

CELL THERAPEUTICS INC  
Form S-3  
July 07, 2008  
Table of Contents

As filed with the Securities and Exchange Commission on July 7, 2008

Registration No. 333-

**UNITED STATES**  
**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  
(State of other jurisdiction of  
incorporation or organization)

2834  
(Primary Standard Industrial  
Classification Code Number)  
501 Elliott Avenue West, Suite 400

91-1533912  
(I.R.S. Employer  
Identification No.)

Seattle, Washington 98119

(206) 282-7100

Edgar Filing: CELL THERAPEUTICS INC - Form S-3

(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)

*Copy to:*

**Karen A. Dempsey, Esq.**

**Donna Cochener, Esq.**

**Heller Ehrman LLP**

**333 Bush Street**

**San Francisco, California 94104**

**(415) 772-6000**

*Approximate date of commencement of proposed sale to the public:*

*From time to time after the effective date of this registration statement as determined by the selling shareholders.*

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 this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. "

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. "

## CALCULATION OF REGISTRATION FEE

<b>Title of Each Class of Shares To Be Registered</b>	<b>Amount to be Registered (1)</b>	<b>Proposed Maximum Offering Price Per Unit (2)</b>	<b>Proposed Maximum Aggregate Offering Price(3)</b>	<b>Amount of Registration Fee</b>
Common Stock, no par value (3)	6,582,268	\$ 0.47	\$ 3,093,666	\$ 121.58

- (1) All such common stock is issuable upon exercise of certain warrants currently owned by the selling shareholders.
- (2) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) under the Securities Act, based upon the average of the high and low sales prices of the registrant's common stock, as reported on the NASDAQ Global Market on July 3, 2008.
- (3) The shares of common stock being registered are the shares of common stock issuable upon exercise of certain warrants, which have an exercise price of \$1.41 per share.

**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 Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.**

**Table of Contents**

**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 these securities and is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.**

**SUBJECT TO COMPLETION, DATED July 7, 2008**

**PROSPECTUS**

**6,582,268 Shares of Common Stock Issuable Upon Exercise of the Warrants**

The selling shareholders identified in this prospectus may from time to time sell up to an aggregate of 6,582,268 shares of our common stock issuable upon exercise of certain warrants. The warrants are exercisable at an exercise price of \$1.41 per shares. The warrants were originally issued by us in a private placement in March 2008 in connection with the issuance of our 9% Convertible Senior Notes due 2012. The selling shareholders may offer and sell the shares issuable on conversion of the warrants in public or private transactions, or both. These sales may occur at fixed prices, at market prices prevailing at the time of sale, at prices related to prevailing market price, or at negotiated prices.

The selling shareholders may sell shares through underwriters, broker-dealers or agents, who may receive compensation in the form of discounts, concessions or commissions from the selling shareholders, the purchasers of the shares, or both. See Plan of Distribution for a more complete description of the ways in which the shares may be sold. We will not receive any of the proceeds from the sale of the shares by the selling shareholders.

Our common stock is quoted on the Nasdaq Global Market and on the MTA in Italy under the symbol CTIC . On July 1, 2008, the last reported sale price of our common stock on the Nasdaq Global Market was \$0.48.

**Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page 5 of this prospectus.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of 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 July 7, 2008

**Table of Contents**

**TABLE OF CONTENTS**

	<b>Page</b>
<u>About This Prospectus</u>	ii
<u>Special Note Regarding Forward-Looking Statements</u>	ii
<u>Summary</u>	1
<u>Risk Factors</u>	5
<u>Use of Proceeds</u>	20
<u>Description of Capital Stock</u>	20
<u>Selling Shareholders</u>	22
<u>Plan of Distribution</u>	24
<u>Legal Matters</u>	26
<u>Experts</u>	26
<u>Where You Can Find More Information</u>	27
<u>Documents Incorporated by Reference</u>	27

No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus or any prospectus supplement. You must not rely on any unauthorized information or representations. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or any applicable prospectus supplement is current only as of its date, and the information contained in any document incorporated by reference in this prospectus is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any prospectus supplement or any sale of a security.

**Table of Contents**

**ABOUT THIS PROSPECTUS**

This prospectus relates to the resale of up to 6,582,268 shares of common stock issuable upon exercise of certain warrants. Those warrants were originally issued by us in a private placement in March 2008 in connection with the issuance of our 9% Convertible Senior Notes due 2012. We will not receive any proceeds from the potential sale of the shares offered by the selling shareholders. However, we will receive the exercise price of the warrants upon the exercise if they are cash exercised.

This prospectus constitutes part of the registration statement of Form S-3 filed with the Securities and Exchange Commission under the Securities Act of 1933, as amended (the Securities Act), utilizing a shelf registration or continuous offering process. It omits some of the information contained in the registration statement and reference is made to the registration statement for further information with regard to us and the securities being offered by the selling shareholders. Any statement contained in the prospectus concerning the provisions of any document filed as an exhibit to the registration statement or otherwise filed with the Securities and Exchange Commission is not necessarily complete, and in each instance, reference is made to the copy of the document filed.

**SPECIAL NOTE 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 contained in and incorporated by reference into this prospectus when evaluating an investment in our common stock. This prospectus and the documents incorporated by reference into this prospectus include forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (Exchange Act). All statements other than statements of historical fact are forward-looking statements for purposes of these provisions, including:

any statement regarding the performance, or likely performance, or outcomes or economic benefits of any licensing or other agreement, including any agreement with Novartis Pharma AG or its affiliates, including whether or not such partner will elect to participate, terminate or otherwise make elections under any such partnership agreement or whether any regulatory authority required to enable such agreement will be obtained;

any projections of revenues, operating expenses 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 operations, plans, regulatory filings or approvals;

any statements on plans regarding proposed or potential clinical trials or new drug filing strategies or timelines;

any statements concerning proposed new products or services, any statements regarding pending or future mergers or acquisitions; and

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, estimate, potential, or continue or the negative thereof or other comparable terminology. There can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those 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

## Edgar Filing: CELL THERAPEUTICS INC - Form S-3

inherent risks and uncertainties, including, but not limited to, the risk factors set forth 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.

**Table of Contents****SUMMARY**

*The following summary highlights information contained elsewhere, or incorporated by reference, in this prospectus. The following summary does not contain all the information that you should consider before investing in our common stock. You should read this entire prospectus carefully, including the documents that we incorporate by reference into this prospectus. Unless otherwise indicated, CTI, Company, we, us, and similar terms refer to Cell Therapeutics, Inc. and its subsidiaries.*

**Our Company**

We develop, acquire and commercialize novel treatments for cancer. Our goal is to build a leading biopharmaceutical company with a diversified portfolio of proprietary oncology drugs. Our research, development, acquisition and in-licensing activities concentrate on identifying and developing new, less toxic and more effective ways to treat cancer.

On December 21, 2007, we completed our acquisition of the U.S. development, sales and marketing rights to the radiopharmaceutical product Zevalin® (Ibritumomab Tiuxetan), or Zevalin, from Biogen Idec Inc., or Biogen, pursuant to an Asset Purchase Agreement. Zevalin was the first radioimmunotherapy approved by the U.S. Food and Drug Administration, or FDA. It was approved in 2002 to treat patients with relapsed or refractory low-grade, follicular, or B-cell non-Hodgkin's lymphoma, or NHL. The assets acquired included the Zevalin FDA registration, FDA dossier, U.S. trademark, trade name and trade dress, customer list, certain patents and the assignment of numerous contracts. Additionally, we entered into a seventy-eight month supply agreement with Biogen to manufacture Zevalin for sale in the United States as well as a security agreement providing Biogen a first priority security interest in the assets purchased in the transaction. We made an upfront payment to Biogen of \$10.1 million at the time of closing and are also responsible for up to \$20 million in contingent milestone payments based on positive trial outcomes and FDA approval for label expansion. We are also obligated to make additional royalty payments based on net sales of Zevalin.

On June 16, 2008, we entered into an Access Agreement with Bayer Schering Pharma AG, or Bayer, which holds the rights to Zevalin outside of the United States. Under the agreement, Bayer has agreed to give us access to data from Bayer's phase III first-line indolent trial, or FIT trial, of Zevalin. We expect to use the data from the trial to begin discussions with the U.S. Food and Drug Administration, or FDA, regarding the potential for a supplemental Biologics License Application, or sBLA, for Zevalin based on the FIT trial results. Under the terms of that agreement, we will make an initial payment to Bayer of \$2 million. Beginning January 1, 2009, we will also pay Bayer royalties on net sales of Zevalin until an aggregate of \$11.5 million in royalties has been paid to Bayer under the agreement. We will make an additional payment of \$3 million to Bayer if we are able to obtain FDA approval of an sBLA for Zevalin based on the FIT trial results.

On July 31, 2007, we completed our acquisition of Systems Medicine, Inc., or SM, a privately held oncology company, in a stock for stock merger valued at \$20 million. SM stockholders can also receive a maximum of \$15 million in additional consideration (payable in cash or stock at our election, subject to certain Nasdaq limitations on issuance of stock) upon the achievement of certain FDA regulatory milestones. Under the agreement, SM became Systems Medicine LLC and operates as a wholly owned subsidiary of CTI. SM holds worldwide rights to use, develop, import and export brostallicin, a synthetic DNA minor groove binding agent that has demonstrated anti-tumor activity and a favorable safety profile in clinical trials in which more than 200 patients have been treated to date. SM currently uses a genomic-based platform to guide development of brostallicin; we expect to use that platform to guide development of our licensed oncology products in the future. SM also has a strategic affiliation with the Translational Genomics Research Institute, or TGen, and has the ability to use TGen's extensive genomic platform and high throughput capabilities to target a cancer drug's context-of-vulnerability, which is intended to guide clinical trials toward patient populations where the highest likelihood of success should be observed, thereby potentially lowering risk and shortening time to market.

