

CELL THERAPEUTICS INC  
Form 10-K  
March 26, 2008  
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UNITED STATES

**SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

**FORM 10-K**

(Mark One)

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2007

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 Or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 001-12465

**CELL THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

Washington  
(State or other jurisdiction of incorporation or organization)

501 Elliott Avenue West, Suite 400

Seattle, WA 98119  
(Address of principal executive offices)

Registrant's telephone number, including area code: (206) 282-7100

91-1533912  
(I.R.S. Employer Identification Number)

98119  
(Zip Code)

Securities registered pursuant to Section 12(b) of the Act:

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Title of each class	Name of each exchange on which registered
Common Stock, no par value	NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:

None.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer  (Do not check if a smaller reporting company)

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes  No

As of June 30, 2007, the aggregate market value of the registrant's common equity held by non-affiliates was \$141,508,000. Shares of common stock held by each executive officer and director and by each person known to the Company who beneficially owns more than 5% of the outstanding Common Stock have been excluded in that such persons may under certain circumstances be deemed to be affiliates. This determination of executive officer or affiliate status is not necessarily a conclusive determination for other purposes.

The number of outstanding shares of the registrant's common stock as of March 19, 2008 was 94,607,850.

#### DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III of this Report, to the extent not set forth herein, will be incorporated herein by reference from the registrant's definitive proxy statement relating to the annual meeting of shareholders to be held in 2008, which definitive proxy statement or amendment to this annual report shall be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year ended December 31, 2007 to which this Report relates.

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**Forward Looking Statements**

This Form 10-K and the documents incorporated by reference contain, in addition to historical information, forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act ) and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act ). These statements relate to our future plans, objectives, expectations, intentions and financial performance, and assumptions that underlie these statements. All statements other than statements of historical fact are forward-looking statements for the purposes of these provisions, including:

any statement regarding the performance, or likely performance, or outcomes or economic benefit 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 authorizations required to enable such agreement will be obtained;

any projections of revenues, estimated operating expenses or other financial items;

any statements of the plans and objectives of management for future operations or programs;

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 statement regarding future economic conditions or performance, and any statement of assumption underlying any of the foregoing.

When used in this Form 10-K, terms such as anticipates, believes, continue, could, estimates, expects, intends, may, plans, potential, should, or will or the negative of those terms or other comparable terms are intended to identify such forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors that may cause industry trends or actual results, level of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these statements. Our actual results may differ significantly from the results discussed in such forward-looking statements. These factors include, but are not limited to, those listed under Item 1A Risk Factors, Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations, Item 1 Business and elsewhere in this Form 10-K.

We do not intend to update any of the forward-looking statements after the date of this Form 10-K to conform these statements to actual results or changes in our expectations. Readers are cautioned not to place undue reliance on these forward-looking statements, which apply only as of the date of this Form 10-K.

You may review a copy of this annual report on Form 10-K, including exhibits and any schedule filed therewith, and obtain copies of such materials at prescribed rates, at the Securities and Exchange Commission's Public Reference Room in Room 1580, 100 F Street, NE, Washington, D.C. 20549-0102. You may obtain information on the operation of the Public Reference Room by calling the Securities and Exchange Commission at 1-800-SEC-0330. The Securities and Exchange Commission maintains a website (<http://www.sec.gov>) that contains reports, proxy and information statements and other information regarding registrants, such as Cell Therapeutics, Inc., that file electronically with the Securities and Exchange Commission.



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**PART I**

**Item 1. Business Overview**

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 non-inferiority 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

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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 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.

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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.

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.

We were incorporated in Washington in 1991. Our principal executive offices are located at 501 Elliott Avenue West, Seattle, Washington 98119. Our telephone number is (206) 282-7100. Our website can be found at [www.CellTherapeutics.com](http://www.CellTherapeutics.com). We make available free of charge on our website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and other filings pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and amendments to such filings, as soon as reasonably practicable after each is electronically filed with, or furnished to, the Securities and Exchange Commission, or the SEC.

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.



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### **CTI Strategy**

Our goal is to become a leading cancer drug company. The following are the key elements of our business strategy:

We target development and registration strategies in the United States and Europe that take advantage of the ability to accelerate approval either because there is an unmet medical need, or because our product profiles demonstrate significant improvement in efficacy, toxicity or safety over competitive drugs.

We plan to devote a substantial portion of our efforts to develop and commercialize Zevalin for current and additional indications and to further develop paclitaxel poliglumex, pixantrone and brostallicin.

We are developing our own sales and marketing capabilities in the U.S. for Zevalin and may establish collaborations to commercialize our product and potential future products.

We may seek to expand our products and product candidates in the future by actively exploring opportunities to in-license or acquire complementary products, technologies or companies.

We are developing our supply chain capabilities.

We plan to use a genomic-based platform to guide development of our oncology products in order to help identify and select patient populations that will be specifically responsive to our drug candidates in clinical trials.

We are investigating approaches to improving current therapeutic agents against validated drug targets in order to discover novel agents with improved side effect and efficacy profiles compared to competitor drugs.

### **The Oncology Market**

*Overview.* According to the American Cancer Society, or ACS, cancer is the second leading cause of death in the United States, resulting in close to 560,000 deaths annually, or more than 1,500 people per day. The National Cancer Institute estimates that approximately 10.5 million people in the United States with a history of cancer were alive in January 2003, and it is estimated that slightly more than one in three American women, and slightly less than one in two American men will develop cancer in their lifetime. Approximately 1.5 million new cases of cancer were expected to be diagnosed in 2007 in the United States. The most commonly used methods for treating patients with cancer are surgery, radiation and chemotherapy. Patients usually receive a combination of these treatments depending upon the type and extent of their disease.

Despite recent advances in sequencing the human genome and the introduction of new biologic therapies for the treatment of cancer, almost all patients with advanced cancer will receive chemotherapy at some point during the treatment of their disease. The cornerstone classes of chemotherapy agents include anthracyclines, camptothecins, platinates and taxanes. Unfortunately, there are significant limitations and complications associated with these agents that result in a high rate of treatment failure. The principal limitations of chemotherapy include:

treatment-related toxicities,

inability to selectively target tumor tissue, and

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the development of resistance to the cancer-killing effects of chemotherapy.

*Treatment-related toxicities.* The majority of current chemotherapy agents kill cancer cells by disrupting the cell division and replication process. Although this mechanism often works in cancer cells, which grow rapidly through cell division, non-cancerous cells are also killed because they too undergo routine cell division. This is especially true for cells that line the mouth, stomach and intestines, hair follicles, blood cells and reproductive cells (sperm and ovum). Because the mechanism by which conventional cancer drugs work is not limited to cancer cells, their use is often accompanied by toxicities. These toxicities limit the effectiveness of cancer drugs and seriously impact the patient's quality of life.

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*Inability to selectively target tumor tissue.* When administered, chemotherapy circulates through the bloodstream, reaching both tumor and normal tissues. Normally dividing tissues are generally as sensitive as tumor cells to the killing effects of chemotherapy and toxic side effects limit the treatment doses that can be given to patients with cancer.

*Chemotherapy resistance.* Resistance to the cancer killing effects of conventional chemotherapy is a major impediment to continued effective treatment of cancer. Many cancer patients undergoing chemotherapy ultimately develop resistance to one or more chemotherapy agents and eventually die from their disease. Because many chemotherapies share similar properties, when a tumor develops resistance to a single drug, it may become resistant to many other drugs as well. Drugs that work differently from existing chemotherapies and are less susceptible to the same mechanisms of resistance have consequently begun to play an important role in treating resistant tumors.

We believe developing agents which improve on the cornerstone chemotherapy classes, in addition to novel drugs designed to treat specific types cancer and cancer patients, fills a significant unmet need for cancer patients. Our cancer drug development pipeline includes a taxane, a modified anthracycline, a DNA minor groove binding agent, and a radioimmunotherapy; each of which has the potential to treat a variety of cancer types.

### **Zevalin (Ibritumomab Tiuxetan)**

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 provided the data 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 for Zevalin in 2008 to remove the requirement of a biodistribution scan.

### **Paclitaxel poliglumex**

We are developing paclitaxel poliglumex, a novel biologically enhanced chemotherapeutic agent which links a widely used anti-cancer agent, paclitaxel, to a polyglutamate polymer for the potential treatment of NSCLC and ovarian and other cancers. Paclitaxel poliglumex utilizes a biodegradable polymer to deliver the chemotherapeutic agent paclitaxel preferentially to tumor tissue. By linking paclitaxel to a biodegradable amino acid carrier, the conjugated chemotherapeutic agent is inactive in the bloodstream, sparing normal tissues the toxic side effects of chemotherapy. The chemotherapeutic agent is activated and released once inside tumor tissue by the action of an enzyme called cathepsin B. The activity of this enzyme and thus the rate of release of paclitaxel poliglumex is increased in the presence of estrogen. Preclinical data presented at the 2006 European Organization for Research and Treatment of Cancers, National Cancer Institute and American Association for Cancer Research, or EORTC-NCI-AACR, meeting demonstrated that the efficacy of paclitaxel poliglumex is enhanced in certain human tumors when mice are given additional estrogen. More than 1,900 patients were treated in our four pivotal phase III trials of paclitaxel poliglumex for the treatment of NSCLC. While the STELLAR 2, 3, and 4 trials missed their primary endpoint of superior overall survival, women treated with paclitaxel poliglumex for newly diagnosed advanced NSCLC in STELLAR 3 and 4 had a significant

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improvement in their overall survival compared to women or men treated with standard chemotherapy. In addition, with single-agent paclitaxel poliglumex, we observed a significant reduction in most of the severe toxic side effects associated with the standard chemotherapy agents studied in the STELLAR trials.

Taxanes, which include paclitaxel and docetaxel, are one of the best-selling classes of chemotherapies. Paclitaxel is approved for the treatment of NSCLC, ovarian cancer and breast cancer, although it is considered a standard of care in lung and ovarian cancers, where it is most widely used. Paclitaxel poliglumex, a novel biologically enhanced chemotherapeutic, links polyglutamate to paclitaxel, the active ingredient in Taxol. Taxol is a formulation of paclitaxel in a mixture of polyethoxylated castor oil (Cremaphor) and ethanol, which is extremely irritating to blood vessels and requires surgical placement of a large catheter for administration. It also can cause severe life threatening allergic reactions that typically require pre-medications with steroids and antihistamines in addition to a minimum of three hours of intravenous infusion and transportation of patients to and from their treatment location. Unlike formulations of paclitaxel, paclitaxel poliglumex uses a biodegradable protein polymer to deliver chemotherapy preferentially to tumor tissue. Paclitaxel poliglumex is approximately 80,000 times more water-soluble than paclitaxel alone, allowing it to be dissolved in a simple water and sugar based solution and infused in the patient over approximately ten to twenty minutes. Paclitaxel poliglumex does not require routine pre-medication with steroids and antihistamines to prevent severe allergic reactions and patients can drive themselves to and from treatment centers. The distribution and metabolism of paclitaxel poliglumex to tumor tissue and subsequent release of active paclitaxel chemotherapy appears to be enhanced by estrogen allowing for superior effectiveness in women with pre-menopausal estrogen levels. This gender-targeted benefit could also be exploited in post-menopausal women or men through estrogen supplementation.

*Paclitaxel poliglumex for non-small cell lung cancer*

The cancer drug most commonly used to treat NSCLC in the United States is paclitaxel. The ACS estimates that 185,000 new cases of NSCLC will be diagnosed in the United States in 2008 and approximately 128,000 of these patients are expected to receive chemotherapy. Of the estimated 128,000 NSCLC patients who receive chemotherapy, approximately 32,000 are classified as PS2. These patients tolerate chemotherapy poorly and have a significantly shorter median survival than healthier patients.

In March 2005, we announced that our paclitaxel poliglumex phase III pivotal trial, known as STELLAR 3, for the potential use in combination with platinum as first-line treatment of PS2 patients with NSCLC missed its primary endpoint of superior overall survival. Paclitaxel poliglumex had a reduction in certain side effects, including hair loss, muscle and joint pain, and cardiac symptoms. In May 2005, we announced that both the STELLAR 2 and 4 clinical trials missed their primary endpoints of superior overall survival, but had significant reductions in certain severe side effects compared to the comparator agents. The STELLAR 2 pivotal trial was evaluating paclitaxel poliglumex for potential use as second-line single agent treatment for patients with NSCLC, and the STELLAR 4 pivotal trial was evaluating paclitaxel poliglumex for potential use as first-line single agent treatment for PS2 patients with NSCLC.

In July 2005, at the 11th World Conference on Lung Cancer, we announced that in a pooled analysis of our STELLAR 3 and 4 pivotal trials the 97 women who received paclitaxel poliglumex had a significant increase in median and overall survival (9.5 months vs. 7.7 months, hazard ratio 0.70, log rank  $p=0.03$ ) and in 1-year survival (40% vs. 25%,  $p=0.013$ ) compared to 101 women who received comparator control agents. These results pooled data from all women randomized on the STELLAR 3 and 4 trials (a so-called intent to treat analysis). Individually, neither study reached statistical significance for overall survival for women, although a positive trend was observed in both trials, with a strong trend in the STELLAR 4 trial ( $p=0.069$ ). While analysis of survival by gender was pre-specified in the analysis plans for the trials, a gender specific survival advantage for women over men was not a pre-specified endpoint in either trial.

In September 2005, we presented results from a phase II clinical trial, known as PGT202, of paclitaxel poliglumex in the first-line treatment of men and women with advanced NSCLC, which demonstrated a survival advantage for women receiving paclitaxel poliglumex as first-line therapy for NSCLC when compared to men. In

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this single arm study, the 35 women who received paclitaxel poliglumex plus carboplatin had a 36% probability of living at least one year compared to 16% in the 39 men receiving the same regimen. A pooled analysis of the 463 patients treated with paclitaxel poliglumex in the STELLAR 3, STELLAR 4 and PGT202 trials demonstrated a statistically significant survival advantage for women treated when compared to men, with women having a 39% probability of surviving at least one year compared to 25% for men (hazard ratio 0.63, log rank  $p=0.014$ ).

In December 2005, we initiated the PIONEER, or PGT305, study comparing paclitaxel poliglumex to paclitaxel in the first-line treatment of PS2 women with advanced NSCLC. In addition, we initiated preclinical studies on the effect of gender/hormonal status on paclitaxel poliglumex biodistribution, cellular uptake and metabolism to support the hypothesis for survival improvement in women.

In February 2006, we presented results that confirm the observation of enhanced efficacy in the presence of estrogen seen in the STELLAR first-line trials. In the three first-line trials of paclitaxel poliglumex (PGT202, STELLAR 3, and STELLAR 4), women of pre-menopausal age or with normal estrogen levels had the strongest survival advantage over their counterparts. In an analysis of the 113 of 198 women in the pooled STELLAR 3 and 4 trial data who are of pre-menopausal age or have normal estrogen levels, women treated with paclitaxel poliglumex had a highly significant prolongation in the 1-year and overall survival estimates compared to women treated with standard chemotherapy, with the paclitaxel poliglumex patients having a 44% reduction in the overall risk of dying (log rank  $p=0.008$ ) and a 43% 1-year survival estimate compared to 19% for women on standard chemotherapy ( $p=0.003$ ). We believe these data indicate a potential favorable alternative for women with normal estrogen levels who have NSCLC.

In addition, our phase III trials demonstrated that, with the exception of neuropathy known to be associated with taxane therapy, single agent paclitaxel poliglumex (175-210mg/m<sup>2</sup>) has a significantly reduced incidence of severe side effects, including a reduction in severe neutropenia, febrile neutropenia, infection and anemia when compared to patients receiving standard chemotherapy agents gemcitabine, vinorelbine or docetaxel. Paclitaxel poliglumex also resulted in less severe allergic reactions, hair loss, and significant reduction in the requirement for transfusions and use of hematopoietic growth factor support such as Neupogen<sup>®</sup>, Neulasta<sup>®</sup>, Aranesp<sup>®</sup> and/or Epogen<sup>®</sup> compared to patients receiving standard chemotherapy.

In November 2006, at the 18th Annual EORTC-NCI-AACR meeting, CTI scientists presented new preclinical data on the effect of circulating estrogen levels on tumor growth and levels of cathepsin B in tumor tissue. The study showed that when additional estrogen was given, it substantially increased the tumor growth rate in colon cancer (HT-29) and NSCLC (H460) models. In addition, cathepsin B activity in the tumors increased by 35% to 40% in the presence of estrogen. The study also found that in estradiol-supplemented female mice, paclitaxel poliglumex demonstrated a nearly two-fold increase in anti-tumor activity compared to non-supplemented animals in the colon cancer tumor model. Studies are ongoing to evaluate the effect of estrogen on paclitaxel poliglumex activity in the non-small cell lung tumor model.

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 an 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 but have not initiated the PGT306 trial. 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 an NDA in the United States.

In early 2008, we limited enrollment on the PGT307 study to U.S. sites only, until either approval of an MAA for paclitaxel poliglumex by the EMEA or until positive results from the GOG212 trial of paclitaxel poliglumex for first-line maintenance therapy in ovarian cancer are reported.

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We submitted an MAA in Europe for paclitaxel poliglumex on March 4, 2008 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 SAWP; the EMEA agreed that switching the primary endpoint from superiority to non-inferiority 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.

*Paclitaxel poliglumex for ovarian cancer*

The ACS estimates that approximately 22,000 new cases of ovarian cancer will be diagnosed in the United States in 2008. The standard of care for first-line treatment of ovarian cancer is paclitaxel and carboplatin. In April 2004, we announced that we entered into a clinical trial agreement with the Gynecologic Oncology Group, or GOG, to perform a phase III trial of paclitaxel poliglumex as maintenance therapy in patients with ovarian cancer. In July 2004, the GOG submitted an Investigational New Drug application, or IND, along with the protocol for an SPA to the FDA. The GOG reached agreement with the FDA regarding the SPA in December 2004 and initiated the phase III study in March 2005. This study 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 and approval in 2010. The primary endpoint of this trial is overall survival. Progression-free survival, safety and side effect profile are secondary endpoints.

**Pixantrone**

We are developing pixantrone, a novel anthracycline derivative, for the treatment of NHL. In the United States, according to the National Cancer Institute's SEER database, there were nearly 400,000 people with NHL in 2004. The American Cancer Society estimates that 66,000 people will be diagnosed with NHL in 2008 and more than 19,000 are expected to die. Since the early 1970's, incidence rates for NHL have nearly doubled. It is the fifth most common cancer in the U.S. The standard of care for first-line treatment of NHL is known as CHOP, which is a combination chemotherapy regimen consisting of cyclophosphamide, doxorubicin (an anthracycline), vincristine and prednisone. CHOP is used either alone or in conjunction with rituximab, and is able to induce complete responses, or CRs, in approximately 60% to 70% of patients. However, approximately 30% to 50% of patients eventually relapse and many are unable to undergo an additional course of CHOP therapy due to the risk of cardiac toxicity from anthracyclines.

Anthracyclines are one of the most potent classes of anti-cancer agents used in first-line treatment of aggressive NHL, leukemia, and breast cancer. For these diseases, anthracycline-containing regimens can often produce long-term cancer remissions and cures. However, the currently marketed anthracyclines can cause severe, permanent and life threatening cardiac toxicity when administered beyond widely recognized cumulative lifetime doses. This toxicity often prevents repeat use of anthracyclines in patients who relapse after first-line anthracycline treatment. In addition, the cardiac toxicity of anthracyclines prevents their use in combination with other drugs, such as trastuzumab, that also can cause cardiac toxicity. As a result, chemotherapy regimens that do not include anthracyclines often are used for the second-line treatment of relapsed NHL. There are no drugs approved in the United States for second- or third-line treatment for patients with relapsed aggressive NHL.

We believe a next-generation anthracycline with better ease of administration, greater anti-tumor activity and less cardiac toxicity could gain a significant share of the anthracycline market. We also believe that such a drug could allow repeat therapy in relapsed patients and could allow combination therapy with a broader range of chemotherapies. Preclinical data and phase I and phase II clinical studies in approximately 410 patients indicate that pixantrone is easy to administer, may exhibit significantly lower potential for cardiac toxicity and may have more potent anti-tumor activity than marketed anthracyclines.

*Pixantrone for relapsed aggressive non-Hodgkin's lymphoma*

We have several clinical trials ongoing, including a pivotal phase III trial, known as the EXTEND or PIX301 study, for the treatment of patients with relapsed aggressive NHL, a condition for which there are no

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chemotherapy drugs approved in the United States. This study is an international, randomized trial comparing pixantrone to a single agent of the treating physician's choice. The primary endpoint of the study is complete response rate. An interim analysis of the EXTEND 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 from 320 patients 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 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.

In July 2004, we announced that the FDA granted fast-track designation for pixantrone for the treatment of relapsed aggressive NHL.

Preliminary results of our RAPID trial of CHOP combined with rituximab versus CPOP combined with rituximab for the initial treatment of patients with aggressive NHL were reported at the 49<sup>th</sup> Annual Meeting of the American Society of Hematology, or ASH, in December 2007. The interim analysis, in which 78 patients were evaluated for safety and 40 of the 78 patients were evaluated for efficacy, was reported in July 2007. The FDA agreed that randomized safety data from the RAPID study could be used to support the EXTEND results in an NDA submission for pixantrone. In early 2008, we closed enrollment on the RAPID study based on adequate sample size to demonstrate difference in cardiac events and other clinically relevant side effects between pixantrone and doxorubicin.

*Pixantrone for other indications*

Other clinical data suggest pixantrone may be useful in treating indolent NHL, a less rapidly progressive but ultimately fatal form of NHL. In November 2005, CTI presented results from a multi-center randomized trial, known as AZA302. This trial, evaluating pixantrone plus rituximab versus rituximab alone among patients with relapsed or refractory indolent NHL, was modified and reduced, as announced in our annual filing on Form 10-K in 2004, as a result of our strategy to conduct a pivotal phase III trial in aggressive NHL, which we believe provides the fastest route to registration for pixantrone. Of the 38 patients evaluable for response, patients receiving the combination of rituximab and pixantrone had an 87% overall improvement in time to progression, or TTP, compared to rituximab alone. The median TTP estimate for the pixantrone/rituximab recipients was 13.2 months compared to 8.1 months for rituximab alone (hazard ratio 0.13, log rank  $p < 0.001$ ). The one- and two-year progression-free survival estimates were 66% and 44% for the pixantrone/rituximab recipients compared to 0% for the rituximab patients for both measurement intervals ( $p < 0.001$  and 0.003, respectively). The study also demonstrated a significant improvement in major objective responses ( $\geq 50\%$  shrinkage in tumor size). The pixantrone-rituximab combination produced a complete response (CR) in seven patients (35%), with eight patients (40%) experiencing a partial response (PR) and four patients (20%) with stable disease (SD). Rituximab monotherapy produced a CR in two patients (11%), PR in four patients (22%) with six patients having SD (33%). This corresponds to a major objective response rate of 75% in the combination therapy arm compared to 33% in the rituximab group ( $p=0.021$ ). Side effects on pixantrone were generally mild to moderate (grade 1 or 2) with the exception of three cases of serious neutropenia associated with the pixantrone/rituximab arm. The median cumulative dose of pixantrone administered was 1014 mg/m<sup>2</sup>; no cases of treatment-related grade 3 or 4 cardiac toxicity were reported.

In May 2007, we received SPA approval for a new protocol 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, and we received fast track designation from the FDA for pixantrone for the treatment of relapsed or refractory indolent NHL. The protocol, which became our phase III PIX303 trial, was launched in September 2007. However, we closed the trial in January 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 landscape in second line follicular NHL.

**Table of Contents****Brostallicin**

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. 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 EORTC. 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 at multiple sites with US Oncology with the first combinations expected to be completed in 2008.

**CT-2106 (polyglutamate camptothecin)**

We were developing a novel polyglutamate-camptothecin molecule, CT-2106 with phase I/II studies in colorectal and ovarian cancers. Camptothecins are an important and fast growing class of anti-cancer drugs. However, like taxanes, their full benefit is limited by poor solubility and significant toxicity.

We are currently focusing our efforts on Zevalin, paclitaxel poliglumex, pixantrone and brostallicin, and have no immediate plans to conduct any further CT-2106 clinical studies.

**TRISENOX**

On July 18, 2005, we completed the divestiture of TRISENOX and certain proteasome assets to Cephalon Inc. for aggregate consideration of \$71.9 million, net of broker fees. In connection with the divestiture, we were required to repay our royalty obligation to PharmaBio Development, or PharmaBio, and after this repayment, our net proceeds from both transactions were approximately \$32.5 million. The divestiture included all TRISENOX assets, including the capital stock of two of our wholly owned subsidiaries, Cell Therapeutics (UK) Limited, a United Kingdom corporation, and PolaRx Pharmaceuticals, Inc., a Delaware corporation.

**CTI s Ongoing Clinical Trials**

The following table lists our active clinical trials (indicated by a status of "open") and trials that have recently closed to enrollment.

<b>Product Candidate</b>	<b>Indication/Intended Use</b>	<b>Phase/Status</b>
<b>Zevalin</b>	Aggressive NHL, first-line consolidation for patients treated with CHOP-R chemotherapy (106-20)	III / open
	Indolent NHL, first-line consolidation for patients treated with CVP-R chemotherapy (106-NH-301)	III / open
<b>Paclitaxel</b>	NSCLC, first-line, doublet therapy, PS0-2, females with pre-menopausal estrogen levels (PGT307)	III / open
<b>Poliglumex</b>		
<b>(CT-2103)</b>	Ovarian first-line maintenance (GOG212)	III / open
<b>Pixantrone</b>	Aggressive NHL, > 3 relapses, single-agent (PIX301)	III / closed



## Edgar Filing: CELL THERAPEUTICS INC - Form 10-K

	Aggressive NHL, front-line, CPOP-R (PIX 203)	II / closed
	Relapsed or refractory indolent NHL, randomized (PIX 303)	III / closed
	Advanced or metastatic soft tissue sarcoma, first-line, single agent (BRTA-0100-015)	II / open
<b>Brostallicin</b>	Advanced soft tissue sarcoma targeted to patients with specific genomic translocations (BRS202)	II / open
	Combination with other chemotherapeutic drugs (BRS101)	I / open

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### **Research and Preclinical Development**

We are also working on a number of drug targets and agents in discovery research. Among these programs are bisplatinum agents in advanced preclinical development with lead compounds identified, HIF-1 / p300 inhibitors, and proteasome inhibitors with indirect inhibition properties in earlier preclinical development. If resources are available, we may elect to move the bisplatinum program into early development in 2008. In addition to discovery research, preclinical activities are focused on product lifecycle management, including the development of alternative dosage forms for existing products in the development pipeline.

Research and development is essential to our business. We spent \$72.0 million, \$62.0 million, and \$68.8 million in 2007, 2006 and 2005, respectively, on Company sponsored research and development activities.

### **Collaboration, Licensing and Milestone Arrangements**

*Biogen Idec Inc.* In December 2007, we acquired the U.S. sales, marketing and distribution rights to Zevalin from Biogen pursuant to an asset purchase agreement. We made an upfront payment of \$10.1 million at the time of closing and are obligated to make additional milestone payments of up to \$20 million, contingent on positive trial outcomes and FDA approval for label expansion. We also assumed royalty obligations and agreed to additional royalty obligations to be paid to Biogen based on net sales of Zevalin. Additionally, we entered into a supply agreement with Biogen as well as a security agreement providing Biogen a first security interest in the assets purchased in the transaction.

*Systems Medicine, Inc.* In July 2007, we completed the acquisition of Systems Medicine Inc., or SM, in a stock for stock merger. 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. We are obligated to make additional milestone payments of up to \$15 million to the stockholders of SM, to be paid in either cash or CTI's common stock at our election, upon the completion of certain regulatory milestones relating to the FDA approval process in the development of brostallicin.

