CELL THERAPEUTICS INC
Form S-3
February 11, 2004
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As filed with the Securities and Exchange Commission on February 11, 2004

Registration No. 333-

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-3

REGISTRATION STATEMENT

Under

The Securities Act of 1933

CELL THERAPEUTICS, INC.

(Exact name of Registrant as specified in its charter)

Washington	**2834**	**91-1533912**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification Number)**

501 Elliott Avenue West, Suite 400

Seattle, Washington 98119

(206) 282-7100

(Address, including zip code, and telephone number, including area code, of Registrant s principal executive offices)

James A. Bianco, M.D.

President and Chief Executive Officer

Cell Therapeutics, Inc.

501 Elliott Avenue West, Suite 400

Seattle, Washington 98119

(206) 282-7100

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Michael J. Kennedy, Esq.

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Wilson Sonsini Goodrich & Rosati

Professional Corporation

One Market, Spear Street Tower, Suite 3300

San Francisco, CA 94105

(415) 947-2000

Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this Registration Statement.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ¨

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. ¨

CALCULATION OF REGISTRATION FEE

Title of Securities to be Registered	**Proposed Maximum Aggregate Offering Price(1)**	**Amount of Registration Fee(2)**
Common Stock, no par value	$75,000,000	$9,503

(1) There is being registered an indeterminate number of shares of common stock of the registrant as may be sold from time to time by the registrant. In no event will the aggregate offering price of all securities issued from time to time pursuant to this registration statement exceed $75,000,000.
(2) Calculated pursuant to Rule 457(o) under the Securities Act.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission acting pursuant to said Section 8(a) may determine.

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The Information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell securities and is not soliciting an offer to buy securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED FEBRUARY 11, 2004

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 offerred 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 , 200

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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

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disrupting activities through protests and other means. To the extent the activities of these groups are successful, our business could be materially harmed by delaying or interrupting our research and development activities.

Risks Related to the Securities Markets

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

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.

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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;
- 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,

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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 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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$75,000,000

COMMON STOCK

PROSPECTUS

, 2004

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PART II

INFORMATION NOT REQUIRED IN THE PROSPECTUS

Item 14. ***Other Expenses of Issuance and Distribution***

The aggregate estimated expenses to be paid by the Registrant in connection with this offering are as follows:

Securities and Exchange Commission registration fee	$ 9,503
Accounting fees and expenses	50,000
Legal fees and expenses	150,000
Miscellaneous	20,000
Total	$ 229,503

Item 15. ***Indemnification of Directors and Officers of Cell Therapeutics, Inc.***

Sections 23B.08.500 through 23B.08.600 of the Washington Business Corporation Act (the WBCA) authorize a court to award, or a corporation s board of directors to grant, indemnification to directors and officers on terms sufficiently broad to permit indemnification under certain circumstances for liabilities arising under the Securities Act of 1933. Article IX of the Registrant s Restated Bylaws provides for indemnification of the Registrant s directors, officers, employees and agents to the maximum extent permitted by Washington law. The directors and officers of the Registrant also may be indemnified against liability they may incur for serving in such capacity pursuant to a liability insurance policy maintained by the Company for such purpose.

Section 23B.08.320 of the WBCA authorizes a corporation to limit a director s liability to the corporation or its shareholders for monetary damages for acts or omissions as a director, except in certain circumstances involving intentional misconduct, knowing violations of law or illegal corporate losses or distributions, or any transaction from which the director personally receives a benefit in money, property or services to which the director is not legally entitled. Article VI of the Registrant s Restated Articles of Incorporation contains provisions implementing, to the fullest extent permitted by Washington law, such limitations on a director s liability to the Registrant and its shareholders.

The Registrant has entered into an indemnification agreement with each of its executive officers and directors in which the Registrant agrees to hold harmless and indemnify the officer or director to the fullest extent permitted by Washington law. The Registrant agrees to hold harmless and indemnify the officer or director against any and all losses, claims, damages, liabilities or expenses incurred in connection with any actual, pending or threatened action, suit, claim or proceeding, whether civil, criminal, administrative or investigative and whether formal or informal, in which the officer or director is, was or becomes involved by reason of the fact that the officer or director is or was a director, officer, employee, trustee or agent of the Registrant or any related company, partnership or enterprise, including service with respect to an employee benefit plan, whether the basis of such proceeding is alleged action (or inaction) by the officer or director in an official capacity and any action, suit, claim or proceeding instructed by or at the direction of the officer or director unless such action, suit, claim or proceeding is or was authorized by the Registrant s Board of Directors. No indemnity pursuant to the indemnification agreements shall be provided by the Registrant

on account of any suit in which a final, unappealable judgment is rendered against the officer or director for an accounting of profits made from the purchase or sale by the officer or director of securities of the Registrant in violation of the provisions of Section 16(b) of the Securities Exchange Act of 1934, and amendments thereto, or for damages that have been paid directly to the officer or director by an insurance carrier under a policy of directors and officers liability insurance maintained by the Registrant.

