CELL THERAPEUTICS INC
Form 10-K
March 16, 2009
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2008

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	**91-1533912**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
501 Elliott Avenue West, Suite 400	
Seattle, WA 98119	**98119**
(Address of principal executive offices)	**(Zip Code)**

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

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

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 x

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 x

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 x 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 x
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 x

As of June 30, 2008, the aggregate market value of the registrant s common equity held by non-affiliates was $65,872,000. 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 9, 2009 was 321,839,696.

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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, pote 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 innovative 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.

We are developing pixantrone (BBR 2778), a novel DNA major groove binder with an aza-anthracenedione molecular structure, differentiating it from anthracycline chemotherapy agents. A new chemical compound for the treatment of non-Hodgkin s lymphoma, or NHL, and various other hematologic malignancies, solid tumors, and immunological disorders, pixantrone is being developed to improve activity and safety in treating cancers currently treated with the anthracycline family of anti-cancer agents. Based on the outcome of our phase III EXTEND, or PIX 301, clinical trial, as described below, and on the basis of pre-NDA communication we received from the Food and Drug Administration, or FDA, relating to that phase III trial, we expect to begin a rolling New Drug Application, or NDA, submission to the FDA in the first half of 2009. If the NDA is granted priority review status, the FDA could provide a decision on the NDA as early as six months after the final submission of the NDA.

Pixantrone was studied in our EXTEND, or PIX301, clinical trial which is a phase III single-agent trial of pixantrone for patients with relapsed, aggressive non-Hodgkin s lymphoma who received two or more prior therapies and who were sensitive to treatment with anthracyclines. An interim analysis of the EXTEND study of pixantrone was performed by the independent Data Monitoring Committee in the third quarter of 2006 and the study was continued based on that review. The trial enrolled 140 patients who were randomized to receive either pixantrone or another single-agent drug currently used for the treatment of this patient population, as selected by the physician. In November 2008, we announced that this trial achieved the primary efficacy endpoint. Patients randomized to treatment with pixantrone achieved a significantly higher rate of confirmed and unconfirmed complete remissions compared to patients treated with standard chemotherapy, had a significantly increased overall response rate, experienced a statistically significant improvement in median progression free survival and had a low incidence of certain side effects, including severe neutropenia complicated by either fever or documented infections, severe vomiting or diarrhea and hair loss, a very common side effect of other drugs in this class. Overall, the incidence of serious adverse events was similar between pixantrone and the control arm. The pixantrone patients had a higher incidence of leucopenia and neutropenia and numerically more severe cardiac events than in the control arm. Disease progression reported as an adverse event was less frequent in the pixantrone arm than in the control arm.

In February 2009, we entered into an agreement with IDIS Limited, or IDIS, to manage pixantrone as an investigational drug on a named patient basis in Europe. Pixantrone will be supplied by IDIS to healthcare professionals for the treatment of individual patients with relapsing aggressive non-Hodgkin s lymphoma. The program is expected to be initiated by the second quarter of 2009.

We also conducted the RAPID, or PIX203, phase II study (CHOP-R vs. CPOP-R) in which pixantrone is substituted for doxorubicin in the CHOP-R regimen compared to the standard CHOP-R regimen in patients with aggressive NHL. An interim analysis of the RAPID study, reported in July 2007, 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 less left ventricular ejection fraction (LVEF) drops, infections, and thrombocytopenia (a reduction in platelets in the blood), as well as significant reduction in febrile neutropenia. In early 2008, we closed enrollment on the RAPID trial because we had adequate sample size to demonstrate differences in cardiac events and other clinically relevant side effects between pixantrone and doxorubicin. We expect to report results from this trial in the fourth quarter of 2009.

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We 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 our 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 OPAXIO (paclitaxel poliglumex), which we have previously referred to as XYOTAX, for the treatment of non-small cell lung cancer, or NSCLC, and ovarian cancer. While our STELLAR 2, 3 and 4 phase III clinical studies for OPAXIO, completed in the first half of 2005, did not meet their primary endpoints of superior overall survival, we believe that the reduction in toxicities coupled with superior convenience and less supportive care 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 PS2 NSCLC patients. In March 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 was accepted for review in April 2008 and the MAA has now entered the marketing approval review process, which generally takes 15 to 18 months. We expect to receive an opinion from the EMEA by June 2009.

We are also developing OPAXIO for women with pre-menopausal levels of estrogen, regardless of age, who have advanced NSCLC with normal or poor performance status. 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. Based on a pooled analysis of STELLAR 3 and 4 phase III trials for treatment of first-line NSCLC PS2 patients, we believe that there is a demonstrated statistically significant survival advantage among women receiving OPAXIO when compared to women or men receiving standard chemotherapy. A survival advantage for women over men was also demonstrated in a first-line phase II clinical trial of OPAXIO and carboplatin, known as the PGT202 trial, supporting the potential benefit observed in the STELLAR 3 and 4 trials. In December 2005, we initiated a phase III clinical trial, known as the PIONEER, or PGT305, study for OPAXIO as first-line monotherapy in PS2 women with NSCLC, however, we agreed with the recommendation of the Data Safety Monitoring Board and closed the study in December 2006 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 protocols, known as PGT306 and PGT307, focus exclusively on NSCLC in women with pre-menopausal estrogen levels, the subset of patients where OPAXIO demonstrated the greatest potential survival advantage in the STELLAR trials. We initiated the PGT307 trial in September 2007. Although the FDA has established the requirement that two adequate and well-controlled pivotal studies demonstrating a statistically significant improvement in overall survival will be required for approval of OPAXIO in the NSCLC setting, we believe that compelling results from a single trial, PGT307, along with supporting evidence from prior clinical trials, may enable us to submit 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 the MAA by the EMEA or until positive results from the GOG0212 trial of OPAXIO for first-line maintenance therapy in ovarian cancer, discussed below, are reported.

We are also developing OPAXIO as potential maintenance therapy for women with advanced stage ovarian cancer who achieve a complete remission following first-line therapy with paclitaxel and carboplatin. This study,

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the GOG0212 trial, is under the control of the Gynecologic Oncology Group, or GOG, and is expected to enroll 1,100 patients by early 2012. Based on the number of events in the database, we are requesting an interim analysis be conducted by the GOG in late 2009. If the GOG agrees to this timing and the interim analysis is successful, it could lead to an NDA filing in 2010.

As of March 9, 2009, we are engaged in the process of divesting our interest in the radiopharmaceutical product Zevalin® (ibritumomab tiuxetan) by selling our 50% interest in the Zevalin joint venture to Spectrum Pharmaceuticals, Inc., or Spectrum. Zevalin is a form of cancer therapy called radioimmunotherapy and is indicated for treatment of relapsed or refractory, low-grade or follicular B-cell NHL, including patients with rituximab refractory follicular NHL. Zevalin is also indicated, under accelerated approval, for the treatment of relapsed or refractory, rituximab-naïve, low-grade and follicular NHL. It was approved by the FDA in February 2002 as the first radioimmunotherapeutic agent for the treatment of NHL. We acquired the U.S. development, sales and marketing rights to Zevalin from Biogen Idec Inc., or Biogen, pursuant to an asset purchase agreement in December 2007. In December 2008, we formed a 50/50 owned joint venture with Spectrum, RIT Oncology, LLC, or RIT Oncology, to commercialize and develop Zevalin in the United States. We contributed all assets owned by us and exclusively related to Zevalin to that joint venture, including the Zevalin FDA registration, FDA dossier, U.S. trademark, trade name and trade dress, customer list, certain patents and the assignment of numerous contracts. We received an initial payment of $7.5 million at the closing of the initial formation of the joint venture, an additional $7.5 million in early January 2009 and we may receive up to $15 million in product sales milestone payments upon achievement of certain revenue targets.

The amended and restated operating agreement for the joint venture (the LLC Agreement) provides CTI with an option to sell to Spectrum our remaining 50% interest in the Zevalin joint venture for $18 million, as adjusted. Our board of directors made a strategic decision to focus our resources on developing pixantrone and our other products, and because the option provided the most viable source for non-dilutive financing, in February 2009, we exercised the option to sell our remaining interest in Zevalin. Upon satisfaction of certain closing conditions, Spectrum is obligated to deliver either the entire purchase price in a single payment, or at their option, one-third of the purchase price in cash, plus a full-recourse, non-interest bearing secured promissory note for the remaining two-thirds of the purchase price, within 30 days following the exercise of the option. On March 2, 2009, we received $6.5 million of the purchase price and will receive the remaining balance of the purchase price within 90 days following the closing of the sale of our interest; however, as of March 9, 2009, we are currently in discussions with Spectrum to finalize the terms of the transaction, including the timing of the payment schedule. As a result of the sale option transaction, CTI will have transferred all ownership and control of Zevalin to Spectrum.

In addition, on June 16, 2008, we entered into an Access Agreement with Bayer Schering Pharma AG, or Bayer, which holds the rights to Zevalin outside of the United States. Under the agreement, Bayer gave us access to data from Bayer s phase III first-line indolent trial, or FIT trial, of Zevalin. Under the terms of the agreement with Bayer, we made an initial payment to Bayer of $2 million. We submitted a supplemental biologics license application, or sBLA, on September 30, 2008 for use of Zevalin in consolidation therapy of first remission in advanced stage follicular NHL based on the data received from Bayer; that sBLA was also contributed to the joint venture. In connection with the joint venture transaction, the Access Agreement was assigned to RIT Oncology.

We are developing brostallicin through our wholly owned subsidiary Systems Medicine LLC, or SM, which 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 230 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. We also have a strategic affiliation with the Translational Genomics Research Institute, or TGen, and have 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.

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A phase II study of brostallicin in relapsed/refractory soft tissue sarcoma met its predefined activity and safety hurdles and resulted in a first-line phase II study that is currently being conducted by the European Organization for Research and Treatment of Cancer, or EORTC. Planned enrollment for this study was completed in August 2008 and the EORTC plans to conduct the final data analysis in 2009. Brostallicin has also demonstrated synergy with new targeted agents as well as established treatments in preclinical trials; consequently, we began a multi-arm combination study with brostallicin and other agents, including Avastin (bevacizumab) which was substantially completed in the fourth quarter of 2008.

We acquired our rights to brostallicin through our acquisition of Systems Medicine Inc., a privately held oncology company, completed in July 2007 through a stock-for-stock merger valued at $20 million. Systems Medicine Inc. 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.

We are currently focusing our efforts on pixantrone, OPAXIO, brostallicin and bisplatinates.

We were incorporated in Washington in 1991. Our principal executive offices are located at 501 Elliott Avenue West, Suite 400, Seattle, Washington 98119. Our telephone number is (206) 282-7100. The address for our website is 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 OPAXIO are our proprietary marks. RIT Oncology owns the rights to the mark Zevalin for use in the United States. All other product names, trademarks and trade names referred to in this prospectus are the property of their respective owners.

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 11.1 million people in the United States with a history of cancer were alive in January 2005, 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 1.4 million new cases of cancer were expected to be diagnosed in 2008 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, palatinates 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
- 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.

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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.

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 of cancer and cancer patients, fills a significant unmet need for cancer patients. Our cancer drug development pipeline includes a taxane, a modified anthracycline, and a DNA minor groove binding agent, each of which has the potential to treat a variety of cancer types.

Pixantrone

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. Pixantrone is being developed to improve the activity and safety in treating cancers usually treated with the anthracycline family of anti-cancer agents. It is a novel DNA major groove binder with an aza-anthracenedione molecular structure, differentiating it from anthracycline chemotherapy agents. Pixantrone has been studied in both indolent and aggressive NHL. The drug has demonstrated encouraging activity as a single agent in aggressive NHL, and recent clinical results suggest the compound also may be synergistic with other agents commonly used in combination therapy.

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 with pixantrone, including a pivotal phase III trial, known as the EXTEND, or PIX301, trial of pixantrone (BBR2778) for the treatment of patients with relapsed aggressive NHL, a

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condition for which there are no 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 remission rate. The trial enrolled 140 patients and patients were randomized to receive either pixantrone or another single-agent drug currently used for the treatment of this patient population, as selected by the physician. We announced in November 2008 that we had achieved the primary efficacy endpoint of the PIX 301 trial. Patients randomized to treatment with pixantrone achieved a high rate of confirmed and unconfirmed complete remissions compared to patients treated with standard chemotherapy (14/70 (20.0%) for pixantrone arm compared to 4/70 (5.7%) for the standard chemotherapy arm, p = 0.02). No patient (0%) in the standard chemotherapy arm achieved a confirmed complete remission compared to 8/70 (11%) of pixantrone recipients. Pixantrone treatment also significantly increased the overall response rate (CR/CRu+PR) with 26/70 (37.1%) for pixantrone arm compared to 10/70 (14.3%) for the control arm, p = 0.003. On an intent-to-treat analysis, pixantrone recipients who achieved a complete remission did so during the first 2 cycles of therapy, compared to 4 cycles among standard chemotherapy recipients, (1.9 months vs. 3.6 months, pixantrone vs. standard chemotherapy). The duration of response in the patients was similar in the 37% of pixantrone patients who had either a partial or complete response compared to the 14% of comparator patients with a major response. However, the overall progression-free survival (PFS) results that show patients treated with pixantrone experienced a statistically significant improvement in median progression-free survival, compared with other single-agent chemotherapeutic (4.7 months vs. 2.6 months, hazard ratio = 0.6; p =0.0074, pixantrone vs. standard chemotherapy) based on an intent-to-treat analysis. Progression-free survival, CR/CRu and ORR were determined by an independent assessment panel that was blinded to the treatment assignments. Pixantrone recipients had a low incidence of severe neutropenia complicated by either fever or documented infections, or severe vomiting or diarrhea and a low incidence of hair loss, a very common side effect of other drugs in this class. Overall, the incidence of serious adverse events was similar between pixantrone and the control arm. The pixantrone patients had a higher incidence of leucopenia and neutropenia and numerically more severe cardiac events (5 vs. 2) than in the control arm. Disease progression reported as an adverse event was less frequent in the pixantrone arm than in the control arm (1.5% vs. 13.4%).

