CELL THERAPEUTICS INC
Form S-3/A
August 29, 2008
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As filed with the Securities and Exchange Commission on August 29, 2008

Registration No. 333- 152172

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Amendment No. 1 to

FORM S-3

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

CELL THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Washington	2834	91-1533912
(State of other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

501 Elliott Avenue West, Suite 400

Seattle, Washington 98119

(206) 282-7100

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

James A. Bianco, M.D.

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

Title of Each Class of Shares To Be Registered	Amount to be Registered (1)	Proposed Maximum Offering Price Per Unit (2)	Proposed Maximum Aggregate Offering Price (3)	Amount of Registration Fee (4)
Common Stock, no par value (3)	17,468,354	$0.47	$8,210,126	$526.07

(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 $0.79 per share.

(4) Previously paid.

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.

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The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell 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 AUGUST 29, 2008

PROSPECTUS

Making cancer more treatable ®

17,468,354 Shares of Common Stock Issuable Upon Exercise of Warrants

The selling shareholders identified in this prospectus may from time to time sell up to an aggregate of 17,468,354 shares of our common stock issuable upon exercise of certain warrants. The warrants are exercisable at an exercise price of $0.79 per share. The warrants were originally issued by us in a private placement in April 2008 in connection with the issuance of our 13.5% Convertible Senior Notes due 2014. The selling shareholders may offer and sell their warrants or shares 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 August 28, 2008, the last reported sale price of our common stock on the Nasdaq Global Market was $0.25.

NOTE: We have declared a one-for-ten reverse split of our common stock effective August 31, 2008. All numbers in this prospectus are unadjusted and do not take into account the reverse split.

Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page 6 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 August 29, 2008

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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.

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ABOUT THIS PROSPECTUS

This prospectus relates to the resale of up to 17,468,354 shares of common stock issuable upon exercise of certain warrants. Those warrants were originally issued by us in a private placement in April 2008 in connection with the issuance of our 13.5% Convertible Senior Notes due 2014. 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 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 continuous resale 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 , estima 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 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.

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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. The first meeting with the FDA to discuss the potential for label expansion of Zevalin based on the FIT data is scheduled for September 2008. Under the terms of the agreement with Bayer, we made 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 (paclitaxel poliglumex), 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.

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

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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, discussed below, 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, the GOG212 trial, is under the control of the Gynecologic Oncology Group and is expected to enroll 1,100 patients by early 2012. A potential interim analysis, based on the number of events in the database, is planned for late 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 had 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, 101 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. 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 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. Planned enrollment for this study was completed in August 2008 and data from that trial is expected to be available as early as early 2009. 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.

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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 June 30, 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 our 2008 convertible notes outstanding was paid at the notes maturity on June 15, 2008.

Restructuring of Resources

On January 30, 2008, we announced a plan to refocus our resources on late-stage and marketed products, which involves 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.

Lack of Liquidity

As of June 30, 2008 we had cash and cash equivalents, securities available-for-sale and interest receivable of approximately $12.4 million, and total current liabilities of $50.2 million. Our current cash and cash equivalents, securities available-for-sale and interest receivable continue to be significantly less than our total current liabilities. Currently, we do not have sufficient cash to fund our operations past September and we need to raise additional capital in order to meet our operation needs. We will need to continue to raise additional capital to fund our operations in 2008 and beyond. See Risk Factors.

In addition, our auditors, Stonefield Josephson, have expressed substantial doubt about our ability to continue to operate as a going concern in their audit opinion dated March 26, 2008 in connection with our audited financial statements for the year ended December 31, 2007. If we are not successful in raising substantial additional financing and/or capital, we will have insufficient funds to continue operations past September.

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.