*Cephalon Inc.* In July 2005, we completed the divestiture of TRISENOX and certain proteasome assets to Cephalon Inc. for aggregate consideration of \$71.9 million, net of broker fees. In connection with the divestiture, we were required to repay our royalty obligation to PharmaBio and after this repayment, our net proceeds from both transactions were approximately \$32.5 million. In addition, we may receive up to an additional \$100 million in payments upon achievement by Cephalon of specified sales and development milestones. However, achievement of such milestones is uncertain.

*Novartis International Pharmaceutical Ltd.* In September 2006, we entered into an exclusive worldwide licensing agreement with Novartis International Pharmaceutical Ltd., or Novartis, for the development and commercialization of paclitaxel poliglumex. Total product registration and sales milestones due from Novartis for paclitaxel poliglumex under the agreement could reach up to \$270 million. The agreement also provides Novartis with an option to develop and commercialize pixantrone based on agreed terms. If Novartis exercises its option on pixantrone under certain conditions, Novartis would pay CTI a \$7.5 million license fee, up to \$104 million in registration and sales related milestones and a royalty on pixantrone worldwide net sales as well as reimbursement for certain expenses. In connection with the licensing agreement, we also entered into a securities purchase agreement with Novartis, under which we agreed to sell and Novartis agreed to purchase an aggregate of 8,670,520 shares of our common stock for a total purchase price of \$15 million. In October 2006, both the co-development and securities purchase agreements became effective upon the receipt of antitrust regulatory clearance and, accordingly, we closed the sale of the shares of common stock to Novartis.

*PharmaBio Development.* In December 2004, we entered into a six-year financing and services agreement with PharmaBio, the strategic partnering group of Quintiles Transnational, Corp., or Quintiles, involving our cancer therapy, TRISENOX. Under the agreement, in return for cash and services, we were required to pay PharmaBio royalties based on a percentage of net sales of TRISENOX in the United States and certain European

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countries beginning in 2006. The agreement also provided PharmaBio Development with a security interest in TRISENOX related to our royalty payment obligations. In July 2005, the agreement was terminated in connection with the divestiture of TRISENOX to Cephalon and we were required to pay \$39.4 million for the extinguishment of the royalty obligation.

*Nippon Shinyaku Co. Ltd.* In December 2002, we entered into a distribution agreement with Nippon Shinyaku Co. Ltd., or Nippon. This agreement granted certain rights to Nippon to exclusively market and distribute TRISENOX in Japan, South Korea and Taiwan. Under the agreement, we received and recognized as revenue a milestone payment in June 2003 for Nippon's submission of an NDA in Japan. We were also eligible to receive future milestone payments upon attainment of certain regulatory achievements. In October 2004, Nippon received approval from the Japanese Ministry of Health to market TRISENOX for patients with relapsed or refractory acute promyelocytic leukemia, or APL, in Japan. Under the agreement, we received an additional milestone payment from Nippon upon its receipt of approval to market TRISENOX in Japan. In December 2004, Nippon launched TRISENOX for the treatment of relapsed/refractory APL in Japan. Pursuant to a supply agreement we entered into with Nippon, we recorded product sales during 2004 and 2005. Cephalon assumed the agreement with Nippon in connection with the TRISENOX divestiture.

*Chugai Pharmaceutical Co., Ltd.* In October 2001, we entered into a licensing agreement with Chugai Pharmaceutical Co., Ltd., or Chugai, for the development and commercialization of paclitaxel poliglumex. This agreement granted an exclusive license to Chugai to develop and commercialize paclitaxel poliglumex in several Asian markets. Upon execution of the agreement, Chugai paid us an initial payment and we received and recognized as revenue a milestone payment in 2002. In October 2005, we received a letter from Chugai proposing the termination of the License Agreement. This agreement was terminated effective March 2006.

*PG-TXL Company, L.P.* In June 1998, we entered into an agreement, which was subsequently amended in February 2006, with PG-TXL Company, L.P. granting us an exclusive worldwide license for the rights to PG-TXL, known as paclitaxel poliglumex, and to all potential uses of PG-TXL Company's polymer technology. Under the terms of the agreement, we acquired the rights to fund the research, development, manufacture, marketing and sale of anti-cancer drugs developed using this polymer technology. We are obligated to make payments upon the attainment of significant development milestones, as defined in the agreement. We also granted warrants to purchase 87,500 shares of our common stock to PG-TXL Company, L.P., which became exercisable in 2001 upon our entering a licensing agreement for paclitaxel poliglumex with Chugai Pharmaceutical Co., Ltd and will expire in November 2008. The milestone payments set forth in the agreement may become due upon the achievement of goals, such as trial commencements and completions, filings and regulatory approvals.

**Patents and Proprietary Rights**

We dedicate significant resources to protecting our intellectual property, which is important to our business. Through our acquisition of PolaRx Biopharmaceuticals, Inc., or PolaRx, we obtained rights to four pending patent families that, in the aggregate, cover dosage formulations, methods of administration and methods of use for various forms of arsenic trioxide and related compounds. This portfolio included six issued U.S. patents, and 36 U.S. and foreign pending or issued patent applications directed to TRISENOX. In July 2005, TRISENOX and related assets were sold to Cephalon, including the patents and pending patents acquired from PolaRx.

We have licensed 45 pending and issued U.S. patents applications directed to Zevalin. It should be noted that as approved under a Biologics License Application with the FDA, there are currently no mechanisms by which a generic Zevalin can be approved. We have exclusive rights to six issued U.S. patents and 126 U.S. and foreign pending or issued patent applications relating to our polymer drug delivery technology. There are six issued U.S. patents, two granted European patents and 72 pending or issued U.S. and foreign patent applications directed to paclitaxel poliglumex. Of the six issued U.S. patents, two of them and another 20 pending U.S. and foreign patent applications are directed to CT-2106. Additionally, we have four issued U.S. patents and 71

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foreign pending and issued patents directed to pixantrone and have licensed 6 U.S. patents and 181 pending and issued U.S. and foreign patent applications directed to brostallicin.

**Manufacturing**

We currently use, and expect to continue to be dependent upon, contract manufacturers to manufacture our marketed product, Zevalin, and each of our product candidates. For instance, Zevalin drug supply for commercial sale is manufactured and distributed for CTI by Biogen and other third party vendors. We have established a quality control and quality assurance program, including a set of standard operating procedures and specifications, designed to ensure that our products and product candidates are manufactured in accordance with current Good Manufacturing Practices, or cGMPs, and other applicable domestic and foreign regulations. We will need to invest in additional manufacturing development, manufacturing and supply chain resources, and may seek to enter into additional collaborative arrangements with other parties that have established manufacturing capabilities. It is likely that we will continue to rely on third-party manufacturers for our development and commercial products on a contract basis. Currently, we have agreements with third-party vendors to produce, test, and distribute Zevalin, paclitaxel poliglumex, pixantrone, and brostallicin drug supply for clinical studies. We will be dependent upon these third-party vendors to supply CTI in a timely manner with products manufactured in compliance with cGMPs or similar standards imposed by U.S. and/or foreign regulatory authorities where our products are being developed, tested, and/or marketed.

In December 2007, in connection with our acquisition of Zevalin, we entered into a seventy-eight month supply agreement with Biogen to manufacture Zevalin for sale in the United States pursuant to which we will purchase from Biogen, and Biogen will provide to us, kits to make single doses as part of one treatment to a patient, of either (i) Indium-111 Ibritumomab Tiuxetan (In-111 Zevalin) or (ii) Yttrium-90 Ibritumomab Tiuxetan (Y-90 Zevalin) either as single kits or in packages containing one dose of each of In-111 Zevalin and Y-90 Zevalin, each for sale to end-users in the United States at a cost plus manufacturing price. From the effective date of the supply agreement through June 9, 2014, unless earlier terminated, we have agreed to purchase such kits and/or packages solely from Biogen unless and until both we and Biogen agree to the establishment of a replacement manufacturing source in accordance with the terms and conditions of the Supply Agreement. Each party has agreed to indemnify the other party from and against certain third-party claims related to the manufacture, sale, distribution or use of the goods, as the case may be. We provide rolling forecasts of our supply requirements to Biogen in six-month increments for the next 30 months; however, under the terms of the agreement we are required to purchase a minimum of 150 packages, or 300 kits, for each six-month period in 2008, 2009 and 2010, and a minimum of 250 packages, or 500 kits, for each six month period thereafter until the expiration of the term. Each forecast for the next six months must be accompanied by a firm order, and we may not place orders more frequently than twice a year.

Also in December 2007, in connection with our acquisition of Zevalin, we assumed from Biogen a manufacturing and supply agreement with MDS (Canada) Inc., MDS Nordion Division, or MDS (Canada), pursuant to which MDS (Canada) supplies us with yttrium-90, a radioisotope used in connection with the administration of Zevalin. Under the terms of the agreement, we are required to purchase, and MDS (Canada) is required to manufacture and supply, all of our yttrium-90 requirements for commercial uses of Zevalin. The agreement expires under its current terms in February 2010 and may be terminated by MDS (Canada) at any time without cause on 24 months written notice or by CTI at any time without cause on 6 months written notice.

In September 2001, we entered into a purchase agreement with Natural Pharmaceuticals, Inc., or NPI, to purchase \$6.0 million of paclitaxel, a starting material for paclitaxel poliglumex, which was to be delivered by NPI over several years. This material was intended to be used primarily for research and development activities. We paid for the entire purchase upon execution of the agreement in 2001 and recorded the amount as a prepaid asset. As we had adequate supply of paclitaxel on hand to support our validation campaigns and clinical activities, we amended our supply agreement with NPI in 2005 to reduce the amount of material we would receive and we were refunded \$0.8 million of our prepayment. In addition, the agreement, as amended, granted

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NPI the exclusive right to purchase up to 5 kilograms of our paclitaxel supply at our original cost through September 1, 2007. The amended agreement also allowed NPI the right to sell some or all of the paclitaxel supply to its customers and replace the material within 60 days with newer material having a longer expiration date. In August 2007, we entered into an additional amendment whereby NPI repurchased 3.7 kilograms of our paclitaxel that was in NPI's possession. The amount paid by NPI would offset the cost of 5.3 kilograms of new paclitaxel supply that NPI originally agreed to provide us by November 1, 2007. We received a portion of this new paclitaxel supply in December 2007 and the remaining amount is expected to be delivered by April 2008.

## **Competition**

Competition in the pharmaceutical and biotechnology industries is intense. We face competition from a variety of companies focused on developing oncology drugs. We compete with large pharmaceutical companies and with other specialized biotechnology companies, including but not limited to: Genentech, Biogen Idec, GlaxoSmithKline, Eli Lilly, Cephalon, Genta, Genmab, Favrilite, and Genitope for Zevalin, Bristol-Myers Squibb Co., Aventis, Genentech, OSI Pharmaceuticals, Eli Lilly, American Pharmaceutical Partners, Neopharm Inc., and Telik Inc. for paclitaxel poliglumex and PharmaMar for brostallicin. Many of our existing or potential competitors have substantially greater financial, technical and human resources than us and may be better equipped to develop, manufacture and market products. Smaller companies may also prove to be significant competitors, particularly through collaborative arrangements with large pharmaceutical and established biotechnology companies. Many of these competitors have products that have been approved or are in development and operate large, well-funded research and development programs.

We expect to encounter significant competition for the principal pharmaceutical products we plan to develop. Companies that complete clinical trials, obtain required regulatory approvals and commence commercial sales of their products before us may achieve a significant competitive advantage if their products work through a similar mechanism as our products and if the approved indications are similar. We do not believe competition is as intense among products that treat cancer through novel delivery or therapeutic mechanisms where these mechanisms translate into a clinical advantage in safety and/or efficacy. A number of biotechnology and pharmaceutical companies are developing new products for the treatment of the same diseases being targeted by us. In some instances, such products have already entered late-stage clinical trials or received FDA approval. However, cancer drugs with distinctly different mechanisms of action are often used together in combination for treating cancer, allowing several different products to target the same cancer indication or disease type. Such combination therapy is typically supported by clinical trials that demonstrate the advantage of combination therapy over that of a single-agent treatment.

We believe that our ability to compete successfully will be based on our ability to create and maintain scientifically advanced technology, develop proprietary products, attract and retain scientific personnel, obtain patent or other protection for our products, obtain required regulatory approvals and manufacture and successfully market our products, either alone or through outside parties. We will continue to seek licenses with respect to technology related to our field of interest and may face competition with respect to such efforts.

## **Government Regulation**

The research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing, among other things, of our products are extensively regulated by governmental authorities in the United States and other countries. In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, Public Health Service Act, or PHSA, and their implementing regulations. Failure to comply with applicable U.S. requirements may subject us to administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications or supplemental applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution.

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*Drug and Therapeutic Biologic Approval Process.* None of our drugs or biologic products may be marketed in the United States until such drug or biologic has received FDA approval. The steps required before a drug or biologic may be marketed in the United States include:

preclinical laboratory tests, animal studies and formulation studies;

submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin;

adequate and well-controlled human clinical trials to establish the safety and efficacy of the investigational product for each indication;

submission to the FDA of an NDA or BLA;

satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced, tested, and distributed to assess compliance with cGMPs; and

FDA review and approval of the NDA or BLA.

Preclinical tests include laboratory evaluation of product chemistry, toxicity and formulation, as well as animal studies. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. We cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND.

Clinical trials typically are conducted in three sequential phases, but the phases may overlap or be combined. The study protocol and informed consent information for study subjects in clinical trials must also be approved by an Institutional Review Board for each institution where the trials will be conducted. Study subjects must sign an informed consent form before participating in a clinical trial. Phase I usually involves the initial introduction of the investigational product into people to evaluate its short-term safety, dosage tolerance, metabolism, pharmacokinetics and pharmacologic actions, and, if possible, to gain an early indication of its effectiveness. Phase II usually involves trials in a limited patient population to (i) evaluate dosage tolerance and appropriate dosage, (ii) identify possible adverse effects and safety risks, and (iii) evaluate preliminarily the efficacy of the product candidate for specific indications. Phase III trials usually further evaluate clinical efficacy and test further for safety by using the product candidate in its final form in an expanded patient population. There can be no assurance that phase I, phase II or phase III testing will be completed successfully within any specified period of time, if at all. Furthermore, we or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

The FDA and IND sponsor may agree in writing on the design and size of clinical studies intended to form the primary basis of an effectiveness claim in an NDA or BLA application. This process is known as special protocol assessment, or SPA. These agreements may not be changed after the clinical studies begin, except in limited circumstances. The existence of an SPA, however, does not assure approval of a product candidate.

Assuming successful completion of the required clinical testing, the results of the preclinical studies and of the clinical studies, together with other detailed information, including information on the manufacture and



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composition of the investigational product, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. The testing and approval process requires substantial time, effort and financial resources. Submission of an NDA or BLA requires payment of a substantial review user fee to the FDA. The FDA will review the application and may deem it to be inadequate to support commercial marketing, and we cannot be sure that any approval will be granted on a timely basis, if at all. The FDA may also seek the advice of an advisory committee, typically a panel of clinicians practicing in the field for which the product is intended, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of the advisory committee.

The FDA has various programs, including fast track, priority review and accelerated approval, that are intended to expedite or simplify the process for reviewing drugs and/or provide for approval on the basis of surrogate endpoints. Generally, drugs that may be eligible for one or more of these programs are those for serious or life threatening conditions, those with the potential to address unmet medical needs and those that provide meaningful benefit over existing treatments. We cannot be sure that any of our drugs will qualify for any of these programs, or that, if a drug does qualify, the review time will be reduced or that the product will be approved.

Before approving an NDA or BLA, the FDA usually will inspect the facility or the facilities where the product is manufactured, tested and distributed and will not approve the product unless cGMP compliance is satisfactory. If the FDA evaluates the NDA or BLA and the manufacturing facilities as acceptable, the FDA may issue an approval letter, or in some cases, an approvable letter. An approvable letter contains a number of conditions that must be met in order to secure final approval of the NDA or BLA. When and if those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter. The approval letter authorizes commercial marketing of the drug for specific indications. As a condition of approval, the FDA may require post marketing testing and surveillance to monitor the product's safety or efficacy, or impose other post-approval commitment conditions.

After approval, certain changes to the approved product, such as adding new indications, making certain manufacturing changes or making certain additional labeling claims, are subject to further FDA review and approval. Obtaining approval for a new indication generally requires that additional clinical studies be conducted.

*Post-Approval Requirements.* Holders of an approved NDA or BLA are required to: (i) report certain adverse reactions to the FDA, (ii) comply with certain requirements concerning advertising and promotional labeling for their products, and (iii) continue to have quality control and manufacturing procedures conform to cGMP after approval. The FDA periodically inspects the sponsor's records related to safety reporting and/or manufacturing and distribution facilities; this latter effort includes assessment of compliance with cGMP. Accordingly, manufacturers must continue to expend time, money and effort in the area of production, quality control and distribution to maintain cGMP compliance. We use and will continue to use third-party manufacturers to produce our products in clinical and commercial quantities, and future FDA inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA or BLA, including withdrawal of the product from the market.

Marketing of prescription drugs is also subject to significant regulation through federal and state agencies tasked with consumer protection and prevention of medical fraud, waste and abuse. We must comply with restrictions on off-label use promotion, anti-kickback, ongoing clinical trial registration, and limitations on gifts and payments to physicians. In addition, we have entered into a corporate integrity agreement, or CIA, with the Office of the Inspector General, Health and Human Services, or OIG-HHS, as part of our 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. The CIA, which became effective in December 2007 upon our acquisition of a commercially marketed drug, Zevalin, requires us to establish a compliance committee and compliance program and adopt a formal code of conduct.



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*Non-U.S. Regulation.* Before our products can be marketed outside of the United States, they are subject to regulatory approval similar to that required in the United States, although the requirements governing the conduct of clinical trials, including additional clinical trials that may be required, product licensing, pricing and reimbursement vary widely from country to country. No action can be taken to market any product in a country until an appropriate application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices may not be approved for such product.

In Europe, marketing authorizations may be submitted at a centralized, a decentralized or national level. The centralized procedure is mandatory for the approval of biotechnology products and provides for the grant of a single marketing authorization that is valid in all European Union member states. As of January 1995, a mutual recognition procedure is available at the request of the applicant for all medicinal products that are not subject to the centralized procedure. There can be no assurance that the chosen regulatory strategy will secure regulatory approvals on a timely basis or at all.

## **Environmental Regulation**

In connection with our research and development activities, we are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and wastes. Although we believe that we have complied with these laws, regulations and policies in all material respects and have not been required to take any significant action to correct any noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our research and development involves the controlled use of hazardous materials, including, but not limited to, certain hazardous chemicals and radioactive materials. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources.

## **Employees**

As of December 31, 2007, we employed 230 individuals, including 159 in the United States and 71 in Europe. In the United States, 14 employees hold doctoral degrees while 32 hold doctoral degrees in Europe. Our U.S. employees do not have a collective bargaining agreement. Our European employees are subject to a collective bargaining agreement. We consider our relations with our employees to be good.

Information regarding our executive officers is set forth in Item 10 of this Report, which information is incorporated herein by reference.

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**Item 1a. Risk Factors**

*This annual report on Form 10-K contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks faced by us described below and elsewhere in this annual report on Form 10-K.*

**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 approximately \$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. Approximately \$13.9 million of the net proceeds received from our convertible debt offering 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

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March 19, 2008 we had approximately 59.1 million available under this 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 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.

*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

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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 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

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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. 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 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;



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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 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.

*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

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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



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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.

*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

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corporate integrity agreement with the HHS-OIG that requires us to establish a compliance committee and compliance program and adopt a formal code of conduct. The USAO settlement does not address separate claims brought against the Company by the private party plaintiff in this matter, which generally relate to attorney's fees and employment related claims. In 2007, the United States District Court dismissed the private party plaintiff's employment claims as barred by applicable statutes of limitation, and the private party plaintiff has advised us that he intends to seek a court order awarding approximately \$1 million in attorney's fees. We 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 administration of Zevalin therapy. MDS (Canada) is currently our sole source of Yttrium-90, which must be manufactured and shipped in such a way as to ensure the appropriate potency of the isotope based on its radioactive half-life at the time of administration to the patient is valid. If MDS (Canada) were to have problems with the manufacture or supply of Yttrium-90, our business could be materially impacted, and we may not be able to find an additional supplier of the isotope on acceptable terms or at all. We also rely on Malinckrodt and GE for the manufacture and supply of Indium-111, a radioactive isotope used in the administration of Zevalin diagnostic for clinical purposes. Malinckrodt and GE are currently our two qualified sources of Indium-111, which must be manufactured and shipped in such a way as to ensure the appropriate potency of the isotope based on its radioactive half-life at the time of administration of the diagnostic dose to the patient. If both companies were to have problems with the manufacture or supply of Indium-111, our business could be materially impacted, and we may not be able to find an additional supplier of the isotope on acceptable terms or at all.

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

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

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

If we are successful in bringing 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<sup>®</sup>, 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.

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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,

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.

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

Since our inception in 1991, we have dedicated substantially all of our resources to the research and development of our technologies and related compounds. 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:

be found ineffective or cause harmful side effects during preclinical testing or clinical trials,

fail to receive necessary regulatory approvals,

be difficult to manufacture on a scale necessary for commercialization,

be uneconomical to produce,

fail to achieve market acceptance, or

be precluded from commercialization by proprietary rights of third parties.

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

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

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

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*If any of our license agreements for intellectual property underlying Zevalin, paclitaxel poliglumex, pixantrone, brostallicin, or any other products are terminated, we may lose our rights to develop or market that product.*

We have licensed intellectual property, including patent applications relating to intellectual property for pixantrone, brostallicin and Zevalin. We have also in-licensed the intellectual property for our drug delivery technology relating to paclitaxel poliglumex that uses polymers that are linked to drugs, known as polymer-drug conjugates. Some of our product development programs depend on our ability to maintain rights under these licenses. Each licensor has the power to terminate its agreement with us if we fail to meet our obligations under these licenses. We may not be able to meet our obligations under these licenses. If we default under any license agreements, we may lose our right to market and sell any products based on the licensed technology.

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

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

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

protect trade secrets, and

prevent others from infringing on our proprietary rights.

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

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

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

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

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

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

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

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

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

We will be dependent upon these third parties to supply us in a timely manner with products manufactured in compliance with cGMPs or similar manufacturing standards imposed by US and/or foreign regulatory authorities where our products will be tested and/or marketed. While the FDA and other regulatory authorities maintain oversight for cGMP compliance of drug manufacturers, contract manufacturers may at times violate cGMPs. The FDA and other regulatory authorities may take action against a contract manufacturer who violates cGMPs. One of our products under development, paclitaxel poliglumex, has a complex manufacturing process, which may prevent us from obtaining a sufficient supply of drug product for the clinical trials and commercial activities currently planned or underway on a timely basis, if at all. The active pharmaceutical ingredients and finished products for pixantrone and brostallicin are both manufactured by a single vendor. The drug substance for Zevalin is produced under contract by Biogen and the drug product and finished product is manufactured and distributed at a contract manufacturer and contract distribution facility.

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

We divested our commercial product, TRISENOX, in July 2005 and only acquired a new commercial product, Zevalin, in December 2007. Our ability to generate significant revenues from Zevalin is dependent in part on our ability to find new markets for the product, including through gaining wider acceptance and use of the drug by physicians and through FDA approval of expanded uses for the product. There is no guarantee that we

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will be successful in accomplishing either of these goals. Paclitaxel poliglumex, pixantrone, brostallicin and label expansions for Zevalin are currently in clinical trials and may not be successful. For example, our STELLAR phase III clinical trials for paclitaxel poliglumex for the treatment of non-small cell lung cancer failed to meet their primary endpoints. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in advanced clinical trials, even after reporting promising results in earlier trials. We will need to commit significant time and resources to develop this and additional product candidates. Our product candidates will be successful only if:

our product candidates are developed to a stage that will enable us to commercialize them or sell related marketing rights to pharmaceutical companies;

we are able to commercialize product candidates in clinical development or sell the marketing rights to third parties; and

our product candidates, if developed, are approved by the regulatory authorities.

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

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

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

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

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

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

We may not obtain authorization to permit product candidates that are already in the preclinical development phase to enter the human clinical testing phase. Authorized preclinical or clinical testing may not be completed successfully within any specified time period by us, or without significant additional resources or expertise to those originally expected to be necessary. Many drugs in human clinical trials fail to demonstrate the desired safety and efficacy characteristics. Clinical testing may not show potential products to be safe and efficacious and potential products may not be approved for a specific indication. Further, the results from preclinical studies and early clinical trials may not be indicative of the results that will be obtained in later-stage clinical trials. Data obtained from clinical trials are susceptible to varying interpretations. Government regulators and our collaborators may not agree with our interpretation of our clinical trial results. In addition, we or regulatory authorities may suspend clinical trials at any time on the basis that the participants are being exposed to unacceptable health risks or for other reasons. Completion of clinical trials depends on, among other things,

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

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

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

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

We have entered into collaborative arrangements with third-parties to develop and/or commercialize product candidates and are currently seeking additional collaborations. For example, we entered into an agreement with the Gynecologic Oncology Group to perform a phase III trial of paclitaxel poliglumex in patients with ovarian cancer. Additional collaborations might be necessary in order for us to fund our research and development activities and third-party manufacturing arrangements, seek and obtain regulatory approvals and successfully commercialize our existing and future product candidates. If we fail to enter into additional collaborative arrangements or fail to maintain our existing collaborative arrangements, the number of product candidates from which we could receive future revenues would decline. For example, in 2005 we sold our product TRISENOX to Cephalon and, pursuant to the terms of the purchase agreement under which TRISENOX was sold, we are entitled to receive milestone payments upon the approval by the FDA of new labeled uses for TRISENOX, however, Cephalon may decide not to submit any additional information to the FDA to apply for label expansion of TRISENOX, in which case we would not receive a milestone payment under the agreement.

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

collaborative arrangements may not be on terms favorable to us;

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

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

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

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

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



the terms and conditions of the relevant agreements may no longer be suitable.  
The occurrence of any of these events could adversely affect the development or commercialization of our products.

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

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

*We 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.

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

## Edgar Filing: CELL THERAPEUTICS INC - Form 10-K

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

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

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

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

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

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

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

*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.

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

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

The market price for securities of biopharmaceutical and biotechnology companies, including ours, historically has been highly volatile, and the market from time to time has experienced significant price and volume fluctuations that are unrelated to the operating performance of such companies. For example, during the twelve month period ended March 19, 2008, our stock price, as adjusted to reflect the one-for-four reverse stock split effected in April 2007, has ranged from a low of \$0.47 to a high of \$7.56. Fluctuations in the trading price or liquidity of our common stock may adversely affect the value of your investment in our common stock.

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

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

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

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

our quarterly operating results;

developments or disputes concerning patent or other proprietary rights;

developments in our relationships with collaborative partners;

acquisitions or divestitures;

litigation and government proceedings;

adverse legislation, including changes in governmental regulation;

third-party reimbursement policies;

changes in securities analysts' recommendations;

changes in health care policies and practices;

economic and other external factors; and

general market conditions.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted. For example, in the case of our company, beginning in March 2005, several class action lawsuits were instituted against CTI and certain directors and officers of CTI and a derivative action lawsuit was filed against CTI's full board of directors. While these lawsuits were dismissed with prejudice, as a result of these types of lawsuits, we could incur substantial legal fees and our management's attention and resources could be diverted from operating our business as we respond to the litigation. We maintain significant insurance to cover these risks for the Company and our directors and officers, but our insurance is subject to high deductibles to reduce premium expense, and there is no guarantee that the

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insurance will cover any specific claim that we may face in the future, or that it will be adequate to cover all potential liabilities and damages.