We also conducted the RAPID, or PIX203, phase II study (CHOP-R vs. CPOP-R) in which pixantrone is substituted for doxorubicin in the CHOP-R regimen compared to the standard CHOP-R regimen in patients with aggressive NHL. Preliminary results of this trial were reported at the 49th 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. We expect to report results from this trial in the fourth quarter of 2009.

Based on the results of our EXTEND trial and pre-NDA communications from the FDA in January 2009 relating to the EXTEND trial, we expect to begin a rolling NDA submission to the FDA for pixantrone in the first half of 2009. If the NDA is granted priority review status, the FDA could provide us with a decision on the NDA before the end of 2009.

In February 2009, we entered into an agreement with IDIS Limited, or IDIS, to manage pixantrone as an investigational drug on a named patient basis in Europe. Pixantrone will be supplied by IDIS to healthcare professionals for the treatment of individual patients with relapsing aggressive non-Hodgkin s lymphoma. The program is expected to be initiated by the second quarter of 2009.

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, we 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 a result of our strategy to conduct a pivotal

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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 (≥ 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/m²; 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.

OPAXIO

OPAXIO (paclitaxel poliglumex, CT-2103) is our novel biologically enhanced chemotherapeutic agent that links paclitaxel to a biodegradable polyglutamate polymer, resulting in a new chemical entity. We are developing OPAXIO for the potential treatment of NSCLC, ovarian and other cancers.

OPAXIO was designed to improve the delivery of paclitaxel to tumor tissue while protecting normal tissue from toxic side effects. Unlike vessels in healthy tissue, those in tumor tissue have openings that make them porous. Due to the larger size of OPAXIO compared to standard paclitaxel, OPAXIO leaks through the pores in tumor blood vessels and is preferentially trapped and distributed to the tumor tissue. Once in the tumor tissue, OPAXIO is taken up by the tumor cells through a cellular process called endocytosis. Because the biopolymer OPAXIO is made up of biodigestible amino acids, it is slowly metabolized by lysosomal enzymes (principally cathepsin B) inside the lysosome of the tumor cell. This metabolism releases the active chemotherapy agent, paclitaxel. The activity of this enzyme and thus the rate of release of OPAXIO is increased in the presence of estrogen.

Because the polymer is water-soluble, OPAXIO can be administered without solvents and other routine pre-medications (such as steroids and antihistamines) generally used to prevent severe allergic reactions, and can be infused over an average of ten to twenty minutes. Patients can drive themselves to and from their treatment centers. OPAXIO remains stable in the bloodstream for several days after administration; this prolonged circulation allows the passive accumulation of OPAXIO in tumor tissue.

Taxanes, including paclitaxel (Taxol®) and docetaxel (Taxotere®), currently are widely used for the treatment of various solid tumors, including non-small cell lung, ovarian, breast and prostate cancers. Paclitaxel is considered a standard-of-care in lung and ovarian cancers, where it is most widely used. Because taxanes are small, hydrophobic agents, their therapeutic potential is limited by unfavorable pharmacokinetic properties. Solvents (such as Cremaphor) are needed for administration, and these solvents are often extremely irritating to blood vessels, requiring surgical placement of a large catheter for administration and a minimum of three hours

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for infusion. They also can cause severe life threatening allergic reactions that typically require pre-medications with steroids and antihistamines. Patients usually require transportation to and from their treatment location. Taxanes exhibit high peak levels of drug immediately following administration that expose normal tissues to toxic effects. Rapid elimination of the drug from blood limits tumor exposure.

The distribution and metabolism of OPAXIO 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. 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 OPAXIO is enhanced in certain human tumors when mice are given additional estrogen. In subsequent clinical studies, more than 1,900 patients were treated in our four pivotal phase III trials of OPAXIO for the treatment of NSCLC. While the STELLAR 2, 3 and 4 trials missed their primary endpoint of superior overall survival, women treated with OPAXIO for newly diagnosed advanced NSCLC in STELLAR 3 and 4 had a significant improvement in their overall survival compared to women or men treated with standard chemotherapy. In addition, with single-agent OPAXIO, we observed a significant reduction in most of the severe toxic side effects associated with the standard chemotherapy agents studied in the STELLAR trials.

OPAXIO 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 OPAXIO phase III pivotal trial, known as STELLAR 3, for the potential use of OPAXIO in combination with platinum as first-line treatment of PS2 patients with NSCLC missed its primary endpoint of superior overall survival. However, in the STELLAR 3 trial, OPAXIO 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 also had significant reductions in certain severe side effects compared to the comparator agents. The STELLAR 2 pivotal trial was evaluating OPAXIO for potential use as second-line single agent treatment for patients with NSCLC, and the STELLAR 4 pivotal trial was evaluating OPAXIO 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 OPAXIO 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 OPAXIO in the first-line treatment of men and women with advanced NSCLC which demonstrated a survival advantage for women receiving OPAXIO as first-line therapy for NSCLC when compared to men. In this single-arm study, the 35 women who received OPAXIO 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 OPAXIO in

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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 OPAXIO 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 OPAXIO 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 OPAXIO (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 OPAXIO had a highly significant prolongation in the 1-year and overall survival estimates compared to women treated with standard chemotherapy, with the OPAXIO 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 OPAXIO (175-210mg/m²) 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. OPAXIO also resulted in less severe allergic reactions, less hair loss, and significant reduction in the requirement for transfusions and use of hematopoietic growth factor support, such as Neupogen®, Neulasta®, Aranesp® and/or Epogen® 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, OPAXIO 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 OPAXIO activity in the NSCLC 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 OPAXIO demonstrated the greatest potential survival advantage in the STELLAR trials. We believe the lack of safe and effective treatment for women with advanced first-line NSCLC who have pre-menopausal estrogen levels represents an unmet medical need. We initiated the PGT307 trial in September 2007. Although the FDA has established the requirement that two adequate and well-controlled pivotal studies demonstrating a statistically significant improvement in overall survival will be required for approval of OPAXIO in the NSCLC setting, we believe that compelling results from a single trial, PGT307, along with supporting evidence from prior clinical trials, may enable us to submit 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 OPAXIO by the EMEA or until positive results from the GOG0212 trial of OPAXIO for first-line maintenance therapy in ovarian cancer are reported.

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We submitted an MAA in Europe for OPAXIO 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.

OPAXIO 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 OPAXIO 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 2012. Based on the number of events in the database, we are requesting an interim analysis to be conducted by the GOG in late 2009. If the GOG agrees to this timing and the clinical trial is successful, it could lead to an NDA filing in 2010. The primary endpoint of this trial is overall survival. Progression-free survival, safety and side effect profile are secondary endpoints.

Brostallicin

We are developing brostallicin, which is a small molecule, chemotherapeutic agent with a unique mechanism of action and composition of matter patent coverage. Data in more than 230 patients treated with brostallicin in phase I/II clinical trials reveal evidence of activity in patients with refractory cancer and patient/physician-friendly dosage and administration. A phase II study of brostallicin in relapsed/refractory soft tissue sarcoma met its pre-defined activity and safety hurdles and resulted in a first-line phase II study that is currently being conducted by the European Organization for Research and Treatment of Cancer, or EORTC. Planned enrollment for this study was completed in August 2008 and the EORTC plans to conduct the final data analysis in 2009. Brostallicin has also demonstrated synergy with new targeted agents as well as established treatments in preclinical trials; consequently, we began a multi-arm combination study with brostallicin and other agents, including Avastin (bevacizumab) which was substantially completed in the fourth quarter of 2008.

Zevalin (Ibritumomab Tiuxetan)

Zevalin is a form of cancer therapy called radioimmunotherapy and is indicated for the treatment of patients with relapsed or refractory low-grade or follicular 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.

We developed Zevalin from our acquisition of that product line in December 2007 until the transfer of Zevalin to RIT Oncology in December 2008; as of March 9, 2009, we are engaged in the process of selling our remaining 50% interest in RIT Oncology to Spectrum.

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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.

Product Candidate	Indication/Intended Use	Phase/Status
Pixantrone	Aggressive NHL, > 3 relapses, single-agent (PIX301)	III / closed
	Aggressive NHL, front-line, CPOP-R (PIX203)	II / closed
OPAXIO (CT-2103)	NSCLC, first-line, doublet therapy, PS0-2, females with pre-menopausal estrogen levels (PGT307)	III/open
	Ovarian first-line maintenance (GOG0212)	III / open
Brostallicin	Advanced or metastatic soft tissue sarcoma, first-line, single agent (EORTC 62061)	II / closed
	Myxoid liposarcoma with specific genomic translocations (BRS202)	II/ closed
	Combination with other anti-cancer drugs (BRS101)	I / closed

Research and Preclinical Development

Cisplatin is a platinum-based chemotherapy drug used to treat a wide variety of cancers. We are developing new analogues of the dinuclear-platinum complex, CT-3610 that is more potent than cisplatin. CT-3610 is endowed with a unique mechanism of action, active in preclinical studies on a large panel of tumor models, sensitive and refractory to cisplatin, and has a safety profile comparable to that of cisplatin. The novel bisplatinum analogues are rationally designed and synthesized to have improved biopharmaceutical properties that reduce the intrinsic reactivity of the molecule and that demonstrate preclinical anti-tumor efficacy in solid tumor models.

Research and development is essential to our business. We spent $51.6 million, $72.0 million and $62.0 million in 2008, 2007 and 2006, respectively, on Company-sponsored research and development activities.

Collaboration, Licensing and Milestone Arrangements

Spectrum Pharmaceuticals, Inc. In December 2008, we formed our 50/50 owned joint venture, RIT Oncology, with Spectrum to commercialize and develop Zevalin in the United States. At the closing of the joint venture transaction, we contributed all assets exclusively related to Zevalin in exchange for a 50% membership interest in RIT Oncology, an initial payment from RIT Oncology of $7.5 million upon closing of the transaction and an additional payment of $7.5 million in early January 2009. In addition, we may receive up to $15 million in product sales milestone payments upon RIT Oncology s achievement of certain revenue targets. In February 2009, we exercised our option to sell our 50% interest in RIT Oncology to Spectrum, received an initial payment of $6.5 million on March 2, 2009 and, as of March 9, 2009, are currently engaged in the process of negotiating the transaction terms with Spectrum which will be completed within 30 days of our exercise of the option.

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, plus certain royalties to Biogen as well as up to two additional future payments to Biogen in the amount of $10 million each in the event that we reached certain milestones related to regulatory approval of additional uses of Zevalin. In December 2008, in connection with the joint venture, the milestones were amended and, along with the royalty payments, were assumed by RIT Oncology upon its formation.

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PG-TXL Company, L.P. We have an amended agreement with PG-TXL Company, L.P. which grants us an exclusive worldwide license for the rights to OPAXIO 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 $6.1 million in milestone payments, including a $0.5 million payment that became due upon the acceptance of our MAA for review by the EMEA in March 2008. In addition, we could be obligated to make additional payments of up to $14.4 million in the future if additional milestones are met, including a $5.0 million payment upon approval of the MAA filing by the EMEA, which may occur in the second half of 2009.

Gynecologic Oncology Group. We have an agreement with the Gynecologic Oncology Group, or GOG, related to the GOG0212 trial which the GOG is conducting. Under this agreement we are required to pay up to $6.1 million in additional milestone payments related to the trial. Included in this amount is a $1.0 million milestone payment that became due in the fourth quarter of 2008 based on patient enrollment but had not been paid as of March 9, 2009. We also estimate that an additional milestone payment of $1.6 million may become due in the fourth quarter of 2009 based on patient enrollment.

Acquisition of Systems Medicine, Inc. In connection with our acquisition of Systems Medicine, Inc. we may be required to pay its stockholders a maximum of $15.0 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 for brostallicin.

Brostallicin. Under a license agreement entered into for brostallicin, we may be required to pay up to $80.0 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.

Cephalon. Pursuant to an acquisition agreement entered into with Cephalon, Inc. in connection with the sale of our former drug, TRISENOX, in June 2005, we may receive up to $100 million in payments upon achievement by Cephalon of specified sales and development milestones related to TRISENOX. However, the achievement of any such milestones is uncertain at this time.

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 OPAXIO. Total product registration and sales milestones due from Novartis for OPAXIO 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 and we are able to negotiate and sign a definitive license agreement with Novartis, 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, 2008, we have not received any milestone payments and we will not receive any milestone payments unless Novartis elects to participate in the development and commercialization of pixantrone or OPAXIO.

Patents and Proprietary Rights

We dedicate significant resources to protecting our intellectual property, which is important to our business. We have exclusive rights to 12 issued U.S. patents and 123 U.S. and foreign pending or issued patent applications relating to our polymer drug delivery technology. There are 7 issued U.S. patents, 2 granted European patents and 88 pending or issued U.S. and foreign patent applications directed to OPAXIO. We have 3 issued U.S. patents and another 19 pending or issued U.S. and foreign patent applications that are directed to

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CT-2106. Additionally, we have 4 issued U.S. patents and 75 U.S. and foreign pending and issued patents directed to pixantrone and have licensed 5 granted U.S. patents and 379 pending and issued U.S. and foreign patent applications directed to brostallicin.