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, at an exercise price of $0.95 per share, and a warrant to purchase up to $67.5 million in additional debt and warrant securities at an exercise price of $1,000 per unit, which we refer to as the B Warrant. Pursuant to the terms of the transaction documents, in June 2008 the investor exchanged all 9,000 shares of Series

E 13.5% preferred stock along with accrued and unpaid dividends into an additional $9.118 million principal amount of our 13.5% senior convertible notes. In July 2008, we entered into an amendment to the purchase agreement and B Warrant, whereby we agreed to repurchase $17,518,000 principal amount of the 13.5% senior convertible notes held by such holder, and the holder agreed to surrender for cancellation the 11,012,658 warrants associated with such repurchased notes. Furthermore, the exercise price of the remaining warrants was reduced from $0.95 to $0.79 per share. (The shares of common stock underlying the remaining 17,468,354 warrants are the shares covered by this prospectus.)

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The 13.5% senior convertible notes bear an annual interest rate of 13.5% and are convertible into our common stock at a conversion price of $0.79. Upon conversion of the notes or upon exercise by the holder of a one-time right to require early redemption of the notes (which may be exercised in May 2011), we shall be required to pay a make-whole amount to the holders of the notes so converted or redeemed equal to $810 per $1,000 principal amount of the converted or redeemed notes less any interest paid on such notes prior to the conversion or redemption date. The maximum potential make-whole amount is equal to the total amount of interest due over the life of the notes. We placed an amount adequate to pay the make-whole payment on the notes in escrow to be held for a period of one year. Pursuant to the terms of the escrow agreement, the funds may be used only to make interest payments or to pay the make-whole amount upon conversion of the notes. At the end of one year, all funds remaining in escrow will be released to us.

The total purchase price paid in April 2008 by the investor for these 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 the escrow account. The remaining proceeds to the Company, before fees and expenses, was $22.9 million.

In May and June 2008, the investor converted an aggregate of $27,600,000 principal amount of the 13.5% senior convertible notes into shares of our common stock.

In June 2008, the B Warrant was amended and the investor then partially exercised the B Warrant; upon such exercise of the B Warrant we issued $23.0 million principal amount of our 15% senior convertible notes due 2011 and warrants to purchase up to 14,556,962 shares of our common stock, at an exercise price of $0.95 per share, in exchange for payment by the investor of $23.0 million. The notes bear an annual interest rate of 15% and are convertible into common stock at a conversion price of $0.79 per share. Upon conversion of the notes we shall be required to pay a make-whole amount to the holders of the notes so converted equal to $450 per $1,000 principal amount of the converted notes less any interest paid on such notes prior to the conversion date. The maximum potential make-whole amount is equal to the total amount of interest due over the life of the notes. We placed an amount adequate to pay the make-whole payment on the notes in escrow to be held for a period of one year. Pursuant to the terms of the escrow agreement, the funds may be used only to pay interest payments or to pay the make-whole amount upon conversion of the notes. At the end of one year, all funds remaining in escrow will be released to us. Of the $23.0 million purchase price, $10.35 million was deposited into the escrow account. The remaining proceeds to the Company, before fees and expenses, was $12.65 million.

In July 2008, the B Warrant was further amended and the investor agreed to exercise 22,250 of the remaining 44,500 units of the B Warrant by July 25, 2008 and to exercise the remaining 22,250 units by August 25, 2008. In connection with each respective exercise, we agreed to repurchase $8.759 million of our 13.5% convertible senior notes due 2014 along with the cancellation of related common stock purchase warrants. Furthermore, subject to certain regulatory filings with the Nasdaq Stock Market, the B Warrant may be further amended to provide for an additional 44,500 units, exercisable upon mutual agreement of us and the investor. Upon the first exercise of the further amended B Warrant, we issued $22.25 million principal amount of our 18.33% senior convertible notes due 2011 and warrants to purchase 14,082,278 shares of our common stock, at an exercise price of $0.79 per share, in exchange for payment by the investor of $22.25 million. The notes will bear an annual interest rate of 18.33% and are convertible into common stock at a conversion price of $0.79 per share. Upon conversion of the notes we shall be required to pay a make-whole amount to the holders of the notes so converted equal to $549.90 per $1,000 principal amount of the converted notes less any interest paid on such notes prior to the conversion date. The maximum potential make-whole amount is equal to the total amount of interest due over the life of the notes. We have placed an amount adequate to pay the make-whole payment on the notes in escrow to be held for a period of one year. Pursuant to the terms of the escrow agreement, the funds may be used only to pay interest payments or to pay the make-whole amount upon conversion of the notes. At the end of one year, all funds remaining in escrow will be released to us. Of the $22.25 million purchase price, $12.24 million was deposited into the escrow account and we repurchased $8.759 million principal amount of the investor s 13.5% convertible senior notes and associated common stock warrants. Of the make-whole payments related to these repurchased notes, $3.26 million was release to us from escrow and the remainder was released to the investor. The remaining proceeds to the Company, before fees and expenses, was $4.51 million.

