment of MDS, also known as smoldering leukemia or preleukemia, which are a group of diseases in which the bone marrow does not function normally and insufficient numbers of mature blood cells are in circulation; and

MGI Pharma, which is developing decitabine, which has been accepted for a rolling NDA submission by the FDA in MDS.

Because pixantrone is intended to provide less toxic treatment to patients who have failed standard chemotherapy treatment, if pixantrone is brought to market, it is not expected to compete directly with many existing chemotherapy drugs. However, pixantrone will face competition from currently marketed anthracyclines, such as mitoxantrone (Novantrone®), and new anti-cancer drugs with reduced toxicity that may be developed and marketed, including vincristine sulfate liposome for injection (Marquibo), a product being developed by Inex Pharmaceuticals Corporation (Inex) that is currently in NDA review. In January 2004, Enzon Pharmaceuticals (Enzon) entered into a partnership with Inex in which Enzon received exclusive North American commercialization rights for Inex s vincristine product for all indications.

Many of our competitors, either alone or together with their collaborators and in particular, the multinational pharmaceutical companies, have substantially greater financial resources and development and marketing teams

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

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

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

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

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

The integration of Novuspharma s business and operations is a challenging, complex, time-consuming and expensive process and may disrupt our business if not completed in a timely and efficient manner.

The challenges involved in the integration of Novuspharma include the following:

- effectively pursuing the clinical development and regulatory approvals of all product candidates while effectively marketing our approved product (TRISENOX);
- successfully commercializing products under development and increasing revenues from TRISENOX;

retaining certain existing strategic partners;

retaining and integrating management and other key employees;

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

integrating purchasing and procurement operations in multiple locations;

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- maintaining an adequate level of liquidity to fund our continuing operations and expansion;
- integrating the business culture of Novuspharma with our culture and maintaining employee morale;
- transitioning all facilities to a common information technology system;
- developing and maintaining uniform standards, controls, procedures and policies relating to financial reporting and employment related matters that comply with both United States and Italian laws and regulations;
- maintaining adequate focus on the core business of the combined company while integrating operations;
- maintaining relationships with employees, strategic partners, manufacturers and suppliers while integrating management and other key personnel;
- realizing the benefits and synergies to the extent or in the time frame anticipated; and
- coping with unanticipated expenses related to integration.

We may not succeed in addressing these challenges or any other problems encountered in connection with integration following the merger, which may be exacerbated by the geographic separation of our operations in the United States and in Italy. If management is not able to address these challenges, we may not achieve the anticipated benefits of the merger, which may have a material adverse effect on our business and could result in the loss of key personnel.

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

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

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

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

commercialization of any products we develop. A successful product liability claim in excess of our insurance coverage could exceed our net worth.

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

Our research and development activities involve the controlled use of hazardous materials, chemicals and various radioactive compounds. We are subject to federal, state, local and international laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and certain waste products. Although we

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

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

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

Risks Related To This Offering

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

The market price for securities of biopharmaceutical and biotechnology companies, including ours, historically has been highly volatile, and the market from time to time has experienced significant price and volume fluctuations that are unrelated to the operating performance of such companies. For example, during the twelve months ended September 30, 2004, our stock price ranged from a low of $4.55 to a high of $12.49. Fluctuations in the trading price or liquidity of our common stock may adversely affect the value of your investment in our common stock.

Factors that may have a significant impact on the market price and marketability of our common stock include:

- announcements of technological innovations or new commercial therapeutic products by us, our collaborative partners or our present or potential competitors;
- our quarterly operating results;
- announcements by us or others of results of pre-clinical testing and clinical trials;
- developments or disputes concerning patent or other proprietary rights;
- developments in our relationships with collaborative partners;

our success in integrating the business and operations of Novuspharma;

acquisitions;

litigation and government proceedings;

adverse legislation, including changes in governmental regulation and the status of our regulatory approvals or applications;

third-party reimbursement policies;

changes in securities analysts recommendations;

changes in health care policies and practices;

economic and other external factors; and

general market conditions.

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In the past, following periods of volatility in the market price of a company s securities, securities class action litigation has often been instituted. If a securities class action suit is filed against us, we would incur substantial legal fees and our management s attention and resources would be diverted from operating our business in order to respond to the litigation.

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

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

- a classified board so that only approximately one third of the board of directors is elected each year;
- elimination of cumulative voting in the election of directors;
- procedures for advance notification of shareholder nominations and proposals;
- the ability of our board of directors to amend our bylaws without shareholder approval;
- the ability of our board of directors to issue up to 10,000,000 shares of preferred stock without shareholder approval upon the terms and conditions and with the rights, privileges and preferences as the board of directors may determine; and
- a shareholder rights plan.

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

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

Our issuance of shares pursuant to future collaborations or other agreements or under our shelf registration statement will dilute the equity ownership of our existing stockholders.

We may enter into certain other agreements involving our issuance of additional shares of common stock. In connection with any such collaboration or any other similar agreement that we may enter into in the future, we may issue additional shares of common stock or other equity securities, and the value of the securities issued may be substantial. Shares sold in connection with this offering will dilute existing shareholders. In addition, we may register additional shares with the SEC for sale in the future.

You will experience immediate dilution in the book value per share of the common stock you purchase.

Because the price per share of our common stock being offered is substantially higher than the net tangible book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. Based on the offering price to the public of $7.10 per share, if you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of $8.26 per share in the net tangible book value of the common stock. See the section entitled Dilution below for a more detailed discussion of the dilution you will incur if you purchase common stock in this offering.

We do not intend to pay cash dividends on our common stock in the foreseeable future.

We do not anticipate paying cash dividends on our common stock in the foreseeable future. Any payment of cash dividends will depend upon our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. Furthermore, we may become subject to contractual restrictions or prohibitions on the payment of dividends.

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USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately $2.0 million, with a public offering price of $7.10 per share, after deducting estimated offering expenses payable by us.

We expect to use the net proceeds from this offering for:

- further clinical development of product candidates, particularly for TRISENOX, XYOTAX and pixantrone;
- expansion of TRISENOX commercial activities, particularly within Europe;
- XYOTAX pre-launch and launch activities;
- potential acquisitions of products, technologies and businesses;
- product manufacturing; and
- other general corporate purposes.