In connection with the formation of the joint venture, we transferred to RIT Oncology ownership or licenses to 43 pending and issued U.S. patents applications directed to Zevalin.

Manufacturing

We currently use, and expect to continue to be dependent upon, contract manufacturers to manufacture each of our product candidates. 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 European 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 pixantrone, OPAXIO 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 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 OPAXIO, 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 in 2009.

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: Bristol-Myers Squibb Co., Sanofi Aventis, Wyeth, Roche, Genentech, OSI Pharmaceuticals, Eli Lilly, Abraxis, Neopharm Inc., Telik Inc., TEVA Pharmaceuticals and PharmaMar. 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

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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.

Drug Approval Process. None of our drugs may be marketed in the United States until such drug has received FDA approval. The steps required before a drug 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
- 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
- FDA review and approval of the NDA

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.

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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 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 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 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, that the review time will be reduced or that the product will be approved.

Before approving an NDA, 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 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. 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 are required to: (i) report certain adverse reactions to the FDA, (ii) comply with certain requirements concerning advertising and promotional labeling for

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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, 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.

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 members 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.

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Employees

As of December 31, 2008, we employed 194 individuals, including 127 in the United States and 67 in Europe. In the United States, 18 employees hold doctoral degrees while 33 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.

In connection with the exercise of our option to sell our interest in Zevalin and RIT Oncology to Spectrum, in March 2009 we announced the plan to terminate 34 employees in the United States who were directly and indirectly responsible for sales and marketing and other operations related to Zevalin. In addition, in connection with our efforts to reduce operating costs, we are seeking to divest our operations in Europe. However, to date we have not been able to find an adequate partner or buyer for those operations and have therefore notified the trade union representing our employees in Bresso, Italy that we intend to close our Italian operations and implement a collective dismissal procedure under Italian law relating to all 62 remaining employees at our Bresso facility. While we believe our relations with our employees to be good, there is the possibility that our employees in Italy may go on strike in relation to our negotiations with the Trade Unions relating to employee dismissals connected to closing the facility in Bresso.

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

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 need to raise additional funds and expect that we will need to continue to raise funds in the future, and funds may not be available on acceptable terms, or at all; failure to raise significant additional funds may cause us to cease development of our products and operations.

We have substantial operating expenses associated with the development of our product candidates and as of December 31, 2008 we had cash and cash equivalents, securities available-for-sale and interest receivable of approximately $10.7 million, which does not take into account $7.5 million in gross proceeds received from Spectrum in January 2009 in connection with the initial formation of RIT Oncology, or $6.5 million in gross proceeds received from Spectrum in March 2009 in connection with the sale of our 50% interest in RIT Oncology to Spectrum. As of March 9, 2009, we are engaged in the process of negotiating the transaction terms related to this sale with Spectrum and, upon finalizing the terms of that sale, we expect to receive approximately an additional $10.0 million to $11.5 million from Spectrum no later than 90 days following the closing. As of December 31, 2008, our total current liabilities were approximately $42.3 million and we also had a substantial amount of debt outstanding. The aggregate principal balance of our debt as of December 31, 2008 was approximately $142.2 million in convertible notes with interest rates ranging from 4% to 10% which does not take into account $18.0 million in conversions of our 10% notes due 2011. We expect that our existing cash and cash equivalents, securities available-for-sale, interest receivable, proceeds received from our offerings to date as well as the additional funds of approximately $10.0 million to $11.5 million to be received from Spectrum will not provide sufficient working capital to fund our presently anticipated operations beyond May 2009 and we therefore need to raise additional capital.

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We may seek to raise such capital through public or private equity financings, partnerships, joint ventures, dispositions of assets, debt financings or restructurings, bank borrowings or other sources. However, additional funding may not be available on favorable terms or at all. If adequate funds are not otherwise available, we will further curtail operations significantly, including the delay, modification or cancellation of operations and plans related to pixantrone, OPAXIO and brostallicin, and may be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection. 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, such as our transfer of Zevalin assets to RIT Oncology and our subsequent sale of our 50% interest in RIT Oncology. 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.

If our shareholders do not approve an increase in our authorized shares, we may not be able to raise additional funds through equity offerings.

Our shareholders have been asked to vote on a proposal to amend our articles of incorporation to increase the number of authorized shares of common stock at the special meeting of the shareholders to be held on March 24, 2009. Even though our quorum requirement has been reduced to one-third of the shares entitled to vote being present or represented at the meeting, the proposed amendment to the articles of incorporation requires an approval of a majority of the shares entitled to vote on the measure. There is a risk that we may not get shareholder approval to increase the number of authorized shares of common stock. Because of the number of shares reserved for issuance under various convertible securities, derivative securities and otherwise, we do not have enough shares authorized at present to effect an equity financing of any substantial amount. If we do not receive shareholder approval for the proposed increase in authorized shares, our ability to raise capital through equity financings may be adversely affected.

We need to implement a reduction in expenses across our operations.

We need substantial additional capital to fund our current operations. Even if we are able to secure additional financing on acceptable terms in the near future, we expect to implement a number of additional cost reduction initiatives, such as further reductions in the cost of our workforce and the discontinuation of a number of business initiatives to further reduce our rate of cash utilization and extend our existing cash balances. We believe that these additional cost reduction initiatives, if undertaken, will provide us with additional time to continue our pursuit of additional funding sources and also strategic alternatives. In the event that we are unable to obtain financing on acceptable terms and reduce our expenses, we may be required to limit or cease our operations, pursue a plan to sell our operating assets, or otherwise modify our business strategy, which could materially harm our future business prospects.

In November 2007, we converted our Bresso, Italy subsidiary into a corporate branch to reduce expenses related to having a subsidiary in Italy. In February 2009, in an effort to curtail the expenses related to our preclinical drug development operations in Bresso, Italy, we engaged a strategic advisory consulting firm to assist us with developing strategic options for a partnership, asset divestment or joint venture for our Italian branch. However, to date we have been unable to find an appropriate buyer or partner for the Bresso facility, therefore the Board has approved taking the appropriate steps to close that facility and cease our operations in Europe. In February 2009, we notified our employees at the Bresso facility that we would commence a collective dismissal procedure under Italian law, which gives us 75 days to consult with the Trade Unions in Italy regarding solutions that may reduce the social impact of the dismissal.

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, 2008, we had an accumulated deficit of approximately $1.3 billion. We are pursuing regulatory approval for

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pixantrone, OPAXIO and brostallicin. 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 and we need to raise capital to continue to fund our operations. Unless we raise substantial additional capital and reduce our operating expenses, we will not be able to pay all of our operating expenses or repay our debt or the interest, liquidated damages or other payments that may become due with respect to our debt.

Our common stock is listed on The NASDAQ Capital Market and the MTA stock market in Milan, Italy and we may not be able to maintain those listings or trading on these exchanges may be halted or suspended, which may make it more difficult for investors to sell shares of our common stock.

Effective with the opening of trading on January 8, 2009, the U.S. listing of our common stock was transferred to The NASDAQ Capital Market, subject to meeting a minimum market value of listed securities of $35 million. The NASDAQ Listing Qualifications Panel (the Panel) approved this transfer after our market capitalization did not comply with the minimum market capitalization required for companies listed on The NASDAQ Global Market, and we presented a plan to the Panel for regaining compliance with the NASDAQ Marketplace Rules. On January 23, 2009, we received an Additional Staff Determination Letter (the Determination Letter) from The NASDAQ Stock Market (NASDAQ) that stated the NASDAQ staff had concluded that we had violated Marketplace Rule 4350(i)(1)(C), which requires shareholder approval in connection with an acquisition if the issuance or potential issuance is greater than 20% of the pre-acquisition shares outstanding, and that we had at times not complied with Marketplace Rule 4310(c)(17) regarding submission of a Listing of Additional Shares form. On February 18, 2009, we updated the Panel on our plan for regaining compliance and requested an extension of the deadline to regain compliance with the minimum market capitalization requirement for The NASDAQ Capital Market. On March 6, 2009, we were notified by NASDAQ that the Panel had determined to continue the listing of our common stock on The NASDAQ Capital Market, subject to the condition that, on or before April 6, 2009, we demonstrated compliance with all applicable standards for continued listing on The NASDAQ Capital Market, including the $35 million minimum market capitalization requirement. The panel also advised that The NASDAQ Marketplace Rules do not allow for an extension for compliance beyond April 6, 2009. In addition, the Panel issued a public reprimand for our prior failures to comply with the shareholder approval requirements and late filing of Listing of Additional Shares forms.

Even if we continue to be listed on The NASDAQ Capital Market, trading in our common stock may be halted or suspended due to market conditions or if NASDAQ, CONSOB or the Borsa Italiana determines that trading in our common stock is inadvisable. Trading in our common stock was halted by the Borsa Italiana on February 10, 2009, and, as a consequence, trading in our common stock was halted by NASDAQ. After we provided CONSOB with additional information and clarification on our business operations and financial condition as requested and published a press release containing such information in Italy, CONSOB and NASDAQ lifted the trading halt on our stock. CONSOB may make additional inquiries about our business and financial conditions at any time, and there can be no guarantee that CONSOB or NASDAQ will not halt trading in our shares again in the future.

If our common stock ceases to be listed for trading on The NASDAQ Stock Market, the MTA, or both for any reason or if trading in our stock is halted or suspended on The NASDAQ Stock Market, the MTA, or both, it may harm our stock price, increase the volatility of our stock price and make it more difficult for investors to buy or sell shares of our common stock. Moreover, if our common stock ceases to be listed for trading on The NASDAQ Stock Market or if trading in our stock is halted or suspended on The NASDAQ Stock Market, we

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may become subject to obligations to redeem certain shares of preferred stock at a premium and/or repay on an accelerated basis certain convertible notes. In addition, if we are not listed on The NASDAQ Stock Market and/or if our public float remains below $75 million, we will be limited in our ability to file new shelf registration statements on SEC Form S-3 and/or to fully use one or more registration statements on SEC Form S-3. We have relied significantly on shelf registration statements on SEC Form S-3 for most of our financings in recent years, so any such limitations may have a material adverse effect on our ability to raise the capital we need.

The global financial crisis may have an impact on our business and financial condition in ways that we currently cannot predict, and may further limit our ability to raise additional funds.

The continued credit crisis and related turmoil in the global financial system has had and may continue to have an impact on our business and our financial condition. We may face significant challenges if conditions in the financial markets do not improve or continue to worsen. In particular, our ability to access the capital markets and raise funds required for our operations may be severely restricted at a time when we would like, or need, to do so, which could have an adverse effect on our ability to meet our current and future funding requirements and on our flexibility to react to changing economic and business conditions.

We have received audit reports with a going concern disclosure 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 reports on our December 31, 2008 and 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 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 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. In addition, the Borsa Italiana and CONSOB have made several requests for information asking us to provide additional clarifications about our business operations and financial condition, and we have complied with such requests and have met with CONSOB on several occasions to answer questions. 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 two years, beginning in April 2007. After working 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, which has since terminated. After meeting with CONSOB in 2008 to further discuss their requirements for a more general listing prospectus, we filed a new listing prospectus on December 31, 2008 which has not yet been

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published. We are continuing to work with CONSOB to meet their requirements to publish this new listing prospectus. As a result, we are required to raise money using alternative forms of securities; for example, we use convertible preferred stock and convertible debt in lieu of common stock as convertible preferred stock and convertible debt are not subject to the 10% limitation imposed by Italian law.

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

A portion of our business is currently based in Italy, although we are seeking to divest our Italian assets or, alternatively, shut down our operations in Italy. However, as long as we continue to have operations 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 and which may complicate our efforts to divest or cease our Italian operations;
- European data protection regulations, under which we will be unable to send private personal data, including many employment records and some clinical trial data, from our Italian offices to our U.S. offices until our U.S. offices self-certify their adherence to the safe harbor framework established by the U. S. Department of Commerce in consultation with the European Commission;
- tariffs, customs, duties and other trade barriers; and
- capital controls, terrorism and other political risks.

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

- effectively pursuing the clinical development and regulatory approvals of all product candidates;
- successfully commercializing products under development;
- coordinating research and development activities to enhance introduction of new products and technologies;
- coalescing the Italian business culture with our own and maintaining employee morale; and
- maintaining appropriate uniform standards, controls, procedures and policies relating to financial reporting and employment-related matters, and the conduct of development activities that comply with both U.S. and Italian laws and regulations.

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

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

As long as we continue to have 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, so long as we continue to have operations in Italy, a portion of our consolidated financial obligations will arise in euros. In addition, as long as we continue to have operations in Italy, the carrying value of some of our assets and liabilities will be affected by fluctuations in the value of the U.S. dollar as compared to the euro. Changes in the value of the U.S. dollar as compared to the euro might have an adverse effect on our reported results of operations and financial condition.

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We have reported material weaknesses in our internal control over financial reporting and if material weaknesses are discovered in the future, our stock price and investor confidence in us may be adversely affected.

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 our annual or interim financial statements will not be prevented or detected on a timely basis. We identified that as of December 31, 2006 we had material weaknesses in our European branch relative to the effectiveness of our internal control over financial reporting which were remedied during 2007.

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

Our financial condition may be adversely affected if Spectrum Pharmaceuticals, Inc. becomes insolvent, experiences other financial hardship or defaults in the performance of contractual obligations.