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

Our common stock is listed on the Nasdaq Global Market. The Nasdaq Global Market has several quantitative and qualitative requirements companies must comply with to maintain this listing, including a \$1.00 minimum bid price per share and \$50 million minimum value of listed securities. As of March 20, 2008, our common stock had a closing bid price below \$1.00 for 13 consecutive days. If our closing bid price remains below \$1.00 for 30 consecutive days, under the current Nasdaq Global Market rules we will have a period of 180 days to attain compliance by again meeting the \$1.00 minimum bid price. We would then have the option to transfer to the Nasdaq Capital Market, assuming we meet all other initial listing qualifications for the Nasdaq Capital Market, where we can receive an additional 180 days to regain compliance. If we are unable to attain compliance with the minimum bid price we may be delisted. In addition, if we fail to maintain the minimum value of listed securities, we may have to transfer to the Nasdaq Capital Market or may be delisted. The level of trading activity of our common stock may decline if it is no longer listed on the Nasdaq Global Market or Nasdaq Capital Market. Furthermore, our failure to maintain a listing on the Nasdaq market may constitute an event of default under certain of our indebtedness which would accelerate the maturity date of such date. As such, if our

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common stock ceases to be listed for trading on the Nasdaq Global Market or Nasdaq Capital Market for any reason, it may harm our stock price, increase the volatility of our stock price and make it more difficult for investors to sell shares of our common stock.

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

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

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

elimination of cumulative voting in the election of directors;

procedures for advance notification of shareholder nominations and proposals;

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

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

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

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

### **Item 1b. Unresolved Staff Comments**

None.

### **Item 2. Properties**

During 2007, we leased approximately 68,000 square feet of lab and office space at 201 Elliott Avenue West in Seattle, Washington; however, that lease expired in January 2008 and we did not renew it. We had entered into subleases for approximately 38,000 square feet of this space which also expired in January 2008 and had vacated the remaining space. We also lease approximately 77,000 square feet of space at 501 Elliott Avenue West in Seattle, Washington under an amended lease for our executive offices and administrative operations which expires in July 2012. In addition, for our European offices, we lease approximately 62,000 square feet of office and laboratory space in Bresso (Milan), Italy. The leases expire in 2010 and 2013. Our wholly owned subsidiary SM, acquired in July 2007, leases approximately 5,100 square feet of office and laboratory space in Tucson and Scottsdale, Arizona with the latest lease expiration date of 2012. Our majority owned subsidiary Aequus Biopharma, Inc. leases approximately 750 feet of office space on Bainbridge Island, Washington which will expire in 2008. We believe our existing and planned facilities are adequate to meet our present requirements. We anticipate that additional space will be available, when needed, on commercially reasonable terms.

### **Item 3. Legal Proceedings**

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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). Pursuant to this settlement agreement, we made a single payment of \$10.6 million to the USAO, which included a settlement amount of \$10.5 million and interest



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accrued on that amount since the date of reaching an agreement in principle, in return for a release of all government claims in connection with a qui tam action brought by a private plaintiff and related matters. In addition, in connection with this settlement we entered into a Corporate Integrity Agreement with the Office of the Inspector General, Health and Human Services which became effective when we acquired Zevalin in December 2007. The settlement agreement does not address separate claims brought against the Company by the private party plaintiff in such matters, which generally relate to attorneys' fees and employment related claims. The private party plaintiff's wrongful termination claims have been dismissed by the federal district court with prejudice. As of December 31, 2006, \$10.5 million related to the USAO litigation matter was included in *accrued expenses*. As of March 31, 2007, this amount was increased by approximately \$0.1 million to \$10.6 million. We made the settlement payment of \$10.6 million in April 2007.

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, seeking recovery of damages, including losses incurred by the Company in connection with our above referenced 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 January 2, 2008, Tang Capital Partners LP, or 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 that was executed by CTI 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.

In addition to the litigation discussed above, we are from time to time subject to legal proceedings and claims arising in the ordinary course of business, some of which may be covered in whole or in part by insurance.

**Item 4. Submission of Matters to a Vote of Security Holders**

Not applicable.

**Table of Contents****PART II****Item 5. Market for Registrant's Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities**

Our common stock is traded on the Nasdaq Global Market under the symbol "CTIC", and effective January 2, 2004, we commenced the trading of our common stock on MTA (formerly known as the MTAX and, prior to that, as the Nuovo Mercato) in Italy, also under the ticker symbol

CTIC. The following table sets forth, for the periods indicated, the high and low reported sales prices per share of the common stock as reported on the Nasdaq National Market, our principal trading market (as adjusted to reflect the one-for-four reverse stock split effect in April 2007).

	High	Low
<b>2006</b>		
First Quarter	9.36	7.16
Second Quarter	8.08	5.24
Third Quarter	10.12	4.48
Fourth Quarter	7.80	5.68
<b>2007</b>		
First Quarter	7.24	5.64
Second Quarter	7.56	2.85
Third Quarter	4.97	3.00
Fourth Quarter	3.89	1.59

On March 19, 2008, the last reported sale price of our common stock on the Nasdaq Global Market was \$0.48 per share. As of March 19, 2008, there were approximately 276 shareholders of record of our common stock.

**Dividend Policy**

We have never declared or paid any cash dividends on our common stock and do not currently anticipate declaring or paying cash dividends on our common stock in the foreseeable future. Except for dividends payable on the Series A 3% Convertible Preferred Stock, the Series B 3% Convertible Preferred Stock, the Series C 3% Convertible Preferred Stock and Series D 7% Convertible Preferred Stock, we currently intend to retain all of our future earnings, if any, to finance operations. Any future determination relating to our dividend policy will be made at the discretion of our board of directors and will depend on a number of factors, including future earnings, capital requirements, financial conditions, future prospects, contractual restrictions and other factors that our board of directors may deem relevant.

**Sales of Unregistered Securities**

Not Applicable.

**Stock Repurchases in the Fourth Quarter**

Not Applicable.

**Table of Contents****Equity Compensation Plan Information**

The following table gives information about our common stock that may be issued upon the exercise of options, warrants and rights under all of our existing compensation plans as of December 31, 2007, including the 2007 Equity Incentive Plan, Novuspharma S.p.A. Stock Option Plan, 1994 Equity Incentive Plan and the 2007 Employee Stock Purchase Plan.

<b>Plan Category</b>	<b>(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights</b>	<b>(b) Weighted Average Exercise Price of Outstanding Options, Warrants, and Rights</b>	<b>(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))</b>	<b>(d) Total of Securities Reflected in Columns (a) and (c)</b>
Plans Approved by Shareholders	2,181,802(1)	\$ 26.24	2,773,974(2)	4,995,776
Plan Not Approved by Shareholders(3)	50,180	\$ 12.05	None	50,180

- (1) Consists of the 2007 Equity Incentive Plan and the 1994 Equity Incentive Plan.
- (2) Consists of 2,523,974 shares available for future issuance under the 2007 Equity Incentive Plan and 250,000 shares available for future issuance under the 2007 Employee Stock Purchase Plan.
- (3) Consists of the Novuspharma S.p.A. Stock Option Plan adopted in connection with the merger between CTI and Novuspharma which expired on December 31, 2006.

**Table of Contents****Stock Performance Graph**

	<b>3/31/03</b>	<b>6/30/03</b>	<b>9/30/03</b>	<b>12/31/03</b>
Cell Therapeutics, Inc.	\$ 114.03	\$ 134.25	\$ 155.71	\$ 119.26
Nasdaq Stock Index (U.S.)	\$ 100.60	\$ 121.29	\$ 133.54	\$ 149.52
Nasdaq Pharmaceutical Index	\$ 108.26	\$ 135.78	\$ 143.39	\$ 146.59
	<b>3/31/04</b>	<b>6/30/04</b>	<b>9/30/04</b>	<b>12/31/04</b>
Cell Therapeutics, Inc.	\$ 116.37	\$ 101.38	\$ 94.36	\$ 111.97
Nasdaq Stock Index (U.S.)	\$ 148.48	\$ 152.89	\$ 141.87	\$ 162.72
Nasdaq Pharmaceutical Index	\$ 153.01	\$ 151.35	\$ 144.75	\$ 156.13
	<b>3/31/05</b>	<b>6/30/05</b>	<b>9/30/05</b>	<b>12/31/05</b>
Cell Therapeutics, Inc.	\$ 49.38	\$ 37.28	\$ 39.34	\$ 29.99
Nasdaq Stock Index (U.S.)	\$ 149.48	\$ 154.54	\$ 161.93	\$ 166.18
Nasdaq Pharmaceutical Index	\$ 137.11	\$ 143.60	\$ 168.80	\$ 171.93
	<b>3/31/06</b>	<b>6/30/06</b>	<b>9/30/06</b>	<b>12/31/06</b>
Cell Therapeutics, Inc.	\$ 26.27	\$ 19.81	\$ 23.52	\$ 24.07
Nasdaq Stock Index (U.S.)	\$ 176.27	\$ 164.33	\$ 170.76	\$ 182.57
Nasdaq Pharmaceutical Index	\$ 176.58	\$ 157.97	\$ 165.05	\$ 168.28
	<b>3/31/07</b>	<b>6/30/07</b>	<b>9/30/07</b>	<b>12/31/07</b>
Cell Therapeutics, Inc.	\$ 21.87	\$ 10.49	\$ 12.62	\$ 6.46
Nasdaq Stock Index (U.S.)	\$ 182.84	\$ 195.89	\$ 202.11	\$ 197.98
Nasdaq Pharmaceutical Index	\$ 164.68	\$ 171.94	\$ 180.03	\$ 176.97

**Table of Contents****Item 6. Selected Consolidated Financial Data**

The data set forth below should be read in conjunction with Item 7. Management's Discussion and Analysis of Consolidated Financial Condition and Results of Operations and the Consolidated Financial Statements and Notes thereto appearing at Item 8 of this report.

	Year ended December 31,				
	2007	2006	2005	2004	2003
	(In thousands, except per share data)				
<b>Consolidated Statements of Operations Data:</b>					
Revenues:					
Product sales	\$ 47	\$	\$ 14,599	\$ 26,626	\$ 22,105
License and contract revenue	80	80	1,493	2,968	2,660
<b>Total revenues</b>	<b>127</b>	<b>80</b>	<b>16,092</b>	<b>29,594</b>	<b>24,765</b>
Operating expenses:					
Cost of product sold	49		518	1,104	840
Research and development	72,019	61,994	68,767	101,127	89,534
Selling, general and administrative	35,316	35,303	61,717	78,522	55,641
Acquired in-process research and development(1)	24,615			87,375	
Amortization of purchased intangibles	913	792	1,254	2,294	1,335
Restructuring charges and related asset impairments(2)	201	591	12,780		
Gain on divestiture of TRISENOX(3)			(71,211)		
<b>Total operating expenses</b>	<b>133,113</b>	<b>98,680</b>	<b>73,825</b>	<b>270,422</b>	<b>147,350</b>
<b>Loss from operations</b>	<b>(132,986)</b>	<b>(98,600)</b>	<b>(57,733)</b>	<b>(240,828)</b>	<b>(122,585)</b>
Other income (expense):					
Investment and other income	2,430	2,866	2,588	1,636	1,880
Interest expense	(12,517)	(19,829)	(16,546)	(10,988)	(9,326)
Foreign exchange gain (loss)	4,657	1,877	8	(2,118)	
Make-whole interest expense	(2,310)	(24,753)	(1,013)		
Debt conversion expense			(23,608)		
Gain on derivative liabilities	3,672	6,024	236		
Gain (loss) on exchange of convertible notes	(972)	7,978			
Settlement expense	(160)	(11,382)			
Loss on extinguishment of royalty obligation			(6,437)		
<b>Loss before minority interest</b>	<b>(138,186)</b>	<b>(135,819)</b>	<b>(102,505)</b>	<b>(252,298)</b>	<b>(130,031)</b>
Minority interest in net loss of subsidiary	78				
<b>Net loss</b>	<b>\$ (138,108)</b>	<b>\$ (135,819)</b>	<b>\$ (102,505)</b>	<b>\$ (252,298)</b>	<b>\$ (130,031)</b>
Preferred stock beneficial conversion feature	(9,549)				
Preferred stock dividends	(648)				
<b>Net loss attributable to common shareholders</b>	<b>\$ (148,305)</b>	<b>\$ (135,819)</b>	<b>\$ (102,505)</b>	<b>\$ (252,298)</b>	<b>\$ (130,031)</b>
<b>Basic and diluted net loss per common share(4)</b>	<b>\$ (3.27)</b>	<b>\$ (4.84)</b>	<b>\$ (6.35)</b>	<b>\$ (18.67)</b>	<b>\$ (15.57)</b>
<b>Shares used in calculation of basic and diluted net loss per common share</b>	<b>45,292</b>	<b>28,070</b>	<b>16,138</b>	<b>13,513</b>	<b>8,354</b>



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	2007	2006	December 31, 2005 (In thousands)	2004	2003
<b>Consolidated Balance Sheets Data:</b>					
Cash and cash equivalents, securities available-for-sale and interest receivable	\$ 18,392	\$ 54,407	\$ 69,067	\$ 116,020	\$ 92,838
Restricted cash(5)			25,596		
Working capital	(30,909)	30,166	76,288	93,813	71,898
Total assets	73,513	101,821	155,440	184,996	146,090
7.5% Convertible senior notes(6)	32,220	48,186			
6.75% Convertible senior notes(7)	6,922	6,945	79,046		
5.75% Convertible senior notes(8)	23,287				
5.75% Convertible senior subordinated notes(9)	16,907	27,407	66,929	85,459	85,459
4.0% Convertible senior subordinated notes(10)	55,150	55,150	55,150	75,000	75,000
5.75% Convertible subordinated notes(11)	2,910	28,490	29,640	29,640	29,640
Series A 3% Convertible preferred stock	5,188				
Series B 3% Convertible preferred stock	11,881				
Series C 3% Convertible preferred stock	6,229				
Series D 7% Convertible preferred stock	2,938				
Royalty obligation				25,123	
Other long-term obligations, less current portion	9,879	4,667	7,326	6,363	5,012
Accumulated deficit	(1,109,413)	(961,108)	(825,289)	(722,784)	(470,486)
Total shareholders' deficit	(134,125)	(101,604)	(107,097)	(70,708)	(82,542)

- (1) The 2007 amount represents the value of SM's and Zevalin's purchased technology which had not reached technological feasibility at the time of the acquisitions. Acquired IPRD for SM was \$21.4 million and was related to brostallicin. Acquired IPRD for Zevalin was \$3.2 million related to label expansions for indications not approved by the FDA. The 2004 amount represents the value of Novuspharma's research and development projects and technologies which had no alternative use and which had not reached technological feasibility as of January 1, 2004, the effective date of the merger between CTI and Novuspharma.
- (2) The 2005 amount represents costs related to our 2005 restructuring activities which includes excess facilities charges of \$7.1 million, employee separation costs of \$3.5 million, lease termination payments of \$1.2 million and restructuring related asset impairment charges of \$1.0 million. The 2007 and 2006 balances represent adjustments to these amounts.
- (3) Amount represents the gain recognized on the divestiture of TRISENOX and certain proteasome assets to Cephalon as well as transition services provided to Cephalon related to TRISENOX and proteasome assets.
- (4) See Notes 1 and 16 of Notes to Consolidated Financial Statements for a description of the computation of the number of shares and net loss per share.
- (5) The 2005 amount represents approximately \$24.6 million held in escrow to fund potential redemptions of up to 30% of the aggregate amount of our 6.75% convertible senior notes and approximately \$1.0 million held in connection with the liquidation of Cell Therapeutics (Ireland) Holding Limited.
- (6) The 7.5% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 119.6298 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of approximately \$8.36 per share. The 2006 amount includes \$2.3 million which is included in *current portion of derivative liability*.
- (7) The 6.75% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 95.0925 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of approximately \$10.52 per share.
- (8) The 5.75% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 333.33 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of approximately \$3.00 per share.
- (9) The 5.75% convertible senior subordinated notes are convertible into shares of CTI common stock at a conversion rate of 25 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of \$40.00 per share.
- (10) The 4.0% convertible senior subordinated notes are convertible into shares of CTI common stock at a conversion rate of 18.5185 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of approximately \$54.00 per share.
- (11) The 5.75% convertible subordinated notes are convertible into shares of CTI common stock at a conversion rate of 7.353 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of approximately \$136.00 per share.

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**Table of Contents****Item 7. Management's Discussion and Analysis of Consolidated Financial Condition and Results of Operations**

The following discussion should be read in conjunction with the Selected Consolidated Financial Data and the Consolidated Financial Statements and the related Notes included in Items 6 and 8 of this Form 10-K. The following discussion contains forward-looking statements that involve risks and uncertainties. Such statements, which include statements concerning product sales, research and development expenses, selling, general and administrative expenses, additional financings and additional losses, are subject to risks and uncertainties, including, but not limited to, those discussed below and elsewhere in this Form 10-K, particularly in Item 1A Risk Factors that could cause actual results to differ significantly from those projected. Although we believe that expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. We do not intend to update any of the forward-looking statements after the date of this Form 10-K to conform these statements to actual results or changes in our expectations. Readers are cautioned not to place undue reliance on these forward-looking statements, which apply only as of the date of this Form 10-K.

**Overview**

We develop, acquire and commercialize novel treatments for cancer. Our goal is to build a leading biopharmaceutical company with a diversified portfolio of proprietary cancer drugs. Our research and in-licensing activities are concentrated on identifying new, less toxic and more effective ways to treat cancer. As of December 31, 2007, we had incurred aggregate net losses of approximately \$1.1 billion since inception. We expect to continue to incur operating losses for at least the next couple of years.

In December 2007, we acquired 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 is the first U.S. Food and Drug Administration, or FDA, approved radioimmunotherapy and was approved in 2002 to treat patients with relapsed or refractory low-grade, follicular, or B-cell NHL, including patients with Rituximab-refractory follicular 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, CTI entered into a seventy-eight month supply agreement with Biogen to manufacture Zevalin for sale in the United States. CTI made an upfront payment to Biogen of \$10.1 million at the time of closing and is also responsible for up to \$20 million in contingent milestone payments based on positive trial outcomes and FDA approval for label expansion. CTI is also obligated to make additional royalty payments based on net sales of Zevalin.

In July 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.

In September 2006, we entered into an exclusive worldwide licensing agreement with Novartis International Pharmaceutical Ltd., or Novartis, for the development and commercialization of paclitaxel poliglumex. Total product registration and sales milestones due from Novartis for paclitaxel poliglumex under the agreement could reach up to \$270 million. The agreement also provides Novartis with an option to develop and commercialize pixantrone based on agreed terms. If Novartis exercises its option on pixantrone under certain conditions, Novartis would pay CTI a \$7.5 million license fee, up to \$104 million in registration and sales related milestones and a royalty on pixantrone worldwide net sales as well as reimbursement for certain expenses.



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On July 18, 2005, we completed the divestiture of TRISENOX<sup>®</sup> (arsenic trioxide), an anti-cancer compound, and certain proteasome assets to Cephalon Inc., or Cephalon. Proceeds from the divestiture, net of broker fees, were approximately \$71.9 million which includes proceeds received from transition services provided. In addition, in the future we may potentially receive up to an additional \$100 million if Cephalon is successful in achieving certain sales and development milestones, although achievement of such milestones is uncertain.

In December 2004, we entered into a royalty interest financing arrangement with PharmaBio for \$25.0 million in financing and \$5.0 million in services to be provided by PharmaBio and its affiliates and paid by PharmaBio. Upon the divestiture of TRISENOX, we made a payment to PharmaBio of \$39.4 million from the proceeds received from the divestiture, terminating our obligations under the financing agreement with PharmaBio. PharmaBio's obligation to provide to us the remainder of the \$5.0 million in services survived the termination of our obligations, which has been provided in full as of December 31, 2007.

On January 1, 2004, we completed our merger with Novuspharma S.p.A., a public biopharmaceutical company located in Italy, which is now our European branch. This merger provided us with worldwide rights to pixantrone, approximately \$92.5 million of cash and cash equivalents upon closing of the acquisition, and a drug discovery organization and staff with an extensive track record in cancer drug development. The merger, including the addition of pixantrone to our pipeline, is consistent with our strategy of growth by strategic acquisition and our goal to develop improved cancer therapies.

## **Critical Accounting Policies and Estimates**

Management makes certain judgments and uses certain estimates and assumptions when applying accounting principles generally accepted in the United States in the preparation of our consolidated financial statements. We evaluate our estimates and judgments on an on-going basis and base our estimates on historical experience and on assumptions that we believe to be reasonable under the circumstances. Our experience and assumptions form the basis for our judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may vary from what we anticipate and different assumptions or estimates about the future could change our reported results. We believe the following accounting policies are the most critical to us, in that they are important to the portrayal of our consolidated financial statements and require our most difficult, subjective or complex judgments in the preparation of our consolidated financial statements.

### *Product Sales*

We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, title has passed and delivery has occurred, the price is fixed and determinable, and collectability is reasonably assured. Product sales are generally recorded upon shipment net of an allowance for estimated product returns and rebates. We analyze historical returns patterns for our products in determining an appropriate estimate for returns allowance. We may need to adjust our estimates if actual results vary which could have an impact on our earnings in the period of adjustment. If customers have product acceptance rights or product return rights, and we are unable to reasonably estimate returns related to that customer or market, we defer revenue recognition until such rights have expired. Our 2007 product sales relate to Zevalin which was acquired from Biogen in December 2007. Our 2005 product sales relate to TRISENOX which was sold to Cephalon in July 2005.

### *License and Contract Revenue*

We may generate revenue from technology licenses, collaborative research and development arrangements, cost reimbursement contracts and research grants. Revenue under technology licenses and collaborative agreements typically consists of nonrefundable and/or guaranteed technology license fees, collaborative research funding, and various milestone and future product royalty or profit-sharing payments.

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Revenue associated with up-front license fees and research and development funding payments under collaborative agreements is recognized ratably over the relevant periods specified in the agreement, generally the research and development period. If the time period is not defined in the agreement, we calculate the revenue recognition period based on our current estimate of the research and development period considering experience with similar projects, level of effort and the stage of development. Should there be a change in our estimate of the research and development period, we will revise the term over which the initial payment is recognized. Revenue from substantive at-risk milestones and future product royalties is recognized as earned based on the completion of the milestones and product sales, as defined in the respective agreements. Revenue under cost reimbursement contracts and research grants is recognized as the related costs are incurred. Payments received in advance of recognition as revenue are recorded as deferred revenue.

We evaluate multiple element arrangements pursuant to Emerging Issues Task Force, or EITF, 00-21, *Revenue Arrangements with Multiple Deliverables*. For multiple element arrangements that have continuing performance obligations, we recognize contract, milestone or license fees together with any up-front payments over the term of the arrangement as we complete our performance obligation, unless the delivered technology has stand alone value to the customer and there is objective, reliable evidence of fair value of the undelivered element in the arrangement. Additionally, pursuant to the guidance of Securities and Exchange Commission Staff Accounting Bulletin 104, or SAB, No. 104, unless evidence suggests otherwise, revenue from consideration received is recognized on a straight-line basis over the expected term of the arrangement.

### *Impairment of Long-lived Assets*

We review our long-lived assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Each impairment test is based on a comparison of the undiscounted future cash flows to the recorded value of the asset. If an impairment is indicated, the asset is written down to its estimated fair value based on quoted fair market values.

### *Valuation of Goodwill*

In accordance with Statement of Financial Accounting Standards, or SFAS, No. 142, *Goodwill and Other Intangible Assets*, we review goodwill for impairment annually and whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Goodwill is tested for impairment by comparing the fair value of our single reporting unit to its carrying value. Our estimate of fair value is based on our current market capitalization. If the implied fair value of goodwill is less than its carrying value, an impairment charge would be recorded.

### *Restructuring of Debt Securities*

We evaluate whether modifications or exchanges of existing debt instruments result in substantial changes as defined by EITF 96-19, *Debtor's Accounting for a Modification or Exchange of Debt Instruments*. We use the assistance of independent valuation consultants in these determinations and to estimate the fair value of the original and modified or exchanged debt instruments as part of our evaluation. Different judgments could yield different results. If we determine that a substantial change has occurred with respect to the modifications or exchanges, we treat the transaction as an extinguishment of the original debt and recognize a gain or loss on the transaction.

### *Derivatives Embedded in Certain Debt Securities*

We evaluate financial instruments for freestanding or embedded derivatives in accordance with SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, and related guidance. Derivative instruments are recorded at fair value with changes in value recognized in the period of change.

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Our 6.75% convertible senior notes, or 6.75% notes, and our 7.5% convertible senior notes, or 7.5% notes, contain certain features providing for payments in cash or common stock to be made in the event of certain conversions or repurchases of the debt. In the event of any conversion of our 6.75% notes to common stock, the feature calls for make-whole payments equal to the interest on the debt over its term less any amounts paid prior to the date of the conversion. Our 7.5% notes include a feature that calls for make-whole payments in the event of automatic conversion or if the holder requires us to repurchase the notes upon certain non-stock changes in control. This payment is equal to \$225 per \$1,000 principal amount of the notes less any interest amounts paid prior to the date of conversion or repurchase.

These make-whole features represent embedded derivatives which are required to be accounted for separately from the related debt securities. The fair value of the derivative for the 6.75% notes is calculated based on a discounted cash flow model. The fair value of the derivative related to the 7.5% notes is calculated using a Monte Carlo simulation model that incorporates factors such as the current price of our common stock, its volatility, and time to expiration of the make-whole feature. As of December 31, 2006, we determined that we would make additional discretionary make-whole payments to certain investors in 2007. These additional payments constitute modifications to the terms of the agreement and have been included in the valuation model. The value of these payments as of December 31, 2006 were recorded in *current portion of derivative liability*. Changes in the estimated fair value of the liabilities are included in *gain on derivative liabilities* and will be required until the relevant feature expires or all of the relevant notes are converted or repurchased.

The interest make-whole provision of the 5.75% convertible senior notes represents an embedded derivative. At the issuance of the 5.75% notes, no value was assigned to the fair value of the interest make-whole feature.

*Purchase price allocation*

Based on the provisions of SFAS No. 141, *Business Combinations*, the purchase price for our acquisitions is allocated to the tangible and identifiable intangible assets acquired and liabilities assumed based on their estimated fair values at the acquisition date. For each acquisition, we engage an independent third-party valuation firm to assist in determining the fair value of in-process research and development and identifiable intangible assets. Such a valuation requires significant estimates and assumptions including but not limited to: determining the timing and expected costs to complete the in-process projects, projecting regulatory approvals, estimating future cash flows from product sales resulting from in-process projects, and developing appropriate discount rates and probability rates by project. We believe the fair values assigned to the assets acquired and liabilities assumed are based on reasonable assumptions. However, these assumptions may be inaccurate, and unanticipated events and circumstances may occur.

*Restructuring Charges*

We have recorded charges in connection with our restructuring activities in 2005, including estimates pertaining to employee separation costs, the related abandonment of excess facilities and impairment of fixed assets, and certain contract termination costs. Restructuring charges are recorded in accordance with SFAS 146, *Accounting for Costs Associated with Exit or Disposal Activities*. The recognition of restructuring charges requires management to make certain judgments regarding the nature, timing and amount associated with the planned restructuring activities. At the end of each reporting period, we evaluate the appropriateness of the remaining accrued balances.

*Stock-Based Compensation Expense*

On January 1, 2006, we adopted Financial Accounting Standards Board, or FASB, Statement No. 123(R), *Share-Based Payment (Revised 2004)*, or SFAS 123(R), which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors including employee stock options, share awards, and employee stock purchases related to the Employee Stock Purchase Plan based

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on estimated fair values. Prior to January 1, 2006, we accounted for share-based payments under the recognition and measurement provisions of Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, or APB 25, and related interpretations, as permitted by FASB Statement No. 123, *Accounting for Stock-Based Compensation*, or SFAS 123. In accordance with APB 25, no compensation cost was required to be recognized for options granted that had an exercise price equal to the market value of the underlying common stock on the date of grant. We adopted SFAS 123(R) using the modified-prospective transition method, which required the application of the accounting standard as of January 1, 2006, the first day of our fiscal year 2006.