We are developing OPAXIO (OPAXIO), which we have previously referred to as XYOTAX, for the treatment of non-small cell lung cancer, or NSCLC, and ovarian cancer. As announced in March and May 2005, our STELLAR 2, 3 and 4 phase III clinical studies for OPAXIO did not meet their primary endpoints of superior overall survival. However, we believe that the reduction in toxicities coupled with superior convenience and less medical resource utilization demonstrated in the STELLAR 4 phase III clinical trial merits consideration for approval as single agent therapy for patients with advanced NSCLC who have poor performance status, or PS2. Currently there are no drugs approved for patients with PS2 NSCLC. On March 4, 2008, we submitted a Marketing Authorization Application, or MAA, to the European Medicines Agency, or EMEA, for first-line treatment of patients with advanced NSCLC who are PS2, based on a non-inferior survival and improved side effect profile which we believe was demonstrated in our STELLAR clinical trials. The application is based on a positive opinion we received from the EMEA's Scientific Advice Working Party, or SAWP; the EMEA agreed that switching the primary endpoint from superiority to noninferiority is feasible if the retrospective justification provided in the marketing application is adequate. The discussions with the SAWP focused on using the STELLAR 4 study as primary evidence of non-inferiority and the STELLAR 3 study as supportive of the MAA. The application was accepted for review in April 2008 and the MAA has now entered the marketing approval review process, which generally takes 15 to 18 months.





---

**Table of Contents**

We are also developing OPAXIO for women with pre-menopausal levels of estrogen who have advanced NSCLC with normal or poor performance status. The basis for this clinical study was in part related to a pooled analysis of STELLAR 3 and 4 phase III trials for treatment of first-line NSCLC patients who have PS2 which we believe demonstrates a statistically significant survival advantage among women receiving OPAXIO when compared to women or men receiving standard chemotherapy. A survival advantage for women over men was also demonstrated in a first-line phase II clinical trial of OPAXIO and carboplatin, known as the PGT202 trial, supporting the potential benefit observed in the STELLAR 3 and 4 trials. In December 2005, we initiated a phase III clinical trial, known as the PIONEER, or PGT305, study, for OPAXIO as first-line monotherapy in PS2 women with NSCLC. In December 2006, we agreed with the recommendation of the Data Safety Monitoring Board to close the PIONEER lung cancer clinical trial due, in part, to the diminishing utility of the PIONEER trial given our plans to submit a new protocol to the FDA. In early 2007, we submitted two new protocols under a Special Protocol Assessment, or SPA, to the FDA. The new trials, known as PGT306 and PGT307, focus exclusively on NSCLC in women with pre-menopausal estrogen levels, the subset of patients where OPAXIO demonstrated the greatest potential survival advantage in the STELLAR trials. We believe the lack of safe and effective treatment for women with advanced first-line NSCLC who have pre-menopausal estrogen levels represents an unmet medical need. We initiated the PGT307 trial in September 2007. Although the FDA has established the requirement that two adequate and well-controlled pivotal studies demonstrating a statistically significant improvement in overall survival will be required for approval of OPAXIO in the NSCLC setting, we believe that compelling results from a single trial, PGT307, along with supporting evidence from prior clinical trials, may enable us to submit a new drug application, or NDA, in the United States. In early 2008, we limited enrollment on the PGT307 study to U.S. sites only, until either approval of the MAA by the EMEA or until positive results from the GOG212 trial of OPAXIO for first-line maintenance therapy in ovarian cancer are reported.

We are also developing OPAXIO as potential maintenance therapy for women with advanced stage ovarian cancer who achieve a complete remission following first-line therapy with paclitaxel and carboplatin. This study is under the control of the Gynecologic Oncology Group and is expected to enroll 1,100 patients by 2010. A potential interim analysis, based on the number of events in the database, is planned for 2009, and if successful could lead to an NDA filing in 2010.

We are developing pixantrone, a novel anthracycline derivative, for the treatment of NHL. An interim analysis of our ongoing phase III study of pixantrone, known as the EXTEND or PIX301 study, was performed by the independent Data Monitoring Committee in the third quarter of 2006. Based on their review, the study continued. In September 2007, we announced that we reduced the enrollment target and decided to conduct a full analysis of the EXTEND trial, instead of an interim analysis as previously planned. In March 2008, we completed enrollment of approximately 140 patients in the EXTEND trial, 97 of which are currently evaluable according to Histological Intent to Treat, or HITT, criteria. An analysis of the data is expected in the second half of 2008 and, if final study results are adequate, we could submit an NDA with the FDA in early 2009 with potential approval in the second half of 2009. The FDA agreed that randomized safety data from the RAPID study (CHOP-R vs. CPOP-R) could be used to support the EXTEND results in an NDA submission for pixantrone. The RAPID, or PIX203, study is a phase II study in which pixantrone is substituted for doxorubicin in the CHOP-R regimen compared to the standard CHOP-R regimen in patients with previously untreated diffuse large B-cell lymphoma. An interim analysis of the RAPID study was reported in July 2007. The interim analysis of the study showed that to date a majority of patients on both arms of the study achieved a major objective anti-tumor response (complete response or partial response). Patients on the pixantrone arm of the study had clinically significant reductions in the incidence of severe heart damage, infections, and thrombocytopenia (a reduction in platelets in the blood) as well as significant reduction in febrile neutropenia. Three deaths occurred in the pixantrone arm versus none in the control arm. Based on subsequent follow-up, we believe this discrepancy is probably due to the early nature of the data. In early 2008, we closed enrollment on the RAPID trial because we had adequate sample size to demonstrate differences in cardiac events and other clinically relevant side effects between pixantrone and doxorubicin.

We also launched a phase III trial of pixantrone in indolent NHL, the PIX303 trial, in September 2007, which was designed to evaluate the combination of fludarabine, pixantrone and rituximab versus fludarabine and rituximab in patients who have received at least one prior treatment for relapsed or refractory indolent NHL. We closed the PIX303 trial in early 2008 based on, among other considerations, our plans to refocus the Company's resources on obtaining pixantrone approval based on the EXTEND phase III trial before making additional substantive investments in alternative indications for pixantrone as well as the changing competitive landscape in second line follicular NHL. In May 2007, we received fast track designation from the FDA for pixantrone for the treatment of relapsed or refractory indolent NHL.

We are developing brostallicin, which is a small molecule, anti-cancer drug with a novel, unique mechanism of action and composition of matter patent coverage, through our wholly owned subsidiary, SM. Data in more than 200 patients treated with brostallicin in phase I/II clinical trials reveal evidence of activity in patients with refractory cancer and patient/physician-friendly

---

## **Table of Contents**

dosage and administration. A phase II study of brostallicin in relapsed/refractory soft tissue sarcoma met its pre-defined activity and safety hurdles and resulted in a first-line phase II study that is currently being conducted by the European Organization for Research and Treatment of Cancer, or EORTC. Additionally, we initiated a phase II myxoid liposarcoma trial in 2007. Brostallicin also has demonstrated synergy with new targeted agents as well as established treatments in preclinical trials; consequently, we have begun a multi-arm combination study with brostallicin and other agents, including Avastin. This study is being conducted in conjunction with U.S. Oncology at multiple sites in the United States with the first combinations expected to be completed in 2008.

We are developing Zevalin for additional indications. Zevalin is a form of cancer therapy called radioimmunotherapy and is indicated for the treatment of patients with relapsed or refractory low-grade, follicular, or B-cell NHL, including patients with Rituximab-refractory follicular NHL. It was approved by the FDA in February 2002 as the first radioimmunotherapeutic agent for the treatment of NHL. At the American Society of Hematology meeting in December 2007, Bayer published the results of their FIT trial for Zevalin. In April 2008, based on these data Bayer received approval from the European Medicines Commission for use of Zevalin in consolidation therapy after remission induction in previously untreated patients with follicular lymphoma. We were able to obtain access to the data from the FIT trial under the Access Agreement that we entered into with Bayer in June 2008. If the data from the FIT trial results is suitable for FDA filing, we plan to submit an sBLA for Zevalin consolidation of first remission in advanced stage follicular lymphoma in the second half of 2008. We also intend to file an sBLA to remove the requirement for a biodistribution scan from the Zevalin label in 2008.

We are currently focusing our efforts on Zevalin, OPAXIO, pixantrone, and brostallicin, and have no immediate plans to conduct any further clinical studies on CT-2106, polyglutamate camptothecin, or any other early-stage drug candidates.

CTI and OPAXIO are our proprietary marks, and we also own the U.S. rights to the mark Zevalin. All other product names, trademarks and trade names referred to in this prospectus are the property of their respective owners.

As of March 31, 2008, we had incurred aggregate net losses of approximately \$1.2 billion since inception. We expect to continue to incur additional operating losses for at least the next couple of years.

## **Recent Developments**

### **Debt Restructuring**

We have a substantial amount of debt outstanding, and our annual interest expense with respect to our debt is significant. In December 2007 and February 2008, we completed partial restructurings of our convertible notes due in 2008, which retired a portion of such debt, extended the maturity date on certain such debt to 2011 and involved the issuance of additional shares of common stock to holders of the exchanged notes. The remaining approximately \$10.7 million of such 2008 convertible notes outstanding was paid at the notes' maturity on June 15, 2008.

On January 30, 2008, we announced a plan to refocus our resources on late-stage and marketed products, which involve increasing sales of Zevalin in the United States and preparing the marketing applications for OPAXIO and pixantrone described above, while advancing the clinical development of brostallicin. This plan was intended to reduce operating expenses and projected net cash operating expenses in 2008. As part of these refocusing efforts, approximately 30 of our U.S. employees were terminated.

As of March 31, 2008 we had cash and cash equivalents, securities available-for-sale and interest receivable of approximately \$15.3 million, and total current liabilities of \$47.9 million. As a result, we will need to continue to raise additional capital to fund our operations in 2008 and beyond. See Risk Factors.

### **Recent Financings**

In January 2008, we sold 800,000 shares of our common stock to Société Générale under the Step-Up Equity Financing Agreement we have in place with Société Générale. The 800,000 shares of common stock were sold at a price of \$1.07, or approximately \$1.59, per share, which raised approximately \$1.3 million ( \$0.9 million) in aggregate gross proceeds. In June 2008, we received notice from counsel for Société Générale asserting that the Step-Up Equity Financing Agreement was terminated by Société Générale effective June 6, 2008 on the basis that the going concern statement included in our Annual Report on Form 10-K, as well as a notice we received from Nasdaq on April 16, 2008 regarding our failure to comply with the minimum price requirements under the listing requirements of the Nasdaq Global Market, constitute a material adverse change under the Financing Agreement, permitting Société Générale to terminate the Financing Agreement. We disagree with Société Générale's allegations that such events permit Société Générale to terminate the Financing Agreement and are reviewing our options to cause Société Générale to continue to provide financing under the Financing Agreement, although there can be no assurance that Société Générale will do so.



---

## **Table of Contents**

In March 2008, we sold \$51.7 million in 9% senior convertible notes due March 2012; of these gross proceeds, approximately \$16.2 million was used to make payments to holders of our preferred stock to induce them to convert their shares of preferred stock into common stock and an additional \$13.9 million was placed in an escrow account to be used to make interest payments and make-whole payments on those notes for 12 months following the closing of that offering.