Because we do not currently have any marketed products producing revenue, our business is dependent on the performance by third parties, including Spectrum, of their responsibilities under contractual relationships, including the timely payment by Spectrum of the remaining purchase price for the sale of our remaining 50% interest in RIT Oncology. If Spectrum were to default on the performance of its obligations in connection with the sale, we could suffer significant financial losses and operational problems, which could in turn adversely affect our financial performance, cash flows or results of operations and may jeopardize our ability to maintain our operations. Additionally, if RIT Oncology fails to perform its obligations owed to Biogen under certain Zevalin related contracts, including the payment of any milestones, Biogen may look to us in connection with those obligations under the guarantee in favor of Biogen. Spectrum is required to reimburse us for payment of such obligations based upon our percentage ownership of RIT Oncology, and we are dependent on Spectrum to fulfill such reimbursement obligation.

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

We have entered into a License and Co-Development agreement related to OPAXIO and pixantrone with Novartis International Pharmaceutical Ltd., or Novartis, pursuant to which Novartis received an exclusive worldwide license for the development and commercialization of OPAXIO and an option to enter into an exclusive worldwide license to develop and commercialize pixantrone. We will not receive any royalty or milestone payments under this agreement unless Novartis exercises its option related to pixantrone and we are able to reach a definitive agreement or Novartis elects to participate in the development and commercialization of OPAXIO. 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. In the event Novartis does not elect to participate in the development of OPAXIO or pixantrone, we may not be able to find another suitable partner for the commercialization and development of those products, which may have an adverse effect on our ability to bring those drugs to market. In addition, we would need to obtain a release from Novartis prior to entering into any agreement to develop and commercialize pixantrone or OPAXIO with a third party. We may never receive the necessary regulatory approvals and our products may not reach the necessary sales levels to generate royalty or milestone payments even if Novartis elects to exercise its option with regard to pixantrone or to participate in the development and commercialization of OPAXIO. Novartis has the right under the agreement in its sole discretion to terminate such agreement at any time on written notice to us.

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

There are no guarantees that we will obtain regulatory approval to manufacture or market 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 part on obtaining regulatory approval of OPAXIO. In March 2005, we announced the results of STELLAR 3, and in May 2005, we announced the results of STELLAR 2 and 4, our phase III clinical trials of OPAXIO in non-small cell lung cancer. All three trials failed to achieve their primary endpoints of superior overall survival compared to current marketed agents for treating NSCLC.

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

Based on discussions with the EMEA Scientific Advice Working Party, we submitted an MAA for OPAXIO in Europe on March 4, 2008 based on results of the STELLAR trials. The MAA was accepted for review by the EMEA in April 2008, however a successful regulatory outcome from the EMEA is not assured as the EMEA s final opinion cannot be predicted until they have had the opportunity to complete a thorough review of the clinical data that was presented in the MAA. We expect to receive an opinion from the EMEA by June 2009.

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. None of our current product candidates have received approval for marketing in any country. In March 2008, we submitted an MAA to the EMEA for OPAXIO. In April 2008, the EMEA accepted the MAA for review and we expect to receive an opinion from the EMEA by June 2009. In addition, we expect to begin submission of a rolling NDA to the FDA and request priority review for pixantrone to treat relapsed aggressive NHL in the first half of 2009. If priority review status is granted, the FDA could provide a decision on the NDA as early as six months after the final submission of the NDA. 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. In addition, data obtained from clinical trials are susceptible to varying interpretations, and government regulators and our collaborators may not agree with our interpretation of our clinical trial results. 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.

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In the event that we receive marketing approval for any of our product candidates, we will be subject to numerous regulations and statutes regulating the manner of selling and obtaining reimbursement for those products. 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 we will likely need to develop a new sales force for any future marketed products, 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 we also entered into a corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services that requires us to establish a compliance committee and compliance program and adopt a formal code of conduct.

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:

Because pixantrone is intended to provide less toxic treatments to patients who have failed standard chemotherapy treatment, if we are successful in bringing pixantrone 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 OPAXIO to market, we will face direct competition from oncology-focused multinational corporations. OPAXIO will compete with other taxanes. Many oncology-focused multinational corporations currently market or are developing taxanes, epothilones, and other cytotoxic agents, which inhibit cancer cells by a mechanism similar to taxanes, or similar products including, among others, Bristol-Myers Squibb Co. and others, which markets paclitaxel and generic forms of paclitaxel; Aventis, which markets docetaxel; Genentech, Roche and OSI Pharmaceuticals, which markets Tarceva ; Genentech and Roche, which markets Avastin , Eli Lilly, which markets

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Alimta®, and American Pharmaceutical Partners, which markets Abraxane . In addition, other companies such as NeoPharm Inc. and Telik, Inc. are also developing products which could compete with OPAXIO.

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. In addition, legislation and regulations affecting the pricing of pharmaceuticals may change in ways adverse to us before or after any of our proposed products are approved for marketing.

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

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

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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.

If any of our license agreements for intellectual property underlying pixantrone, OPAXIO, brostallicin, or any other products are terminated, we may lose the right to develop or market that product.

We have licensed intellectual property, including patent applications relating to intellectual property for pixantrone and brostallicin. We have also in-licensed the intellectual property for our drug delivery technology relating to OPAXIO which 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 agreement, 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, OPAXIO 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,

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licenses and patent applications may also decrease. Patent applications in which we have rights may never issue as patents and the claims of any issued patents may not afford meaningful protection for our technologies or products. In addition, patents issued to us or our licensors may be challenged and subsequently narrowed, invalidated or circumvented. Litigation, interference proceedings or other governmental proceedings that we may become involved in with respect to our proprietary technologies or the proprietary technology of others could result in substantial cost to us. Patent litigation is widespread in the biotechnology industry, and any patent litigation could harm our business. Costly litigation might be necessary to protect a patent position or to determine the scope and validity of third-party proprietary rights, and we may not have the required resources to pursue any such litigation or to protect our patent rights. Any adverse outcome in litigation with respect to the infringement or validity of any patents owned by third parties could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using a product or technology.

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

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

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

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

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

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June 2008 and we expect to have quorum at the special meeting of shareholders to be held on March 24, 2009. At the meeting in June 2008, our shareholders approved a proposal to reduce our quorum requirement from a majority of outstanding voting shares to one-third of outstanding voting shares. However, obtaining a quorum at future meetings even at the lower threshold and obtaining necessary shareholder approvals will depend in part upon the willingness of the Italian depository banks to continue participating in the custody transfer arrangements, and we cannot be assured that those banks that have participated in the past will continue to participate in custody transfer arrangements in the future. We are continuing to explore other alternatives to achieve quorum for and shareholder representation at 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 or obtain shareholder approval of proposals when needed.

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 us. In addition, brokers may only vote on those matters for which broker discretionary voting is allowed under Rule 452, and we may not be able to obtain the required number of votes to approve certain proposals that require a majority of all outstanding shares to approve the proposal due to our reliance on broker discretionary voting. Therefore it is possible that even if we are able to obtain a quorum for our meetings of the shareholders we still may not receive enough votes to approve proxy proposals presented at such meeting and, depending on the proposal in question, including the proposal being submitted to the shareholders at the upcoming meeting on March 24, 2009 to increase the number of authorized shares of common stock, such failure could have a materially adverse effect on us.

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

We are required under the NASDAQ Marketplace Rules to obtain shareholder approval for any issuance of additional equity securities that would comprise more than 20% of our total shares of common stock outstanding before the issuance of such securities sold 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. If we are unable to obtain financing due to shareholder approval difficulties, such failure may have a material adverse effect on our ability to continue operations.

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

We may not be able to continue to purchase the materials necessary to produce OPAXIO, including paclitaxel, in adequate volume and quality. Paclitaxel is derived from certain varieties of yew trees and the supply of paclitaxel is controlled by a limited number of companies. Paclitaxel is available and we have purchased it from several sources. We purchase the raw materials paclitaxel and polyglutamic acid from single sources. 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 qualify and 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.

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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 and contract service providers may at times violate cGMPs. The FDA and other regulatory authorities may take action against a contract manufacturer who violates cGMPs. One of our products under development, OPAXIO, has a complex manufacturing process and supply chain, 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 drug products for pixantrone and brostallicin are both manufactured by a single vendor. Finished product manufacture and distribution for both pixantrone and brostallicin are to be manufactured and distributed by different single vendors.

If we do not successfully develop our products candidates into marketable 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. We transferred Zevalin to RIT Oncology, a joint venture with Spectrum, in December 2008 and, as of March 9, 2009, are currently engaged in the process of selling our remaining interest in the joint venture (and therefore our remaining interest in Zevalin) to Spectrum. Unless we are able to develop one of our product candidates into an approved commercial product, we will not generate any significant revenues from product sales, royalty payments, license fees or otherwise. Pixantrone, OPAXIO and brostallicin are currently in clinical trials; these clinical trials may not be successful and, even if they are, we may not be successful in developing any of them into a commercial product. For example, our STELLAR phase III clinical trials for OPAXIO for the treatment of non-small cell lung cancer failed to meet their primary endpoints. In addition, 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 these and any 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 in-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. All of our product candidates in clinical development are in-licensed from a third party, including pixantrone, OPAXIO 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.

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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. For example:

- 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 require significant time, resources or expertise to those originally expected to be necessary;
- clinical testing may not show potential products to be safe and efficacious and, as with many drugs, may fail to demonstrate the desired safety and efficacy characteristics in human clinical trials;
- clinical testing may show that potential products are not appropriate for the specific indication for which they are being tested;
- 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;
- 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; and
- completion of clinical trials depends on, among other things, the number of patients available for enrollment in a particular trial, which is a function of many factors, including the number of patients with the relevant conditions, the nature of the clinical testing, the proximity of patients to clinical testing centers, the eligibility criteria for tests as well as competition with other clinical testing programs involving the same patient profile but different treatments.

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

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

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

We have entered into collaborative arrangements with third-parties to develop and/or commercialize product candidates and are currently seeking additional collaborations. For example, we entered into an agreement with the Gynecologic Oncology Group to perform a phase III trial of OPAXIO in patients with ovarian cancer. Additional collaborations might be necessary in order for us to fund our research and development activities and third-party manufacturing arrangements, seek and obtain regulatory approvals and successfully commercialize our existing and future product candidates. If we fail to enter into additional collaborative arrangements or fail to maintain our existing collaborative arrangements, the number of product candidates from which we could receive future revenues would decline. For example, in 2005 we sold our product TRISENOX to Cephalon and, pursuant to the terms of the purchase agreement under which TRISENOX was sold, we are entitled to

receive milestone payments upon the approval by the FDA of new labeled uses for TRISENOX; however, Cephalon may decide not to submit any additional information to the FDA to apply for label expansion of TRISENOX, in which case we would not receive a milestone payment under the agreement.

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

- collaborative arrangements may not be on terms favorable to us;
- disagreements with partners may result in delays in the development and marketing of products, termination of our collaboration agreements or time consuming and expensive legal action;
- we cannot control the amount and timing of resources partners devote to product candidates or their prioritization of product candidates and partners may not allocate sufficient funds or resources to the development, promotion or marketing of our products, or may not perform their obligations as expected;
- partners may choose to develop, independently or with other companies, alternative products or treatments, including products or treatments which compete with ours;
- agreements with partners may expire or be terminated without renewal, or partners may breach collaboration agreements with us;
- business combinations or significant changes in a partner s business strategy might adversely affect that partner s willingness or ability to complete its obligations to us; and
- the terms and conditions of the relevant agreements may no longer be suitable.

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

Because we base several of our drug candidates on unproven 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 will not develop into commercial products.

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

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

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

Our research and development activities involve the controlled use of hazardous materials, chemicals and various radioactive compounds. We are subject to 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

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

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

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

Risks Related To the Securities Markets

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

The market price for securities of biopharmaceutical and biotechnology companies, including ours, historically has been highly volatile, and the market from time to time has experienced significant price and volume fluctuations that are unrelated to the operating performance of such companies. For example, during the twelve month period ended March 9, 2009, our stock price has ranged from a low of $0.05 to a high of $9.60. Fluctuations in the trading price or liquidity of our common stock may adversely affect the value of your investment in our common stock.

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

- announcements by us or others of results of preclinical testing and clinical trials and regulatory actions;
- announcements of technological innovations or new commercial therapeutic products by us, our collaborative partners or our present or potential competitors;
- our issuance of additional debt, equity or other securities, which we need to pursue in 2009 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;

short selling;

changes in health care policies and practices;

halting or suspension of trading in our common stock by NASDAQ, CONSOB or the Borsa Italiana;

economic and other external factors; and

general market conditions.

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

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

We currently 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. Our European offices also lease approximately 60,000 square feet of office and laboratory space in Bresso (Milan), Italy with the latest lease expiration of 2013. In addition, our wholly owned subsidiary SM, acquired in July 2007, leases approximately 4,000 square feet of office and laboratory space in Scottsdale, Arizona with the latest lease expiration date of 2012. 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

On January 2, 2008, Tang Capital Partners LP (Tang) filed a civil action in the United States District Court for the Southern District of New York in which Tang alleged that we breached a Securities Purchase Agreement, executed on or about April 16, 2007 in connection with the issuance of Series B Preferred Stock. On January 3, 2009, the Company entered into a settlement agreement with Tang with respect to the civil action filed

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by Tang on January 2, 2008. In exchange for the full release of all claims arising directly or indirectly out of or related to Tang s purchase, acquisition, ownership, interest in or rights under Series B 3% Convertible Preferred Stock, the Company agreed to pay Tang $5.1 million. Final payment was completed on January 29, 2009. A holder of Series C Convertible Preferred Stock, Enable Capital Management LLC (Enable), filed a lawsuit on January 23, 2008 in the Supreme Court of the State of New York with similar claims to the Tang action. On September 29, 2008, Enable entered into a release agreement with CTI to fully resolve this action. On May 5, 2008, RHP Master Fund, Ltd. (RHP), a holder of our Series A Preferred Stock filed suit in the United States District Court for the Southern District of New York alleging breach of contract and violation of Washington Business Corporation Act, and breach of fiduciary duty by certain officer and director defendants. On February 4, 2009, CTI settled all claims that were filed or could have been filed by RHP.

