

CELL THERAPEUTICS INC
Form 424B5
April 25, 2008
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Filed Pursuant to Rule 424(b)(5)
Registration No. 333-149981

PROSPECTUS

**\$23,250,000 5.75% Senior Convertible Notes and
8,920,205 Shares of Common Stock**

We issued the notes and shares of common stock offered by this prospectus in a private placement in December 2007. This prospectus will be used by selling securityholders to resell their notes, shares and the common stock issuable upon conversion of the notes. We will not receive any proceeds from this offering.

The selling securityholders may offer and sell their 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 securityholders may sell shares through underwriters, broker-dealers or agents, who may receive compensation in the form of discounts, concessions or commissions from the selling securityholders, 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.

Holders may convert the notes into shares of our common stock at any time before their maturity unless we have previously redeemed or repurchased them. The notes will be due on December 15, 2011. The conversion rate is 333.333 shares per each \$1,000 principal amount of notes, subject to adjustment in certain circumstances. This is equivalent to an initial conversion price of \$3.00 per share.

We will pay interest on the notes on June 15 and December 15 of each year. The first interest payment will be made on June 15, 2008. The notes rank *pari passu* in right of payment with all of our existing and future senior indebtedness, including our 6.75% Convertible Senior Notes due 2010, 7.5% Convertible Senior Notes due 2011, 9% Convertible Senior Notes due 2012 and rank senior in right of payment to our currently outstanding 5.75% Convertible Senior Subordinated notes due June 2008, 5.75% Convertible Subordinated Notes due June 2008 and 4% Convertible Senior Subordinated Notes due 2010.

The notes are not listed on any securities exchange or included in any automated quotation system. The notes are eligible for trading on PORTAL, a NASDAQ Institutional Market. Our common stock is quoted on the Nasdaq Global Market and on the MTA in Italy under the symbol CTIC. On April 23, 2008, the last reported sale price of our common stock on the Nasdaq Global Market was \$0.84.

Investing in our common stock involves a high degree of risk. See Risk Factors beginning on page 8 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 April 23, 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 \$23,250,000 in aggregate principal amount of our 5.75% Convertible Senior Notes due 2011 and up to 8,920,205 shares of our common stock by the selling securityholders, which includes the 7,749,992 shares issuable upon conversion of the notes. The notes and 1,170,213 shares not issuable upon conversion of the notes were issued to the selling securityholders in a private placement in December 2007. We will not receive any proceeds from the potential sale of the notes or shares offered by the selling securityholders.

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 securityholders. 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 supplement and accompanying prospectus, you should carefully consider the risk factors contained in and incorporated by reference into this prospectus supplement and accompanying prospectus when evaluating an investment in our notes and common stock into which the notes are convertible. This prospectus supplement and accompanying prospectus and the documents incorporated by reference into this prospectus supplement and accompanying 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.

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In some cases, forward-looking statements can be identified by the use of terminology such as *may*, *will*, *expects*, *plans*, *anticipates*, *estimates*, *potential*, or *continue* or the negative thereof or other comparable terminology. There can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from these projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including, but not limited to, the risk factors set forth 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 do not intend 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, our 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 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 paclitaxel poliglumex, which we have previously referred to as XYOTAX, for the treatment of non-small cell lung cancer, or NSCLC, and ovarian cancer. Based on feedback related to our European marketing application submission, we intend to rebrand XYOTAX and therefore now refer to it by its generic name, paclitaxel poliglumex. As announced in March and May 2005, our STELLAR 2, 3, and 4 phase III clinical studies for paclitaxel poliglumex 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 will be formally reviewed for validation by the end of March. Upon validation, the marketing approval review process begins, which generally takes 15 to 18 months.

We are also developing paclitaxel poliglumex 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 paclitaxel poliglumex when compared to women or men

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receiving standard chemotherapy. A survival advantage for women over men was also demonstrated in a first-line phase II clinical trial of paclitaxel poliglumex 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 paclitaxel poliglumex 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 paclitaxel poliglumex 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 paclitaxel poliglumex 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 paclitaxel poliglumex for first-line maintenance therapy in ovarian cancer are reported.

We are also developing paclitaxel poliglumex 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 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.