In April 2008, we sold to a single institutional investor \$36.0 million in principal amount of our 13.5% senior convertible notes due 2014, 9,000 shares of our Series E 13.5% preferred stock, warrants to purchase up to 28,481,012 shares of our common stock and a warrant to purchase up to \$67.5 million in additional debt and warrant securities, which we refer to as the B Warrant. The total purchase price for the securities was \$64.6 million. Of this amount, \$5.3 million was credited to the investor upon surrender of 9% senior convertible notes due 2012 and related warrants that were previously purchased by the investor, and \$36.5 million was deposited into an escrow account to be used to make interest payments and make-whole payments on the 13.5% senior convertible notes for 12 months following the closing of that offering. The remaining proceeds to the Company, before fees and expenses, was \$22.9 million.

In June 2008, the B Warrant was amended and the investor subsequently partially exercised the B Warrant; upon such exercise of the B Warrant we issued \$23.0 million in principal amount of our 15% senior convertible notes due 2011 and warrants to purchase up to 14,556,962 shares of our common stock in exchange for payment by the investor of \$23.0 million. Of the \$23.0 million purchase price, \$10.35 million was deposited into an escrow account to be used to make interest payments and make-whole payments on the 15% convertible notes for 12 months following the issuance of the 15% convertible notes. The remaining proceeds to the Company, before fees and expenses, was \$12.65 million.

## **Recent Legal Proceedings**

Based on language (the Disputed Language ) contained in the Articles of Amendment to the Company s Articles of Incorporation (the Amendments ) filed in connection with the issuance of the Company s Series A, Series B and Series C Convertible Preferred Stock (the Preferred Stock ), certain holders thereof (the Shareholders ) asserted a right to consent (or not) to the transactions contemplated by the Exchange Agreements entered into by the Company and certain holders of its then existing convertible debt on December 12, 2007 (the Exchange ). The Company is of the view that inclusion of the Disputed Language in the Amendments constitutes a scrivener s error without legal force or effect, and filed Articles of Correction with the Secretary of State of Washington in accordance with Section 23B.01.240 of the Revised Code of Washington. On January 2, 2008, Tang Capital Partners LP ( Tang ) filed a civil action in the United States District Court for the Southern District of New York in which Tang alleged that the Company breached a Securities Purchase Agreement, executed on or about April 16, 2007, and executed in connection with the issuance of Series B Preferred Stock. Tang alleges that the Company s filing of Articles of Correction to the Articles of Amendment to the Amended and Restated Articles of Incorporation on or around December 11, 2007, materially and adversely altered the powers, preferences or rights conferred through its Securities Purchase Agreement, thereby constituting a Triggering Event, and as a result, Tang is entitled to redemption of its Preferred Stock in consideration for 130% of its Stated Value, plus other available relief, if any. Another holder of Preferred Stock, Enable Capital Management LLC ( Enable ), filed a lawsuit on January 23, 2008 in the Supreme Court of the State of New York with similar claims to the Tang action. On March 21, 2008, Enable filed an amended complaint, asserting an additional claim against CTI for breach of contract and breach of the covenant of good faith and fair dealing. Enable alleges that on or about March 4, 2008, CTI committed a further breach of its obligations by offering and/or paying consideration to certain holders of CTI preferred stock to induce those holders to convert their preferred stock into common stock without making the same offer to Enable. Additional holders of our preferred stock may assert claims similar to those asserted by Tang and Enable. CTI disputes each of the claims asserted against it and intends to defend itself vigorously.

## **Other Information**

We were incorporated in Washington in 1991. Our principal executive offices are located at 501 Elliott Avenue West, Suite 400, Seattle, Washington 98119. Our telephone number is (206) 282-7100. Our website can be found at [www.CellTherapeutics.com](http://www.CellTherapeutics.com). Information contained in, or accessible through, our website does not constitute a part of this prospectus.

---

**Table of Contents**

**RISK FACTORS**

You should carefully consider the risks described below and other information in this prospectus and in the documents incorporated by reference into this prospectus before deciding to invest in our securities. Additional risks and uncertainties that we do not presently know or that we currently deem immaterial may also impair our business, financial condition, operating results and prospects. If any of the following risks actually occur, they could materially adversely affect our business, financial condition, operating results or prospects. In that case, the trading price of our securities could decline.

**Factors Affecting Our Operating Results and Financial Condition**

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

We were incorporated in 1991 and have incurred a net operating loss every year. As of March 31, 2008, we had an accumulated deficit of approximately \$1.2 billion. We are pursuing regulatory approval for OPAXIO, pixantrone and brostallicin and plan to seek regulatory approval for the expansion of approved uses of Zevalin. We will need to conduct research, development, testing and regulatory compliance activities and undertake manufacturing and drug supply activities, expenses which, together with projected general and administrative expenses, will result in operating losses for the foreseeable future. We may never become profitable, even if we are able to commercialize products currently in development or otherwise.

*Our debt and operating expenses exceed our net revenues.*

We have a substantial amount of debt outstanding, and our annual interest expense with respect to our debt is significant. We have a single drug we are marketing, Zevalin, and the net proceeds of sales of this drug are not sufficient to pay our debt and operating expenses on a current basis. We do not currently project that net revenues from sales of any of our products will be sufficient to cover our existing debt and operating expenses within the next twelve months. Unless we raise substantial additional capital, we will not be able to pay all of our operating expenses or repay our debt or the interest, liquidated damages or other payments that may become due with respect to our debt.

*We need to raise additional funds immediately and expect that we will need to continue to raise funds in the future, and funds may not be available on acceptable terms, or at all.*

We have substantial operating expenses associated with the development of our product candidates and as of March 31, 2008 we had cash and cash equivalents, securities available-for-sale and interest receivable of approximately \$15.3 million, and total current liabilities of approximately \$47.9 million. We also have a substantial amount of debt outstanding: as of March 31, 2008, we had an aggregate principal balance of approximately \$152.4 million in convertible notes, which does not take into account an additional \$45 million in aggregate principal balance of convertible notes and Series E preferred stock which was subsequently exchanged for convertible notes, both issued in April 2008 as disclosed in a Form 8-K, \$23 million in aggregate principal balance of convertible notes issued in June 2008 as disclosed in a Form 8-K, and the repayment at maturity of approximately \$10.7 million in aggregate principal balance of convertible notes in June 2008. Furthermore, as a result of our preferred stock financings in 2007, we may be obligated to redeem such preferred stock starting in February 2009. We expect that our existing cash and cash equivalents, securities available-for-sale and interest receivable, including proceeds received from our offerings through June 30, 2008, will not provide sufficient working capital to fund our presently anticipated operations for the next 12 months or even through the third quarter of 2008, and we will therefore need to raise additional capital.

We may seek to raise such capital through public or private equity financings, partnerships, joint ventures, dispositions of assets, debt financings or restructurings, bank borrowings or other sources. However, additional funding may not be available on favorable terms or at all. If adequate funds are not otherwise available, we will further curtail operations significantly, including the delay, modification or cancellation of operations and plans related to OPAXIO, pixantrone, brostallicin, expanded uses of Zevalin and other products we may be developing. 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. In addition, some financing alternatives may require us to meet additional regulatory requirements in Italy and the U.S., which may increase our costs and adversely affect our ability to obtain financing. To the extent that additional capital is raised through the sale of equity, or securities convertible into equity, shareholders may experience dilution of their proportionate ownership of us.

*We have received a going concern opinion on our consolidated financial statements*

Due to our need to raise additional financing to fund our operations and satisfy obligations as they become due, our independent registered public accounting firm has included an explanatory paragraph in their report on our December 31, 2007 consolidated financial statements regarding their substantial doubt as to our ability to continue as a going concern. This may have a negative impact on the trading price of our

common stock and we may have a more difficult time obtaining necessary financing.

## Table of Contents

*We are required to comply with the regulatory structure of Italy because our stock is traded on the MTA, which could result in administrative challenges.*

Our stock is traded on the MTA stock market in Milan, Italy and we are required to also comply with the rules and regulations of the Commissione Nazionale per le Società e la Borsa, or CONSOB, which is the public authority responsible for regulating the Italian securities market and the Borsa Italiana, which ensures the development of the managed market in Italy. Collectively these agencies regulate companies listed on Italy's public markets. Conducting our operations in a manner that complies with all applicable laws and rules requires us to devote additional time and resources to regulatory compliance matters. For example, the process of seeking to understand and comply with the laws of each country, including tax, labor and regulatory laws, might require us to incur the expense of engaging additional outside counsel, accountants and other professional advisors and might result in delayed business initiatives as we seek to ensure that each new initiative will comply with all applicable regulatory regimes. Compliance with Italian regulatory requirements may delay additional issuances of our common stock; we are currently taking steps to attempt to conform to the requirements of the Italian stock exchange and CONSOB to allow such additional issuances.

In addition, under Italian law, we must publish a listing prospectus that has been approved by CONSOB prior to issuing common stock in any twelve-month period that exceeds 10% of the number of shares of common stock outstanding at the beginning of that period. We have attempted to publish a listing prospectus in Italy to cover our general offerings for the past year. We filed our initial listing prospectus with CONSOB in April 2007 and worked with CONSOB to meet their requirements to publish that listing prospectus for the remainder of 2007. We were finally able to publish a listing prospectus in January 2008, however, that listing prospectus was limited to shares to be issued to Société Générale under the Step-Up Equity Financing Agreement we entered into with Société Générale in 2006. We continue to pursue the possibility of publishing a listing prospectus to cover other financing efforts under Italian law, however, at the present time we have not been successful in getting approval from the Italian regulators for such a listing prospectus. As a result, we are required to raise money using alternative forms of securities; for example, we use convertible preferred stock and convertible debt in lieu of common stock as convertible preferred stock and convertible debt are not subject to the 10% limitation imposed by Italian law.

*We are subject to additional legal duties, additional operational challenges and additional political and economic risks related to our operations in Italy.*

A portion of our business is based in Italy. We are subject to duties and risks arising from doing business in Italy, such as:

Italian employment law, including collective bargaining agreements negotiated at the national level and over which we have no control;

European data protection regulations, under which we will be unable to send private personal data, including many employment records and some clinical trial data, from our Italian offices to our U.S. offices until our U.S. offices self-certify their adherence to the safe harbor framework established by the U. S. Department of Commerce in consultation with the European Commission;

tariffs, customs, duties and other trade barriers; and

capital controls, terrorism and other political risks.