On January 22, 2007, we filed a complaint in King County Washington Superior Court against The Lash Group, Inc. and Documedics Acquisition Co., Inc., our former third party reimbursement expert for TRISENOX, seeking recovery of damages, including losses incurred by the Company in connection with our investigation, defense and settlement of claims by the United States concerning Medicare reimbursement for TRISENOX. On February 28, 2007, defendant The Lash Group, Inc. removed the case to federal court in the Western District of Washington. On June 19, 2008, the trial judge dismissed our claims and the Company filed a timely notice of appeal in the Ninth Circuit Court of Appeals. That appeal remains pending. If successful on appeal, we intend to return to the United States District Court for trial. There is no guarantee that we will prevail in the appeal or at trial.

In April 2007, we entered into a settlement agreement with the United States Attorney s Office, or USAO, for the Western District of Washington arising out of their investigation into certain of our prior marketing practices relating to TRISENOX® (arsenic trioxide). We made the settlement payment of $10.6 million in April 2007. The settlement agreement did not address separate claims brought against us by the private party plaintiff for his attorneys fees and expenses. After further litigation concerning attorneys fees and expenses, on January 28, 2009 all remaining claims were settled for approximately $0.5 million, and in consequence, the case has been fully and finally resolved.

On May 1, 2008 i3, a contract research organization, sent a letter claiming that CTI owed i3 $2.2 million pursuant to clinical support work. All of these charges have been previously invoiced to CTI, but the invoices are being evaluated for the association of the work being billed to the contract assignments, as well as the relationship of the pass-through costs to approvable work. On November 6, 2008, i3 filed a demand for arbitration of this dispute with the American Arbitration Association, seeking damages of $2.2 million. That arbitration is pending. While it is probable that some money will be owed to i3, it is not possible at this time to estimate the amount.

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. The Company currently has one arbitration action, but no pending court litigation against it.

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

Not applicable.

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PART II

Item 5. Market for Registrant s Common Equity, Related Shareholder Matters and Issuer Purchases of Equity Securities

Our common stock is currently traded on the Nasdaq Capital Market under the symbol CTIC and the MTA (formerly known as the MTAX and, prior to that, as the Nuovo Mercato) in Italy, also under the ticker symbol CTIC . Prior to January 8, 2009, our common stock was traded on the Nasdaq Global Market. 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 effective April 15, 2007 and the one-for-ten reverse stock split effective August 31, 2008).

	High	Low
2007		
First Quarter	72.40	56.40
Second Quarter	75.60	28.50
Third Quarter	49.70	30.00
Fourth Quarter	38.90	15.90
2008		
First Quarter	19.90	4.70
Second Quarter	9.60	4.60
Third Quarter	4.90	0.58
Fourth Quarter	0.89	0.12

On March 9, 2009, the last reported sale price of our common stock on the Nasdaq Capital Market was $0.06 per share. As of March 9, 2009, there were approximately 180 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 or our Series F Preferred Stock in the foreseeable future. Except for dividends payable on the Series A 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.

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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, 2008, including the 2007 Equity Incentive Plan, Novuspharma S.p.A. Stock Option Plan, 1994 Equity Incentive Plan and the 2007 Employee Stock Purchase Plan.

Plan Category	(a) Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(b) Weighted Average Exercise Price of Outstanding Options, Warrants, and Rights	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))	(d) Total of Securities Reflected in Columns (a) and (c)
Plans Approved by Shareholders	294,103(1)	$ 178.11	250,766(2)	544,869
Plan Not Approved by Shareholders (3)	4,337	$ 128.40	None	4,337

(1) Consists of the 2007 Equity Incentive Plan and the 1994 Equity Incentive Plan.
(2) Consists of 234,166 shares available for future issuance under the 2007 Equity Incentive Plan and 16,600 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.

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Stock Performance Graph

	3/31/04	6/30/04	9/30/04	12/31/04
Cell Therapeutics, Inc.	$ 97.58	$ 85.01	$ 79.12	$ 93.89
Nasdaq Stock Index (U.S.)	$ 99.31	$ 102.26	$ 94.89	$ 108.84
Nasdaq Pharmaceutical Index	$ 104.38	$ 103.25	$ 98.74	$ 106.51

	3/31/05	6/30/05	9/30/05	12/31/05
Cell Therapeutics, Inc.	$ 41.41	$ 31.26	$ 32.99	$ 25.14
Nasdaq Stock Index (U.S.)	$ 99.98	$ 103.38	$ 108.31	$ 111.16
Nasdaq Pharmaceutical Index	$ 93.54	$ 97.96	$ 115.16	$ 117.29

	3/31/06	6/30/06	9/30/06	12/31/06
Cell Therapeutics, Inc.	$ 22.03	$ 16.61	$ 19.72	$ 20.18
Nasdaq Stock Index (U.S.)	$ 117.90	$ 109.92	$ 114.22	$ 122.11
Nasdaq Pharmaceutical Index	$ 120.46	$ 107.76	$ 112.60	$ 114.81

	3/31/07	6/30/07	9/30/07	12/31/07
Cell Therapeutics, Inc.	$ 18.34	$ 8.79	$ 10.58	$ 5.42
Nasdaq Stock Index (U.S.)	$ 122.29	$ 131.03	$ 135.18	$ 132.42
Nasdaq Pharmaceutical Index	$ 112.35	$ 117.31	$ 122.82	$ 120.74

	3/31/08	6/30/08	9/30/08	12/31/08
Cell Therapeutics, Inc.	$ 1.90	$ 1.38	$ 0.21	$ 0.04
Nasdaq Stock Index (U.S.)	$ 114.06	$ 114.58	$ 106.57	$ 63.80
Nasdaq Pharmaceutical Index	$ 114.24	$ 116.89	$ 122.22	$ 112.34

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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,				
	2008	2007	2006	2005	2004
	(In thousands, except per share data)				
Consolidated Statements of Operations Data:					
Revenues:					
Product sales	$ 11,352	$ 47	$	$ 14,599	$ 26,626
License and contract revenue	80	80	80	1,493	2,968
Total revenues	11,432	127	80	16,092	29,594
Operating expenses, net:					
Cost of product sold	3,244	49		518	1,104
Research and development	51,614	72,019	61,994	68,767	101,127
Selling, general and administrative	41,445	35,316	35,303	61,717	78,522
Amortization of purchased intangibles	1,658	913	792	1,254	2,294
Gain on sale of Zevalin(1)	(9,444)				
Acquired in-process research and development(2)	36	24,615			87,375
Restructuring charges and related asset impairments(3)	162	201	591	12,780	
Gain on divestiture of TRISENOX(4)				(71,211)	
Total operating expenses, net	88,715	133,113	98,680	73,825	270,422
Loss from operations	(77,283)	(132,986)	(98,600)	(57,733)	(240,828)
Other income (expense):					
Investment and other income, net	549	2,430	2,866	2,588	1,636
Interest expense	(8,559)	(8,237)	(8,852)	(14,283)	(10,019)
Amortization of debt discount and issuance costs	(66,530)	(4,280)	(10,977)	(2,263)	(969)
Foreign exchange gain (loss)	3,637	4,657	1,877	8	(2,118)
Make-whole interest expense	(70,243)	(2,310)	(24,753)	(1,013)	
Gain on derivative liabilities	69,739	3,672	6,024	236	
Gain (loss) on exchange of convertible notes	(25,103)	(972)	7,978		
Debt conversion expense				(23,608)	
Write-off of financing arrangement costs	(2,846)				
Equity loss from investment in joint venture	(123)				
Settlement expense	(3,393)	(160)	(11,382)		
Loss on extinguishment of royalty obligation				(6,437)	
Loss before minority interest	(180,155)	(138,186)	(135,819)	(102,505)	(252,298)
Minority interest in net loss of subsidiary	126	78			
Net loss	$ (180,029)	$ (138,108)	$ (135,819)	$ (102,505)	$ (252,298)
Preferred stock beneficial conversion feature	(1,067)	(9,549)			
Preferred stock dividends	(662)	(648)			
Deemed dividends on conversion of preferred stock	(21,149)				
Net loss attributable to common shareholders	$ (202,907)	$ (148,305)	$ (135,819)	$ (102,505)	$ (252,298)
Basic and diluted net loss per common share(5)	$ (7.00)	$ (32.75)	$ (48.39)	$ (63.51)	$ (186.75)

Shares used in calculation of basic and diluted net loss per common share	28,967	4,529	2,807	1,614	1,351

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	2008	2007	December 31, 2006	2005	2004
			(In thousands)		
Consolidated Balance Sheets Data:					
Cash and cash equivalents, securities available-for-sale and interest receivable	$ 10,680	$ 18,392	$ 54,407	$ 69,067	$ 116,020
Restricted cash(6)	6,640			25,596	
Working capital	(13,962)	(30,909)	30,166	76,288	93,813
Total assets	64,243	73,513	101,821	155,440	184,996
10% Convertible senior notes(7)	19,784				
9% Convertible senior notes(8)	4,104				
7.5% Convertible senior notes(9)	32,601	32,220	48,186		
6.75% Convertible senior notes(10)	6,926	6,922	6,945	79,046	
5.75% Convertible senior notes(11)	23,808	23,287			
5.75% Convertible senior subordinated notes(12)		16,907	27,407	66,929	85,459
4.0% Convertible senior subordinated notes(13)	55,150	55,150	55,150	55,150	75,000
5.75% Convertible subordinated notes(14)		2,910	28,490	29,640	29,640
Series A 3% Convertible preferred stock	417	5,188			
Series B 3% Convertible preferred stock	4,031	11,881			
Series C 3% Convertible preferred stock	3,221	6,229			
Series D 7% Convertible preferred stock	734	2,938			
Royalty obligation					25,123
Other long-term obligations, less current portion	2,907	9,879	4,667	7,326	6,363
Accumulated deficit	(1,312,320)	(1,109,413)	(961,108)	(825,289)	(722,784)
Total shareholders deficit	(132,061)	(134,125)	(101,604)	(107,097)	(70,708)

(1) The gain on sale of Zevalin for the year ended December 31, 2008 related to the gain recognized, net of transaction costs, on the sale of Zevalin to RIT Oncology, our 50/50 joint venture with Spectrum. As of March 9, 2009, we are engaged in the process of selling our 50% interest in RIT Oncology to Spectrum.

(2) 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.

(3) 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 2008, 2007 and 2006 balances represent adjustments to these amounts.

(4) 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.

(5) 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.

(6) The 2008 amount represents cash held in escrow to fund potential make-whole payments on certain of our convertible senior notes. 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.

(7) The 10% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 7.29927 shares of common stock per $1.00 principal amount of the notes, which is equivalent to a conversion price of approximately $0.137 per share.

(8) The 9% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 70.922 shares of common stock per $1,000 principal amount of the notes, which is equivalent to a conversion price of approximately $14.10 per share.

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(9) The 7.5% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 11.96298 shares of common stock per $1,000 principal amount of the notes, which is equivalent to a conversion price of approximately $83.59 per share. The 2006 amount includes $2.3 million which is included in *current portion of derivative liability*.

(10) The 6.75% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 9.50925 shares of common stock per $1,000 principal amount of the notes, which is equivalent to a conversion price of approximately $105.16 per share.

(11) The 5.75% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 33.33333 shares of common stock per $1,000 principal amount of the notes, which is equivalent to a conversion price of approximately $30.00 per share.

(12) The 5.75% convertible senior subordinated notes were convertible in shares of CTI common stock at a conversion rate of 2.5 shares of common stock per $1,000 principal amount of the notes, which is equivalent to a conversion price of $400.00 per share. These notes matured in June 2008.

(13) The 4.0% convertible senior subordinated notes are convertible into shares of CTI common stock at a conversion rate of 1.85185 shares of common stock per $1,000 principal amount of the notes, which is equivalent to a conversion price of approximately $540.00 per share.

(14) The 5.75% convertible subordinated notes were convertible in shares of CTI common stock at a conversion rate of 0.7353 shares of common stock per $1,000 principal amount of the notes, which is equivalent to a conversion price of $1,360.00 per share. These notes matured in June 2008.

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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, 2008, we had incurred aggregate net losses of approximately $1.3 billion since inception. We expect to continue to incur operating losses for at least the next couple of years.

In December 2008, we formed a 50/50 owned joint venture with Spectrum Pharmaceuticals, Inc., or Spectrum. The joint venture, RIT Oncology LLC, or RIT Oncology, was formed to commercialize and develop Zevalin® (Ibritumomab Tiuxetan), or Zevalin, a radiopharmaceutical product to which we acquired the U.S. development, sales and marketing rights from Biogen Idec, Inc., or Biogen, in December 2007 for an upfront payment of $10.1 million, up to $20 million in contingent milestone payments and certain royalty payments based on net sales of Zevalin. The milestone and royalty payment obligations were transferred to RIT Oncology in connection with the formation of the joint venture. Upon formation of RIT Oncology, we contributed all assets exclusively related to Zevalin and in exchange received a 50% membership interest in RIT Oncology and $15.0 million in payments from RIT Oncology, of which $7.5 million was received upon formation and $7.5 million was received in January 2009. We also made an initial capital contribution of $1.8 million to RIT Oncology upon the closing of the joint venture transaction. At that time, RIT Oncology also issued to Spectrum a 50% membership interest in exchange for its capital contribution, a portion of which funded the purchase price paid to us by RIT Oncology.