The risk-free interest rate used in the Black-Scholes valuation method is based on the implied yield currently available in U.S. Treasury securities at maturity with an equivalent term. We have not declared or paid any dividends on our common stock and do not currently expect to do so in the future. The expected term of options represents the period that our stock-based awards are expected to be outstanding and was determined based on historical weighted average holding periods and projected holding periods for the remaining unexercised shares. Consideration was given to the contractual terms of our stock-based awards, vesting schedules and expectations of future employee behavior. Expected volatility is based on the annualized daily historical volatility, including consideration of the implied volatility and market prices of traded options for comparable entities within our industry.

Our stock price volatility and option lives involve management's best estimates, both of which impact the fair value of the option calculated under the Black-Scholes methodology and, ultimately, the expense that will be recognized over the life of the option. SFAS 123(R) also requires that we recognize compensation expense for only the portion of options expected to vest. Therefore, we applied an estimated forfeiture rate that we derived from historical employee termination behavior. If the actual number of forfeitures differs from our estimates, additional adjustments to compensation expense may be required in future periods.

## **Results of Operations**

*Years ended December 31, 2007 and 2006.*

*Product sales.* Product sales for the year ended December 31, 2007 relates to Zevalin, our commercial product acquired from Biogen in December 2007 and approved by the FDA to treat patients with relapsed or refractory low-grade, follicular, or B-cell NHL. There were no product sales during the comparable period in 2006.

*License and contract revenue.* License and contract revenue for the year ended December 31, 2007 and 2006 represents recognition of deferred revenue from the sale of Lisofylline material to Diakine.

*Cost of product sold.* Cost of product sold for the year ended December 31, 2007 relates to sales of Zevalin subsequent to its acquisition in December 2007 and consists primarily of contractual royalties on product sales in addition to cost of product sold to customers. Inventory management fees as well as shipping and handling costs are also included in cost of product sold. There was no cost of product sold for the year ended December 31, 2006 as there were no product sales during this period.

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*Research and development expenses.* Our research and development expenses for compounds under development and discovery research are as follows (in thousands):

	2007	2006
Compounds under development:		
Paclitaxel poliglumex	\$ 20,751	\$ 24,722
Pixantrone	16,630	10,404
Brostallicin	4,205	
Other compounds	721	848
Operating expenses	27,391	24,545
Discovery research	2,321	1,475
 Total research and development expenses	 \$ 72,019	 \$ 61,994

Costs for compounds under development include external direct expenses such as principal investigator fees, clinical research organization charges and contract manufacturing fees incurred for preclinical, clinical, manufacturing and regulatory activities associated with preparing the compounds for submissions of NDAs or similar regulatory filings to the FDA, EMEA or other regulatory agencies outside the United States and Europe. Operating costs include our personnel and occupancy expenses associated with developing these compounds. Discovery research costs include primarily personnel, occupancy and laboratory expenses associated with the discovery and identification of new drug targets and lead compounds. We do not allocate operating costs to the individual compounds under development as our accounting system does not track these costs by individual compound. As a result, we are not able to capture the total cost of each compound. Direct external costs incurred to date for paclitaxel poliglumex, pixantrone and brostallicin are approximately \$213.2 million, \$40.5 million and \$4.2 million, respectively. Costs for pixantrone prior to our merger with Novuspharma S.p.A, a public pharmaceutical company located in Italy in January 2004 are excluded from this amount. Costs for brostallicin prior to our acquisition of SM on July 31, 2007 are also excluded from this amount.

Research and development expenses increased to approximately \$72.0 million for the year ended December 31, 2007, from approximately \$62.0 million for the year ended December 31, 2006. Costs for our paclitaxel poliglumex program decreased primarily due to reduced costs associated with our PIONEER trial which was suspended and closed in the fourth quarter of 2006. This decrease was partially offset by start-up costs associated with our PGT307 trial as well as an increase in manufacturing costs. Pixantrone costs increased primarily due to start-up costs associated with our PIX303 trial, as well as an increase in costs associated with our RAPID trial, mainly due to an increase in patient enrollment and costs for comparator drug. In early 2008, we closed enrollment on the RAPID trial based on adequate sample size to demonstrate differences in cardiac events and other clinically relevant side effects between pixantrone and doxorubicin. We also closed the PIX303 trial 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 substantial investments in alternative indications for pixantrone as well as the changing competitive landscape in the second line follicular NHL. These increases in pixantrone costs were partially offset by a decrease in costs associated with our EXTEND trial primarily related to a reduction in contract research organization costs and investigator fees due to a decrease in patient enrollment. Costs incurred for brostallicin resulted from our acquisition of SM in July 2007 and primarily relate to a license payment due under a development agreement, as well as an increase in clinical development activities related to phase I and phase II studies. Operating expenses increased primarily due to an increase in personnel costs.

Our lead drug candidates, paclitaxel poliglumex, pixantrone and brostallicin are currently in clinical trials and we are developing Zevalin for additional indications. Many drugs in human clinical trials fail to demonstrate the desired safety and efficacy characteristics. Even if our drugs progress successfully through initial human testing, they may fail in later stages of development. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in advanced clinical trials, even after reporting promising results

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in earlier trials. Regulatory agencies, including the FDA and EMEA, regulate many aspects of a product candidate's life cycle, including research and development and preclinical and clinical testing. We or regulatory authorities may suspend clinical trials at any time on the basis that the participants are being exposed to unacceptable health risks. Completion of clinical trials depends on, among other things, the number of patients available for enrollment in a particular trial, which is a function of many factors, including the availability and proximity of patients with the relevant condition. We rely on third parties to conduct clinical trials, which may result in delays or failure to complete trials if the third parties fail to perform or meet applicable standards. Many of our drug candidates are still in research and preclinical development, which means that they have not yet been tested on humans. We will need to commit significant time and resources to develop these and additional product candidates.

Our products will be successful only if:

our product candidates are developed to a stage that will enable us to commercialize, sell, or license related marketing rights to third parties;

our product candidates, if developed, are approved.

We will be dependent on the successful completion of these goals in order to generate revenues. The failure to generate such revenues may preclude us from continuing our research and development of these and other product candidates. We also enter into collaboration agreements for the development and commercialization of our product candidates. We cannot control the amount and timing of resources our collaborators devote to product candidates, which may also result in delays in the development or marketing of products.

Because of these risks and uncertainties, we cannot accurately predict when or whether we will successfully complete the development of our product candidates or the ultimate product development cost. We reported paclitaxel poliglumex STELLAR 3 clinical trial results in March 2005 and STELLAR 2 and 4 results in May 2005, all of which missed their primary endpoints of superior overall survival. We have recently submitted an MAA for paclitaxel poliglumex in the EU 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, however, we do not expect to receive a decision regarding approval of the MAA from the EMEA prior to the second half of 2009. If we do receive approval of that MAA in 2009, we would expect to receive cash inflows in 2009 from sales of the product or through collaborative agreements.

Due to the acquisition of Zevalin, we expect to incur additional costs associated with the implementation of sales and marketing support of Zevalin. In addition, we intend to negotiate with Bayer Schering, which holds the rights to Zevalin outside the United States, for access to their recently published results of their Phase III first line indolent trial of Zevalin, known as the FIT trial, which we do not currently have any rights to use or access. If we are not successful with that negotiation, or if the results of the FIT trial prove to be inadequate for us to submit a supplemental biologics license application, or sBLA, for expanded approved indications of Zevalin, we will need to perform additional clinical trials of our own in order to seek label expansions of Zevalin. We expect to incur additional costs related to obtaining those rights from Bayer Schering and/or the additional clinical trials that may be required to expand approved indications of Zevalin. As a result, any revenue generated by sales of Zevalin may not be enough to fund our company-wide ongoing research, development, and operations for the next couple of years. We anticipate that funding to support our ongoing research, development and general operations will primarily come from public or private debt or equity financings, collaborations, milestones and licensing opportunities from current or future collaborators.

*Selling, general and administrative expenses.* Selling, general and administrative expenses remained consistent at approximately \$35.3 million for the years ended December 31, 2007, and 2006. The increase in our corporate development and compliance activities was approximately \$2.6 million, including an increase in strategic and compliance consulting services as well as an increase in travel expenses related to corporate development activities. Expense for shareholder relations increased approximately \$1.2 million primarily related to costs for our

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shareholder meetings held in 2007 as well as certain financial reporting activities. We also had an increase in compensation and benefits primarily of \$0.6 million due to the acquisition of SM and the formation of Aequus as well as additional general and administrative expenses of approximately \$0.5 million related to these two new subsidiaries. These increases were offset by decreases of \$1.6 million in our stock based compensation expense, \$1.2 million in depreciation and amortization expense related to assets becoming fully depreciated in 2006, \$1.0 million in insurance costs due to decreased premiums and \$0.9 million in legal expenses primarily associated with our litigation with Micromet which was settled in April 2006. We expect selling, general and administrative expenses to increase in 2008 as compared to 2007 due to the development of sales and marketing activities related to Zevalin.

*Acquired in-process research and development.* Acquired in-process research and development for the year ended December 31, 2007 relates to one-time charges of \$21.4 million and \$3.2 million recorded in connection with our acquisitions of SM and Zevalin, respectively.

*Amortization of purchased intangibles.* Amortization for the years ended December 31, 2007 and 2006 is primarily related to the amortization of our assembled workforce asset in our European branch.

*Restructuring charges and related asset impairments.* In 2005, we reduced our workforce through selected layoffs of employees as part of our cost savings initiative in an effort to reduce costs and conserve capital in anticipation of an NDA filing and potential launch of paclitaxel poliglumex. In conjunction with our workforce reduction, we vacated a portion of our laboratory and office facilities. Restructuring activities and asset impairments for the year ended December 31, 2007 and 2006 primarily relate to adjustments related to our excess facilities for a change in our estimate of the timing and amount of cash flows and adjustments for the passage of time as well as changes in the estimates of separation costs due to employees.

*Investment and other income, net.* Investment and other income for the year ended December 31, 2007 and 2006 was approximately \$2.4 million and \$2.9 million, respectively. This decrease is primarily due to lower prevailing interest rates on our investments during the year ended December 31, 2007 as compared to the year ended December 31, 2006. In addition, other income decreased approximately \$0.2 million due to a decrease in interest income on our VAT receivable balance in our European branch.

*Interest expense.* Interest expense decreased to approximately \$12.5 million for the year ended December 31, 2007 from approximately \$19.8 million for the year ended December 31, 2006. This change is primarily due to a \$4.2 million decrease in the amortization of debt issuance costs and a \$3.9 million decrease in the amortization of the debt discount related to the conversion of our 6.75% notes during the year ended December 31, 2006. In addition, interest expense on our 5.75% convertible subordinated and senior subordinated notes decreased approximately \$0.8 million due to exchanges of these notes for our 7.5% notes in April 2006. Interest expense on our 7.5% notes also decreased approximately \$0.2 million due to conversions of these notes during 2006 and 2007. These decreases were offset by an increase in amortization of the debt discount of \$1.5 million on our 7.5% notes primarily due to the conversion of \$13.6 million of these notes during the year ended December 31, 2007. These conversions resulted in accelerated accretion of the additional debt discount that had been recorded in December 2006. In addition, interest expense on our 6.75% notes increased approximately \$0.4 million.

*Foreign exchange gain.* Foreign exchange gains for the years ended December 31, 2007 and 2006 are due to fluctuations in foreign currency exchange rates, primarily related to payables in our European branch denominated in foreign currencies.

*Make-whole interest expense.* Make-whole interest expense of \$2.3 million for the year ended December 31, 2007 is due to payments made related to the conversion of \$13.6 million of our 7.5% notes. This compares to \$24.8 million for the year ended December 31, 2006 which is related to payments of \$23.1 million made upon the conversion of \$69.3 million of our 6.75% notes and \$1.7 million made upon conversion of \$7.4 million of our 7.5% notes.

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*Gain on derivative liabilities.* The gain on derivative liabilities of \$3.7 million for the year ended December 31, 2007 represents the change in the estimated fair value of the derivative liabilities related to the interest make-whole provisions on our 7.5% and 6.75% notes of \$3.6 million and \$0.1 million, respectively. The amount of \$6.0 million for the year ended December 31, 2006 represents the change in the estimated fair value of our derivative liabilities on our 6.75% and 7.5% notes of \$4.1 million and \$1.9 million, respectively.

*Gain (loss) on exchange of convertible notes.* We recorded a loss of approximately \$1.0 million during the year ended December 31, 2007 due to the extinguishment of approximately \$36.1 million aggregate principal amount of our 5.75% convertible senior subordinated and convertible subordinated notes in exchange for approximately \$23.3 million aggregate principal amount of our 5.75% convertible senior notes and approximately 5.5 million shares of our common stock in the fourth quarter of 2007. The loss includes a \$0.1 million write-off of unamortized issuance costs attributed to the extinguished notes. We recorded a gain of \$8.0 million during the year ended December 31, 2006 due to the extinguishment of approximately \$40.7 million aggregate principal amount of our 5.75% convertible senior subordinated and convertible subordinated notes in exchange for approximately \$33.2 million aggregate principal amount of our 7.5% notes in the second quarter of 2006. The gain is net of accrued interest of \$0.9 million and issuance costs of \$0.4 million attributable to the exchanged notes.

*Settlement expense.* Settlement expense for the year ended December 31, 2007 relates to interest accrued on the \$10.5 million payment to the USAO for release of all claims in connection with the investigation of our marketing practices relating to TRISENOX and related matters. Interest was accrued from the date of reaching an agreement in principle with the USAO in the fourth quarter of 2006 and the payment was made in April 2007. Settlement expense for the year ended December 31, 2006 is due to \$10.5 million accrued for the pending settlement of the USAO litigation and approximately \$0.9 million related to the settlement of our dispute with Micromet AG in May 2006 and was net of payables previously due to Micromet.

*Minority interest in net loss of subsidiary.* Minority interest in net loss of subsidiary was approximately \$0.1 million for the year ended December 31, 2007, and represents the minority owner's pro rata allocation of the losses in Aequus Biopharma, Inc.

*Years ended December 31, 2006 and 2005.*

*Product sales.* TRISENOX was, prior to its divestiture to Cephalon in July 2005, our commercial product approved by the FDA, EMEA, and the Japanese Ministry of Health to treat patients with relapsed or refractory acute promyelocytic leukemia. As a result of the divestiture, there were no product sales for the year ended December 31, 2006. We recorded net product sales of approximately \$14.6 million for TRISENOX for the year ended December 31, 2005.

*License and contract revenue.* In October 2001, we entered into a licensing agreement with Chugai Pharmaceutical Co., Ltd., or Chugai, for the development and commercialization of paclitaxel poliglumex. This agreement granted an exclusive license to Chugai to develop and commercialize paclitaxel poliglumex in several Asian markets. Upon execution of the Chugai agreement, we received a \$3.0 million initial payment, which we recorded as deferred revenue and which was being recognized as revenue over the estimated development period of approximately seven years on a straight-line basis. As of December 31, 2005, we recognized the remaining deferred revenue related to this initial payment in anticipation of the termination of our agreement with Chugai which occurred in March 2006.

License and contract revenue for the year ended December 31, 2006 represents recognition of deferred revenue from the sale of Lisofylline material to Diakine. For the year ended December 31, 2005, we recognized approximately \$1.5 million of license and contract revenue consisting primarily of the remaining deferred revenue balance related to the initial payment from Chugai.



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*Cost of product sold.* There was no cost of product sold for the year ended December 31, 2006 due to the divestiture of TRISENOX to Cephalon on July 18, 2005. The cost of product sold during the year ended December 31, 2005 was approximately \$0.5 million. Cost of product sold consisted primarily of manufacturing costs, royalties paid on product sales, and allowances for excess inventory that may expire and become unsaleable.

*Research and development expenses.* Our research and development expenses for compounds under development and discovery research are as follows (in thousands):

	2006	2005
Compounds under development:		
Paclitaxel poliglumex	\$ 24,722	\$ 18,251
Pixantrone	10,404	6,634
TRISENOX		3,682
Other compounds	848	2,019
Operating expenses	24,545	31,871
Discovery research	1,475	6,310
Total research and development expenses	\$ 61,994	\$ 68,767

Research and development expense decreased to approximately \$62.0 million for the year ended December 31, 2006, from approximately \$68.8 million for the year ended December 31, 2005. Costs for our paclitaxel poliglumex program increased primarily due to an increase in clinical activity related to the initiation of the PIONEER trial in the fourth quarter of 2005 offset in part by a decrease related to the STELLAR trials which were completed in 2005. Pixantrone costs increased due to an increase in clinical trial expenses attributable to increased patient enrollment and sites for our phase II and III clinical trials. TRISENOX costs decreased due to the divestiture of TRISENOX to Cephalon. Operating costs decreased primarily due to a reduction in our personnel resulting from our restructuring activities in 2005. Discovery research costs decreased primarily as a result of decreased personnel and other costs due to a reduction in programs.

*Selling, general and administrative expenses.* Selling, general and administrative expenses decreased to approximately \$35.3 million for the year ended December 31, 2006, from approximately \$61.7 million for the year ended December 31, 2005. This decrease is primarily attributed to a \$16.7 million decrease in our sales and marketing expenses related to reduced commercialization efforts and a reduction in sales and marketing personnel associated with the divestiture of TRISENOX to Cephalon in the third quarter of 2005 and a \$6.0 million decrease in operating expenses primarily related to decreased compensation and benefits, occupancy and other expenses resulting from a reduction in general and administrative personnel. In addition, corporate development expenses decreased by \$4.1 million primarily due to a decrease in aircraft operating costs of \$3.4 million resulting from the termination of our aircraft lease in the fourth quarter of 2005 and a decrease of \$0.8 million related to financial advisory fees. There was also a \$0.6 million increase in stock-based compensation expense primarily related to the implementation of SFAS 123(R).

*Amortization of purchased intangibles.* Amortization for the year ended December 31, 2006 decreased slightly as compared to the year ended December 31, 2005, due to a write-down of our assembled workforce asset in December 2005.

*Restructuring charges and related asset impairments.* Restructuring activities and asset impairments for the year ended December 31, 2006 primarily relate to adjustments related to our excess facilities for a change in our estimate of the timing and amount of cash flows and adjustments for the passage of time as well as changes in the estimates of separation costs due to employees. For the year ended December 31, 2005, we recorded approximately \$12.8 million in restructuring and related asset impairment charges including \$7.1 million related to excess facilities charges, \$3.5 million due to a reduction in workforce in both our U.S. and Italian operations,

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\$1.2 million related to the termination of our aircraft operating lease, \$0.8 million in write-downs of tangible assets primarily consisting of lab equipment in the U.S. that ceased to be used due to the consolidation of our research operations with CTI (Europe) and a \$0.2 million write-down of our workforce intangible asset for restructuring related employee terminations in Italy.

*Gain on divestiture of TRISENOX.* The gain of \$71.2 million for year ended December 31, 2005 related to the gain recognized, net of broker fees, on the divestiture of TRISENOX and certain proteasome assets to Cephalon as well as transition services provided to Cephalon related to TRISENOX and proteasome assets for a period of approximately six months subsequent to the date of closing.

*Investment and other income.* Investment and other income for the year ended December 31, 2006 and 2005 was approximately \$2.9 million and \$2.6 million, respectively. This increase is due to a higher average securities available-for-sale balance during the year ended December 31, 2006 compared to the year ended December 31, 2005 offset by a receipt of a \$0.7 million vendor settlement received in 2005.

*Interest expense.* Interest expense increased to approximately \$19.8 million for the year ended December 31, 2006 from approximately \$16.5 million for the year ended December 31, 2005. This increase is due to \$5.1 million in accretion of the debt discount on our 6.75% and 7.5% notes, a \$4.6 million increase in the amortization of 6.75% and 7.5% debt issue costs primarily associated with conversions of these notes and interest expense of \$2.5 million related to our 7.5% notes. These increases were partially offset by a decrease of \$3.1 million in interest expense on our 4.0% senior subordinated and 5.75% subordinated and senior subordinated notes due to the retirement and exchange of a portion of these notes in the fourth quarter of 2005 and first half of 2006, a decrease of \$2.8 million in interest charges related to our royalty financing agreement entered into with PharmaBio in December 2004 and terminated in July 2005 when we divested TRISENOX, a decrease of \$1.2 million related to a liquidated damages payment made in 2005 in connection with the Conversion and Placement Agreement entered into in conjunction with the issuance of our 6.75% notes, a decrease of \$1.0 million in the amortization of our 4.0% and 5.75% debt issuance costs due to conversions and exchanges of these notes in 2005 and the first half of 2006, and a decrease of \$0.7 million in interest expense on our 6.75% notes due to conversions of these notes during 2006.

*Foreign exchange gain.* The foreign exchange gain for the year ended December 31, 2006 is due to fluctuations in foreign currency exchange rates, primarily related to payables denominated in foreign currencies. There was no significant foreign currency exchange activity for the year ended December 31, 2005.

*Make-whole interest expense.* Make-whole interest expense of \$24.8 million for the year ended December 31, 2006 is related to payments of \$23.1 million made upon the conversion of \$69.3 million of our 6.75% notes and \$1.7 million made upon conversion of \$7.4 million of our 7.5% notes. The amount of \$1.0 million for the year ended December 31, 2005 is related to payments made upon the conversion of \$3.0 million of our 6.75% notes.

*Debt conversion expense.* Debt conversion expense for the year ended December 31, 2005 resulted from a conversion inducement consisting of 3.4 million shares and 6.5 million zero strike warrants valued at \$23.6 million to effect the conversion of \$38.4 million of convertible senior subordinated notes.

*Gain (loss) on derivative liabilities.* The gain on derivative liabilities of \$6.0 million for the year ended December 31, 2006 represents the change in the estimated fair value of our derivative liabilities related to the interest make-whole provisions on our 6.75% and 7.5% notes of \$4.1 million and \$1.9 million, respectively. The amount of \$0.2 million for the year ended December 31, 2005 represents the change in the estimated fair value of our derivative liability on our 6.75% notes.

*Gain on exchange of convertible notes.* We recorded a gain of \$8.0 million during the year ended December 31, 2006 due to the extinguishment of approximately \$40.7 million aggregate principal amount of our

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5.75% convertible senior subordinated and convertible subordinated notes in exchange for approximately \$33.2 million aggregate principal amount of our 7.5% notes in the second quarter of 2006. The gain is net of accrued interest of \$0.9 million and issuance costs of \$0.4 million attributable to the exchanged notes.

*Settlement expense.* Settlement expense for the year ended December 31, 2006 is due to \$10.5 million accrued for the pending settlement of our litigation with the USAO for release of all claims in connection with the investigation of our promotional practices relating to TRISENOX and related matters. Expense of approximately \$0.9 million relates to the amount paid under the settlement of our dispute with Micromet AG in May 2006 and is net of payables previously due to Micromet.

*Loss on extinguishment of royalty obligation.* The loss on extinguishment of royalty obligation for the year ended December 31, 2005 relates to the repayment of our royalty obligation to PharmaBio as a result of the divestiture of TRISENOX. The loss of \$6.4 million was calculated based on the excess of our termination payment of \$39.4 million over the amount of the accreted royalty obligation and the unused portion of the prepaid service commitment at the time of extinguishment of \$28.9 million and \$4.1 million, respectively.

**Liquidity and Capital Resources**

As of December 31, 2007, we had approximately \$18.4 million in cash and cash equivalents, securities available-for-sale and interest receivable.

Net cash used in operating activities totaled approximately \$103.6 million in 2007, compared to approximately \$116.6 million in 2006 and \$125.2 million in 2005. The decrease in net cash used in operating activities for the year ended December 31, 2007 as compared to 2006 was primarily due to a decrease in cash paid for interest of approximately \$23.4 million offset in part by a \$10.6 million settlement payment in 2007 related to our litigation with the USAO. The decrease in net cash used in operating activities for the year ended December 31, 2006 as compared to 2005 was due to the change in our net loss, offset by the gain on the divestiture of TRISENOX in 2005, non-cash items including debt conversion expense, and the increase in our accrued expenses balance. For the year ended December 31, 2007, our net loss included \$2.3 million in make-whole interest payments related to conversions of our 7.5% notes. For the year ended December 31, 2006, our net loss included \$24.8 million in make-whole interest payments related to conversions of our 6.75% and 7.5% notes. For the year ended December 31, 2005, our net loss included \$1.0 million in make-whole interest payments related to conversions of our 6.75% notes.

Net cash provided by investing activities totaled approximately \$21.5 million in 2007, as compared to net cash used in investing activities of \$17.9 million in 2006 and net cash provided by investing activities of \$60.3 million in 2005. The net cash provided by investing activities during the year ended December 31, 2007 was primarily due to the net amount of cash received from sales, maturities and purchases of securities available-for-sale offset by cash paid for the acquisition of Zevalin. The net cash used in investing activities in 2006 was primarily due to the net amount of cash paid from purchases, sales and maturities of securities available-for-sale. Net cash provided by investing activities in 2005 was primarily due to proceeds from the divestiture of TRISENOX and proceeds from sales and maturities of securities available-for-sale, offset in part by purchases of securities available-for-sale.

Net cash provided by financing activities totaled approximately \$84.7 million in 2007, \$102.7 million in 2006 and \$12.1 million in 2005. The net cash provided by financing activities for the year ended December 31, 2007 was primarily due to net proceeds of \$18.6 million received from the sale of 20,000 shares of our Series A 3% convertible preferred stock and common stock warrants in February 2007, net proceeds of \$34.8 million received from the sale of 37,200 shares of our Series B 3% convertible preferred stock and common stock warrants in April 2007, net proceeds of \$18.9 million received from the sale of 20,250 shares of our Series C 3% convertible preferred stock and common stock warrants in July 2007, and net proceeds of \$6.1 million received from the sale of 6,500 shares of our Series D 7% convertible preferred stock and common stock warrants in

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December 2007 and net proceeds of \$7.0 million received from the sale of our common stock and common stock warrants in December 2007. The net cash provided by financing activities for the year ended December 31, 2006 was primarily due to net proceeds of \$34.7 million received from the sale of our common stock in September 2006, including the repurchase of stock and warrants in October 2006, \$31.2 million received from the issuance of our 7.5% notes, \$24.6 million due to the release of restricted cash associated with the mandatory redemptions of our 6.75% notes and \$14.8 million in net proceeds received from the sale of our common stock to Novartis. The net cash provided by financing activities during 2005 was primarily due to net proceeds of \$77.7 million from the issuance of our 6.75% notes, offset by \$24.6 million of restricted cash held in escrow until April 30, 2006 to fund the potential redemption of a portion of these notes. These amounts were also partially offset by the repayment of \$39.4 million for our royalty obligation with PharmaBio.

We have prepared our financial statements assuming that we will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business. We have incurred net losses since inception and we expect to generate losses from operations for at least the next couple of years primarily due to research and development costs for Zevalin, paclitaxel poliglumex, pixantrone, and brostallicin. We raised approximately \$1.3 million in gross proceeds 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. Approximately \$13.9 million of the net proceeds received from our convertible debt offering is restricted and is being held in escrow to fund potential make-whole payments due upon conversions of these notes. Our existing cash and cash equivalents, securities available-for-sale and interest receivable, including these proceeds, is not sufficient to fund our planned operations for the next twelve months as well as repay approximately \$10.7 million in principal due on our convertible subordinated and senior subordinated notes in June 2008. This raises substantial doubt about our ability to continue as a going concern. Accordingly, we have commenced a cost savings initiative and plan to reduce the Company's projected net cash operating expenses to a forecasted \$77 million in 2008. However, we will also need to raise additional funds and are currently exploring alternative sources of equity or debt financing. We have a \$60 million (approximately \$88 million as of December 31, 2007) Step-Up Equity Financing Agreement with Société Générale of which approximately \$59.1 million is available as of March 19, 2008. While we may be able to utilize this agreement to provide additional equity funding, access to that funding may not be available on favorable terms or at all. If additional funds are raised by issuing equity securities, substantial dilution to existing shareholders may result. If we fail to obtain capital when required, we may be required to delay, scale back, or eliminate some or all of our research and development programs.