Although we currently have no plans to acquire any complementary businesses, our management has broad discretion as to the allocation of the net proceeds received in this offering and may use these proceeds for that purpose in the future. Pending use of the net proceeds, we intend to invest the net proceeds in interest-bearing, investment-grade securities.

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CAPITALIZATION

The following table shows our cash and cash equivalents and capitalization as of September 30, 2004:

- on an actual basis; and
- as adjusted to give effect to the sale by us of 281,690 shares of our common stock in this offering at a public offering price of $7.10 per share, after deducting estimated offering expenses payable by us.

	Actual	As adjusted (unaudited, dollars in thousands)
Cash, cash equivalents, securities available for sale and interest receivable	$ 103,248	$ 105,243
Long-term debt, less current portion:		
5.75% Convertible senior subordinated notes	85,459	85,459
4.0% Convertible senior subordinated notes	75,000	75,000
5.75% Convertible subordinated notes	29,640	29,640
Other long-term obligations, less current portion	6,283	6,283
Total long-term debt	196,382	196,382
Shareholders deficit:		
Preferred stock, no par value:		
Authorized shares 10,000,000		
Series C, 100,000 shares designated, none issued and outstanding		
Common Stock, no par value:		
Authorized shares 200,000,000		
61,030,514 actual and 61,312,204 as adjusted issued and outstanding	633,589	635,584
Deferred stock-based compensation	(3,707)	(3,707)
Accumulated other comprehensive loss	(2,354)	(2,354)
Accumulated deficit	(679,247)	(679,247)
Total shareholders deficit	(51,719)	(49,724)
Total capitalization	$ 144,663	$ 146,658

The number of shares outstanding is based on the number of shares outstanding as of September 30, 2004 and excludes:

- 6,090,260 shares of common stock subject to outstanding options as of September 30, 2004 under our stock option plans at a weighted average exercise price of $14.66 per share;

4,252,702 shares of common stock reserved for future stock option grants and restricted stock awards as of September 30, 2004 under our stock option plans;

313,545 shares of common stock reserved for issuance as of September 30, 2004 under our employee stock purchase plan; and

599,125 shares of our common stock subject to warrants outstanding as of September 30, 2004 at a weighted average exercise price of $15.92 per share.

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DILUTION

Our unaudited net tangible book value as of September 30, 2004 was approximately $(73.2) million, or $(1.20) per share of common stock. Net tangible book value per share is calculated by subtracting our total liabilities from our total tangible assets, which is total assets less intangible assets, and dividing this amount by the number of shares of common stock outstanding. After giving effect to the sale by us of the 281,690 shares of common stock offered in this offering, at a public offering price of $7.10 per share and after deducting the estimated offering expenses payable by us, our net tangible book value as of September 30, 2004 would have been approximately $(71.2) million, or $(1.16) per share of common stock. This represents an immediate increase in net tangible book value of $0.04 per share to our existing shareholders and an immediate and substantial dilution of $8.26 per share to new investors. The following table illustrates this per share dilution:

Assumed public offering price per share		$ 7.10
Net tangible book value per share as of September 30, 2004	$ (1.20)	
Increase per share attributable to new investors	0.04	
As adjusted net tangible book value per share after this offering		$ (1.16)
Dilution per share to new investors		$ 8.26

The above discussion and table is based on 61,030,514 shares of common stock issued and outstanding as of September 30, 2004 and excludes:

- 6,090,260 shares of common stock subject to outstanding options as of September 30, 2004 under our stock option plans at a weighted average exercise price of $14.66 per share;
- 4,252,702 shares of common stock reserved for future stock option grants and restricted stock awards as of September 30, 2004 under our stock option plans;
- 313,545 shares of common stock reserved for issuance as of September 30, 2004 under our employee stock purchase plan; and
- 599,125 shares of our common stock subject to warrants outstanding as of September 30, 2004 at a weighted average exercise price of $15.92 per share.

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PRICE RANGE OF OUR COMMON STOCK

Our common stock is quoted on the Nasdaq National Market and the Nuovo Mercato under the symbol CTIC. The following table sets forth, for the periods indicated, the high and low (intra-day) reported sale prices per share of our common stock as reported on the Nasdaq National Market.

Fiscal year ended December 31, 2002	**High**	**Low**
First quarter	$ 27.45	$ 19.31
Second quarter	25.50	4.57
Third quarter	5.89	2.68
Fourth quarter	9.85	3.85

Fiscal year ended December 31, 2003	**High**	**Low**
First quarter	$ 8.89	$ 5.18
Second quarter	15.70	7.76
Third quarter	13.76	9.35
Fourth quarter	12.49	7.49

Fiscal year ended December 31, 2004	**High**	**Low**
First quarter	$ 10.25	$ 7.80
Second quarter	9.43	6.75
Third quarter	7.43	4.55
Fourth quarter (through December 17, 2004)	8.35	5.69

As of December 17, 2004, there were approximately 249 holders of record of our common stock. On December 17, 2004, the last sale price reported on the Nasdaq National Market for our common stock was $8.20 per share.

DIVIDEND POLICY

We have not paid any cash dividends since our inception and do not anticipate paying any cash dividends in the foreseeable future.

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PLAN OF DISTRIBUTION

We are offering these shares to a selected institutional investor at a price of $7.10 per share.

There is no requirement that any minimum number of shares or dollar amount of common stock be sold in this offering and there can be no assurance that we will sell all or any of the shares being offered.

We will pay all of the expenses incurred in this offering. Our estimated expenses of the offering are $5,000. This assumes that all 281,690 shares of common stock offered by this prospectus supplement are sold in this offering.

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LEGAL MATTERS

Wilson Sonsini Goodrich & Rosati, Professional Corporation, San Francisco, California will pass upon the validity of the common stock offered by this prospectus supplement for us.

EXPERTS

Ernst & Young LLP, independent registered public accounting firm, audited our consolidated financial statements and schedule included in our Annual Report on Form 10-K for the year ended December 31, 2003, as set forth in their report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements and schedule are incorporated by reference in reliance on Ernst & Young LLP s report, given on their authority as experts in accounting and auditing.

Ernst & Young LLP resigned as our independent auditors on August 31, 2004. Our audit committee engaged Grant Thornton LLP as our new independent auditors on October 18, 2004.