Under the terms of the operating agreement for the joint venture, we had an option to sell our 50% interest in the joint venture to Spectrum for $18 million, as adjusted, and in February 2009, we exercised that option. In March 2009 we received from Spectrum a payment of $6.5 million (a portion of which was used to pay a consent fee owed to Biogen) in connection with the sale of our 50% interest in RIT Oncology and, as of March 9, 2009, are engaged in the process of finalizing the transaction terms, including the terms of payment for the remainder of the purchase price (which will be received no later than 90 days following the closing). As a result of this transaction, we will be fully divested of our 50% interest in the joint venture, and thereby our remaining interest in 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 may 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.

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In September 2006, we entered into an exclusive worldwide licensing agreement with Novartis International Pharmaceutical Ltd., or Novartis, for the development and commercialization of OPAXIO. If Novartis elects to participate in the development and commercialization of OPAXIO, total product registration and sales milestones due from Novartis for OPAXIO 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.

On July 18, 2005, we completed the divestiture of TRISENOX® (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 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.

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 subjective or complex judgment 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. All product sales for 2008 and 2007 were derived from Zevalin. 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. Following the transfer of Zevalin to RIT Oncology in December 2008, we do not currently have any marketed products generating sales revenue.

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.

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

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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.

Derivatives Embedded in Certain Debt Securities

We evaluate financial instruments for freestanding or embedded derivatives in accordance with Statement of Financial Accounting Standards, or 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 statement of operations in the period of change.

Except for our 5.75% and 7.5% notes, all of our convertible senior notes include a feature that calls for make-whole payments upon any conversion of these notes. Our 7.5% convertible senior 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. These make-whole features along with the conversion options on the notes represent embedded derivatives that must be accounted for separately from the related debt securities except where our convertible senior notes are recorded entirely at fair value pursuant to the guidance in EITF 96-19, *Debtor s Accounting for a Modification or Exchange of Debt Instruments*. The fair value of the derivative for our 6.75% convertible senior notes is calculated based on a discounted cash flow model. The fair value of the derivatives related to all other convertible senior notes is calculated using a Monte Carlo simulation model that incorporates factors such as the current price of our common stock, its volatility and estimated time to expiration of the make-whole feature.

Changes in the estimated fair value of the derivative liabilities related to the convertible senior notes are included in *gain on derivative liabilities* and will be remeasured at the end of each reporting period until the relevant feature expires or all of the relevant notes are converted or repurchased.

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Purchase price allocation

Based on the provisions of SFAS No. 141, *Business Combinations,* for transactions that occurred prior to December 31, 2008, the purchase price for our acquisitions was 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 engaged 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 restructuring activities, 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 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.

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Results of Operations

Years ended December 31, 2008 and 2007.

Product sales. Product sales for the year ended December 31, 2008 and 2007 relate to Zevalin and increased due to the fact that we did not acquire Zevalin from Biogen until December 2007.

License and contract revenue. License and contract revenue for the year ended December 31, 2008 and 2007 represents recognition of deferred revenue from the sale of Lisofylline material to Diakine.

Cost of product sold. Cost of product sold for the years ended December 31, 2008 and 2007 relates to sales of Zevalin and consists primarily of contractual royalties on product sales in addition to cost of product sold to customers. The increase in cost of product sold is consistent with the increase in product sales.

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

	2008	2007
Compounds under development:		
Pixantrone	$ 8,238	$ 16,630
Zevalin	5,271	143
OPAXIO	4,145	20,751
Brostallicin	3,860	4,205
Other compounds	391	813
Operating expenses	27,878	27,156
Discovery research	1,831	2,321
Total research and development expenses	$ 51,614	$ 72,019

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 OPAXIO, pixantrone, brostallicin and Zevalin are approximately $217.3 million, $48.7 million, $8.1 million and $5.4 million, respectively. Costs for pixantrone prior to our merger with Novuspharma S.p.A in January 2004 and costs for brostallicin prior to our acquisition of SM in July 2007 are excluded from this amount. Costs for Zevalin prior to its acquisition in December 2007 and subsequent to its sale to RIT Oncology in December 2008 are also excluded from this amount.

Research and development expenses decreased to approximately $51.6 million for the year ended December 31, 2008, from approximately $72.0 million for the year ended December 31, 2007. Pixantrone costs decreased primarily due to a decrease in clinical development activity mainly related to the closure of our PIX303 clinical trial in the fourth quarter of 2007 as well as a discontinuance of patient enrollment during 2008 in our RAPID and EXTEND trials. We 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 second line follicular NHL. 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

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effects between pixantrone and doxorubicin. Additionally, we closed enrollment on the EXTEND trial during 2008 as we believed that the current accrual rate would not contribute substantially to the trial s chance of success. These decreases were partially offset by an increase in manufacturing activity for pixantrone. Costs for Zevalin increased due to our acquisition of the product in December 2007 and primarily relate to clinical development activity including $2.0 million in expense related to our payment to Bayer Schering for access to the data from the FIT trial. Our Zevalin product was contributed to RIT Oncology, a joint venture we formed with Spectrum, on December 15, 2008 and all related expenses subsequent to this date have been assumed by the joint venture. In addition, as of March 9, 2009, we are engaged in the process of selling our interest in the joint venture to Spectrum. Costs for our OPAXIO program decreased primarily due to a decrease in clinical development activity related to our PGT307 trial, which was reduced in scope to U.S. sites only in early 2008, reduced costs associated with our PIONEER trial which was suspended and closed in the fourth quarter of 2006 and incurred certain wrap-up costs in the first half of 2007 and a decrease in the GOG0212 study related to the amendment to our contract with the GOG. Manufacturing activity for OPAXIO also decreased as we extended activities into 2009 in an effort to conserve cash in 2008. Costs for brostallicin decreased primarily due to a non-recurring license payment during 2007 related to a development agreement, partially offset by an increase in clinical development activities related to phase I and phase II studies. Our operating expenses remained fairly consistent in both years, while our discovery research decreased slightly due to a shift in focus to our commercial product Zevalin, which was transferred to the joint venture, as well as other products closer to commercialization.

Our lead drug candidates, pixantrone, OPAXIO and brostallicin, are currently in clinical trials. 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 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. We have drug candidates that 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 and we will be able to generate revenues 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; and
- our product candidates, if developed, are approved.

Failure to generate such revenues may preclude us from continuing our research, development and commercial activities for 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 submitted an MAA for OPAXIO in Europe in March 2008 based on the results of the STELLAR trials. The MAA was accepted for review by the EMEA in April 2008, however, a successful regulatory outcome from the EMEA is not assured as the EMEA s final opinion cannot be predicted until they have had the opportunity to complete a thorough review of the clinical data that was presented in the MAA. We expect to receive an opinion from the

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EMEA by June 2009 and, if we obtain a favorable review by the European Commission, could receive marketing authorization in the second half of 2009. If we do receive approval of that MAA in 2009, we would expect to receive cash inflows in 2009 through collaborative agreements or from sales of the product.

Selling, general and administrative expenses. Selling, general and administrative expenses increased to approximately $41.6 million for the year ended December 31, 2008, from approximately $35.5 million for the year ended December 31, 2007. This is primarily attributed to a $4.8 million increase in sales and marketing expenses due to the acquisition of Zevalin in December 2007 and subsequent expansion of our sales force. In addition, we incurred approximately $1.2 million in legal and consulting fees associated with the potential spin-off, asset divestment, or creation of a joint venture with regard to certain of our operations and assets. We also had an increase in our stock-based compensation expense of approximately $1.8 million as well as an increase in our legal expenses of approximately $0.9 million primarily due to our claim against the Lash Group, Inc. and Documedics Acquisition Co., Inc. Compensation and benefits also increased approximately $0.6 million in part due to key executive personnel hired in 2008. These increases were offset by a $1.3 million decrease in finance and administration and human resources expenses in our Italian operations due to a reduced level of activities. In addition, corporate development expenses decreased approximately $0.8 million primarily related to a reduction in travel costs. Finance and administration expenses also decreased approximately $0.8 million primarily due to a decrease in expenses associated with our shareholder meetings as well as a decrease in certain taxes and insurance premiums. We expect selling, general and administrative expenses to decrease in 2009 as compared to 2008 due to the divestiture of Zevalin to Spectrum Pharmaceuticals, Inc. as well as the divestiture or closure of our Bresso facility in the first quarter of 2009.

Amortization of purchased intangibles. Amortization for the year ended December 31, 2008 increased to approximately $1.7 million from approximately $0.9 million for the year ended December 31, 2007 primarily due to the amortization of intangible assets acquired in connection with our acquisition of Zevalin in December 2007.

Gain on sale of Zevalin. The gain on sale of Zevalin for the year ended December 31, 2008 related to the gain recognized, net of transaction costs, on the sale of Zevalin to RIT Oncology, the 50/50 joint venture we formed with Spectrum. Due to the fact that we received cash for assets contributed, we recorded a gain based on the difference between the book value of the assets contributed and the fair value of these assets as recorded under the joint venture.

Acquired in-process research and development. Acquired in-process research and development for the year ended December 31, 2008 relates to adjustments to our one-time charge recorded in connection with our acquisition of Zevalin in December 2007. These adjustments resulted from changes in the estimated acquisition costs used in determining the total estimated purchase price of the acquisition. The amount 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.

Investment and other income, net. Investment and other income for the year ended December 31, 2008 decreased to approximately $0.5 million as compared to $2.4 million for the year ended December 31, 2007 primarily due to a lower average securities available-for-sale balance.

Interest expense. Interest expense increased to approximately $8.6 million for the year ended December 31, 2008 from approximately $8.2 million for the year ended December 31, 2007. This was primarily due to increases of approximately $3.0 million related to interest on our 5.75% convertible senior notes issued in December 2007 as well as interest on our 9% notes, 15% notes, 18.33% notes, 9.66% notes and 10% notes due 2012 which were all issued during 2008. These increases were offset by a decrease of $2.8 million in interest expense on our 5.75% convertible subordinated and senior subordinated notes due to the exchange of approximately $36.1 million of these notes for our 5.75% senior notes in December 2007, the cancellation of $9.1 million of these notes in exchange for shares of our common stock in February 2008 and repayment of the remaining amount upon maturity in June 2008.

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Amortization of debt discount and issuance costs. Amortization of debt discount and issuance costs increased to $66.5 million for the year ended December 31, 2008 as compared to $4.3 million for the year ended December 31, 2007. This increase was primarily due to the accelerated amortization of debt discount and issuance costs related to conversions of certain of our convertible notes issued in 2008. For the year ended December 31, 2008, amortization of the debt discount related to our 13.5% notes, 9% notes, 15.5% notes, 18.33% notes, 10% notes due 2012, 10% notes due 2011 and 9.66% notes was approximately $23.4 million, $13.2 million, $8.6 million, $5.6 million, $3.4 million, $2.2 million and $1.8 million, respectively, and the amortization of debt issuance costs was approximately $2.0 million, $1.9 million, $0.3 million, $0.5 million, $0.4 million, $0.2 million and $0.3 million, respectively. This amortization was primarily due to conversions of these notes during the year ended December 31, 2008. These increases were offset by a decrease of $2.9 million in amortization of debt discount and issuance costs on our 7.5% notes primarily related to conversions of these notes during the year ended December 31, 2007.

Foreign exchange gain. Foreign exchange gains for the years ended December 31, 2008 and 2007 are due to fluctuations in foreign currency exchange rates, primarily related to payables and receivables in our European branch denominated in foreign currencies.

Make-whole interest expense. Make whole interest expense of $70.2 million for the year ended December 31, 2008 is related to $22.4 million in payments made upon the conversion of $27.6 million of our 13.5% notes, $15.5 million in payments made upon conversion of $28.3 million of our 18.33% notes, $11.0 million in payments made upon conversion of $40.8 million of our 9% notes, $8.8 million in payments made upon conversion of $14.2 million of our 15.5% notes, $4.5 million in payments made upon conversion of $15.7 million of our 9.66% notes, $4.4 million in payments made upon conversion of $14.7 million of our 10% notes due 2011 and $3.6 million in payments made upon conversion of $9.0 million of our 10% notes due 2012. 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.

Gain on derivative liabilities. The gain on derivative liabilities of $69.7 million for the year ended December 31, 2008 is primarily due to gains of $22.3 million, $12.0 million, $8.6 million, $6.9 million, $4.6 million, $3.4 million, $2.4 million and $2.2 million resulting from the change in the estimated fair value of the derivative liabilities related to the embedded conversion options on our 13.5% notes, 9% notes, 15.5% notes, 18.33% notes, 15% notes, 10% notes due 2012, 9.66% notes and 10% notes due 2011, respectively. There was also a gain of $7.3 million due to the change in the estimated fair value of the derivative liability related to the Series B Unit Warrant that was issued in connection with the issuance of our 13.5% notes and Series E preferred stock financing and modified in connection with the issuance of our 15% and 18.33% notes. The gain on derivative liabilities of $3.7 million for the year ended December 31, 2007 primarily represents the change in the estimated fair value of the derivative liabilities related to the interest make-whole provisions on our 7.5% notes.