We may receive certain grants and subsidized loans from the Italian government and the EU through our Italian operations. However, to date such grants have not been significant and we may not receive such funding because the grants and subsidies are awarded at the discretion of the relevant authorities. However, our Italian branch will continue to apply for public financing when possible. In addition, our future capital requirements will depend on many factors, including:

results of our clinical trials;

success in acquiring or divesting products, technologies or businesses;

progress in and scope of our research and development activities; and

competitive market developments.

Future capital requirements will also depend on the extent to which we acquire or invest in businesses, products and technologies or sell or license our products to others. We will require additional financing and such financing may not be available when needed or, if available, we may not be able to obtain it on terms favorable to us or to our shareholders. Insufficient funds may require us to delay, scale back or eliminate some or all of our research and development programs, or may adversely affect our ability to operate as a going concern. If additional funds are raised by issuing equity securities, substantial dilution to existing shareholders may result.

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The following table includes information relating to our contractual obligations as of December 31, 2007 (in thousands):

Contractual Obligations	Payments Due by Period				
	Total	1 Year	2-3 Years	4-5 Years	After 5 Years
7.5% Convertible senior notes(1)	\$ 33,458	\$	\$	\$ 33,458	\$
6.75% Convertible senior notes(2)	7,000		7,000		
5.75% Convertible senior notes(3)	23,250			23,250	
5.75% Convertible senior subordinated notes(4)	16,907	16,907			
4.0% Convertible senior subordinated notes(5)	55,150		55,150		
5.75% Convertible subordinated notes(6)	2,910	2,910			
Interest on convertible notes	21,013	7,046	11,864	2,103	
Operating leases:					
Facilities	29,521	6,352	12,033	10,168	968
Long-term obligations(7)	2,155	500	805	850	
Purchase commitments(8)	3,461	958	640	1,064	799
	\$ 194,825	\$ 34,673	\$ 87,492	\$ 70,893	\$ 1,767

- (1) The 7.5% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 119.6298 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of approximately \$8.36 per share.
- (2) The 6.75% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 95.0925 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of approximately \$10.52 per share.
- (3) The 5.75% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 333.3333 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of approximately \$3.00 per share.
- (4) The 5.75% convertible senior subordinated notes are convertible into shares of CTI common stock at a conversion rate of 25 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of \$40.00 per share.
- (5) The 4.0% convertible senior subordinated notes are convertible into shares of CTI common stock at a conversion rate of 18.5185 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of approximately \$54.00 per share.
- (6) The 5.75% convertible subordinated notes are convertible into shares of CTI common stock at a conversion rate of 7.353 shares of common stock per \$1,000 principal amount of the notes, which is equivalent to a conversion price of approximately \$136.00 per share.
- (7) Long-term obligations does not include \$6.2 million of contingent consideration related to our acquisition of Zevalin, \$1.5 million related to excess facilities charges and \$1.0 million recorded as a long-term obligation for benefits owed to our Italian employees pursuant to Italian Law. The timing of the payments related to this obligation is unknown as the benefit is paid upon an employee's separation from the Company.
- (8) We purchase Zevalin from Biogen pursuant to a supply agreement that we entered into with Biogen on December 21, 2007 in connection with the acquisition of U.S. rights to develop, market and sell Zevalin. Under the terms of the supply agreement, we are required to purchase from Biogen an amount of Zevalin every six months. We provide rolling forecasts of our supply requirements to Biogen in six-month increments for the next 30 months; however, under the terms of the agreement we are required to purchase a minimum of 150 packages, or 300 kits, for each six-month period in 2008, 2009 and 2010, and a minimum of 250 packages, or 500 kits, for each six-month period thereafter until the expiration of the term on June 9, 2014, unless earlier terminated. Each forecast for the next six-month period must be accompanied by a firm order.

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### *Additional Milestone Activities*

Pursuant to the amended agreement with PG-TXL Company L.P. which grants us an exclusive worldwide license for the rights to paclitaxel poliglumex and to all potential uses of PG-TXL's polymer technology, we may be required to pay \$14.9 million in milestone payments. We filed an MAA with the EMEA on March 4, 2008. We will be required to make a \$0.5 million payment within 30 days of the EMEA's acceptance of our MAA filing, which is expected to occur at the end of the first quarter of 2008. Additionally, we will be required to make a \$3.0 million payment upon approval of the MAA filing by the EMEA, which is expected to occur in the second half of 2009. The timing of the remaining milestone payments under the amended agreement is based on trial commencements and completions and regulatory and marketing approval with the FDA and EMEA.

Under a license agreement entered into for brostallicin, we may be required to pay up to \$80 million in milestone payments, based on the achievement of certain product development results. Due to the early stage of development that brostallicin is in, we are not able to determine whether the clinical trials will be successful and therefore cannot make a determination that the milestone payments are reasonably likely to occur at this time.

Pursuant to an acquisition agreement entered into with Cephalon, Inc. in June 2005, we may receive up to \$100 million in payments upon achievement by Cephalon of specified sales and development milestones. However, the achievement of any such milestones is uncertain.

Under our agreement with Novartis Pharmaceutical Company Ltd., or Novartis, if Novartis elects to participate in the development and commercialization of paclitaxel poliglumex or if Novartis exercises its option to develop and commercialize pixantrone, we may receive up to \$374 million in registration and sales related milestone payments. Novartis is under no obligation to make such election or exercise such right and may never do so. Additionally, even if Novartis exercises such rights, any milestone payments we may be eligible to receive from Novartis are subject to the receipt of the necessary regulatory approvals which we may never receive.

### **Impact of Inflation**

In the opinion of management, inflation has not had a material effect on our operations including selling prices, capital expenditures and operating expenses.

### **Recent Accounting Pronouncements**

On December 4, 2007, Statement of Financial Standard No. 141(R), *Business Combinations*, or SFAS 141(R), was issued. This standard will require an acquiring company to measure all assets acquired and liabilities assumed, including contingent considerations and all contractual contingencies, at fair value as of the acquisition date. In addition, an acquiring company is required to capitalize IPR&D as an indefinite lived intangible asset and either amortize it over the life of the product, or write it off if the project is abandoned or impaired. The acquiring company will be required to expense the acquisition costs rather than be added to the cost of the acquisition. The standard is effective for transactions occurring on or after January 1, 2009. We are evaluating the impact this standard will have on our financial statements.

On December 4, 2007, Statement of Financial Standard No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51*, or SFAS 160, was issued. This standard changes the accounting for and reporting of noncontrolling or minority interests in consolidated financial statements. The standard is effective January 1, 2009; however, the presentation and disclosure requirements of SFAS 160 regarding noncontrolling interests shall be applied retrospectively. We are evaluating the impact, if any, this standard will have on our financial statements.

In November 2007, the EITF reached a consensus on Issue 07-1. EITF 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*, is focused on how the

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parties to a collaborative agreement should account for costs incurred and revenue generated on sales to third parties, how sharing payments pursuant to a collaborative agreement should be presented in the income statement and certain related disclosure questions. EITF 07-1 is effective for periods beginning after December 15, 2008. We are evaluating the requirements of these issues and have not yet determined the impact on the financial statements.

In June 2007, the EITF reached a consensus on Issue 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, or EITF 07-3, which focuses on whether non-refundable advance payments for goods or services that will be performed in future research and development activities should be accounted for as research and development costs or deferred and capitalized until the goods have been delivered or the related services have been rendered. EITF 07-3 is effective for periods beginning after December 15, 2007. We are evaluating the impact, if any, this EITF will have on our financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115*, or SFAS 159. The Statement permits entities to choose, at specified election dates, to measure many financial instruments and certain other items at fair value that are not currently measured at fair value. Unrealized gains and losses on items for which the fair value option has been elected would be reported in earnings at each subsequent reporting date. SFAS 159 also establishes presentation and disclosure requirements in order to facilitate comparisons between entities choosing different measurement attributes for similar types of assets and liabilities. SFAS 159 does not affect existing accounting requirements for certain assets and liabilities to be carried at fair value. SFAS 159 is effective for fiscal years beginning after November 15, 2007, and adopted by us beginning January 1, 2008. We are evaluating the requirements of SFAS 159 and have not yet determined the impact on the financial statements.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, or SFAS 157, which provides guidance on how to measure assets and liabilities that use fair value. This statement clarifies the principle that fair value should be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. SFAS 157 will apply whenever another generally accepted accounting principle requires, or permits, assets or liabilities to be measured at fair value but does not expand the use of fair value to any new circumstances. This statement will also require additional disclosures in both annual and quarterly reports. SFAS 157 is effective for fiscal years beginning after November 2007, and adopted by us beginning January 1, 2008. We are evaluating the impact, if any, this standard will have on our financial statements.

**Item 7a. Quantitative and Qualitative Disclosures about Market Risk**

*Interest Rate Market Risk*

We are exposed to market risk related to changes in interest rates that could adversely affect the value of our investments. We maintain a short-term investment portfolio consisting of interest bearing securities with an average maturity of less than one year. These securities are classified as available-for-sale. These securities are interest bearing and thus subject to interest rate risk and will fall in value if market interest rates increase. Since we generally hold our fixed income investments until maturity, we do not expect our operating results or cash flows to be affected to any significant degree by a sudden change in market interest rates related to our securities portfolio. The fair value of our securities available-for-sale at December 31, 2007 and 2006 was \$2.5 million and \$36.7 million, respectively. For each one percent change in interest rates, the fair value of our securities available-for-sale would change by approximately \$12,000 and \$135,000 as of December 31, 2007 and 2006, respectively.

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*Foreign Exchange Market Risk*

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 unhedged foreign currency transactions 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. Although our reporting currency remains the U.S. dollar, a significant portion of our consolidated costs now arise in euros, which we translate into U.S. dollars for purposes of financial reporting, based on exchange rates prevailing during the applicable reporting period. In addition, the reported carrying value of our euro-denominated assets and liabilities will be affected by fluctuations in the value of the U.S. dollar as compared to the euro. Accordingly, changes in the value of the U.S. dollar relative to the euro might have an adverse effect on our reported results of operations and financial condition, and fluctuations in exchange rates might harm our reported results and accounts from period to period.

We have foreign exchange risk related to euro-denominated cash, cash equivalents and interest receivable ( foreign funds ). Based on the balance of foreign funds at December 31, 2007 of \$5.5 million, an assumed 5%, 10% and 20% negative currency movement would result in fair value declines of \$0.3 million, \$0.6 million and \$1.1 million, respectively.



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**Item 8. Consolidated Financial Statements and Supplementary Data**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and

Shareholders of Cell Therapeutics, Inc.

We have audited Cell Therapeutics, Inc.'s internal control over financial reporting as of December 31, 2007, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Cell Therapeutics, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Cell Therapeutics, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

As described in Management's Report on Internal Controls appearing under item 9A, management has excluded Systems Medicine, LLC and the commercial product Zevalin, from its assessment of internal controls over financial reporting as of December 31, 2007 because they were acquired by the Company during 2007. We have also excluded Systems Medicine, LLC, whose financial statements reflect total assets of 1% and net sales of 0%, respectively, of the related consolidated financial statements as of and for the year then ended December 31, 2007 and the commercial product Zevalin, whose financial statements reflect total assets of 21% and net sales of 37%, respectively, of the related consolidated financial statements as of and for the year ended December 31, 2007, from our audit of internal control over financial reporting.

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We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets and the related statements of operation, stockholders' deficit and other comprehensive loss, and cash flows of Cell Therapeutics, Inc., and our report dated March 26, 2008 expressed an unqualified opinion.

/s/ Stonefield Josephson, Inc.

Stonefield Josephson, Inc.

Los Angeles, CA

March 26, 2008

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

Board of Directors and Shareholders

Cell Therapeutics, Inc.

We have audited the accompanying balance sheets of Cell Therapeutics, Inc. as of December 31, 2007 and 2006, and the related statements of operations, shareholders' deficit and other comprehensive loss, and cash flows for each of the years in the three-year period ended December 31, 2007. Our audits also included the consolidated financial statement schedule listed in the index at Item 15(a)(ii) as of and for the years ended December 31, 2007 and 2006. Cell Therapeutics Inc.'s management is responsible for these financial statements and schedule. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Cell Therapeutics, Inc. as of December 31, 2007 and 2006, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2007 in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has substantial monetary liabilities in excess of monetary assets as of December 31, 2007, including approximately nineteen million, eight hundred thousand dollars of convertible subordinated notes and senior subordinated notes which mature in June 2008. The Company's ability to satisfy these obligations upon maturity raises substantial doubt about the Company's ability to continue as a going concern. Management's plans concerning these matters are described in Note 1. These consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded assets, or the amounts and classification of liabilities that might be necessary in the event the Company cannot continue in existence.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Cell Therapeutics, Inc.'s internal control over financial reporting as of December 31, 2007, based on criteria established in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 26, 2008 expressed an unqualified opinion.

/s/ Stonefield Josephson, Inc.

Stonefield Josephson, Inc.

Los Angeles, Ca

March 26, 2007

**Table of Contents****CELL THERAPEUTICS, INC.****CONSOLIDATED BALANCE SHEETS****(In thousands, except share amounts)**

	December 31, 2007	December 31, 2006
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 15,798	\$ 17,129
Securities available-for-sale	2,548	36,708
Interest receivable	46	570
Accounts receivable, net	51	
Inventory	290	
Prepaid expenses and other current assets	3,904	10,131
<b>Total current assets</b>	<b>22,637</b>	<b>64,538</b>
Property and equipment, net	6,025	7,915
Goodwill	17,064	17,064
Other intangibles, net	15,957	1,663
Other assets	11,830	10,641
<b>Total assets</b>	<b>\$ 73,513</b>	<b>\$ 101,821</b>
<b>LIABILITIES AND SHAREHOLDERS DEFICIT</b>		
Current liabilities:		
Accounts payable	\$ 6,595	\$ 639
Accrued expenses	26,034	28,567
Current portion of deferred revenue	80	80
Current portion of long-term obligations	1,020	2,816
Current portion of derivative liability		2,270
Current portion of convertible senior subordinated notes	16,907	
Current portion of convertible subordinated notes	2,910	
<b>Total current liabilities</b>	<b>53,546</b>	<b>34,372</b>
Deferred revenue, less current portion	398	478
Long-term obligations, less current portion	9,879	4,667
7.5% convertible senior notes	32,220	45,916
6.75% convertible senior notes	6,922	6,945
5.75% convertible senior notes	23,287	
Convertible senior subordinated notes	55,150	82,557
Convertible subordinated notes		28,490
<b>Total liabilities</b>	<b>181,402</b>	<b>203,425</b>
Commitments and contingencies		
Minority interest in subsidiary		
Preferred stock, no par value:		
Authorized shares 10,000,000		
Series A 3% Convertible Preferred Stock, \$1,000 stated value, 20,000 shares designated; 6,850 and 0 shares issued and outstanding at December 31, 2007 and 2006, respectively	5,188	
Series B 3% Convertible Preferred Stock, \$1,000 stated value, 37,200 shares designated; 15,380 and 0 shares issued and outstanding at December 31, 2007 and 2006, respectively	11,881	
Series C 3% Convertible Preferred Stock, \$1,000 stated value, 20,250 shares designated; 8,284 and 0 shares issued and outstanding at December, 2007 and 2006, respectively	6,229	
Series D 7% Convertible Preferred Stock, \$1,000 stated value, 6,500 shares designated; 4,000 and 0 shares issued and outstanding at December, 2007 and 2006, respectively	2,938	
Shareholders' deficit:		
Common stock, no par value:		

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Authorized shares	100,000,000		
Issued and outstanding shares	62,444,239 and 36,397,230 at December 31, 2007 and 2006, respectively	979,295	860,691
Accumulated other comprehensive loss		(4,007)	(1,187)
Accumulated deficit		(1,109,413)	(961,108)
Total shareholders' deficit		(134,125)	(101,604)
Total liabilities and shareholders' deficit		\$ 73,513	\$ 101,821

See accompanying notes.

**Table of Contents****CELL THERAPEUTICS, INC.****CONSOLIDATED STATEMENTS OF OPERATIONS****(In thousands, except per share amounts)**

	Year Ended December 31,		
	2007	2006	2005
<b>Revenues:</b>			
Product sales	\$ 47	\$	\$ 14,599
License and contract revenue	80	80	1,493
<b>Total revenues</b>	<b>127</b>	<b>80</b>	<b>16,092</b>
<b>Operating expenses:</b>			
Cost of product sold	49		518
Research and development	72,019	61,994	68,767
Selling, general and administrative	35,316	35,303	61,717
Acquired in-process research and development	24,615		
Amortization of purchased intangibles	913	792	1,254
Restructuring charges and related asset impairments	201	591	12,780
Gain on divestiture of TRISENOX			(71,211)
<b>Total operating expenses</b>	<b>133,113</b>	<b>98,680</b>	<b>73,825</b>
Loss from operations	(132,986)	(98,600)	(57,733)
<b>Other income (expense):</b>			
Investment and other income, net	2,430	2,866	2,588
Interest expense	(12,517)	(19,829)	(16,546)
Foreign exchange gain	4,657	1,877	8
Make-whole interest expense	(2,310)	(24,753)	(1,013)
Debt conversion expense			(23,608)
Gain on derivative liabilities	3,672	6,024	236
Gain (loss) on exchange of convertible notes	(972)	7,978	
Settlement expense	(160)	(11,382)	
Loss on extinguishment of royalty obligation			(6,437)
<b>Other expense, net</b>	<b>(5,200)</b>	<b>(37,219)</b>	<b>(44,772)</b>
Loss before minority interest	(138,186)	(135,819)	(102,505)
Minority interest in net loss of subsidiary	78		
<b>Net loss</b>	<b>(138,108)</b>	<b>(135,819)</b>	<b>(102,505)</b>
Preferred stock beneficial conversion feature	(9,549)		
Preferred stock dividends	(648)		
<b>Net loss attributable to common shareholders</b>	<b>\$ (148,305)</b>	<b>\$ (135,819)</b>	<b>\$ (102,505)</b>
Basic and diluted net loss per common share	\$ (3.27)	\$ (4.84)	\$ (6.35)
Shares used in calculation of basic and diluted net loss per common share	45,292	28,070	16,138

See accompanying notes.





**Table of Contents****CELL THERAPEUTICS, INC.****CONSOLIDATED STATEMENTS OF SHAREHOLDERS DEFICIT AND OTHER COMPREHENSIVE LOSS**

(In thousands)

	Common Stock		Deferred	Accumulated	Other	Total
	Shares	Amount	Stock-based Compensation	Deficit	Comprehensive Income/(Loss)	Shareholders (Deficit)
Balance at December 31, 2004	15,966	652,773	(2,736)	(722,784)	2,039	(70,708)
Conversion of convertible senior subordinated notes to common stock	831	39,047				39,047
Equity instruments issued to induce conversion of convertible senior subordinated notes to common stock	845	23,608				23,608
Issuance of warrants to underwriter of convertible senior notes		564				564
Conversion of 6.75% convertible senior notes to common stock	285	3,000				3,000
Proceeds from stock options exercised and stock sold via employee stock purchase plan	20	238				238
Deferred compensation	410	2,186	(2,186)			
Amortization of deferred compensation of restricted stock			3,253			3,253
Equity-based compensation	(1)	(49)				(49)
Conversion of restricted share rights to common stock		177				177
Comprehensive loss:						
Foreign currency translation loss					(4,174)	(4,174)
Unrealized gains on securities available-for-sale					16	16
Unrealized gains on interest rate swap					436	436
Net loss for the year ended December 31, 2005				(102,505)		(102,505)
Comprehensive loss						(106,227)
Balance at December 31, 2005	18,356	721,544	(1,669)	(825,289)	(1,683)	(107,097)
Conversion of 6.75% convertible senior notes to common stock	6,594	69,345				69,345
Proceeds from issuance of common stock, net	5,780	37,764				37,764
Repurchase of common stock and warrants	(274)	(3,025)				(3,025)
Conversion of 7.5% convertible senior notes to common stock	2,101	17,560				17,560
Exercise of warrants to common stock	1,649	164				164
Proceeds from issuance of common stock to Novartis, net	2,168	14,837				14,837
Conversion of convertible senior subordinated notes to common stock		4				4
Proceeds from stock sold via employee stock purchase plan	4	17				17
Deferred compensation	(3)	(1,669)	1,669			
Equity-based compensation		4,150				4,150
Conversion of restricted share rights to common stock	22					
Comprehensive loss:						
Foreign currency translation gain					419	419
Realized loss on liquidation of foreign subsidiary					41	41
Unrealized gains on securities available-for-sale					36	36
Net loss for the year ended December 31, 2006				(135,819)		(135,819)
Comprehensive loss						(135,323)
Balance at December 31, 2006	36,397	\$ 860,691	\$	\$ (961,108)	\$ (1,187)	\$ (101,604)
Conversion of convertible preferred stock to common stock	9,233	37,648				37,648
Proceeds from issuance of warrants in connection with issuance of convertible preferred stock, net		14,526				14,526
Value of beneficial conversion feature of preferred stock		9,549		(9,549)		
Conversion of 7.5% convertible senior notes to common stock	1,830	15,294				15,294
Issuance of common stock in connection with SMI acquisition	4,212	19,872				19,872
	5,459	13,704				13,704

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Issuance of common stock in connection with exchange of 5.75% senior subordinated and subordinated notes					
Proceeds from issuance of common stock and warrants, net	3,470	6,537			6,537
Equity-based compensation	1,853	1,588			1,588
Other	(10)	(114)			(114)
Dividends on preferred stock				(648)	(648)
Comprehensive loss:					
Foreign currency translation gain				(2,807)	(2,807)
Unrealized losses on securities available-for-sale				(13)	(13)
Net loss for the year ended December 31, 2007				(138,108)	(138,108)
Comprehensive loss					(140,928)
Balance at December 31, 2007	62,444	\$ 979,295	\$	\$ (1,109,413)	\$ (4,007) \$ (134,125)

See accompanying notes.

**Table of Contents****CELL THERAPEUTICS, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS**

(In thousands)

	Year Ended December 31,		
	2007	2006	2005
<b>Operating activities</b>			
Net loss	\$ (138,108)	\$ (135,819)	\$ (102,505)
Adjustments to reconcile net loss to net cash used in operating activities:			
Acquired in-process research and development	24,615		
Depreciation and amortization	4,955	6,430	9,975
Minority interest in net loss of subsidiary	(78)		
Equity-based compensation expense	1,588	4,150	3,381
Loss on disposition of property and equipment	22	63	157
Amortization (accretion) of investment premium (discount)	(261)	74	303
Non-cash loss (gain) on exchange of convertible notes	972	(7,978)	
Non-cash gain on derivative liabilities	(3,672)	(6,024)	(236)
Non-cash interest expense	4,280	10,977	2,930
Non-cash loss on liquidation of subsidiary		41	
Asset impairments			3,020
Debt conversion expense			23,608
Gain on divestiture of TRISENOX			(71,211)
Loss on extinguishment of royalty obligation			6,437
Non-cash rent (benefit) expense	(192)	(15)	180
Loss (gain) on sale of investment securities	(3)	(1)	14
Changes in operating assets and liabilities:			
Restricted cash		1,054	(1,045)
Accounts receivable, net	(51)		
Interest receivable	524	(383)	(40)
Inventory	(290)		4
Prepaid expenses and other current assets	6,431	2,283	1,077
Other assets	(1,216)	2,907	(1,452)
Accounts payable	4,297	(2,925)	(3,451)
Accrued expenses	(4,961)	11,476	(5,181)
Deferred revenue	(80)	(80)	(1,081)
Excess facilities obligations	(2,403)	(2,383)	6,334
Other long-term obligations	13	(453)	3,550
Total adjustments	34,490	19,213	(22,727)
Net cash used in operating activities	(103,618)	(116,606)	(125,232)
<b>Investing activities</b>			
Cash acquired in acquisition of Systems Medicine, Inc., net	555		
Cash paid for acquisition of Zevalin	(11,735)		
Net proceeds from divestiture of TRISENOX			70,417
Purchases of securities available-for-sale	(36,463)	(68,905)	(46,827)
Proceeds from maturities of securities available-for-sale	22,442	14,665	22,693
Proceeds from sales of securities available-for-sale	48,431	36,353	15,815
Purchases of property and equipment	(1,753)	(534)	(2,016)
Proceeds from sale of property and equipment		539	253
Net cash provided by (used in) investing activities	21,477	(17,882)	60,335

See accompanying notes.



**Table of Contents****CELL THERAPEUTICS, INC.****CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued)****(In thousands)**

	<b>Year Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
<b>Financing activities</b>			
Proceeds from issuance of Series A 3% convertible preferred stock and warrants, net	18,607		
Proceeds from issuance of Series B 3% convertible preferred stock and warrants, net	34,836		
Proceeds from issuance of Series C 3% convertible preferred stock and warrants, net	18,938		
Proceeds from issuance of Series D 7% convertible preferred stock and warrants, net	6,073		
Proceeds from sale of common stock and warrants, net	7,007		
Sale of common stock, net of offering costs		37,764	
Repurchase of common stock and warrants		(3,025)	
Proceeds from issuance of 7.5% convertible senior notes, net		31,174	
Proceeds from issuance of common stock to Novartis, net		14,837	
Proceeds from issuance of 6.75% convertible senior notes, net			77,704
Restricted cash from issuance of 6.75% convertible senior notes, net			(24,600)
Release of restricted cash related to 6.75% convertible senior notes		24,600	
Mandatory redemptions of 6.75% convertible senior notes		(2,655)	
Proceeds from common stock warrants exercised		164	
Repayment of royalty obligation			(39,388)
Payment of dividends on preferred stock	(395)		
Proceeds from common stock options exercised and stock sold via the employee stock purchase plan		17	238
Proceeds from long-term obligations	99		
Repayment of long-term obligations	(429)	(138)	(1,805)
Common stock activity related to vesting of equity instruments	(36)		
Net cash provided by financing activities	84,700	102,738	12,149
Effect of exchange rate changes on cash and cash equivalents	(3,890)	(1,143)	(2,263)
Net decrease in cash and cash equivalents	(1,331)	(32,893)	(55,011)
Cash and cash equivalents at beginning of period	17,129	50,022	105,033
Cash and cash equivalents at end of period	\$ 15,798	\$ 17,129	\$ 50,022
<b>Supplemental disclosure of cash flow information</b>			
Cash paid during the period for interest	\$ 10,759	\$ 34,177	\$ 12,640
Cash paid for taxes	\$	\$	\$
<b>Supplemental disclosure of noncash financing and investing activities</b>			
Issuance of common stock for acquisition of Systems Medicine, Inc.	\$ 19,872	\$	\$
Conversion of series A 3% convertible preferred stock to common stock	\$ 9,959	\$	\$
Conversion of series B 3% convertible preferred stock to common stock	\$ 16,855	\$	\$
Conversion of series C 3% convertible preferred stock to common stock	\$ 8,998	\$	\$
Conversion of series D 7% convertible preferred stock to common stock	\$ 1,836	\$	\$
Conversion of 6.75% convertible senior notes to common stock	\$	\$ 69,345	\$ 3,000
Conversion of 7.5% convertible senior notes to common stock	\$ 15,294	\$ 17,560	\$

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Conversion of convertible senior subordinated notes to common stock, including accrued interest	\$		4	\$ 39,047
Issuance of warrants to underwriter of convertible senior notes	\$	\$		\$ 564
Extinguishment of 5.75% convertible senior subordinated notes in exchange for 7.5% convertible senior notes	\$	\$	39,518	\$
Extinguishment of 5.75% convertible subordinated notes in exchange for 7.5% convertible senior notes	\$	\$	1,150	\$
Issuance of 7.5% convertible senior notes in exchange for 5.75% subordinated and senior subordinated notes	\$	\$	33,156	\$
Extinguishment of 5.75% convertible senior subordinated notes in exchange for 5.75% convertible senior notes and common stock	\$ 10,500	\$		\$
Extinguishment of 5.75% convertible subordinated notes in exchange for 5.75% convertible senior notes and common stock	\$ 25,580	\$		\$
Issuance of 5.75% convertible senior notes in exchange for 5.75% convertible senior subordinated and convertible subordinated notes	\$ 23,250	\$		\$
Issuance of common stock in exchange for 5.75% convertible senior subordinated and convertible subordinated notes	\$ 13,704	\$		\$

See accompanying notes.