We are also subject to the following operational challenges, among others, as a result of having a portion of our business and operations based in Italy:

effectively pursuing the clinical development and regulatory approvals of all product candidates;

successfully commercializing products under development;



## Edgar Filing: CELL THERAPEUTICS INC - Form S-3

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

coalescing the Italian business culture with our own and maintaining employee morale; and

## Table of Contents

maintaining appropriate uniform standards, controls, procedures and policies relating to financial reporting and employment related matters, and the conduct of development activities that comply with both U.S. and Italian laws and regulations.

We may not succeed in addressing these challenges, risks and duties, any of which may be exacerbated by the geographic separation of our operations in the United States and in Italy. These risks related to doing business in Italy could harm the results of our operations.

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

As a result of operations in Italy, we are exposed to risks associated with foreign currency transactions insofar as we 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, we are exposed to risks associated with the translation of euro-denominated financial results and accounts into U.S. dollars. Our reporting currency will remain as the U.S. dollar; however, a portion of our consolidated financial obligations will arise in euros. In addition, the carrying value of some of our assets and liabilities will be affected by fluctuations in the value of the U.S. dollar as compared to the euro. Changes in the value of the U.S. dollar as compared to the euro might have an adverse effect on our reported results of operations and financial condition.

*In 2006, we identified material weaknesses in our internal control over financial reporting and we received an adverse opinion on internal control over financial reporting from our independent registered public accounting firm in connection with their annual internal control attestation process for fiscal year 2006.*

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. We identified that as of December 31, 2006 we had material weaknesses in our European branch relative to the effectiveness of our internal control over financial reporting which were remedied during 2007.

The existence of a material weakness is an indication that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. If we fail to maintain an effective system of internal controls, we may not be able to report our financial results accurately, which may deprive management of important financial information needed to manage the Company effectively, may cause investors to lose confidence in our reported financial information and may have an adverse effect on the trading price of our common stock.

*If we are not able to successfully integrate recent and future acquisitions, our management's attention could be diverted, and efforts to integrate future acquisitions could consume significant resources.*

The acquisitions of SM and of Zevalin, or any other future acquisition that we may undertake, involve numerous risks related to the integration of the acquired asset or entity into the Company after the acquisition is completed. These risks include the following:

difficulties in integrating the operations, technologies, and products of the acquired companies;

difficulties in implementing internal controls over financial reporting;

diversion of management's attention from normal daily operations of the business;

inability to maintain the key business relationships and the reputations of acquired businesses;

entry into markets in which we have limited or no prior experience and in which competitors have stronger market positions;

dependence on unfamiliar affiliates and partners;

reduction in the development or commercialization of existing products due to increased focus on the development or commercialization of the acquired products;

responsibility for the liabilities of acquired businesses;

---

**Table of Contents**

inability to maintain our internal standards, controls, procedures and policies at the acquired companies or businesses; and

potential loss of key employees of the acquired companies.

In addition, if we finance or otherwise complete acquisitions by issuing equity or convertible debt securities, our existing shareholders may be diluted.

*If we are unable to expand label usage of Zevalin, or maintain or obtain improved reimbursement rates, we may not recognize the full value of the asset and there may be adverse effects on our expected financial and operating results.*

We intend to seek expansion of the approved uses, or labeled uses, of Zevalin in the United States. However, we may be unable to obtain approval for such label expansion in full or in part. If we are not able to obtain approval for expansion of the labeled uses for Zevalin, or if we are otherwise unable to fulfill our marketing, sales and distribution plans for Zevalin, we may not recognize the full anticipated value of Zevalin. If we do not expand the approved uses of Zevalin, we may have insufficient net revenues to finance our current levels of debt and operations unless we are able to market and sell other products. We recently entered into an agreement with Bayer Schering for access to data from their first line indolent trial, or FIT trial, and we are currently evaluating whether or not that data can be used to support a supplemental biologics license application, or sBLA, for additional approved uses of Zevalin. However, there can be no guarantee that such data will be adequate or suitable for submission to the FDA in support of a n sBLA for additional approved uses of Zevalin, or that the FDA will approve such an sBLA if it is submitted.

In 2007, the Centers for Medicare and Medicaid Services, or CMS, implemented new outpatient reimbursement rates to be put in place in 2008 for radiopharmaceuticals, including Zevalin. These new rates are below the acquisition costs of Zevalin. Although Congress passed legislation in late 2007 to delay the implementation of those new rates and stabilize reimbursement rates for the first six months of 2008 with the intention of giving drug manufacturers and CMS more time to reach an agreement that more adequately reflects hospitals' costs associated with the therapy, there can be no guarantee that CMS will agree to a rate or methodology that provides an acceptable reimbursement on radiopharmaceuticals such as Zevalin. In the event that CMS does not agree to a reimbursement rate that is adequate to cover the acquisition costs of Zevalin, we may face immediate and significant difficulty in getting care providers to use Zevalin, which would have an adverse impact on our expected financial and operating results.

*We may face difficulties in achieving broader market acceptance of Zevalin if we do not invest significantly in our sales and marketing infrastructure.*

We currently market Zevalin using a direct sales force that we recently hired in connection with our acquisition of Zevalin from Biogen. U.S. sales of Zevalin by its prior owner either declined or remained flat over the past several years and we expect such sales to remain flat in 2008. We believe that our sales and marketing strategy, in conjunction with our efforts to obtain approval by the FDA for expanded uses of Zevalin, will increase sales of and revenue from Zevalin over the next few years. Our sales and marketing strategy intends to take advantage of the recent lowering of barriers to adoption, including greater economic incentives and practice efficiencies for Zevalin compared to rituximab, the recent adoption of positron emission tomography in community oncology practices, which facilitates use of Zevalin, and implementation of a Zevalin community access program, which targets facilitation of on-site ordering, receipt, and administration of Zevalin by the 100 largest community oncology group practices. However, implementation of the sales and marketing strategy will require an investment of resources and may not increase Zevalin revenues according to our forecasts. In addition, creation and expansion of an effective sales force may take time, and competition for sales and marketing personnel in our industry is intense. Therefore, we will need to effectively manage and expand our sales force, hire individuals with additional technical expertise, expand our distribution capacity or otherwise grow our sales and marketing infrastructure in order to achieve broader market acceptance and additional sales revenue from Zevalin. In addition to the factors just listed, if we do not effectively manage our sales force, our financial condition and operating results may suffer.

*We may not realize any royalties, milestone payments or other benefits under the License and Co-Development agreement entered into with Novartis Pharmaceutical Company Ltd.*

We have entered into a License and Co-Development agreement related to OPAXIO and pixantrone with Novartis International Pharmaceutical Ltd., or Novartis, pursuant to which Novartis received an exclusive worldwide license for the development and commercialization of OPAXIO and an option to enter into an exclusive worldwide license to develop and commercialize pixantrone. We will not receive any royalty or milestone payments under this agreement unless Novartis elects to participate in the development and commercialization of OPAXIO or if Novartis exercises its option related to pixantrone and we are able to reach a definitive agreement. Novartis is under no obligation to make such election or exercise such right



## Table of Contents

and may never do so. In addition, even if Novartis exercises such rights, any royalties and milestone payments we may be eligible to receive from Novartis are subject to the receipt of the necessary regulatory approvals and the attainment of certain sales levels. We may never receive the necessary regulatory approvals and our products may not reach the necessary sales levels.

*We may be delayed, limited or precluded from obtaining regulatory approval of OPAXIO given that our three STELLAR phase III clinical trials for the treatment of non-small cell lung cancer did not meet their primary endpoints.*

There are no guarantees that we will obtain regulatory approval to manufacture, market, or expand the marketing of any of our drug candidates. Obtaining regulatory approval to market drugs to treat cancer is expensive, difficult and risky. Preclinical and clinical data can be interpreted in different ways, which could delay, limit or preclude regulatory approval. Negative or inconclusive results or adverse medical events during a clinical trial could delay, limit or prevent regulatory approval.

Our future financial success depends in large part on obtaining regulatory approval of OPAXIO. In March 2005, we announced the results of STELLAR 3, and in May 2005, we announced the results of STELLAR 2 and 4, our phase III clinical trials of OPAXIO in non-small cell lung cancer. All three trials failed to achieve their primary endpoints of superior overall survival compared to current marketed agents for treating NSCLC.

In December 2006, we closed the PIONEER clinical trial and in 2007, we initiated a new study in the United States, PGT307, which focuses on the primary efficacy endpoint of survival in women with NSCLC and pre-menopausal estrogen levels. We have decided not to initiate an additional study, the PGT306 trial, for which we have submitted a special protocol assessment, or SPA, to conserve limited financial resources. We also feel that compelling evidence from one trial, the PGT307 trial, along with supporting evidence from earlier clinical trials, may be adequate to submit an NDA for OPAXIO even though the FDA has established a requirement that two adequate and well-controlled pivotal studies demonstrating a statistically significant improvement in overall survival will be required for approval of OPAXIO in the NSCLC setting. We may not receive compelling evidence or any positive results from the PGT307 trial, which would preclude our planned submission of an NDA to the FDA, and would preclude us from marketing OPAXIO in the United States.

Based on discussions with the EMEA Scientific Advice Working Party, we submitted an MAA for OPAXIO in Europe on March 4, 2008 based on results of the STELLAR trials. The MAA was accepted for review by the EMEA in April 2008, however a successful regulatory outcome from the EMEA is not assured as the EMEA's final opinion cannot be predicted until they have had the opportunity to complete a thorough review of the clinical data that will be presented in the MAA.

*We are subject to extensive government regulation.*

We are subject to rigorous and extensive regulation by the FDA in the United States and by comparable agencies in other states and countries. Failure to comply with regulatory requirements could result in various adverse consequences, including possible delay in approval or refusal to approve a product, withdrawal of approved products from the market, product seizures, injunctions, regulatory restrictions on our business and sales activities, monetary penalties, or criminal prosecution.

Our products may not be marketed in the United States until they have been approved by the FDA and may not be marketed in other countries until they have received approval from the appropriate agencies. With the exception of Zevalin, none of our current products have received approval. Obtaining regulatory approval requires substantial time, effort and financial resources, and we may not be able to obtain approval of any of our products on a timely basis, or at all. If our products are not approved quickly enough to provide net revenues to defray our debt and operating expenses, our business and financial condition will be adversely affected.