Gain (loss) on exchange of convertible notes. The loss on exchange of convertible notes of $25.1 million for the year ended December 31, 2008 is due to the repurchase of certain of our convertible notes in exchange for new convertible notes or common stock. In July and August 2008, we recorded a $10.3 million loss due to the repurchase of approximately $17.5 million aggregate principal of our 13.5% notes in connection with the issuance of our 18.33% notes. A loss of $5.5 million was due to the repurchase of $18.2 million of our 15% notes in connection with the issuance of our 9.66% notes in October 2008. In addition, we repurchased the remaining $4.8 million of our 15% notes, $16.3 million of our 18.33% and $9.0 million of our 9.66% in connection with the issuance of our 10% notes due 2011 and recorded a $3.7 million loss. We also recorded a $3.3 million loss due to the exchange of $5.3 million of our 9% notes for units of our 13.5% notes, Series E preferred stock and related warrants issued in April 2008 and a loss of $2.3 million due to the extinguishment of approximately $9.1 million aggregate principal amount of our 5.75% convertible senior subordinated and convertible subordinated notes in exchange for approximately 0.7 million shares of our common stock in February 2008.

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The loss of approximately $1.0 million during the year ended December 31, 2007 is 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.

Write-off of financing arrangement costs. The write-off of financing arrangement costs of $2.8 million for the year ended December 31, 2008 primarily relates to a $2.4 million write-off of offering costs associated with the Step-Up Equity Financing Agreement with Société Générale, including costs related to the Italian Listing Prospectus that was published in January 2008 as an Italian regulatory requirement to issue shares under this agreement. The write-off was primarily due to significant uncertainty regarding our ability to pursue further financings under this agreement which terminated in January 2009. In addition, we wrote-off $0.5 million in expenses associated with our equity line of credit with Midsummer Investment, Ltd., or Midsummer, based on our plans to terminate the agreement; that termination occurred in March 2009.

Equity loss from investment in joint venture. The loss for the year ended December 31, 2008 relates to our 50% interest in RIT Oncology, which we account for using the equity method of accounting.

Settlement expense. Settlement expense of $3.4 million for the year ended December 31, 2008 was primarily related to $2.9 million in payments accrued or made to certain of our preferred stock holders for the release of all claims against us in connection with our alleged breach of contract related to their preferred stock held. In addition, we recorded expense of $0.5 million for the settlement of attorney s fees and costs related to claims brought against us by a private party plaintiff in connection with our litigation with the United States Attorney s Office, or USAO, as discussed in Legal Proceedings.

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.

Minority interest in net loss of subsidiary. Minority interest in net loss of subsidiary was approximately $0.1 million for the years ended December 31, 2008 and 2007, and represents the minority owner s pro rata allocation of the losses in Aequus Biopharma, Inc.

Years ended December 31, 2007 and 2006.

Product sales. Product sales for the year ended December 31, 2007 relate to Zevalin. We had 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 and consists primarily of contractual royalties on product sales in addition to cost of product sold to customers. There was no cost of product sold for the year ended December 31, 2006 as we did not acquire Zevalin until December 2007.

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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:		
OPAXIO	$ 20,751	$ 24,722
Pixantrone	16,630	10,404
Brostallicin	4,205	
Other compounds	956	848
Operating expenses	27,156	24,545
Discovery research	2,321	1,475
Total research and development expenses	$ 72,019	$ 61,994

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 OPAXIO 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 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.

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 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.

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.

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.

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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 $8.2 million for the year ended December 31, 2007 from approximately $8.9 million for the year ended December 31, 2006. This change is primarily due to a decrease in interest expense on our 5.75% convertible subordinated and senior subordinated notes of 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 interest expense on our 6.75% notes of approximately $0.4 million.

Amortization of debt discount and issuance costs. Amortization of debt discount and issuance costs decreased to approximately $4.3 million for the year ended December 31, 2007 from approximately $11.0 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. 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.

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.

Gain on derivative liabilities, net. 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

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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.

Liquidity and Capital Resources

As of December 31, 2008, we had approximately $10.7 million in cash and cash equivalents, securities available-for-sale and interest receivable. We expect our average cash burn rate for 2009 to be approximately $4.0 million per month.

Net cash used in operating activities totaled approximately $80.2 million in 2008, compared to approximately $103.6 million in 2007 and $116.6 million in 2006. The decrease in net cash used in operating activities for the year ended December 31, 2008 as compared to 2007 was primarily due to a decrease in our *selling, general and administrative* and *research and development expenses* as well as an increase in cash collected from our sales of Zevalin. 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. For the years ended December 31, 2008, 2007 and 2006 our net loss included $70.2 million, $2.3 million and $24.8 million in make-whole interest payments related to conversions of certain of our convertible notes. Our make-whole payments for the year ended December 31, 2008 were paid with restricted cash held in escrow to fund these payments and, therefore, did not affect cash used in operating activities for 2008.

Net cash provided by investing activities totaled approximately $4.4 million in 2008 as compared to $21.5 million in 2007 and net cash used in investing activities of $17.9 million in 2006. Net cash provided by investing activities during the year ended December 31, 2008 was primarily due to $6.8 million in net cash received in December 2008 in connection with our disposition of Zevalin to RIT Oncology in exchange for a 50% interest in RIT Oncology as well as proceeds from sales and maturities of securities available-for-sale, offset by purchases of securities available-for-sale, purchases of property and equipment and cash paid for acquisition costs related to our purchase of Zevalin in December 2007. 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 financing activities totaled approximately $73.7 million in 2008, $84.7 million in 2007 and $102.7 million in 2006. Net cash provided by financing activities for the year ended December 31, 2008 was primarily due to issuances of our convertible senior notes. Proceeds from the issuance of our 9% notes were approximately $35.4 million, net of issuance costs and restricted cash placed in escrow to fund make-whole payments. We also made a deemed dividend payment of approximately $16.2 million to induce existing holders of our Series A, B, C and D convertible preferred stock to convert their shares of preferred stock into common stock in connection with this issuance. Proceeds from the issuance of our 13.5% notes and Series E preferred stock were approximately $19.6 million, net of issuance costs, restricted cash placed in escrow to fund make-whole payments and the cancellation of $5.3 million of our 9% notes. Upon cancellation of these notes, $1.4 million was released to us from the amount placed in escrow to fund make-whole payments. Proceeds from the issuance of our 15% notes were approximately $11.4 million, net of issuance costs and restricted cash placed in escrow to fund make-whole payments. We received approximately $1.8 million in proceeds from the issuance of

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our 18.33% notes, net of issuance costs, restricted cash placed in escrow to fund make-whole payments and the repurchase of approximately $17.5 million of our 13.5% notes and warrants. Upon cancellation of the 13.5% notes and warrants, $6.5 million was released to us from the amount placed in escrow to fund make-whole payments. We received proceeds of approximately $10.1 million from the issuance of our 10% notes due 2012 and 15.5% notes, net of issuance costs and restricted cash placed in escrow to fund make-whole payments. In connection with these issuances, we made another deemed dividend payment of approximately $2.0 million to induce an existing holder of our Series C preferred stock to convert its shares of preferred stock into common stock. We made a net payment of $1.1 million for the issuance of our 9.66% notes and the cancellation of $18.2 million of our 15% notes, net of issuance costs and a net payment of $6.5 million for the issuance of our 10% notes due 2011 and the cancellation of $16.3 million of our 18.33% notes, $9.0 million of our 9.66% notes and $4.8 million of our 15% notes, net of issuance costs. In connection with the cancellations of these notes, $20.8 million was released to us from amounts placed in escrow to fund make-whole payments. We also received $5.1 million in net proceeds from the sale of our common stock under equity financing agreements. Cash received from these financings were offset by the repayment of the outstanding $10.7 million principal balance on our 5.75% convertible subordinated and senior subordinated notes upon their maturity in June 2008. 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, 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 December 2007 and net proceeds of $7.0 million received from the sale of our common stock and common stock warrants in December 2007. 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.

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 pixantrone, OPAXIO and brostallicin. We received $7.5 million in gross proceeds from Spectrum in January 2009 in connection with the initial formation of RIT Oncology. In addition, we received approximately $6.5 million in gross proceeds in connection with the sale of our 50% interest in RIT Oncology to Spectrum in March 2009. As of March 9, 2009, we are engaged in the process of negotiating the transaction terms, including terms of payment, related to this sale with Spectrum and, upon finalizing the terms of the sale, we expect to receive approximately an additional $10.0 million to $11.5 million from Spectrum no later than 90 days following the closing. Our existing cash and cash equivalents, securities available-for-sale and interest receivable including proceeds from offerings to date as well as the additional funds of approximately $10.0 million to $11.5 million to be received from Spectrum is not sufficient to fund our presently anticipated operations beyond May 2009. Accordingly, we continue to seek alternatives to reduce our cost of operations, including the divestiture or closing of our facility in Bresso, Italy. However, we must raise additional funds and are currently exploring alternative sources of equity or debt financings. 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 and may be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection.

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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;
- finding appropriate partners for the development and commercialization of our products if they are approved for marketing; 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.

The following table includes information relating to our contractual obligations as of December 31, 2008 (in thousands):

Contractual Obligations	Payments Due by Period				
	Total	1 Year	2-3 Years	4-5 Years	After 5 Years
10% Convertible senior notes(1)	$ 18,000	$	$ 18,000	$	$
9% Convertible senior notes(2)	5,585			5,585	
7.5% Convertible senior notes(3)	33,458		33,458		
6.75% Convertible senior notes(4)	7,000		7,000		
5.75% Convertible senior notes(5)	23,000		23,000		
4.0% Convertible senior subordinated notes(6)	55,150		55,150		
Interest on convertible notes(7)	20,793	8,813	11,892	88	
Operating leases:					
Facilities	23,535	6,232	12,113	5,155	35
Long-term obligations(8)	1,636	401	879	356	
	$ 188,157	$ 15,446	$ 161,492	$ 11,184	$ 35

(1) The 10% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 7,299.27 shares of common stock per $1,000 principal amount of the notes, which is equivalent to a conversion price of approximately $0.137 per share.

(2) The 9% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 70.922 shares of common stock per $1,000 principal amount of the notes, which is equivalent to a conversion price of approximately $14.10 per share.

(3) The 7.5% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 11.96298 shares of common stock per $1,000 principal amount of the notes, which is equivalent to a conversion price of approximately $83.59 per share.

(4) The 6.75% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 9.50925 shares of common stock per $1,000 principal amount of the notes, which is equivalent to a conversion price of approximately $105.16 per share.

(5) The 5.75% convertible senior notes are convertible into shares of CTI common stock at a conversion rate of 33.33333 shares of common stock per $1,000 principal amount of the notes, which is equivalent to a conversion price of approximately $30.00 per share.

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(6) The 4.0% convertible senior subordinated notes are convertible into shares of CTI common stock at a conversion rate of 1.85185 shares of common stock per $1,000 principal amount of the notes, which is equivalent to a conversion price of approximately $540.00 per share.
(7) $6.6 million of interest due on convertible notes is included in our restricted cash balance and is being held in an escrow account.
(8) Long-term obligations does not include $1.1 million related to excess facilities charges and $0.9 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.

During 2008, we purchased Zevalin inventory from Biogen pursuant to a supply agreement that we entered into with Biogen on December 21, 2007 in connection with our acquisition of Zevalin. The supply agreement was amended and, along with any purchase obligations under the agreement, transferred to RIT Oncology in connection with the formation of the joint venture in December 2008.

Additional Milestone Activities

We have an amended agreement with PG-TXL Company L.P. which grants us an exclusive worldwide license for the rights to OPAXIO and to all potential uses of PG-TXL s polymer technology. Pursuant to this agreement we were required to pay a $0.5 million milestone payment that became due upon the acceptance of our MAA for review by the EMEA in March 2008. We may also be required to pay up to $14.4 million in additional milestone payments under this agreement including a $5.0 million payment upon approval of the MAA filing by the EMEA, which may 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.

We have an agreement with the Gynecologic Oncology Group, or GOG, related to the GOG0212 trial which the GOG is conducting. Under this agreement we are required to pay up to $6.1 million in additional milestone payments related to the trial. Included in this amount is a $1.0 million milestone payment that became due in the fourth quarter of 2008 based on patient enrollment but had not been paid as of March 9, 2009. We also estimate that an additional milestone payment of $1.6 million may become due in the fourth quarter of 2009 based on patient enrollment.

Under a license agreement entered into for brostallicin, we may be required to pay up to $80.0 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.

In connection with our acquisition of Systems Medicine, Inc. we may be required to pay its stockholders a maximum of $15.0 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 for brostallicin.

In connection with our acquisition of Zevalin in December 2007, we were required to pay Biogen up to $20.0 million in additional milestone payments based on positive trial outcomes and FDA approval for label expansion. In connection with the formation of the joint venture in December 2008 the milestone payments were amended and assumed by RIT Oncology. Both Spectrum and we have given Biogen a guarantee of the obligations of RIT Oncology, including a guarantee for the payment of those amounts in the event RIT Oncology defaults on its obligations; however, Spectrum has an obligation to reimburse us based upon percentage ownership in RIT Oncology for amounts paid in connection with claims by Biogen under such guarantee.

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 related to TRISENOX. However, the achievement of any such milestones is uncertain at this time.

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Under our agreement with Novartis Pharmaceutical Company Ltd., or Novartis, if Novartis elects to participate in the development and commercialization of OPAXIO or if Novartis exercises its option to develop and commercialize pixantrone and we are able to negotiate a definitive agreement with Novartis, 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.