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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 Schering, which holds the rights to Zevalin outside of the United States, published the results of their Phase III first-line indolent trial of Zevalin, known as the FIT trial. In March 2008, Bayer Schering received a positive opinion from the European Committee for Medicinal Products for Human Use, or CHMP, recommending Zevalin as consolidation therapy after remission induction in previously untreated patients with follicular lymphoma in Europe. Upon a favorable review by the European Commission, Bayer Schering could receive marketing authorization for this indication of Zevalin later this year. While we do not currently have any rights to use or access the data from the FIT trial, we intend to negotiate with Bayer Schering for access to those results. If we are successful in obtaining access to the FIT trial results and the data is suitable for FDA filing, we plan to submit a supplemental biologics license application, or 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, paclitaxel poliglumex, 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 XYOTAX 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 Form 10-K are the property of their respective owners.

As of December 31, 2007, we had incurred aggregate net losses of approximately \$1.1 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. We recently completed partial restructurings of our 2008 convertible notes in December 2007 and February 2008, which retired a portion of such debt, extended the maturity date on a portion of such debt to 2011 and involved the issuance of additional shares of common stock to holders of the exchanged notes. However, approximately \$10.7 million of such 2008 convertible notes remain outstanding and are due on June 15, 2008. We may consider additional alternatives to satisfy our obligations on the remaining outstanding 2008 convertible notes.

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 XYOTAX and pixantrone described above, while advancing the clinical development of brostallicin. This plan is intended to reduce operating expenses throughout the company by approximately 35% and reduce the company's projected net cash operating expenses to a forecasted \$77 million in 2008. As part of these refocusing efforts, approximately 30 of our U.S. employees were terminated.

As of December 31, 2007 we had cash and cash equivalents, securities available-for-sale and interest receivable of approximately \$18.4 million, and total current liabilities of \$53.5 million. We currently forecast net cash operating expenses of approximately \$77 million in 2008. 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 December 2007, we sold 6,500 shares of our Series D 7% Convertible Preferred Stock and warrants to purchase 1,244,016 shares of our common stock to institutional investors for aggregate gross proceeds of \$6.5 million. In addition, we also sold 3,469,999 shares of common stock and warrants to purchase an additional 3,469,999 shares of common stock at \$2.02 per share in a registered offering in December 2007 to institutional investors for aggregate gross proceeds of approximately \$7.0 million.

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 \$1,272,000 (less \$56,000) in aggregate gross proceeds.

On March 3, 2008 we issued approximately \$51.7 million of our 9% convertible senior notes due 2012 plus warrants to purchase 7,326,950 shares of our common stock at an exercise price of \$1.41 per share. The notes will bear interest at an annual rate of 9% and be convertible into our common stock at an initial rate of approximately 709.22 shares per \$1,000 principal amount of the notes, which is equivalent to an initial

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conversion price of approximately \$1.41. Upon conversion of the notes, we will be required to pay a make-whole amount to the holders of the converted notes equal to \$270 per \$1,000 principal amount of the converted notes less any interest paid on such notes prior to the conversion date, or make-whole payment. An amount adequate to pay the make-whole payments on all outstanding notes will be held in escrow for a period of one year. As of March 19, 2008, \$28.8 million of these notes had been converted.

In connection with this debt issuance, certain existing holders of our series A, B, C, and D convertible preferred stock converted their shares of preferred stock into common stock. These conversions included 6,300, 10,162, 2,000 and 3,000 shares of series A, B, C and D convertible preferred stock, respectively. To induce these conversions, we paid an aggregate cash payment of approximately \$16.2 million.

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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 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. One other holder of Preferred Stock, Enable Capital Management LLC, asserted similar claims in correspondence with the Company in December 2007 and in January 2008 subsequently filed a lawsuit with similar claims to the Tang action. At this time, we are not able to make a determination whether the likelihood of an unfavorable outcome is probable or remote.

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 supplement.

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The Offering

The following is a brief summary of some of the terms of the notes and shares of common stock offered for resale in this prospectus. For a more complete description of the terms of the notes, see the "Description of Notes" section in this prospectus. For a more complete description of the terms of the common stock, see the "Description of Capital Stock" section in this prospectus.