Our marketed products, such as Zevalin, are and will be subject to extensive regulations regarding their promotion and commercialization. For instance, 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. Because our sales force is relatively new, we may have a greater risk of such violations from lack of adequate training or experience. The expense to retain and pay legal counsel and consultants to defend against any such proceedings would be substantial, and together with the diversion of management's time and attention to assist in any such defense, may negatively affect our financial condition and results of operations.



**Table of Contents**

In addition, both before and after approval, our contract manufacturers and our products are subject to numerous regulatory requirements covering, among other things, testing, manufacturing, quality control, labeling, advertising, promotion, distribution and export. Manufacturing processes must conform to current Good Manufacturing Practice, or 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. Failure to comply with FDA, EMEA or other applicable regulations may cause us to curtail or stop the manufacture of such products until we obtain regulatory compliance.

The marketing and promotion of pharmaceuticals is also heavily regulated, particularly with regard to prohibitions on the promotion of products for off-label uses. In April 2007, we paid a civil penalty of \$10.5 million and entered into a settlement agreement with the United States Attorney's Office, or USAO, for the Western District of Washington arising out of their investigation into certain of our prior marketing practices relating to TRISENOX, which was divested to Cephalon Inc. in July 2005. As part of that settlement agreement, and in connection with the acquisition of Zevalin, a commercially approved drug, we also entered into a corporate integrity agreement with the HHS-OIG that requires us to establish a compliance committee and compliance program and adopt a formal code of conduct. The USAO settlement does not address separate claims brought against the Company by the private party plaintiff in this matter, which generally relate to attorney's fees and employment related claims. In 2007, the United States District Court dismissed the private party plaintiff's employment claims as barred by applicable statutes of limitation, and the private party plaintiff has advised us that he intends to seek a court order awarding approximately \$1 million in attorney's fees.

*We rely on third parties for the manufacture and supply of Zevalin and for the manufacture and supply of radioactive isotopes used in the administration of Zevalin.*

We currently rely on Biogen to manufacture and supply Zevalin to us through a long-term manufacturing agreement, and Biogen may, in turn, rely on other third-party manufacturers to fill its requirements for manufacturing Zevalin. If Biogen or any third party contract manufacturing organization, or CMO, or contract service provider, or CSP, upon which it relies does not produce or test and release Zevalin in sufficient quantities and on a timely and cost-effective basis, or if Biogen or any third party CMO or CSP does not obtain and maintain all required manufacturing approvals, our business could be harmed. In addition, we rely on MDS (Canada) for the manufacture and supply of Yttrium-90, a radioactive isotope used in the administration of Zevalin therapy. MDS (Canada) is currently our sole source of Yttrium-90, which must be manufactured and shipped in such a way as to ensure the appropriate potency of the isotope based on its radioactive half-life at the time of administration to the patient is valid. If MDS (Canada) were to have problems with the manufacture or supply of Yttrium-90, our business could be materially impacted, and we may not be able to find an additional supplier of the isotope on acceptable terms or at all. We also rely on Malinckrodt and GE for the manufacture and supply of Indium-111, a radioactive isotope used in the administration of Zevalin diagnostic for clinical purposes. Malinckrodt and GE are currently our two qualified sources of Indium-111, which must be manufactured and shipped in such a way as to ensure the appropriate potency of the isotope based on its radioactive half-life at the time of administration of the diagnostic dose to the patient. If both companies were to have problems with the manufacture or supply of Indium-111, our business could be materially impacted, and we may not be able to find an additional supplier of the isotope on acceptable terms or at all.

*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 market 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 the market. 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:

Zevalin currently competes with Bexxar<sup>®</sup>, which is marketed by GlaxoSmithKline, and any rituximab-containing chemotherapy regimen. Rituximab is marketed in the U.S. by Genentech and Biogen Idec. In addition, other companies such as Cephalon, Eli Lilly, Genta, Genmab, Favrilite, and Genitope are developing products which could compete with Zevalin.

If we are successful in bringing OPAXIO to market, we will face direct competition from oncology-focused multinational corporations. OPAXIO will compete with other taxanes. Many oncology-focused multinational corporations currently market or are developing taxanes, epothilones, and other cytotoxic agents, which inhibit cancer cells by a mechanism similar to taxanes, or similar products including, among others, Bristol-Myers Squibb Co. and others, which markets paclitaxel and generic forms of paclitaxel; Aventis, which markets docetaxel; Genentech and OSI Pharmaceuticals, which markets Tarceva; Genentech, which markets Avastin; Eli Lilly, which markets Alimta<sup>®</sup>, and American Pharmaceutical Partners, which markets Abraxane. In addition, other companies such as



Edgar Filing: CELL THERAPEUTICS INC - Form S-3

NeoPharm Inc. and Telik, Inc. are also developing products which could compete with OPAXIO.

---

**Table of Contents**

Because pixantrone is intended to provide less toxic treatment to patients who have failed standard chemotherapy treatment, if pixantrone is brought to market, it is not expected to compete directly with many existing chemotherapies. However, pixantrone will face competition from currently marketed anthracyclines, such as mitoxantrone (Novantrone<sup>®</sup>), and new anti-cancer drugs with reduced toxicity that may be developed and marketed.

If we are successful in bringing brostallicin to market, we will face direct competition from other minor groove binding agents including Yondelis<sup>®</sup>, which is currently developed by PharmaMar and has received Authorization of Commercialization from the European Commission for soft tissue sarcoma.

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, less expensive, have fewer side effects or 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.

*Uncertainty regarding third-party reimbursement and healthcare cost containment initiatives may limit our returns.*

The ongoing efforts of governmental and third-party payors to contain or reduce the cost of healthcare may affect our ability to commercialize our products successfully. Governmental and other third-party payors continue to attempt to contain healthcare 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 healthcare in the United States, the growth of organizations such as health maintenance organizations, and legislative proposals to reform healthcare and government insurance programs could significantly influence the purchase of healthcare services and products, resulting in lower prices and reducing demand for our products. In addition, in almost all European markets, pricing and choice of prescription pharmaceuticals are subject to governmental control. Therefore, the price of our products and their reimbursement in Europe will be determined by national regulatory authorities.

Even if we succeed in bringing any of our proposed products to the market, they may not be considered cost-effective and third-party reimbursement might not be available or sufficient. If adequate third-party coverage is not available, we may not be able to maintain price levels sufficient to realize an appropriate return on our investment in research and product development. As discussed above, CMS proposed new rates for 2008 for Zevalin that, if implemented, would result in reimbursement rates below our acquisition cost of Zevalin. 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.

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

## Edgar Filing: CELL THERAPEUTICS INC - Form S-3

Since our inception in 1991, we have dedicated substantially all of our resources to the research and development of our technologies and related compounds. All of our compounds, with the exception of Zevalin, currently are in research or development, and have not received marketing approval.

Prior to commercialization, each product candidate requires significant research, development and preclinical testing and extensive clinical investigation before submission of any regulatory application for marketing approval. The development of

## Table of Contents

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 preclinical testing or clinical trials,

fail to receive necessary regulatory approvals,

be difficult to manufacture on a scale necessary for commercialization,

be uneconomical to produce,

fail to achieve market acceptance, or

be precluded from commercialization by proprietary rights of third parties.

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

*The intellectual property and assets related to Zevalin are subject to a security agreement with Biogen; if we were to default on certain payments or reimbursement owed to Biogen or certain third parties, those assets would be subject to foreclosure by Biogen and we could lose our ability to continue development, sales and marketing activities with respect to Zevalin.*

On December 21, 2007, in connection with our purchase of Zevalin, we entered into a Security Agreement with Biogen granting a first priority security interest to Biogen in all of our right, title and interest (a) in and to the assets related to Zevalin that we purchased from Biogen, together with any other assets or rights related to any of such assets or otherwise used in the development, manufacture or commercialization of Zevalin, and (b) under certain license, sublicense and supply agreements entered into in connection with our purchase of Zevalin. In the event we were to default on certain of our obligations under the Security Agreement, the Asset Purchase Agreement pursuant to which we continue to owe royalties and milestone payments to Biogen, or the related sublicense and service agreements, or in the event we were to make an application for, or consent to, the appointment of a receiver, trustee or liquidator of all or a substantial portion of our assets, transfer our assets as part of a general assignment or other arrangement for the benefit of creditors, become insolvent, file a voluntary or involuntary petition under the provisions of the United States Bankruptcy Code, or in the event of an attachment or execution upon, or seizure of, all or substantially all of our assets, Biogen may take any action with respect to the collateral under the Security Agreement that it deems necessary or advisable to accomplish the purposes of the Security Agreement. The Security Agreement will remain in effect until all obligations secured by that agreement have been satisfied. If Biogen were to foreclose on the collateral under this Security Agreement, it would have a material adverse impact on our business.

*If any of our license agreements for intellectual property underlying Zevalin, OPAXIO, pixantrone, brostallicin, 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 relating to intellectual property for pixantrone, brostallicin and Zevalin. We have also in-licensed the intellectual property for our drug delivery technology relating to OPAXIO that uses polymers that are linked to drugs, known as polymer-drug conjugates. 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 adequately protect our intellectual property, our competitive position could be harmed.*

## Edgar Filing: CELL THERAPEUTICS INC - Form S-3

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

---

**Table of Contents**

prevent others from infringing on our proprietary rights.

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

The patent position of biopharmaceutical firms generally is highly uncertain and involves complex legal and factual questions. The U.S. Patent and Trademark Office has not established a consistent policy regarding the breadth of claims that it will allow in biotechnology patents. If it allows broad claims, the number and cost of patent interference proceedings in the United States and the risk of infringement litigation may increase. If it allows narrow claims, the risk of infringement may decrease, but the value of our rights under our patents, licenses and patent applications may also decrease. Patent applications in which we have rights may never issue as patents and the claims of any issued patents may not afford meaningful protection for our technologies or products. 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 a patent position or to determine the scope and validity of third-party proprietary rights, and we may not have the required resources to pursue any such litigation or to protect our patent rights. Any adverse outcome in litigation with respect to the infringement or validity of any patents owned by third parties could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using a product or technology.