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**CELL THERAPEUTICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**December 31, 2007**

**1. Description of Business and Summary of Significant Accounting Policies**

*Description of Business*

Cell Therapeutics, Inc., or CTI or the Company, focuses on the development, acquisition and commercialization of drugs for the treatment of cancer. Our principal business strategy is focused on cancer therapeutics, an area with significant market opportunity that we believe is not adequately served by existing therapies. Our operations are primarily conducted in the United States and Italy.

We operate in a highly regulated and competitive environment. The manufacturing and marketing of pharmaceutical products require approval from, and are subject to, ongoing oversight by the Food and Drug Administration, or FDA, in the United States, by the European Agency for Evaluation of Medicinal Products, or EMEA, in Europe and by comparable agencies in other countries. Obtaining approval for a new therapeutic product is never certain and may take many years and involve expenditure of substantial resources.

In December 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 FDA-approved radioimmunotherapy and was approved in 2002 to treat patients with relapsed or refractory low-grade, follicular, or B-cell non-Hodgkin's lymphoma, or NHL.

In addition, in July 2007, we completed our acquisition of Systems Medicine, Inc., or SM, a privately held oncology company, in a stock for stock merger. 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.

*Principles of Consolidation*

The consolidated financial statements include the accounts of Cell Therapeutics, Inc. and its wholly owned subsidiaries which include CTI Corporate Development, Inc., SM (from the date of acquisition on July 31, 2007), and CTI Technologies, Inc., which was liquidated in the fourth quarter of 2007. In addition, Cell Therapeutics Inc. Sede Secondaria, or CTI (Europe), was merged into Cell Therapeutics, Inc. on November 30, 2007 and now operates as a branch of the Company. Cell Therapeutics (Ireland) Holding Limited was liquidated in the fourth quarter of 2006 and the Company's wholly owned subsidiaries, Cell Therapeutics (UK) Limited and PolaRx Biopharmaceuticals, Inc., or PolaRx, were sold to Cephalon in connection with the divestiture of TRISENOX in July 2005.

As of December 31, 2007, the Company also has a 69% interest in its majority owned subsidiary, Aequus Biopharma, Inc. Stock ownership by outside and related parties in Aequus Biopharma, Inc. is recorded as *minority interest in subsidiary* and stated net after allocation of losses in the subsidiary.

All intercompany transactions and balances are eliminated in consolidation.

*Reverse Stock-Split*

On April 15, 2007, we effected a one-for-four reverse stock split of our common stock. All impacted amounts included in the consolidated financial statements and notes thereto have been retroactively adjusted for the stock split. Impacted amounts include shares of common stock authorized and outstanding, share issuances, shares underlying stock options and warrants, shares reserved and loss per share.

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**Table of Contents****CELL THERAPEUTICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)***Liquidity*

Our accompanying consolidated financial statements have been prepared assuming that we will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business for the twelve month period following the date of these financials. However, we have incurred losses since inception and we expect to generate losses from operations for at least the next couple of years primarily due to research and development costs for Zevalin, paclitaxel poliglumex, pixantrone, and brostallicin. Our available *cash and cash equivalents, securities available-for-sale* and *interest receivable* are approximately \$18.4 million as of December 31, 2007. In addition, we raised approximately \$1.3 million in gross proceeds 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 an inducement payment for conversions of convertible preferred stock, in March 2008. Approximately \$13.9 million of the net proceeds received from our convertible debt offering is restricted and is being held in escrow to fund potential make-whole payments due upon conversions of this debt. These amounts are not sufficient to fund our planned operations for the next twelve months as well as repay approximately \$10.7 million in principal due on our convertible subordinated and senior subordinated notes in June 2008 which raises substantial doubt about our ability to continue as a going concern. Accordingly, we have commenced a cost savings initiative but will also need to raise additional funds and are currently exploring alternative sources of equity or debt financing. We have a 60 million (approximately \$88 million as of December 31, 2007) Step-Up Equity Financing Agreement with Société Générale, of which approximately 59.1 million is available as of March 19, 2008. While we may be able to utilize this agreement to provide additional equity funding, additional funding may not be available on favorable terms or at all. If additional funds are raised by issuing equity securities, substantial dilution to existing shareholders may result. If we fail to obtain additional capital when needed, we may be required to delay, scale back, or eliminate some or all of our research and development programs. The accompanying consolidated financial statements do not include any adjustments that may result from the outcome of this uncertainty.

*Use of Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. For example, estimates include assumptions used in calculating stock compensation expense, our allocation of purchase price to acquired assets and liabilities, our liability for excess facilities, the useful lives of fixed assets, the fair value of our derivatives, calculating our tax provision and related valuation allowance, determining potential impairment of goodwill and other intangible assets, our sales return reserve and any inventory obsolescence reserve. Actual results could differ from those estimates.

*Cash and Cash Equivalents*

We consider all highly liquid debt instruments with maturities of three months or less at the time acquired to be cash equivalents. Cash equivalents represent short-term investments consisting of investment-grade corporate and government obligations, carried at cost, which approximates market value.

*Securities Available-for-Sale*

We determine the appropriate classification of debt securities at the time of purchase. We currently classify our investment portfolio as available-for-sale which consists of U.S. government, municipal and corporate obligations with maturities of up to one year and carries the securities at fair value based on quoted market prices with unrealized gains and losses included in accumulated other comprehensive loss. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Interest on securities available-for-sale and amortization and accretion of premiums and discounts are included in



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**CELL THERAPEUTICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

investment income. Realized gains and losses and declines in value judged to be other-than-temporary on available-for-sale securities, if any, are included in investment income. The cost of securities sold is based on the specific identification method.

*Certain Risks and Concentrations*

We are exposed to risks associated with foreign currency transactions to use U.S. dollars to make contract payments denominated in euros or vice versa. As the net positions of our unhedged foreign currency transactions fluctuate, our earnings might be negatively affected. In addition, we are exposed to risks associated with the translation of euro-denominated financial results and amounts into U.S. dollars. We currently do not utilize forward exchange contracts or any type of hedging instruments to hedge foreign exchange risk as we believe our overall exposure is relatively limited.

We are subject to concentration of credit risk primarily from our cash investments. Under our investment guidelines, credit risk is managed by diversification of the investment portfolio and by the purchase of investment-grade securities. We do not require collateral or other security to support credit sales, but provide an allowance for bad debts when warranted.

If we are unable to obtain sufficient quantities of needed starting materials for the manufacture of our products in development from existing suppliers, or if we were unable to source these materials and services from other suppliers and manufacturers, certain research and development and sales activities may be delayed.

We are exposed to certain labor risks related to our European employees, who represent approximately 31% of our total employees as of December 31, 2007, and who are subject to a collective bargaining agreement as well as to local regulations governing employment.

Additionally, see Note 15, *Customer and Geographic Concentrations*, for further concentration disclosure.

*Product Sales*

We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, title has passed and delivery has occurred, the price is fixed and determinable, and collectability is reasonably assured. Product sales are generally recorded upon shipment net of an allowance for estimated product returns and rebates. We analyze historical return patterns for our products in determining an appropriate estimate for returns allowance. We may need to adjust our estimates if actual results vary which could have an impact on our earnings in the period of adjustment. If customers have product acceptance rights or product return rights, and we are unable to reasonably estimate returns related to that customer or market, we defer revenue recognition until such rights have expired. Our 2007 product sales relate to Zevalin which was acquired from Biogen in December 2007. Our 2005 product sales relate to TRISENOX which was sold to Cephalon in July 2005.

*License and Contract Revenues*

We may generate revenue from technology licenses, collaborative research and development arrangements, cost reimbursement contracts and research grants. Revenue under technology licenses and collaborative agreements typically consists of nonrefundable and/or guaranteed technology license fees, collaborative research funding, and various milestone and future product royalty or profit-sharing payments.

Revenue associated with up-front license fees and research and development funding payments under collaborative agreements is recognized ratably over the relevant periods specified in the agreement, generally the

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**CELL THERAPEUTICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

research and development period. If the time period is not defined in the agreement, we calculate the revenue recognition period based on our current estimate of the research and development period considering experience with similar projects, level of effort and the stage of development. Should there be a change in our estimate of the research and development period, we will revise the term over which the initial payment is recognized. Revenue from substantive at-risk milestones and future product royalties is recognized as earned based on the completion of the milestones and product sales, as defined in the respective agreements. Revenue under cost reimbursement contracts and research grants is recognized as the related costs are incurred. Payments received in advance of recognition as revenue are recorded as deferred revenue.

We evaluate multiple element arrangements pursuant to Emerging Issues Task Force, or EITF, 00-21, *Revenue Arrangements with Multiple Deliverables* for multiple element arrangements that have continuing performance obligations, we recognize contract, milestone or license fees together with any up-front payments over the term of the arrangement as we complete our performance obligation, unless the delivered technology has stand alone value to the customer and there is objective, reliable evidence of fair value of the undelivered element in the arrangement. Additionally, pursuant to the guidance of Securities and Exchange Commission Staff Accounting Bulletin 104, or SAB 104, unless evidence suggests otherwise, revenue from consideration received is recognized on a straight-line basis over the expected term of the arrangement.

*Cost of Product Sold*

Cost of product sold consists of the cost of the product sold to our customers, including any necessary allowances for excess inventory that may expire and become unsaleable. Contractual royalties based on product sales, inventory management fees and shipping and handling costs are also included in cost of product sold.

*Inventory*

Inventory is stated at the lower of cost or market. If the cost of the inventory exceeds the expected market value, provisions are recorded for the difference between the cost and the net realizable value. When required, an allowance for excess inventory that may expire and become unsaleable is recorded. All inventory as of December 31, 2007 consists of finished goods inventory for Zevalin.

*Accounts Receivable*

Our accounts receivable balance includes trade receivables related to Zevalin as of December 31, 2007. Allowance for doubtful accounts are based on estimates of losses related to customer receivable balances. We estimate the allowance based upon the age of the outstanding receivables and our historical experience of collections, adjusting for risk of loss for specific customer accounts. We periodically review the estimation process and make changes to the estimates as necessary. When it is deemed probable that a customer account is uncollectible, that balance is written off against the existing allowance. Allowances for uncollectible accounts receivable and product returns, which are offset against our accounts receivable balance, totaled approximately \$1,575 as of December 31, 2007.

*Research and Development Expenses*

Research and development expenses include related salaries and benefits, clinical trial and related manufacturing costs, contract and other outside service fees, and facilities and overhead costs related to our research and development efforts. Research and development expenses also consist of costs incurred for proprietary and collaboration research and development and include activities such as product registries and

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**CELL THERAPEUTICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

investigator-sponsored trials. Research and development costs are expensed as incurred. Generally, in instances where we enter into agreements with third parties for research and development activities, costs are expensed upon the earlier of when non-refundable amounts are due or as services are performed unless there is an alternative future use of the funds in other research and development projects. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments, and payments upon the completion of milestones or receipt of deliverables.

*Acquired in-process research and development*

Costs to acquire in-process research and development, or IPRD, projects and technologies which have no alternative future use and which have not reached technological feasibility as of acquisition date are expensed as incurred.

*Value Added Tax Receivable*

Our European operations are subject to Value Added Tax, or VAT, which is usually applied to all goods and services purchased and sold throughout Europe. The VAT receivable is approximately \$7.2 million and \$10.6 million as of December 31, 2007 and December 31, 2006, respectively, of which \$6.5 million and \$5.5 million is included in *other assets* and \$0.7 million and \$5.1 million is included in *prepaid expenses and other current assets* as of December 31, 2007 and December 31, 2006, respectively. This receivable balance relates to our Italian operations and typically has a three year collection period. We review our VAT receivable balance for impairment whenever events or changes in circumstances indicate the carrying amount might not be recoverable.

*Property and Equipment*

Property and equipment are carried at cost, less accumulated depreciation and amortization. Depreciation commences at the time assets are placed in service. It is calculated using the straight-line method over the estimated useful lives of the assets ranging from three to five years for assets other than leasehold improvements which are amortized over the lesser of their useful life of 10 years or the term of the applicable lease using the straight-line method.

*Impairment of Long-lived Assets*

We review our long-lived assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Each impairment test is based on a comparison of the undiscounted future cash flows to the recorded value of the asset. If an impairment is indicated, the asset is written down to its estimated fair value based on quoted fair market values. During 2005 we recorded a charge of approximately \$1.0 million for asset impairments associated with our restructuring activities (see Note 11, *Restructuring Activities*).

*Goodwill and Other Intangible Assets*

Goodwill is not amortized but is tested for impairment at least annually, or more frequently if indicators of impairment are present. If goodwill is impaired it is written down; however, no impairment of goodwill has been found to date.

There were no changes in the net carrying amount of goodwill during the years ended December 31, 2007, 2006 and 2005.

Other intangible assets consist of acquisition-related intangible assets. These other intangible assets have finite lives and are carried at cost less accumulated amortization.

**Table of Contents****CELL THERAPEUTICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Other intangible assets are composed of the following as of December 31 (in thousands):

	Gross Carrying Amount	2007 Accumulated Amortization	Net Carrying Amount
Developed and core technologies	\$ 11,306	\$ (28)	\$ 11,278
Manufacturing intangible asset	3,712	(16)	3,696
Assembled workforce	5,699	(4,716)	983
Other intangibles assets	\$ 20,717	\$ (4,760)	\$ 15,957

	Gross Carrying Amount	2006 Accumulated Amortization	Net Carrying Amount
Assembled workforce	\$ 5,088	\$ (3,425)	\$ 1,663

The change in the value of other intangible assets is as follows:

	Developed and Core Technologies	Manufacturing Intangible Asset	Assembled Workforce
Balance as of January 1, 2005	\$	\$	\$ 4,175
Impairment			(232)
Amortization			(1,254)
Decrease due to exchange rate			(450)
Balance as of December 31, 2005			2,239
Amortization			(792)
Increase due to exchange rate			216
Balance as of December 31, 2006			1,663
Increase due to acquisitions	11,306	3,712	68
Amortization	(28)	(16)	(869)
Increase due to exchange rate			121
Balance as of December 31, 2007	\$ 11,278	\$ 3,696	\$ 983

Amortization of the assembled workforce intangible asset is computed using the straight-line method over the estimated useful life of the assembled workforce asset, which is approximately 5 years. In 2005, *restructuring charges and related asset impairments* included an impairment charge of \$0.2 million due to the termination of certain Italian employees included in the original valuation of this asset. We expect amortization expense on assembled workforce to be approximately \$0.9 million for 2008, \$14,000 from 2009 to 2011, and \$8,000 for 2012.

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In 2007, we recorded certain intangible assets in connection with the acquisition of Zevalin. Developed and core technologies are amortized over the terms of the patents related to such technologies of approximately 11.2 years based on a method of amortization that reflects the pattern in which the economic benefit of the intangibles are consumed in accordance with SFAS No. 42, *Goodwill and Other Intangible Assets*. The expected amortization for each of the five succeeding years is approximately \$0.1 million in 2008, and \$1.0 million for each of the years from 2009 to 2012. The manufacturing intangible asset is amortized straight-line over the term of the supply agreement, which is approximately 6.5 years. The expected amortization on the agreement is

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**CELL THERAPEUTICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

approximately \$0.6 million for each of the years from 2008 to 2012. We also review our intangible assets for impairment when events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. If future events or circumstances indicate that the carrying value of these assets may not be recoverable, we may be required to record additional charges to our results of operations.

*Royalty Obligation*

Our royalty obligation to PharmaBio Development, or PharmaBio, was recorded as debt as we had significant continuing involvement in the generation of cash flows due to PharmaBio. The obligation was accreted using the effective interest method and an imputed interest rate that was based on our estimates of total royalty and interest payments due under the arrangement. The amount of royalty and interest payments varied depending on whether we reached certain TRISENOX targets and certain other factors as described in the agreement. We reassessed the imputed interest rate as circumstances changed. We extinguished the royalty obligation in July 2005.

*Stock-Based Compensation*

On January 1, 2006, we adopted Financial Accounting Standards Board, or FASB, Statement No. 123(R), *Share-Based Payment (Revised 2004)*, or SFAS 123(R), which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors including employee stock options, share awards, and employee stock purchases related to the Employee Stock Purchase Plan based on estimated fair values. Prior to January 1, 2006, we accounted for share-based payments under the recognition and measurement provisions of Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, or APB 25, and related interpretations, as permitted by FASB Statement No. 123, *Accounting for Stock-Based Compensation*, or SFAS 123. In accordance with APB 25, no compensation cost was required to be recognized for options granted that had an exercise price equal to the market value of the underlying common stock on the date of grant. We adopted SFAS 123(R) using the modified-prospective transition method, which required the application of the accounting standard as of January 1, 2006, the first day of our fiscal year 2006.

Under SFAS 123(R), stock-based compensation expense recognized is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period. Based on this, our stock-based compensation is reduced for estimated forfeitures at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. In our pro forma information required under SFAS 123 for the periods prior to January 1, 2006, we accounted for forfeitures as they occurred.

Stock compensation expense for options granted to non-employees has been determined in accordance with SFAS 123(R) and EITF Issue No. 96-18, *Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling, Goods or Services*, at the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured. The fair value of options granted to non-employees is periodically remeasured as the underlying options vest.

*Advertising Costs*

The costs of advertising are expensed as incurred. We incurred advertising costs of \$0.6 million, \$0.4 million and \$1.8 million in 2007, 2006, and 2005 respectively.

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**CELL THERAPEUTICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*Net Loss per Share*

Basic net loss per share is calculated based on the net loss divided by the weighted average number of shares outstanding for the period excluding any dilutive effects of options, warrants, unvested restricted stock awards and convertible securities. Diluted earnings per share assumes the conversion of all dilutive convertible securities, such as convertible subordinated debt using the if-converted method, and assumes the exercise or vesting of other dilutive securities, such as options, warrants and restricted stock using the treasury stock method.

*Derivatives Embedded in Certain Debt Securities*

We evaluate financial instruments for freestanding or embedded derivatives in accordance with SFAS, No. 133, *Accounting for Derivative Instruments and Hedging Activities*, or SFAS 133, and related guidance. Derivative instruments are recorded at fair value with changes in value recognized in the period of change.

Our 6.75% convertible senior notes, or 6.75% notes, contain a feature that provides for a make-whole payment upon any conversion of these notes. The payment is equal to the interest on the debt over its term less any amounts paid prior to the date of the conversion. This make-whole feature represents an embedded derivative which is required to be accounted for separately from the related debt securities. The fair value of this derivative is calculated based on a discounted cash flow model.

Our 7.5% convertible senior notes, or 7.5% notes, include a feature that calls for make-whole payments in the event of automatic conversion or if the holder requires us to repurchase the notes upon certain non-stock changes in control. This payment is equal to \$225 per \$1,000 principal amount of the notes less any interest amounts paid prior to the date of conversion or repurchase. This make-whole feature also represents an embedded derivative that must be accounted for separately from the related debt securities. The fair value of this derivative is calculated using a Monte Carlo simulation model that incorporates factors such as the current price of our common stock, its volatility, and time to expiration of the make-whole feature. As of December 31, 2006 we determined that we would make additional discretionary make-whole payments to certain investors during 2007. These additional payments constituted modifications to the terms of the agreement and have been included in the valuation model as of December 31, 2006. All additional planned discretionary make-whole payments were made during the three months ended March 31, 2007.

Changes in the estimated fair value of the derivative liabilities related to both our 6.75% and 7.5% notes are included in *gain on derivative liabilities* and will be calculated until the relevant feature expires or all of the relevant notes are converted or repurchased.

The interest make-whole provision of the 5.75% convertible senior notes represents an embedded derivative. At the issuance of the 5.75% notes, no value was assigned to the fair value of the interest make-whole feature.

*Other Financial Instruments*

At December 31, 2007 and 2006, the carrying value of financial instruments such as receivables and payables approximated their fair values based on the short-term maturities of these instruments. The carrying value of other long-term liabilities approximated fair values because the underlying interest rates approximate market rates at the balance sheet dates.

The estimated fair values of our convertible preferred stock, convertible senior notes, convertible senior subordinated notes and convertible subordinated notes are determined using either discounted cash flow modeling techniques or, where practical, estimated trading prices. The carrying values of the respective notes are net of accretion of debt discount and changes in the fair value of derivative liabilities, if any.

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The estimated fair values of our convertible senior notes, convertible senior subordinated notes, convertible subordinated notes and convertible preferred stock are determined using either discounted cash flow modeling techniques or, where practical, estimated trading prices. The carrying values of our convertible notes are net of accretion of debt discount and changes in the fair value of derivative liabilities, if any. The carrying values of our convertible preferred stock are net of issuance costs and the proceeds which were allocated to stock warrants based on a relative market value approach.

The following is a summary of the estimated fair value of our convertible senior notes, convertible senior subordinated notes and convertible subordinated notes as of December 31, 2007 and 2006 (in thousands):

	<b>December 31,</b>	
	<b>2007</b>	<b>2006</b>
7.5% convertible senior notes	\$ 29,756	\$ 42,780
5.75% convertible senior notes	\$ 26,650	\$
6.75% convertible senior notes	\$ 6,100	\$ 6,549
4.0% convertible senior subordinated notes	\$ 45,403	\$ 34,193
5.75% convertible senior subordinated	\$ 16,907	\$ 20,555
5.75% convertible subordinated notes	\$ 2,910	\$ 19,373

The estimated fair value of our convertible preferred stock as of December 31, 2007 is as follows (in thousands):

	<b>December 31,</b>
	<b>2007</b>
Series A 3% convertible preferred stock	\$ 6,231
Series B 3% convertible preferred stock	\$ 13,799
Series C 3% convertible preferred stock	\$ 7,744
Series D 7% convertible preferred stock	\$ 4,195

*Foreign Currency Translation and Transaction Gains and Losses*

We record foreign currency translation adjustments and transaction gains and losses in accordance with SFAS 52, *Foreign Currency Translation*. For our operations that have a functional currency other than the U.S. dollar, gains and losses resulting from the translation of the functional currency into U.S. dollars for financial statement presentation are not included in determining net loss but are accumulated in the cumulative foreign currency translation adjustment account as a separate component of shareholders' deficit. The Company and its subsidiaries also have transactions in foreign currencies other than the functional currency. We record transaction gains and losses in our consolidated statements of income related to the recurring measurement and settlement of such transactions.

*Comprehensive Loss*

Comprehensive loss is comprised of net loss and other comprehensive income or loss. SFAS 130, *Reporting Comprehensive Income*, provides for unrealized gains and losses on our securities available-for-sale and net exchange gains or losses resulting from the translation of assets and liabilities of foreign subsidiaries to be included in other comprehensive income or loss. Total comprehensive loss was \$140.9 million, \$135.3 million and \$106.2 million as of December 31, 2007, 2006 and 2005, respectively.



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Information regarding the components of accumulated other comprehensive loss is as follows (in thousands):

	2007	2006
Foreign currency translation adjustment	\$ (4,010)	\$ (1,203)
Net unrealized gain on securities available-for-sale	3	16
<b>Total other accumulated comprehensive loss</b>	<b>\$ (4,007)</b>	<b>\$ (1,187)</b>

*Recently Issued Accounting Pronouncements*

On December 4, 2007, Statement of Financial Standard No. 141(R), *Business Combinations*, or SFAS 141(R), was issued. This standard will require an acquiring company to measure all assets acquired and liabilities assumed, including contingent considerations and all contractual contingencies, at fair value as of the acquisition date. In addition, an acquiring company is required to capitalize IPR&D as an indefinite lived intangible asset and either amortize it over the life of the product, or write it off if the project is abandoned or impaired. The acquiring company will be required to expense the acquisition costs rather than be added to the cost of the acquisition. The standard is effective for transactions occurring on or after January 1, 2009. We are evaluating the impact this standard will have on our financial statements.

On December 4, 2007, Statement of Financial Standard No. 160, *Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB No. 51*, or SFAS 160, was issued. This standard changes the accounting for and reporting of noncontrolling or minority interests in consolidated financial statements. The standard is effective January 1, 2009, however the presentation and disclosure requirements of SFAS 160 regarding noncontrolling interests shall be applied retrospectively. We are evaluating the impact, if any, this standard will have on our financial statements.

In November 2007, the EITF reached a consensus on Issue 07-1. EITF 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property*, is focused on how the parties to a collaborative agreement should account for costs incurred and revenue generated on sales to third parties, how sharing payments pursuant to a collaborative agreement should be presented in the income statement and certain related disclosure questions. EITF 07-1 is effective for periods beginning after December 15, 2008. We are evaluating the requirements of these issues and have not yet determined the impact on the financial statements.

In June 2007, the EITF reached a consensus on Issue 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities*, or EITF 07-3, which focuses on whether non-refundable advance payments for goods or services that will be performed in future research and development activities should be accounted for as research and development costs or deferred and capitalized until the goods have been delivered or the related services have been rendered. EITF 07-3 is effective for periods beginning after December 15, 2007. We are evaluating the impact, if any, this EITF will have on our financial statements.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115*, or SFAS 159. The Statement permits entities to choose, at specified election dates, to measure many financial instruments and certain other items at fair value that are not currently measured at fair value. Unrealized gains and losses on items for which the fair value option has been elected would be reported in earnings at each subsequent reporting date. SFAS 159 also establishes presentation and disclosure requirements in order to facilitate comparisons between entities

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choosing different measurement attributes for similar types of assets and liabilities. SFAS 159 does not affect existing accounting requirements for certain assets and liabilities to be carried at fair value. SFAS 159 is effective for fiscal years beginning after November 15, 2007, and adopted by us beginning January 1, 2008. We are evaluating the requirements of SFAS 159 and have not yet determined the impact on the financial statements.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, or SFAS 157, which provides guidance on how to measure assets and liabilities that use fair value. This statement clarifies the principle that fair value should be based on the assumptions market participants would use when pricing an asset or liability and establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. SFAS 157 will apply whenever another generally accepted accounting principle requires, or permits, assets or liabilities to be measured at fair value but does not expand the use of fair value to any new circumstances. This statement will also require additional disclosures in both annual and quarterly reports. SFAS 157 is effective for fiscal years beginning after November 2007, and adopted by us beginning January 1, 2008. We are evaluating the impact, if any, this standard will have on our financial statements.

*Reclassifications*

Certain prior year items have been reclassified to conform to current year presentation.

**2. Securities Available-for-Sale**

Securities available-for-sale consist of the following debt securities as of December 31 (in thousands):

	2007			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate obligations	\$ 1,001	\$	\$ (1)	\$ 1,000
Municipal obligations	799	3		802
U.S. government obligations	745	1		746
	\$ 2,545	\$ 4	\$ (1)	\$ 2,548
	2006			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate obligations	\$ 22,980	\$ 21	\$ (4)	\$ 22,997
Municipal obligations	7,442	2	(4)	7,440
U.S. government obligations	6,270	2	(1)	6,271
	\$ 36,692	\$ 25	\$ (9)	\$ 36,708

As of December 31, 2007, and 2006, all securities available-for-sale had contractual maturities of less than one year. Gross realized gains and losses to date have not been material.