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| Securities Offered | \$23,250,000 aggregate principal amount, 1,170,213 shares of common stock, and 7,749,992 shares of common stock issuable upon conversion of the notes. |
| Issuer | Cell Therapeutics, Inc. |
| Maturity | The notes mature December 15, 2011. |
| Offering Price | 100% of the principal amount. |
| Interest | Interest is payable on the notes at a rate of 5.75% per annum, payable in cash, common stock or some combination of common stock having a fair market value equal to the interest payment due, semi-annually on June 15 and December 15 of each year, beginning on June 15, 2008. For purposes of this provision, the fair market value of our common stock shall be equal to 95% of its volume-weighted average price for the five consecutive trading days ending on the trading day immediately preceding the interest payment date. |
| Conversion | Holders have the option to convert the notes into shares of our common stock at a conversion rate of 333.333 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of \$3.00 per share. The conversion rate is subject to adjustment as described more fully in "Description of Notes - Conversion Rights." |

Holders may convert the notes at any time before the close of business on the maturity date, unless we have previously redeemed or repurchased the notes; provided, however, that if a note is subject to redemption, holders will be entitled to convert the note at any time before the close of business on the date immediately preceding the date fixed for redemption.

See "Description of Notes - Conversion Rights."

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| Optional Redemption | Prior to December 15, 2009, we will not have the right to redeem any notes at our option. On or after December 15, 2009, we may redeem some or all of the notes for cash at any time at a redemption price equal to 100% of the aggregate principal amount of the outstanding notes at the time of such redemption plus a Make-Whole Payment and accrued and unpaid interest to, but not including, the redemption rate. |
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See "Description of Notes - Optional Redemption."

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| Automatic Conversion | Subject to certain conditions, the notes will automatically convert if, at any time after December 15, 2009 and prior to maturity, the closing price per share of our common stock has exceeded 140% of the conversion price then in effect for at least 20 trading days within any 30 consecutive trading day period. |
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See "Description of Notes - Automatic Conversion."

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| Repurchase at Option of Holders Upon Change in Control | Upon certain changes in control (as defined in the indenture), holders will have the right, subject to certain conditions and restrictions, to require us to repurchase their notes, in whole or in part, at a repurchase price equal to 100% of the aggregate principal amount of such holders' outstanding notes at the time of such repurchase, plus a Make-Whole Payment and accrued and unpaid interest to, but not including, the repurchase date. We are required to pay 100% of the aggregate principal amount of the notes in cash to holders upon such a repurchase. |
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See Description of Notes Repurchase Option of Holders Upon Change in Control.

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Make-Whole Provision

Upon automatic conversion of the notes, or upon exercise of the right to option redemption or repurchase upon change in control (as defined in the indenture), we will pay the holder an amount equal to \$115 per \$1,000 principal amount of the notes so converted, repurchased or redeemed less the amount of any interest paid on such notes prior to the conversion, repurchase or redemption date. This payment may be made in cash, common stock or some combination of cash and common stock. For purposes of this provision, the fair market value of our common stock shall be equal to 95% of its volume-weighted average price for the five consecutive trading days ending on the trading day immediately preceding the conversion, repurchase or redemption date. No make-whole amount shall be payable upon any conversion, repurchase or redemption of the notes other than in connection with the an automatic conversion of the notes, repurchase of the notes in connection with a change in control (as defined in the indenture) or an optional redemption by the Company.

See Description of Notes Make-Whole Provision.

Ranking

The notes rank *pari passu* in right of payment with all of our existing and future senior indebtedness, including our 6.75% Convertible Senior Notes due 2010, 7.5% Convertible Senior Notes due 2011 and 9% Convertible Senior Notes due 2012 and rank senior in right of payment to our currently outstanding 5.75% Convertible Senior Subordinated notes due June 2008, 5.75% Convertible Subordinated Notes due June 2008 and 4% Convertible Senior Subordinated Notes due 2010. The notes are also effectively senior in right of payment to liabilities of our subsidiaries.

See Description of Notes Ranking.

Use of Proceeds

We will not receive any proceeds from the sale by any selling securityholder of the notes or the shares offered by this prospectus.

Covenants

We have agreed not to incur or suffer to exist, and to not permit our subsidiaries to incur or suffer to exist (i) any indebtedness that is structurally senior or senior by its terms to these notes, or (ii) secured indebtedness, in an aggregate principal amount for both clauses (i) and (ii) exceeding \$10,000,000 unless, in the case of clause (ii) only, these notes are equally and ratably secured with such secured indebtedness, except that we may incur liens or encumbrances in connection with biopharmaceutical licensing and/or partnering arrangements without any such limitations.