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

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

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

*We may be unable to obtain a quorum for meetings of our shareholders and therefore be unable to take certain corporate actions.*

Our articles require that a quorum, consisting of one-third of the outstanding shares of voting stock, be represented in person or by proxy in order to transact business at a meeting of our shareholders. A substantial number of our common shares are held by Italian institutions and under Italian laws and regulations, it is difficult to communicate with the beneficial holders of those shares to obtain votes. In 2006, when a quorum required a majority of the outstanding shares of our voting stock be represented in person or by proxy, we scheduled two annual meetings of shareholders but were unable to obtain quorum at either meeting. Following that failure to obtain quorum, we contacted certain depository banks in Italy where significant numbers of shares of our common stock were held and asked them to cooperate by making a book entry transfer of their share positions at Monte Titoli to their U.S. correspondent bank, who would then transfer the shares to an account of the Italian bank at a U.S. broker-dealer that is an affiliate of that bank. Certain of the banks contacted agreed to make the share transfer pursuant to these arrangements as of the record date of the meeting, subject to the relevant beneficial owner taking no action to direct the voting of such shares. Under Rule 452 of the New York Stock Exchange, the U.S. broker-dealer may vote shares absent direction from the beneficial owner on certain matters, such as the uncontested election of directors, an amendment to the Company's articles of incorporation to increase authorized shares that are to be used for general corporate purposes, and the ratification of our auditors. As a result of this custody transfer, we were able to hold special meetings of the shareholders in April 2007 and January 2008 and annual meetings of the shareholders in September 2007 and June 2008. At the meeting in June 2008, our shareholders approved a proposal to reduce our quorum

## Table of Contents

requirement from a majority of outstanding voting shares to one-third of outstanding voting shares. However, obtaining a quorum at future meetings even at the lower threshold will depend in part upon the willingness of the Italian depository banks to continue participating in the custody transfer arrangements, and we cannot be assured that those banks that have participated in the past will continue to participate in custody transfer arrangements in the future. We are continuing to explore other alternatives to achieve quorum for our meetings, however, we cannot be certain that we will find an alternate method if we are unable to continue to use the custody transfer arrangements. As a result, we may be unable to obtain quorum at future annual or special meetings of shareholders. If we are unable to obtain a quorum at our shareholder meetings and thus fail to get shareholder approval of corporate actions, such failure could have a materially adverse effect on the Company. In addition, brokers may only vote on those matters for which broker discretionary voting is allowed under Rule 452, and we may not be able to obtain the required number of votes to approve certain proposals that require a majority of all outstanding shares to approve the proposal due to our reliance on broker discretionary voting. Therefore it is possible that even if we are able to obtain a quorum for our meetings of the shareholders we still may not receive enough votes to approve proxy proposals presented at such meeting and, depending on the proposal in question, such failure could have a materially adverse effect on the Company.

*We could fail in financing efforts or be delisted from Nasdaq if we fail to receive shareholder approval when needed.*

We are required under the Nasdaq Marketplace Rules to obtain shareholder approval for any issuance of additional equity securities that would comprise more than 20% of our total shares of common stock outstanding before the issuance of the securities at a discount to the greater of book or market value in an offering that is not deemed to be a public offering by Nasdaq. Funding of our operations in the future may require issuance of additional equity securities that would comprise more than 20% of our total shares of common stock outstanding, but we might not be successful in obtaining the required shareholder approval for such an issuance, particularly in light of the difficulties we have experienced in obtaining a quorum and holding shareholder meetings as outlined above.

*We may be unable to obtain the raw materials necessary to produce our OPAXIO 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 OPAXIO, including paclitaxel, in adequate volume and quality. Paclitaxel is derived from certain varieties of yew trees and the supply of paclitaxel is controlled by a limited number of companies. Paclitaxel is available and we have purchased it from several sources. We purchase the raw materials paclitaxel and 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, should a supplier fail to deliver in a timely fashion or at all, or should these relationships terminate, we may not be able to obtain a sufficient supply from alternate sources on acceptable terms, or at all.

*Our dependence on third-party manufacturers means that we do not always have direct control over the manufacture, testing or distribution of our products.*

We do not currently have internal analytical laboratory or manufacturing facilities to allow the testing or production and distribution of drug products in compliance with cGMPs. Because we do not directly control our suppliers, these vendors may not be able to provide us with finished product when we need it.

We will be dependent upon these third parties to supply us in a timely manner with products manufactured in compliance with cGMPs or similar manufacturing standards imposed by US and/or foreign regulatory authorities where our products will be tested and/or marketed. While the FDA and other regulatory authorities maintain oversight for cGMP compliance of drug manufacturers, contract manufacturers may at times violate cGMPs. The FDA and other regulatory authorities may take action against a contract manufacturer who violates cGMPs. One of our products under development, OPAXIO, 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. The active pharmaceutical ingredients and finished products for pixantrone and brostallicin are both manufactured by a single vendor. The drug substance for Zevalin is produced under contract by Biogen and the drug product and finished product is manufactured and distributed at a contract manufacturer and contract distribution facility.

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

We divested our commercial product, TRISENOX, in July 2005 and only acquired a new commercial product, Zevalin, in December 2007. Our ability to generate significant revenues from Zevalin is dependent in part on our ability to find new markets for the product, including through gaining wider acceptance and use of the drug by physicians and through FDA





---

**Table of Contents**

approval of expanded uses for the product. There is no guarantee that we will be successful in accomplishing either of these goals. OPAXIO, pixantrone, brostallicin and label expansions for Zevalin are currently in clinical trials and may not be successful. For example, our STELLAR phase III clinical trials for OPAXIO for the treatment of non-small cell lung cancer failed to meet their primary endpoints. 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. We will need to commit significant time and resources to develop this 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.

*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 Zevalin, OPAXIO, pixantrone, and brostallicin.

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

Before regulatory approval for any potential product can be obtained, we must undertake extensive clinical testing on humans to demonstrate the safety and efficacy of the product. Although for planning purposes we forecast the commencement and completion of clinical trials, the actual timing of these events can vary dramatically due to a number of factors. On March 4, 2008, we submitted an MAA to the EMEA for OPAXIO. In April 2008, the EMEA accepted the MAA for review, however, we do not expect a regulatory decision on an MAA prior to the second half of 2009. Analysis of the data from our EXTEND trial is expected in the second half of 2008 and, if final study results are adequate, we could submit an NDA with the FDA in early 2009 with potential approval in the second half of 2009.

We may not obtain authorization to permit product candidates that are already in the preclinical development phase to enter the human clinical testing phase. Authorized preclinical 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 preclinical 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 clinical trial results. In addition, we or regulatory authorities may suspend clinical trials at any time on the basis that the participants are being exposed to unacceptable health risks or for other reasons. Completion of clinical trials depends on, among other things, the number of patients available for enrollment in a particular trial, which is a function of many factors, including the number of patients with the relevant conditions, the nature of the clinical testing, the proximity of patients to clinical testing centers, the eligibility criteria for tests as well as competition with other clinical testing programs involving the same patient profile but different treatments.

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

standards.

## **Table of Contents**

If we fail to commence or complete, need to perform more or larger clinical trials than planned or experience delays in any of our present or planned clinical trials, our development costs may increase and/or our ability to commercialize our product candidates may be adversely affected. If delays or costs are significant, our financial results and our ability to commercialize our product candidates may be adversely affected.

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

We have entered into collaborative arrangements with third-parties to develop and/or commercialize product candidates and are currently seeking additional collaborations. For example, we entered into an agreement with the Gynecologic Oncology Group to perform a phase III trial of OPAXIO in patients with ovarian cancer. 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. For example, in 2005 we sold our product TRISENOX to Cephalon and, pursuant to the terms of the purchase agreement under which TRISENOX was sold, we are entitled to receive milestone payments upon the approval by the FDA of new labeled uses for TRISENOX, however, Cephalon may decide not to submit any additional information to the FDA to apply for label expansion of TRISENOX, in which case we would not receive a milestone payment under the agreement.

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

collaborative arrangements may not be on terms favorable to us;

disagreements with partners may result in delays in the development and marketing of products, termination of our collaboration agreements or time consuming and expensive legal action;

we cannot control the amount and timing of resources partners devote to product candidates or their prioritization of product candidates and partners may not allocate sufficient funds or resources to the development, promotion or marketing of our products, or may not perform their obligations as expected;

partners may choose to develop, independently or with other companies, alternative products or treatments, including products or treatments which compete with ours;

agreements with partners may expire or be terminated without renewal, or partners may breach collaboration agreements with us;

business combinations or significant changes in a partner's business strategy might adversely affect that partner's willingness or ability to complete its obligations to us; and

the terms and conditions of the relevant agreements may no longer be suitable.

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

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

We base several of our product candidates upon novel technologies that we are using to develop drugs for the treatment of cancer. These technologies have not been proven. Furthermore, preclinical results in animal studies may not predict outcomes in human clinical trials. Our

## Edgar Filing: CELL THERAPEUTICS INC - Form S-3

product candidates may not be proven safe or effective. If these technologies do not work, our drug candidates may not develop into commercial products.

*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, marketing and sale of human pharmaceutical products, and we may not be able to avoid significant product liability exposure. While we have insurance covering marketing and sales of Zevalin as well as product use in our clinical trials for our product candidates, it is possible that we will not be able to maintain such insurance on acceptable terms or that any insurance obtained will not 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 Zevalin or any products we develop. A successful product liability claim in excess of our insurance coverage could exceed our net worth.

## **Table of Contents**

*Adverse events related to our products can negatively impact our product sales and results from operations.*

Our commercial product, Zevalin, has the possibility of causing significant side effects in patients, and deaths associated with an infusion reaction symptom complex, though rare, have occurred within 24 hours of infusions of rituximab, a component of Zevalin. In addition, Yttrium-90 Zevalin administration often results in severe and prolonged cytopenias in most patients, while severe cutaneous and mucocutaneous reactions have also been reported. While side effects are common in oncology drugs, adverse events such as these could negatively impact sales of Zevalin, which in turn could negatively impact our results from operations.

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

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

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

## **Risks Related To the Securities Markets**

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

The market price for securities of biopharmaceutical and biotechnology companies, including ours, historically has been highly volatile, and the market from time to time has experienced significant price and volume fluctuations that are unrelated to the operating performance of such companies. For example, during the twelve month period ended July 1, 2008, our stock price, has ranged from a low of \$0.45 to a high of \$4.97. Fluctuations in the trading price or liquidity of our common stock may adversely affect the value of your investment in our common stock.