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WHERE YOU CAN FIND MORE INFORMATION

We are a reporting company and file annual, quarterly and current reports, proxy statements and other information with the SEC. This prospectus supplement is part of a registration statement on Form S-3 filed by us with the SEC under the Securities Act of 1933, as amended. As permitted by the SEC, this prospectus supplement does not contain all the information in the registration statement filed with the SEC. For a more complete understanding of this offering, you should refer to the complete registration statement on Form S-3 that may be obtained from the locations described below. You may read and copy the registration statement, as well as our reports, proxy statements and other information, at the SEC s public reference rooms at 450 Fifth Street, N.W., Washington, D.C. 20549. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference rooms. Our SEC filings are also available at the SEC s web site at http://www.sec.gov.

Statements contained in this prospectus supplement about the contents of any contract or other document are not necessarily complete. If we have filed any contract or other document as an exhibit to the registration statement or any other document incorporated by reference into the registration statement, you should read the exhibit for a more complete understanding of the document or matter involved. Each statement regarding a contract or other document is qualified in its entirety by reference to the actual document.

INFORMATION INCORPORATED BY REFERENCE

The SEC allows us to incorporate by reference the information we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus supplement, and certain information that we file later with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and any additional documents filed by us with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended (other than reports or portions furnished under Items 9 or 12 of Form 8-K), unless otherwise specifically stated in such current report on Form 8-K, until we complete our offering of the securities:

- our annual report on Form 10-K for the fiscal year ended December 31, 2003;
- our quarterly reports on Form 10-Q for the fiscal quarters ended March 31, 2004, June 30, 2004 and September 30, 2004;
- our current reports on Form 8-K, as amended, filed on January 13, 2004, February 5, 2004, March 22, 2004, June 4, 2004, July 13, 2004, September 7, 2004, September 10, 2004, October 4, 2004, October 19, 2004, October 25, 2004, November 2, 2004 and November 22, 2004;
- the description of our common stock contained in our registration statement on Form 10 as filed with the SEC on April 29, 1996, as amended; and
- the description of our preferred stock purchase rights contained in our registration statement on Form 8-A filed with the SEC on November 11, 1996, as amended.

Documents incorporated by reference, excluding exhibits except to the extent such exhibits are specifically incorporated by reference, are available from us without charge. You may obtain documents incorporated by reference by requesting them in writing from:

Cell Therapeutics, Inc.

501 Elliot Avenue West, Suite 400

Seattle, Washington 98119

United States of America

Attn: Investor Relations

(206) 282-7100

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PROSPECTUS

$75,000,000

COMMON STOCK

Cell Therapeutics, Inc. may offer shares of its common stock from time to time. We will specify in an accompanying prospectus supplement the terms of any offering. Our common stock is traded on the Nasdaq National Market and on the Nuovo Mercato in Italy under the symbol CTIC. The common stock offered by this prospectus will have an aggregate public offering price of up to $75,000,000.

You should read this prospectus, any prospectus supplement and the documents incorporated by reference in this prospectus and any prospectus supplement carefully before you invest. **This prospectus may not be used to offer or sell any securities unless accompanied by a prospectus supplement**.

Investing in our common stock involves a high degree of risk. You should carefully consider the Risk Factors beginning on page 2 of this prospectus before you make an investment decision.

The common stock offered by this prospectus may be sold directly by us to investors, through agents designated from time to time or to or through underwriters or dealers. We will set forth the names of any underwriters or agents in the accompanying prospectus supplement. For additional information on the methods of sale, you should refer to the section entitled Plan of Distribution. The net proceeds we expect to receive from such sale will also be set forth in a prospectus supplement.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is March 22, 2004

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CELL THERAPEUTICS, INC.

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, clinical development and in-licensing activities are concentrated on identifying new, less toxic and more effective ways to treat cancer. We currently have one approved cancer drug, TRISENOX, which we market in the U.S. and in the European Union, or EU. TRISENOX has been approved for the treatment of patients with a type of blood cell cancer called Acute Promyelocytic Leukemia, or APL, who have relapsed or failed standard therapies. We have additional clinical trials ongoing related to potential market expansion for this product. We are developing XYOTAX, which utilizes a biodegradable protein polymer to deliver the chemotherapy drug, paclitaxel, more selectively to tumor tissue. We have completed patient enrollment for one pivotal phase III trial and expect to complete enrollment in the first half of 2004 of two more pivotal phase III trials of XYOTAX for the treatment of non-small cell lung cancer. We are also developing Pixantrone, a novel anthracycline with potentially less cardiac toxicity and greater anti-tumor activity than marketed anthracylines. We expect to begin a pivotal phase III trial of Pixantrone for the treatment of aggressive non-Hodgkin s lymphoma in the first quarter of 2004. We are also developing CT-2106 which is entering phase II trials for the treatment of small cell lung cancer and other solid tumors.

On January 1, 2004, we completed our acquisition of Novuspharma, S.p.A., an Italian biopharmaceutical company focused on oncology. Through this acquisition, we obtained worldwide rights to Pixantrone and a high-quality drug discovery organization with an extensive track record in cancer drug development. The Novuspharma acquisition and its drug candidates are consistent with our strategy of growth by strategic acquisition and our goal to develop less toxic more effective cancer therapies.

We were incorporated in Washington in 1991. Our principal office is located at 501 Elliott Avenue West, Suite 400, Seattle, WA 98119. Our telephone number is (206) 282-7100. Our world wide web address is *http://www.cticseattle.com*. Information on our website does not constitute part of this prospectus. CTI, TRISENOX , XYOTAX (formerly referred to as PG-TXL) and Pixantrone are our proprietary marks. All other product names, trademarks and trade names referred to in this prospectus are the property of their respective owners.

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the SEC using a shelf registration process. Under this shelf registration process, we may sell common stock in one or more offerings up to a total dollar amount of $75,000,000. This prospectus provides you with a general description of the common stock we may offer. Each time we sell common stock we will provide a prospectus supplement that will contain more specific information about the shares offered. We may also add, update or change in the prospectus supplement any of the information contained in this prospectus. This prospectus, together with applicable prospectus supplements, includes all material information relating to this offering. Please carefully read both this prospectus and any prospectus supplement together with the additional information described below under Where You Can Find More Information and Information Incorporated by Reference.