The August 2008 $22.25 million exercise of the further amended B Warrant was the same, as to amount and all other details and all related transactions, as the above-described July 2008 $22.25 million exercise of the further amended B Warrant.

Also in July 2008, we issued to a single institutional investor a warrant to purchase up to the lesser of $12,000,000 in shares of our common stock or the number of shares of common stock equal to 19.9% of our outstanding common stock on July 29, 2008, in order to effectuate an equity line of credit relationship. We have the right to raise cash under the agreement for shares of our common stock on a periodic basis. The number and price per share of each issuance are determined by a contractual formula based on the trading volume and a discount to the volume weighted average price of our common stock, as reported by the MTA, over the preceding three trading days.

Recent Legal Proceedings

Based on language (the Disputed Language) contained in the Articles of Amendment to our Articles of Incorporation (the Amendments) filed in connection with the issuance of our 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 us and certain holders of our then existing convertible debt on December 12, 2007 (the Exchange). We are 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

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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 we breached a Securities Purchase Agreement, executed on or about April 16, 2007 in connection with the issuance of Series B Preferred Stock. Tang alleges that our 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 us for breach of contract and breach of the covenant of good faith and fair dealing. Enable alleges that on or about March 4, 2008, we committed a further breach of our obligations by offering and/or paying consideration to certain holders of our 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. On May 5, 2008, RHP Master Fund, Ltd. (RHP), a holder of our Series A Preferred Stock filed suit in the United States District Court for the Southern District of New York against us and certain officers and directors alleging breach of contract and violation of Washington Business Corporation Act by us and breach of fiduciary duty by the officer and director defendants. RHP alleges claims similar to those raised in Enable s amended complaint, namely that we breached our obligations to RHP by offering and paying consideration to certain holders of our Series A Preferred Stock to induce those holders to convert their preferred stock into common stock as part of the March 4, 2008 transaction without making the same offer to RHP. Following the filing of a motion to dismiss the complaint by the officer and director defendants, RHP filed an amended complaint on July 31, 2008. The amended complaint asserts the same causes of action as the original. We dispute each of the claims asserted against it and intend to defend ourselves vigorously. At this time, we are not able to make a determination whether the likelihood of an unfavorable outcome is probable or remote.

On January 22, 2007, we filed a complaint in King County Washington Superior Court against The Lash Group, Inc. and Documedics Acquisition Co., Inc., our former third party reimbursement expert for TRISENOX, seeking recovery of damages, including losses incurred by the Company in connection with our USAO investigation, defense and settlement of claims by the government concerning Medicare reimbursement for TRISENOX. On February 28, 2007, defendant The Lash Group, Inc. removed the case to federal court in the Western District of Washington. On June 19, 2008, the trial judge dismissed our claims against The Lash Group. The parties have completed production of documents and fact witness depositions, and served expert reports. On June 19, 2008, the trial court entered judgment dismissing our claims for indemnification against The Lash Group on the legal ground that all False Claims Act (FCA) defendants are legally barred from filing such claims, notwithstanding that there has been no finding that the defendant engaged in any wrongdoing, and notwithstanding that the party sued may have been directly responsible for the conduct at issue in the FCA as a result of its erroneous advice, negligent services, and its own false and misleading statements about reimbursement to the government and physicians. We disagree with the Court s legal conclusion that negligent consultants may not be sued for indemnification pursuant to the express language of their contracts, and on July 19, 2008, we filed a Notice of Appeal with the Ninth Circuit Court of Appeals. We will seek a ruling that no law prohibits a defendant who settles FCA claims with the government from pursuing meritorious claims for contractual indemnification from responsible consultants. If successful, we intend to return to the United States District Court for trial, and seek more than $20 million in damages for liabilities and business losses that we contend were caused by Lash s negligent or reckless advice and its misleading communications concerning Medicare s obligation to reimburse doctors for TRISENOX. There is no guarantee that we will prevail in its appeal or at trial.