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Events of Default

The following will be events of default under the indenture for the notes:

we fail to pay the principal of or any premium on the notes when due;

we fail to pay any interest on the notes when due and that default continues for 30 days;

we fail to give the notice that we are required to give if there is a change in control (as defined in the indenture);

we fail to perform any other covenant in the indenture and that failure continues for 30 days after written notice to us by the trustee or the holders of at least \$1,000,000 in aggregate principal amount of outstanding notes;

we fail to pay when due the principal of any indebtedness for money borrowed by us or any of our subsidiaries in excess of \$10 million if the indebtedness is not discharged and such failure continues for 30 days or more, or if such indebtedness has been accelerated and such acceleration is not annulled, within 30 days after written notice to us by the trustee or the holders of at least \$1,000,000 in aggregate principal amount of the outstanding notes;

we fail to pay when due any amount due to preferred stock holders of the company or any subsidiary and that failure continues for 30 days, or if the liquidation preference of such preferred stock has been accelerated and such acceleration is not annulled, within 30 days after written notice to us by the trustee or the holders of at least \$1,000,000 in aggregate principal amount of the notes;

the Company or a subsidiary redeems, purchases or otherwise acquires directly or indirectly any preferred stock in exchange for cash, cash equivalents or indebtedness with a maturity prior to that of these notes, except after payment of outstanding principal and any accrued interest on these notes; and

certain events of bankruptcy, insolvency or reorganization with respect to Cell Therapeutics, Inc. and its significant subsidiaries specified in the indenture.

See Description of Notes Events of Default.

CTIC

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Nasdaq Global Market Symbol for
Our Common Stock

Financial Ratios

Our ratio of earnings to fixed charges for each of the periods indicated is as follows:

| | Year Ended December 31, | | | | |
|---------------------------------------|-------------------------|------|------|------|------|
| | 2003 | 2004 | 2005 | 2006 | 2007 |
| Ratio of earnings to fixed charges(1) | | | | | |

- (1) For the purposes of computing ratio of earnings to fixed charges, earnings consist of income (loss) before provision for income taxes plus fixed charges. Fixed charges consist of interest charges and that portion of rental payments under operating leases we believe to be representative of interest. Earnings for the years ended December 31, 2003, 2004, 2005, 2006 and 2007, were insufficient to cover fixed charges by \$130,031, \$252,298, \$102,505, \$135,819 and \$148,305 (in thousands) respectively. For this reason, no ratios are provided for these periods.

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RISK FACTORS

You should carefully consider the risks described below and other information in this prospectus supplement and in the documents incorporated by reference into this prospectus supplement 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 December 31, 2007, we had an accumulated deficit of approximately \$1.1 billion. We are pursuing regulatory approval for paclitaxel poliglumex, pixantrone, 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 repay this debt or the interest, liquidated damages or other payments that may become due with respect to our debt. Approximately \$10.7 million of this debt is due in June 2008. Prior to this debt becoming due, we may engage in one or more restructuring transactions which could involve, among other things, an effective increase in interest rates, alteration of terms or exchanges involving the issuance of additional shares of common stock or other arrangements which may dilute or be adverse to the value of our common stock and preferred stock.

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.

In 2007, we were able to raise capital through the sale of preferred stock and common stock, and raised a total of \$91.0 million in gross proceeds, with an additional \$1.3 million in gross proceeds raised from an equity offering under our Step-Up Equity Financing Agreement with Société Générale in January 2008 and approximately \$35.5 million in proceeds from a convertible debt offering, net of inducement payments for conversions of convertible preferred stock, in March 2008. In addition, approximately \$13.9 million of this amount is restricted and is being held in escrow to fund potential make-whole payments due upon conversions of this debt. However, we have substantial operating expenses associated with the development of our product candidates and as of December 31, 2007 we had cash and cash equivalents, securities available-for-sale and interest receivable of approximately \$18.4 million, and total current liabilities of approximately \$53.5 million. We also have a substantial amount of debt outstanding, including an aggregate of approximately \$152.5 million in convertible notes as of March 19, 2008, of which \$10.7 million is due 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 March 15, 2008, will not provide sufficient working capital to fund our presently anticipated operations for the next 12 months and repay our notes due in June 2008, and we will therefore need to raise additional capital.

We have a \$60 million (approximately \$88 million as of December 31, 2007) Step-Up Equity Financing Agreement with Société Générale which we may be able to utilize to provide additional equity funding. As of March 19, 2008 we had approximately \$59.1 million available under this financing agreement. Additionally, we may 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, including any obtained under the Financing Agreement, 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 paclitaxel poliglumex, 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

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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.