You should rely only on the information contained or incorporated by reference in this prospectus or a prospectus supplement. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus or any prospectus supplement, as well as information we have previously filed with the SEC and incorporated by reference, is accurate as of the date on the front of those documents only. Our business, financial condition, results of operations and prospectus may have changed since those dates. **This prospectus may not be used to consummate a sale of our securities unless it is accompanied by a prospectus supplement.**

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RISK FACTORS

An investment in our securities involves a high degree of risk. You should carefully consider the risks described below before making an investment decision. You should also refer to the other information in this prospectus, including our financial statements and the related notes incorporated by reference into this prospectus. The risks and uncertainties described below are not the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. If any of the following risks actually occur, our business, results of operations and financial condition could suffer. In that event, the trading price of our common stock could decline, and you may lose all or part of your investment in our common stock. The risks discussed below also include forward-looking statements and our actual results may differ substantially from those discussed in these forward-looking statements.

Risks Related To Our Business

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

We were incorporated in 1991 and have incurred a net operating loss every year. As of September 30, 2003, we had an accumulated deficit of approximately $433.8 million, not including losses of Novuspharma. We may never become profitable, even if we are able to commercialize additional products. We will need to conduct significant research, development, testing and regulatory compliance activities that, together with projected general and administrative expenses, we expect will result in substantial increasing operating losses for at least the next several years. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

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

We have only one product, TRISENOX, for relapsed or refractory acute promyelocytic leukemia, or APL, that has received marketing approval to date. Our leading drug candidates, TRISENOX for other indications, XYOTAX, Pixantrone and CT-2106, are currently in clinical trials and may not be successful. Even if our drugs progress successfully through initial human testing, they may fail in later stages of development. Many drugs in human clinical trials fail to demonstrate the desired safety and efficacy characteristics. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in advanced clinical trials, even after reporting promising results in earlier trials. For example, in our first phase III human trial for lisofylline, completed in March 1998, we failed to meet our two primary endpoints, or goals, even though we met our endpoints in two earlier phase II trials for lisofylline. As a result, we are no longer developing lisofylline as a potential product. Many of our drug candidates are still in research and pre-clinical development, which means that they have not yet been tested on humans. We will need to commit significant time and resources to develop these and additional product candidates. Our product candidates will be successful only if:

- our product candidates are developed to a stage that will enable us to commercialize them or sell related marketing rights to pharmaceutical companies;
- we are able to commercialize product candidates in clinical development or sell the marketing rights to third parties; and
- our product candidates, if developed, are approved by the regulatory authorities.

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

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

We expect that our existing capital resources and the interest earned thereon will enable us to maintain our planned operations through at least early 2005. We expect to receive certain grants and subsidized loans from the Italian government and the European Union through our Italian subsidiary into which Novuspharma s operating assets and liabilities will be contributed. However, we may not receive the relevant funding because the grants and subsidies are awarded at the discretion of the relevant authorities.

Beyond early 2005, or if our plans or assumptions change or are inaccurate, 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 may raise such capital through public or private equity financings, partnerships, debt financings, bank borrowings or other sources.

Additional funding may not be available on favorable terms or at all. If adequate funds are not otherwise available, we may curtail operations significantly, including the delay, modification or cancellation of research and development programs aimed at bringing new products to market. To obtain additional funding, we may need to enter into arrangements that require us to relinquish rights to certain technologies, drug candidates, products and/or potential markets. To the extent that additional capital is raised through the sale of equity, or securities convertible into equity, you may experience dilution of your proportionate ownership of us.

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

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

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

Before regulatory approval for any potential product can be obtained, we must undertake extensive clinical testing on humans to demonstrate the safety and efficacy of the product, both on its own terms, and as compared to the other principal drugs on the market that have the same therapeutic indication. Although for planning purposes we forecast the commencement and completion of clinical trials, the actual timing of these events can vary dramatically due to a number of factors.

We may not obtain authorization to permit product candidates that are already in the pre-clinical development phase to enter the human clinical testing phase. Authorized pre-clinical or clinical testing may not be completed successfully within any specified time period by us, or without significant additional resources or expertise to those originally expected to be necessary. Many drugs in human clinical trials fail to demonstrate the desired safety and efficacy characteristics. Clinical testing may not show potential products to be safe and efficacious and potential products may not be approved for a specific indication. Further, the results from pre-clinical studies and early clinical trials may not be indicative of the

results that will be obtained in later-stage clinical trials. Data obtained from clinical trials are susceptible to varying interpretations. Government regulators and our collaborators may not agree with our interpretation of our future clinical trial results. In addition, we or regulatory authorities may suspend clinical trials at any time on the basis that the participants are being exposed

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to unacceptable health risks. Completion of clinical trials depends on, among other things, the number of patients available for enrollment in a particular trial, which is a function of many factors, including the number of patients with the relevant conditions, the nature of the clinical testing, the proximity of patients to clinical testing centers, the eligibility criteria for tests as well as competition with other clinical testing programs involving the same patient profile but different treatments.

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

If we fail to commence or complete, or experience delays in any of our present or planned clinical trials, including the Phase III clinical trials of XYOTAX, the Phase II clinical trials of TRISENOX and the Phase II and Phase III clinical trials of Pixantrone, our ability to conduct our business as planned could be harmed. Our development costs may increase if we experience any future delays in our clinical trials for XYOTAX, TRISENOX, Pixantrone or our other product candidates or if we need to perform more or larger clinical trials than planned. If delays or costs are significant, our financial results and our ability to commercialize our product candidates may be adversely affected.

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

Since our inception in 1991, we have dedicated substantially all of our resources to the research and development of our technologies and related compounds. With the exception of TRISENOX for patients with APL who have relapsed or failed standard therapies, all of our compounds currently are in research or development, and none has been submitted for marketing approval. 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 pre-clinical testing and extensive clinical investigation before submission of any regulatory application for marketing approval. The development of anti-cancer drugs, including those we are currently developing, is unpredictable and subject to numerous risks. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons including that they may:

- be found ineffective or cause harmful side effects during pre-clinical testing or clinical trials;
- fail to receive necessary regulatory approvals;
- be difficult to manufacture on a scale necessary for commercialization;
- be uneconomical to produce;
- fail to achieve market acceptance; or

be precluded from commercialization by proprietary rights of third parties.

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

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

We have entered into collaborative arrangements with third parties to develop and/or commercialize product candidates and are currently seeking additional collaborations. For example, we have entered into an agreement

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

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

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

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

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

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

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

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

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

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

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

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

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

protect trade secrets; and

prevent others from infringing on our proprietary rights.