Recently Adopted Accounting Pronouncements

On January 1, 2008, we adopted certain provisions of SFAS 157 which provides guidance on how to measure assets and liabilities that use fair value. SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles, and expands disclosures about fair value measurements. In February 2008, the FASB issued Staff Position No. 157-2 which delays the effective date of SFAS 157 one year for all nonfinancial assets and nonfinancial liabilities, except those recognized or disclosed at fair value in the financial statements on a recurring basis. The partial adoption of SFAS 157 did not have a material impact on our financial statements. We will adopt the provisions of SFAS 157 as it relates to nonfinancial assets and liabilities that are not recognized or disclosed at fair value on a recurring basis on January 1, 2009 and we are evaluating the impact, if any, the full adoption will have on our financial statements.

On January 1, 2008, we adopted SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115,* or SFAS 159. This Statement permits entities to choose, at specified election dates, to measure many financial instruments and certain other items at fair value. Subsequent unrealized gains and losses on items for which the fair value option has been elected will be reported in earnings. As we did not elect fair value treatment for qualifying instruments that existed as of January 1, 2008, the adoption of the Statement did not have an impact on our financial statements. We may elect to measure qualifying instruments at fair value in the future.

On January 1, 2008, we adopted EITF 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 provides guidance 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. Adoption of this standard did not have a material impact on our financial statements.

Recently Issued Accounting Pronouncements

On December 4, 2007, Statement of Financial Accounting Standards 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 IPRD 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 add them 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 Accounting Standards 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

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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 March 2008, Statement of Financial Accounting Standards No. 161, *Disclosures about Derivative Instruments and Hedging Activities an amendment of FASB Statement No. 133,* or SFAS 161, was issued. This standard enhances disclosures about an entity s derivative and hedging activities and thereby improves the transparency of financial reporting. The standard is effective for fiscal years beginning after November 15, 2008. This standard encourages but does not require comparative disclosures for earlier period at initial adoption. We are currently evaluating the impact this standard will have on our financial statements.

In May 2008, the FASB issued Statement of Financial Accounting Standards No. 162, *The Hierarchy of Generally Accepted Accounting Principles*, or SFAS 162. This standard identifies the source of accounting principles and the framework for selecting principles to be used in the preparation and presentation of financial statements in accordance with generally accepted accounting principles. SFAS 162 directs the hierarchy to the entity, rather than the independent auditors. This standard is effective 60 days after the Securities and Exchange Commission approves the Public Company Accounting Oversight Board amendments to remove the hierarchy of generally accepted accounting principles from the auditing standards. We do not anticipate that the adoption of this standard will have an effect on our consolidated financial statements.

In June 2008, the FASB ratified EITF Issue No. 07-5, *Determining Whether an Instrument (or an Embedded Feature) is Indexed to an Entity s Own Stock*, or EITF 07-5. EITF 07-5 provides that an entity should use a two step approach to evaluate whether an equity-linked financial instrument (or embedded feature) is indexed to its own stock, including evaluating the instrument s contingent exercise and settlement provisions. EITF 07-5 is effective for fiscal years beginning after December 15, 2008. We are currently evaluating the impact, if any, this standard will have on our financial statements.

In June 2008, the FASB issued EITF Issue No. 08-4, *Transition Guidance for Conforming Changes to Issue No. 98-5*, or EITF 08-4. The objective of EITF 08-4 is to provide transition guidance for conforming changes made to EITF Issue No. 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios* that result from EITF Issue No. 00-27, *Application of Issue No. 98-5 to Certain Convertible Instruments,* and SFAS Issue No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity.* EITF is effective for financial statements issued for fiscal years ending after December 15, 2008 and early application is permitted. We are currently evaluating the impact of EITF 08-4 on the accounting for our convertible notes and related warrant transactions.

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

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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, 2008 and 2007 was $0.6 million and $2.5 million, respectively. For each one percent change in interest rates, the change in the fair value of our securities available-for-sale would be immaterial.

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, 2008 of $0.3 million, an assumed 5%, 10% and 20% negative currency movement would result in fair value declines of less than $0.1 million.

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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, 2008, 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, 2008, 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 the commercial product Zevalin from its assessment of internal controls over financial reporting as of December 31, 2008 because the product was contributed to a Joint Venture prior to December 31, 2008. We have also excluded the commercial product Zevalin from our audit of internal control over financial reporting as of December 31, 2008.

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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 as of December 31, 2008 and 2007 and the related statements of income, stockholders equity, and cash flows for each of the years in the three-year period ended December 31, 2008, of Cell Therapeutics, Inc, and our report dated March 16, 2009 expressed an unqualified opinion.

/s/ Stonefield Josephson, Inc.

Stonefield Josephson, Inc.

Los Angeles, California

March 16, 2009

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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 the accompanying balance sheets of Cell Therapeutics, Inc. (the Company) as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders equity, and cash flows for each of the years in the three-year period ended December 31, 2008. Our audits also included the financial statement schedule listed in the index at Item 15. These financial statements and the schedule are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements 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 consolidated financial position of Cell Therapeutics, Inc. as of December 31, 2008 and 2007, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2008, in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

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 sustained loss from operations over the audit periods, incurred an accumulated deficit, and has substantial monetary liabilities in excess of monetary assets as of December 31, 2008. Given the above factors and the Company s inability to demonstrate its ability to satisfy the monetary liabilities 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), the Company s internal control over financial reporting as of December 31, 2008, 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 16, 2009 expressed an unqualified opinion.

/s/ Stonefield Josephson, Inc.

Stonefield Josephson, Inc.

Los Angeles, California

March 16, 2009

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CELL THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share amounts)

	December 31, 2008	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 10,072	$ 15,798
Restricted cash	6,640	
Securities available-for-sale	599	2,548
Interest receivable	9	46
Accounts receivable, net	982	51
Inventory		290
Note receivable from joint venture	7,500	
Prepaid expenses and other current assets	2,359	3,904
Total current assets	28,161	22,637
Property and equipment, net	4,324	6,025
Goodwill	17,064	17,064
Other intangibles, net		15,957
Investment in joint venture	5,830	
Other assets	8,864	11,830
Total assets	$ 64,243	$ 73,513
LIABILITIES AND SHAREHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 9,327	$ 6,595
Accrued expenses	29,308	26,034
Warrant liability	2,830	
Current portion of deferred revenue	80	80
Current portion of long-term obligations	757	1,020
Current portion of convertible senior subordinated notes		16,907
Current portion of convertible subordinated notes		2,910
Total current liabilities	42,302	53,546
Deferred revenue, less current portion	319	398
Long-term obligations, less current portion	2,907	9,879
10% convertible senior notes due 2011	19,784	
9% convertible senior notes	4,104	
7.5% convertible senior notes	32,601	32,220
6.75% convertible senior notes	6,926	6,922
5.75% convertible senior notes	23,808	23,287
4% convertible senior subordinated notes	55,150	55,150
Total liabilities	187,901	181,402
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; 550 and 6,850 shares issued and outstanding at December 31, 2008 and 2007, respectively	417	5,188
Series B 3% Convertible Preferred Stock, $1,000 stated value, 37,200 shares designated; 5,218 and 15,380 shares issued and outstanding at December 31, 2008 and 2007, respectively	4,031	11,881
Series C 3% Convertible Preferred Stock, $1,000 stated value, 20,250 shares designated; 4,284 and 8,284 shares issued and outstanding at December, 2008 and 2007, respectively	3,221	6,229

Series D 7% Convertible Preferred Stock, $1,000 stated value, 6,500 shares designated; 1,000 and 4,000 shares issued and outstanding at December, 2008 and 2007, respectively	734	2,938
Shareholders deficit:		
Common stock, no par value:		
Authorized shares 400,000,000		
Issued and outstanding shares 186,411,922 and 6,244,423 at December 31, 2008 and 2007, respectively	1,188,071	979,295
Accumulated other comprehensive loss	(7,812)	(4,007)
Accumulated deficit	(1,312,320)	(1,109,413)
Total shareholders deficit	(132,061)	(134,125)
Total liabilities and shareholders deficit	$ 64,243	$ 73,513

See accompanying notes.

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CELL THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

	Year Ended December 31,		
	2008	**2007**	**2006**
Revenues:			
Product sales	$ 11,352	$ 47	$
License and contract revenue	80	80	80
Total revenues	11,432	127	80
Operating expenses, net:			
Cost of product sold	3,244	49	
Research and development	51,614	72,019	61,994
Selling, general and administrative	41,607	35,517	35,894
Amortization of purchased intangibles	1,658	913	792
Gain on sale of Zevalin	(9,444)		
Acquired in-process research and development	36	24,615	
Total operating expenses, net	88,715	133,113	98,680
Loss from operations	(77,283)	(132,986)	(98,600)
Other income (expense):			
Investment and other income, net	549	2,430	2,866
Interest expense	(8,559)	(8,237)	(8,852)
Amortization of debt discount and issuance costs	(66,530)	(4,280)	(10,977)
Foreign exchange gain	3,637	4,657	1,877
Make-whole interest expense	(70,243)	(2,310)	(24,753)
Gain on derivative liabilities, net	69,739	3,672	6,024
Gain (loss) on exchange of convertible notes	(25,103)	(972)	7,978
Write-off of financing arrangement costs	(2,846)		
Equity loss from investment in joint venture	(123)		
Settlement expense	(3,393)	(160)	(11,382)
Other expense, net	(102,872)	(5,200)	(37,219)
Loss before minority interest	(180,155)	(138,186)	(135,819)
Minority interest in net loss of subsidiary	126	78	
Net loss	(180,029)	(138,108)	(135,819)
Preferred stock beneficial conversion feature	(1,067)	(9,549)	
Preferred stock dividends	(662)	(648)	
Deemed dividends on conversion of preferred stock	(21,149)		
Net loss attributable to common shareholders	$ (202,907)	$ (148,305)	$ (135,819)
Basic and diluted net loss per common share	$ (7.00)	$ (32.75)	$ (48.39)
Shares used in calculation of basic and diluted net loss per common share	28,967	4,529	2,807

See accompanying notes.

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CELL THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' DEFICIT AND OTHER COMPREHENSIVE LOSS

(In thousands)

	Common Stock		Deferred		Other	Total
	Shares	Amount	Stock-based Compensation	Accumulated Deficit	Comprehensive Income/(Loss)	Shareholders (Deficit)
Balance at December 31, 2005	1,835	721,544	(1,669)	(825,289)	(1,683)	(107,097)
Conversion of 6.75% convertible senior notes to common stock	659	69,345				69,345
Proceeds from issuance of common stock, net	578	37,764				37,764
Repurchase of common stock and warrants	(27)	(3,025)				(3,025)
Conversion of 7.5% convertible senior notes to common stock	210	17,560				17,560
Exercise of warrants to common stock	165	164				164
Proceeds from issuance of common stock to Novartis, net	217	14,837				14,837
Conversion of convertible senior subordinated notes to common stock		4				4
Proceeds from stock sold via employee stock purchase plan		17				17
Deferred compensation		(1,669)	1,669			
Equity-based compensation		4,150				4,150
Conversion of restricted share rights to common stock	2					
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	3,639	$ 860,691	$	$ (961,108)	$ (1,187)	$ (101,604)
Conversion of convertible preferred stock to common stock	924	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	183	15,294				15,294
Issuance of common stock in connection with SMI acquisition	421	19,872				19,872
Issuance of common stock in connection with exchange of 5.75% senior subordinated and subordinated notes	546	13,704				13,704
Proceeds from issuance of common stock and warrants, net	347	6,537				6,537
Equity-based compensation	185	1,588				1,588
Other	(1)	(114)				(114)
Dividends on preferred stock				(648)		(648)
Comprehensive loss:						
Foreign currency translation loss					(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	6,244	$ 979,295	$	$ (1,109,413)	$ (4,007)	$ (134,125)

See accompanying notes.

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CELL THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' DEFICIT AND OTHER COMPREHENSIVE LOSS (Continued)

(In thousands)

	Common Stock		Deferred		Other	Total
	Shares	Amount	Stock-based Compensation	Accumulated Deficit	Comprehensive Income/(Loss)	Shareholders (Deficit)
Conversion of convertible preferred stock to common stock	463	17,832				17,832
Conversion of 18.33% convertible senior notes to common stock	3,576	28,250				28,250
Conversion of 15.5% convertible senior notes to common stock	11,189	14,210				14,210
Conversion of 13.5% convertible senior notes to common stock	3,494	27,600				27,600
Conversion of 10% convertible senior notes due 2012 to common stock	7,087	9,000				9,000
Conversion of 10% convertible senior notes due 2011 to common stock	106,944	14,651				14,651
Conversion of 9.66% convertible senior notes to common stock	41,316	15,700				15,700
Conversion of 9% convertible senior notes to common stock	2,895	40,820				40,820
Conversion of 5.75% convertible senior notes to common stock	8	250				250
Issuance of common stock in connection with exchange of 5.75% convertible subordinated and senior subordinated notes	685	11,133				11,133
Issuance of common stock in connection with financing agreement	80	1,183				1,183
Issuance of common stock under the Midsummer Equity Line	1,545	4,351				4,351
Premium on 15% convertible senior notes due to exercise of Series B warrant		11,158				11,158
Issuance of warrants in connection with the 9% convertible senior notes		3,358				3,358
Issuance of warrants in connection with the 13.5%, 15% and 18.33% convertible senior notes		7,491				7,491
Repurchase of warrants in connection with the issuance of 13.5% and 18.33% notes		(2,042)				(2,042)
Equity-based compensation	878	3,995				3,995
Minority interest		(126)				(126)
Other	8	(38)				(38)
Dividends on preferred stock				(662)		(662)
Preferred stock beneficial conversion feature				(1,067)		(1,067)
Deemed dividends on conversion of preferred stock				(21,149)		(21,149)
Comprehensive loss:						