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

announcements by us or others of results of preclinical testing and clinical trials and regulatory actions;

announcements of technological innovations or new commercial therapeutic products by us, our collaborative partners or our present or potential competitors;

our issuance of additional debt, equity or other securities, which we need to pursue in 2008 to generate additional funds to cover our current debt and operating expenses;

our quarterly operating results;

Edgar Filing: CELL THERAPEUTICS INC - Form S-3

developments or disputes concerning patent or other proprietary rights;

developments in our relationships with collaborative partners;

acquisitions or divestitures;

---

**Table of Contents**

litigation and government proceedings;

adverse legislation, including changes in governmental regulation;

third-party reimbursement policies;

changes in securities analysts' recommendations;

short selling;

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. For example, in the case of our company, beginning in March 2005, several class action lawsuits were instituted against us and certain of our directors and officers and a derivative action lawsuit was filed against our full board of directors. While these lawsuits were dismissed with prejudice, as a result of these types of lawsuits, we could incur substantial legal fees and our management's attention and resources could be diverted from operating our business as we respond to the litigation. We maintain significant insurance to cover these risks for the Company and our directors and officers, but our insurance is subject to high deductibles to reduce premium expense, and there is no guarantee that the insurance will cover any specific claim that we may face in the future, or that it will be adequate to cover all potential liabilities and damages.

*Our common stock is listed on the Nasdaq Global Market and we may not be able to maintain that listing, which may make it more difficult for investors to sell shares of our common stock.*

Our common stock is listed on the Nasdaq Global Market. The Nasdaq Global Market has several quantitative and qualitative requirements companies must comply with to maintain this listing, including a \$1.00 minimum bid price per share and \$50 million minimum value of listed securities. On April 16, 2008, we received notice from the Nasdaq Stock Market that our common stock had a closing bid price below \$1.00 for at least 30 consecutive business days and therefore we are not in compliance with the listing standards of the Nasdaq Global Market. Under the current Nasdaq Global Market rules, we have a period of 180 days from the date of notice, or until October 13, 2008, to attain compliance by again meeting the \$1.00 minimum bid price for ten consecutive business days. A reverse stock split could, if used, increase our minimum bid price; but it would not increase our total market capitalization. If we are unable to meet that compliance criteria before October 13, 2008, we may have the option to transfer to the Nasdaq Capital Market, assuming we meet all other initial listing qualifications for the Nasdaq Capital Market, where we can receive an additional 180 days to regain compliance. If we are unable to attain compliance with the minimum bid price we may be delisted. In addition, if we fail to maintain the minimum value of listed securities, we may have to transfer to the Nasdaq Capital Market or may be delisted. The level of trading activity of our common stock may decline if it is no longer listed on the Nasdaq Global Market or Nasdaq Capital Market. Furthermore, our failure to maintain a listing on the Nasdaq market may constitute an event of default under certain of our indebtedness which would accelerate the maturity date of such debt. As such, if our common stock ceases to be listed for trading on the Nasdaq Global Market or Nasdaq Capital Market for any reason, it may harm our stock price, increase the volatility of our stock price and make it more difficult to for investors to sell shares of our common stock.

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

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

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

elimination of cumulative voting in the election of directors;

procedures for advance notification of shareholder nominations and proposals;

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



**Table of Contents**

the ability of our board of directors to issue 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.

In addition, as a Washington corporation, we are subject to Washington law which imposes restrictions on some transactions between a corporation and certain significant shareholders. These provisions, alone or together, could have the effect of deterring or delaying changes in incumbent management, proxy contests or changes in control.

---

**Table of Contents**

**USE OF PROCEEDS**

All shares of our common stock offered by this prospectus are being registered for the account of the selling shareholders. We will not receive any of the proceeds from the sale of these shares. However, we would receive \$1.41 per share from exercise of the warrants, if they are exercised for cash.

**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 amended and restated articles of incorporation, our bylaws, as amended, and all applicable provisions of Washington law.*

**General**

We are authorized to issue 400,000,000 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 July 1, 2008, there were 139,754,341 shares of our common stock outstanding. We also had 550 shares of our Series A 3% convertible preferred stock outstanding, 5,218 shares of our Series B 3% convertible preferred stock outstanding, 6,284 shares of our Series C 3% convertible preferred stock outstanding, and 1,000 shares of our Series D 7% convertible preferred stock outstanding. All of our Series E 13.5% preferred stock was exchanged for convertible debt in June 2008 at the election of the holder of such preferred stock pursuant to our amended and restated articles of incorporation.

**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;

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

As of July 1, 2008, 550 shares of our Series A 3% convertible preferred stock were outstanding, 5,218 shares of our Series B 3% convertible preferred stock were outstanding, 6,284 shares of our Series C 3% convertible preferred stock were outstanding, and 1,000 shares of our Series D 7% convertible preferred stock were outstanding.

**Anti-Takeover Effects of Provisions of Washington Law and our Charter and Bylaws**

Washington law contains certain provisions that may have the effect of delaying, deterring or preventing a change in control of the Company. Chapter 23B.11 and 23B.12 of the Washington Business Corporation Act (WBCA) permits a merger, sale of assets or liquidation of the company, subject to certain requirements. In addition, Chapter 23B.12 of the WBCA prohibits the company, with certain exceptions, from engaging in certain significant business transactions with an acquiring person (defined as a 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 benefits 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.

**Table of Contents**

Our board of directors is divided into three approximately equal classes of directors serving staggered three-year terms. In addition, our amended and restated articles of incorporation provide that directors may be removed from office only at a meeting of the shareholders called expressly for that purpose and only for cause. Our amended and 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 amended and restated articles of incorporation or amended and restated bylaws, or a contract with the company. Further, our amended and restated bylaws require a shareholder to provide notice to the company of such shareholder's intention 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 or, in the case of an election to be held at a special meeting of the 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 may have the effect of deterring hostile takeovers or delaying change in control of the management of the company.

**Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Computershare Investor Services, LLC.

**Table of Contents****SELLING SHAREHOLDERS**

All of the shares offered hereby underlie warrants to purchase the shares of Common Stock which are owned by the selling shareholders. All of the warrants were acquired by the selling shareholders in a private placement in March 2008 in connection with the issuance of our 9% Convertible Senior Notes due 2012.

The following table sets forth the names of the selling shareholders, the number of shares of common stock beneficially owned by the selling shareholders immediately prior to the date of this prospectus, and the total number of shares that may be offered pursuant to this prospectus. The table also provides information regarding the beneficial ownership of our common stock by the selling shareholders as adjusted to reflect the assumed sale of all of the shares offered under this prospectus. Percentage of beneficial ownership is based on 139,754,341 shares of our common stock outstanding as of July 1, 2008. The selling shareholders may offer the shares for sale from time to time in whole or in part. Except where otherwise noted, the selling shareholders named in the following table has, to our knowledge, sole voting and investment power with respect to the shares beneficially owned by them.

Selling Stockholder	Number of Shares Beneficially Owned Before Offering (1)	Number of Shares Being Registered	Beneficial Ownership After Offering	
			Shares (2)(3)	Percent (3)
Firebird Global Master Fund, Ltd.	670,705	446,807	223,898	*
Firebird Global Master Fund II, Ltd.	426,077	297,872	128,205	*
Whitebox Hedged High Yield Partners, LP	180,425	180,425		
Whitebox Convertible Arbitrage Partners, LP	1,098,801	838,723	260,078	*
Guggenheim Portfolio Company XXXI, LLC	122,216	93,333	28,883	*
GPC LIX, LLC	61,986	61,986		
Pandora Select Partners, LP	155,319	155,319		
Harvest Offshore Investors LTD	60,475	60,475		
Harvest Capital LP	30,757	30,757		
Harvest Master Enhanced LTD	109,063	109,063		
Wolverine Convertible Arbitrage Funds Trading Limited	3,594,600	1,950,355	1,644,245	1.2%
GPC LX, LLC (4)	326,781	177,305	149,476	*
Context Advantage Master Fund, LP	1,492,585	1,234,043	258,542	*
Rockmore Investment Master Fund Ltd.	207,854	106,383	101,471	*
Any other holder of warrants or future transferee, pledge, donee or successor of any holder		839,422		

\* Less than 1%

(1) Does not include any shares of common stock issuable upon the conversion of our outstanding convertible debt owned by a holder.

**Table of Contents**

- (2) Calculated based on Rule 13d-3(d)(1)(i) of the Exchange Act using 139,754,341 shares of common stock outstanding as of July 1, 2008. We did not assume the issuance of any other shares issuable upon conversion of any outstanding securities convertible into common stock.
- (3) Assumes issuance of all shares covered by this prospectus issuable upon exercise of the selling securityholder's warrants.
- (4) Guggenheim Advisors, LLC is the limited liability company manager of GPC LX, LLC, and Wolverine Asset Management, LLC is the investment manager of GPC LX, LLC. Christopher Gust is the portfolio manager that oversees the investments of the assets of GPC LX, LLC. Each of Guggenheim Advisors, LLC, Wolverine Asset Management, LLC and Mr. Gust disclaim beneficial ownership of the securities registered herein.

IAM Capital Corporation, a limited purpose registered broker/dealer, is an indirect affiliate of GPC LC, LLC. IAM Capital Corporation and GPC LX, LLC are under the common control of The Governor and Company of the Bank of Ireland, through its subsidiaries.

The selling shareholders provided us with information with respect to their share ownership. Because the selling shareholders may sell all, part or none of its shares, we are unable to estimate the number of shares that will be held by the selling shareholders upon resale of shares of common stock being registered hereby. We have, therefore, assumed for the purposes of the registration statement related to this prospectus that the selling shareholders will sell all of their shares. See Plan of Distribution.

**Table of Contents**

**PLAN OF DISTRIBUTION**

The selling shareholders and any of their pledgees, assignees and successors-in-interest may, from time to time, sell any or all of the shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. The selling shareholders may use any one or more of the following methods when selling shares:

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

settlement of short sales;

broker-dealers may agree with the selling stockholder to sell a specified number of such shares at a stipulated price per share;

a combination of any such methods of sale;

through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise; or

any other method permitted pursuant to applicable law.

The selling shareholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling shareholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling shareholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The selling shareholders do not expect these commissions and discounts relating to its sales of shares to exceed what is customary in the types of transactions involved.

In connection with the sale of our common stock or interests therein, the selling shareholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling shareholders may also sell shares of our common stock short and deliver these securities to close out its short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling shareholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

## Edgar Filing: CELL THERAPEUTICS INC - Form S-3

The selling shareholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be underwriters within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. The selling shareholders have informed us that it does not have any agreement or understanding, directly or indirectly, with any person to distribute the common stock.

Because the selling shareholders may be deemed to be underwriters within the meaning of the Securities Act, they will be subject to the prospectus delivery requirements of the Securities Act. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than under this prospectus. The selling shareholders have advised us that they have not entered into any agreements, understandings or arrangements with any underwriter or broker-dealer regarding the sale of the resale shares. There is no underwriter or coordinating broker acting in connection with the proposed sale of the resale shares by the selling shareholders.