When polymers are linked, or conjugated, to drugs, the results are referred to as polymer-drug conjugates. We are developing drug delivery technology that links chemotherapy drugs to biodegradable polymers. For example, XYOTAX is paclitaxel, the active ingredient in TAXOL®, one of the world s best selling cancer drugs, linked to polyglutamate. We may not receive a patent for our polymer-drug 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 United States Patent and Trademark Office has not established a consistent policy regarding the breadth of claims that it will allow in biotechnology patents. If it allows broad claims, the number and cost of patent interference proceedings in the United States, and the risk of infringement litigation may increase. If it allows narrow claims, the risk of infringement may decrease, but the value of our rights under our patents, licenses and patent applications may also decrease. Patent applications in which we have rights may never issue as patents and the claims of any issued patents may not afford meaningful protection for our technologies or products. In addition, patents issued to us or our licensors may be challenged and subsequently narrowed, invalidated or circumvented. Litigation, interference proceedings or other governmental proceedings that we may become involved in with respect to our proprietary technologies or the proprietary technology of others could result in substantial cost to us. Patent litigation is widespread in the biotechnology industry, and any patent litigation could harm our business. Costly litigation might be necessary to protect our orphan drug designations in the United States or EU, which are designations for products meeting criteria based on the size of the potential United States or EU patient population for a drug, respectively, and which entitle that drug to seven years of exclusive rights in the United States market or ten years in the EU market, as applicable, or to protect a patent position or to determine the scope and validity of third party proprietary rights, and we may not have the required resources to pursue any such litigation or to protect our patent rights. Any adverse outcome in litigation with respect to the infringement or validity of any patents owned by third parties could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using a product or technology.

We also rely upon trade secrets, proprietary know-how and continuing technological innovation to remain competitive. Third parties may independently develop such know-how or otherwise obtain access to our

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technology. While we require our employees, consultants and corporate partners with access to proprietary information to enter into confidentiality agreements, these agreements may not be honored.

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.

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

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

One component of our business strategy is in-licensing drug compounds developed by other pharmaceutical and biotechnology companies or academic research laboratories. Substantially all of our product candidates in clinical development are in-licensed from a third party, including TRISENOX, XYOTAX and Pixantrone. Competition for new promising compounds and commercial products can be intense. If we are not able to identify future in-licensing opportunities and enter into future licensing arrangements on acceptable terms, our future product portfolio and potential profitability could be harmed.

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

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

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

We do not currently have internal facilities for the GMP manufacture of any of our development or commercial products. In addition, TRISENOX, our first commercial product, is currently manufactured by a single vendor. In 2002, we began the process of qualifying an additional supplier for our finished product manufacturing for TRISENOX. This additional supplier received FDA approval to manufacture TRISENOX in June 2003. Because we do not directly control our suppliers, these vendors may not be able to provide us with finished product when we need it. Plans are in place to develop additional manufacturing resources, such as entering into collaborative arrangements with other parties that have established manufacturing capabilities or elect to have other additional third parties manufacture our products on a contract basis.

We will be dependent upon these third parties to supply us in a timely manner with products manufactured in compliance with current good manufacturing practices, or cGMPs, or similar manufacturing standards

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imposed by foreign regulatory authorities where our products will be tested and/or marketed. While the FDA and other regulatory authorities maintain oversight for cGMP compliance of drug manufacturers, contract manufacturers may at times violate cGMPs. The FDA and other regulatory authorities may take action against a contract manufacturer who violates cGMPs. Such actions may include requiring the contract manufacturer to cease its manufacturing activities.

Another one of our products under development, XYOTAX, has a complex manufacturing process, which may prevent us from obtaining a sufficient supply of drug product for the clinical trials and commercial activities currently planned or underway on a timely basis, if at all.

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

Regulatory agencies have approved only one of our products, TRISENOX, for sale in the United States and the European Union, to treat patients with a type of blood cancer called acute promyelocytic leukemia, or APL, who have relapsed or failed standard therapies. Before we can market TRISENOX for other indications in the United States, or EU, we must obtain additional FDA approval and/or approval of the European Agency for the Evaluation of Medical Products, or the EMEA. Our other products are in development, and will have to be approved by the FDA before they can be marketed in the United States and by the EMEA before they can be marketed in the EU. Obtaining FDA or other national regulatory approval requires substantial time, effort and financial resources, and we may not obtain approval on a timely basis, if at all. If the FDA or the EMEA do not approve our developmental 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 currently marketed products and product candidates are subject to comprehensive regulation by the FDA and the EMEA. Regulation by the FDA and EMEA begins before approval for marketing is granted and continues during the life of each product. For example, TRISENOX was approved by the FDA under its accelerated approval process and by the EMEA under exceptional circumstances and we committed to completing several post-approval requirements to both the FDA and the EMEA, including the conduct of additional clinical studies. If we fail to fulfill these obligations, the FDA or EMEA may withdraw approval of TRISENOX. In addition, the FDA and other regulatory authorities regulate, for example, research and development, including pre-clinical and clinical testing, safety, effectiveness, manufacturing, labeling, advertising, promotion, export, and marketing of our products. Manufacturing processes must conform to cGMPs. The FDA and other regulatory authorities periodically inspect manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort to maintain compliance. Also, a drug may not be promoted for other than its approved indication, and the FDA, EMEA and other regulatory authorities may institute enforcement actions against companies that do so. Our failure to comply with this or other FDA or other regulatory requirements may result in various adverse consequences, including possible delay in approval or refusal to approve a product, recalls, seizures, withdrawal of an approved product from the market, and/or the imposition of civil or criminal sanctions.

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

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

As a result of our merger with Novuspharma, our operations now need to comply not only with applicable laws of and rules of the United States, including Washington law and the rules and regulations of the Securities and Exchange Commission and the Nasdaq National Market, but also the EU legal system and the Republic of Italy, including the rules and regulations of CONSOB and Borsa Italiana, which collectively regulate companies listed on Italy s public markets such as the Nuovo Mercato. Conducting our operations in a manner that complies with all applicable laws and rules will require us to devote additional time and resources to regulatory compliance matters. For example, the process of seeking to understand and comply with the laws of each country, including tax, labor and regulatory laws, might require us to incur the expense of engaging additional outside counsel, accountants and other professional advisors and might result in delayed business initiatives as we seek to ensure that each new initiative will comply with both regulatory regimes.