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Property and equipment are composed of the following as of December 31 (in thousands):

	2007	2006
Leasehold improvements	\$ 11,644	\$ 11,208
Lab equipment	7,452	6,311
Furniture and office equipment	18,300	17,878
	37,396	35,397
Less: accumulated depreciation and amortization	(31,371)	(27,482)
	\$ 6,025	\$ 7,915

Depreciation expense of \$4.1 million, \$5.6 million and \$8.9 million was recognized during 2007, 2006, and 2005, respectively. We also recorded fixed asset impairments of \$0.8 million during 2005 related to our restructuring activities.

**4. Accrued Liabilities**

Accrued liabilities consist of the following as of December 31 (in thousands):

	2007	2006
Clinical development and regulatory expense	\$ 11,936	\$ 8,855
USAO litigation claim (see note 19, <i>Legal Proceedings</i> )		10,500
Employee compensation and related expenses	4,738	4,261
Manufacturing expense	2,319	1,286
Corporate development and sales and marketing expense	1,924	911
Insurance financing and accrued interest expense	689	917
Other research and development expenses	464	241
Other	3,964	1,596
	\$ 26,034	\$ 28,567

**5. Contractual Arrangements and Commitments***Lease Agreements*Facilities

We lease our office and laboratory space under operating leases. Leases for our corporate office space contain an annual escalation clause of approximately 3% and the related rent expense is recognized on a straight-line basis over the term of the respective lease. In connection with a lease agreement, we have a \$0.7 million irrevocable, unconditional standby letter of credit which is secured by a certificate of deposit classified in our consolidated balance sheet in *other assets* as of December 31, 2007 and 2006. Rent expense amounted to approximately \$4.0 million, \$3.8

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million and \$7.3 million for the years ended December 31, 2007, 2006 and 2005, respectively. Rent expense is net of sublease income and amounts offset to excess facilities charges (see Note 11, Restructuring Activities).

During 2004 through 2007, we entered into sublease agreements to sublet a portion of our facilities considered to be in excess of current requirements. Total sublease rental income for fiscal years 2007, 2006 and

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2005 was \$1.0 million, \$0.9 million and \$0.2 million, respectively, recorded as an offset to lease expense. Total future sublease income to be recognized is approximately \$0.1 million for 2008 at which time the term of our existing subleases expires.

**Aircraft**

In 2005, we terminated an aircraft operating lease agreement. Rent expense under the lease amounted to \$1.9 million for the year ended December 31, 2005. In 2005 we also made a \$1.2 million payment in connection with the early termination of the lease which is included in *restructuring charges and related asset impairments*.

**Capital Leases**

We have two capital lease agreements related to our European branch to finance lab equipment. One of these capital leases has a rate of 5.1% and terminates in February 2008 and the other has a rate of 6.0% and terminates in May 2010. The gross amount of assets under capital lease obligations was approximately \$0.8 million as of December 31, 2007 and 2006, respectively. The related accumulated depreciation was approximately \$0.4 million and \$0.3 million as of December 31, 2007 and 2006, respectively.

**Future Minimum Lease Payments**

Future minimum lease commitments for noncancelable operating and capital leases at December 31, 2007 are as follows (in thousands):

	<b>Capital Leases</b>	<b>Operating Leases</b>
2008	\$ 73	\$ 6,352
2009	19	6,042
2010	9	5,991
2011		5,899
2012		4,269
Thereafter		968
<b>Total minimum lease commitments</b>	<b>\$ 101</b>	<b>\$ 29,521</b>
Less interest	(4)	
<b>Present value of lease obligation</b>	<b>97</b>	
Less current portion of long-term obligation	(73)	
<b>Long-term obligation</b>	<b>\$ 24</b>	

As of December 31, 2007, 2006 and 2005, we had a liability of approximately \$1.5 million, \$4.0 million and \$6.3 million, respectively, in charges for excess facilities under our current operating leases in accordance with SFAS 146. These charges included lease commitments, net of estimated sublease income (see Note 11, *Restructuring Activities*).

**Supply Agreements****Zevalin**

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In December 2007, in connection with our acquisition of Zevalin, we entered into a seventy-eight month supply agreement with Biogen to manufacture Zevalin for sale in the United States pursuant to which we will purchase from Biogen, and Biogen will provide to us, kits to make single doses as part of one treatment to a patient, of either (i) Indium-111 Ibritumomab Tiuxetan (In-111 Zevalin) or (ii) Yttrium-90 Ibritumomab Tiuxetan (Y-90 Zevalin) either as single kits or in packages containing one dose of each of In-111 Zevalin and Y-90 Zevalin, each

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for sale to end-users in the United States at a cost plus manufacturing price. From the effective date of the supply agreement through June 9, 2014, unless earlier terminated, we have agreed to purchase such kits and/or packages solely from Biogen unless and until both we and Biogen agree to the establishment of a replacement manufacturing source in accordance with the terms and conditions of the Supply Agreement. Each party has agreed to indemnify the other party from and against certain third-party claims related to the manufacture, sale, distribution or use of the goods, as the case may be. We provide rolling forecasts of our supply requirements to Biogen in six-month increments for the next 30 months; however, under the terms of the agreement we are required to purchase a minimum of 150 packages, or 300 kits, for each six-month period in 2008, 2009 and 2010, and a minimum of 250 packages, or 500 kits, for each six month period thereafter until the expiration of the term. Each forecast for the next six months must be accompanied by a firm order, and we may not place orders more frequently than twice a year.

Future purchase obligations under this agreement are as follows (in thousands):

2008	\$ 958
2009	320
2010	320
2011	532
2012	532
Thereafter	799
<b>Total purchase obligations</b>	<b>\$ 3,461</b>

Also in December 2007, in connection with our acquisition of Zevalin, we assumed from Biogen a manufacturing and supply agreement with MDS (Canada) Inc., MDS Nordion Division, or MDS (Canada), pursuant to which MDS (Canada) supplies us with yttrium-90, a radioisotope used in connection with the administration of Zevalin. Under the terms of the agreement, we are required to purchase, and MDS (Canada) is required to manufacture and supply, all of our yttrium-90 requirements for commercial uses of Zevalin. The agreement expires under its current terms in February 2010 and may be terminated by MDS (Canada) at any time without cause on 24 months written notice or by CTI at any time without cause on 6 months written notice.

**Paclitaxel**

In September 2001, we entered into a purchase agreement with Natural Pharmaceuticals, Inc., or NPI, to purchase \$6.0 million of paclitaxel, a starting material for paclitaxel poliglumex, which was to be delivered by NPI over several years. This material was intended to be used primarily for research and development activities. We paid for the entire purchase upon execution of the agreement in 2001 and recorded the amount as a prepaid asset. As we had adequate supply of paclitaxel on hand to support our validation campaigns and clinical activities, we amended our supply agreement with NPI in 2005 to reduce the amount of material we would receive and we were refunded \$0.8 million of our prepayment. In addition, the agreement, as amended, granted NPI the exclusive right to purchase up to 5 kilograms of our paclitaxel supply at our original cost through September 1, 2007. The amended agreement also allows NPI the right to sell some or all of the paclitaxel supply to its customers and replace the material within 60 days with newer material having a longer expiration date. In August 2007, we entered into an additional amendment whereby NPI repurchased 3.7 kilograms of our prepaid paclitaxel which was currently in NPI's possession. The amount paid by NPI would offset the cost of 5.3 kilograms of new paclitaxel supply that NPI originally agreed to provide us by November 1, 2007. We received a portion of this new paclitaxel supply in December 2007 and the remaining amount is expected to be delivered by April 2008.

As of December 31, 2007 and 2006, we had paclitaxel supply of \$0.7 million and \$1.1 million, respectively, which is included in *prepaid expenses and other current assets*. The amount as of December 31, 2007 and 2006 includes approximately \$0.5 million and \$0.4 million in supply due from NPI. These costs have been capitalized





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since there is a ready market for this active pharmaceutical ingredient. The paclitaxel supply was adjusted during the second quarter of 2005 to reflect a \$1.7 million write-down to its estimated re-sale value based on current prices obtained from an external vendor.

**6. Acquisitions****Systems Medicine, Inc.**

On July 31, 2007, we completed the acquisition of SM, in a stock for stock merger. Pursuant to the terms of the acquisition, we issued to SM stockholders an aggregate of 4,211,856 shares of our common stock in exchange for outstanding SM common stock. Of the total shares issued, 421,186 remain in an escrow account subject to any claim for indemnification made by us. Upon the one-year anniversary of the closing date, the acquisition agreement provides instructions on the release of the remaining escrowed shares. Under the agreement, SM became Systems Medicine, LLC, and now operates as a wholly owned subsidiary of CTI.

SM's 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. At this time, it is not possible to predict whether these milestones will be achieved; accordingly, the following estimated purchase price does not reflect the payment of this contingent consideration.

The total cost of the acquisition is estimated to be approximately \$20.4 million, based on the fair value of our common stock of \$4.718, the average price of our common stock during a 5-business day period prior to the date of the acquisition agreement (July 17, 18, 19, 20 and 23, 2007) and related transaction costs, consisting primarily of financial advisory, legal and accounting fees. The total purchase price of the acquisition is as follows (in thousands):

Total value of CTI common stock, including escrowed shares	\$ 20,000
Direct transaction costs	499
<b>Total purchase price</b>	<b>\$ 20,499</b>

Based on the provisions of SFAS No. 141, *Business Combinations*, or SFAS 141, and EITF Issue No. 98-3, *Determining Whether a Nonmonetary Transaction Involves Receipt of Productive Assets or of a Business*, or EITF 98-3 we determined the transaction to be an asset acquisition, and accordingly, the total estimated purchase price as shown in the table above was allocated to SM's net tangible and intangible assets, including IPRD, based on their relative fair values as of July 31, 2007, the closing date of the acquisition. The estimated fair value of these assets in excess of the purchase price was then allocated on a pro rata basis to reduce in-process research and development and non-monetary long-lived assets. The allocation of the purchase price as of the date of the acquisition is as follows (in thousands):

Cash and cash equivalents	\$ 3,100
Prepaid expenses and other current assets	14
Other receivables	116
Notes receivable	99
Property and equipment	4
Intangible assets	68
Other non current assets	2
Accounts payable and accrued expenses	(2,297)
Promissory notes	(2,000)

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Acquired in-process research and development	21,393
<b>Total</b>	<b>\$ 20,499</b>

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Acquired IPRD for the acquisition was evaluated utilizing the present value of the estimated after-tax cash flows expected to be generated by purchased technology related to brostallicin, which, at the effective time of the acquisition, had not reached technological feasibility. Brostallicin is a novel synthetic second-generation DNA minor groove binder that has proven anti-cancer activity and has demonstrated synergy in combination with standard cytotoxic agents as well as with newer targeted therapies in preclinical experimental tumor models. The cash flow projections for future revenues used in the present value calculation of IPRD are based on estimates of growth rates and the aggregate size of the respective market for brostallicin, probability of technical success given the state of development at the time of acquisition, royalty rates based on an assessment of industry market rates, product sales cycles, and the estimated life of a product's underlying technology. These revenue projections include assumptions that significant cash flows from product revenue would commence in 2011. Estimated operating expenses and income taxes are deducted from estimated revenue projections to arrive at estimated after-tax cash flows. Projected operating expenses include cost of goods sold, selling, general and administrative expenses, and research and development costs. The rate utilized to discount projected cash flows was approximately 18%, and was based on the relative risk of the in-process technology and was based primarily on risk adjusted rates of return for similar research and development programs in the industry and the weighted average cost of capital for CTI at the time of the acquisition.

The values associated with this program represent values ascribed by CTI's management, based on the discounted cash flows currently expected from the technology acquired and a pro rata allocation of the estimated fair values of non-monetary assets acquired in excess of the purchase price. The estimated cash flows include the estimated development costs and estimated product launch date with the estimated life of the product ending fourteen years after approval. If the project is not successfully developed, the business, our results of operations and financial condition may be adversely affected. As of the date of the acquisition, we concluded that once completed, the technology under development can only be economically used for the specific and intended purpose and that the in-process technology has no alternative future use after taking into consideration the overall objective of the project, progress toward the objective, and uniqueness of development to this objective. Due to this, all IPRD was expensed on the acquisition date.

**Zevalin**

On December 21, 2007, we acquired the U.S. development, sales and marketing rights to the radiopharmaceutical product Zevalin from Biogen pursuant to an Asset Purchase Agreement. Zevalin is the first FDA-approved radioimmunotherapy and was approved in 2002 to treat patients with relapsed or refractory low-grade, follicular, or B-cell 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. The acquisition did not include physical facilities, an employee base, or working capital accounts. Additionally, CTI 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. The purchase consideration consisted of an initial purchase price of \$10.1 million in cash and other acquisition costs of approximately \$2.0 million, consisting primarily of financial advisory, legal and accounting fees. The direct transaction costs are estimated, pending resolution of certain accruals related to the acquisition. We are also responsible for up to \$20 million in contingent milestone payments consisting of two \$10 million payments, based on positive trial outcomes and FDA approval for label expansion, or contingent consideration. We believe the likelihood of making one such \$10 million payment is remote as we have determined that label expansion for an aggressive NHL indication is remote at this time. To date, no contingent payments have been made. CTI is also obligated to make additional royalty payments based on net sales of Zevalin.

Based on the provisions of SFAS 141, and EITF 98-3, we determined the transaction to be a business combination and was accounted for using the purchase method of accounting. The results of operations of

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Zevalin have been included in our consolidated financial statements effective December 21, 2007. The purchase price was allocated to Zevalin's intangible assets, including IPRD, based on their fair values at the date of acquisition as determined by management. A valuation of the intangible assets was performed by an independent third party, and was used as the basis for management's consideration of these fair values. The total estimated purchase consideration was allocated as follows (in thousands):

Core technology	\$ 9,755
Developed technology	1,551
Manufacturing intangible asset	3,712
Acquired in-process research and development	3,222
Contingent purchase price	(6,180)
 Total estimated purchase price	 \$ 12,060

The fair value of the assets acquired exceeded the unconditional consideration paid by approximately \$6.2 million. Because the acquisition involved contingent consideration, we were required to recognize additional purchase consideration equal to the lesser of the excess fair value or the maximum amount of contingent consideration of \$20 million. Accordingly, contingent consideration totaling approximately \$6.2 million has been recorded as a liability, thereby reducing the excess fair value. This amount is included in *long-term obligations, less current portion*.

When the contingency is resolved and the consideration is issued or becomes issuable, any excess of the fair value of the contingent consideration issued or issuable over the amount that was recognized as a liability shall be recognized as an additional cost of the acquired entity. If the amount initially recognized as a liability exceeds the fair value of the consideration issued or issuable, that excess will be allocated as a pro rata reduction of the amounts assigned to the assets acquired. Any amount that remains after reducing those assets to zero will be recognized as an extraordinary gain.

The developed technology asset relates to intellectual property and rights thereon related to Zevalin as approved by the FDA for relapsed or refractory low-grade, follicular, or B-cell NHL. The core technology asset represents the value of the intellectual property and rights thereon expected to be leveraged in the development of label expansions for Zevalin.

Acquired IPRD for the acquisition was evaluated utilizing the present value of the estimated after-tax cash flows expected to be generated by purchased undeveloped technology related to Zevalin for label expansions for indications that have not been approved by the FDA which, at the effective time of the acquisition, had not reached technological feasibility. The cash flow projections for future revenues used in the present value calculation of IPRD are based on estimates of growth rates and the aggregate size of the respective market for Zevalin as it relates to label expansions, the expected annual price per script and the expected discounts, returns and allowances, distribution charges, and rebates per unit. The projections for revenues related to label expansions include assumptions that cash flows from product revenue would commence in 2009. Estimated operating expenses and income taxes are deducted from estimated revenue projections to arrive at estimated after-tax cash flows. Projected operating expenses include cost of goods sold, selling, general and administrative expenses, and research and development costs. The rate utilized to discount projected cash flows was approximately 45%, and was based on the relative risk of the in-process technology and was based primarily on risk adjusted rates of return for research and development and the weighted average cost of capital for CTI at the time of the acquisition.

The value associated with IPRD represents the value ascribed by CTI's management, based on the discounted cash flows under the multi-period excess earnings method currently expected from the technology

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acquired. The estimated cash flows include the estimated development costs and estimated revenues related to label expansions from the commencement date referred to above with the estimated economic life of the product ending 14 years after its approval for additional indications. If label expansions for Zevalin are not approved by the FDA, the business, our results of operations and financial condition may be adversely affected. As of the date of the acquisition, we concluded that once completed, the technology under development can only be economically used for the specific and intended purpose and that the in-process technology has no alternative future use after taking into consideration the overall objective of the project, progress toward the objective, and uniqueness of development to this objective. Due to this, all IPRD was expensed on the acquisition date.

*Pro forma results of operations (unaudited)*

Our consolidated statements of operations for the year ended December 31, 2007 include SM's results of operations from July 31, 2007 and Zevalin's results of operations from December 21, 2007.

The following table sets forth the pro forma combined results of operations of CTI, SM and Zevalin for the years ended December 31, 2007 and 2006 (in thousands, except per share amounts):

	<b>Year Ended</b>	
	<b>December 31,</b>	
	<b>(unaudited)</b>	
	<b>2007</b>	<b>2006</b>
Revenues	\$ 13,829	\$ 16,498
Net loss attributable to common shareholders	(159,065)	(160,192)
Basic and diluted net loss per common share	\$ (3.21)	\$ (4.96)

For pro forma purposes:

CTI's consolidated results of operations for the years ended December 31, 2007 and 2006 have been combined with SM's results of operations and Zevalin's statement of net revenues and direct expenses for the years ended December 31, 2007 and 2006 as if the mergers had occurred on January 1, 2007 and 2006, respectively;

The pro forma results do not include the effect or the charge for IPRD for the year ended December 31, 2006 as this is a non-recurring charge resulting from the acquisitions. As our consolidated statement of operations for the year ended December 31, 2007 includes IPRD, for consistency purposes the pro forma amounts above also include IPRD for this period.

The unaudited pro forma combined financial data is intended for information purposes only and does not purport to represent what our results of operations would actually have been if the acquisition had in fact occurred on the dates indicated or to project our financial position or results of operations as of any future date or any future period.

**7. Convertible Preferred Stock**

*Series A 3% Convertible Preferred Stock*

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In February 2007, we issued 20,000 shares of our Series A 3% Convertible Preferred Stock, or Series A preferred stock, in a registered offering at an issue price of \$1,000 per share with an annual dividend rate of 3%, payable quarterly. The Series A preferred stock is convertible at any time into a number of shares of our common stock determined by dividing the stated value of the preferred stock to be converted, which is \$1,000 per share, by the conversion price, which is currently \$6.69 following adjustment for our one-for-four reverse stock split on April 15, 2007. The initial conversion price is subject to adjustment in certain events. The Series A preferred stock votes on an as-converted basis with the common stock.

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**CELL THERAPEUTICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In connection with the Series A preferred stock issuance, we issued warrants to purchase an additional 1,494,766 shares of our common stock at an exercise price of \$6.44 per share. The warrants became exercisable on April 16, 2007 and will terminate two years after this date.

The holders of Series A preferred stock have the right to require us to redeem all or a portion of the Series A preferred stock shares, payable in common stock, upon the occurrence of certain triggering events, as discussed below, for a redemption amount equal to the greater of (a) 130% of the stated value or (b) the product of (1) the volume weighted average price of the common stock on the trading day preceding the conversion and (2) the stated value divided by the conversion price; plus all accrued and unpaid dividends or other payments on such shares. In addition, at any time after the two-year anniversary of the original issue date, holders of Series A preferred stock have the right to require us to redeem any of their outstanding Series A preferred stock for cash at the stated value plus any accrued but unpaid dividends or other payments due on the shares being redeemed. The initial stated value of the convertible preferred stock is \$1,000 per share. With respect to our accounting for the preferred stock, because redemption is at the option of the holder of the Series A preferred stock and is not certain to occur, it is considered contingently redeemable and is not classified as a liability under the scope of SFAS 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*. In addition, EITF Topic D-98, *Classification and Measurement of Redeemable Securities*, states that Rule 5-02.28 of Regulation S-X requires securities with redemption features that are not solely within the control of the issuer to be recorded outside of permanent equity. As the Series A preferred stock shares include certain redemption features that may be triggered by events or actions that are outside our control, we have classified these shares as mezzanine equity.

The net proceeds from the issuance of the Series A preferred stock of approximately \$18.6 million were allocated between the fair value of the warrants and the Series A preferred stock. Using the Black-Scholes option pricing model, we calculated the relative fair value of the warrants to purchase 1,494,766 of our common stock to be approximately \$3.5 million. This relative fair value has been recorded as a reduction of the mezzanine equity balance for the preferred stock and an addition to common stock. Additionally, we calculated a beneficial conversion feature charge related to the conversion price for the preferred stock to common stock of approximately \$2.6 million. As the preferred stock can be converted immediately, the amount of the beneficial conversion feature was immediately accreted and resulted in a deemed dividend. This charge was recorded as a dividend expense included in *preferred stock beneficial conversion feature* in determining the net loss attributable to common shareholders.

During the year ended December 31, 2007, 13,150 shares of Series A preferred stock were converted into 1,965,619 shares of common stock. As of December 31, 2007, we had approximately \$51,000 of Series A preferred stock dividends accrued which were paid in January 2008.

*Series B 3% Convertible Preferred Stock*

In April 2007, we issued 37,200 shares of our Series B 3% convertible preferred stock, or Series B preferred stock, in a registered offering at an issue price of \$1,000 per share with an annual dividend rate of 3%, payable quarterly. The Series B preferred stock is convertible at any time into a number of shares of our common stock determined by dividing the stated value of the preferred stock to be converted, which is initially \$1,000 per share, by the conversion price, which is initially \$6.73. The initial conversion price is subject to adjustment in certain events. The Series B preferred stock votes on an as-converted basis with the common stock.

In connection with the Series B preferred stock issuance, we issued warrants to purchase an additional 2,763,731 shares of our common stock at an exercise price of \$6.48 per share. The warrants became exercisable on October 16, 2007 and will terminate two years from this date.



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The holders of Series B preferred stock have the right to require us to redeem all or a portion of the Series B preferred stock shares, payable in common stock, upon the occurrence of certain triggering events, as discussed below, for a redemption amount equal to the greater of (a) 130% of the stated value or (b) the product of (1) the volume weighted average price of the common stock on the trading day preceding the conversion multiplied by (2) the stated value divided by the conversion price; plus all accrued and unpaid dividends or other payments on such shares. In addition, at any time after the two-year anniversary of the original issue date and subject to the prior rights of the Series A preferred stock, holders of Series B preferred stock have the right to require us to redeem any of their outstanding Series B preferred stock for cash at the stated value plus any accrued but unpaid dividends or other payments due on the shares being redeemed. Based on these redemption features, which are comparable to the redemption features of our other preferred stock, we have classified these shares as mezzanine equity in accordance with the guidance discussed above in the Series A preferred stock.

The net proceeds from the issuance of the Series B preferred stock of approximately \$34.8 million were allocated between the fair value of the warrants and the Series B preferred stock. Using the Black-Scholes option pricing model, we calculated the relative fair value of the warrants to purchase 2,763,731 shares of our common stock to be approximately \$6.1 million. This relative fair value has been recorded as a reduction of the mezzanine equity balance for the Series B preferred stock and an addition to common stock. Additionally, we calculated a beneficial conversion feature charge related to the conversion price for the Series B preferred stock to common stock of approximately \$1.8 million. As the Series B preferred stock can be converted immediately, the amount of the beneficial conversion feature was immediately accreted and resulted in a deemed dividend. This charge was recorded as a dividend expense included in *preferred stock beneficial conversion feature* in determining the net loss attributable to common shareholders.

During the year ended December 31, 2007, 21,820 shares of Series B preferred stock were converted into 3,242,190 shares of common stock. As of December 31, 2007, we had approximately \$115,000 of Series B preferred stock dividends accrued which were paid in January 2008.

*Series C 3% Convertible Preferred Stock*

In July 2007, we issued 20,250 shares of our Series C 3% convertible preferred stock, or Series C preferred stock, in a registered offering at an issue price of \$1,000 per share with an annual dividend rate of 3%, payable quarterly. The Series C preferred stock is convertible at any time into a number of shares of our common stock determined by dividing the stated value of the preferred stock to be converted, which is initially \$1,000 per share, by the conversion price, which is initially \$3.90. The initial conversion price is subject to adjustment in certain events. The Series C preferred stock will have the right to the number of votes equal to the stated value, or \$1,000 per share, divided by \$4.53 in all matters as to which shareholders are required or permitted to vote with the common stock.

In connection with the Series C preferred stock issuance, we issued warrants to purchase an additional 2,596,148 shares of our common stock at an exercise price of \$4.53 per share. The warrants will not be exercisable until January 27, 2008 and will terminate on the second anniversary of the date upon which they become exercisable.

The holders of Series C preferred stock have the right to require us to redeem all or a portion of the Series C preferred stock shares, payable in common stock, upon the occurrence of certain triggering events, as discussed below, for a redemption amount equal to the greater of (a) 130% of the stated value or (b) the product of (1) the volume weighted average price of the common stock on the trading day preceding the conversion multiplied by (2) the stated value divided by the conversion price; plus all accrued and unpaid dividends or other payments on such shares. In addition, at any time after the two-year anniversary of the original issue date and subject to the prior rights of the Series A and B preferred stock, holders of Series C preferred stock have the right to require us

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**CELL THERAPEUTICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

to redeem any of their outstanding Series C preferred stock for cash at the stated value plus any accrued but unpaid dividends or other payments due on the shares being redeemed. Based on these redemption features, which are comparable to the redemption features of our other preferred stock, we have classified these shares as mezzanine equity in accordance with the guidance discussed above in the Series A preferred stock.

The net proceeds from the issuance of the Series C preferred stock of approximately \$18.9 million were allocated between the fair value of the warrants and the Series C preferred stock. Using the Black-Scholes option pricing model, we calculated the relative fair value of the warrants to purchase 2,596,148 shares of our common stock to be approximately \$3.7 million. This relative fair value has been recorded as a reduction of the mezzanine equity balance for the Series C preferred stock and an addition to common stock. Additionally, we calculated a beneficial conversion feature charge related to the conversion price for the Series C preferred stock to common stock of approximately \$3.9 million. As the Series C preferred stock can be converted immediately, the amount of the beneficial conversion feature was immediately accreted and resulted in a deemed dividend. This charge was recorded as a dividend expense included in *preferred stock beneficial conversion feature* in determining the net loss attributable to common shareholders.

During the year ended December 31, 2007, 11,966 shares of Series C preferred stock were converted into 3,068,195 shares of common stock. As of December 31, 2007, we had approximately \$62,000 of Series C preferred stock dividends accrued which were paid in January 2008.

*Series D 7% Convertible Preferred Stock*

In December 2007, we issued 6,500 shares of our Series D 7% convertible preferred stock, or Series D preferred stock, in a registered offering at an issue price of \$1,000 per share with an annual dividend rate of 7%, payable quarterly. The Series D preferred stock is convertible at any time into a number of shares of our common stock determined by dividing the stated value of the preferred stock to be converted, which is initially \$1,000 per share, by the conversion price, which is initially \$2.6125. The initial conversion price is subject to adjustment in certain events. The Series D preferred stock votes on an as-converted basis with the common stock.

In connection with the Series D preferred stock issuance, we issued warrants to purchase an additional 1,244,016 shares of our common stock at an exercise price of \$2.55 per share. The warrants will not be exercisable until June 3, 2008 and will terminate on the second anniversary of the date upon which they become exercisable.

The holders of Series D preferred stock have the right to require us to redeem all or a portion of the Series D preferred stock shares, payable in common stock, upon the occurrence of certain triggering events, as discussed below, for a redemption amount equal to the greater of (a) 130% of the stated value or (b) the product of (1) the volume weighted average price of the common stock on the trading day preceding the conversion multiplied by (2) the stated value divided by the conversion price; plus all accrued and unpaid dividends or other payments on such shares. In addition, at any time after the two-year anniversary of the original issue date and subject to the prior rights of the Series A, B and C preferred stock, holders of Series D preferred stock have the right to require us to redeem any of their outstanding Series D preferred stock for cash at the stated value plus any accrued but unpaid dividends or other payments due on the shares being redeemed. Based on these redemption features, which are comparable to the redemption features of our other preferred stock, we have classified these shares as mezzanine equity in accordance with the guidance discussed above in the Series A preferred stock.