**Table of Contents**

The shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Securities Exchange Act of 1934, as amended (the Exchange Act ), any person engaged in the distribution of the resale shares may not simultaneously engage in market making activities with respect to our common stock for a period of two business days prior to the commencement of the distribution. In addition, the selling shareholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of shares of our common stock by the selling shareholders or any other person. We will make copies of this prospectus available to the selling shareholders and have informed the selling shareholders of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale.

We will not receive any proceeds from the sale of the shares by the selling shareholders.

**Table of Contents**

**LEGAL MATTERS**

The validity of the securities offered hereby and certain other legal matters in connection therewith will be passed upon for us by Heller Ehrman LLP, Seattle, Washington.

**EXPERTS**

Stonefield Josephson, Inc., an independent registered public accounting firm, has audited our consolidated financial statements and consolidated financial statement schedule at December 31, 2007, and for each of the three years in the period ended December 31, 2007, included in our Annual Report on Form 10-K for the year ended December 31, 2007, as set forth in its report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Such consolidated financial statements and consolidated financial statement schedule are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

## **Table of Contents**

### **WHERE YOU CAN FIND MORE INFORMATION**

We are subject to the information requirements of the Securities Exchange Act of 1934 (hereinafter the Exchange Act ). In accordance with the Exchange Act, we file reports, proxy statements and other information with the SEC. Such reports, proxy statements and other information filed by us are available free of charge on our web site, <http://www.celltherapeutics.com>, and may be inspected and copied at the public reference facilities maintained by the SEC at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the public reference facilities by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site at <http://www.sec.gov> that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC.

Our common stock is listed on the Nasdaq Global Market and such reports, proxy statements and other information concerning us may be inspected at the offices of The Nasdaq Stock Market, 1735 K Street, N.W., Washington, D.C. 20006.

### **DOCUMENTS INCORPORATED BY REFERENCE**

SEC rules allow us to incorporate by reference into this prospectus the information we file 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 Commission will automatically update and supersede this information. We incorporate by reference the documents listed below:

our Annual Report on Form 10-K for the fiscal year ended December 31, 2007, as amended;

our Quarterly Report on Form 10-Q for the quarter ended March 31, 2008;

our definitive Proxy Statement on Schedule 14A, dated and filed with the SEC on May 23, 2008 for our 2008 Special Meeting in lieu of Annual Meeting of Shareholders;

our Current Reports on Form 8-K, and Amended Current Reports filed on Form 8-K/A, filed on January 3, 2008, January 14, 2008, January 18, 2008, January 29, 2008, February 5, 2008, February 19, 2008, March 5, 2008, March 11, 2008, March 21, 2008, April 4, 2008, April 18, 2008, April 30, 2008, May 2, 2008 June 13, 2008, June 20, 2008 and June 24, 2008; and

The description of our capital stock contained in our Registration Statements on Form 10 filed with the SEC on June 27, 1996 and June 28, 1996, including any amendment or reports filed for the purpose of updating that description.

In addition, we also incorporate by reference into this prospectus additional information that we may subsequently file with the Securities and Exchange Commission under Sections 13(a), 13(c), 14 and 15(d) of the Exchange Act prior to the termination of the offering. These documents include Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, as well as proxy statements.

Notwithstanding the foregoing, unless specifically stated to the contrary, none of the information that we disclose under Items 2.02 or 7.01 of any Current Report on Form 8-K that we may from time to time furnish to the Securities and Exchange Commission will be incorporated by reference into, or otherwise included in, this prospectus.

We are subject to the information and reporting requirements of the Exchange Act, and file periodic reports, proxy statements and we make available to our stockholders annual reports containing audited financial information for each year and quarterly reports for the first three quarters of each fiscal year containing unaudited interim financial information.

We will provide without charge to each person, including any beneficial owner of our common stock, to whom this prospectus is delivered, upon written or oral request, a copy of any and all of the documents that have been incorporated by reference in the prospectus but not delivered with this prospectus (without exhibits, unless the exhibits are specifically incorporated by reference but not delivered with this prospectus). Requests should be directed to:

Edgar Filing: CELL THERAPEUTICS INC - Form S-3

Louis A. Bianco

Executive Vice President, Finance and Administration

Cell Therapeutics, Inc.

501 Elliott Avenue West, Suite 400

Seattle, Washington 98119

(206) 282-7100

**Table of Contents**

**You should rely only on the information contained in this prospectus. We have not authorized any person to provide you with information different from that contained in this prospectus. This prospectus may be used only where it is legal to sell the common stock of Cell Therapeutics, Inc. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the date of delivery of this prospectus or of any sale of the common stock of Cell Therapeutics, Inc.**

**Table of Contents****PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 14. Other Expenses of Issuance and Distribution**

The following table sets forth an estimate of the fees and expenses payable by the registrant in connection with the registration of the securities offered hereby. All of such fees expenses, except for the Registration Fee, are estimated:

Securities and Exchange Commission registration fee	\$ 122
Accounting fees and expenses	5,000
Legal fees and expenses	15,000
Miscellaneous	5,000
Total	\$ 25,122

All expenses in connection with the issuance and distribution of the securities being offered shall be borne by the registrant, other than underwriting discounts and selling commissions, if any.

**Item 15. Indemnification of Directors and Officers**

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.



**Table of Contents**

**Item 16. Exhibits and Financial Statement Schedules**

(a) Exhibits

<b>Exhibit Number</b>	<b>Description</b>
4.1	Registrant's Amended and Restated Articles of Incorporation (1)
4.2	Registrant's Amended and Restated Bylaws. (2)
4.3	Specimen Common Stock Certificate (3)
4.4	Form of Warrant (4)
5.1	Opinion of Heller Ehrman LLP
23.1	Consent of Stonefield Josephson, Inc., Independent Registered Public Accounting Firm
23.2	Consent of Heller Ehrman LLP (included in Exhibit 5.1)
24.1	Power of Attorney (included on signature page of the Registration Statement hereto)

- (1) Incorporated by reference to exhibits to the Registrant's Current Report on Form 8-K filed June 24, 2008.
- (2) Incorporated by reference to appendix H to the Registrant's Registration Statement on Form S-4 (No. 333-106906).
- (3) Incorporated by reference to exhibits to the Registrant's Registration Statement on Form 10, as amended.
- (4) Incorporated by reference to exhibits to the Registrant's Current Report of Form 8-K filed March 5, 2008.

**Item 17. Undertakings**

(a) 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 of 1933;

(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 offering range may be reflected in the form of prospectus filed with the Commission 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 (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement.

2. That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment 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.

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



Edgar Filing: CELL THERAPEUTICS INC - Form S-3

4. That, for the purposes of determining liability under the Securities Act of 1933 to any purchaser:

(i) If the registrant is relying on Rule 430B:

(A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

II-2

**Table of Contents**

(B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

5. That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities: The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) 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.

(c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 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 Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such 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 such 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 of 1933 and will be governed by the final adjudication of such issue.

**Table of Contents****SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant named below 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 this 7th day of July, 2008.

**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 the undersigned officers and directors of Cell Therapeutics, Inc., a Washington corporation, do hereby constitute and appoint James A. Bianco and Louis A. Bianco and each of them individually, the lawful attorneys-in-fact and agents, each with full power of substitution or re-substitution, with full power and authority to do any and all acts and things and to execute any and all instruments which said attorneys-in-fact and agents, or either one of them, determine may be necessary or advisable or required to enable said corporation to comply with the Securities Act of 1933, as amended, and any rules or regulation or requirements of the Securities and Exchange Commission in connection with this Registration Statement. Without limiting the generality of the foregoing power and authority, the powers granted include the power and authority to sign the names of the undersigned officers and directors in the capacities indicated below to this Registration Statement, to any and all amendments, both pre-effective and post-effective, and supplements to this Registration Statement and to any and all instruments or documents filed as part of or in conjunction with this Registration Statement or amendments or supplements thereto, and each of the undersigned hereby ratifies and confirms all that said attorneys-in-fact and agents, or either one of them, shall do or cause to be done by virtue hereof. This Power of Attorney may be signed in several counterparts.

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

**Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed below by the following persons in the capacities and on the dates indicated.**

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<i>/s/ Phillip M. Nudelman</i> <b>Phillip M. Nudelman, Ph.D.</b>	Chairman of the Board	June 30, 2008
<i>/s/ James A. Bianco</i> <b>James A. Bianco, M.D.</b>	President, Chief Executive Officer and Director (Principal Executive Officer)	June 30, 2008
<i>/s/ Louis A. Bianco</i> <b>Louis A. Bianco</b>	Executive Vice President, Finance and Administration (Principal Financial Officer and Principal Accounting Officer)	June 30, 2008
<i>/s/ John H. Bauer</i> <b>John H. Bauer</b>	Director	June 30, 2008
<i>/s/ Vartan Gregorian</i> <b>Vartan Gregorian, Ph.D.</b>	Director	June 25, 2008
<i>/s/ Richard L. Love</i> <b>Richard L. Love</b>	Director	June 30, 2008
<i>/s/ Mary O. Munding</i>	Director	June 24, 2008

Edgar Filing: CELL THERAPEUTICS INC - Form S-3

**Mary O. Munding, Dr. PH**

/s/ Jack W. Singer  
**Jack W. Singer, M.D.**

Director

June 24, 2008

/s/ Frederick W. Telling  
**Frederick W. Telling, Ph.D.**

Director

June 27, 2008

II-4

**Table of Contents**

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
4.1	Registrant s Amended and Restated Articles of Incorporation (1)
4.2	Registrant s Amended and Restated Bylaws. (2)
4.3	Specimen Common Stock Certificate (3)
4.4	Form of Warrant (4)
5.1	Opinion of Heller Ehrman LLP
23.1	Consent of Stonefield Josephson, Inc., Independent Registered Public Accounting Firm
23.2	Consent of Heller Ehrman LLP (included in Exhibit 5.1)
24.1	Power of Attorney (included on signature page of the Registration Statement hereto)

- (1) Incorporated by reference to exhibits to the Registrant s Current Report on Form 8-K filed June 24, 2008.
- (2) Incorporated by reference to appendix H to the Registrant s Registration Statement on Form S-4 (No. 333-106906).
- (3) Incorporated by reference to exhibits to the Registrant s Registration Statement on Form 10, as amended.
- (4) Incorporated by reference to exhibits to the Registrant s Current Report of Form 8-K filed March 5, 2008.