In April 2007, we 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® (arsenic trioxide). We made the settlement payment of $10.6 million in April 2007. The settlement agreement did not address separate claims brought against us by the private party plaintiff. The private party plaintiff filed a petition for attorney s fees and costs in the approximate amount of $1.2 million on July 31, 2008. We intend to oppose this petition. There is no guarantee that we will partially or wholly prevail in opposing the petition for fees. At this time, no estimate of loss can be made.

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. Information contained in, or accessible through, our website does not constitute a part of this prospectus.

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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 June 30, 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. We need to raise capital to continue to fund our operations as our current cash resources would not fund us past September. 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 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 June 30, 2008 we had cash and cash equivalents, securities available-for-sale and interest receivable of approximately $12.4 million, and total current liabilities of approximately $50.2 million. We also have a substantial amount of debt outstanding: as of June 30, 2008, we had an aggregate principal balance of approximately $164.7 million in convertible notes, which does not take into account $44.5 million in aggregate principal balance of 18.33% and Series B 18.33% convertible senior notes issued in July/August 2008, conversions of $22.3 million of these notes, and the repurchase of approximately $17.5 million in aggregate principal balance of our outstanding 13.5% convertible senior notes. We have also implemented an ongoing equity line of credit that provides for the sale of up to an aggregate of $12.0 million (or 19.9% of our outstanding common stock on the date the agreement was executed, if sooner) which provides for multiple closings based on the trading volume of our common stock on the MTA and which may be suspended from time to time. As of August 28, 2008, we have received gross proceeds of approximately $4.0 million under that equity line of credit. We expect that our existing cash and cash equivalents, securities available-for-sale and interest receivable, including proceeds received from our offerings through August 28, 2008, will not provide sufficient working capital to fund our presently anticipated operations past September, and we 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.

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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;
- 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
- 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.

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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.

We may not be successful in transferring certain of our operations to a new entity, which may mean that certain expenses incurred in connection with the proposed spin-off would not be reimbursed.

We currently expect to spin out certain of our operations into a new entity to be funded in part by outside investors, and have incurred legal fees and other costs in connection with that spin out. While we expect most of those fees to be repaid upon the funding of the new entity and the completion of the transfer of our related operations, there can be no assurance that the new entity will be funded or that we can complete the transfer of the related operations. If the new entity is not formed and the related operations are not transferred to that new entity, we will be required to pay all expenses we have incurred in connection with the spin out without reimbursement and may be required to continue to support such business operations in full.

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;

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. 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 and subsequently passed legislation in July 2008 to extend that delay an additional 18 months, to January 1, 2010, 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. However, 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 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. Novartis has the right under the agreement in its sole discretion to terminate such agreement at any time on written notice to us.

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.

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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 European Medicines Agency, or EMEA, Scientific Advice Working Party, we submitted a Marketing Authorization Application, or 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 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.

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, however, in July 2008 the private party plaintiff filed a petition seeking approximately $1.2 million in attorneys fees and costs. While we intend to oppose this petition, there can be no guarantee that we will partially or wholly prevail in such opposition to the petition for 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

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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 Mallinckrodt and GE for the manufacture and supply of Indium-111, a radioactive isotope used in the administration of Zevalin diagnostic for clinical purposes. Mallinckrodt 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®, 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, Favrille, and Genitope are developing products which could compete with Zevalin.