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

As a result of our merger with Novuspharma, a portion of our business is based in Italy. We are subject to duties and risks arising from doing business in Italy, such as:

- Italian employment law, including collective bargaining agreements negotiated at the national level and over which we have no control;
- EU data protection regulations, under which we will be unable to send private personal data, including many employment records and some clinical trial data, from our Italian offices to our United States offices until our United States offices self-certify their adherence to the safe harbor framework established by the United States Department of Commerce in consultation with the European Commission;
- tariffs, customs, duties and other trade barriers; and
- capital controls, terrorism and other political risks.

These risks related to doing business in Italy could harm the results of our operations.

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 may 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;

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

denying coverage altogether.

The trend toward managed 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

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reducing demand for our products. In addition, in almost all European markets, pricing and choice of prescription pharmaceuticals are subject to governmental control. Therefore, the price of our products and their reimbursement in Europe will be determined by national regulatory authorities.

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

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

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

If we are successful in bringing XYOTAX to market, we will face direct competition from oncology-focused multinational corporations. XYOTAX will compete with other taxanes, which are drugs that inhibit cell growth by stopping cell division and are widely used as treatments for cancer. Many oncology-focused multinational corporations currently market or are developing taxanes, epothilones, which inhibit cancer cells by a mechanism similar to taxanes, or similar products (including, among others, Bristol-Myers Squibb Co., which markets Taxol®, one of the best-selling cancer drugs and Aventis, which markets Taxotere®. In addition, several companies are also developing novel taxanes and formulations which could compete with our products.

In the hematology market, we hope to receive approval to market TRISENOX to larger indications than currently authorized. We will face competition from a number of biopharmaceutical companies, including:

Celgene Corporation, which currently sells thalidomide used in the treatment of multiple myeloma, a cancer of the bone marrow, and is developing ImiDs;

Millennium Pharmaceuticals, Inc., which recently launched Velcade for treatment of multiple myeloma;

Pharmion Corporation, which has signed an agreement with Celgene to expand internationally the marketing of thalidomide and is developing 5-Azacytidine for myelodyplastic syndromes, or MDS, also known as smoldering leukemia or preleukemia, which are a group of diseases in which the bone marrow does not function normally, and insufficient numbers of mature blood cells are in circulation; and

SuperGen Corporation, which is developing decitabine, which is in phase III studies in MDS.

Because Pixantrone is intended to provide less toxic treatment to patients who have failed standard chemotherapy treatment, if Pixantrone is brought to market, it is not expected to compete directly with many existing chemotherapy drugs. However, Pixantrone will face competition from currently marketed anthracyclines, such as mitoxantrone (Novantrone®), and new anti-cancer drugs with reduced toxicity that may be developed and marketed, including Vincristine Sulfate Liposome for Injection, or VSLI, a product being developed by Inex Pharmaceuticals Corporation that is currently in late stage clinical trials.

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

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

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

The integration of Novuspharma s business and operations will be a challenging, complex, time-consuming and expensive process and may disrupt our business if not completed in a timely and efficient manner.

The challenges involved in the integration of Novuspharma include the following:

- effectively pursuing the clinical development and regulatory approvals of all product candidates while effectively marketing our current approved product (TRISENOX);
- successfully commercializing products under development and increasing revenues from TRISENOX;
- retaining certain existing strategic partners;
- retaining and integrating management and other key employees;
- coordinating research and development activities to enhance introduction of new products and technologies;
- integrating purchasing and procurement operations in multiple locations;
- maintaining an adequate level of liquidity to fund our continuing operations and expansion;

integrating the business culture of Novuspharma with our culture and maintaining employee morale;

transitioning all facilities to a common information technology system;

developing and maintaining uniform standards, controls, procedures and policies relating to financial reporting and employment related matters that comply with both United States and Italian laws and regulations;

maintaining adequate focus on the core business of the combined company while integrating operations;

maintaining relationships with employees, strategic partners, manufacturers and suppliers while integrating management and other key personnel;

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realizing the benefits and synergies to the extent or in the time frame anticipated; and

coping with unanticipated expenses related to integration.

We may not succeed in addressing these challenges or any other problems encountered in connection with integration following the merger, which may be exacerbated by the geographic separation of our operations in the United States and in Italy. If management is not able to address these challenges, we may not achieve the anticipated benefits of the merger, which may have a material adverse effect on our business and could result in the loss of key personnel.

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

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

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

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

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

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

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

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

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Risks Related to the Securities Markets

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

The market price for securities of biopharmaceutical and biotechnology companies, including ours, historically has been highly volatile, and the market from time to time has experienced significant price and volume fluctuations that are unrelated to the operating performance of such companies. For example, during the twelve months ended December 31, 2003, our stock price ranged from a low of $5.18 to a high of $15.70. 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 pre-clinical testing and clinical trials;
- developments or disputes concerning patent or other proprietary rights;
- developments in our relationships with collaborative partners;
- our success in integrating the business and operations of Novuspharma;
- acquisitions;
- litigation and government proceedings;
- adverse legislation, including changes in governmental regulation and the status of our regulatory approvals or applications;
- third-party reimbursement policies;
- changes in securities analysts recommendations;

changes in 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.

Our charter documents contain provisions that may prevent or delay removal of incumbent management or a change of control.

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

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

elimination of cumulative voting in the election of directors;

procedures for advance notification of shareholder nominations and proposals;

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

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

a shareholder rights plan.

In addition, as a Washington corporation, we are subject to Washington law, including Chapter 23 of the Washington Business Corporations Act, which prohibits public companies from engaging in some business combinations without the approval of a majority of the votes within each voting group entitled to vote separately on the transaction.

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

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DISCLOSURE REGARDING FORWARD-LOOKING STATEMENTS

In addition to the other information contained or incorporated by reference in this prospectus, you should carefully consider the risk factors disclosed in this prospectus or any prospectus supplement when evaluating an investment in our common stock. This prospectus includes forward-looking statements within the meaning of Section 27A of the Securities Act, and Section 21E of the Exchange Act. All statements other than statements of historical fact are forward-looking statements for purposes of these provisions, including any projections of earnings, revenues or other financial items, any statements of the plans and objectives of management for future operations, any statements concerning proposed new products or services, any statements regarding future economic conditions or performance, and any statement of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as may, will, expects, plans, anticipates, estimates, potential, or continue or the negative thereof or other comparable terminology. There can be no assu that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from these projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including but not limited to the risk factors set forth above and those described elsewhere in this prospectus. All forward-looking statements and reasons why results may differ included in this prospectus are made as of the date hereof, and we assume no obligation to update any such forward-looking statement or reason why actual results might differ.

USE OF PROCEEDS

Unless otherwise indicated in any accompanying prospectus supplement, we expect to use the net proceeds from the sale of any common stock offered hereby for clinical development and manufacturing of our existing product candidates, TRISENOX, XYOTAX and Pixantrone, discovery and development of additional product opportunities, potential strategic acquisitions of complementary businesses or products and working capital. Pending use of the net proceeds, we intend to invest the net proceeds in interest-bearing, investment-grade securities.

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DESCRIPTION OF CAPITAL STOCK

This summary does not purport to be complete and is subject to, and qualified in its entirety by, the provisions of our restated articles of incorporation, as amended, our bylaws, as amended, and all applicable provisions of Washington law.

General

We are authorized to issue 100,000,000 shares of common stock, no par value, and 10,000,000 shares of preferred stock, no par value. As of the close of business on January 31, 2004, there were 50,291,605 shares of common stock issued and outstanding and no shares of preferred stock issued and outstanding.

Common Stock

Each holder of common stock is entitled to one vote for each share held on all matters to be voted upon by the shareholders and there are no cumulative voting rights. Subject to preferences that may be applicable to any outstanding preferred stock, holders of common stock are entitled to receive ratably the dividends, if any, that are declared from time to time by the board of directors out of funds legally available for that purpose. In the event of a liquidation, dissolution or winding up of the company, the holders of common stock are entitled to share in our assets remaining after the payment of liabilities and the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock. Holders of common stock have no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of common stock are fully paid and nonassessable. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate in the future.

Preferred Stock

The board of directors has the authority, without action by the shareholders, to designate and issue preferred stock in one or more series and to designate the rights, preferences and privileges of each series, which may be greater than the rights of the common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock upon the rights of holders of the common stock until the board of directors determines the specific rights of the holders of this preferred stock. However, the effects might include, among other things:

- restricting dividends on the common stock;
- diluting the voting power of the common stock;
- impairing the liquidation rights of the common stock; or

delaying or preventing a change in control of the company without further action by the shareholders.

We designated 100,000 shares of our preferred stock as Series C preferred stock in November 1996 in connection with the adoption of a shareholder rights plan as described below. In November 1999, we designated 10,000 shares of our preferred stock as 5% Series D preferred stock in connection with a private placement of those shares. No shares of Series D preferred stock are outstanding.

Warrants and Other Obligations to Issue Capital Stock

As of January 31, 2004, we had outstanding warrants to purchase an aggregate of 599,125 shares of our common stock. These warrants have a weighted average exercise price of $15.92 per share. These warrants expire between 2003 and 2008. In connection with the achievement in 2003 of a $20 million TRISENOX sales threshold, we are obligated to pay $5 million in either cash, common stock, or a combination of both within thirty days following the end of the first calendar quarter after the end of the previous four calendar quarter period in which the

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threshold was achieved. We are also obligated to make an additional payout, payable in cash or common stock at the then fair market value of our stock, for any calendar year that sales of TRISENOX exceed $40 million.

Anti-takeover Effects of Provisions of Washington Law and Our Charter Documents

Washington law contains certain provisions that may have the effect of delaying, deterring or preventing a change in control of the company. Chapter 23B.17 of the Washington Business Corporation Act (the WBCA) prohibits, subject to certain exceptions, a merger, sale of assets or liquidation of the company involving an interested shareholder (defined as a person or group of affiliated persons who own beneficially 20% or more of the company s voting securities) unless the transaction is determined to be at a fair price or otherwise approved by a majority of the company s disinterested directors or is approved by holders of two-thirds of the company s outstanding voting securities, other than those held by the interested shareholder. A Washington corporation may, in its articles of incorporation, exempt itself from coverage of this provision, but the company has not done so. In addition, Chapter 23B.19 of the WBCA prohibits the company, with certain exceptions, from engaging in certain significant business transactions with an acquiring person (defined as a person or group of persons who acquire 10% or more of the company s voting securities without the prior approval of the company s board of directors) for a period of five years following the acquiring person s share acquisition date. The prohibited transactions include, among others, a merger or consolidation with, disposition of assets to, or issuance or redemption of stock to or from, the acquiring person, or otherwise allowing the acquiring person to receive any disproportionate benefit as a shareholder. The company may not exempt itself from coverage of this statute. These statutory provisions may have the effect of delaying, deterring or preventing a change in control of the company.

Our board of directors is divided into three approximately equal classes of directors serving staggered three-year terms. In addition, our restated articles of incorporation provide that directors may be removed from office only at a meeting of shareholders called expressly for that purpose and only for cause. Our restated articles of incorporation limit cause to willful misfeasance having a material adverse effect on the company or conviction of a felony, provided that any action by a director shall not constitute cause if, in good faith, the director believed the action to be in or not opposed to the best interests of the company or if the director is entitled to be indemnified with respect to such action under applicable law, our restated articles of incorporation or bylaws, or a contract with the company. Further, our bylaws require a shareholder to provide notice to the company of such shareholder s intent to nominate a person or persons for election as directors not later than 90 days prior to the first anniversary of the previous year s annual meeting of shareholders or, in the case of an election to be held at a special meeting of shareholders for the election of directors, the close of business on the tenth day following the date on which notice of such meeting is first given to shareholders. A shareholder must also provide us with notice of such shareholder s intent to make any proposal at an annual meeting of shareholders not later than 90 days prior to the first anniversary of the previous year s annual meeting of shareholders. These provisions may have the effect of deterring hostile takeovers or delaying change in control or management of our company.

Shareholder Rights Plan

On November 11, 1996, our board of directors adopted a shareholder rights plan and declared a distribution of one preferred stock purchase right (a right) for each outstanding share of common stock to shareholders of record as of the close of business November 21, 1996 and for each share of common stock issued thereafter pursuant to a rights agreement entered into on November 11, 1996 and amended November 20, 2002, between the company and Computershare Investor Services, LLC as Rights Agent (the rights agreement). One right will be issued for each share of common stock issued upon the conversion of the notes. In connection with the adoption of the rights agreement, we reserved for issuance 100,000 shares of series C preferred stock. The series C preferred stock will only be issued in the event rights issued pursuant to the rights agreement are exercised.