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Item 16. ***Exhibits***

The following exhibits are filed herewith or incorporated by reference herein:

EXHIBIT INDEX

Exhibit Number	Description of Document
1.1(1)	Form of Underwriting Agreement.
4.1(2)	Form of Rights Agreement dated as of November 11, 1996, between the Registrant and Harris Trust Company of California, which includes the Form of Rights Certificate as Exhibit A, the Summary of Rights to Purchase Preferred Stock as Exhibit B and the Form of Certificate of Designation of the Series C Preferred Stock as Exhibit C.
4.2(3)	First Amendment to Rights Agreement dated as of November 20, 2002, between the Registrant, Harris Trust Company of California and Computershare Investor Services, LLC.
5.1	Opinion of Wilson Sonsini Goodrich & Rosati, Professional Corporation.
23.1	Consent of Ernst & Young LLP, Independent Auditors.
23.2	Consent of KPMG S.p.A. with respect to financial statements of Novuspharma S.p.A.
23.3	Consent of Wilson Sonsini Goodrich & Rosati, Professional Corporation (included in Exhibit 5.1).
24.1	Power of Attorney of certain directors and officers of Cell Therapeutics, Inc. (included on signature page hereof).

(1) To be filed by amendment or as an exhibit to a current report of the registrant on Form 8-K and incorporated herein by reference.
(2) Incorporated by reference to exhibits to the Registrant s Registration Statement on Form 8-A.
(3) Incorporated by reference to exhibits to the Registrant s Form 8A-12B/A, filed on January 10, 2003.

Item 17. ***Undertakings***

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) to include any prospectus required by Section 10(a)(3) of the Securities Act;

(ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or

high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and

(iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that paragraphs (1)(i) and (1)(ii) do not apply if the registration statement is on Form S-3, Form S-8 or Form F-3, and the information required to be included in a post-effective

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amendment by those paragraphs is contained in periodic reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or 15(d) of the Exchange Act that are incorporated by reference in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act, each post-effective amendment shall be deemed to be a new registration statement relating to the securities it offers, and the offering of the securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered that remain unsold at the termination of this offering.

(4) That: (i) for purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of the registration statement in reliance upon Rule 430A and contained in the form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of the registration statement as of the time it was declared effective; and (ii) for the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(5) That, for purposes of determining any liability under the Securities Act, each filing of the registrant s annual report pursuant to section 13(a) or section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan s annual report pursuant to section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC this form of indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against these liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by a director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of this issue.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3, and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Seattle, State of Washington on February 11, 2004.

CELL THERAPEUTICS, INC.

By: /s/ JAMES A. BIANCO

James A. Bianco, M.D.

President and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints James A. Bianco and Louis A. Bianco, his or her true and lawful agent, proxy and attorney-in-fact, each acting alone, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to (i) act on, sign, and file with the SEC any and all amendments (including post-effective amendments) to this registration statement together with all schedules and exhibits thereto, (ii) act on, sign and file such certificates, instruments, agreements and other documents as may be necessary or appropriate in connection therewith, (iii) act on and file any supplement to any prospectus included in this registration statement or any such amendment or any subsequent registration statement filed pursuant to Rule 462(b) under the Securities Act, and (iv) take any and all actions which may be necessary or appropriate to be done, as fully for all intents and purposes as he or she might or could do in person, hereby approving, ratifying and confirming all that such agent, proxy and attorney-in-fact or any of his substitutes may lawfully do or cause to be done by virtue thereof.

IN WITNESS WHEREOF, each of the undersigned has executed this Power of Attorney as of the date indicated.

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Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed below by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ MAX E. LINK **MAX E. LINK, PH.D.**	Chairman of the Board	February 11, 2004
/s/ JAMES A. BIANCO **JAMES A. BIANCO**	President, Chief Executive Officer and Director (Principal Executive Officer)	February 11, 2004
/s/ LOUIS A. BIANCO **LOUIS A. BIANCO**	Executive Vice President, Finance and Administration (Principal Financial Officer and Principal Accounting Officer)	February 11, 2004
/s/ JACK L. BOWMAN **JACK L. BOWMAN**	Director	February 11, 2004
 JOHN M. FLUKE	Director	February 11, 2004
/s/ VARTAN GREGORIAN **VARTAN GREGORIAN, PH.D.**	Director	February 11, 2004
/s/ MARY O NEILL MUNDINGER **MARY O NEILL MUNDINGER, DR. PH**	Director	February 11, 2004
/s/ PHILLIP M. NUDELMAN **PHILLIP M NUDELMAN, PH.D.**	Director	February 11, 2004
/s/ JACK W. SINGER **JACK W. SINGER, M.D.**	Director	February 11, 2004
/s/ ERICH PLATZER **ERICH PLATZER, M.D.**	Director	February 11, 2004
/s/ SILVANO SPINELLI **SILVANO SPINELLI**	Director	February 11, 2004

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EXHIBIT INDEX

Exhibit Number	Description
1.1(1)	Form of Underwriting Agreement.
4.1(2)	Form of Rights Agreement dated as of November 11, 1996, between the Registrant and Harris Trust Company of California, which includes the Form of Rights Certificate as Exhibit A, the Summary of Rights to Purchase Preferred Stock as Exhibit B and the Form of Certificate of Designation of the Series C Preferred Stock as Exhibit C.
4.2(3)	First Amendment to Rights Agreement dated as of November 20, 2002, between the Registrant, Harris Trust Company of California and Computershare Investor Services, LLC.
5.1	Opinion of Wilson Sonsini Goodrich & Rosati, Professional Corporation.
23.1	Consent of Ernst & Young LLP, Independent Auditors.
23.2	Consent of KPMG S.p.A. with respect to financial statements of Novuspharma S.p.A.
23.3	Consent of Wilson Sonsini Goodrich & Rosati, Professional Corporation (included in Exhibit 5.1)
24.1	Power of Attorney of certain directors and officers of Cell Therapeutics, Inc. (included on signature page).

(1) To be filed by amendment or as an exhibit to a current report of the registrant of Form 8-K and incorporated herein by reference.
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