The net proceeds from the issuance of the Series D preferred stock of approximately \$6.0 million were allocated between the fair value of the warrants and the Series D preferred stock. Using the Black-Scholes option pricing model, we calculated the relative fair value of the warrants to purchase 1,244,016 shares of our common stock to be approximately \$1.3 million. This relative fair value has been recorded as a reduction of the mezzanine

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**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

equity balance for the Series D preferred stock and an addition to common stock. Additionally, we calculated a beneficial conversion feature charge related to the conversion price for the Series D preferred stock to common stock of approximately \$1.2 million. As the Series D preferred stock can be converted immediately, the amount of the beneficial conversion feature was immediately accreted and resulted in a deemed dividend. This charge was recorded as a dividend expense included in *preferred stock beneficial conversion feature* in determining the net loss attributable to common shareholders.

During the year ended December 31, 2007, 2,500 shares of Series D preferred stock were converted into 956,936 shares of common stock. As of December 31, 2007, we had approximately \$23,000 of Series D preferred stock dividends accrued which were paid in January 2008.

*Triggering Events*

Triggering events that will cause the Series A, B, C and D Preferred Stock to become redeemable are as follows:

We fail to provide an effective registration statement for the common stock issuable on conversion of the convertible preferred stock, subject to a grace period of 20 calendar days;

We fail to deliver stock certificates for the common stock issued on a conversion of the convertible preferred stock before the fifth trading day after the certificates are required to be delivered;

We provide notice to the holders or public notice that we do not intend to comply with requests for conversion of the convertible preferred stock;

We fail to have available a sufficient number of authorized and unreserved shares of common stock for issuance on conversion of the convertible preferred stock;

We fail to observe or perform a covenant, agreement or warranty contained in, or otherwise commit a breach, of the purchase agreement and related transaction documents under which the convertible preferred stock are being sold, and such failure or breach is not cured within 30 calendar days after we receive notice of such failure or breach;

We are a party to a change of control transaction which transfers control of greater than 33% of the legal or beneficial ownership of the company or which is a merger, consolidation, sale of assets or similar transaction following which our shareholders immediately prior to the transaction own less than 66% of the aggregate voting power of the surviving or acquiring entity;

We enter into voluntary or involuntary bankruptcy proceedings that are not dismissed within 60 days, are adjudicated bankrupt or insolvent, have a custodian appointed for any significant part of our assets, make a general assignment for the benefit of creditors, call a meeting of our creditors with a view to arranging a composition, adjustment or restructuring of our debts, or act or fails to act in such a manner that it expressly indicates our consent to, approval of or acquiescence in any such proceedings;

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Our common stock is not listed or quoted for trading on the NASDAQ Global Market or NASDAQ Capital Market for more than 5 trading days, even if such days are not consecutive; or

any monetary judgment, writ or similar final process is entered or filed against the Company or a subsidiary or any of its property or assets for greater than \$50,000 and such judgment, writ or similar final process is not vacated, bonded or stayed within 45 calendar days.

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## CELL THERAPEUTICS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**8. Convertible Notes and Long-Term Obligations**

The following table summarizes the changes in the principal balances of our convertible notes during the years ended December 31, 2007 and 2006 (in thousands):

	5.75% Convertible Senior Notes	7.5% Convertible Senior Notes	6.75% Convertible Senior Notes	4% Convertible Senior Subordinated Notes	5.75% Convertible Senior Subordinated Notes	5.75% Convertible Subordinated Notes
Balance at January 1, 2006	\$	\$	\$ 79,000	\$ 55,150	\$ 66,929	\$ 29,640
Issued		66,312				
Converted		(17,560)	(69,345)		(4)	
Redeemed			(2,655)			
Exchanged					(39,518)	(1,150)
Balance at December 31, 2006		48,752	7,000	55,150	27,407	28,490
Issued	23,250					
Converted		(15,294)				
Exchanged					(10,500)	(25,580)
Balance at December 31, 2007	\$ 23,250	\$ 33,458	\$ 7,000	\$ 55,150	\$ 16,907	\$ 2,910

*5.75% convertible senior notes*

In December 2007, we issued approximately \$23.3 million aggregate principal amount of our 5.75% convertible senior notes, or 5.75% senior notes, and approximately 5.5 million shares of our common stock in exchange for \$10.5 million of our 5.75% convertible senior subordinated notes and \$25.58 million of our 5.75% convertible subordinated notes. The exchange was accounted for as an extinguishment of debt in accordance with the provisions of EITF 96-19, *Debtor's Accounting for a Modification or Exchange of Debt Instruments*, since the terms of the 5.75% senior notes resulted in substantially different cash flows. Accordingly, the 5.75% senior notes are initially recorded at an estimated fair value of \$26.7 million, and a debt discount of approximately \$3.4 million relating to the difference between the fair value and face value of the 5.75% senior notes is being accreted over the four-year life of the notes as additional interest expense using the effective interest method. We recorded interest expense of \$37,000 for the year ended December 31, 2007. The exchange resulted in a loss of approximately \$1.0 million including a write-off of \$0.1 million of unamortized issuance costs attributed to the extinguished notes. Issuance costs related to this transaction were approximately \$0.5 million which are recorded in *other assets* and are being amortized to interest expense using the effective interest method over the four-year life of the notes.

The notes are due December 15, 2011 with interest payable semi-annually in June and December. The notes are convertible, at the option of the holder, into shares of our common stock at any time prior to maturity, redemption or repurchase at an initial conversion rate of 333.333 shares of common stock per \$1,000 principal amount of the notes, which is subject to adjustments in certain circumstances. This conversion rate is equivalent to a conversion price of approximately \$3.00 per share. On or after December 15, 2009, we have the option to redeem all of the notes for cash at any time at a redemption price equal to par plus accrued and unpaid interest up to but not including the redemption date. 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. Upon a change in control, the holder can require us to repurchase the notes at 100% of their principal amount, plus accrued and unpaid interest and any other amounts due up to, but not including, the



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repurchase date. In addition, upon any of these occurrences (redemption, automatic conversion, or repurchase) we will pay the holder of the notes a make-whole interest payment equal to \$115 per \$1,000 principal amount of the notes so converted, less any interest paid on such notes prior to the conversion date.

Additionally, we entered into a registration rights agreement, pursuant to which we have agreed to prepare and file a resale registration statement with respect to the 5.75% senior notes, common stock issuable upon conversion of the 5.75% senior notes and the common stock issued in the exchange transaction as described above, no later than 90 days following the issuance of the notes and the common stock. We have also agreed to use our best efforts to cause such registration statement to be declared effective within 180 days of the issuance of the notes. If we fail to timely file or cause such shelf registration to be declared effective, we are required to pay additional interest at 0.50% per annum per U.S. \$1,000 principal amount of the notes that are payable, not exceeding the applicable maximum amount of 4.5% per annum or 12% per annum when combined with the stated interest on the notes, regardless of whether one or multiple registration defaults exist. In accordance with FASB Staff Position, or FSP, EITF 00-19-2, *Accounting for Registration Payment Arrangements*, if the transfer of consideration under a registration payment arrangement is probable and can be reasonably estimated at inception, the contingent liability under the registration payment arrangement shall be included in the allocation of proceeds from the related financing transaction using the measurement guidance in SFAS No.5, *Accounting for Contingencies*. At the time of the closing of the exchange, we concluded that the probability of triggering such liquidated damages was remote.

*7.5% convertible senior notes*

In April 2006, we issued approximately \$66.3 million aggregate principal amount of our 7.5% notes, approximately \$33.2 million of which was issued in a registered offering for cash with net proceeds of approximately \$31.2 million, after deducting expenses and the initial purchaser's discounts and commissions. Approximately \$33.2 million was issued in a private exchange for approximately \$39.5 million aggregate principal amount of our 5.75% convertible senior subordinated notes and approximately \$1.2 million aggregate principal amount of our 5.75% convertible subordinated notes. We recognized a net gain of \$8.0 million on the early extinguishment and exchange of these notes which is based on the carrying value of the exchanged notes less the fair value of the new notes, net of issuance costs of \$0.4 million and accrued interest of \$0.9 million attributable to the exchanged notes. We recorded issuance costs related to the 7.5% notes of approximately \$2.0 million which are recorded in *other assets* and are being amortized to interest expense using the effective interest method over the five-year life of the notes.

The notes are due April 30, 2011 with interest payable semi-annually in April and October. The notes are convertible, at the option of the holder, into shares of our common stock at any time prior to maturity, redemption or repurchase at an initial conversion rate of 119.63 shares of common stock per \$1,000 principal amount of the notes, which is subject to adjustments in certain circumstances. This conversion rate is equivalent to a conversion price of approximately \$8.36 per share. On or after April 30, 2009, we have the option to redeem all of the notes for cash at any time at a redemption price equal to par plus accrued and unpaid interest up to but not including the redemption date. Subject to certain conditions, the notes will automatically convert if, at any time after June 26, 2006 and prior to maturity, the closing price per share of our common stock has exceeded 125% of the conversion price then in effect for at least 20 trading days within any 30-consecutive trading day period. In addition, upon certain non-stock changes in control, the holder can require us to repurchase the notes at 100% of their principal amount, plus accrued and unpaid interest to, but not including, the repurchase date. Upon any automatic conversion of the notes, or if the holder exercises their right to require us to repurchase notes in connection with a non-stock change of control, we will pay the holder of the notes a make-whole interest payment equal to \$225 per \$1,000 principal amount of the notes so converted, less any interest paid on such notes prior to the conversion date.

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For the years ended December 31, 2007 and 2006, \$15.3 million and \$17.6 million of our 7.5% notes were converted into 1.8 million and 2.1 million shares of common stock. In connection with the conversion of \$13.6 million of these notes in 2007, we made discretionary interest make-whole payments of approximately \$2.3 million which is included in *make-whole interest expense* for the year ended December 31, 2007. In connection with the conversion of \$7.4 million of these notes in May 2006, we made a discretionary interest make-whole payment of approximately \$1.7 million which is included in *make-whole interest expense* for the year ended December 31, 2006.

*6.75% convertible senior notes*

In November 2005, we completed the issuance of \$82 million of 6.75% convertible senior notes due October 31, 2010 with interest payable semi-annually in April and October. Net proceeds to us were approximately \$77.7 million, after deducting expenses and the initial purchaser's discounts and commissions. We recorded issuance costs related to the notes of approximately \$4.9 million which includes approximately \$0.6 million related to the Black-Scholes estimated fair value of warrants issued to the initial purchaser of the notes. These issuance costs are recorded in *other assets* and are being amortized to interest expense using the effective interest method over the five-year life of the notes.

The notes are convertible, at the option of the holder, into shares of our common stock at any time prior to maturity, redemption or repurchase at an initial conversion rate of 95.09 shares of common stock per \$1,000 principal amount of the notes, which is subject to adjustment in certain circumstances. This conversion rate is equivalent to a conversion price of approximately \$10.52 per share. We also issued warrants to purchase 87,500 shares of common stock within five years at an exercise price of \$14.00 per share to the initial purchaser of these notes. We have the option to redeem all of the notes if the closing price per share of our common stock has exceeded 125% of the conversion price then in effect for at least 20 trading days within any 30-consecutive trading day period. The redemption price will be par including accrued and unpaid interest up to but not including the redemption date. Upon any conversion of the notes, we will pay the holder of the notes a make-whole interest payment equal to \$337.50 per \$1,000 principal amount of the notes so converted, less any interest paid on such notes prior to the conversion date.

On April 30, 2006, holders of the notes had the right to cause us to redeem in cash up to 30% of the aggregate amount of the notes, or approximately \$24.6 million, on a pro-rata basis, excluding any accrued and unpaid interest. Certain holders of the notes exercised their right and we redeemed approximately \$2.7 million in aggregate principal of these notes. For the years ended December 31, 2006 and 2005, \$69.3 million and \$3.0 million of the 6.75% notes were converted into 6.6 million and 0.3 million shares of common stock, respectively. This resulted in make-whole interest payments of \$23.1 million and \$1.0 million for the years ended December 31, 2006 and 2005, respectively. There were no conversions of 6.75% notes for the year ended December 31, 2007.

*Conversion and Placement Agreement*

In November 2005, in conjunction with issuance of the 6.75% convertible senior notes, we entered into a Conversion and Placement Agreement, or CAP agreement, with two existing holders of approximately \$18.5 million of our outstanding 5.75% Convertible Senior Subordinated Notes, or 5.75% notes, and approximately \$19.9 million of our 4% Convertible Senior Subordinated Notes, or 4% notes. Pursuant to the original terms of the agreement, the CAP holders agreed to exercise their right to convert their 5.75% notes and 4% notes into approximately 0.8 million shares of our common stock. In connection with the conversion, we also issued to the CAP holders a \$23.6 million conversion inducement which consisted of 0.8 million shares of common stock and



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1.6 million shares issuable upon exercise of zero strike price warrants. The shares and warrants were valued based on the trading price of our common stock on the effective date of the agreement. The conversion inducement was recorded as *debt conversion expense* during the year ended December 31, 2005.

Under the terms of this agreement we were required to file a resale registration statement with respect to these shares which was required to be declared effective by November 30, 2005. We filed the resale registration statement on November 30, 2005, however it was not declared effective until December 2005 and as a result, we were required to make a liquidated damages payment of approximately \$1.2 million which is included in *interest expense* for the year ended December 31, 2005.

*Convertible senior subordinated notes*

In June 2003, we issued \$75.0 million principal amount of 4.0% convertible senior subordinated notes due July 1, 2010 with interest payable semi-annually in January and July. Net proceeds to us were approximately \$72.1 million, after deducting expenses and the initial purchaser's discounts and commissions. We recorded issuance costs related to the notes of approximately \$2.9 million. These issuance costs are recorded as *other assets* and are being amortized to interest expense using the effective interest method, over the seven-year life of the notes.

The notes are convertible, at the option of the holder, into shares of our common stock at any time prior to maturity, redemption or repurchase at an initial conversion rate of 18.5185 shares of common stock per \$1,000 principal amount of notes, which is subject to adjustment in certain circumstances. This conversion rate is equivalent to a conversion price of approximately \$54.00 per share. Prior to maturity, we may redeem the notes upon certain conditions, the most significant of which is that the closing price of our common stock must exceed 150% of the conversion price for at least 20 trading days within a period of 30 consecutive trading days. Upon such redemption, we would make an additional payment of \$280.00 per \$1,000 note, less any interest previously paid on the notes. The holder may elect to convert their notes prior to any such redemption.

In connection with the exchange of convertible subordinated notes in December 2002 as described below, we issued \$85.5 million of 5.75% convertible senior subordinated notes and recorded additional issuance costs of approximately \$2.1 million, which are recorded in *other assets* and are being amortized to interest expense using the effective interest method, over the remaining life of the notes. The terms of the new notes are similar to the convertible subordinated notes except for the conversion price and provisional redemption provision. The conversion rate for these notes is 25 shares per \$1,000 principal note; this is equivalent to a conversion price of \$40.00 per share. We can redeem the notes at specified redemption prices ranging from 103.286% to 100% of the principal amount. The redemption prices will vary depending on the year redeemed. The holder may elect to convert their notes prior to any such redemption.

In December 2007, \$10.5 million of 5.75% convertible senior subordinated notes were cancelled in exchange for approximately 2.4 million shares of our common stock and \$4.8 million of our 5.75% convertible senior notes as described above. We recognized a net loss of \$24,000 on the early extinguishment of these notes resulting from the acceleration of the remaining unamortized debt issuance costs.

Additionally, in February 2008, approximately \$8.9 million of the 5.75% convertible senior subordinated notes were cancelled in exchange for approximately 6.7 million shares of our common stock.

*Convertible subordinated notes*

In June and September 2001, we issued a total of \$175.0 million principal amount of 5.75% convertible subordinated notes due June 15, 2008 with interest payable semi-annually in June and December. Net proceeds to us

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were approximately \$168.0 million, after deducting expenses and the initial purchaser's discounts and commissions. We recorded issuance costs related to the notes of approximately \$7.0 million. Issuance costs are recorded in *other assets* and amortized to interest expense over the life of the notes using the effective interest method.

The notes are convertible, at the option of the holder, into shares of our common stock at any time prior to maturity or redemption at a conversion rate of 7.353 shares per each \$1,000 principal note, subject to adjustment in certain circumstances. This is equivalent to a conversion price of \$136.00 per share. We can redeem the notes at specified redemption prices ranging from 103.286% to 100% of the principal amount. The redemption prices will vary depending on the year redeemed. The holder may elect to convert their notes prior to any such redemption.

In December 2002, we completed an exchange offer for the 5.75% convertible subordinated notes, in which approximately \$145.4 million of our convertible subordinated notes were tendered in exchange for approximately \$85.5 million of our new convertible senior subordinated notes. We recognized a net gain of \$55.3 million on the early extinguishment of these notes. This net gain is based on the carrying value of the exchanged notes less the fair value of the new notes, net of issuance costs of \$4.6 million attributable to the exchanged notes. In addition, \$1.2 million of these notes were exchanged for our 7.5% notes in April 2006 as described above.

In December 2007, \$25.6 million of 5.75% convertible subordinated notes were cancelled in exchange for approximately 3.0 million shares of our common stock and \$18.5 million of our 5.75% convertible senior notes as described above. We recognized a net loss of \$75,000 on the early extinguishment of these notes resulting from the acceleration of the remaining unamortized debt issuance costs.

Additionally, in February 2008, \$150,000 of the 5.75% convertible subordinated notes were cancelled in exchange for approximately 0.1 million shares of our common stock.

*Embedded Features*

The interest make-whole provision of the 7.5% notes represents an embedded derivative which is required to be accounted for separate from the underlying notes. At the issuance of the 7.5% notes, the interest make-whole feature was estimated to have a fair value of approximately \$3.7 million and the initial recorded value of the 7.5% notes was reduced by this allocation. In addition, at December 31, 2006, we recorded an increase to the derivative balance of \$1.8 million which represents the changes in value as a result of the modification of the terms of the make-whole provision related to certain investors. The resulting discount to the notes is being accreted over the life of the notes as additional interest expense using the effective interest method. Accordingly, we recorded interest expense of \$2.9 million and \$1.4 million for the years ended December 31, 2007 and 2006, respectively, the majority of which represents accelerated accretion due to note conversions. The estimated fair value of the derivative liability is adjusted quarterly for changes in the estimated market value. The change in the estimated fair value for the years ended December 31, 2007 and 2006 was \$3.6 million and \$1.9 million, respectively, and is included in *gain on derivative liabilities*. At December 31, 2007, no value was assigned to the fair value of the derivative liability. At December 31, 2006, the fair value of the derivative was \$3.6 million, \$2.3 of which is recorded in *current portion of derivative liability* and \$1.3 million of which is recorded in *7.5% convertible senior notes*.

The interest make-whole provision of the 6.75% notes represents an embedded derivative which is required to be accounted for separate from the underlying notes and was recorded as a derivative liability and a discount to the carrying value of the notes. At the issuance of the 6.75% senior notes, the interest make-whole feature was estimated to have a fair value of approximately \$4.5 million and the initial recorded value of the 6.75% senior notes was reduced by this allocation. The resulting discount to the notes is being accreted over the life of the

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notes as additional interest expense using the effective interest method. Accordingly, we recorded interest expense of approximately \$0.1 million, \$4.0 million and \$0.3 million for the years ended December 31, 2007, 2006 and 2005, respectively. The expense recorded for 2006 and 2005 was primarily related to accelerated accretion due to note conversions. The estimated fair value of the derivative liability is adjusted quarterly for changes in the estimated market value. Changes in the estimated fair value for the years ended December 31, 2007, 2006 and 2005 were \$0.1 million, \$4.1 million and \$0.2 million, respectively, and included in *gain on derivative liabilities*. At December 31, 2007 and 2006, the fair value of the derivative was \$0.1 million and \$0.2 million and was recorded in *6.75% convertible senior notes*.

The interest make-whole provision of the 5.75% convertible senior notes represents an embedded derivative. At the issuance of the 5.75% notes, no value was assigned to the fair value of the interest make-whole feature.

*Long-term obligations*

Long-term obligations consist of the following as of December 31 (in thousands):

	2007	2006
Capital lease equipment financing agreement, due May 2010, monthly payments of \$1, including interest at 6.0%	\$ 44	\$ 63
Capital lease equipment financing agreement, due February 2008, monthly payments of \$7, including interest at 5.1%	54	125
Excess facilities liability	1,547	3,951
Accrued rent	1,567	1,759
Employee defined benefit plan (see Note 14, <i>Employee Benefit Plans</i> )	1,034	923
European public loans	241	529
Other long-term obligations	6,412	133
	10,899	7,483
Less current portion	(1,020)	(2,816)
	\$ 9,879	\$ 4,667

As of December 31, 2007, maturities of the convertible senior, convertible senior subordinated, and convertible subordinated notes as well as other long-term obligations listed above, excluding contingent consideration classified as a non-current liability, our liability for excess facilities and the employee defined benefit plan, are as follows (in thousands):

Years Ending December 31,	
2008	\$ 20,311
2009	408
2010	62,538
2011	57,199
2012	356
Thereafter	
	\$ 140,812

**9. Significant Agreements**

*Collaboration and Licensing Agreements*

*Zevalin acquisition.* On August 15, 2007, we entered into an asset purchase agreement with Biogen for the acquisition of the U.S. rights to develop, market and sell Zevalin, a radiopharmaceutical. We closed this acquisition on December 21, 2007 with an up-front payment of \$10 million; however, the terms of the asset

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purchase agreement also require us to pay royalties to Biogen for the U.S. rights to Zevalin until the latest of (a) the expiration date of the last to expire of any patents related to Zevalin, (b) the first date on which any third person lawfully sells a biosimilar product in the United States or (c) December 31, 2015. In addition, we are required under that agreement to make up to two additional future payments to Biogen in the amount of \$10 million each in the event that we reach certain milestones related to regulatory approval of additional uses of Zevalin.

*Novartis International Pharmaceutical Ltd.* In September 2006, we entered into an exclusive worldwide licensing agreement with Novartis International Pharmaceutical Ltd., or Novartis, for the development and commercialization of paclitaxel poliglumex. Total product registration and sales milestones due from Novartis for paclitaxel poliglumex under the agreement could reach up to \$270 million. The agreement also provides Novartis with an option to develop and commercialize pixantrone based on agreed terms. If Novartis exercises its option on pixantrone under certain conditions, Novartis would pay CTI a \$7.5 million license fee, up to \$104 million in registration and sales related milestones and a royalty on pixantrone worldwide net sales as well as reimbursement for certain expenses. As of December 31, 2007, we have not received any milestone payments.

*Nippon Shinyaku Co., Ltd.* In December 2002, we entered into a distribution agreement with Nippon Shinyaku Co., Ltd., or Nippon, which Cephalon assumed in connection with the TRISENOX divestiture in July 2005. This agreement granted an exclusive license to Nippon to market and distribute TRISENOX in Japan, South Korea and Taiwan. Pursuant to a supply agreement we entered into with Nippon, we recorded \$1.3 million in product sales during 2005.

*Chugai Pharmaceutical Co., Ltd.* In October 2001, we entered into a licensing agreement with Chugai for the development and commercialization of paclitaxel poliglumex in several Asian territories. Upon execution of the agreement, Chugai paid us a \$3.0 million upfront fee which was recorded as deferred revenue and originally recognized as revenue over the estimated development period of approximately seven years on a straight-line basis. In October 2005, Chugai notified us of their intent to terminate the agreement and accordingly, we recognized the remaining deferred revenue of \$1.4 million in the fourth quarter of 2005 as there was no additional planned development period. The agreement was terminated effective March 2006.

*PG-TXL Company, L.P.* In 1998, we entered into an agreement with PG-TXL Company, L.P., as amended in February 2006, granting us an exclusive worldwide license for the rights to polyglutamic acid paclitaxel, a water soluble form of the cancer drug Taxol, and to all potential uses of PG-TXL Company, L.P.'s polymer technology. Under the terms of the agreement, we acquired the rights to the research, development, manufacture, marketing and sale of anti-cancer drugs developed using this polymer technology.

We are obligated to make payments to PG-TXL Company upon the achievement of certain development and regulatory milestones. To date we have made \$5.6 million in milestone payments and could be obligated to make additional payments of up to \$14.9 million in the future if additional milestones are met. We also granted warrants to purchase 87,500 shares of our common stock to PG-TXL Company, L.P. which became exercisable upon our entering a licensing agreement for paclitaxel poliglumex with Chugai Pharmaceutical Co., Ltd (see Note 12, *Capital Stock and Warrants*).

In connection with the agreement with PG-TXL Company, we also entered into Signing Bonus and Restricted Stock and Share Grant Agreements and Consulting Agreements with certain individuals affiliated with PG-TXL Company, L.P., or the PG-TXL Affiliates. The Company also granted 25,916 restricted share rights to the PG-TXL Affiliates, 22,000 of which vested and were issued in February 2006 in connection with the amendment to the License Agreement. For the year ended December 31, 2005, we recorded approximately \$0.2

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million in research and development expense in anticipation of the vesting of these restricted share rights. The remaining restricted share rights vest upon certain performance conditions which include successfully completing a phase III clinical trial of a licensed product and receiving regulatory approval of an NDA by the FDA. We will begin to record compensation expense at the time the vesting of the share rights become probable.

*Financing Agreement*

On June 21, 2006, we entered into a Step-Up Equity Financing Agreement, as amended on December 15, 2006, with Société Générale. Subject to certain conditions, the agreement allows us to issue to Société Générale shares of our common stock in a series of tranches over a period of 24 months beginning January 31, 2007. Under the agreement, we can initially issue up to 45 million worth of our common stock based on a pre-determined formula and have the right to increase the total amount of all issuances to up to 60 million (approximately \$88 million as of December 31, 2007) worth of our common stock. Any issuance of our common stock pursuant to this agreement is at our election and we are not required to issue any common stock. In addition, our ability to issue our common stock under this agreement depends in part on complying with certain Italian regulations.

Upon effectiveness of the agreement we paid a fee of approximately \$1.1 million and, including this payment, have incurred total expenses related to this agreement of approximately \$1.2 million which are recorded in *other assets* as of December 31, 2007. In addition, we incurred costs of approximately \$1.1 million to file a Listing Prospectus in Italy in order to utilize the funding under this agreement. These costs are also recorded in *other assets* as of December 31, 2007. These amounts will be reduced against future equity issuances under the agreement. Upon each settlement of a share issuance, we must pay a subscriber fee equal to 3.5% of the selling price as well as 2.0% of the aggregate selling amount raised during each fiscal quarter. As of December 31, 2007, there had not been any shares of common stock issued under this agreement.

In January 2008, we sold 800,000 shares to Société Générale under this agreement in a registered offering at an issue price of 1.07 per share. Gross proceeds were approximately \$1.3 million.

*Security Agreement*

On December 21, 2007, in connection with our acquisition of Zevalin, we entered into a security agreement with Biogen pursuant to which we granted a first priority security interest to Biogen in all of our right, title and interest (a) in and to certain assets that we purchased in connection with the acquisition of Zevalin, together with any other assets or rights related to any of such assets or otherwise used in the development, manufacture or commercialization of Zevalin and (b) under certain license, sublicense and supply agreements entered into pursuant to the acquisition of Zevalin. Upon the occurrence of an ongoing event of default including, without limitation, our failure to pay or perform our obligations under the security agreement, the asset purchase agreement, which includes future royalty and milestone payments due to Biogen, or the related sublicense and service agreements, a breach by us of our representations and warranties under the secur