Transfer Agent and Registrar

The Transfer Agent and Registrar for our common stock is Computershare Investor Services, LLC.

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PLAN OF DISTRIBUTION

We may sell our common stock through underwriters or dealers, through agents, or directly to one or more purchasers. A prospectus supplement or supplements will describe the terms of the offering of the common stock, including:

- the name or names of any underwriters, if any;
- the purchase price of the common stock and the proceeds we will receive from the sale;
- any over-allotment options under which underwriters may purchase additional securities from us;
- any agency fees or underwriting discounts and other items constituting agents or underwriters compensation;
- any public offering price;
- any discounts or concessions allowed or reallowed or paid to dealers; and
- any securities exchange or market on which the securities may be listed.

Only underwriters named in the prospectus supplement are underwriters of the common stock offered by the prospectus supplement.

If underwriters are used in the sale, they will acquire the common stock for their own account and may resell the stock from time to time in one or more transactions at a fixed public offering price. The obligations of the underwriters to purchase the common stock will be subject to the conditions set forth in the applicable underwriting agreement. We may offer the common stock to the public through underwriting syndicates represented by managing underwriters or by underwriters without a syndicate. Subject to certain conditions, the underwriters will be obligated to purchase all the shares of common stock offered by the prospectus supplement. Any public offering price and any discounts or concessions allowed or reallowed or paid to dealers may change from time to time. We may use underwriters with whom we have a material relationship. We will describe in the prospectus supplement, naming the underwriter, the nature of any such relationship.

We may sell common stock directly or through agents we designate from time to time. We will name any agent involved in the offering and sale of common stock and we will describe any commissions we will pay the agent in the prospectus supplement. Unless the prospectus supplement states otherwise, our agent will act on a best-efforts basis for the period of its appointment.

We may authorize agents or underwriters to solicit offers by certain types of institutional investors to purchase common stock from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. We will describe the conditions to these contracts and the commissions we must pay for solicitation of these contracts in the prospectus supplement.

We may provide agents and underwriters with indemnification against civil liabilities related to this offering, including liabilities under the Securities Act, or contribution with respect to payments that the agents or underwriters may make with respect to these liabilities. Agents and underwriters may engage in transactions with, or perform services for, us in the ordinary course of business.

Any underwriter may engage in overallotment, stabilizing transactions, short covering transactions and penalty bids in accordance with Regulation M under the Exchange Act. Overallotment involves sales in excess of the offering size, which create a short position. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Short covering transactions involve purchases of the common stock in the open market after the distribution is completed to cover short positions.

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Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the common stock originally sold by the dealer is purchased in a covering transaction to cover short positions. Those activities may cause the price of the common stock to be higher than it would otherwise be. If commenced, the underwriters may discontinue any of the activities at any time.

Any underwriters who are qualified market makers on the Nasdaq National Market may engage in passive market making transactions in the common stock on the Nasdaq National Market in accordance with Rule 103 of Regulation M, during the business day prior to the pricing of the offering, before the commencement of offers or sales of the common stock. Passive market makers must comply with applicable volume and price limitations and must be identified as passive market makers. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for such security; if all independent bids are lowered below the passive market maker s bid, however, the passive market maker s bid must then be lowered when certain purchase limits are exceeded.

LEGAL MATTERS

The validity of common stock offered hereby will be passed upon by Wilson Sonsini Goodrich & Rosati, Professional Corporation, San Francisco, California.

EXPERTS

Ernst & Young LLP, independent auditors, have audited our consolidated financial statements and schedule included in our Annual Report on Form 10-K/A for the year ended December 31, 2002, as set forth in their report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements and schedule are incorporated by reference in reliance on Ernst & Young LLP s report, given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We are a reporting company and file annual, quarterly and current reports, proxy statements and other information with the SEC. We have filed with the SEC a registration statement on Form S-3 under the Securities Act with respect to the shares of common stock we are offering under this prospectus. This prospectus does not contain all of the information set forth in the registration statement and the exhibits to the registration statement. For further information with respect to us and the securities we are offering under this prospectus, we refer you to the registration statement and the exhibits and schedules filed as a part of the registration statement. You may read and copy the registration statement, as well as our reports, proxy statements and other information, at the SEC s public reference rooms at Room 1024, 450 Fifth Street, N.W., Washington, D.C. 20549, as well as at the SEC s regional offices at 500 West Madison Street, Suite 1400, Chicago, IL 60661 and at 233 Broadway, New York, NY 10279. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference rooms. Our SEC filings are also available at the SEC s web site at http://www.sec.gov. In addition, you can read and copy our SEC filings at the office at the National Association of Securities Dealers, Inc. at 1735 K Street, N.W., Washington, D.C. 20006.

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INFORMATION INCORPORATED BY REFERENCE

The SEC allows us to incorporate by reference into this prospectus the information we filed with the SEC. This means that we can disclose important information by referring you to those documents. The information incorporated by reference is considered to be a part of this prospectus. Information that we file later with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings made by us with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act (other than reports or portions furnished under Items 9 or 12 of Form 8-K) until we complete our offering of the securities:

- our annual report on Form 10-K for the fiscal year ended December 31, 2002, as amended;
- our quarterly reports on Form 10-Q for the fiscal quarters ended March 31, 2003, June 30, 2003 and September 30, 2003;
- our current report on Form 8-K filed on June 17, 2003;
- our current report on Form 8-K filed on June 19, 2003;
- our current report on Form 8-K filed October 20, 2003;
- our current report on Form 8-K filed December 22, 2003;
- our current report on Form 8-K filed December 30, 2003;
- our current report on Form 8-K filed on January 13, 2004, as amended on February 5, 2004;
- the description of our common stock contained in our registration statement on Form 10 filed with the SEC on April 29, 1996, as amended; and
- the description of our preferred stock purchase rights contained in our registration statement on Form 8-A filed with the SEC on November 11, 1996, as amended.

Documents incorporated by reference, excluding exhibits except to the extent such exhibits are specifically incorporated by reference, are available from us without charge. You may obtain documents incorporated by reference by requesting them in writing from:

Cell Therapeutics, Inc.

501 Elliot Avenue West, Suite 400

Seattle, Washington 98119

United States of America

Attn: Investor Relations

(206) 282-7100

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