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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.

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

Our bylaws require that a quorum, consisting of a majority 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, 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 will 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, in the event that the broker receives no voting instruction from the beneficial owner. As a result of this custody transfer, we were able to hold a special meeting of the shareholders in April 2007, an annual meeting of the shareholders in September 2007 and another special meeting of the shareholders in January 2008. However, obtaining a quorum at future meetings depends 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 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 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

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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.

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 the following material weaknesses relative to the effectiveness of our internal control over financial reporting:

We did not maintain an effective review and approval process in our European subsidiary, or CTI (Europe), to ensure the accuracy of accounts payable and accrued expenses for certain activities shared by headquarters and CTI (Europe) in conformity with generally accepted accounting principles.

We did not maintain effective internal controls related to the financial reporting process to detect errors that are not identified by the process level controls in CTI (Europe).

During 2007, to remedy the material weaknesses in our internal control over financial reporting, we implemented enhanced review and approval procedures that are designed to help ensure we accurately record accounts payable and accrued expense balances in CTI (Europe), and trained personnel in key finance positions in CTI (Europe) regarding the enhanced procedures and appropriate levels of oversight and review.

In November 2007, we merged CTI (Europe) with and into CTI in a roll-up merger under Washington law. As a result, all of our operations in Italy are now directly part of CTI and CTI (Europe) is now a branch of the Company.

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 identify and complete valuable acquisition opportunities, we may not achieve the anticipated growth we would otherwise achieve were such acquisitions accomplished.

We have in the past and may in the future seek to further expand our product portfolio through acquisitions of other complementary businesses or technologies or marketed products. For example, in July 2007, we acquired SM, a privately held oncology company, and gained worldwide rights to brostallicin, a DNA minor groove binding agent with proven anti-tumor activity which is currently in phase II clinical studies. Additionally, in December 2007, we acquired Zevalin from Biogen Idec, or Biogen, for development, marketing and sale in the United States.

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Mergers and acquisitions are inherently risky, and we cannot assure that we will be able to complete future acquisitions, or that our acquisitions will be successful. The successful execution of our acquisition strategy will depend, in part, on our ability to identify, negotiate, complete and integrate such

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acquisitions and, if necessary, obtain satisfactory debt or equity financing to fund those acquisitions. Failure to manage and successfully integrate acquired businesses could harm our business.

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. While we intend to negotiate with Bayer Schering for access to data from their first line indolent trial, or FIT trial, we currently have no rights to that data, and there is no assurance that Bayer Schering will agree to give us access to their data on reasonable terms or at all. In addition, even if we are able to use the data from Bayer Schering's FIT trial, there can be no guarantee

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that such data will be adequate or suitable for submission to the FDA in support of a supplemental biologics license application for additional approved uses of Zevalin, or that the FDA will approve such supplemental biologics license application.

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.

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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 paclitaxel poliglumex and pixantrone with Novartis International Pharmaceutical Ltd., or Novartis, pursuant to which Novartis received an exclusive worldwide license for the development and commercialization of paclitaxel poliglumex 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 paclitaxel poliglumex 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.

We may be delayed, limited or precluded from obtaining regulatory approval of paclitaxel poliglumex 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 paclitaxel poliglumex. 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 paclitaxel poliglumex 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 paclitaxel poliglumex 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 paclitaxel poliglumex 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 paclitaxel poliglumex in the United States.

Based on discussions with the EMEA Scientific Advice Working Party, we submitted an MAA in Europe on March 4, 2008 based on results of the STELLAR trials, 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.

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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, and the private party plaintiff has advised us that he intends to seek a court order awarding approximately \$1 million in attorneys' fees. We are not able to reasonably estimate the potential cost of any award that may be made pursuant to this claim.

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

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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®, 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, Favril, and Genitope are developing products which could compete with Zevalin.

If we are successful in bringing paclitaxel poliglumex to market, we will face direct competition from oncology-focused multinational corporations. Paclitaxel poliglumex 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; and American Pharmaceutical Partners, which markets Abraxane. In addition, other companies such as NeoPharm Inc. and Telik, Inc. are also developing products which could compete with paclitaxel poliglumex.

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®), 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®, 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,

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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.

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 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: