

CELL THERAPEUTICS INC  
Form 10-K  
February 16, 2011  
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UNITED STATES  
**SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, D.C. 20549

**FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2010

OR

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

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

Commission file number: 001-12465

**CELL THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

Washington  
(State or other jurisdiction of incorporation or organization)

501 Elliott Avenue West, Suite 400

Seattle, WA 98119  
(Address of principal executive offices)

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

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

98119  
(Zip Code)

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

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Title of each class  
Common Stock, no par value

Name of each exchange on which registered  
The NASDAQ Stock Market LLC

Preferred Stock Purchase Rights

None

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

None.

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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

Large accelerated filer ☐

Accelerated filer ☒

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

Smaller reporting company ☐

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

As of June 30, 2010, the aggregate market value of the registrant's common equity held by non-affiliates was \$260,667,156. Shares of common stock held by each executive officer and director and by each person known to the registrant who beneficially owns more than 5% of the outstanding shares of the registrant's 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 registrant has no non-voting common stock outstanding.

The number of outstanding shares of the registrant's common stock as of February 14, 2011 was 900,799,566.

### DOCUMENTS INCORPORATED BY REFERENCE

None.

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### **Forward Looking Statements**

This Annual Report on Form 10-K and the documents incorporated by reference may contain, in addition to historical information, forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, or 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 statements regarding future operations, plans, regulatory filings or approvals;

any statement regarding the performance, or likely performance, or outcomes or economic benefit of any licensing or other agreement, including any agreement with Novartis International Pharmaceutical Ltd., or Novartis, or its affiliates, including whether or not such partner will elect to participate, terminate or otherwise make elections under any such agreement or whether any regulatory authorizations required to enable such agreement will be obtained;

any projections of cash resources, revenues, operating expenses or other financial terms;

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

any statements concerning proposed new products or services;

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

any statements regarding compliance with the listing standards of The NASDAQ Stock Market, or NASDAQ;

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 Annual Report on Form 10-K, terms such as anticipates, believes, continue, could, estimates, expects, intends, may, potential, predicts, 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 Part I, Item 1 Business, Item 1A Risk Factors, Item 7 Management's Discussion and Analysis of Financial Condition and Results of Operations, and elsewhere in this Annual Report on Form 10-K.

We do not intend to update any of the forward-looking statements after the date of this Annual Report on 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 Annual Report on 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 U.S. Securities and Exchange Commission's, or the SEC, Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330.

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The SEC 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 SEC.

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**PART I**

**Item 1. Business Overview**

We develop, acquire and commercialize novel treatments for cancer. Our goal is to build a leading biopharmaceutical company with a diversified portfolio of proprietary oncology drugs. Our research, development, acquisition and in-licensing activities concentrate on identifying and developing new, less toxic and more effective ways to treat cancer. We are currently focusing our efforts on Pixuvri (pixantrone dimaleate), or Pixuvri, OPAXIO (paclitaxel poliglumex), or OPAXIO, brostallicin and bisplatinates.

We are developing Pixuvri, a novel anthracycline derivative, for the treatment of hematologic malignancies and solid tumors. Pixuvri was studied in our EXTEND, or PIX301, clinical trial, which is the first randomized, controlled, phase III single-agent clinical trial of Pixuvri for patients with relapsed, aggressive non-Hodgkin's lymphoma, or NHL, who received two or more prior therapies and who were sensitive to treatment with anthracyclines. We filed a Marketing Authorization Application, or MAA, for commercialization of Pixuvri in Europe, which was accepted for review by the European Medicines Agency, or the EMA, in December 2010. In the U.S., we filed an appeal in December 2010 with the U.S. Food and Drug Administration, or the FDA, Center for Drug Evaluation and Research regarding the FDA's decision in April 2010 to not approve Pixuvri for relapsed/refractory aggressive NHL. The appeal was filed under the FDA's formal dispute resolution process asking the Office of New Drugs to conclude that PIX301 demonstrated efficacy. We are awaiting a decision on the appeal. We are preparing for the initiation of an additional Pixuvri clinical trial, PIX-R TRIAL, or PIX306, to study Pixuvri in combination with rituximab in patients with relapsed, aggressive NHL that received at least one prior therapy. This study will serve as a post-approval confirmatory study or as a second registration study for approval in the U.S. depending on the outcome of our FDA appeal. Pixuvri is also being studied in a phase II clinical trial in patients with HER2-negative breast cancer being conducted by the North Central Cancer Treatment Group, or NCCTG.

Our other late-stage drug candidate, OPAXIO is being studied as a potential maintenance therapy for women with advanced stage ovarian cancer who achieve a complete remission following first-line therapy with paclitaxel and carboplatin. This phase III study, the GOG0212 trial, is under the control of the Gynecologic Oncology Group, or GOG, and is expected to enroll 1,100 patients with 765 patients enrolled as of December 31, 2010. OPAXIO is also being studied in phase II trials for the treatment of metastatic esophageal cancer and brain cancer. These trials completed in 2010 and demonstrated encouraging response to therapy.

We are also developing brostallicin, which is a new class of cancer drug—a synthetic DNA minor groove binding agent with a unique mechanism of action. Brostallicin is currently in a phase II trial for the treatment of metastatic triple-negative breast cancer. This study is being conducted by the NCCTG and is in the process of enrolling patients.

We are also in the early stages of developing a novel dinuclear-platinum complex. There are three platinates currently commercially available (cisplatin, carboplatin, and oxaliplatin), which are first-line agents in ovarian cancer, lung cancer, testicular cancer, and colorectal cancer, as well as a broad variety of other diseases. We are developing the dinuclear-platinum complex CT-47463, which has a different mechanism of action than the platinum compounds currently commercially available and is substantially more active on many preclinical models, including those with resistance to monoplatinates. We have initiated active pharmaceutical ingredient and formulation development as prerequisites to IND enabling activities for bisplatinates.

**Table of Contents****Product Candidate**

Our products are focused on addressing key unmet medical needs in the area of oncology. The following table summarizes our key clinical and preclinical programs for our lead product candidates.

<b>Product Candidate</b>	<b>Indications/Intended Use</b>	<b>Phase/Enrollment Status</b>
<b>Pixuvri</b> (pixantrone dimaleate)	Aggressive NHL, > 1 relapse, combination with rituximab (PIX306)	III/planned
	Aggressive NHL, > 3 relapses, single-agent (PIX301)	III/closed
	Aggressive NHL, front-line, CPOP-R (PIX203)	II/closed
	Metastatic HER2-negative breast cancer (NCCTG)	II/open
<b>OPAXIO</b> (paclitaxel poliglumex)	Ovarian cancer, first-line maintenance (GOG0212-Gynecologic Oncology Group)	III/open
	Metastatic brain cancer (Brown University Oncology Group)	II/closed
	Esophageal cancer (Brown University Oncology Group)	II/closed
<b>Brostallicin</b>	Metastatic triple-negative breast cancer (NCCTG)	II/open
<b>Bisplatinates</b>	Expected to be solid tumors	Preclinical

**Oncology Market Overview and Opportunity**

*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 570,000 deaths annually, or more than 1,500 people per day. The National Cancer Institute estimates that approximately 11.4 million people in the United States with a history of cancer were alive in January 2006, and it is estimated that slightly more than one in three American women, and slightly less than one in two American men will develop cancer in their lifetime. Approximately 1.5 million new cases of cancer were expected to be diagnosed in 2010 in the United States. The most commonly used methods for treating patients with cancer are surgery, radiation and chemotherapy. Patients usually receive a combination of these treatments depending upon the type and extent of their disease.

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

treatment-related toxicities,

inability to selectively target tumor tissue, and

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

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



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

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

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

## **Drug Candidates**

### **Pixuvri**

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 can also cause cardiac toxicity. As a result, chemotherapy regimens that do not include anthracyclines often are used for the second-line treatment of aggressive NHL, leukemia and breast cancer.

We are developing Pixuvri, a novel aza-anthracenedione derivative, for the treatment of non-Hodgkin's lymphoma, or NHL, and various other hematologic malignancies, and solid tumors. 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. Pixuvri 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. Pixuvri is an aza-anthracenedione that has distinct structural and physiochemical properties that make its anti-tumor unique in this class of anti-cancer agents. Similar to anthracyclines, Pixuvri inhibits topo-isomerase II, but, unlike anthracyclines, rather than intercalation with DNA, Pixuvri hydrogen bonds to and alkylates DNA, thus forming stable DNA adducts with particular specificity for CpG rich, hypermethylated sites. In addition, the structural motifs on anthracycline-like agents are responsible for the generation of oxygen free radicals and the formation of toxic drug-metal complexes have also been modified in Pixuvri to prevent iron binding and perpetuation of superoxide production, both of which are the putative mechanism of anthracycline induced acute cardiotoxicity. These novel pharmacologic differences may allow re-introduction of anthracycline-like potency in the treatment of patients who are otherwise at their lifetime recommended doxorubicin exposure.

### *Pixuvri for relapsed aggressive NHL*

NHL is caused by the abnormal proliferation of lymphocytes, which are cells key to the functioning of the immune system. NHL usually originates in lymph nodes and spreads through the lymphatic system. NHL can be

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broadly classified into two main forms aggressive NHL is a rapidly growing form of the disease that moves into advanced stages much faster than indolent NHL, which progresses more slowly. According to the National Cancer Institute's SEER database, on January 1, 2006, there were approximately 419,533 people in the U.S. living with a history of NHL. The American Cancer Society estimated that 65,540 people would be diagnosed with NHL in 2010 with 20,210 estimated to die from this disease. It is the fifth most common cancer in the United States.

There are many subtypes of NHL, but aggressive NHL is one of the more common types of NHL and accounts for about 60% of all NHL cases. Initial therapy for aggressive NHL with anthracycline-based combination therapy cures up to 50% of patients. Of the remaining patients, approximately only half will respond to second-line treatment, but few are cured and there is no effective therapy for patients relapsing after or refractory to second-line treatment. There are no drugs approved in the United States for patients with aggressive NHL that relapse after, or are refractory to, second-line treatment.

Pixuvri was studied in our EXTEND, or PIX301, clinical trial, which was a phase III single-agent trial of Pixuvri for patients with relapsed, refractory aggressive NHL who received two or more prior therapies and who were sensitive to treatment with anthracyclines. In November 2008, we announced that this trial achieved the primary efficacy endpoint. Based on the outcome of the EXTEND trial and on the basis of pre-New Drug Application, or NDA, communication we received from the Food and Drug Administration, or FDA, relating to this phase III trial, we began a rolling NDA submission to the FDA in April 2009. We completed the submission in June 2009.

The FDA completed its inspection of the facilities at NerPharMa DS, S.r.l. and NerPharMa, S.r.l. (two independent pharmaceutical manufacturing companies belonging to Nerviano Medical Sciences S.r.l., in Nerviano, Italy). The FDA found both manufacturing sites in compliance and acceptable for continued manufacturing of the drug in early March 2010. NerPharMa, S.r.l. agreed to manufacture our drug product, Pixuvri, which will be used for clinical supplies.

On March 22, 2010, the FDA's Oncologic Drugs Advisory Committee, or ODAC, panel voted unanimously that the clinical trial data was not adequate to support approval of Pixuvri for this patient population. In early April 2010, we received a Complete Response Letter from the FDA regarding our NDA for Pixuvri recommending that we design and conduct an additional trial to demonstrate the safety and efficacy of Pixuvri. We met with the FDA in August 2010 at an end of review meeting at which time the FDA informed us that the Pixuvri IND and NDA applications were being transferred to the newly-formed Division of Hematology Drug Products. We are preparing for the initiation of an additional Pixuvri clinical trial, PIX306, that would serve as either a post-approval confirmatory study, if Pixuvri were to be approved on the basis of the current NDA, or as a registration study for approval in the U.S. On August 3, 2010, we filed for a Special Protocol Assessment, or SPA, with the FDA for the design of our additional clinical trial of Pixuvri. In September 2010, we submitted a SPA package with expanded information to the newly-formed Division of Hematology Drug Products. Additional information relating to the SPA was submitted in December 2010 and at this time discussion of the SPA with the FDA is ongoing.

We believe the results of the EXTEND trial showed that patients randomized to treatment with Pixuvri achieved a significantly higher rate of confirmed and unconfirmed complete response compared to patients treated with standard chemotherapy, had a significantly increased overall response rate and experienced a statistically significant improvement in median progression free survival. Pixuvri was well tolerated when administered at the proposed dose and schedule in the EXTEND clinical trial in heavily pre-treated patients. The most common (incidence greater than or equal to 10%) grade 3/4 adverse events reported for Pixuvri-treated subjects across studies were neutropenia and leukopenia. Use of growth factor support was minimal. Other common adverse events (any grade) included infection, anemia, leukopenia, thrombocytopenia, asthenia, pyrexia and cough. Overall, the incidence of grade 3 or greater cardiac adverse events was 7% (five patients) on the Pixuvri arm and 2% (one patient) on the comparator arm. There were an equal number of deaths due to an adverse event in both the Pixuvri and comparator arm.

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We also conducted the RAPID, or PIX203, phase II clinical trial study (CHOP-R vs. CPOP-R) in which Pixuvri is substituted for doxorubicin in the CPOP-R regimen compared to the standard CHOP-R regimen in patients with aggressive NHL. The study enrolled 124 patients, 61 on the CPOP-R arm and 63 on the CHOP-R arm. An interim analysis of the RAPID trial, reported in July 2007, showed that at that time, a majority of patients on both arms of the study achieved a major objective anti-tumor response (complete response or partial response). Preliminary results were presented in the fourth quarter of 2010 and we expect additional study data to be presented in 2011. Three patients on the CPOP-R arm died on study compared to none of the patients on the CHOP-R arm. These events were observed in patients age 79 years old or older with higher risk disease. The median number of cycles for the CPOP-R arm was eight compared to six for the CHOP-R arm. Pixuvri patients had fewer severe cardiac events including declines in left ventricular ejection fraction of 20% (1 versus 8), cases of congestive heart failure (0 versus 4) and on study elevations in levels of Troponin T, a marker of cardiac damage. Other important treatment related side effects such as bone marrow suppression and infections were essentially equivalent between the study arms.

In July 2009, we were notified by the EMA that Pixuvri is eligible to be submitted for a MAA, through the EMA's centralized procedure. The centralized review process provides for a single coordinated review for approval of pharmaceutical products that is conducted by the EMA on behalf of all European Union, or EU, member states. The EMA also designated Pixuvri as a New Active Substance, or NAS; if approved by the EMA, compounds designated as an NAS are eligible to receive a 10-year market exclusivity period in EU member states. In September 2009, we applied to the EMA for orphan drug designation for Pixuvri, which was granted in December 2009. In September 2009, we also submitted a Pediatric Investigation Plan, or PIP, to the EMA as part of the required filing process for approval of Pixuvri for treating relapsed, refractory aggressive NHL in Europe. In April 2010, the EMA recommended that we submit an updated PIP for Pixuvri following discussions with us about the preclinical and clinical Pixuvri data, including EXTEND, and the desire to explore the potential benefits Pixuvri may offer to children with lymphoid malignancies and solid tumors. We submitted an expanded PIP to the Pediatric Committee of the EMA, or PDCO, in July 2010. The expanded PIP was accepted for review by the PDCO in August 2010. On October 19, 2010, we announced that the PDCO had adopted an opinion agreeing to our PIP. The PDCO also recommended deferral of the initiation of the clinical studies until after Pixuvri receives EMA approval. In November 2010, the MAA seeking approval for Pixuvri for the treatment of adult patients with multiple relapsed or refractory aggressive NHL was validated and accepted for review by the EMA. Since Pixuvri was initially granted orphan drug status by the EMA for the treatment of diffuse large B-cell lymphoma (DLBCL), we agreed to withdraw the orphan designation from the EU register in November 2010 based on the expansion of the MAA to the broader aggressive NHL population.

### *Pixuvri for metastatic breast cancer*

Pixuvri is also being studied in patients with HER2-negative metastatic breast cancer who have tumor progression after at least two, but not more than three, prior chemotherapy regimens. In the second quarter of 2010, the NCCTG opened for enrollment of this phase II study.

## **OPAXIO**

OPAXIO is our novel biologically enhanced chemotherapeutic agent that links paclitaxel to a biodegradable polyglutamate polymer, resulting in a new chemical entity. We are currently focusing our development of OPAXIO on ovarian, brain and esophageal cancer.

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

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cathepsin B) inside the lysosome of the tumor cell. This metabolism releases the active chemotherapy agent, which is 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. Treatment does not affect the patient's ability to 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 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, potentially 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.

### *OPAXIO for ovarian cancer*

The ACS estimated that approximately 21,180 new cases of ovarian cancer would be diagnosed in the United States in 2010. 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 GOG to perform a phase III trial of OPAXIO as maintenance therapy in patients with ovarian cancer. The GOG initiated the phase III study in March 2005. This study, the GOG0212 trial, is expected to enroll 1,100 patients with 765 patients enrolled as of December 31, 2010. The GOG Data Monitoring Committee plans to conduct an interim analysis of overall survival, which could be conducted as early as 2011. If successful, we could utilize those results to form the basis of an NDA for OPAXIO.

### *OPAXIO for brain cancer*

In November 2010, results were presented by the Brown University Oncology group from a phase II trial of OPAXIO combined with temozolomide, or TMZ, and radiotherapy in patients with newly-diagnosed, high-grade gliomas, a type of brain cancer. The trial demonstrated a high rate of complete and partial responses and an encouragingly high rate of six month progression-free survival. Based on these results, we plan to work with the Brown University Oncology Group to conduct an additional study in a subset of patients with high-grade lymphoma with specific genetic markers for which we believe OPAXIO and radiotherapy could be more beneficial than standard treatment of TMZ and radiotherapy.

### *OPAXIO for esophageal cancer*

In June 2009, we announced that, in a study released from Brown University at the 2009 American Society for Clinical Oncology Annual Meeting, patients with cancer of the lower esophagus had evidence of a high pathological complete response rate when given OPAXIO in addition to cisplatin and full-course radiotherapy. In this phase II clinical trial study, data suggests that OPAXIO may provide enhanced radiation sensitization as

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compared to standard therapy. We plan to assess the viability of progressing OPAXIO to a phase III study for this indication.

### *OPAXIO for non-small cell lung cancer*

In March 2008, we submitted an MAA to the EMA for first-line treatment of patients with advanced non-small cell lung cancer, or NSCLC, who are poor performance status, or PS2, based on a non-inferior survival and improved side effect profile which we believe was demonstrated in our previous clinical trials. The application was based on a positive opinion we received from the EMA's Scientific Advice Working Party, or SAWP; the EMA agreed that switching the primary endpoint from superiority to non-inferiority is feasible if the retrospective justification provided in the marketing application is adequate. In September 2009, we notified the EMA of our decision to withdraw the MAA and we refocused our resources on the development of OPAXIO for its potential superiority indication in maintenance therapy for ovarian cancer and as a radiation sensitizer in the treatment of esophageal cancer.

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.

We continue to monitor the use of OPAXIO in 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 the 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 September 2007, we initiated our PGT307 trial, which focuses 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. Due to limited resources, during the second quarter of 2010, we ceased enrollment in the PGT307 trial and a clinical trial report will be prepared.

### **Brostallicin**

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. Brostallicin is 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. We use a genomic-based platform to guide the development of brostallicin.

In the second quarter of 2010, the NCCTG opened for enrollment a phase II study of brostallicin in combination with cisplatin in patients with metastatic triple-negative breast cancer, or mTNBC. mTNBC is defined by tumors lacking expression of estrogen, progesterone receptors and without over-expression of HER2. Women with mTNBC have very limited effective treatments and based on the novel mechanism of action of brostallicin and the recognized activity of cisplatin in this disease, the combination of the two agents will be explored by the NCCTG. In addition to standard clinical efficacy measures, biological endpoints will also be evaluated to assist in understanding the specific activity of brostallicin in this disease.

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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 clinical trial study that was 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 conducted final data analysis in 2009. The data was reported at the American Society of Clinical Oncology Annual Meeting in June 2010. The EORTC trial demonstrated, in this hard to treat patient group, a modest level of clinical activity with an acceptable level of toxicity. No further development is planned in this indication.

## **Research and Preclinical Development**

Platinates are an important class of chemotherapy agents used to treat a wide variety of cancers. There are three platinates currently commercially available (cisplatin, carboplatin, and oxaliplatin), which are first-line agents in ovarian cancer, lung cancer, testicular cancer, and colorectal cancer, as well as a broad variety of other diseases. We are developing the dinuclear-platinum complex CT-47463. CT-47463 has a different mechanism of action than the commercially available platinum compounds and is substantially more active on many preclinical models including those with resistance to monoplatinates. We have initiated active pharmaceutical ingredient and formulation development as prerequisites to IND enabling activities for bisplatinates.

## **Zevalin (Ibritumomab Tiuxetan)**

In March 2009, we divested our interest in the radiopharmaceutical product Zevalin® (ibritumomab tiuxetan), or Zevalin, by selling our 50% interest in the Zevalin joint venture, RIT Oncology, LLC, or RIT Oncology, to Spectrum Pharmaceutical, Inc., or Spectrum, for \$16.5 million. Previously, in December 2008, we closed our transaction with Spectrum to form RIT Oncology, to commercialize and develop Zevalin in the United States. We originally acquired the U.S. rights to develop, market and sell Zevalin from Biogen Idec Inc., or Biogen, in December 2007. We received an initial payment of \$6.5 million in gross proceeds from Spectrum in March 2009, \$0.8 million of which was used to pay a consent fee to Biogen, and an additional \$6.5 million in gross proceeds in April 2009. The remaining \$3.5 million we expected to receive from Spectrum, subject to certain adjustments, was disputed and was ultimately released to Spectrum based on the outcome of an arbitration hearing held in May 2009. In addition, as part of the divestiture transaction, we agreed to forego the right to receive up to \$15 million in product sales milestone payments in connection with the original transaction establishing the joint venture.

## **Research and Development Costs**

Research and development is essential to our business. We spent \$27.0 million, \$30.2 million and \$51.6 million in 2010, 2009, and 2008, respectively, on company-sponsored research and development activities. Because of the risks and uncertainties associated with the development of a product candidate, we cannot accurately predict when or whether we will successfully complete the development of our product candidates or the ultimate product development cost. Specific comments for individual product candidates are below.

*Pixuvri.* Pixuvri is an aza-anthracenedione that has distinct structural and physiochemical properties that make its anti-tumor unique in this class of agents. The novel pharmacologic differences between Pixuvri and the other agents in the class, may allow re-introduction of anthracycline-like potency in the treatment of patients who are otherwise at their lifetime recommended doxorubicin exposure. We are unable to provide the nature, timing, and estimated costs of the efforts necessary to complete the development of Pixuvri because, among other reasons, we cannot predict with any certainty the pace of enrollment of our clinical trials and our additional clinical trial for Pixuvri has not commenced. Even after a clinical trial is enrolled, preclinical and clinical data can be interpreted in different ways, which could delay, limit or preclude regulatory approval and advancement of this compound through the development process. For these reasons, among others, we cannot estimate the date on which clinical development of Pixuvri will be completed or when we will be able to begin commercializing Pixuvri to generate material net cash inflows.

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**OPAXIO.** OPAXIO (paclitaxel polyglumex, 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 currently focusing our development of OPAXIO on ovarian and esophageal cancer. We are unable to provide the nature, timing, and estimated costs of the efforts necessary to complete the development of OPAXIO because, among other reasons, a third party is conducting the key clinical trial of OPAXIO and even after a clinical trial has been enrolled, preclinical and clinical data can be interpreted in different ways, which could delay, limit or preclude regulatory approval and advancement of this compound through the development process. For these reasons, among others, we cannot estimate the date on which clinical development of OPAXIO will be completed or when we will be able to begin commercializing OPAXIO to generate material net cash inflows.

**Brostallicin.** Brostallicin is a synthetic DNA minor groove binding agent that has demonstrated anti-tumor activity. The NCCTG is conducting a phase II study of brostallicin in combination with cisplatin in patients with metastatic triple-negative breast cancer, or mTNBC. We are unable to provide the nature, timing, and estimated costs of the efforts necessary to complete the development of brostallicin because, among other reasons, a third party is conducting the clinical trial of brostallicin for which enrollment is subject to their control and even after a clinical trial has been enrolled, preclinical and clinical data can be interpreted in different ways, which could delay, limit or preclude regulatory approval and advancement of this compound through the development process. For these reasons, among others, we cannot estimate the date on which clinical development of brostallicin will be completed or when we will be able to begin commercializing brostallicin to generate material net cash inflows.

**Bisplatinates (CT-47463).** Cisplatin is a platinum-based chemotherapy drug used to treat a wide variety of cancers. We are developing new analogues of CT-47463, a dinuclear-platinum complex. CT-47463 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. We are unable to provide the nature, timing, and estimated costs of the efforts necessary to complete the development of CT-47463 because, among other reasons, a third party is conducting the preclinical trial for CT-47463, no clinical trial design for CT-47463 has been developed yet and even after a clinical trial is enrolled, preclinical and clinical data can be interpreted in different ways, which could delay, limit or preclude regulatory approval and advancement of this compound through the development process. For these reasons, among others, we cannot estimate the date on which clinical development of CT-47463 will be completed or when we will be able to begin commercializing CT-47463 to generate material net cash inflows.

The risks and uncertainties associated with completing development on schedule and the consequences to operations, financial position and liquidity if the project is not completed timely are discussed in more detail in the following risk factors, which begin on page 17 of this Form 10-K: *Our financial condition may be adversely affected if third parties default in the performance of contractual obligations. ; We may be delayed, limited or precluded from obtaining regulatory approval of OPAXIO as a maintenance therapy for advanced stage ovarian cancer. ; We are subject to extensive government regulation. ; Even if our drug candidates are successful in clinical trials, we may not be able to successfully commercialize them. ; If we do not successfully develop our product candidates into marketable products, we may be unable to generate significant revenue or become profitable. ; and We may take longer to complete our clinical trials than we expect, or we may not be able to complete them at all.*

## **License Agreements and Additional Milestone Activities**

### **PG-TXL**

We have an agreement with PG-TXL Company, L.P., or PG-TXL, which grants us an exclusive worldwide license for the rights to OPAXIO and to all potential uses of PG-TXL's polymer technology, or the PG-TXL

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Agreement. Pursuant to the PG-TXL Agreement, we acquired the rights to research, develop, manufacture, market and sell anti-cancer drugs developed using this polymer technology. Pursuant to the PG-TXL Agreement, we are obligated to make payments to PG-TXL upon the achievement of certain development and regulatory milestones of up to \$14.4 million. The timing of the remaining milestone payments under the PG-TXL Agreement is based on trial commencements and completions for compounds protected by PG-TXL license rights, and regulatory and marketing approval of those compounds by the FDA and the EMA. Additionally, we are required to make royalty payments to PG-TXL based on net sales. Our royalty payments range from low-single digits to mid-single digits as a percentage of net sales. Unless otherwise terminated, the term of the PG-TXL Agreement continues until no royalties are payable to PG-TXL. We may terminate the PG-TXL Agreement (i) upon advance written notice to PG-TXL in the event issues regarding the safety of the products licensed pursuant to the PG-TXL Agreement arise during development or clinical data obtained reveal a materially adverse tolerability profile for the licensed product in humans or (ii) for any reason upon advance written notice. In addition, either party may terminate the PG-TXL Agreement (a) upon advance written notice in the event certain license fee payments are not made; (b) in the event of an uncured material breach of the respective material obligations and conditions of the PG-TXL Agreement; or (c) in the event of liquidation or bankruptcy of a party.

### *Gynecologic Oncology Group*

We have an agreement with the Gynecologic Oncology Group, or the GOG, related to the GOG0212 trial, which the GOG is conducting. We recorded a \$1.6 million payment due to the GOG, based on the 650 patient enrollment milestone achieved in the first quarter of 2010, of which \$1.1 million remained outstanding and is included in *accounts payable* as of December 31, 2010. Subsequent to period end, we paid the remaining \$1.1 million due to the GOG in January 2011. Under this agreement we are required to pay up to \$3.5 million in additional milestone payments related to the trial of which \$1.7 million will become due when 800 patients are enrolled and \$0.5 million will become due upon receipt of the interim analysis and data transfer, both of which may occur in 2011.

### *Nerviano Medical Sciences*

Under a license agreement entered into with Nerviano Medical Sciences, S.r.l. 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., or Cephalon, in June 2005, we may receive up to \$100.0 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*

In September 2006, we entered into an exclusive worldwide licensing agreement with Novartis, or the Novartis Agreement, for the development and commercialization of OPAXIO. Total product and registration milestones to us for OPAXIO under the Novartis Agreement could reach up to \$270 million. Royalty payments to us for OPAXIO are based on worldwide OPAXIO net sales volumes and range from the low-twenties to mid-twenties as a percentage of net sales.

Pursuant to the Novartis Agreement, we are responsible for the development costs of OPAXIO and have control over development of OPAXIO unless and until Novartis exercises its development rights, or the Development Rights. In the event that Novartis exercises its Development Rights, then from and after the date of



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such exercise, or the Novartis Development Commencement Date, Novartis will be solely responsible for the development of OPAXIO. Prior to the Novartis Development Commencement Date, we are solely responsible for all costs associated with the development of OPAXIO, but will be reimbursed by Novartis for certain costs after the Novartis Development Commencement Date. After the Novartis Development Commencement Date, Novartis will be responsible for costs associated with the development of OPAXIO, subject to certain limitations; however, we are also responsible for reimbursing Novartis for certain costs pursuant to the Novartis Agreement.

The Novartis Agreement also provides Novartis with an option to develop and commercialize Pixuvri based on agreed terms. If Novartis exercises its option on Pixuvri under certain conditions and we are able to negotiate and sign a definitive license agreement with Novartis, Novartis would be required to pay us a \$7.5 million license fee, up to \$104 million in registration and sales related milestones and a royalty on Pixuvri worldwide net sales. Royalty payments to us for Pixuvri are based on worldwide Pixuvri net sales volumes and range from the low-double digits to the low-thirties as a percentage of net sales.

Royalties for OPAXIO are based on worldwide sales volumes of OPAXIO and royalties for Pixuvri are based on sales volumes in the U.S. and sales volumes in other countries.

Royalties for OPAXIO and Pixuvri are payable from the first commercial sale of a product until the later of the expiration of the last to expire valid claim of the licensor or the occurrence of other certain events, or the Royalty Term. Unless otherwise terminated, the term of the Novartis Agreement continues on a product-by-product and country-by-country basis until the expiration of the last-to-expire Royalty Term with respect to a product in such certain country. In the event Novartis does not exercise its Development Rights until the earlier to occur of (i) the expiration of 30 days following receipt by Novartis of the product approval information package pursuant to the Novartis Agreement or (ii) Novartis determination, in its sole discretion, to terminate the Development Rights exercise period by written notice to us (events (i) and (ii) collectively being referred to as the Development Rights Exercise Period), the Novartis Agreement will automatically terminate upon expiration of the Development Rights Exercise Period. In the event of an uncured material breach of the Novartis Agreement, the non-breaching party may terminate the Novartis Agreement. Either party may terminate the Novartis Agreement without notice upon the bankruptcy of the other party. In addition, Novartis may terminate the Novartis Agreement without cause at any time (a) in its entirety within 30 days written notice prior to the exercise by Novartis of its Development Rights or (b) on a product-by-product or country-by-country basis on 180 days written notice after the exercise by Novartis of its Development Rights. If we experience a change of control that involves certain major pharmaceutical companies, Novartis may terminate the Novartis Agreement by written notice within a certain period of time to us or our successor entity.

As of December 31, 2010, we have not received any milestone payments and we will not receive any milestone payments unless Novartis elects to exercise its option to participate in the development and commercialization of Pixuvri or exercise its Development Rights for OPAXIO.

## **Patents and Proprietary Rights**

We dedicate significant resources to protecting our intellectual property, which is important to our business. We have filed numerous patent applications in the U.S. and various other countries seeking protection of inventions originating from our research and development and we have also obtained rights to various patents and patent applications under licenses with third parties. Patents have been issued on many of these applications. We have issued patents pending or issued in the U.S. and foreign countries directed to OPAXIO, Pixuvri, brostallicin and other product candidates. Patents for the individual products extend for varying periods according to the date of the patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. The OPAXIO-directed patents will expire on various dates ranging from 2017 through 2018. The Pixuvri-directed patents will expire in 2014. We have licensed intellectual property rights for brostallicin. The brostallicin-directed patents will expire on various dates ranging from 2017 to 2023. The patent expiration ranges given above are only for U.S. issued patents, and do not account for potential extensions that

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may be available in certain countries. For example, certain Pixuvri-directed patents may be subject to possible patent-term extensions that could provide extensions through 2019 in the U.S. and 2021 in Europe.

### **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 with the goal 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 Pixuvri, OPAXIO and brostallicin drug supply for clinical studies. We will be dependent upon these third-party vendors to supply us 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.

We have a manufacturing supply agreement, or the NerPharMa Agreement, with NerPharMa, S.r.l., or NerPharMa (a pharmaceutical manufacturing company belonging to Nerviano Medical Sciences, S.r.l., in Nerviano, Italy), for our drug candidate Pixuvri. The NerPharMa Agreement is a five year non-exclusive agreement and provides for both the commercial and clinical supply of Pixuvri. The NerPharMa Agreement commenced on July 9, 2010 and expires on the fifth anniversary date of the first government approval obtained either in the United States or Europe. The NerPharMa Agreement may be terminated for an uncured material breach, insolvency or the filing of bankruptcy, or by mutual agreement. We may also terminate the NerPharMa Agreement (i) upon prior written notice in the event of failure of three or more of seven consecutive lots of product or (ii) in the event NerPharMa is acquired or a substantial portion of NerPharMa's assets related to the NerPharMa Agreement are sold to another entity.

We have a purchase agreement with Natural Pharmaceuticals, Inc., or NPI, which was assumed by Phyton Biotech, LLC, or Phyton, upon their purchase of NPI in 2009. Under this purchase agreement, Phyton currently must supply us with either 3.5 kilograms of paclitaxel or the cash equivalent of \$0.5 million.

### **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 Company, Sanofi-Aventis, Wyeth, Roche Group, Genentech, Inc., Astellas Pharma, Eli Lilly and Company, Abraxis, Neopharm Inc., Telik, Inc., TEVA Pharmaceuticals Industries Ltd. 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 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

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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; and

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 a special protocol assessment, or SPA. These agreements may not be changed after the clinical studies begin, except in limited circumstances. The existence of a 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, the review time will be reduced or the product will be approved.

Before approving a 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, a complete response letter. A complete response 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 EU 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 federal, state and local 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, 2010, we employed 87 individuals in the United States and one in Europe. Our U.S. employees do not have a collective bargaining agreement. Our European employee is subject to a collective bargaining agreement. We believe our relations with our employees to be good.

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

### **Corporate Information**

We were incorporated in Washington in 1991. Our principal executive offices are located at 501 Elliott Avenue West, Suite 400, Seattle, Washington 98119. Our telephone number is (206) 282-7100. CTI and OPAXIO are our proprietary marks. All other product names, trademarks and trade names referred to in this prospectus are the property of their respective owners.

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 Exchange Act, and amendments to such filings, as soon as reasonably practicable after each is electronically filed with, or furnished to, the SEC.

### **Item 1a. Risk Factors**

*This Annual Report on Form 10-K contains forward-looking statements that involve risks and uncertainties. The occurrence of any of the following risks described below and elsewhere in this document, including the risk that our actual results may differ materially from those anticipated in these forward-looking statements, could materially adversely affect our business, financial condition, operating results or prospects and the trading price of our securities. Additional risks and uncertainties that we do not presently know or that we currently deem immaterial may also impair our business, financial condition, operating results and prospects and the trading price of our securities.*

### **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 additional 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, 2010, we had cash and cash equivalents of \$22.6 million. As of December 31, 2010, our total current liabilities were \$41.1 million, including \$10.3 million and \$10.9 million outstanding principal balance related to our 7.5% and 5.75% convertible senior notes, respectively, which are due within the next 12 months. We repaid the outstanding principal amount and accrued unpaid interest on our 4% convertible senior subordinated notes, or 4% Notes, in July 2010. We do not expect that our existing cash and cash equivalents, as well as proceeds received from our offerings to date, will provide sufficient working capital to fund our presently anticipated operations through the second quarter of 2011.

Raising additional capital will likely require that we issue additional shares of our common stock. Because of the number of shares reserved for issuance under various convertible securities, derivative securities and otherwise, we have a limited number of authorized shares of common stock available for issuance and it is difficult for us to obtain an increase in our authorized shares. If we do not have enough shares authorized to effect an equity financing, our ability to raise capital through equity financings may be adversely affected.

To the extent that we raise additional capital through the sale of equity securities, or securities convertible into our equity securities, our shareholders may experience dilution of their proportionate ownership of us. We

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have held preliminary discussions with several investment funds regarding a potential investment in our company, but we have no current agreements or commitments with respect to any investment by these investment funds or any other investors. There can be no assurance that our discussions with these investment funds or any other investors will result in an investment in our company or that we will have sufficient earnings, access to liquidity or cash flow in the future to meet our operating expenses and other obligations, including our debt service obligations.

We may not be able to raise such capital or, if we can, it may not be on favorable terms. We may seek to raise additional capital through public or private equity financings, partnerships, joint ventures, dispositions of assets, debt financings or restructurings, bank borrowings or other sources. To obtain additional funding, we may need to enter into arrangements that require us to relinquish rights to certain technologies, drug candidates, products and/or potential markets. In addition, some financing alternatives may require us to meet additional regulatory requirements in Italy and the United States and we may be subject to certain contractual limitations, which may increase our costs and adversely affect our ability to obtain additional funding. 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 Pixuvri, OPAXIO, brostallicin, and bisplatinates and may be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection. Bankruptcy may result in the termination of agreements pursuant to which we license certain intellectual property rights, including the rights to Pixuvri, OPAXIO and brostallicin.

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

We need substantial additional capital to fund our current operations. If we are unable to secure additional financing on acceptable terms in the near future, we will need to implement 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, could 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, seek bankruptcy protection, or otherwise modify our business strategy, which could materially harm our future business prospects.

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

We were incorporated in 1991 and have incurred a net operating loss every year since our formation. As of December 31, 2010, we had an accumulated deficit of \$1.6 billion. We are pursuing regulatory approval for Pixuvri, OPAXIO and brostallicin. We will need to conduct research, development, testing and regulatory compliance activities and undertake manufacturing and drug supply activities the costs of which, together with projected general and administrative expenses, may 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. Unless we raise substantial additional capital and reduce our operating expenses, we may not be able to pay all of our operating expenses or repay our debt or the interest on our debt, liquidated damages or other payments that may become due with respect to our debt. In the event we are unable to reduce our expenses and/or repay our debt or the interest on our debt, we may be required to limit or cease our operations, pursue a plan to sell our operating assets, seek bankruptcy protection, or otherwise modify our business strategy, which could materially harm our future business prospects. Bankruptcy may result in the termination of agreements pursuant to which we license certain intellectual property rights, including the rights to Pixuvri, OPAXIO and brostallicin.



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*We may be unable to use our net operating losses.*

We have substantial tax loss carryforwards for U.S. federal income tax purposes. As a result of prior changes in the stock ownership of the Company, our ability to use such carryforwards to offset future income or tax liability is limited under section 382 of the Internal Revenue Code of 1986, as amended. Moreover, future changes in the ownership of our stock, including those resulting from the issuance of shares of our common stock upon exercise of outstanding warrants, may further limit our ability to use our net operating losses.

*We have received audit reports with a going concern disclosure on our consolidated financial statements.*

As we may 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, 2010, 2009 and 2008 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.

*If we make any acquisitions, we will incur a variety of costs and may never realize the anticipated benefits.*

If appropriate opportunities become available, we may attempt to acquire businesses and assets that we believe are a strategic fit with our business. We currently have no agreements to consummate any material acquisitions. If we pursue any such transaction, the process of negotiating the acquisition and integrating an acquired business and assets may result in operating difficulties and expenditures and may require significant management attention that would otherwise be available for ongoing development of our business, whether or not any such transaction is ever consummated. Moreover, we may never realize the anticipated benefits of any acquisition. Future acquisitions could result in potentially dilutive issuances of equity securities, the incurrence of debt, contingent liabilities and/or amortization expenses related to goodwill and other intangible assets, which could harm our business, financial condition, operating results and prospects and the trading price of our securities.

*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 ongoing 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 are required to comply with the regulatory structure of Italy because our stock is traded on the Mercato Telematico Azionario stock market in Italy, or the MTA, which could result in administrative and other challenges and additional expenses.*

Our common stock is traded on the MTA and we are required to also comply with the rules and regulations of the Commissione Nazionale per la Società e la Borsa, or CONSOB, which is the public authority responsible for regulating the Italian securities market, and the Borsa Italiana, which ensures the development of the managed market in Italy. Collectively, these entities regulate companies listed on Italy's public markets. Conducting our operations in a manner that complies with all of the 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 of

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the 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 that exceeds, in any twelve-month period, 10% of the number of shares of our common stock outstanding at the beginning of that period (except for certain applicable exceptions).

If we are unable to maintain a listing prospectus to cover general financing efforts under Italian law, we may be required to raise money using alternative forms of securities. For example, we may need to use convertible preferred stock and convertible debt since the common stock resulting from the conversion of such securities, subject to the provisions of European Directive No. 71/2003 and according to the interpretations of the Committee of European Securities Regulators (CESR), is not subject to the 10% limitation imposed by EU and Italian law.

Moreover, on December 23, 2008, CONSOB sent a notice to us requesting that we issue (i) immediately, a press release providing, among other things, information about our debt restructuring plan, the current state of compliance with the relevant covenants regulating our debt and the equity line of credit agreement we entered into with Midsummer Investment Ltd. on July 29, 2008, and (ii) by the end of each month and starting from the month of December 2008, a press release providing certain information relating to our management and financial situation, updated to the previous month, or the Monthly CONSOB Press Release. On July 31, 2009, CONSOB sent us a notice asserting three violations of the provisions of Section 114, paragraph 5 of the Italian Legislative Decree no. 58/98, as follows: (a) the non-disclosure without delay of the press release described under point (i) above and the subsequent incomplete disclosure of the relevant information through press releases dated January 9, 2009 and January 13, 2009; (b) the non-disclosure of the Monthly CONSOB Press Release in December 2008; and (c) the incomplete disclosure of the Monthly CONSOB Press Release in January 2009. The sanctions established by Section 193, paragraph 1 of the Italian Legislative Decree no. 58/98 for such violations are pecuniary administrative sanctions amounting to between 5,000 and 500,000, or approximately \$6,700 to \$670,000 as of December 31, 2010, applicable to each one of the three asserted violations. According to the applicable Italian legal provisions, CONSOB may impose such administrative sanctions by means of a decree stating the grounds of its decision only after evaluating our possible defenses that were submitted to CONSOB on August 28, 2009 (within 30 days of July 31, 2009, the notification date of the relevant charges, according to the applicable Italian rules). On May 5, 2010, CONSOB (1) notified us that it had begun the preliminary investigation for its decision on these administrative proceedings and (2) provided us with a preliminary investigation report in response to our defenses submitted on August 28, 2009. On June 4, 2010 (within 30 days of May 5, 2010, the notification date of the beginning of the aforesaid preliminary investigation, according to the applicable Italian rules), we submitted further defenses that CONSOB will have to evaluate before imposing any possible administrative sanctions. On January 21, 2011, CONSOB notified us of a resolution confirming the occurrence of the three asserted violations and applying a fine for each of them in the following amounts: 20,000 for sanction (a) above; 50,000 for sanction (b) above; and 30,000 for sanction (c) above, for an aggregate fine of 100,000, or approximately \$136,000 as of January 21, 2011, for these sanctions. We anticipate paying the fine according to the terms and conditions established by the applicable Italian rules and prior to the deadline of March 22, 2011 (i.e., the deadline after which default interest and/or increases in the amount of the fines will be charged).

Separately, on December 10, 2009, CONSOB sent us a notice claiming two violations of the provisions of Section 114, paragraph 1 of the Italian Legislative Decree no. 58/98 due to the asserted late disclosure of certain information then reported, at CONSOB's request, in press releases disseminated on December 19, 2008 and March 23, 2009. Such information concerned, respectively: (i) the conversion by BAM Opportunity Fund LP of 9.66% notes into shares of common stock that occurred between October 24, 2008 and November 19, 2008; and (ii) the contents of the opinion expressed by Stonefield Josephson, Inc., an independent registered public

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accounting firm, with respect to our 2008 financial statements. The sanctions established by Section 193, paragraph 1 of the Italian Legislative Decree no. 58/98 for such violations are pecuniary administrative sanctions amounting to between 5,000 and 500,000, or approximately \$6,700 to \$670,000 as of December 31, 2010, applicable to each of the two asserted violations. According to the applicable Italian legal provisions, CONSOB may impose such administrative sanctions by means of a decree stating the grounds of its decision only after evaluating our possible defenses that were submitted to CONSOB on January 8, 2010 (within 30 days of December 10, 2009, the notification date of the relevant charges, according to the applicable Italian rules). On July 12, 2010, CONSOB (a) notified us that it had begun the preliminary investigation for its decision on these administrative proceedings and (b) provided us with a preliminary investigation report in response to our defenses submitted on January 8, 2010. On August 12, 2010 (within 30 days of July 12, 2010, the notification date of the beginning of the aforesaid preliminary investigation, according to the applicable Italian rules), we submitted further defenses that CONSOB will have to evaluate before imposing any possible administrative sanctions. Based on our assessment, the likelihood that these pecuniary administrative sanctions will be imposed on the Company is probable.

*Our assets and liabilities that remain in our Italian branches make us subject to increased risk regarding currency exchange rate fluctuations.*

We are exposed to risks associated with the translation of euro-denominated financial results and accounts into U.S. dollars. As long as we continue to have assets and liabilities held in our Italian branches, the carrying value of these 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.

*We may owe additional amounts for value added taxes related to our operations in Europe.*

Our European operations are subject to value added tax, or VAT, which is usually applied to all goods and services purchased and sold throughout Europe. The VAT receivable is \$5.3 million and \$6.3 million as of December 31, 2010 and December 31, 2009, respectively. On April 14, 2009 and December 21, 2009, the Italian Tax Authority, or the ITA, issued notices of assessment to CTI (Europe) based on the ITA's audit of CTI (Europe)'s VAT returns for the years 2003 and 2005, respectively. On June 25, 2010, the ITA issued notices of assessment to CTI (Europe) for the years 2006 and 2007 based on similar findings for the 2003 and 2005 assessments. The ITA audits concluded that CTI (Europe) did not collect and remit VAT on certain invoices issued to non-Italian clients for services performed by CTI (Europe). The assessments, including interest and penalties, for the years 2003, 2005, 2006 and 2007 are 0.5 million, 5.5 million, 2.5 million and 0.8 million, or approximately \$0.7 million, \$7.4 million, \$3.4 million and \$1.1 million as of December 31, 2010, respectively. We believe that the services invoiced were non-VAT taxable consultancy services and that the VAT returns are correct as originally filed. We are vigorously defending ourselves against the assessments both on procedural grounds and on the merits of the case. If the decision of the Provincial Tax Court of Milan, or the Tax Court, is unfavorable, then we expect to appeal to the higher courts in order to further defend our interests. However, if we are unable to successfully defend ourselves against the assessments issued by the ITA, we may be requested to pay to the ITA an amount ranging from 4.9 million to 9.4 million, or approximately \$6.6 million to \$12.6 million as of December 31, 2010, plus collection fees, notification expenses and additional interest for the period lapsed between the date in which the assessments were issued and the date of effective payment. On February 2, 2011, we paid to the ITA the required deposit in respect of the 2005 VAT in the amount of 1.5 million, or approximately \$2.0 million converted using the currency exchange rate as of December 31, 2010.

**2003 VAT.** We have not received a notice from the ITA requesting a deposit payment for the VAT based on the 2003 assessment as of December 31, 2010. The Tax Court has scheduled the first hearing for the discussion of the merits of the case on March 18, 2011.

**2005 VAT.** On July 14, 2010, the ITA issued a notice requiring a deposit payment for the VAT to CTI (Europe) based on the 2005 assessment, including 50% of the assessed VAT, interest and collection fees for an

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amount of 1.5 million, or approximately \$2.0 million converted using the currency exchange rate as of December 31, 2010. We successfully filed a petition with the Tax Court for suspension of the 2005 notice of deposit payment. On September 28, 2010, the merits of the case for the year 2005 were discussed in a public hearing before the Tax Court. On January 13, 2011, the Tax Court issued decision no. 4/2010 in which the Tax Court (i) partially accepted our appeal and declared that no penalties can be imposed against us, (ii) confirmed the right of the Italian Tax Authorities to reassess the VAT (plus interest) in relation to the transactions identified in the 2005 notice of assessment and (iii) repealed the suspension of the notice of deposit payment. As a result of this decision, our exposure for 2005 VAT assessment is currently reduced by the waiver of penalties of 2.6 million, or approximately \$3.5 million converted using the currency exchange rate as of December 31, 2010. The ITA has the right to appeal the decision to request for confirmation of the penalties. On February 2, 2011, we paid to the ITA the required deposit in respect of the 2005 VAT in the amount of 1.5 million, or approximately \$2.0 million converted using the currency exchange rate as of December 31, 2010, prior to the due date of February 6, 2011. We do not believe that the Tax Court has carefully reviewed all of our arguments, relevant documents and other supporting evidence that our counsel filed and presented during the hearing, including an appraisal from an independent expert, and, therefore, that there are grounds of appeal in order to ask the judges of the higher court to further consider all of our arguments in support of invalidating the entire notice of assessment. Accordingly, we will appeal to the Regional Tax Court and file a complaint with the European Commission.

While we contend that services invoiced were non-VAT taxable consulting services and that the VAT returns are correct as originally filed, we have recorded a reserve for VAT assessed, interest and collection fees totalling 2.6 million, or approximately \$3.5 million as of December 31, 2010 of which \$3.0 million is included in *long-term obligations, less current portion* and \$0.5 million of the reserve is accounted for as an offset to VAT receivable included in *other assets*.

**2006 VAT.** On January 10, 2011, we received a notice from the ITA requiring a deposit payment for VAT to CTI (Europe) based on the 2006 assessment, including 50% of the assessed VAT, interest and collection fees for an amount of 0.4 million, or approximately \$0.6 million converted using the currency exchange rate as of December 31, 2010, payable in the first quarter 2011. We filed a request for suspension of the collection of such amount.

**2007 VAT.** We have not received a notice from the ITA requesting a deposit payment for the VAT based on the 2007 assessment nor has the Tax Court scheduled a hearing as of December 31, 2010.

*Our financial condition may be adversely affected if third parties default in the performance of contractual obligations.*

Our business is dependent on the performance by third parties of their responsibilities under contractual relationships and if third parties default on their performance of their contractual obligations, 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.

*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 Pixuvri with 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 Pixuvri. We will not receive any royalty or milestone payments under this agreement unless Novartis exercises its option related to Pixuvri 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 and enter into a definitive license agreement 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

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certain sales levels. In the event Novartis does not elect to participate in the development of OPAXIO or Pixuvri, 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 Pixuvri or OPAXIO with a third party. As announced on April 9, 2010, we received a Complete Response Letter from the FDA, regarding our NDA for Pixuvri. The FDA cited as its primary reason for the action its concerns previously raised at the ODAC meeting on March 22, 2010 and recommended that we conduct an additional trial to demonstrate the safety and efficacy of Pixuvri. In December 2010, we filed an appeal with the FDA's Office of New Drugs' Center for Drug Evaluation and Research regarding the FDA's April 2010 decision to not approve Pixuvri for relapsed/refractory aggressive NHL. We filed our appeal under the FDA's formal dispute resolution process asking the Office of New Drugs to conclude that PIX301 demonstrated efficacy. We are awaiting a decision on our appeal, but we cannot predict or guarantee the outcome of our appeal. 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 Pixuvri and enter into a definitive license agreement 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 upon written notice to us.

*We cannot guarantee 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.

At the ODAC meeting on March 22, 2010, the ODAC panel did not recommend approval of our NDA for Pixuvri. Subsequently, in April 2010, we received a Complete Response Letter from the FDA regarding our NDA for Pixuvri. The FDA cited as its primary reason for the action its concerns previously raised at the ODAC meeting on March 22, 2010, and recommended that we conduct one additional clinical trial to demonstrate the safety and efficacy of Pixuvri. Moreover, we expect that we will need at least an additional clinical trial to obtain FDA approval of our NDA for Pixuvri and we do not know what this trial will cost or whether the FDA will accept our SPA for this trial. We may also need more than one additional clinical trial or we may need to take additional steps to obtain regulatory approval of Pixuvri. The expense to design and conduct clinical trials are substantial and any additional clinical trials or actions we may need to pursue to obtain approval of our NDA for Pixuvri may negatively affect our business, financial condition and results of operations.

*We may be delayed, limited or precluded from obtaining regulatory approval of OPAXIO as a maintenance therapy for advanced stage ovarian cancer.*

Our future financial success depends in part on obtaining regulatory approval of OPAXIO. We are currently focusing our development of OPAXIO as a potential maintenance therapy for women with advanced stage ovarian cancer who achieve a complete remission following first-line therapy with paclitaxel and carboplatin. This study, the GOG0212 trial, is under the control of the GOG and is expected to enroll 1,100 patients with 765 patients enrolled as of December 31, 2010. The GOG Data Monitoring Committee plans to conduct an interim analysis of overall survival and based on current enrollment and study duration, the interim analysis could be conducted as early as 2011. If successful, we could utilize those results to form the basis of a New Drug Application, NDA, for OPAXIO. However, prior clinical trials for OPAXIO have not been successful. 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 NSCLC. All three trials failed to achieve their primary endpoints of superior overall survival compared to current marketed agents for treating NSCLC. Accordingly, there can be no assurance that the GOG0212 will provide compelling evidence or any positive results, which would preclude our planned submission of an NDA to the FDA. In addition, we cannot predict the outcome of the GOG0212 study and that study may not demonstrate or be adequate to support regulatory approval of OPAXIO by the FDA.

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In March 2008, we submitted an MAA to the EMA for first-line treatment of patients with advanced non-small cell lung cancer, or NSCLC, who are poor performance status, or PS2, based on a non-inferior survival and improved side effect profile which we believe was demonstrated in our previous clinical trials. The application was based on a positive opinion we received from the EMA's Scientific Advice Working Party, or SAWP; the EMA agreed that switching the primary endpoint from superiority to non-inferiority is feasible if the retrospective justification provided in the marketing application is adequate. In September 2009, we notified the EMA of our decision to withdraw the MAA and we refocused our resources on the development of OPAXIO for its potential superiority indication in maintenance therapy for ovarian cancer and as a radiation sensitizer in the treatment of esophageal cancer.

*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, including the EMA's review of our MAA for Pixuvri. 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. On April 13, 2009, we began submission of a rolling NDA to the FDA for Pixuvri to treat relapsed aggressive NHL. We completed the submission in June 2009 and as announced on April 9, 2010, we received a Complete Response Letter from the FDA regarding our NDA for Pixuvri. The FDA cited as its primary reason for the action its concerns previously raised at the Oncologic Drugs Advisory Committee, or ODAC, meeting on March 22, 2010 and recommended that we conduct an additional trial to demonstrate the safety and effectiveness of Pixuvri. Based on the FDA's ODAC presentation, which provided ODAC and us with alternative options to consider making investigational drugs available to patients if drugs need to be studied further prior to approval, we will evaluate the establishment of an expanded access program for Pixuvri while we conduct an additional study in aggressive NHL.

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 preclinical and 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, financial condition and results of operations will be adversely affected.

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 us or our 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 business, 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,

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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, EMA 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 \$10.6 million and entered into a settlement agreement with the United States Attorney's Office 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, which required 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:

If we are successful in bringing Pixuvri to market, Pixuvri 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. Such corporations include, among others, Bristol-Myers Squibb Co. and others, which market paclitaxel and generic forms of paclitaxel; Sanofi-Aventis, which markets docetaxel; Genentech, Roche and OSI Pharmaceuticals, which market Tarceva; Genentech and Roche, which market Avastin; Eli Lilly, which markets Alimta; and Abraxis, 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, particularly the multinational pharmaceutical companies, either alone or together with their collaborators, have substantially greater financial resources and substantially larger 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 current or future products would likely suffer and we might never recoup the significant investments we are making to develop these product candidates.

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*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 or the EMA, 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 or EMA marketing approval; and

denying coverage altogether.

The continuing efforts of government and insurance companies, health maintenance organizations and other payers of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability, and the future revenues and profitability of our potential customers, suppliers and collaborative partners and the availability of capital. In the United States, given the comprehensive health care reform legislation that the President signed into law on March 23, 2010, under the Patient Protection and Affordable Care Act (HR 3590), or the PPACA, the U.S. Congress and state legislatures will likely continue to focus on health care reform, the cost of healthcare services and products and on the reform of the Medicare and Medicaid systems. While we cannot predict whether any such legislative or regulatory proposals will be adopted, the announcement or adoption of these proposals 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.

*If users of our products are unable to obtain adequate reimbursement from third-party payers, or if new restrictive legislation is adopted, market acceptance of our products may be limited and we may not achieve anticipated revenues.*

Our ability to commercialize our products will depend in part on the extent to which appropriate reimbursement levels for the cost of our products and related treatment are obtained by governmental authorities, private health insurers and other organizations, such as health maintenance organizations, or HMOs. Third-party payers are increasingly challenging the prices charged for medical care. Also, the trend toward managed health care in the United States and the concurrent growth of organizations such as HMOs, which could control or significantly influence the purchase of health care services and products, as well as legislative proposals to further reform health care or reduce government insurance programs, may all result in lower prices for our products if approved for commercialization. The cost containment measures that health care payers and providers are instituting and the effect of any health care reform could materially harm our ability to sell our products at a profit.



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*Products that appear promising in research and development may be delayed or fail to reach later stages of development or the market.*

The successful development of pharmaceutical products is highly uncertain and obtaining regulatory approval to market drugs to treat cancer is expensive, difficult and risky. Products that appear promising in research and development may be delayed or fail to reach later stages of development or the market for several reasons, including:

clinical trial results may show the product to be less effective than desired or to have harmful or problematic side effects;

preclinical tests may show the product to be toxic or lack efficacy in animal models;

failure to receive the necessary U.S. and international regulatory approvals or a delay in receiving such approvals;

difficulties in formulating the product, scaling the manufacturing process or getting approval for manufacturing;

manufacturing costs, pricing, reimbursement issues or other factors may make the product uneconomical to commercialize;

other companies or people have or may have proprietary rights to a product candidate, such as patent rights, and will not let the product candidate be sold on reasonable terms, or at all; or

the product candidate is not cost effective in light of existing therapeutics.

Preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent regulatory approval. Negative or inconclusive results or adverse medical events during a clinical trial could delay, limit or prevent regulatory approval. In addition, any significant problem in the production of our products, such as the inability of a supplier to provide raw materials or supplies used to manufacture our products, equipment obsolescence, malfunctions or failures, product quality or contamination problems, or changes in regulatory requirements or standards that require modifications to our manufacturing process could delay, limit or prevent regulatory approval which could harm our business, financial condition and results or the trading price of our securities. There can be no assurance as to whether or when we will receive regulatory approvals for our products.

*If any of our license agreements for intellectual property underlying Pixuvri, 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 Pixuvri 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 there is an adverse outcome in the securities class action and shareholder derivative litigation that have been filed against us, our business may be harmed.*

We and certain of our officers and directors are named as defendants in purported securities class actions and shareholder derivative lawsuits filed in the U.S. District Court for the Western District of Washington. These securities class action lawsuits are brought on behalf of a putative class of purchasers of our securities from March 25, 2008 through March 22, 2010, and seek unspecified damages. All of the purported securities class actions have been consolidated into one securities class action, a lead plaintiff has been appointed, and a



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consolidated amended complaint has been filed. The defendants filed a motion to dismiss the consolidated amended complaint on October 27, 2010. Plaintiffs filed their opposition to the motion on December 3, 2010, and the defendants filed their reply on December 22, 2010. The motion was heard on January 28, 2011. On February 4, 2011, the court issued an order denying in large part the defendants' motion. Defendants must file an answer to the remaining claims in the amended consolidated complaint by February 18, 2011. The currently filed shareholder derivative lawsuits have also been consolidated into one derivative action and co-lead plaintiffs have been appointed. The court ordered the derivative action stayed pending the outcome of the defendants' motion to dismiss in the securities class action. On February 4, 2011, the court lifted the stay. As with any litigation proceeding, we cannot predict with certainty the eventual outcome of pending litigation. Furthermore, we may have to incur substantial expenses in connection with these lawsuits. In the event of an adverse outcome, our business could be materially harmed.

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

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

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*Our products could infringe upon 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 amended and restated articles of incorporation 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 amended and restated articles of incorporation, 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 being given notice before such record date and 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 amended and restated articles of incorporation to increase authorized shares that are to be used for general corporate purposes, and the ratification of our auditors. We were able to obtain a quorum to hold special meetings of the shareholders in April 2007, January 2008 and March 2009 and annual meetings of the shareholders in September 2007, June 2008, October 2009 and September 2010. 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 a 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 harm us. Even if we obtain a quorum, we may not obtain enough votes to approve matters to be resolved upon at the shareholders' meeting. In addition, brokers may only vote on those matters for which broker discretionary voting is allowed under Rule 452 and Rule 452 could be revised or we may not be able to obtain the required number of votes to approve certain proposals (i.e., such as a proposal to

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increase the number of authorized shares) that require a majority of all outstanding shares to approve the proposal due to our reliance on broker discretionary voting. Our ability to obtain necessary shareholder approvals may also depend on obtaining broker discretionary voting as under Rule 452 of the New York Stock Exchange, or Rule 452. Revisions to Rule 452 that further limit matters for which broker discretionary voting is allowed may harm our ability to obtain a quorum and shareholder approval of certain matters. 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 if a proposal is submitted to our shareholders to increase the number of authorized shares of common stock, such failure could harm us. For example, a proposal to approve a reverse stock split failed to receive sufficient votes to pass at the March 2009 shareholders meeting.

*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 the total shares of our 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 the total shares of our 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 harm our ability to continue operations.

*Our common stock is listed on The NASDAQ Capital Market and the MTA 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 \$35.0 million. The NASDAQ Stock Market LLC, or NASDAQ, Listing Qualifications Panel, or 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 from NASDAQ that stated that the NASDAQ staff had concluded that we had violated NASDAQ Marketplace Rule 4350(i)(1)(C) (now NASDAQ Marketplace Rule 5635), 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 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 \$35.0 million minimum market capitalization requirement. 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. On April 2, 2009, we were notified by NASDAQ that we had complied with the Panel's decision dated March 6, 2009, and, accordingly, the Panel determined to continue the listing of our common stock on The NASDAQ Capital Market.

NASDAQ reinstated the \$1.00 minimum bid price requirement on August 3, 2009. On May 3, 2010, we received notice from NASDAQ indicating that for the last 30 consecutive business days the closing bid price of

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our common stock was below the minimum \$1.00 per share requirement for continued listing of our common stock on The NASDAQ Capital Market under NASDAQ Marketplace Rule 5550(a)(2). This notification has no immediate effect on the listing of or the ability to trade our common stock on The NASDAQ Capital Market. In accordance with NASDAQ Marketplace Rule 5810(c)(3)(A), we were provided a grace period of 180 calendar days, or until November 1, 2010, to regain compliance. We would have achieved compliance if the bid price of our common stock closed at \$1.00 per share or more for a minimum of ten consecutive trading days before November 1, 2010. Alternatively, we were eligible for an additional 180-day grace period if we met all of the initial listing standards of NASDAQ, with the exception of the closing bid price. On November 2, 2010, we received notice from NASDAQ that it granted us an additional 180 days, or until May 2, 2011, to regain compliance with the minimum \$1.00 per share requirement for continued listing of our common stock on The NASDAQ Capital Market under NASDAQ Marketplace Rule 5550(a)(2). We may achieve compliance during the additional 180-day period if the closing bid price of our common stock is at least \$1.00 per share for a minimum of ten consecutive trading days before May 2, 2011.

There can be no assurance that our closing bid price will achieve \$1.00 per share or more for the applicable period. If we are unable to attain compliance with the minimum bid price, whether by effecting a reverse stock split of our common stock or otherwise, we may be delisted. In addition, if we fail to maintain the minimum value of listed securities, we may be delisted. In the event that we receive a delisting determination from NASDAQ, we may request a hearing before the Panel. Following the hearing request, our common stock would continue to be listed on The NASDAQ Capital Market pending the conclusion of the hearing process and during any extension period which may be granted by the Panel. There can be no assurance that the Panel would delay an unfavorable delisting decision or grant any extension period.

The level of trading activity of our common stock may decline if it is no longer listed on The NASDAQ Capital Market. Furthermore, our failure to maintain a listing on The NASDAQ Capital Market may constitute an event of default under certain of our indebtedness which would accelerate the maturity date of such debt. As such, if our common stock ceases to be listed for trading on The NASDAQ Capital Market for any reason, it may harm our stock price, increase the volatility of our stock price and make it more difficult for investors to sell shares of our common stock. In the event our common stock is delisted from The NASDAQ Capital Market, we currently expect that our common stock would be eligible to be listed on the OTC Bulletin Board or Pink Sheets. We do not know what impact delisting from The NASDAQ Capital Market may have on our listing with the Borsa Italiana.

Although 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 determine 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 also 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, the Borsa Italiana, and NASDAQ lifted the trading halts on our common stock. In addition, on March 23, 2009, the Borsa Italiana halted trading of our common stock on the MTA and resumed trading prior to the opening of the MTA the next day after we filed a press release regarding the explanatory paragraph in our auditor's 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. As a consequence, NASDAQ also halted trading in our common stock on March 23, 2009, but re-initiated trading later that day. Although we file press releases with CONSOB at the end of each month regarding our business and financial condition, CONSOB may make additional inquiries about our business and financial condition at any time, and there can be no guarantee that the Borsa Italiana, 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 Capital Market or the MTA, or both, for any reason, or if trading in our stock is halted or suspended on The NASDAQ Capital Market or the MTA, or both, such events may harm the trading price of our securities, increase the volatility of the trading price of our

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securities 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 Capital Market or if trading in our stock is halted or suspended on The NASDAQ Capital Market, we may become subject to certain obligations. In addition, if we are not listed on The NASDAQ Capital Market and/or if our public float falls 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 harm our ability to raise the capital we need.

*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. 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.

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 United States 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. Failure to comply with FDA, EMA or other applicable regulations may cause us to curtail or stop the manufacture of such products until we obtain regulatory compliance.

In addition, one of our other 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 Pixuvri and brostallicin are both manufactured by a single vendor. Finished product manufacture and distribution for both Pixuvri and brostallicin are to be manufactured and distributed by different single vendors. We are currently disputing our right to cancel the exclusive manufacturing contract between us and the former manufacturer of Pixuvri. We assert multiple grounds for terminating this exclusive manufacturing agreement, which the former manufacturer disputes. The former manufacturer has asserted that we do not have the right to terminate the manufacturing contracts and has filed a lawsuit in the Court of Milan to compel us to source Pixuvri from that manufacturer. A hearing was held on January 21, 2010 to discuss preliminary matters and set a schedule for future filings and hearings. On November 11, 2010 a hearing was held aimed at examining and discussing the requests for evidence submitted by the parties in the briefs filed pursuant to article 183, paragraph 6 of the Italian code of civil procedure. At the hearing of November 11, the judge declared that the case does not require any discovery or evidentiary phase, as it may be decided on the basis of the documents and pleadings filed by the parties. The judge fixed accordingly the last hearing for October 11, 2012, for the parties to definitively submit to the judge their requests.

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

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

Prior to commercialization, each product candidate requires significant research, development and preclinical testing and extensive clinical investigation before submission of any regulatory application for marketing approval. The development of anti-cancer drugs, including those we are currently developing, is unpredictable and subject to numerous risks. Potential products that appear to be promising at early stages of development may not reach the market for a number of reasons including that they may:

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

fail to receive necessary regulatory approvals;

be difficult to manufacture on a scale necessary for commercialization;

be uneconomical to produce;

fail to achieve market acceptance; or

be precluded from commercialization by proprietary rights of third parties.

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

*If we do not successfully develop our product 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 fully divested our commercial product, Zevalin, in March 2009. Currently, we do not have a marketed product, and unless we are able to develop one of our product candidates, such as Pixuvri, into an approved commercial product, we will not generate any significant revenues from product sales, royalty payments, license fees or otherwise. Pixuvri, 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. Even if our trials are viewed as successful, we may not get regulatory approval. 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



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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.

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*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 Pixuvri, 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.

*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 significantly more time, resources or expertise than 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.

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*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

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

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

collaborative arrangements may not be on terms favorable to us;

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

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

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

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

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

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

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

*Because we base several of our drug candidates on unproven 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.

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

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

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

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

*The unfavorable outcome of litigation and other claims against us could have a material adverse impact on our financial condition and results of operations.*

We are subject to a variety of claims and lawsuits from time to time, some of which arise in the ordinary course of our business. Adverse outcomes in some or all of such pending cases may result in significant monetary damages or injunctive relief against us. While we currently believe that resolution of these matters, individually or in the aggregate, will not have a material adverse impact on our financial position, results of operations or trading price of our securities, the ultimate outcome of litigation and other claims is subject to inherent uncertainties, and our view of these matters may change in the future. It is possible that our financial condition and results of operations could be harmed in any period in which the effect of an unfavorable final outcome becomes probable and reasonably estimable.

*Our financial condition and results of operations could be adversely affected by public health issues, wars and other military action, as well as terrorist attacks and threats and government responses thereto, especially if any such actions were directed at us or our facilities or customers.*

Public health issues, terrorist attacks in the United States and elsewhere, government responses thereto, and military actions in Iraq, Afghanistan and elsewhere, may disrupt our operations or those of our customers and suppliers and may affect the availability of materials needed to manufacture our products or the means to transport those materials to manufacturing facilities and finished products to customers. A health pandemic could cause damage or disruption to international commerce by creating economic and political uncertainties that may have a strong negative impact on the global economy, us, and our customers or suppliers. Should a severe public health issues arise, we could be negatively impacted by the need for more stringent employee travel restrictions, additional limitations in the availability of freight services, governmental actions limiting the movement of products between various regions and disruptions in the operations of our customers or suppliers. The long-term effects public health issues, the terrorist attacks, and the ongoing war on terrorism on our business and on the global economy remain unknown. In addition, any of these events could increase volatility in the United States and world financial markets which may depress the price of our common stock and may limit the capital resources available to us or our customers or suppliers, which could result in decreased orders from customers, less favorable financing terms from suppliers, and scarcity or increased costs of materials and components of our

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products. Additionally, terrorist attacks directly upon us may significantly disrupt our ability to conduct our business. Any of these occurrences could have a significant impact on our operating results, revenues and costs and may result in increased volatility of the trading price of our securities.

*Higher health care costs could adversely affect our business.*

We will be impacted by the recent passage of the PPACA. Under the PPACA, we may be required to amend our health care plans to, among other things, provide affordable coverage, as defined in the PPACA, to all employees, or otherwise be subject to a payment per employee based on the affordability criteria in the Act: cover adult children of our employees to age 26; delete lifetime limits; and delete pre-existing condition limitations. Many of these requirements will be phased in over a period of time. Additionally, some states and localities have passed state and local laws mandating the provision of certain levels of health benefits by some employers. Increased health care costs could harm our business, financial condition and results of operations.

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

*The market price of our common stock 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 February 14, 2011, our stock price has ranged from a low of \$0.12 to a high of \$1.25. 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 2011 to generate additional funds to cover our current debt and operating expenses;

failure to increase our authorized common stock available for issuance;

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;



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economic and other external factors; and

general market conditions.

In the past, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted. For example, in the case of our company, we and certain of our officers and directors are named as defendants in purported securities class action and shareholder derivative lawsuits brought on behalf of a putative class of purchasers of our securities from March 25, 2008 through March 22, 2010. These lawsuits seek unspecified damages and, as with any litigation proceeding, we cannot predict with certainty the eventual outcome of pending litigation. Furthermore, we may have to incur substantial expenses in connection with these lawsuits 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 us 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 currently face or may face in the future, or that it will be adequate to cover all potential liabilities and damages.

*Shares of common stock are equity securities and are subordinate to our existing and future indebtedness.*

Shares of our common stock are common equity interests. This means that our common stock ranks junior to our outstanding shares of Series 8 Preferred Stock and any preferred stock that we may issue in the future, to our indebtedness and to all creditor claims and other non-equity claims against us and our assets available to satisfy claims on us, including claims in a bankruptcy or similar proceeding. Our existing and future indebtedness and our preferred stock may restrict payment of dividends on our common stock.

Additionally, unlike indebtedness, where principal and interest customarily are payable on specified due dates, in the case of our common stock, (i) dividends are payable only when and if declared by our board of directors or a duly authorized committee of our board of directors, and (ii) as a corporation, we are restricted to making dividend payments and redemption payments out of legally available assets. We have never paid a dividend on our common stock and have no current intention to pay dividends in the future. Furthermore, our common stock places no restrictions on our business or operations or on our ability to incur indebtedness or engage in any transactions, subject only to the voting rights available to shareholders generally.

*The market price of our common stock may be adversely affected by market conditions affecting the stock markets in general, including price and trading fluctuations on The NASDAQ Capital Market.*

The market price of our common stock may be adversely affected by market conditions affecting the stock markets in general, including price and trading fluctuations on The NASDAQ Capital Market. These conditions may result in (i) volatility in the level of, and fluctuations in, the market prices of stocks generally and, in turn, our shares of common stock, and (ii) sales of substantial amounts of our common stock in the market, in each case that could be unrelated or disproportionate to changes in our operating performance.

*There may be future sales or other dilution of our equity, which may adversely affect the market price of shares of our common stock.*

Our existing and future preferred stock, warrants or other securities convertible into or exchangeable for our common stock may contain adjustment provisions that could increase the number of shares issuable upon exercise, conversion or exchange, as the case may be, and decrease the exercise, conversion or exchange price. The market price of our shares of common stock or preferred stock could decline as a result of sales of a large number of shares of our common stock or preferred stock or similar securities in the market, the triggering of any such adjustment provisions or the perception that such sales could occur in the future.

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*Anti-takeover provisions in our charter documents, in our shareholder rights plan, or rights plan, 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 amended and restated articles of incorporation and amended and restated 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 of directors so that only approximately one third of our 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 amended and restated 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.

Pursuant to our rights plan, an acquisition of 20% or more of our common stock could result in the exercisability of the preferred stock purchase right accompanying each share of our common stock (except those held by a 20% shareholder, which become null and void), thereby entitling the holder to receive upon exercise, in lieu of a number of units of preferred stock, that number of shares of our common stock having a market value of two times the exercise price of the right. The existence of our rights plan could have the effect of delaying, deferring or preventing a third party from making an acquisition proposal for us and may inhibit a change in control that some, or a majority, of our shareholders might believe to be in their best interest or that could give our shareholders the opportunity to realize a premium over the then-prevailing market prices for their shares. 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 43,000 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. We also lease approximately 4,700 square feet of warehouse space in Seattle, Washington with a lease expiration of May 2012 and 2,700 square feet in Milan, Italy with a lease expiration date of December 2015. 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 22, 2007, we filed a complaint in King County Washington Superior Court against The Lash Group, Inc., or Lash, and Documedics Acquisition Co., Inc., our former third-party reimbursement expert for TRISENOX, seeking recovery of damages, including losses incurred by us in connection with our investigation, defense and settlement of claims by the United States concerning Medicare reimbursement for TRISENOX and other claims. On February 28, 2007, Lash removed the case to U.S. District Court in the Western District of



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Washington. On June 19, 2008, the trial judge dismissed our claims and we filed a timely notice of appeal in the Ninth Circuit Court of Appeals. An appeal hearing was held on August 31, 2009, and on November 18, 2009, the Ninth Circuit reversed the trial court and held that the False Claims Act, or the FCA, did not preclude us from seeking recovery and bringing claims against Lash for indemnification under our service agreement based upon its acts that gave rise to the government's FCA and other claims. On December 1, 2009, Lash filed a petition for rehearing with the Ninth Circuit Court of Appeals, which was formally denied on January 6, 2010. The case has been remanded for trial in the District Court. On April 30, 2010, the District Court denied a motion by Lash to strike our supplemental damages disclosure, and granted our motion for leave to amend our complaint to more fully address our claims for supplemental and independent damages. On May 21, 2010, the District Court issued a minute order setting trial and related dates. On May 24, 2010, Lash filed its answer to the amended complaint and asserted counterclaims for contractual indemnification, common law indemnification and contribution, and declaratory relief. On June 3, 2010, Lash filed a motion to bifurcate the trial to address in the first phase only its assertion that our claims are barred due to FCA liability. We opposed the motion, and on June 10, 2010, we filed our own motion to strike Lash's affirmative defense based on its FCA liability claim. On August 3, 2010, the court entered an order denying Lash's motion to bifurcate and granting our motion to strike Lash's FCA liability affirmative defense. The case is currently scheduled for trial on September 6, 2011. There is no guarantee that we will prevail at trial.

Moreover, on December 23, 2008, CONSOB sent a notice to us requesting that we issue (i) immediately, a press release providing, among other things, information about our debt restructuring plan, the current state of compliance with the relevant covenants regulating our debt and the equity line of credit agreement we entered into with Midsummer Investment Ltd. on July 29, 2008, and (ii) by the end of each month and starting from the month of December 2008, a press release providing certain information relating to our management and financial situation, updated to the previous month, or the Monthly CONSOB Press Release. On July 31, 2009, CONSOB sent us a notice asserting three violations of the provisions of Section 114, paragraph 5 of the Italian Legislative Decree no. 58/98, as follows: (a) the non-disclosure without delay of the press release described under point (i) above and the subsequent incomplete disclosure of the relevant information through press releases dated January 9, 2009 and January 13, 2009; (b) the non-disclosure of the Monthly CONSOB Press Release in December 2008; and (c) the incomplete disclosure of the Monthly CONSOB Press Release in January 2009. The sanctions established by Section 193, paragraph 1 of the Italian Legislative Decree no. 58/98 for such violations are pecuniary administrative sanctions amounting to between 5,000 and 500,000, or approximately \$6,700 to \$670,000 as of December 31, 2010, applicable to each one of the three asserted violations. According to the applicable Italian legal provisions, CONSOB may impose such administrative sanctions by means of a decree stating the grounds of its decision only after evaluating our possible defenses that were submitted to CONSOB on August 28, 2009 (within 30 days of July 31, 2009, the notification date of the relevant charges, according to the applicable Italian rules). On May 5, 2010, CONSOB (1) notified us that it had begun the preliminary investigation for its decision on these administrative proceedings and (2) provided us with a preliminary investigation report in response to our defenses submitted on August 28, 2009. On June 4, 2010 (within 30 days of May 5, 2010, the notification date of the beginning of the aforesaid preliminary investigation, according to the applicable Italian rules), we submitted further defenses that CONSOB will have to evaluate before imposing any possible administrative sanctions. On January 21, 2011, CONSOB notified us of a resolution confirming the occurrence of the three asserted violations and applying a fine for each of them in the following amounts: 20,000 for sanction (a) above; 50,000 for sanction (b) above; and 30,000 for sanction (c) above, for an aggregate fine of 100,000, or approximately \$136,000 as of January 21, 2011, for these sanctions. We anticipate paying the fine according to the terms and conditions established by the applicable Italian rules and prior to the deadline of March 22, 2011 (i.e., the deadline after which default interest and/or increases in the amount of the fines will be charged). We have accrued approximately \$0.1 million for this amount as of December 31, 2010, which is included in *accrued expenses*.

Separately, on December 10, 2009, CONSOB sent us a notice claiming two violations of the provisions of Section 114, paragraph 1 of the Italian Legislative Decree no. 58/98 due to the asserted late disclosure of certain information then reported, at CONSOB's request, in press releases disseminated on December 19, 2008 and March 23, 2009. Such information concerned, respectively: (i) the conversion by BAM Opportunity Fund LP of

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9.66% notes into shares of common stock that occurred between October 24, 2008 and November 19, 2008; and (ii) the contents of the opinion expressed by Stonefield Josephson, Inc., an independent registered public accounting firm, with respect to our 2008 financial statements. The sanctions established by Section 193, paragraph 1 of the Italian Legislative Decree no. 58/98 for such violations are pecuniary administrative sanctions amounting to between 5,000 and 500,000, or approximately \$6,700 to \$670,000 as of December 31, 2010, applicable to each of the two asserted violations. According to the applicable Italian legal provisions, CONSOB may impose such administrative sanctions by means of a decree stating the grounds of its decision only after evaluating our possible defenses that were submitted to CONSOB on January 8, 2010 (within 30 days of December 10, 2009, the notification date of the relevant charges, according to the applicable Italian rules). On July 12, 2010, CONSOB (a) notified us that it had begun the preliminary investigation for its decision on these administrative proceedings and (b) provided us with a preliminary investigation report in response to our defenses submitted on January 8, 2010. On August 12, 2010 (within 30 days of July 12, 2010, the notification date of the beginning of the aforesaid preliminary investigation, according to the applicable Italian rules), we submitted further defenses that CONSOB will have to evaluate before imposing any possible administrative sanctions. Based on our assessment, the likelihood that these pecuniary administrative sanctions will be imposed on the Company is probable.

On April 14, 2009 and December 21, 2009, the Italian Tax Authority, or the ITA, issued notices of assessment to CTI (Europe) based on the ITA's audit of CTI (Europe)'s VAT returns for the years 2003 and 2005, respectively. On June 25, 2010, the ITA issued notices of assessment to CTI (Europe) for the years 2006 and 2007 based on similar findings for the 2003 and 2005 assessments. The ITA audits concluded that CTI (Europe) did not collect and remit VAT on certain invoices issued to non-Italian clients for services performed by CTI (Europe). The assessments, including interest and penalties, for the years 2003, 2005, 2006 and 2007 are 0.5 million, 5.5 million, 2.5 million and 0.8 million, or approximately \$0.7 million, \$7.4 million, \$3.4 million and \$1.1 million as of December 31, 2010, respectively. We believe that the services invoiced were non-VAT taxable consultancy services and that the VAT returns are correct as originally filed. We are vigorously defending ourselves against the assessments both on procedural grounds and on the merits of the case. If the decision of the Provincial Tax Court of Milan, or the Tax Court, is unfavorable, then we expect to appeal to the higher courts in order to further defend our interests. However, if we are unable to successfully defend ourselves against the assessments issued by the ITA, we may be requested to pay to the ITA an amount ranging from 4.9 million to 9.4 million, or approximately \$6.6 million to \$12.6 million as of December 31, 2010, plus collection fees, notification expenses and additional interest for the period lapsed between the date in which the assessments were issued and the date of effective payment. On February 2, 2011, we paid to the ITA the required deposit in respect of the 2005 VAT in the amount of 1.5 million, or approximately \$2.0 million converted using the currency exchange rate as of December 31, 2010.

**2003 VAT.** We have not received a notice from the ITA requesting a deposit payment for the VAT based on the 2003 assessment as of December 31, 2010. The Tax Court has scheduled the first hearing for the discussion of the merits of the case on March 18, 2011.

**2005 VAT.** On July 14, 2010, the ITA issued a notice requiring a deposit payment for the VAT to CTI (Europe) based on the 2005 assessment, including 50% of the assessed VAT, interest and collection fees for an amount of 1.5 million, or approximately \$2.0 million converted using the currency exchange rate as of December 31, 2010. We successfully filed a petition with the Tax Court for suspension of the 2005 notice of deposit payment. On September 28, 2010, the merits of the case for the year 2005 were discussed in a public hearing before the Tax Court. On January 13, 2011, the Tax Court issued decision no. 4/2010 in which the Tax Court (i) partially accepted our appeal and declared that no penalties can be imposed against us, (ii) confirmed the right of the Italian Tax Authorities to reassess the VAT (plus interest) in relation to the transactions identified in the 2005 notice of assessment and (iii) repealed the suspension of the notice of deposit payment. As a result of this decision, our exposure for 2005 VAT assessment is currently reduced by the waiver of penalties of 2.6 million, or approximately \$3.5 million converted using the currency exchange rate as of December 31, 2010. The ITA has the right to appeal the decision to request for confirmation of the penalties. On February 2, 2011, we

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paid to the ITA the required deposit in respect of the 2005 VAT in the amount of 1.5 million, or approximately \$2.0 million converted using the currency exchange rate as of December 31, 2010, prior to the due date of February 6, 2011. We do not believe that the Tax Court has carefully reviewed all of our arguments, relevant documents and other supporting evidence that our counsel filed and presented during the hearing, including an appraisal from an independent expert, and, therefore, that there are grounds of appeal in order to ask the judges of the higher court to further consider all of our arguments in support of invalidating the entire notice of assessment. Accordingly, we will appeal to the Regional Tax Court and file a complaint with the European Commission.

While we contend that services invoiced were non-VAT taxable consulting services and that the VAT returns are correct as originally filed, we have recorded a reserve for VAT assessed, interest and collection fees totalling 2.6 million, or approximately \$3.5 million as of December 31, 2010 of which \$3.0 million is included in *long-term obligations, less current portion* and \$0.5 million of the reserve is accounted for as an offset to VAT receivable included in *other assets*.

**2006 VAT.** On January 10, 2011, we received a notice from the ITA requiring a deposit payment for VAT to CTI (Europe) based on the 2006 assessment, including 50% of the assessed VAT, interest and collection fees for an amount of 0.4 million, or approximately \$0.6 million converted using the currency exchange rate as of December 31, 2010, payable in the first quarter 2011. We filed a request for suspension of the collection of such amount.

**2007 VAT.** We have not received a notice from the ITA requesting a deposit payment for the VAT based on the 2007 assessment nor has the Tax Court scheduled a hearing as of December 31, 2010.

On August 3, 2009, Sicor Italia, or Sicor, filed a lawsuit in the Court of Milan to compel us to source Pixuvri from Sicor according to the terms of a supply agreement executed between Sicor and NovusPharma on October 4, 2002. Sicor alleges that the agreement was not terminated according to its terms. We assert that the supply agreement in question was properly terminated and that we have no further obligation to comply with its terms. A hearing was held on January 21, 2010 to discuss preliminary matters and set a schedule for future filings and hearings. The parties filed the authorized pleadings and submitted to the Court their requests for evidence. On November 11, 2010, a hearing was held aimed at examining and discussing the requests for evidence submitted by the parties in the briefs filed pursuant to article 183, paragraph 6 of the Italian code of civil procedure. At the hearing of November 11, 2010, the judge declared that the case does not require any discovery or evidentiary phase, and may be decided on the basis of the documents and pleadings already filed by the parties. A final hearing is scheduled for October 11, 2012, for the parties to definitively submit to the judge their requests. No estimate of a loss, if any, can be made at this time in the event that we do not prevail.

On March 12, 2010, a purported securities class action complaint was filed in the United States District Court for the Western District of Washington against the Company and certain of its officers and directors, styled *Cyril Sabbagh, individually and on behalf of all others similarly situated v. Cell Therapeutics, Inc., Dr. James A. Bianco, M.D., and Dr. Jack W. Singer* (Case No. 2:10-sv-00414), or the *Sabbagh* action. On March 19, 2010, a substantially similar class action complaint was filed in the same court, styled *Michael Laquidari, individually and on behalf of all others similarly situated v. Cell Therapeutics, Inc., Dr. James A. Bianco, M.D., and Dr. Jack W. Singer* (Case No. 2:10-cv-00480), or the *Laquidari* action. On March 31, 2010, a third substantially similar class action complaint was filed in the same court, styled *William Snyder, individually and on behalf of all others similarly situated v. Cell Therapeutics, Inc., James A. Bianco, Phillip M. Nudelman, Louis A. Bianco, John H. Bauer, Richard L. Love, Mary O. Mundinger, Jack W. Singer, Frederick W. Telling and Rodman & Renshaw, LLC* (Case No. 2:10-cv-00559), or the *Snyder* action. The securities actions are pending before Judge Marsha Pechman in the Western District of Washington. The securities complaints allege that the defendants violated the federal securities laws by making certain alleged false and misleading statements. The plaintiffs in the *Sabbagh* and *Laquidari* actions seek unspecified damages on behalf of a putative class of purchasers of the Company's securities from May 5, 2009 through February 8, 2010. The plaintiffs in the *Snyder* action seek unspecified damages on behalf of a putative class of purchasers of the Company's securities from May 5, 2009

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through March 19, 2010, including purchasers of securities issued pursuant to or traceable to the Company's July 22, 2009 public offering. On August 2, 2010, the court consolidated the securities actions, appointed lead plaintiffs, and approved lead plaintiffs' counsel. On September 27, 2010, lead plaintiff filed an amended consolidated complaint with a purported class period of March 25, 2008 through March 22, 2010. On October 27, 2010, the defendants filed a motion to dismiss the amended consolidated complaint. Plaintiffs filed an opposition on December 3, 2010, and defendants filed their reply on December 22, 2010. The hearing on the motion to dismiss was held on January 28, 2011. On February 4, 2011, the court issued an order denying in large part the defendants' motion. Defendants must file an answer to the remaining claims in the amended consolidated complaint by February 18, 2011.

On April 1, 2010, a shareholder derivative complaint was filed in the United States District Court for the Western District of Washington, derivatively on behalf of the Company against the members of its Board of Directors, styled *Shackleton v. John A. Bauer, James A. Bianco, Vartan Gregorian, Richard L. Love, Mary O'Neil Mundinger, Phillip M. Nudelman, Jack W. Singer, and Frederick W. Telling* (Case No. 2:10-cv-564). On April 5, 2010, and April 13, 2010, substantially similar derivative actions were filed in the same court, styled, respectively, *Marbury v. James A. Bianco, et al.* (Case No. 2:10-cv-00578) and *Cyrek v. John H. Bauer, et al.* (Case No. 2:10-cv-00625). The derivative actions are also pending before Judge Marsha Pechman. The derivative complaints allege that the defendants breached their fiduciary duties to the Company under Washington law by making or failing to prevent the disclosure of certain alleged false and misleading statements. The allegations in the derivative actions are substantially similar to those in the securities actions. On May 10, 2010, pursuant to the parties' stipulation, the Court consolidated these three shareholder derivative actions and appointed the law firms Robbins Umeda LLP and Federman & Sherwood as co-lead counsel for derivative plaintiffs.

On June 1, 2010, a fourth related shareholder derivative action was filed in the Western District of Washington, *Souda v. John H. Bauer et al.* (Case No. 2:10-cv-00905). It was subsequently transferred to Judge Pechman and consolidated with the consolidated derivative actions. Plaintiff Souda filed a motion to reconsider the portion of the Court's Order dated May 10, 2010, appointing Robbins Umeda and Federman & Sherwood as co-lead derivative counsel. Souda's motion for reconsideration was denied on November 16, 2010.

On July 27, 2010, a fifth related shareholder derivative action, *Bohland v. John H. Bauer et al.* (Case No. 2:10-cv-1213), was filed in the Western District of Washington and assigned to Judge John C. Coughenour. It was subsequently transferred to Judge Pechman. Plaintiff Bohland filed a motion to consolidate the *Bohland* action with the consolidated derivative actions and to reconsider the portion of the Court's Order dated May 10, 2010, appointing Robbins Umeda and Federman & Sherwood as co-lead derivative counsel. Bohland's motion for reconsideration was denied on November 16, 2010, and *Bohland* was ordered consolidated with the other derivative actions.

On October 4, 2010, a sixth related derivative complaint was filed in the Superior Court of Washington, County of King, *Alexander v. James A. Bianco, et al.* (Case No. 10-2-34849-2-SEA). On October 5, 2010, the complaint was removed to the Western District of Washington and assigned to Judge Pechman. On October 29, 2010, nominal defendant Cell Therapeutics, Inc. filed a Notice of Related Case in the lead derivative case, *Shackleton v. John H. Bauer, et al.*, Case No. 2:10-cv-00564 (Doc. No. 42). Cell Therapeutics notified the Court of this action and requested that it be consolidated with the Derivative Actions per the Court's May 10, 2010 Consolidation Order. On November 18, 2010, the Court issued an Order to Show Cause re Consolidation in *Alexander*. On November 26, 2010 the parties agreed and the court granted consolidation of *Alexander* and ordered that all proceedings be deferred 60 days pending the outcome of the Defendant's motion to dismiss the Securities Class Action suits. On February 4, 2011, the court lifted the stay. The lawsuits are at a preliminary stage in the proceedings. We believe that the securities class action is without merit and intend to defend it vigorously. For the shareholder derivative action, no estimate of a loss, if any, can be made at this time in the event that we do not prevail.

On July 28, 2010, the former General Manager of our Italian Branch office, CTI (Europe), initiated a Court proceeding against us to challenge the former General Manager's dismissal which occurred in 2009. The former

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General Manager's claims are based on the alleged unlawfulness and lack of justifications of his dismissal. The former General Manager alleged that he had suffered and requested compensation for damages ranging up to approximately 0.7 million, plus the costs of the proceedings. A hearing was scheduled to be held December 9, 2010. On November 23, 2010, we entered into a settlement agreement with the former General Manager and have paid him a settlement amount of approximately \$0.1 million including a contribution to his legal expenses as of December 31, 2010. This amount is included in *settlement expense* for 2010.

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

**Item 4. (Removed and Reserved)**



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

Our common stock is 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 Global or Capital Market, our principal trading market.

	High	Low
<b>2009</b>		
First Quarter	\$ 0.97	\$ 0.05
Second Quarter	\$ 2.23	\$ 0.27
Third Quarter	\$ 1.83	\$ 1.10
Fourth Quarter	\$ 1.30	\$ 0.86
<b>2010</b>		
First Quarter	\$ 1.40	\$ 0.12
Second Quarter	\$ 0.70	\$ 0.29
Third Quarter	\$ 0.47	\$ 0.35
Fourth Quarter	\$ 0.49	\$ 0.35

On February 14, 2011, the last reported sale price of our common stock on the NASDAQ Capital Market was \$0.34 per share. As of February 14, 2011, there were 213 shareholders of record of our common stock.

**Dividend Policy**

We have never declared or paid any cash dividends on our common stock and do not currently anticipate declaring or paying cash dividends on our common stock in the foreseeable future. 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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### Stock Performance Graph

	3/31/06	6/30/06	9/30/06	12/31/06
Cell Therapeutics, Inc.	\$ 87.61	\$ 66.06	\$ 78.44	\$ 80.28
NASDAQ Stock Index (U.S.)	\$ 106.08	\$ 98.89	\$ 102.74	\$ 109.84
NASDAQ Pharmaceutical Index	\$ 102.71	\$ 91.88	\$ 96.00	\$ 97.88
	3/31/07	6/30/07	9/30/07	12/31/07
Cell Therapeutics, Inc.	\$ 72.94	\$ 34.98	\$ 42.09	\$ 21.56
NASDAQ Stock Index (U.S.)	\$ 110.00	\$ 117.86	\$ 121.61	\$ 119.14
NASDAQ Pharmaceutical Index	\$ 95.79	\$ 100.01	\$ 104.72	\$ 102.94
	3/31/08	6/30/08	9/30/08	12/31/08
Cell Therapeutics, Inc.	\$ 7.57	\$ 5.50	\$ 0.84	\$ 0.16
NASDAQ Stock Index (U.S.)	\$ 102.60	\$ 103.10	\$ 95.88	\$ 57.41
NASDAQ Pharmaceutical Index	\$ 97.40	\$ 99.66	\$ 104.20	\$ 95.78
	3/31/09	6/30/09	9/30/09	12/31/09
Cell Therapeutics, Inc.	\$ 0.44	\$ 1.97	\$ 1.41	\$ 1.31
NASDAQ Stock Index (U.S.)	\$ 55.62	\$ 66.48	\$ 76.94	\$ 82.53
NASDAQ Pharmaceutical Index	\$ 89.19	\$ 97.40	\$ 107.37	\$ 107.62
	3/31/10	6/30/10	9/30/10	12/31/10
Cell Therapeutics, Inc.	\$ 0.62	\$ 0.44	\$ 0.45	\$ 0.42
NASDAQ Stock Index (U.S.)	\$ 87.24	\$ 77.34	\$ 86.96	\$ 97.95
NASDAQ Pharmaceutical Index	\$ 117.23	\$ 100.48	\$ 110.60	\$ 116.66

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

The data set forth below should be read in conjunction with Item 7, Management's Discussion and Analysis of Consolidated Financial Condition and Results of Operations and the Consolidated Financial Statements and Notes thereto appearing at Item 8 of this Annual Report on Form 10-K.

	2010	Year ended December 31,			2006
		2009	2008	2007	
(In thousands, except per share data)					
<b>Consolidated Statements of Operations Data:</b>					
Revenues:					
Product sales	\$	\$	\$ 11,352	\$ 47	\$
License and contract revenue	319	80	80	80	80
Total revenues	319	80	11,432	127	80
Operating expenses, net:					
Cost of product sold			3,244	49	
Research and development	27,031	30,179	51,614	72,019	61,994
Selling, general and administrative	48,043	57,725	41,607	35,517	35,303
Amortization of purchased intangibles			1,658	913	792
Restructuring charges and related gain on sale of assets or asset impairments, net(1)		3,979			591
Gain on sale of Zevalin(2)			(9,444)		
Gain on sale of investment in joint venture(3)		(10,244)			
Acquired in-process research and development(4)			36	24,615	
Total operating expenses, net	75,074	81,639	88,715	133,113	98,680
Loss from operations	(74,755)	(81,559)	(77,283)	(132,986)	(98,600)
Other income (expense):					
Investment and other income, net	1,221	133	549	2,430	2,866
Interest expense	(2,334)	(4,806)	(8,559)	(8,237)	(8,852)
Amortization of debt discount and issuance costs	(768)	(5,788)	(66,530)	(4,280)	(10,977)
Foreign exchange gain (loss)	(521)	33	3,637	4,657	1,877
Debt conversion expense	(2,031)				
Provision for VAT Assessments	(3,503)				
Make-whole interest expense		(6,345)	(70,243)	(2,310)	(24,753)
Gain on derivative liabilities, net		7,218	69,739	3,672	6,024
Gain (loss) on exchange of convertible notes		7,381	(25,103)	(972)	7,978
Equity loss from investment in joint venture		(1,204)	(123)		
Milestone modification expense		(6,000)			
Settlement expense, net	(145)	(4,710)	(3,393)	(160)	(11,382)
Write-off of financing arrangement costs			(2,846)		
Net loss before noncontrolling interest	(82,836)	(95,647)	(180,155)	(138,186)	(135,819)
Noncontrolling interest	194	252	126	78	
Net loss attributable to CTI	\$ (82,642)	\$ (95,395)	\$ (180,029)	\$ (138,108)	\$ (135,819)
Gain on restructuring of preferred stock		2,116			
Preferred stock dividends		(24)	(662)	(648)	
Deemed dividends on preferred stock	(64,918)	(23,460)	(22,216)	(9,549)	

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Net loss attributable to common shareholders	\$ (147,560)	\$ (116,763)	\$ (202,907)	\$ (148,305)	\$ (135,819)
Basic and diluted net loss per common share(5)	\$ (0.22)	\$ (0.25)	\$ (7.00)	\$ (32.75)	\$ (48.39)
Shares used in calculation of basic and diluted net loss per common share	684,629	458,356	28,967	4,529	2,807

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	2010	2009	December 31, 2008 (In thousands)	2007	2006
<b>Consolidated Balance Sheets Data:</b>					
Cash and cash equivalents, securities available-for-sale and interest receivable	\$ 22,649	\$ 37,811	\$ 10,671	\$ 18,392	\$ 54,407
Restricted cash(6)			6,640		
Working capital	(14,165)	(21,694)	(14,141)	(30,909)	30,166
Total assets	53,592	69,595	64,243	73,513	101,821
10% Convertible senior notes			19,784		
9% Convertible senior notes			4,104		
7.5% Convertible senior notes	10,215	10,102	32,601	32,220	48,186
6.75% Convertible senior notes			6,926	6,922	6,945
5.75% Convertible senior notes	12,093	11,677	23,808	23,287	
5.75% Convertible senior subordinated notes				16,907	27,407
4.0% Convertible senior subordinated notes		40,363	55,150	55,150	55,150
5.75% Convertible subordinated notes				2,910	28,490
Current portion of long-term obligations	1,717	1,312	757	1,020	2,816
Other long-term obligations, less current portion	4,206	1,861	2,907	9,879	4,667
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	
Common stock purchase warrants	(13,461)	(626)			
Accumulated deficit	(1,576,643)	(1,429,083)	(1,312,320)	(1,109,413)	(961,108)
Total shareholders' deficit	(5,145)	(18,769)	(132,061)	(134,125)	(101,604)

- (1) The 2009 amount primarily relates to the closure of our Bresso Italy operation as well as the termination of Zevalin-related employees.
- (2) 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. We subsequently sold our 50% interest in RIT Oncology to Spectrum in March 2009.
- (3) The gain on sale of investment in joint venture relates to the sale of our 50% interest in RIT Oncology in March 2009. This amount was based on the difference between \$16.5 million in gross proceeds and the \$4.6 million book value of our investment in RIT Oncology at the time of sale, net of \$1.6 million in transaction costs.
- (4) Acquired in-process research and development 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 indication not approved by the FDA.
- (5) See Notes 1 and 17 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.

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

*This Annual Report on Form 10-K, including the following discussion contains forward-looking statements, which involve risks and uncertainties and 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 Annual Report on Form 10-K. When used in this Annual Report on Form 10-K, terms such as anticipates, believes, continue, could, estimates, expects, intends, may, plans, potential, predicts, should, or will or the negative of those terms or other comparable terms are intended to identify such forward-looking statements. 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 known and unknown risks and uncertainties, including, but not limited to, those discussed below and elsewhere in this Annual Report on Form 10-K, particularly in Factors Affecting Our Operating Results and Financial Condition, that could cause actual results, levels of activity, performance or achievements 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 will not update any of the forward-looking statements after the date of this Annual Report on 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 Annual Report on 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, 2010, we had incurred aggregate net losses of \$1.6 billion since inception. Unless, we receive FDA or EMA approval for Pixuvri, we expect to continue to incur operating losses for at least the next couple of years.

We are developing Pixuvri, a novel anthracycline derivative, for the treatment of NHL and various other hematologic malignancies and solid tumors. Pixuvri was studied in our EXTEND, or PIX301, clinical trial, which was a phase III single-agent trial of Pixuvri for patients with relapsed, refractory aggressive NHL who received two or more prior therapies and who were sensitive to treatment with anthracyclines. In November 2008, we announced that this trial achieved the primary efficacy endpoint. Based on the outcome of the EXTEND trial, we began a rolling NDA submission to the FDA in April 2009 and completed the submission in June 2009.

The FDA completed its inspection of the facilities at NerPharMa DS, S.r.l. and NerPharMa, S.r.l. (two independent pharmaceutical manufacturing companies belonging to Nerviano Medical Sciences S.r.l., in Nerviano, Italy). The FDA found both manufacturing sites in compliance and acceptable for continued manufacturing of the drug in early March 2010. NerPharMa, S.r.l. agreed to manufacture our drug product, Pixuvri, which will be used for clinical supplies.

On March 22, 2010, the FDA's Oncologic Drugs Advisory Committee, or ODAC, panel voted unanimously that the clinical trial data was not adequate to support approval of Pixuvri for this patient population. In early April 2010, we received a Complete Response Letter from the FDA regarding our NDA for Pixuvri recommending that we design and conduct an additional trial to demonstrate the safety and efficacy of Pixuvri. The Company met with the FDA in August 2010 at an end of review meeting at which time the FDA informed us that the Pixuvri IND and NDA applications were being transferred to the newly-formed Division of Hematology Drug Products. In December 2010, we filed an appeal with the FDA's Office of New Drugs Center for Drug Evaluation and Research regarding the April 2010 decision to not approve Pixuvri for relapsed/refractory

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aggressive NHL. The appeal was filed under the FDA's formal dispute resolution process asking the Office of New Drugs to conclude that PIX301 demonstrated efficacy. We are awaiting a decision on the appeal.

We are preparing for the initiation of an additional Pixuvri clinical trial, PIX306, that would serve as either a post-approval confirmatory study, if Pixuvri were to be approved on the basis of the current NDA, or as a registration study for approval in the U.S. On August 3, 2010, we filed for a Special Protocol Assessment, or SPA, with the FDA for the design of our additional clinical trial of Pixuvri. In September 2010, we submitted a SPA package with expanded information to the newly-formed Division of Hematology Drug Products. Additional information relating to the SPA was submitted in December 2010 and at this time discussion of the SPA with the FDA is ongoing.

We are also applying for approval of Pixuvri in Europe. In July 2009, we were notified by the European Medicines Agency, or the EMA, that Pixuvri is eligible to be submitted for a Marketing Authorization Application, or MAA, through the EMA's centralized procedure. The centralized review process provides for a single coordinated review for approval of pharmaceutical products that is conducted by the EMA on behalf of all EU member states. The EMA also designated Pixuvri as a New Active Substance, or NAS; if approved, compounds designated as an NAS receive a 10-year market exclusivity period in EU member states. In September 2009, we applied to the EMA for orphan drug designation for Pixuvri, which was granted in December 2009. In September 2009, we also submitted a PIP to the EMA as part of the required filing process for approval of Pixuvri for treating relapsed, refractory aggressive NHL in Europe. In April 2010, the EMA recommended that we submit an updated PIP for Pixuvri following discussions with us about the preclinical and clinical Pixuvri data, including EXTEND, and the desire to explore the potential benefits Pixuvri may offer to children with lymphoid malignancies and solid tumors. We submitted an expanded PIP to the Pediatric Committee of the EMA, or PDCO, in July 2010. The expanded PIP was accepted for review by the PDCO in August 2010. On October 19, 2010, we announced that the PDCO had adopted an opinion agreeing to our PIP. The PDCO also recommended deferral of the initiation of the clinical studies until after the drug receives EMA approval. In November 2010, the MAA seeking approval for Pixuvri for the treatment of adult patients with multiple relapsed or refractory aggressive NHL was validated and accepted for review by the EMA. As Pixuvri was initially granted orphan drug status by the EMA for the treatment of diffuse large B-cell lymphoma (DLBCL), based on the expansion of the MAA to the broader aggressive NHL population, in November 2010 we agreed to withdraw the orphan designation from the EU register.

Our other late-stage drug candidate, OPAXIO (paclitaxel poliglumex) is being studied, as a potential maintenance therapy for women with advanced stage ovarian cancer who achieve a complete remission following first-line therapy with paclitaxel and carboplatin. This phase III study, the GOG0212 trial, is under the control of the Gynecologic Oncology Group, or GOG, and is expected to enroll 1,100 patients with 765 patients enrolled as of December 31, 2010. OPAXIO is also being studied in phase II trials for the treatment of metastatic esophageal cancer and brain cancer. These trials were completed in 2010 and demonstrated encouraging responses to therapy.

We are also developing brostallicin, which is a new class of cancer drug—a synthetic DNA minor groove binding agent with a unique mechanism of action. Brostallicin is currently in a phase II trial for the treatment of metastatic triple-negative breast cancer. This study is being conducted by the North Central Cancer Treatment Group (NCCTG) and is in the process of enrolling patients.

In 2009 and 2010, we reduced our debt by a total of \$97.8 million plus accrued and unpaid interest through exchanges and retirement of our convertible debt. In 2009, we exchanged \$52.9 million principal amount of portions of our 9%, 7.5%, 6.75% and 5.75% convertible senior notes and our 4% Notes for \$7.1 million in cash and 24.2 million shares of our common stock. In addition, we exchanged of \$3.0 million of our 4% Notes and \$1.5 million of our 6.75% convertible senior notes as well as accrued and unpaid interest on these notes for 3.3 million shares of our common stock. In May 2010, we exchanged \$1.8 million of our 4% Notes for common stock and in July 2010 we fully retired \$38.5 million of our 4% Notes.

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In March 2009, we divested our interest in the radiopharmaceutical product Zevalin® (ibritumomab tiuxetan) by selling our 50% interest in the Zevalin joint venture, RIT Oncology, to Spectrum Pharmaceutical, Inc., or Spectrum, for \$16.5 million. Previously, in December 2008, we closed our transaction with Spectrum to form RIT Oncology, to commercialize and develop Zevalin in the United States. We originally acquired the U.S. rights to develop, market and sell Zevalin from Biogen Idec Inc., or Biogen, in December 2007. We received an initial payment of \$6.5 million in gross proceeds from Spectrum in March 2009, \$0.8 million of which was used to pay a consent fee to Biogen, and an additional \$6.5 million in gross proceeds in April 2009. The remaining \$3.5 million we expected to receive from Spectrum, subject to certain adjustments, was disputed and was ultimately released to Spectrum based on the outcome of an arbitration hearing held in May 2009. In addition, as part of the divestiture transaction, we agreed to forego the right to receive up to \$15 million in product sales milestone payments in connection with the original transaction establishing the joint venture.

In July 2007, we completed our acquisition of Systems Medicine, Inc., or SMI, a privately held oncology company, in a stock-for-stock merger, valued at \$20 million. SMI stockholders were also entitled to 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. In August 2009, we entered into an amended agreement under which these milestone payments were replaced by an immediate substitute payment of \$6.0 million payable in shares of our common stock subject to certain conditions, including required shareholder approval. If the conditions were not satisfied, we would have been required to pay the SMI stockholders \$5.0 million in cash in lieu of the \$6.0 million shares of our common stock. In October 2009, our shareholders approved the issuance of \$6.0 million shares of our common stock and we issued approximately 5.6 million shares to the SMI stockholders. Under the original acquisition agreement, SMI became Systems Medicine, LLC, or SM, and operates as our wholly owned subsidiary. 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.

## **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. 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 a 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. All product sales in 2008 consisted of sales of Zevalin prior to the disposition of Zevalin to RIT Oncology in December 2008. Following the transfer of Zevalin, we no longer have a direct ownership in any commercial products generating product sales revenue.



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### *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 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.

For multiple element arrangements that had continuing performance obligations, we recognized contract, milestone or license fees together with any up-front payments over the term of the arrangement as we completed our performance obligation, unless the delivered technology had stand alone value to the customer and there was objective, reliable evidence of fair value of the undelivered element in the arrangement. Additionally, unless evidence suggests otherwise, revenue from consideration received was 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*

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*

Derivative instruments are recorded at fair value with changes in value recognized in the statement of operations in the period of change.

Certain of our convertible senior notes include a feature that calls for make-whole payments upon conversion of these notes. These make-whole features along with the conversion options on the notes represent embedded derivatives that have been accounted for separately from the related debt securities except where our convertible senior notes are recorded entirely at fair value.

We have calculated the fair value of the derivatives related to our convertible notes using either a Monte Carlo simulation model or a discounted cash flow model. Changes in the estimated fair value of the derivative

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

### *Purchase Price Allocation*

For business combination 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. No business combination transactions occurred subsequent to December 31, 2008.

### *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 ASC 420, *Exit or Disposal Cost Obligations*. 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.

### *Share-based Compensation Expense*

Share-based compensation expense for all share-based payment awards made to employees and directors is recognized and measured based on estimated fair values. For option valuations, we have elected to utilize the Black-Scholes valuation method in order to estimate the fair value of options on the date of grant. The risk-free interest rate 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 share-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 share-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. These assumptions underlying the Black-Scholes valuation model involve management's best estimates.

For more complex awards, such as our December 2009 performance awards, we employ a Monte Carlo simulation model to calculate estimated grant-date fair value. For the December 2009 performance awards, the average present value is calculated based upon the expected date the award will vest, or the event date, the expected stock price on the event date and the expected current shares outstanding on the event date. The event date, stock price and the shares outstanding are estimated using the Monte Carlo simulation model, which is based on assumptions by management, including the likelihood of achieving milestones and potential future financings. These assumptions impact the fair value of the equity-based award and the expense that will be recognized over the life of the award.

Generally accepted accounting principles for share-based compensation also requires that we recognize compensation expense for only the portion of awards expected to vest. Therefore, we apply an estimated

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forfeiture rate that we derive from historical employee termination behavior. If the actual number of forfeitures differs from our estimates, adjustments to compensation expense may be required in future periods. For performance-based awards that do not include market-based conditions, we record share-based compensation expense only when the performance-based milestone is deemed probable of achievement. We utilize both quantitative and qualitative criteria to judge whether milestones are probable of achievement. For awards with market-based performance conditions, we recognize the grant-date fair value of the award over the derived service period regardless of whether the underlying performance condition is met.

**Results of Operations**

*Years ended December 31, 2010 and 2009.*

*License and contract revenue.* License and contract revenue for the year ended December 31, 2010 and 2009 represents recognition of deferred revenue from the sale of Lisofylline material to DiaKine Therapeutics, Inc.

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

	2010	2009
Compounds under development:		
Pixuvri	\$ 7,249	\$ 6,256
OPAXIO	2,608	3,365
Brostallicin	115	1,096
Zevalin		987
Other compounds	108	137
Operating expenses	16,297	17,920
Discovery research	654	418
<b>Total research and development expenses</b>	<b>\$ 27,031</b>	<b>\$ 30,179</b>

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, EMA 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 Pixuvri, OPAXIO and brostallicin are \$62.2 million, \$223.3 million, and \$9.3 million, respectively. Costs for Pixuvri prior to our merger with Novuspharma S.p.A, a public pharmaceutical company located in Italy, or CTI (Europe), in January 2004 are excluded from this amount. Costs for brostallicin prior to our acquisition of SM in July 2007 are also excluded from this amount.

Research and development expenses decreased to \$27.0 million for the year ended December 31, 2010 from \$30.2 million for the year ended December 31, 2009. Pixuvri costs increased primarily due to an increase in clinical development activity mainly related to the RAPID trial as it continues to incur costs during its wind-down. Other increases related to Pixuvri costs associated with the startup of the additional clinical trial of Pixuvri, PIX306, in addition to consulting costs. These increases were partially offset by a decrease in the EXTEND trial related to its wind-down. This increase in clinical development activity was partially offset by a decrease in manufacturing expenses due to a reduction in pre-commercialization activities for Pixuvri. In addition, regulatory activities decreased primarily due to the non-recurring expense associated with the filing fee

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for the NDA submission to the FDA, partially offset by an increase in consulting costs primarily associated with the MAA submission. Costs for our OPAXIO program decreased primarily due to a decrease in regulatory and quality assurance activities as well as a decrease in clinical development activity associated with our PGT307 trial. These decreases were partially offset by an increase in clinical development activity associated with our GOG0212 study due to an increase in patient enrollment. Costs for brostallicin relate primarily to clinical development activities related to phase I and phase II studies. Zevalin costs decreased primarily due to the contribution of the product to RIT Oncology, the joint venture we formed with Spectrum on December 15, 2008, which assumed all related Zevalin expenses subsequent to that date. Our operating expenses decreased primarily due to a reduction in personnel and overhead costs associated with the closure of our Bresso, Italy facility as well as external consulting costs and share-based compensation expense, partially offset by an increase in discretionary bonus expense. Discovery research expense relates to the costs incurred in preclinical activities.

Our lead drug candidates, Pixuvri, 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 EMA, 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.

*Selling, general and administrative expenses.* Selling, general and administrative expenses decreased to \$48.0 million for the year ended December 31, 2010 from \$57.7 million for the year ended December 31, 2009. This is primarily due to a \$7.4 million decrease in non-cash share-based compensation and a \$2.1 million decrease in expenses associated with our Bresso, Italy operations due to facility closure. Additionally, there were decreases in compensation and benefits associated with a lower average headcount between periods, and patent expenses. We expect selling, general and administrative expenses to remain consistent in 2011.

*Restructuring charges and related gain on sale of assets, net.* Restructuring charges of \$4.0 million for the year ended December 31, 2009 primarily relate to activities associated with the closure of our Bresso, Italy operations, including \$2.6 million in employee termination benefits and \$1.5 million in contract termination and clean-up charges related to the Bresso facilities. These amounts were offset by a gain of \$0.3 million on the sale of the assets related to the Bresso operations. In addition, we incurred \$0.1 million in restructuring charges related to employee separation costs associated with the termination of Zevalin-related employees in connection with the sale of our 50% interest in RIT Oncology to Spectrum.

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*Gain on sale of investment in joint venture.* During the year ended December 31, 2009, we recorded a \$10.2 million one-time gain on the sale of our 50% interest in RIT Oncology in March 2009. This amount was based on the difference between \$16.5 million in gross proceeds and the \$4.6 million book value of our investment in RIT Oncology at the time of sale, net of \$1.6 million in transaction costs.

*Investment and other income, net.* Investment and other income for the year ended December 31, 2010 increased to \$1.2 million as compared to \$0.1 million for the year ended December 31, 2009. In 2010, we were awarded \$1.0 million in grants by the Internal Revenue Service under the Qualifying Therapeutic Discovery Project Credit Program.

*Interest expense.* Interest expense decreased to \$2.3 million for the year ended December 31, 2010 from \$4.8 million for the year ended December 31, 2009. This decrease is primarily due to the exchanges of \$42.3 million principal balance of our 5.75%, 6.75% and 7.5% convertible senior notes and \$14.8 million of our 4% Notes in 2009. In addition, we fully repaid the \$38.5 million outstanding principal balance of our 4% Notes in July 2010.

*Amortization of debt discount and issuance costs.* Amortization of debt discount and issuance costs decreased to \$0.8 million for the year ended December 31, 2010 as compared to \$5.8 million for the year ended December 31, 2009. During 2009, conversions of our 9% and 10% convertible senior notes resulted in accelerated amortization of debt discount and issuance costs of \$4.4 million. In addition, amortization of debt discount and issuance costs decreased by \$0.5 million due to accelerated amortization of debt discount and amortization costs on our 5.75% and 7.5% convertible senior notes and 4% Notes as a result of exchanges and conversions in 2009 reducing the remaining cost basis and discount amount to be amortized over the remaining term of the respective convertible notes.

*Foreign exchange gain (loss).* Foreign exchange loss for the year ended December 31, 2010 and foreign exchange gain for the year ended December 31, 2009 are due to fluctuations in foreign currency exchange rates, primarily related to payables and receivables in our European branch denominated in foreign currencies.

*Debt conversion expense.* Debt conversion expense of \$2.0 million for the year ended December 31, 2010 is related to the exchange of \$1.8 million principal balance of our 4% Notes in May 2010 for approximately 4.3 million shares of our common stock.

*Provision for VAT assessments.* For the year ended December 31, 2010, we recorded a provision for VAT assessments in the amount of \$3.5 million as discussed in Note 20, *Legal Proceedings* in the Notes to Consolidated Financial Statements under Item 8 in this Annual Report on Form 10-K.

*Make-whole interest expense.* Make-whole interest expense of \$6.3 million for the year ended December 31, 2009 is related to \$5.4 million in payments made upon the conversion of \$18.0 million of our 10% convertible senior notes due 2011 and \$0.9 million in payments made upon the conversion of \$5.3 million of our 9% convertible senior notes.

*Gain on derivative liabilities.* The gain on derivative liabilities of \$7.2 million for the year ended December 31, 2009 is primarily due to a gain of \$4.4 million resulting from the change in the estimated fair value of the derivative liability related to the embedded conversion option on our 10% convertible senior notes due 2011 as well as a gain of \$2.8 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 our 13.5% convertible senior notes and Series E preferred stock financing and modified in July 2008 in connection with the issuance of our 18.33% convertible senior notes. The Series B Unit Warrant expired in the second quarter of 2009.

*Gain (loss) on exchange of convertible notes.* The \$7.4 million gain on exchange of convertible notes for the year ended December 31, 2009 is primarily related to \$7.2 million due to the exchange of \$52.9 million

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principal amount of portions of our 9%, 7.5%, 6.75% and 5.75% convertible senior notes and our 4% Notes for \$7.1 million in cash and 24.2 million shares of our common stock, net of related transaction costs. In addition, we recorded a \$0.2 million gain related to the exchange of \$3.0 million of our 4% Notes and \$1.5 million of our 6.75% convertible senior notes as well as accrued and unpaid interest on these notes for 3.3 million shares of our common stock.

*Equity loss from investment in joint venture.* The equity loss from investment in joint venture for the year ended December 31, 2009 relates to our 50% interest in RIT Oncology, prior to the sale of this interest in March 2009, which we accounted for using the equity method of accounting.

*Milestone modification expense.* Milestone modification expense for the year ended December 31, 2009 was due to a \$6.0 million payment in shares of our common stock to the SMI shareholders based on the August 2009 amendment to our original acquisition agreement pursuant to which we acquired SMI in a stock-for-stock merger in July 2007.

*Settlement expense.* Settlement expense of \$0.1 million for the year ended December 31, 2010 related to a settlement agreement reached with the former General Manager of our Italian Branch office, CTI (Europe) based on claims challenging his dismissal, which occurred in 2009. Settlement expense of \$4.7 million for the year ended December 31, 2009 was due to \$3.2 million related to amounts paid to Spectrum for the settlement of the final installment payment related to our sale of our 50% interest in RIT Oncology based on the outcome of arbitration proceedings. This amount includes the \$3.5 million escrow amount released to Spectrum, our \$0.8 million payment to Spectrum based on arbitration proceedings and \$0.9 million in receivables recognized in prior periods and owed to us by RIT Oncology. The settlement amount is also net of \$2.0 million in payables assumed by Spectrum on our behalf. We also incurred \$1.3 million in settlement expense related to the payment made in accordance with our settlement agreement and release with Ingenix Pharmaceutical Services, Inc., or Ingenix, whereby each party agreed to a full release of the other party from any and all claims related to our dispute with Ingenix. The settlement expense recorded is net of \$0.3 million in payables to Ingenix that were relieved from our books.

*Years ended December 31, 2009 and 2008.*

*Product sales.* Product sales for the year ended December 31, 2008 relate to Zevalin. As we divested Zevalin to our 50% owned joint venture, RIT Oncology, in December 2008, we recorded no product sales related to Zevalin in 2009. We subsequently sold our 50% interest in RIT Oncology to Spectrum in March 2009.

*License and contract revenue.* License and contract revenue for the year ended December 31, 2009 and 2008 represents recognition of deferred revenue from the sale of Lisofylline material to DiaKine Therapeutics, Inc.

*Cost of product sold.* Cost of product sold for the year ended December 31, 2008 relates to sales of Zevalin and consists primarily of contractual royalties on product sales in addition to cost of product sold to customers. We had no cost of product sold during the year ended December 31, 2009 due to our divestiture of Zevalin to RIT Oncology in December 2008.

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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):

	2009	2008
Compounds under development:		
Pixuvri	\$ 6,256	\$ 8,238
OPAXIO	3,365	4,145
Brostallicin	1,096	3,860
Zevalin	987	5,271
Other compounds	137	391
Operating expenses	17,920	27,878
Discovery research	418	1,831
<b>Total research and development expenses</b>	<b>\$ 30,179</b>	<b>\$ 51,614</b>

Research and development expenses decreased to \$30.2 million for the year ended December 31, 2009, from \$51.6 million for the year ended December 31, 2008. Pixuvri costs decreased primarily due to a decrease in clinical development activity mainly related to the cessation of patient enrollment during 2008 in our RAPID and EXTEND trials. 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 Pixuvri 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. Manufacturing activity for Pixuvri decreased during the period. These decreases were partially offset by an increase in clinical activity due to a change in estimate of costs associated with our PIX303 trial, which was closed in early 2008 based on, among other considerations, our plans to refocus our resources on obtaining Pixuvri approval based on the EXTEND trial before making additional substantive investments in alternative indications. In addition, regulatory activities increased primarily due to consulting costs and the filing fee for the NDA submission to the FDA. Costs for our OPAXIO program decreased primarily due to a decrease in regulatory and quality activities as well as investigator-sponsored trial costs mainly due to patient enrollment. These decreases were partially offset by an increase in clinical development activity related to our PGT307 trial as well as an increase in the GOG0212 study related to the August 2008 amendment to our contract with the GOG, which resulted in a reduction in scope of the GOG0212 study and, accordingly, a reversal of accrued expenses during that period. Costs for brostallicin decreased primarily due to a decrease in clinical development activities related to phase I and phase II studies. Zevalin costs decreased primarily due to the contribution of the product to RIT Oncology, the joint venture we formed with Spectrum on December 15, 2008, which assumed all related Zevalin expenses subsequent to that date. The decrease related to the divestiture of the Zevalin product was partially offset by a change in estimate of our costs associated with clinical studies prior to the divestiture of Zevalin. Our operating expenses decreased primarily due to a reduction in personnel and overhead costs associated with the closure of our Bresso, Italy facility as well as external consulting costs, partially offset by an increase in share-based compensation costs associated with restricted stock awards. Discovery research also decreased due to the closure of the Bresso, Italy facility.

*Selling, general and administrative expenses.* Selling, general and administrative expenses increased to \$57.7 million for the year ended December 31, 2009, from \$41.6 million for the year ended December 31, 2008. This is primarily due to an \$18.9 million increase in non-cash share-based compensation mainly related to restricted stock granted and vested during 2009. This was offset, in part by a decrease in compensation and benefits due to a reduction in headcount primarily related to our restructuring activities and our sale of Zevalin.

*Amortization of purchased intangibles.* Amortization for the year ended December 31, 2008 was due to amortization of our workforce intangible related to our Italian operations, which became fully amortized during 2008, and amortization of intangible assets acquired in connection with our acquisition of Zevalin in December 2007, which were contributed to RIT Oncology in December 2008.

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*Restructuring charges and related gain on sale of assets, net.* Restructuring charges of \$4.0 million for the year ended December 31, 2009 primarily relate to activities associated with the closure of our Bresso, Italy operations, including \$2.6 million in employee termination benefits and \$1.5 million in contract termination and clean-up charges related to the Bresso facilities. These amounts were offset by a gain of \$0.3 million on the sale of the assets related to the Bresso operations. In addition, we incurred \$0.1 million in restructuring charges related to employee separation costs associated with the termination of Zevalin-related employees in connection with the sale of our 50% interest in RIT Oncology to Spectrum.

*Gain on sale of Zevalin.* The gain on sale of Zevalin for the year ended December 31, 2008 is 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.

*Gain on sale of investment in joint venture.* During the year ended December 31, 2009, we recorded a \$10.2 million one-time gain on the sale of our 50% interest in RIT Oncology in March 2009. This amount was based on the difference between \$16.5 million in gross proceeds and the \$4.6 million book value of our investment in RIT Oncology at the time of sale, net of \$1.6 million in transaction costs.

*Interest expense.* Interest expense decreased to \$4.8 million for the year ended December 31, 2009 from \$8.6 million for the year ended December 31, 2008. This decrease was primarily due to a reduction of \$2.4 million in interest expense on our 10% (due 2012), 9%, 7.5%, 6.75% and 5.75% convertible senior notes and our 4% Notes as a result of conversions and exchanges of these notes during 2009. There was also a decrease of \$1.1 million related to our 18.33%, 15% and 9.66% convertible senior notes, which were issued in and were entirely converted or exchanged by the end of 2008. In addition, interest expense related decreased by \$0.3 million due to maturity of our 5.75% convertible subordinated and senior subordinated notes in June 2008.

*Amortization of debt discount and issuance costs.* Amortization of debt discount and issuance costs decreased to \$5.8 million for the year ended December 31, 2009 as compared to \$66.5 million for the year ended December 31, 2008. This decrease was primarily due to the accelerated amortization of issuance costs and debt discount related to conversions and exchanges of our 18.33%, 15.5%, 15%, 13.5%, 10% (due 2012), 9.66% and 9% convertible senior notes during 2008. For the year ended December 31, 2009 as compared to the same period in 2008, the decrease in the amortization of the debt discount related to these notes was \$55.2 million and the decrease in the amortization of debt issuance costs was \$5.4 million.

*Foreign exchange gain.* Foreign exchange gains for the years ended December 31, 2009 and 2008 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 \$6.3 million for the year ended December 31, 2009 is related to \$5.4 million in payments made upon the conversion of \$18.0 million of our 10% convertible senior notes (due 2011) and \$0.9 million in payments made upon the conversion of \$5.3 million of our 9% convertible senior notes. The amount 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% convertible senior notes, \$15.5 million in payments made upon conversion of \$28.3 million of our 18.33% convertible senior notes, \$11.0 million in payments made upon conversion of \$40.8 million of our 9% convertible senior notes, \$8.8 million in payments made upon conversion of \$14.2 million of our 15.5% convertible senior notes, \$4.5 million in payments made upon conversion of \$15.7 million of our 9.66% convertible senior notes, \$4.4 million in payments made upon conversion of \$14.7 million of our 10% convertible senior notes (due 2011) and \$3.6 million in payments made upon conversion of \$9.0 million of our 10% convertible senior notes (due 2012).



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*Gain on derivative liabilities, net.* The gain on derivative liabilities of \$7.2 million for the year ended December 31, 2009 is primarily due to a gain of \$4.4 million resulting from the change in the estimated fair value of the derivative liability related to the embedded conversion option on our 10% convertible senior notes (due 2011) as well as a gain of \$2.8 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 our 13.5% convertible senior notes and Series E preferred stock financing and modified in July 2008 in connection with the issuance of our 18.33% convertible senior notes. The Series B Unit Warrant expired in the second quarter of 2009. The gain 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%, 9%, 15.5%, 18.33%, 15%, 10% (due 2012), 9.66% and 10% (due 2011) convertible senior notes, 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.

*Gain (loss) on exchange of convertible notes.* The \$7.4 million gain on exchange of convertible notes for the year ended December 31, 2009 is primarily related to \$7.2 million due to the exchange of \$52.9 million principal amount of portions of our 9%, 7.5%, 6.75% and 5.75% convertible senior notes and our 4% Notes for \$7.1 million in cash and 24.2 million shares of our common stock, net of related transaction costs. In addition, we recorded a \$0.2 million gain related to the exchange of \$3.0 million of our 4% Notes and \$1.5 million of our 6.75% convertible senior notes as well as accrued and unpaid interest on these notes for 3.3 million shares of our common stock.

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 \$17.5 million aggregate principal of our 13.5% convertible senior notes in connection with the issuance of our 18.33% convertible senior notes. A loss of \$5.5 million was due to the repurchase of \$18.2 million of our 15% convertible senior notes in connection with the issuance of our 9.66% convertible senior notes in October 2008. In addition, we repurchased the remaining \$4.8 million of our 15% convertible senior notes, \$16.3 million of our 18.33% convertible senior notes and \$9.0 million of our 9.66% convertible senior notes in connection with the issuance of our 10% convertible senior 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% convertible senior notes for units of our 13.5% convertible senior notes, Series E preferred stock and related warrants issued in April 2008 and a loss of \$2.3 million due to the extinguishment of \$9.1 million aggregate principal amount of our 5.75% convertible senior subordinated and convertible subordinated notes in exchange for 0.7 million shares of our common stock in February 2008.

*Equity loss from investment in joint venture.* The equity loss from investment in joint venture for the years ended December 31, 2009 and 2008 relates to our 50% interest in RIT Oncology, prior to the sale of this interest in March 2009, which we accounted for using the equity method of accounting.

*Milestone modification expense.* Milestone modification expense for the year ended December 31, 2009 was due to a \$6.0 million payment in shares of our common stock to the SMI shareholders based on the August 2009 amendment to our original acquisition agreement pursuant to which we acquired SMI in a stock-for-stock merger in July 2007.

*Settlement expense.* Settlement expense of \$4.7 million for the year ended December 31, 2009 was due to \$3.2 million related to amounts paid to Spectrum for the settlement of the final installment payment related to our sale of our 50% interest in RIT Oncology based on the outcome of arbitration proceedings. This amount includes the \$3.5 million escrow amount released to Spectrum, our \$0.8 million payment to Spectrum based on arbitration proceedings and \$0.9 million in receivables recognized in prior periods and owed to us by RIT Oncology. The settlement amount is also net of \$2.0 million in payables assumed by Spectrum on our behalf. We also incurred \$1.3 million in settlement expense related to the payment made in accordance with our settlement agreement and

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release with Ingenix Pharmaceutical Services, Inc., or Ingenix, whereby each party agreed to a full release of the other party from any and all claims related to our dispute with Ingenix. The settlement expense recorded is net of \$0.3 million in payables to Ingenix that were relieved from our books.

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 shareholders 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.

*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. We terminated this agreement in March 2009.

## **Liquidity and Capital Resources**

As of December 31, 2010, we had \$22.6 million in cash and cash equivalents.

Net cash used in operating activities totaled \$63.1 million in 2010, compared to \$88.2 million in 2009 and \$80.2 million in 2008. The decrease in net cash used in operating activities for the year ended December 31, 2010 as compared to 2009 was primarily due to a reduction in interest payments on convertible notes and a decrease in operating expenses, including *research and development expenses* and *selling, general and administrative expenses*, excluding the allocation of non-cash share-based compensation. The decrease is also attributable to a reduction in cash payments for *prepaid expenses and other current assets* in 2010 as well as non-recurring cash payments made in connection with settlement of legal matters during 2009. We also received one-time grants from the Internal Revenue Service under the Qualifying Therapeutic Discovery Project Credit Program offsetting cash used in operating activities for the year ended December 31, 2010. The increase in net cash used in operating activities for the year ended December 31, 2009 as compared to 2008 was primarily due to an increase in cash payments used to decrease our *accounts payable* and *accrued expenses* for the year ended December 31, 2009 as compared to an increase in these liability amounts during the comparable period in 2008. During 2009, we also had a decrease in cash received from sales of Zevalin as well as increased cash payments due to settlement expenses and restructuring charges. These were offset by a decrease in cash paid for *interest expense* as well as decreased *selling, general and administrative* and *research and development expense*, excluding the allocation of non-cash share-based compensation expense to these activities.

Net cash used in investing activities totaled \$2.3 million in 2010 as compared to net cash provided by investing activities of \$21.8 million in 2009 and \$4.4 million in 2008. Net cash used in investing activities of approximately \$2.3 million for the year ended December 31, 2010 was primarily due to \$2.0 million in purchases of property and equipment and \$0.4 million in purchases of securities available-for-sale. Net cash provided by investing activities during the year ended December 31, 2009 was primarily due to \$6.8 million in net proceeds from Spectrum in January 2009 related to the initial formation of RIT Oncology in December 2008 and \$15.0 million in net proceeds from Spectrum related to the sale of our 50% interest in RIT Oncology in 2009. 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.

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Net cash provided by financing activities totaled \$49.7 million in 2010, \$94.8 million in 2009 and \$73.7 million in 2008. Net cash provided by financing activities for the year ended December 31, 2009 was primarily due to issuances of convertible preferred stock and warrants during the period. In January 2010, we received \$28.0 million in net proceeds from the issuance of 30,000 shares of our Series 3 preferred stock and warrants to purchase up to 8.6 million shares of our common stock. In April 2010, we received \$18.6 million in net proceeds from the issuance of 20,000 shares of our Series 4 preferred stock and warrants to purchase up to 20.0 million shares of our common stock. In May 2010, we received \$19.7 million in net proceeds from the issuance of 21,000 shares of our Series 5 preferred stock and warrants to purchase up to 26.3 million shares of our common stock. In July 2010, we received \$3.0 million in net proceeds from the issuance of 4,060 shares of our Series 6 preferred stock and warrants to purchase up to 5.8 million shares of our common stock. In October 2010, we received \$19.9 million in net proceeds from the issuance of 21,000 shares of our Series 7 preferred stock and warrants to purchase up to 22.7 million shares of our common stock. These proceeds were offset by a \$38.5 million payment to retire the outstanding principal balance on our 4% Notes upon maturity in July 2010. In addition, we paid \$0.9 million for the repurchase of shares in connection with satisfying tax withholding obligations on the vesting of restricted stock awards to employees during 2010.

Net cash provided by financing activities for the year ended December 31, 2009 was primarily due to \$40.3 million in net proceeds from the issuance of 33.7 million shares of our common stock and warrants to purchase up to 8.4 million shares of our common stock in a public offering in July 2009 as well as \$18.9 million in net proceeds from the issuance of 16.0 million shares of our common stock and warrants to purchase 4.8 million shares of our common stock May 2009. We also received \$28.4 million in net proceeds from the issuance of 30,000 shares of our Series 2 preferred stock and warrants to purchase up to 4.7 million shares of our common stock in August 2009. In addition, in May 2009, we received \$18.7 million in net proceeds from the issuance of 20,000 shares of our Series 1 preferred stock and related Class A and Class B warrants as well as \$3.8 million and \$4.3 million upon the exercise of the Class A and Class B warrants in May and October 2009, respectively. These proceeds were offset by \$10.0 million in cash paid, net of transaction costs and in addition to 24.2 million shares of our common stock, for the exchange of \$52.9 million principal amount of our convertible notes. We also repurchased \$6.4 million shares of our common stock for cash in connection with the vesting of employee share awards based on taxes owed by employees due to the vesting of the awards. In addition, we made a \$3.0 million deemed dividend payment in connection with our settlement with Tang Capital Partners LP for full release of all claims against us in connection with our alleged breach of contract related to Tang's Series B preferred stock. This amount was accrued as of December 31, 2008 and paid in January 2009.

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% convertible senior notes were \$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 \$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% convertible senior notes and Series E preferred stock were \$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% convertible senior 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% convertible senior notes were \$11.4 million, net of issuance costs and restricted cash placed in escrow to fund make-whole payments. We received \$1.8 million in proceeds from the issuance of our 18.33% convertible senior notes, net of issuance costs, restricted cash placed in escrow to fund make-whole payments and the repurchase of \$17.5 million of our 13.5% convertible senior notes and warrants. Upon cancellation of the 13.5% convertible senior 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 \$10.1 million from the issuance of our 10% convertible senior notes (due 2012) and 15.5% convertible senior 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 \$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%

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convertible senior notes and the cancellation of \$18.2 million of our 15% convertible senior notes, net of issuance costs and a net payment of \$6.5 million for the issuance of our 10% convertible senior notes (due 2011) and the cancellation of \$16.3 million of our 18.33% convertible senior notes, \$9.0 million of our 9.66% convertible senior notes and \$4.8 million of our 15% convertible senior 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.

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, unless we receive FDA or EMA approval for Pixuvri, we expect to generate losses from operations for at least the next couple of years primarily due to research and development costs for Pixuvri, OPAXIO and brostallicin.

Subsequent to December 31, 2010, we raised \$25.0 million in gross proceeds in connection with the issuance of our Series 8 preferred stock in January 2011. We do not expect that our existing cash and cash equivalents are sufficient to fund our presently anticipated operations through the second quarter of 2011. This raises substantial doubt about our ability to continue as a going concern.

In 2010, we achieved cost savings initiatives to reduce operating expenses, including the reduction of employees related to planned commercial Pixuvri operations and we continue to seek additional areas for cost reductions. However, we must also raise additional funds and are currently exploring alternative sources of financing.

Our future capital requirements will depend on many factors, including:

results of our clinical trials;

regulatory approval of our products;

success in acquiring or divesting products, technologies or businesses;

progress in and scope of our research and development activities;

ability to find 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 may seek to raise such capital through public or private equity financings, partnerships, joint ventures, disposition of assets, debt financings or restructurings, bank borrowings or other sources. However, we may not have sufficient authorized shares of common stock available for issuance or 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. 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. 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.



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The following table includes information relating to our contractual obligations as of December 31, 2010 (in thousands):

Contractual Obligations	Payments Due by Period				
	Total	1 Year	2-3 Years	4-5 Years	After 5 Years
7.5% convertible senior notes(1)	\$ 10,250	\$ 10,250	\$	\$	\$
5.75% convertible senior notes(2)	10,913	10,913			
Interest on convertible notes	853	853			
Operating leases:					
Facilities	6,515	3,878	2,553	84	
Long-term obligations(3)	920	432	476	12	
Purchase commitments	1,005	439	566		
	\$ 30,456	\$ 26,765	\$ 3,595	\$ 96	\$

- (1) 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.
- (2) 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.
- (3) Long-term obligations do not include \$2.0 million related to excess facilities charges and \$3.0 million related to the reserve for VAT assessments.

*Additional Milestone Activities**PG-TXL*

We have an agreement with PG-TXL Company, L.P., or PG-TXL, which grants us an exclusive worldwide license for the rights to OPAXIO and to all potential uses of PG-TXL's polymer technology, or the PG-TXL Agreement. Pursuant to the PG-TXL Agreement, we acquired the rights to research, develop, manufacture, market and sell anti-cancer drugs developed using this polymer technology. Pursuant to the PG-TXL Agreement, we are obligated to make payments to PG-TXL upon the achievement of certain development and regulatory milestones of up to \$14.4 million. The timing of the remaining milestone payments under the PG-TXL Agreement is based on trial commencements and completions for compounds protected by PG-TXL license rights, and regulatory and marketing approval of those compounds by the FDA and the EMA. Additionally, we are required to make royalty payments to PG-TXL based on net sales. Our royalty payments range from low-single digits to mid-single digits as a percentage of net sales. Unless otherwise terminated, the term of the PG-TXL Agreement continues until no royalties are payable to PG-TXL. We may terminate the PG-TXL Agreement (i) upon advance written notice to PG-TXL in the event issues regarding the safety of the products licensed pursuant to the PG-TXL Agreement arise during development or clinical data obtained reveal a materially adverse tolerability profile for the licensed product in humans or (ii) for any reason upon advance written notice. In addition, either party may terminate the PG-TXL Agreement (a) upon advance written notice in the event certain license fee payments are not made; (b) in the event of an uncured material breach of the respective material obligations and conditions of the PG-TXL Agreement; or (c) in the event of liquidation or bankruptcy of a party.

*Gynecologic Oncology Group*

We have an agreement with the Gynecologic Oncology Group, or the GOG, related to the GOG0212 trial, which the GOG is conducting. We recorded a \$1.6 million payment due to the GOG, based on the 650 patient enrollment milestone achieved in the first quarter of 2010, of which \$1.1 million remained outstanding and is included in *accounts payable* as of December 31, 2010. Subsequent to period end, we paid the remaining \$1.1

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million due to the GOG in January 2011. Under this agreement we are required to pay up to \$3.5 million in additional milestone payments related to the trial of which \$1.7 million will become due when 800 patients are enrolled and \$0.5 million will become due upon receipt of the interim analysis and data transfer, both of which may occur in 2011.

### *Nerviano Medical Sciences*

Under a license agreement entered into with Nerviano Medical Sciences, S.r.l. 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., or Cephalon, in June 2005, we may receive up to \$100.0 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*

In September 2006, we entered into an exclusive worldwide licensing agreement with Novartis, or the Novartis Agreement, for the development and commercialization of OPAXIO. Total product and registration milestones to us for OPAXIO under the Novartis Agreement could reach up to \$270 million. Royalty payments to us for OPAXIO are based on worldwide OPAXIO net sales volumes and range from the low-twenties to mid-twenties as a percentage of net sales.

Pursuant to the Novartis Agreement, we are responsible for the development costs of OPAXIO and have control over development of OPAXIO unless and until Novartis exercises its development rights, or the Development Rights. In the event that Novartis exercises its Development Rights, then from and after the date of such exercise, or the Novartis Development Commencement Date, Novartis will be solely responsible for the development of OPAXIO. Prior to the Novartis Development Commencement Date, we are solely responsible for all costs associated with the development of OPAXIO, but will be reimbursed by Novartis for certain costs after the Novartis Development Commencement Date. After the Novartis Development Commencement Date, Novartis will be responsible for costs associated with the development of OPAXIO, subject to certain limitations; however, we are also responsible for reimbursing Novartis for certain costs pursuant to the Novartis Agreement.

The Novartis Agreement also provides Novartis with an option to develop and commercialize Pixuvri based on agreed terms. If Novartis exercises its option on Pixuvri under certain conditions and we are able to negotiate and sign a definitive license agreement with Novartis, Novartis would be required to pay us a \$7.5 million license fee, up to \$104 million in registration and sales related milestones and a royalty on Pixuvri worldwide net sales. Royalty payments to us for Pixuvri are based on worldwide Pixuvri net sales volumes and range from the low-double digits to the low-thirties as a percentage of net sales.

Royalties for OPAXIO are based on worldwide sales volumes of OPAXIO and royalties for Pixuvri are based on sales volumes in the U.S. and sales volumes in other countries.

Royalties for OPAXIO and Pixuvri are payable from the first commercial sale of a product until the later of the expiration of the last to expire valid claim of the licensor or the occurrence of other certain events, or the Royalty Term. Unless otherwise terminated, the term of the Novartis Agreement continues on a product-by-product and country-by-country basis until the expiration of the last-to-expire Royalty Term with respect to a product in such certain country. In the event Novartis does not exercise its Development Rights until

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the earlier to occur of (i) the expiration of 30 days following receipt by Novartis of the product approval information package pursuant to the Novartis Agreement or (ii) Novartis' determination, in its sole discretion, to terminate the Development Rights exercise period by written notice to us (events (i) and (ii) collectively being referred to as the Development Rights Exercise Period), the Novartis Agreement will automatically terminate upon expiration of the Development Rights Exercise Period. In the event of an uncured material breach of the Novartis Agreement, the non-breaching party may terminate the Novartis Agreement. Either party may terminate the Novartis Agreement without notice upon the bankruptcy of the other party. In addition, Novartis may terminate the Novartis Agreement without cause at any time (a) in its entirety within 30 days written notice prior to the exercise by Novartis of its Development Rights or (b) on a product-by-product or country-by-country basis on 180 days written notice after the exercise by Novartis of its Development Rights. If we experience a change of control that involves certain major pharmaceutical companies, Novartis may terminate the Novartis Agreement by written notice within a certain period of time to us or our successor entity.

As of December 31, 2010, we have not received any milestone payments and we will not receive any milestone payments unless Novartis elects to exercise its option to participate in the development and commercialization of Pixuvri or exercise its Development Rights for OPAXIO.

### **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 Standards**

In February 2010, the FASB issued amended guidance on subsequent events to alleviate potential conflicts between FASB guidance and SEC requirements. Under this amended guidance, SEC filers are no longer required to disclose the date through which subsequent events have been evaluated in originally issued and revised financial statements. This guidance was effective immediately and we adopted these new requirements during the first quarter of 2010. The adoption of this guidance did not have a material impact on our consolidated financial statements.

### **Recently Issued Accounting Standards**

In April 2010, the FASB issued guidance on the milestone method for revenue recognition purposes. Previously, definitive guidance on when the use of the milestone method was appropriate did not exist. This guidance provides a framework of the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. This guidance is effective on a prospective basis for milestones achieved in fiscal years and interim periods within those years, beginning on or after June 15, 2010 with early adoption permitted. We do not anticipate the adoption of this guidance will have a material impact on our consolidated financial statements.

In December 2010, the FASB issued additional guidance on when to perform Step 2 of the goodwill impairment test for reporting units with zero or negative carrying amounts. The criteria for evaluating Step 1 of the goodwill impairment test and proceeding to Step 2 was amended for reporting units with zero or negative carrying amounts and requires performing Step 2 if qualitative factors indicate that it is more likely than not that a goodwill impairment exists. For public entities, this guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2010. Upon adoption of the amended guidance, any impairment will be recorded as an adjustment to beginning retained earnings. We are currently evaluating the impact of the pending adoption on our consolidated financial statements.



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**Item 7a. Quantitative and Qualitative Disclosures about Market Risk**  
**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. As of December 31, 2010, our foreign currency transactions are minimal and changes to the exchange rate between the U.S. dollar and foreign currencies would have an immaterial affect on our earnings. In addition, the reported carrying value of our euro-denominated assets and liabilities that remain in our Bresso branch will be affected by fluctuations in the value of the U.S. dollar as compared to the euro. As of December 31, 2010, we had a net asset balance in our European branch. If the euro were to weaken 20% against the dollar, our net asset balance would decrease by approximately \$0.3 million as of this date.

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

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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 consolidated balance sheets of Cell Therapeutics, Inc. (the Company) as of December 31, 2009, and the related consolidated statements of operations, stockholders' deficit and comprehensive loss, and cash flows for each of the years in the two-year period ended December 31, 2009. These financial statements 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, 2009, and the results of their operations and their cash flows for each of the years in the two-year period ended December 31, 2009, in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has sustained losses from operations over the audit periods, incurred an accumulated deficit, it has substantial monetary liabilities in excess of monetary assets as of December 31, 2009. Given these 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 to the consolidated financial statements. 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.

/s/ Stonefield Josephson, Inc.

San Francisco, California

February 26, 2010

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Audit Committee of the

Board of Directors and Shareholders of

Cell Therapeutics, Inc.

We have audited the accompanying consolidated balance sheet of Cell Therapeutics, Inc. (the Company) as of December 31, 2010, and the related consolidated statements of operations, stockholders' deficit and comprehensive loss, and cash flows for the year then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements 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 the consolidated financial statements are free of material misstatement. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Cell Therapeutics, Inc. as of December 31, 2010, and the consolidated results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred losses since its inception, and has a working capital deficiency of approximately \$14.2 million at December 31, 2010. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plans concerning these matters are described in Note 1 to the consolidated financial statements. 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 result from the outcome of this uncertainty.

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, 2010, 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 February 16, 2011 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ Marcum LLP

San Francisco, CA

February 16, 2011

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM ON INTERNAL CONTROL OVER FINANCIAL REPORTING**

To the Board of Directors and

Shareholders of Cell Therapeutics, Inc.

We have audited Cell Therapeutics, Inc.'s (the Company) internal control over financial reporting as of December 31, 2010, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company'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 Annual 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 the 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 degree of compliance with the policies or procedures may deteriorate.

In our opinion, Cell Therapeutics, Inc. maintained, in all material aspects, effective internal control over financial reporting as of December 31, 2010, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheet as of December 31, 2010, and the related consolidated statements of operations, shareholders' deficit and comprehensive loss, and cash flows for the year then ended of Cell Therapeutics, Inc. and our report dated February 16, 2011 expressed an unqualified opinion with an explanatory paragraph as to the uncertainty regarding the Company's ability to continue as a going concern.

/s/ Marcum LLP

San Francisco, CA

February 16, 2011

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

	December 31, 2010	December 31, 2009
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 22,649	\$ 37,811
Prepaid expenses and other current assets	4,256	4,354
Total current assets	26,905	42,165
Property and equipment, net	3,426	3,430
Goodwill	17,064	17,064
Other assets	6,197	6,936
Total assets	\$ 53,592	\$ 69,595
<b>LIABILITIES AND SHAREHOLDERS' DEFICIT</b>		
Current liabilities:		
Accounts payable	\$ 6,037	\$ 7,297
Accrued expenses	11,008	14,807
Current portion of deferred revenue		80
Current portion of long-term obligations	1,717	1,312
7.5% convertible senior notes	10,215	
5.75% convertible senior notes	12,093	
4% convertible senior subordinated notes		40,363
Total current liabilities	41,070	63,859
Deferred revenue, less current portion		239
Long-term obligations, less current portion	4,206	1,861
7.5% convertible senior notes		10,102
5.75% convertible senior notes		11,677
Total liabilities	45,276	87,738
Commitments and contingencies		
Common stock purchase warrants	13,461	626
Shareholders' deficit:		
Common stock, no par value:		
Authorized shares 1,200,000,000		
Issued and outstanding shares 813,751,299 and 590,282,575 at December 31, 2010 and 2009, respectively	1,579,866	1,418,931
Accumulated other comprehensive loss	(7,969)	(8,412)
Accumulated deficit	(1,576,643)	(1,429,083)
Total CTI shareholders' deficit	(4,746)	(18,564)
Noncontrolling interest	(399)	(205)
Total shareholders' deficit	(5,145)	(18,769)
Total liabilities and shareholders' deficit	\$ 53,592	\$ 69,595

See accompanying notes.

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

	Year Ended December 31,		
	2010	2009	2008
Revenues:			
Product sales	\$	\$	\$ 11,352
License and contract revenue	319	80	80
Total revenues	319	80	11,432
Operating expenses, net:			
Cost of product sold			3,244
Research and development	27,031	30,179	51,614
Selling, general and administrative	48,043	57,725	41,607
Amortization of purchased intangibles			1,658
Restructuring charges and related gain on sale of assets, net		3,979	
Gain on sale of Zevalin			(9,444)
Gain on sale of investment in joint venture		(10,244)	
Acquired in-process research and development			36
Total operating expenses, net	75,074	81,639	88,715
Loss from operations	(74,755)	(81,559)	(77,283)
Other income (expense):			
Investment and other income, net	1,221	133	549
Interest expense	(2,334)	(4,806)	(8,559)
Amortization of debt discount and issuance costs	(768)	(5,788)	(66,530)
Foreign exchange gain (loss)	(521)	33	3,637
Debt conversion expense	(2,031)		
Provision for VAT Assessments	(3,503)		
Make-whole interest expense		(6,345)	(70,243)
Gain on derivative liabilities, net		7,218	69,739
Gain (loss) on exchange of convertible notes		7,381	(25,103)
Equity loss from investment in joint venture		(1,204)	(123)
Milestone modification expense		(6,000)	
Settlement expense	(145)	(4,710)	(3,393)
Write-off of financing arrangement costs			(2,846)
Other expense, net	(8,081)	(14,088)	(102,872)
Net loss before noncontrolling interest	(82,836)	(95,647)	(180,155)
Noncontrolling interest	194	252	126
Net loss attributable to CTI	(82,642)	(95,395)	(180,029)
Gain on restructuring of preferred stock		2,116	
Preferred stock dividends		(24)	(662)
Deemed dividends on preferred stock	(64,918)	(23,460)	(22,216)
Net loss attributable to common shareholders	\$ (147,560)	\$ (116,763)	\$ (202,907)



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Basic and diluted net loss per common share	\$	(0.22)	\$	(0.25)	\$	(7.00)
Shares used in calculation of basic and diluted net loss per common share		684,629		458,356		28,967

See accompanying notes.

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

(In thousands)

	Common Stock		Accumulated Deficit	Accumulated Other Comprehensive Income/(Loss)		Noncontrolling Interest	Total Shareholders' (Deficit)
	Shares	Amount					
Balance at December 31, 2007	6,244	\$ 979,295	\$ (1,109,413)	\$ (4,007)	\$	\$	\$ (134,125)
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
Noncontrolling interest		(126)					(126)
Other	8	(38)					(38)
Dividends on preferred stock			(662)				(662)
Deemed dividends on preferred stock			(22,216)				(22,216)
Comprehensive loss:							
Foreign currency translation loss				(3,801)			(3,801)
Unrealized losses on securities available-for-sale				(4)			(4)
Net loss for the year ended December 31, 2008			(180,029)				(180,029)
Comprehensive loss							(183,834)
Balance at December 31, 2008	186,412	\$ 1,188,071	\$ (1,312,320)	\$ (7,812)	\$	\$	\$ (132,061)

See accompanying notes.

**Table of Contents****CELL THERAPEUTICS, INC.****CONSOLIDATED STATEMENTS OF SHAREHOLDERS' DEFICIT AND COMPREHENSIVE LOSS (Continued)**

(In thousands)

	Common Stock			Accumulated			Total
				Other			Shareholders'
	Shares	Amount	Accumulated	Comprehensive	Noncontrolling		(Deficit)
			Deficit	Income/(Loss)	Interest		
Issuance of common stock and warrants	49,732	59,233					59,233
Conversion of 10% convertible senior notes due 2011 to common stock	131,387	18,000					18,000
Conversion of 9% convertible senior notes to common stock	372	5,250					5,250
Conversion of Series F preferred stock to common stock	47,871	3,866					3,866
Issuance and conversion of Series 1 preferred stock to common stock	66,667	18,537					18,537
Issuance and conversion of Series 2 preferred stock to common stock	18,853	27,796					27,796
Value of beneficial conversion features related to Series 1 and 2 preferred stock		13,194					13,194
Issuance of warrants in connection with Series 2 preferred stock		6,138					6,138
Exercise of Class A warrants	9,184	5,222					5,222
Exercise of Class B warrants	10,378	5,732					5,732
Issuance of common stock in exchange for convertible notes	27,535	39,523					39,523
Issuance of common stock in connection with Series A preferred stock settlement	4,000	509					509
Issuance of common stock in exchange for milestone modification	5,607	6,000					6,000
Conversion or exchange of Series A, B and D convertible preferred stock to common stock	3,786	4,288					4,288
Reacquisition of BCF in connection with exchange of Series A, B and C convertible preferred stock for Series F preferred stock		(961)					(961)
Equity-based compensation	33,821	24,937					24,937
Repurchase of shares in connection with taxes on restricted stock vesting	(5,364)	(6,394)					(6,394)
Employee stock purchase plan	42	36					36
Noncontrolling interest		(47)			(205)		(252)
Dividends on preferred stock		1	(24)				(23)
Gain on restructuring of preferred stock			2,116				2,116
Deemed dividends on preferred stock			(23,460)				(23,460)
Comprehensive loss:							
Foreign currency translation loss				(601)			(601)
Unrealized gains on securities available-for-sale				1			1
Net loss for the year ended December 31, 2009			(95,395)				(95,395)
Comprehensive loss							(95,995)
Balance at December 31, 2009	590,283	\$ 1,418,931	\$ (1,429,083)	\$ (8,412)	\$ (205)	\$	(18,769)
Issuance and conversion of Series 3 preferred stock to common stock	24,690	27,761					27,761
Issuance and conversion of Series 4 preferred stock to common stock	40,000	18,621					18,621
Issuance and conversion of Series 5 preferred stock to common stock	52,500	19,464					19,464
	11,600	2,970					2,970

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Issuance and conversion of Series 6 preferred stock to common stock

Issuance and conversion of Series 7 preferred stock to common stock	56,757	19,273	19,273
Value of beneficial conversion features related to preferred stock		39,923	39,923
Issuance of warrants in connection with preferred stock		12,741	12,741
Issuance of common stock in exchange for convertible notes	4,303	3,879	3,879
Exercise of common stock purchase warrants	507	177	177
Equity-based compensation	34,639	17,048	17,048
Repurchase of shares in connection with taxes on restricted stock vesting	(1,570)	(932)	(932)
Employee stock purchase plan	42	10	10
Noncontrolling interest		(194)	(194)
Deemed dividends on preferred stock		(64,918)	(64,918)
Comprehensive loss:			
Foreign currency translation gain		301	301
Unrealized gains on securities available-for-sale		142	142
Net loss for the year ended December 31, 2010		(82,642)	(82,642)

Comprehensive loss			(82,199)
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Balance at December 31, 2010	813,751	\$ 1,579,866	\$ (1,576,643)	\$ (7,969)	\$ (399)	\$ (5,145)
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See accompanying notes.

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

(In thousands)

	Year Ended December 31,		
	2010	2009	2008
<b>Operating activities</b>			
Net loss	\$ (82,642)	\$ (95,395)	\$ (180,029)
Adjustments to reconcile net loss to net cash used in operating activities:			
Non-cash interest expense	768	5,788	66,530
Non-cash gain on derivative liabilities		(7,218)	(69,739)
Non-cash milestone modification expense		6,000	
Gain on disposition of Zevalin to joint venture			(9,444)
Gain on sale of equity investment in joint venture		(10,244)	
(Gain) loss on exchange of convertible notes		(7,381)	25,103
Debt conversion expense	2,031		
Depreciation and amortization	1,842	1,771	5,228
Equity-based compensation expense	17,048	24,937	3,995
Provision for VAT Assessment	3,503		
Equity loss from investment in joint venture		1,204	123
Noncontrolling interest	(194)	(252)	
Other	(450)	(487)	(193)
Changes in operating assets and liabilities:			
Restricted cash		6,640	71,608
Accounts receivable, net		991	(895)
Inventory			291
Prepaid expenses and other current assets	516	(2,649)	1,438
Other assets	(381)	519	2,801
Accounts payable	(1,403)	(1,484)	2,786
Accrued expenses	(3,787)	(10,750)	779
Other liabilities	21	(176)	(589)
Total adjustments	19,514	7,209	99,822
Net cash used in operating activities	(63,128)	(88,186)	(80,207)
<b>Investing activities</b>			
Purchases of securities available-for-sale	(350)		(10,721)
Proceeds from sales of securities available-for-sale			11,550
Proceeds from maturities of securities available-for-sale		600	1,074
Purchases of property and equipment	(2,011)	(1,478)	(1,907)
Proceeds from sales of property and equipment	85	887	
Cash paid for acquisition of Zevalin			(542)
Cash received for disposition of Zevalin to joint venture, net		6,844	6,754
Investment in joint venture			(1,800)
Proceeds received from sale of investment in joint venture, net		14,987	
Net cash provided by (used in) investing activities	(2,276)	21,840	4,408

See accompanying notes.



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

	<b>Year Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
<b>Financing activities</b>			
Proceeds from issuance of Series 1 preferred stock and warrants, net of issuance costs		18,745	
Proceeds from issuance of Series 2 preferred stock and warrants, net of issuance costs		28,430	
Proceeds from issuance of Series 3 preferred stock and warrants, net of issuance costs	27,951		
Proceeds from issuance of Series 4 preferred stock and warrants, net of issuance costs	18,621		
Proceeds from issuance of Series 5 preferred stock and warrants, net of issuance costs	19,704		
Proceeds from issuance of Series 6 preferred stock and warrants, net of issuance costs	3,038		
Proceeds from issuance of Series 7 preferred stock and warrants, net of issuance costs	19,851		
Proceeds from issuance of common stock and warrants, net of issuance costs		59,233	5,080
Proceeds from exercise of Class A warrants		3,765	
Proceeds from exercise of Class B warrants		4,255	
Repayment of 4% convertible senior subordinated notes	(38,515)		
Cash paid for the exchange of convertible notes, net of transaction costs		(9,965)	
Cash paid for the repurchase of shares in connection with taxes on restricted stock vesting	(932)	(6,394)	
Payment of deemed dividends on conversion of preferred stock		(3,000)	(18,149)
Proceeds from issuance of 9% convertible senior notes, net of issuance costs			49,317
Restricted cash from issuance of 9% convertible senior notes			(13,947)
Proceeds from issuance of 13.5% convertible senior notes and Series E preferred stock, net of exchange of 9% convertible senior notes and issuance costs			56,069
Restricted cash from issuance of 13.5% convertible senior notes			(36,456)
Release of restricted cash in connection with exchange of 9% convertible senior notes			1,420
Proceeds from issuance of 15% convertible senior notes, net of issuance costs			21,794
Restricted cash from issuance of 15% convertible senior notes			(10,350)
Proceeds from issuance of 18.33% convertible senior notes, net of repurchase of 13.5% convertible senior notes and issuance costs			26,226
Restricted cash from issuance of 18.33% convertible senior notes			(24,471)
Release of restricted cash in connection with repurchase of 13.5% convertible senior notes			6,525
Proceeds from issuance of 10% convertible senior notes due 2012, net of issuance costs			8,635
Restricted cash from issuance of 10% convertible senior notes due 2012			(3,600)
Proceeds from issuance of 15.5% convertible senior note, net of issuance costs			13,863
Restricted cash from issuance of 15.5% convertible senior notes			(8,811)
Proceeds from issuance of 9.66% convertible senior notes, net of repurchase of 15% convertible senior notes and issuance costs			6,053
Restricted cash from issuance of 9.66% convertible senior notes			(7,158)
Proceeds from issuance of 10% convertible senior notes due 2011, net of repurchase of 9.66%, 15% and 18.33% convertible senior notes and issuance costs			3,252
Restricted cash from issuance of 10% convertible senior notes due 2011			(9,795)
Release of restricted cash in connection with repurchase of 9.66% convertible senior notes			2,553
Release of restricted cash in connection with repurchase of 15% convertible senior notes			10,043
Release of restricted cash in connection with repurchase of 18.33% convertible senior notes			8,224
Repayment of 5.75% convertible subordinated and senior subordinated notes			(10,724)
Transaction costs related to exchange of convertible subordinated and senior subordinated notes			(304)
Payment of additional offering costs related to December 2007 issuance of common stock and warrants			(473)
Payment of dividends on preferred stock		(111)	(708)
Other	4	(183)	(382)
Net cash provided by financing activities	49,722	94,775	73,726



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Effect of exchange rate changes on cash and cash equivalents	520	(690)	(3,653)
Net increase (decrease) in cash and cash equivalents	(15,162)	27,739	(5,726)
Cash and cash equivalents at beginning of year	37,811	10,072	15,798
Cash and cash equivalents at end of year	\$ 22,649	\$ 37,811	\$ 10,072

See accompanying notes.

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

	<b>Year Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
<b>Supplemental disclosure of cash flow information</b>			
Cash paid during the period for interest	\$ 3,137	\$ 12,047	\$ 77,499
Cash paid for taxes	\$	\$	\$
<b>Supplemental disclosure of noncash financing and investing activities</b>			
Conversion of Series 1 preferred stock to common stock	\$	\$ 18,537	\$
Conversion of Series 2 preferred stock to common stock	\$	\$ 27,796	\$
Conversion of Series 3 preferred stock to common stock	\$ 27,761	\$	\$
Conversion of Series 4 preferred stock to common stock	\$ 18,621	\$	\$
Conversion of Series 5 preferred stock to common stock	\$ 19,464	\$	\$
Conversion of Series 6 preferred stock to common stock	\$ 2,970	\$	\$
Conversion of Series 7 preferred stock to common stock	\$ 19,273	\$	\$
Conversion of Series A 3% convertible preferred stock to common stock	\$	\$	\$ 4,771
Conversion of Series B 3% convertible preferred stock to common stock	\$	\$ 2,317	\$ 7,850
Conversion of Series C 3% convertible preferred stock to common stock	\$	\$	\$ 3,008
Conversion of Series D 7% convertible preferred stock to common stock	\$	\$	\$ 2,203
Conversion of Series E 13.5% convertible preferred stock to 13.5% convertible senior notes	\$	\$	\$ 9,118
Conversion of Series F preferred stock to common stock	\$	\$ 3,866	\$
Conversion of 18.33% convertible senior notes to common stock	\$	\$	\$ 28,250
Conversion of 15.5% convertible senior notes to common stock	\$	\$	\$ 14,211
Conversion of 13.5% convertible senior notes to common stock	\$	\$	\$ 27,600
Conversion of 10% convertible senior notes due 2012 to common stock	\$	\$	\$ 9,000
Conversion of 10% convertible senior notes due 2011 to common stock	\$	\$ 18,000	\$ 14,651
Conversion of 9.66% convertible senior notes to common stock	\$	\$	\$ 15,700

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Conversion of 9% convertible senior notes to common stock	\$	\$ 5,250	\$ 40,820
Conversion of 5.75% convertible senior notes to common stock	\$	\$	\$ 250
Exchange of Series A 3% convertible preferred stock for Series F preferred stock	\$	\$ 151	\$
Exchange of Series B 3% convertible preferred stock for Series F preferred stock	\$	\$ 1,713	\$
Exchange of Series C 3% convertible preferred stock for Series F preferred stock	\$	\$ 3,221	\$
Exchange of 4% convertible senior subordinated notes for common stock	\$ 1,848	\$	\$
Issuance of Series F preferred stock for Series A, B and C convertible preferred stock	\$	\$ 3,931	\$
Issuance of common stock in exchange for 5.75% convertible senior subordinated and convertible subordinated notes	\$	\$	\$ 11,437
Issuance of common stock in exchange for Series A 3% convertible preferred stock	\$	\$ 688	\$
Issuance of common stock in exchange for Series D 7% convertible preferred stock	\$	\$ 1,793	\$
Issuance of common stock in exchange for convertible notes	\$	\$ 35,193	\$
Issuance of common stock in exchange for milestone modification	\$	\$ 6,000	\$
Extinguishment of 5.75% convertible senior subordinated notes in exchange for common stock	\$	\$	\$ 8,943
Extinguishment of 5.75% convertible subordinated notes in exchange for common stock	\$	\$	\$ 150

See accompanying notes.

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### **CELL THERAPEUTICS, INC.**

#### **NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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

###### *Description of Business*

Cell Therapeutics, Inc., or CTI or the Company, focuses on the development, acquisition and commercialization of drugs for the treatment of cancer. Our principal business strategy is focused on cancer therapeutics, an area with significant market opportunity that we believe is not adequately served by existing therapies. Subsequent to the closure of our Bresso, Italy operations in September 2009, our operations are now conducted primarily in the United States. During 2008, we had one approved drug generating product sales, Zevalin® (ibritumomab tiuxetan), or Zevalin, which we acquired in 2007. We contributed Zevalin to a joint venture, RIT Oncology, LLC, or RIT Oncology, upon its formation in December 2008 and in March 2009 we finalized the sale of our 50% interest in RIT Oncology to the other member, Spectrum Pharmaceuticals, Inc., or Spectrum. All of our other product candidates, including Pixuvri, OPAXIO™, brostallicin and bisplatinates are under development.

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

###### *Principles of Consolidation*

The consolidated financial statements include the accounts of CTI and its wholly owned subsidiaries, which include Systems Medicine LLC, or SM, CTI Commercial LLC (from the date of formation in July 2008), CTI Life Sciences Limited (from the date of formation in March 2009) and Cell Therapeutics Inc. Sede Secondaria, or CTI (Europe), which is a branch of the Company; however, we ceased operations related to this branch in September 2009. In addition, CTI Corporate Development, Inc. was included in the consolidated financial statements until liquidation in the fourth quarter of 2009.

As of December 31, 2010, we also had a 69% interest in our majority owned subsidiary, Aequus Biopharma, Inc. In accordance with the Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, 810, *Consolidation*, noncontrolling interest in Aequus (previously shown as minority interest) is reported below net loss in *noncontrolling interest* in the consolidated income statement and shown as a component of equity in the consolidated balance sheet.

Additionally, we held a 50% interest in RIT Oncology from the date of its formation in December 2008 to the sale of our interest in March 2009, which we accounted for using the equity method of accounting.

All intercompany transactions and balances are eliminated in consolidation.

###### *Reverse Stock-Split*

We effected a one-for-ten and one-for-four reverse stock split of our common stock on August 31, 2008 and April 15, 2007, respectively. All impacted amounts included in the consolidated financial statements and notes thereto have been retroactively adjusted for the stock splits. Impacted amounts include shares of common stock authorized and outstanding, share issuances, shares underlying preferred stock, convertible notes, warrants and stock options, shares reserved and loss per share.

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### *Liquidity*

Our accompanying consolidated financial statements have been prepared assuming that we will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business for the twelve month period following the date of these consolidated financial statements. However, we have incurred losses since inception and unless we receive FDA or EMA approval for Pixuvri, we expect to generate losses from operations for at least the next couple of years due to research and development costs for Pixuvri, OPAXIO and brostallicin.

Our available *cash and cash equivalents* are \$22.6 million as of December 31, 2010. As of December 31, 2010, we had a working capital deficit of \$14.2 million, including \$10.3 million and \$10.9 million outstanding principal balance related to our 7.5% and 5.75% convertible senior notes, respectively, which are due within the next 12 months. Subsequent to December 31, 2010, we raised \$25.0 million in gross proceeds in connection with the issuance of our Series 8 preferred stock in January 2011 as discussed in Note 22, *Subsequent Events*. We do not expect that we will have sufficient cash to fund our planned operations through the second quarter of 2011, which raises substantial doubt about our ability to continue as a going concern.

We have achieved cost saving initiatives to reduce operating expenses, including the reduction of employees related to planned commercial Pixuvri operations and we continue to seek additional areas for cost reductions. However, we will also need to raise additional funds and are currently exploring alternative sources of equity or debt financing. We may seek to raise such capital through public or private equity financings, partnerships, joint ventures, disposition of assets, debt financings or restructurings, bank borrowings or other sources. However, we have a limited number of authorized shares of common stock available for issuance and additional funding may not be available on favorable terms or at all. If additional funds are raised by issuing equity securities, substantial dilution to existing shareholders may result. If we fail to obtain additional capital when needed, we may be required to delay, scale back, or eliminate some or all of our research and development programs. The accompanying consolidated financial statements do not include any adjustments that may result from the outcome of this uncertainty.

### *Use of Estimates*

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

### *Certain Risks and Concentrations*

We are exposed to risks associated with foreign currency transactions to use U.S. dollars to make contract payments denominated in euros or vice versa. As the net positions of our unhedged foreign currency transactions fluctuate, our earnings might be negatively affected. In addition, the reported carrying value of our euro-denominated assets and liabilities that remain in our Bresso branch will be affected by fluctuations in the value of the U.S. dollar as compared to the euro. We currently do not utilize forward exchange contracts or any type of hedging instruments to hedge foreign exchange risk as we believe our overall exposure is relatively limited.

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

Additionally, see Note 16, *Customer and Geographic Concentrations*, for further concentration disclosure.

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### *Cash and Cash Equivalents*

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

### *Value Added Tax Receivable*

Our European operations were subject to a value added tax, or VAT, which is usually applied to all goods and services purchased and sold throughout Europe. The VAT receivable is approximately \$5.3 million and \$6.3 million as of December 31, 2010 and 2009, of which \$5.2 million and \$5.9 million is included in *other assets* and \$0.1 million and \$0.4 million is included in *prepaid expenses and other current assets* as of December 31, 2010 and 2009, respectively. This receivable balance relates to our Italian operations and typically has a three year collection period. We review our VAT receivable balance for impairment whenever events or changes in circumstances indicate the carrying amount might not be recoverable.

### *Property and Equipment*

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

### *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.

### *Goodwill*

Goodwill represents the excess, at the date of acquisition, of the purchase price of a business acquired over the fair value of the net tangible and intangible assets acquired. Goodwill is not amortized, but is tested for impairment at least annually using a fair-value based, two-step test. An impairment analysis is done more frequently if certain events or circumstances arise that would indicate a change in fair value of the non-financial asset occurred (i.e., an impairment indicator).

We conducted our annual impairment test and concluded that the fair value of our single reporting unit exceeded the carrying value of our net assets (i.e. step one of the impairment test) for the years ended December 31, 2010, 2009 and 2008.

### *Other Financial Instruments*

At December 31, 2010 and 2009, the carrying value of financial instruments such as receivables and payables approximated their fair values based on the short-term maturities of these instruments. The carrying value of other long-term liabilities approximated fair values because the underlying interest rates approximate market rates at the balance sheet dates.

The estimated fair values of our convertible notes are determined using a discounted cash flow modeling technique. The carrying values of our convertible notes are net of accretion of debt discount and changes in the fair value of derivative liabilities, if any.

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The following is a summary of the estimated fair value of our convertible notes as of December 31, 2010 and 2009 (in thousands):

	December 31,	
	2010	2009
7.5% convertible senior notes	\$ 10,035	\$ 9,138
5.75% convertible senior notes	\$ 9,774	\$ 8,777
4.0% convertible senior subordinated notes	\$	\$ 38,512

*Product Sales*

We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, title has passed and delivery has occurred, the price is fixed and determinable, and collectability is reasonably assured. Product sales are generally recorded upon shipment net of an allowance for estimated product returns and rebates. We analyze historical return patterns for our products in determining an appropriate estimate for returns allowance. We may need to adjust our estimates if actual results vary which could have an impact on our earnings in the period of adjustment. If customers have product acceptance rights or product return rights and we are unable to reasonably estimate returns related to that customer or market, we defer revenue recognition until such rights have expired. All product sales in 2008 consisted of sales of Zevalin prior to the disposition of Zevalin to RIT Oncology in December 2008. Following the transfer of Zevalin, we no longer have a direct ownership in any commercial products generating product sales revenue.

*Cost of Product Sold*

Cost of product sold consists of the cost of the product sold to our customers, including any necessary allowances for excess inventory that may expire and become unsaleable. Prior to the transfer of Zevalin assets to RIT Oncology in December 2008, we purchased Zevalin from Biogen Idec Inc., or Biogen, pursuant to a supply agreement entered into in connection with the acquisition of this product. Contractual royalties based on product sales are also included in cost of product sold.

*Research and Development Expenses*

Research and development expenses include related salaries and benefits, clinical trial and related manufacturing costs, contract and other outside service fees, and facilities and overhead costs related to our research and development efforts. Research and development expenses also consist of costs incurred for proprietary and collaboration research and development and include activities such as product registries and investigator-sponsored trials. Research and development costs are expensed as incurred. In instances where we enter into agreements with third parties for research and development activities we may prepay fees for services at the initiation of the contract. We record the prepayment as a prepaid asset and amortize the asset into research and development expense over the period of time the contracted research and development services are performed. Other types of arrangements with third parties may be fixed fee or fee for service, and may include monthly payments or payments upon the completion of milestones or receipt of deliverables.

*Advertising Costs*

The costs of advertising are expensed as incurred. We incurred advertising costs of \$0.9 million, \$1.0 million and \$0.8 million in 2010, 2009 and 2008, respectively.

*Derivatives Embedded in Certain Debt Securities*

Derivative instruments are recorded at fair value with changes in value recognized in the statement of operations in the period of change.

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Certain of our convertible senior notes include a feature that calls for make-whole payments upon conversion of these notes. 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.

We have calculated the fair value of the derivatives related to our convertible notes using either a Monte Carlo simulation model or a discounted cash flow model. Changes in the estimated fair value of the derivative liabilities related to the convertible senior notes are included in *gain on derivative liabilities, net* and are remeasured at the end of each reporting period until the relevant feature expires or all of the relevant notes are converted or repurchased.

### *Foreign Currency Translation and Transaction Gains and Losses*

We record foreign currency translation adjustments and transaction gains and losses in accordance with ASC 830, *Foreign Currency Matters*. For our operations that have a functional currency other than the U.S. dollar, gains and losses resulting from the translation of the functional currency into U.S. dollars for financial statement presentation are not included in determining net loss, but are accumulated in the cumulative foreign currency translation adjustment account as a separate component of shareholders' deficit. We and our subsidiaries also have transactions in foreign currencies other than the functional currency. We record transaction gains and losses in our consolidated statements of income related to the recurring measurement and settlement of such transactions.

### *Income Taxes*

We record a tax provision for the anticipated tax consequences of our reported results of operations. The provision for income taxes is computed using the asset and liability method, under which deferred tax assets and liabilities are recognized for the expected future tax consequences of temporary differences between the financial reporting and tax base of assets and liabilities, and for operating losses and tax credit carryforwards. Deferred tax assets and liabilities are measured using the currently enacted tax rates that apply to taxable income in effect for the years in which those tax assets are expected to be realized or settled. We record a valuation allowance to reduce deferred tax assets to the amount that is more likely than not to be realized.

### *Net Loss per Share*

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

### *Recently Adopted Accounting Standards*

In February 2010, the FASB issued amended guidance on subsequent events to alleviate potential conflicts between FASB guidance and SEC requirements. Under this amended guidance, SEC filers are no longer required to disclose the date through which subsequent events have been evaluated in originally issued and revised financial statements. This guidance was effective immediately and we adopted these new requirements during the first quarter of 2010. The adoption of this guidance did not have a material impact on our consolidated financial statements.

### *Recently Issued Accounting Standards*

In April 2010, the FASB issued guidance on the milestone method for revenue recognition purposes. Previously, definitive guidance on when the use of the milestone method was appropriate did not exist. This



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guidance provides a framework of the criteria that should be met for determining whether the milestone method of revenue recognition is appropriate. This guidance is effective on a prospective basis for milestones achieved in fiscal years and interim periods within those years, beginning on or after June 15, 2010 with early adoption permitted. We do not anticipate the adoption of this guidance will have a material impact on our consolidated financial statements.

In December 2010, the FASB issued additional guidance on when to perform Step 2 of the goodwill impairment test for reporting units with zero or negative carrying amounts. The criteria for evaluating Step 1 of the goodwill impairment test and proceeding to Step 2 were amended for reporting units with zero or negative carrying amounts and requires performing Step 2 if qualitative factors indicate that it is more likely than not that a goodwill impairment exists. For public entities, this guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2010. Upon adoption of the amended guidance, any impairment will be recorded as an adjustment to beginning retained earnings. We are currently evaluating the impact of the pending adoption on our consolidated financial statements.

*Reclassifications*

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

**2. Comprehensive Loss**

Comprehensive loss is comprised of net loss and other comprehensive income or loss. Our other comprehensive income or loss includes unrealized gains and losses on our securities available-for-sale and net exchange gains or losses resulting from the translation of assets and liabilities of foreign subsidiaries. Total comprehensive loss consisted of the following (in thousands):

	2010	2009	2008
Net loss before noncontrolling interest	\$ (82,836)	\$ (95,647)	\$ (180,155)
Foreign currency translation gain (loss)	301	(601)	(3,801)
Net unrealized gain (loss) on securities available-for-sale	142	1	(4)
Comprehensive loss before noncontrolling interest	(82,393)	(96,247)	(183,960)
Noncontrolling interest	194	252	126
Comprehensive loss attributable to CTI	\$ (82,199)	\$ (95,995)	\$ (183,834)

Information regarding the components of accumulated other comprehensive loss as of December 31, 2010 and 2009 is as follows (in thousands):

	2010	2009
Foreign currency translation adjustment	\$ (8,111)	\$ (8,412)
Net unrealized gain on securities available-for-sale	142	
Total accumulated other comprehensive loss	\$ (7,969)	\$ (8,412)

**Table of Contents****3. Property and Equipment**

Property and equipment are composed of the following as of December 31, 2010 and 2009 (in thousands):

	2010	2009
Furniture and office equipment	\$ 13,137	\$ 11,970
Leasehold improvements	2,931	3,277
Lab equipment	464	560
	16,532	15,807
Less: accumulated depreciation and amortization	(13,106)	(12,377)
	\$ 3,426	\$ 3,430

Depreciation expense of \$1.8 million, \$1.8 million and \$3.5 million was recognized during 2010, 2009, and 2008, respectively.

**4. Accrued Liabilities**

Accrued liabilities consist of the following as of December 31, 2010 and 2009 (in thousands):

	2010	2009
Clinical and investigator-sponsored trial expense	\$ 4,554	\$ 5,560
Employee compensation and related expenses	3,386	4,113
Insurance financing and accrued interest expense	218	1,031
Legal expense	949	805
Manufacturing expense	776	651
Royalty and rebate expense		9
Other	1,125	2,638
	\$ 11,008	\$ 14,807

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

We lease our office space under operating leases. The related rent expenses for our leases are recognized on a straight-line basis over the term of the respective lease. In connection with a lease agreement, we have a \$0.7 million irrevocable, unconditional standby letter of credit which is secured by a certificate of deposit classified in our consolidated balance sheet in *other assets* as of December 31, 2010 and 2009. In 2010, we recorded a liability of \$1.5 million for excess facilities under an operating lease upon vacating a portion of our corporate office space. The related charge for excess facilities was recorded as a component of rent expense, which is included in *research and development* and *selling, general and administrative expenses* in 2010. As of December 31, 2010, \$1.4 million remained accrued for excess facilities charges, of which \$0.9 million was included in *current portion of long-term obligations* and \$0.5 million was included in *long-term obligations, less current portion*. Rent expense amounted to \$3.9 million, \$3.4 million and \$4.6 million for the years ended December 31, 2010, 2009 and 2008, respectively. Rent expense is net of sublease income and amounts offset to excess facilities charges.



**Table of Contents****Future Minimum Lease Payments**

Future minimum lease commitments for non-cancelable operating leases at December 31, 2010 are as follows (in thousands):

	<b>Operating Leases</b>
2011	\$ 3,878
2012	2,323
2013	230
2014	84
2015	
Thereafter	
<b>Total minimum lease commitments</b>	<b>\$ 6,515</b>

**6. Restructuring Activities*****Italian Operations***

In September 2009, we closed our Bresso, Italy operations. These operations were used primarily for preclinical research and were underutilized due to our current business model, which is focused on the development of late-stage compounds and their commercialization. We have recorded restructuring charges related to this closure as discussed further below in accordance with ASC 420.

In May 2009, we entered into a severance agreement with the employee unions representing the employees of the Italian branch of CTI that primarily worked in the area of preclinical research and early development. This severance agreement relates to a reduction in force of 56 positions and the closure of our Bresso, Italy operations. Employee separation costs associated with the reduction in force primarily related to severance payments that were initially scheduled to be made over 42 months, with the majority of these payments made through the first 15 months. In June 2010, we made a lump sum payment to satisfy all outstanding obligations under the employee severance agreement. In addition, we have entered into separate severance or termination agreements with all of our Bresso-based scientific directors. All severance payments to our scientific directors were made during 2010.

For the year ended December 31, 2009, we recorded \$2.6 million in employee termination benefits related to these Bresso-based employees and directors. Additionally, we had certain contract termination and clean-up charges related to the closure of the laboratories located in Bresso, Italy. For the year ended December 31, 2009, we recorded \$1.5 million for these charges which was paid during 2009. We also had certain laboratory equipment from the Bresso facility that we sold in connection with the closure of the facility. We recognized a \$0.3 million gain on the sale of these assets. All amounts were included in *restructuring charges and related gain on sale of assets, net* for the year ended December 31, 2009. While we cannot predict additional amounts, if any, we do not expect to have material adjustments to this expense.

The following table summarizes the changes in the liability for restructuring activities during the year ended December 31, 2010 (in thousands):

	<b>Employee Termination Costs</b>
Balance at December 31, 2009	\$ 1,531
Foreign currency adjustments	(183)
Cash payments	(1,348)
 Balance at December 31, 2010	 \$



**Table of Contents***2005 Restructuring*

During 2005, we reduced our workforce in the United States and Europe. In conjunction with this reduction in force, we vacated a portion of our laboratory and office facilities and recorded excess facilities charges. Charges for excess facilities relate to our lease obligation for excess laboratory and office space in the United States that we vacated as a result of the restructuring plan. We recorded these restructuring charges when we ceased using this space. As of December 31, 2010 we had \$0.6 million accrued related to excess facilities charges, of which \$0.4 million was included in *current portion of long-term obligations* and \$0.2 million of which was included in *long-term obligations, less current portion*. We will periodically evaluate our existing needs, the current and estimated future values of our subleases, and other future commitments to determine whether we should record additional excess facilities charges or adjustments to such charges.

The following table summarizes the changes in the liability for our 2005 restructuring activities during the years ended December 31, 2010 and 2009 (in thousands):

	<b>Excess Facilities Liability</b>
Balance at January 1, 2009	\$ 1,128
Adjustments	96
Payments	(370)
Balance at December 31, 2009	854
Adjustments	71
Payments	(375)
Balance at December 31, 2010	\$ 550

**7. Formation of Joint Venture**

In December 2008, we closed our transaction with Spectrum to form a 50/50 owned joint venture, RIT Oncology, to commercialize and develop Zevalin in the United States. We originally acquired the U.S. rights to develop, market and sell Zevalin from Biogen Idec Inc., or Biogen, in December 2007. At the closing of the joint venture transaction, we contributed to RIT Oncology 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 as well as up to \$15.0 million in product sales milestone payments upon RIT Oncology's achievement of certain revenue targets. RIT Oncology also assumed from us all future liabilities and contingent milestone payments related to Zevalin. Also at closing, RIT Oncology 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, and we made an initial \$1.8 million cash capital contribution. Due to the fact that we received cash for the assets contributed, in 2008 we recorded a one-time *gain on sale of Zevalin* of \$9.4 million, based on the difference between the book value of our assets contributed and the fair value of these assets as recorded under the joint venture, net of transaction costs.

Under the terms of the amended and restated operating agreement for RIT Oncology, we held, among other rights, a sale option exercisable in our sole discretion to sell all of our membership interest in RIT Oncology to Spectrum for \$18.0 million, subject to adjustments for any amounts owed between us and RIT Oncology at the time of such sale. In February 2009, we exercised this sale option and we completed the sale of our 50% interest in March 2009 for a renegotiated amount of \$16.5 million. In addition, we agreed to forego our right to receive up to \$15.0 million in product sales milestone payments. In connection with the sale we recorded a \$10.2 million one-time *gain on sale of investment in joint venture* in 2009. This amount was based on the difference between the \$16.5 million in gross proceeds and the \$4.6 million book value of our investment in RIT Oncology at the time of sale. The amount is also net of \$1.6 million in transaction costs, which includes a \$0.8 million consent fee to Biogen for the assignment to Spectrum of our security agreement and guarantee with Biogen.

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Of the \$16.5 million in gross proceeds, we received an initial payment of \$6.5 million and an additional \$6.5 million in April 2009. The remaining \$3.5 million, which was subject to adjustments as discussed above, was not released to us based on the outcome of an arbitration proceeding. In May 2009, the arbitrator ordered that the final installment of \$3.5 million be released from the escrow account and distributed to Spectrum. Additionally, we were ordered to pay \$0.8 million to Spectrum. For the year ended December 31, 2009, we recorded \$3.2 million in *settlement expense* related to the arbitrator's decision. This amount includes the escrow amount released to Spectrum, our payment to Spectrum and \$0.9 million in receivables that we recognized in prior periods and were owed to us by RIT Oncology. The settlement amount is also net of \$2.0 million in payables assumed by Spectrum on our behalf as a result of the arbitration proceeding.

### **8. Long-term Obligations**

#### *Series B Unit Warrant Liability*

As described in Note 9, *Convertible Notes*, a Series B Unit Warrant, or B Unit Warrant, was issued with our 13.5% notes and other financial instruments in April 2008. At issuance, the B Unit Warrant consisted of a warrant to purchase 67,500 units consisting of 12.5% convertible senior notes with an exercise price equal to \$1,000 per unit and additional warrants to purchase common stock at an exercise price of \$9.50 per share.

We determined that the B Unit Warrant was a liability instrument that is marked to fair value with changes in value recognized through earnings at each reporting period. At issuance, we estimated the fair value of the B Unit Warrant to be \$21.3 million.

In June 2008, we entered into an Amendment to the Securities Purchase Agreement and Series B Unit Warrant with the holder, which provided for an increase in the interest rate of the convertible notes issuable upon exercise of the B Unit Warrant from 12.5% to 15% and also required \$23.0 million of partial exercise of the B Unit Warrant. The amendment constituted a modification of terms and accordingly, the increase of \$2.3 million in the fair value of the B Unit Warrant was expensed in the current period and is included in *gain on derivative liabilities, net* for the year ended December 31, 2008. Subsequent to the modification, \$23.0 million of the B Unit Warrant was exercised by the holder, resulting in the issuance of \$23.0 million aggregate principal amount of our 15% notes and additional warrants to purchase 1.5 million shares of common stock at an exercise price of \$9.50 per share. The exercise of the B Unit Warrant resulted in a premium to our 15% notes of \$3.8 million, which was recorded in equity.

In July 2008, we entered into a Second Amendment of Securities Purchase Agreement and Series B Unit Purchase Warrant, or Second Amendment, with the holder, which provided for an increase in the interest rate of the convertible notes issuable upon exercise of the B Unit Warrant from 15% to 18.33%. In addition, the July 2008 amendment also amended the exercise price of the warrants to purchase common stock issued in connection with the 13.5% notes and certain of the warrants to purchase common stock underlying the B Unit Warrant from \$9.50 per share to \$7.90 per share. The B Unit Warrant was also amended to increase its aggregate exercise price from \$67.5 million to \$112 million and to require the partial exercise in two closings of equal amounts of \$22.25 million in July and August 2008. The remaining \$44.5 million in aggregate exercise price could only be exercised by mutual agreement of the holder and us and was contingent on the satisfaction of certain regulatory requirements.

The modifications resulting from the Second Amendment also constituted a modification of terms and resulted in an increase to the fair value of the B Unit Warrant of \$6.1 million which was expensed during the current period and is included in *gain on derivative liabilities, net* for the year ended December 31, 2008. These modifications were valued using Black-Scholes and Monte Carlo simulation models. The modification to the exercise price of the warrants to purchase common stock was valued using the Black Scholes option pricing model, which resulted in an increase to equity and additional discount to the notes of \$0.4 million.

The estimated fair value of the derivative liability was adjusted quarterly for changes in the estimated market value. As of December 31, 2008, the remaining B Unit Warrant was estimated to have a fair value of \$2.8

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million. The net change in the estimated fair value of the B Unit Warrant for the year ended December 31, 2009 and 2008 was a gain of \$2.8 million and \$7.3 million, respectively, and is included in *gain on derivative liabilities, net*. The B Unit Warrant expired in the second quarter of 2009.

### Long-term obligations

Long-term obligations consist of the following as of December 31, 2010 and 2009 (in thousands):

	2010	2009
Accrued rent	\$ 628	\$ 1,165
Excess facilities liability	1,960	854
Employee defined benefit plan (see Note 14, <i>Employee Benefit Plans</i> )		583
Italian Regional Production Tax	259	528
Reserve for VAT Assessments	3,042	
Other long-term obligations	34	43
	5,923	3,173
Less current portion	(1,717)	(1,312)
	\$ 4,206	\$ 1,861

As of December 31, 2010, maturities of the convertible senior notes, as discussed in Note 9, *Convertible Notes*, as well as other long-term obligations listed above, excluding our liability for excess facilities and reserve for VAT assessments, are as follows (in thousands):

### Years Ending December 31,

2011	\$ 21,595
2012	464
2013	12
2014	12
2015	
Thereafter	
	\$ 22,083

## 9. Convertible Notes

The following table summarizes the changes in the principal balances of our convertible notes during the years ended December 31, 2010, 2009 and 2008 (in thousands):

	Balance at January 1, 2010	Exchanged	Matured	Balance at December 31, 2010
7.5% convertible senior notes	\$ 10,250	\$	\$	\$ 10,250
5.75% convertible senior notes	10,913			10,913
4.0% convertible senior subordinated notes	40,363	(1,848)	(38,515)	
Total	\$ 61,526	\$ (1,848)	\$ (38,515)	\$ 21,163





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	Balance at January 1, 2009	Converted	Exchanged, Extinguished or Repurchased	Balance at December 31, 2009
10% convertible senior notes due 2011	\$ 18,000	\$ (18,000)	\$	\$
9% convertible senior notes	5,585	(5,250)	(335)	
7.5% convertible senior notes	33,458		(23,208)	10,250
6.75% convertible senior notes	7,000		(7,000)	
5.75% convertible senior notes	23,000		(12,087)	10,913
4.0% convertible senior subordinated notes	55,150		(14,787)	40,363
<b>Total</b>	<b>\$ 142,193</b>	<b>\$ (23,250)</b>	<b>\$ (57,417)</b>	<b>\$ 61,526</b>

	Balance at January 1, 2008	Issued	Converted	Exchanged, Extinguished or Repurchased	Matured	Balance at December 31, 2008
18.33% convertible senior notes	\$	\$ 44,500	\$ (28,250)	\$ (16,250)	\$	\$
15.5% convertible senior notes		14,211	(14,211)			
15% convertible senior notes		23,000		(23,000)		
13.5% convertible senior notes		45,118	(27,600)	(17,518)		
10% convertible senior notes due 2011		32,651	(14,651)			18,000
10% convertible senior notes due 2012		9,000	(9,000)			
9.66% convertible senior notes		24,700	(15,700)	(9,000)		
9% convertible senior notes		51,655	(40,820)	(5,250)		5,585
7.5% convertible senior notes	33,458					33,458
6.75% convertible senior notes	7,000					7,000
5.75% convertible senior notes	23,250		(250)			23,000
5.75% convertible senior subordinated notes	16,907			(8,943)	(7,964)	
5.75% convertible subordinated notes	2,910			(150)	(2,760)	
4.0% convertible senior subordinated notes	55,150					55,150
<b>Total</b>	<b>\$ 138,675</b>	<b>\$ 244,835</b>	<b>\$ (150,482)</b>	<b>\$ (80,111)</b>	<b>\$ (10,724)</b>	<b>\$ 142,193</b>

**Issuances and Exchanges of Convertible Notes***4% Notes Exchange for Common Stock*

In May 2010, we entered into exchange agreements with certain holders of our 4% convertible senior subordinated notes, or 4% Notes, pursuant to which we issued approximately 4.3 million shares of common stock, upon conversion of the 4% Notes as defined in ASC 470-20, *Debt with Conversion and Other Options*, in exchange for \$1.8 million aggregate outstanding principal amount of our 4% Notes. The transactions were accounted for as induced conversions since, for the purpose of ASC 470-20, the issuance of the common stock effectively resulted in the change to the conversion privileges provided in the terms of our 4% Notes at issuance. We recorded \$2.0 million in *debt conversion expense* for the year ended December 31, 2010. In May 2010, we delivered a notice of termination of the exchange agreements to each of the holders party to the exchange agreements.

*4% and 6.75% Notes Exchange for Common Stock*

In September 2009, we entered into an exchange agreement whereby \$3.0 million of our 4% Notes, \$1.5 million of our 6.75% convertible senior subordinated notes, or 6.75% Notes, and all accrued and unpaid interest

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related to these notes were exchanged for an aggregate of 3.3 million shares of our common stock. In connection with this exchange, we recorded a \$0.2 million *gain on exchange of convertible notes* for the year ended December 31, 2009 which is net of transaction costs of approximately \$25,000. This gain did not materially change the per share *net loss attributable to common shareholders*.

### Tender Offer

In June 2009, we completed exchange offers whereby we issued \$134.50 cash and 458 shares of common stock in exchange for each \$1,000 principal amount of convertible notes exchanged. The exchange offers were open to any and all of the \$118.9 million balance of our convertible notes outstanding prior to exchange and the following principal amounts for each series of convertible notes were exchanged (in thousands):

	Principal Amount Exchanged
4% convertible senior subordinated notes	\$ 11,787
5.75% convertible senior notes	12,087
6.75% convertible senior notes	5,500
7.5% convertible senior notes	23,208
9% convertible senior notes	335
Total principal amount exchanged	\$ 52,917

In connection with the exchanges of these notes, we issued a total of \$7.1 million in cash and 24.2 million shares of common stock and we recorded a \$7.2 million *gain on exchange of convertible notes* for the year ended December 31, 2009 which decreased our *net loss attributable to common shareholders* by \$0.02 per share. Total costs related to the transaction were \$2.8 million and were allocated on a pro rata basis between *common stock* and *gain on exchange of convertible notes* based on the cash and common stock consideration issued.

### 10% Notes Due 2011 Exchanged for 15%, 18.33% and 9.66% Notes

In December 2008, we issued \$32.7 million aggregate principal amount of our 10% convertible senior notes due 2011, or 10% Notes due 2011, under a securities purchase agreement, pursuant to which we also repurchased, for a total repurchase price of \$29.0 million, \$4.8 million, \$16.3 million and \$9.0 million principal amounts of our 15%, 18.33% and 9.66% Notes, respectively, as well as related warrants to purchase 5.2 million shares of common stock. We recorded a *loss on exchange of convertible notes* of \$3.7 million related to this exchange for the year ended December 31, 2008.

In connection with the repurchased notes, \$12.6 million of funds were released from the escrow account established to pay the make-whole and interest payments on the repurchased notes. In addition, \$9.8 million of the gross proceeds received was restricted and held in escrow to fund potential make-whole payments upon any conversion of the 10% Notes due 2011. The make-whole payments were equal to \$300 per \$1,000 principal amount of the notes so converted, less any interest paid on such notes prior to the conversion date.

At the issuance of the 10% Notes due 2011, we recorded a derivative liability related to the embedded features on the notes. For the years ended December 31, 2009 and 2008, we recorded a gain of \$4.4 million and \$0.8 million, respectively, related to the change in the fair value of this derivative liability which was included in *gain on derivative liabilities, net*.

### 9.66% Notes Exchanged for 15% Notes

In October 2008, we issued \$24.7 million aggregate principal amount of our 9.66% convertible senior notes, or 9.66% Notes, under a securities purchase agreement. Additionally, in connection with this issuance, we repurchased \$18.2 million of our 15% convertible senior notes, or 15% Notes, and related warrants to purchase 1.2 million shares of common stock. We recorded a *loss on exchange of convertible notes* of \$5.5 million related to this exchange for the year ended December 31, 2008.

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In connection with the repurchase of the 15% Notes, \$8.2 million was released to us from the escrow account established to pay make-whole and interest payments on the 15% Notes. In addition, \$7.2 million of the gross proceeds received from the issuance of the 9.66% Notes was placed into escrow to fund potential make-whole payments upon any conversion of these notes. The make-whole payments were equal to \$289.80 per \$1,000 principal amount of the notes so converted, less any interest paid on such notes prior to the conversion date.

At the issuance of the 9.66% Notes we recorded a derivative liability related to the embedded features on the notes. For the year ended December 31, 2008, we recorded a gain of \$0.3 million related to the change in the fair value of this derivative liability which was included in *gain on derivative liabilities, net*.

### *Issuance of 10% Notes Due 2012 and 15.5% Notes and Conversion of Series C Preferred Stock*

In September 2008, we issued \$9.0 million aggregate principal amount of our 10% convertible senior notes due 2012, or 10% Notes due 2012, under a securities purchase agreement. This agreement, as amended, also gave us the right, to require the holder of the 10% Notes due 2012 to purchase an additional \$14.2 million of 15.5% convertible senior notes, or 15.5% Notes, which were also issued in September 2008. Of the \$23.2 million in gross proceeds, \$3.6 million and \$8.8 million was placed into escrow to fund potential make-whole payments upon any conversion of the 10% Notes due 2012 and the 15.5% Notes, respectively. The make-whole payments related to the 10% Notes due 2012 and the 15.5% Notes were \$400 and \$620, respectively, per \$1,000 principal amount of the notes so converted, less any interest paid on such notes prior to the conversion date.

In connection with the issuance of the 10% Notes due 2012 and the 15.5% Notes, the holder of these notes converted 2,000 shares of our Series C preferred stock into 51,280 shares of our common stock, induced by an aggregate cash payment \$0.3 million. We also paid to the holder of the notes and its affiliates \$2.4 million in exchange for the prospective satisfaction of any final judgment which may ever be rendered on any and all claims for any relief whatsoever that have been alleged, or that could have been alleged, in our litigation with Enable Capital Management LLC, or Enable, the holder of the notes.

Since the holders of the Series C preferred stock had an option to redeem the stated value of their preferred stock for cash at any time after the two-year anniversary of the original issue date in July 2007, we concluded that the inducement \$0.3 million was not representative of a sufficient inducement to Enable to convert their Series C preferred stock given the value underlying the common stock issued upon conversion. Accordingly, we allocated our total payment of \$2.8 million and determined that \$2.0 million and \$0.8 million pertained to the inducement payment and the settlement payment and are recorded as *deemed dividends on preferred stock* and *settlement expense*, respectively, for the year ended December 31, 2008.

At the issuance of the 10% Notes due 2012 and the 15.5% Notes, we recorded derivative liabilities related to the embedded features on these notes. For the year ended December 31, 2008 we recorded a gain of \$12.0 million related to the change in the fair value of the derivative liabilities which was included in *gain on derivative liabilities, net*.

### *18.33% Notes Exchanged for 13.5% Notes*

In July and August 2008, we issued \$44.5 million aggregate principal amount of our 18.33% convertible senior notes, or 18.33% Notes, and warrants to purchase 2.8 million shares of common stock in connection with the exercise of the B Unit Warrant as described further in Note 8, *Long-Term Obligations*. The warrants were repurchased in entirety in connection with the issuance of our 10% Notes due 2011 as discussed above. Additionally, we repurchased all \$17.5 million of our 13.5% convertible senior notes, or 13.5% Notes, and related warrants to purchase 1.1 million shares of our common stock. We recorded a *loss on exchange of convertible notes* of \$10.3 million related to this exchange for the year ended December 31, 2008.

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In connection with the repurchase of the 13.5% Notes, \$6.5 million was released to us from the escrow account established to pay make-whole payments on the 13.5% Notes. In addition, \$24.5 million of the gross proceeds received from the issuance of the 18.33% Notes was placed into escrow to fund potential make-whole payments upon any conversion of these notes. The make-whole payments were equal to \$549.90 per \$1,000 principal amount of the notes so converted, less any interest paid on such notes prior to the conversion date.

At the issuance of the 18.33% Notes, we recorded a derivative liability related to the embedded features on the notes. For the year ended December 31, 2008, we recorded a gain of \$6.9 million related to the change in the fair value of this derivative liability which was included in *gain on derivative liabilities, net*.

### *Issuance of 15% Notes*

In June 2008, we issued \$23.0 million aggregate principal amount of our 15% Notes and warrants to purchase 1.5 million shares of common stock in connection with the exercise of the B Unit Warrant, as described further in Note 8, *Long-Term Obligations*. The warrants were repurchased in connection with the issuances of our 9.66% Notes and our 10% Notes due 2011 as discussed above.

Of the \$23.0 million in gross proceeds, \$10.4 million was placed into escrow to fund potential make-whole payments upon any conversion of the 15% Notes. The make-whole payments were equal to \$450 per \$1,000 principal amount of the notes so converted, less any interest paid on such notes prior to the conversion date.

At the issuance of the 15% Notes, we recorded a derivative liability related to the conversion option of the notes. For the year ended December 31, 2008, we recorded a gain of \$4.6 million related to the change in the fair value of this derivative liability which was included in *gain on derivative liabilities, net*.

### *13.5% Notes Exchanged for 9% Notes*

In April 2008, we issued \$36.0 million aggregate principal amount of our 13.5% convertible senior notes, or 13.5% Notes, and \$9.0 million aggregate principal amount of our Series E 13.5% convertible exchangeable preferred stock, or Series E preferred stock, which was subsequently exchanged for our 13.5% Notes as described below. We also issued warrants to purchase 2.8 million shares of common stock which were repurchased in connection with the issuance of our 18.33% Notes and our 10% Notes due 2011 as discussed above. In addition, we issued the B Unit Warrant as discussed further in Note 8, *Long-Term Obligations*. All of these securities were issued to a single institutional investor for gross proceeds of \$64.6 million. Additionally, we repurchased \$5.3 million aggregate principal of our 9% convertible senior notes, or 9% Notes, and related warrants. We recorded a *loss on exchange of convertible notes* of \$3.3 million related to this exchange for the year ended December 31, 2008.

In connection with the issuance of these securities, \$36.5 million of the proceeds was placed into escrow to fund potential make-whole payments upon any conversion of the 13.5% Notes. The make-whole payments were equal to \$810 per \$1,000 principal amount of the notes so converted, less any interest paid on such notes prior to the conversion date.

At the issuance of the 13.5% Notes, we recorded a derivative liability related to the embedded features on the notes. For the year ended December 31, 2008, we recorded a gain of \$22.3 million related to the change in the fair value of this derivative liability which was included in *gain on derivative liabilities, net*.

In June 2008, all of our Series E preferred stock and its accrued and unpaid dividends was exchanged by the holder for an additional \$9.1 million aggregate principal amount of our 13.5% Notes. Upon issuance of the Series E preferred stock, we recorded a beneficial conversion feature charge of \$1.1 million related to the conversion price for the Series E preferred stock. The resulting discount was fully recognized as a dividend through the date of the Series E preferred stock exchange and included in *deemed dividends on preferred stock* for the year ended December 31, 2008.

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### *Issuance of 9% Notes and Induced Conversion of Preferred Stock*

In March 2008, we issued \$51.7 million aggregate principal amount of our 9% Notes and warrants to purchase an additional 0.7 million shares of common stock at an exercise price of \$14.10 per share. Additionally, in connection with the issuance, certain existing holders of our Series A, B, C and D convertible preferred stock converted their shares of preferred stock into 0.4 million shares of common stock, induced by an aggregate cash payment of \$16.2 million which we recorded as *deemed dividends on preferred stock* for the year ended December 31, 2008.

In connection with the issuance of the 9% Notes, \$13.9 million of the gross proceeds received was placed into escrow for a period of one year to fund make-whole payments upon any conversion of these notes. The make-whole payments were equal to \$270 per \$1,000 principal amount of the notes so converted, less any interest paid on such notes prior to the conversion date. This amount was released to us in March 2009 upon the one-year anniversary of the issuance of the 9% Notes.

At the issuance of the 9% Notes we recorded a derivative liability related to the embedded features on the notes. For the year ended December 31, 2008, we recorded a gain of \$12.0 million related to the change in the fair value of this derivative liability which was included in *gain on derivative liabilities, net*. At December 31, 2008, the fair value of the derivative liability was less than \$1,000 and, consequently, the *gain on derivative liabilities, net* for the year ended December 31, 2009 was minimal.

The warrants issued in connection with the 9% Notes were exercisable on July 2, 2008 and expire on the third anniversary of this date. Less than 0.1 million of these warrants were repurchased in connection with the issuance of our 13.5% Notes as discussed above and, as no warrants have been exercised, there are 0.7 million warrants still outstanding as of December 31, 2010.

### *Exchanges of 5.75% Senior Subordinated and Subordinated Notes*

In February 2008, \$8.9 million of our 5.75% convertible senior subordinated notes and \$0.2 million of our 5.75% convertible subordinated notes were cancelled in exchanged for 0.7 million and 11,000 shares of our common stock, respectively. We recorded a *loss on exchange of convertible notes* of \$2.3 million related to this exchange for the year ended December 31, 2008.

### *Notes Outstanding as of December 31, 2010*

#### *7.5% Convertible Senior Notes*

Our 7.5% convertible senior notes, or 7.5% Notes, are due April 30, 2011 with interest payable semi-annually in April and October. The notes are convertible, at the option of the holder, into shares of our common stock at any time prior to maturity, redemption or repurchase at a conversion rate of 11.963 shares of common stock per \$1,000 principal amount of the notes, which is subject to adjustments in certain circumstances. This conversion rate is equivalent to a conversion price of approximately \$83.59 per share. On or after April 30, 2009, we have the option to redeem all of the notes for cash at any time at a redemption price equal to par plus accrued and unpaid interest up to but not including the redemption date. Subject to certain conditions, the notes will automatically convert if, at any time after June 26, 2006 and prior to maturity, the closing price per share of our common stock has exceeded 125% of the conversion price then in effect for at least 20 trading days within any 30-consecutive trading day period. In addition, upon certain non-stock changes in control, the holder can require us to repurchase the notes at 100% of their principal amount, plus accrued and unpaid interest to, but not including, the repurchase date. Upon any automatic conversion of the notes, or if the holder exercises their right to require us to repurchase notes in connection with a non-stock change of control, we will pay the holder of the notes a make-whole interest payment equal to \$225 per \$1,000 principal amount of the notes so converted, less any interest paid on such notes prior to the conversion date.

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### *5.75% Convertible Senior Notes*

Our 5.75% convertible senior notes are due December 15, 2011 with interest payable semi-annually in June and December. The notes are convertible, at the option of the holder, into shares of our common stock at any time prior to maturity, redemption or repurchase at a conversion rate of 33.3333 shares of common stock per \$1,000 principal amount of the notes, which is subject to adjustments in certain circumstances. This conversion rate is equivalent to a conversion price of approximately \$30.00 per share. On or after December 15, 2009, we have the option to redeem all of the notes for cash at any time at a redemption price equal to par plus accrued and unpaid interest up to but not including the redemption date. Subject to certain conditions, the notes will automatically convert if, at any time after December 15, 2009 and prior to maturity, the closing price per share of our common stock has exceeded 140% of the conversion price then in effect for at least 20 trading days within any 30-consecutive trading day period. Upon a change in control, the holder can require us to repurchase the notes at 100% of their principal amount, plus accrued and unpaid interest and any other amounts due up to, but not including, the repurchase date. In addition, upon any of these occurrences (redemption, automatic conversion, or repurchase) we will pay the holder of the notes a make-whole interest payment equal to \$115 per \$1,000 principal amount of the notes so converted, less any interest paid on such notes prior to the conversion date.

## **10. Preferred Stock**

### *Series A 3% Convertible Preferred Stock*

During 2008, 6,300 shares of Series A preferred stock were converted into 0.1 million shares of our common stock in connection with the issuance of our 9% Notes as discussed further in Note 9, *Convertible Notes*.

During 2009, 250 shares of Series A preferred stock were exchanged for \$0.1 million and 4.0 million shares of our common stock in connection with our litigation with RHP Master Fund, Ltd, or RHP. In connection with this exchange, we recorded \$0.3 million as *deemed dividends on preferred stock* and \$0.2 million as *settlement expense*. Also during 2009, 100 shares of Series A preferred stock and related warrants to purchase 747 shares of our common stock were exchanged for 0.3 million shares of our common stock and we recorded \$0.1 million as *deemed dividends on preferred stock*. We also exchanged 200 shares of our Series A preferred stock for shares of our Series F preferred stock in 2009 as discussed further below.

As of December 31, 2009, all of our Series A preferred stock had been converted or exchanged.

### *Series B 3% Convertible Preferred Stock*

During 2008, 10,162 shares of Series B preferred stock were converted into 0.2 million shares of our common stock in connection with the issuance of our 9% convertible senior notes as discussed further in Note 9, *Convertible Notes*.

During 2009, 3,000 shares of Series B preferred stock were converted into 44,576 shares of our common stock in connection with our litigation settlement with Tang Capital Partners LP, or Tang. In connection with this conversion and related litigation, \$3.0 million of our payment to Tang was recorded as *deemed dividends on preferred stock* during 2008 and was included in *accrued liabilities* as of December 31, 2008. Also during 2009, 2,218 shares of Series B preferred stock were exchanged for shares of our Series F convertible preferred stock, or Series F preferred stock, as discussed further below.

As of December 31, 2009, all of our Series B preferred stock had been converted or exchanged.

### *Series C 3% Convertible Preferred Stock*

During 2008, 2,000 shares of Series C preferred stock were converted into 51,282 share of our common stock in connection with the issuance of our 9% convertible senior notes as discussed further in Note 9, *Convertible Notes*. An additional 2,000 shares of Series C preferred stock were converted into 51,280 shares of our common stock in connection with the issuance of our 15.5% and 10% convertible senior notes which is also discussed further in Note 9, *Convertible Notes*.

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During 2009, 4,284 shares of Series C preferred stock were exchanged for shares of our Series F preferred stock as discussed further below.

As of December 31, 2009, all of our Series C preferred stock had been converted or exchanged.

### *Series D 7% Convertible Preferred Stock*

During 2008, 3,000 shares of Series D preferred stock were converted into 0.1 million shares of our common stock in connection with the issuance of our 9% convertible senior notes as discussed further in Note 9, *Convertible Notes*.

In 2009, 1,000 shares of Series D preferred stock and related warrants to purchase 19,138 shares of our common stock were exchanged for 3.5 million shares of our common stock and we recorded \$1.1 million as *deemed dividends on preferred stock*.

As of December 31, 2009, all of our Series D preferred stock had been converted or exchanged.

### *Series F Convertible Preferred Stock*

In February 2009, we issued 6,702 shares of our Series F preferred stock in exchange for shares of our Series A, B and C convertible preferred stock as discussed above. The Series F preferred stock had no fixed dividend rate and was convertible into a number of shares of our common stock determined by dividing the state value of the preferred stock to be converted, which was \$1,000 per share, by the conversion price of \$0.14. In connection with this exchange, we recorded a *gain on restructuring of preferred stock* of \$2.1 million which did not materially change our *net loss attributable to common shareholders* for the year ended December 31, 2009.

During 2009, all 6,702 shares of Series F preferred stock were converted into 47.9 million shares of our common stock.

### *Series 1 Convertible Preferred Stock*

In April 2009, we issued the following in a registered offering: (a) 15,000 shares of our Series 1 convertible preferred stock, or Series 1 preferred stock, convertible into 50.0 million shares of our common stock at a conversion price of \$0.30 per share for a purchase price of \$1,000 per share of Series 1 preferred stock and warrants described as follows, (b) Class A warrants to purchase an additional 9.2 million shares of our common stock at an exercise price of \$0.41 per share and (c) Class B warrants to purchase an additional 13.3 million shares of our common stock at an exercise price of \$0.41 per share. In addition, the original holder of the Series 1 preferred stock had the right to purchase up to 5,000 additional shares of Series 1 preferred stock at \$1,000 per share within 60 days of April 13, 2009. The transaction closed on April 13, 2009 and we received gross proceeds of \$15.0 million. Issuance costs related to this transaction were \$1.5 million, which included \$0.2 million related to the placement agent warrants as discussed below.

The Class A warrants were immediately exercisable and the Class B warrants were exercisable six months and one day after the date of issuance. The Class A and B warrants terminate on the fifth anniversary of the date upon which such warrants become exercisable. As the Class A and Class B warrants include a redemption feature that may be triggered upon certain liquidation events that are outside of our control, we classified these warrants as mezzanine equity. We estimated the fair value of the Class A and B warrants using the Black-Scholes pricing model and allocated \$1.5 million and \$1.9 million of the \$15.0 million gross proceeds to the Class A and Class B warrants, respectively.

In April 2009, the original holder exercised the right to purchase the additional 5,000 shares of Series 1 preferred stock as discussed above and we received an additional \$5.0 million in gross proceeds.



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For the year ended December 31, 2009, we recognized \$8.2 million in *deemed dividends on preferred stock* related to the above transactions based upon a relative fair value allocation of the proceeds to the preferred stock and the warrants, which was calculated utilizing the Black-Scholes pricing model.

In connection with this offering, we also issued warrants to purchase 1.0 million shares of our common stock to the placement agent which are classified as mezzanine equity due to the same redemption feature of the Class A and B warrants as described above. The warrants were estimated to have a fair value of \$0.2 million using the Black-Scholes pricing model. These warrants have an exercise price of \$0.45 per share, became exercisable in October 2009 and expire in October 2014. In February 2010, these warrants were partially exercised. As of December 31, 2010, warrants to purchase 0.2 million shares of common stock are outstanding.

In April 2009, all 20,000 shares of Series 1 preferred stock issued were converted in 66.7 million shares of our common stock. Additionally, in May 2009, all of the Class A warrants were exercised for 9.2 million shares of our common stock and we received gross proceeds of \$3.8 million. In October 2009, the Class B warrants were partially exercised for 10.4 million shares of our common stock and we received gross proceeds of \$4.3 million. As of December 31, 2010, Class B warrants to purchase 2.9 million shares of common stock are outstanding.

### *Series 2 Convertible Preferred Stock*

In August 2009, we issued 30,000 shares of our Series 2 convertible preferred stock, or Series 2 preferred stock, which was convertible into 18.9 million shares of our common stock, and warrants to purchase up to 4.7 million shares of our common stock for gross proceeds of \$30.0 million. Issuance costs related to this transaction were \$2.2 million, including \$0.6 million related to the placement agent warrants as discussed below.

Each share of Series 2 preferred stock was convertible into our common stock, at the option of the holder, at a conversion price of \$1.59125 per share. The warrants had an exercise price of \$1.70 per share of our common stock, were exercisable immediately upon issuance and expired nine months after the date of issuance.

For the year ended December 31, 2009, we recognized \$13.8 million in *deemed dividends on preferred stock* related to the above transaction based upon a relative fair value allocation of the proceeds to the preferred stock and the warrants, which was calculated utilizing the Black-Scholes pricing model.

In connection with this offering, we issued warrants to purchase 0.6 million shares of our common stock to the placement agent which were estimated to have a fair value of \$0.6 million using the Black-Scholes pricing model. These warrants have an exercise price of \$1.989 per share, were exercisable immediately upon issuance and expired nine months after the date of issuance.

In August 2009, all 30,000 shares of our Series 2 preferred stock were converted into 18.9 million shares of our common stock.

### *Series 3 Convertible Preferred Stock*

In January 2010, we issued 30,000 shares of our Series 3 convertible preferred stock, or Series 3 preferred stock, which was convertible into 24.7 million shares of our common stock, and warrants to purchase up to 8.6 million shares of our common stock, or Series 3 Warrants, for gross proceeds of \$30.0 million. Issuance costs related to this transaction were \$2.2 million, including \$0.2 million related to the placement agent warrants as discussed below.

Each share of our Series 3 preferred stock was entitled to a liquidation preference equal to the stated value of such share of our Series 3 preferred stock plus any accrued and unpaid dividends. Our Series 3 preferred stock was not entitled to dividends except to share in any dividends actually paid on our common stock or any *pari passu* or junior securities. It was convertible into our common stock, at the option of the holder, at a conversion

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price of \$1.21375 per share, provided that no holder of Series 3 preferred stock could request a conversion of its shares if such conversion would have resulted in the holder and its affiliates owning 10% or more of our common stock. Our Series 3 preferred stock did not have voting rights except for limited protective provisions and except as otherwise required by law.

The Series 3 Warrants have an exercise price of \$1.18 per share of our common stock, were exercisable immediately upon issuance and expired one year and one day after the date of issuance. In July 2010, we entered into a privately negotiated exchange agreement with a certain holder of the Series 3 Warrants to exchange 4.32 million Series 3 Warrants for the same number of warrants to purchase shares of common stock at an exercise price of \$0.42 per share, or Exchange Warrants. The Exchange Warrants are exercisable six months and one day after the date of issuance and expire four years, six months and one day after the date of issuance, provided that the exercisability of the warrants was subject to, and conditioned upon receipt of shareholder approval of an amendment to our amended and restated articles of incorporation to increase the authorized shares of common stock available for issuance by 400 million shares, which was received in September 2010. We estimated the \$0.8 million fair value of the new warrants using the Black-Scholes pricing model, which were recorded in permanent equity. None of the Series 3 Warrants or Exchange Warrants have been exercised as of December 31, 2010.

For the year ended December 31, 2010, we recognized \$17.3 million in *deemed dividends on preferred stock* related to the above transaction based upon a relative fair value allocation of the proceeds to the preferred stock and the warrants, which was calculated utilizing the Black-Scholes pricing model.

In connection with this offering, we also issued warrants to purchase 0.2 million shares of our common stock to the placement agent, which were estimated to have a fair value of \$0.2 million using the Black-Scholes pricing model. These warrants have an exercise price of \$1.517 per share, were exercisable immediately upon issuance and expire one year and one day after the date of issuance. No warrants have been exercised as of December 31, 2010.

In January 2010, all 30,000 shares of our Series 3 preferred stock were converted into 24.7 million shares of our common stock.

### *Series 4 Convertible Preferred Stock*

In April 2010, we issued 20,000 shares of our Series 4 convertible preferred stock, or Series 4 preferred stock, which was convertible into 40.0 million shares of our common stock, and warrants to purchase up to 20.0 million shares of our common stock for gross proceeds of \$20.0 million. Issuance costs related to this transaction were \$1.4 million. Each share of our Series 4 preferred stock was entitled to a liquidation preference equal to the stated value of such share of our Series 4 preferred stock plus any accrued and unpaid dividends. Our Series 4 preferred stock was not entitled to dividends except to share in any dividends actually paid on our common stock or any *pari passu* or junior securities. It was convertible into our common stock, at the option of the holder, at a conversion price of \$0.50 per share, subject to a 4.99% blocker provision. A holder of our Series 4 preferred stock could elect to increase the blocker provision to 9.99% by providing us with 61 days' prior notice. Our Series 4 preferred stock did not have voting rights except for limited protective provisions and except as is otherwise required by law.

The warrants have an exercise price of \$0.6029 per share of our common stock, were exercisable six months and one day after the date of issuance and expire four years and one day after the date of issuance. As the warrants include a redemption feature that may be triggered upon a certain liquidation event that is outside of our control, we classified these warrants as mezzanine equity. No warrants have been exercised as of December 31, 2010.

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For the year ended December 31, 2010, we recognized \$15.5 million in *deemed dividends on preferred stock* related to the above transaction based upon a relative fair value allocation of the proceeds to the preferred stock and the warrants, which was calculated utilizing the Black-Scholes pricing model.

In April 2010, all 20,000 shares of our Series 4 preferred stock were converted into 40.0 million shares of our common stock.

### *Series 5 Convertible Preferred Stock*

In May 2010, we issued 21,000 shares of our Series 5 convertible preferred stock, or Series 5 preferred stock, which was convertible into 52.5 million shares of our common stock, and warrants to purchase up to 26.3 million shares of our common stock for gross proceeds of \$21.0 million. Issuance costs related to this transaction were \$1.5 million, including \$0.2 million related to the placement agent warrants as discussed below. Each share of our Series 5 preferred stock was entitled to a liquidation preference equal to the stated value of such share of our Series 5 preferred stock plus any accrued and unpaid dividends. Our Series 5 preferred stock was not entitled to dividends except to share in any dividends actually paid on our common stock or any pari passu or junior securities. It was convertible into our common stock, at the option of the holder, at a conversion price of \$0.40 per share, subject to a 4.99% blocker provision. A holder of Series 5 preferred stock could elect to increase the blocker provision to 9.99% by providing us with 61 days prior notice. In addition, if 1,000 or less shares of Series 5 preferred stock are outstanding, all outstanding shares of Series 5 preferred stock automatically convert into shares of common stock. Our Series 5 preferred stock did not have voting rights except for limited protective provisions and except as otherwise required by law.

The warrants have an exercise price of \$0.50 per share of our common stock and were exercisable six months and one day after the date of issuance and expire four years, six months and one day after the date of issuance, provided that the exercisability of the warrants was subject to, and conditioned upon receipt of shareholder approval of an amendment to our amended and restated articles of incorporation to increase the authorized shares of common stock available for issuance by 400 million shares, which was obtained in September 2010. As the warrants include a redemption feature that may be triggered upon a certain liquidation event that is outside of our control, we classified these warrants as mezzanine equity. No warrants have been exercised as of December 31, 2010.

For the year ended December 31, 2010, we recognized \$14.6 million in *deemed dividends on preferred stock* related to the above transaction based upon a relative fair value allocation of the proceeds to the preferred stock and the warrants, which was calculated utilizing the Black-Scholes pricing model.

In connection with this offering, we also issued warrants to purchase 1.1 million shares of our common stock to the placement agent, which are classified in mezzanine equity due to the same redemption feature described above. The warrants were estimated to have a fair value of \$0.2 million using the Black-Scholes pricing model. These warrants have an exercise price of \$0.50 per share and are exercisable after six months and one day after the date of issuance and expire five years after the date of issuance, provided that the exercisability of the warrants was subject to, and conditioned upon, our receipt of the shareholder approval or notification described above. No warrants have been exercised as of December 31, 2010. In May 2010, all 21,000 shares of our Series 5 preferred stock were converted into 52.5 million shares of our common stock.

### *Series 6 Convertible Preferred Stock*

In July 2010, we issued 4,060 shares of our Series 6 convertible preferred stock, or Series 6 preferred stock, which was convertible into 11.6 million shares of our common stock, and warrants to purchase up to 5.8 million shares of our common stock for gross proceeds of \$4.1 million. Issuance costs related to this transaction were \$1.1 million, including \$0.1 million related to the placement agent warrants as discussed below.

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Each share of our Series 6 preferred stock was entitled to a liquidation preference equal to the stated value of such share of our Series 6 preferred stock plus any accrued and unpaid dividends. Our Series 6 preferred stock was not entitled to dividends except to share in any dividends actually paid on our common stock or any pari passu or junior securities. It was convertible into our common stock, at the option of the holder, at a conversion price of \$0.35 per share, subject to a 4.99% blocker provision. A holder of Series 6 preferred stock could elect to increase the blocker provision to 9.99% by providing us with 61 days prior notice. In addition, if 1,000 or less shares of Series 6 preferred stock are outstanding, all outstanding shares of Series 6 preferred stock automatically convert into shares of common stock. The Series 6 preferred stock had voting rights to vote with the common stock on an as-converted basis.

The warrants have an exercise price of \$0.42 per share of our common stock and are exercisable six months and one day after the date of issuance and expire four years, six months and one day after the date of issuance, provided that the exercisability of the warrants was subject to, and conditioned upon receipt of shareholder approval of an amendment to our amended and restated articles of incorporation to increase the authorized shares of common stock available for issuance by 400 million shares, which was received in September 2010. As the warrants include a redemption feature that may be triggered upon a certain liquidation event that is outside of our control, we classified these warrants as mezzanine equity. No warrants have been exercised as of December 31, 2010.

For the year ended December 31, 2010, we recognized \$3.1 million in *deemed dividends on preferred stock* related to the above transaction based upon a relative fair value allocation of the proceeds to the preferred stock and the warrants, which was calculated utilizing the Black-Scholes pricing model.

In connection with this offering, we also issued warrants to purchase 0.3 million shares of our common stock to the placement agent, which are classified in mezzanine equity due to the same redemption feature described above. The warrants were estimated to have a fair value of \$0.1 million using the Black-Scholes pricing model. These warrants have an exercise price of \$0.42 per share and are exercisable after six months and one day after the date of issuance and expire four years, six months and one day after the date of issuance. The exercisability of the warrants was also subject to, and conditioned upon, our receipt of the shareholder approval described above. No warrants have been exercised as of December 31, 2010.

In July 2010, all 4,060 shares of our Series 6 preferred stock were converted into 11.6 million shares of our common stock.

### *Series 7 Convertible Preferred Stock*

In October 2010, we issued 21,000 shares of our Series 7 convertible preferred stock, or Series 7 preferred stock, which was convertible into 56.8 million shares of our common stock, and warrants to purchase up to 22.7 million shares of our common stock for gross proceeds of \$21.0 million. Issuance costs related to this transaction were \$1.7 million, including \$0.3 million related to the placement agent warrants as discussed below.

Each share of our Series 7 preferred stock was entitled to a liquidation preference equal to the stated value plus any accrued and unpaid dividends before the holders of our common stock or any other junior securities receive any payments upon such liquidation. The Series 7 preferred stock was not entitled to dividends except to share in any dividends actually paid on our common stock or any pari passu or junior securities. The Series 7 preferred stock was convertible into common stock, at the option of the holder, at an initial conversion price of \$0.37 per share, subject to a 4.99% blocker provision. A holder of Series 7 preferred stock could have elected to increase the blocker provision to 9.99% by providing 61 days prior notice, and the maximum percentage will automatically increase to 19.99% in the event of an automatic conversion. The Series 7 preferred stock had no voting rights.

The warrants have an exercise price of \$0.45 per share of our common stock, are exercisable six months and one day after the date of issuance and expire five years and one day after the date of issuance. No warrants have been exercised as of December 31, 2010.

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For the year ended December 31, 2010, we recognized \$14.4 million in *deemed dividends on preferred stock* related to the above transaction based upon a relative fair value allocation of the proceeds to the preferred stock and the warrants, which was calculated utilizing the Black-Scholes pricing model.

In connection with this offering, we also issued warrants to purchase 1.1 million shares of our common stock to the placement agent, which were estimated to have a fair value of \$0.3 million using the Black-Scholes pricing model. These warrants have an exercise price of \$0.46 per share, are exercisable six months and one day after the date of issuance and expire five years and one day after the date of issuance. No warrants have been exercised as of December 31, 2010.

In October 2010, all 21,000 shares of our Series 7 preferred stock were converted into 56.8 million shares of our common stock.

### 11. Common Stock

In July 2009, we issued 33.7 million shares of our common stock and warrants to purchase up to 8.4 million shares of our common stock in a public offering for gross proceeds of \$43.9 million. The purchase price for each share of our common stock and warrant to purchase 0.25 shares of our common stock was \$1.30. Issuance costs related to this offering were \$4.4 million, which include \$0.9 million related to the fair value of placement agent warrants and warrants granted for financial advisory services which were estimated using a Black-Scholes pricing model. Each warrant to purchase a share of our common stock had an exercise price of \$1.70, was exercisable immediately upon the date of issuance and expired nine months thereafter. In connection with this offering, we issued a warrant to purchase up to 0.6 million shares of our common stock at an exercise price of \$1.70 per share to the underwriter of the offering. This warrant was exercisable commencing on the date six months from the issuance date and expires five years from the closing date of the offering. We also issued a warrant to purchase up to 0.3 million shares of our common stock at an exercise price of \$1.56 per share for certain financial advisory services related to the offering. This warrant was exercisable beginning in January 2010 and expired in April 2010. No warrants issued in connection with this offering had been exercised as of December 31, 2010. Warrants to purchase 0.6 million shares of common stock issued to the underwriter of the offering remained outstanding as of December 31, 2010.

In May 2009, we entered into a securities purchase agreement pursuant to which we issued 16.0 million shares of our common stock and warrants to purchase up to 4.8 million shares of common stock in a registered offering. The purchase price for one share of common stock and a warrant exercisable for 0.30 shares of common stock was \$1.25 and we received gross proceeds of \$20.0 million. Issuance costs related to this common stock offering were \$1.5 million which included \$0.4 million related to the fair value of the placement agent warrants which were estimated using a Black-Scholes pricing model. Each warrant to purchase shares of common stock has an exercise price of \$1.40 per share, was immediately exercisable and terminates on May 11, 2014. In connection with this offering, we also issued warrants to purchase 0.3 million shares of our common stock to the placement agent. These warrants have an exercise price of \$1.56 per share, were exercisable as of November 2009 and expire in November 2014. No warrants issued in connection with this offering had been exercised as of December 31, 2010.

#### Common Stock Reserved

A summary of common stock reserved for issuance is as follows as of December 31, 2010:

Convertible senior notes	486,386
Equity incentive plans	42,048,112
Common stock purchase warrants	95,750,429
Employee stock purchase plan	1,432,491
Restricted share rights	391
	139,717,809

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### **12. Significant Agreements**

#### *Collaboration, Licensing and Milestone Agreements*

##### *PG-TXL*

We have an agreement with PG-TXL Company, L.P., or PG-TXL, which grants us an exclusive worldwide license for the rights to OPAXIO and to all potential uses of PG-TXL's polymer technology, or the PG-TXL Agreement. Pursuant to the PG-TXL Agreement, we acquired the rights to research, develop, manufacture, market and sell anti-cancer drugs developed using this polymer technology. Pursuant to the PG-TXL Agreement, we are obligated to make payments to PG-TXL upon the achievement of certain development and regulatory milestones of up to \$14.4 million. The timing of the remaining milestone payments under the PG-TXL Agreement is based on trial commencements and completions for compounds protected by PG-TXL license rights, and regulatory and marketing approval of those compounds by the FDA and the EMA. Additionally, we are required to make royalty payments to PG-TXL based on net sales. Our royalty payments range from low-single digits to mid-single digits as a percentage of net sales. Unless otherwise terminated, the term of the PG-TXL Agreement continues until no royalties are payable to PG-TXL. We may terminate the PG-TXL Agreement (i) upon advance written notice to PG-TXL in the event issues regarding the safety of the products licensed pursuant to the PG-TXL Agreement arise during development or clinical data obtained reveal a materially adverse tolerability profile for the licensed product in humans or (ii) for any reason upon advance written notice. In addition, either party may terminate the PG-TXL Agreement (a) upon advance written notice in the event certain license fee payments are not made; (b) in the event of an uncured material breach of the respective material obligations and conditions of the PG-TXL Agreement; or (c) in the event of liquidation or bankruptcy of a party.

##### *Gynecologic Oncology Group*

We have an agreement with the Gynecologic Oncology Group, or the GOG, related to the GOG0212 trial, which the GOG is conducting. We recorded a \$1.6 million payment due to the GOG, based on the 650 patient enrollment milestone achieved in the first quarter of 2010, of which \$1.1 million remained outstanding and is included in *accounts payable* as of December 31, 2010. Subsequent to period end, we paid the remaining \$1.1 million due to the GOG in January 2011. Under this agreement we are required to pay up to \$3.5 million in additional milestone payments related to the trial of which \$1.7 million will become due when 800 patients are enrolled and \$0.5 million will become due upon receipt of the interim analysis and data transfer, both of which may occur in 2011.

##### *Nerviano Medical Sciences*

Under a license agreement entered into with Nerviano Medical Sciences, S.r.l. 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., or Cephalon, in June 2005, we may receive up to \$100.0 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*

In September 2006, we entered into an exclusive worldwide licensing agreement with Novartis, or the Novartis Agreement, for the development and commercialization of OPAXIO. Total product and registration

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milestones to us for OPAXIO under the Novartis Agreement could reach up to \$270 million. Royalty payments to us for OPAXIO are based on worldwide OPAXIO net sales volumes and range from the low-twenties to mid-twenties as a percentage of net sales.

Pursuant to the Novartis Agreement, we are responsible for the development costs of OPAXIO and have control over development of OPAXIO unless and until Novartis exercises its development rights, or the Development Rights. In the event that Novartis exercises its Development Rights, then from and after the date of such exercise, or the Novartis Development Commencement Date, Novartis will be solely responsible for the development of OPAXIO. Prior to the Novartis Development Commencement Date, we are solely responsible for all costs associated with the development of OPAXIO, but will be reimbursed by Novartis for certain costs after the Novartis Development Commencement Date. After the Novartis Development Commencement Date, Novartis will be responsible for costs associated with the development of OPAXIO, subject to certain limitations; however, we are also responsible for reimbursing Novartis for certain costs pursuant to the Novartis Agreement.

The Novartis Agreement also provides Novartis with an option to develop and commercialize Pixuvri based on agreed terms. If Novartis exercises its option on Pixuvri under certain conditions and we are able to negotiate and sign a definitive license agreement with Novartis, Novartis would be required to pay us a \$7.5 million license fee, up to \$104 million in registration and sales related milestones and a royalty on Pixuvri worldwide net sales. Royalty payments to us for Pixuvri are based on worldwide Pixuvri net sales volumes and range from the low-double digits to the low-thirties as a percentage of net sales.

Royalties for OPAXIO are based on worldwide sales volumes of OPAXIO and royalties for Pixuvri are based on sales volumes in the U.S. and sales volumes in other countries.

Royalties for OPAXIO and Pixuvri are payable from the first commercial sale of a product until the later of the expiration of the last to expire valid claim of the licensor or the occurrence of other certain events, or the Royalty Term. Unless otherwise terminated, the term of the Novartis Agreement continues on a product-by-product and country-by-country basis until the expiration of the last-to-expire Royalty Term with respect to a product in such certain country. In the event Novartis does not exercise its Development Rights until the earlier to occur of (i) the expiration of 30 days following receipt by Novartis of the product approval information package pursuant to the Novartis Agreement or (ii) Novartis determination, in its sole discretion, to terminate the Development Rights exercise period by written notice to us (events (i) and (ii) collectively being referred to as the Development Rights Exercise Period), the Novartis Agreement will automatically terminate upon expiration of the Development Rights Exercise Period. In the event of an uncured material breach of the Novartis Agreement, the non-breaching party may terminate the Novartis Agreement. Either party may terminate the Novartis Agreement without notice upon the bankruptcy of the other party. In addition, Novartis may terminate the Novartis Agreement without cause at any time (a) in its entirety within 30 days written notice prior to the exercise by Novartis of its Development Rights or (b) on a product-by-product or country-by-country basis on 180 days written notice after the exercise by Novartis of its Development Rights. If we experience a change of control that involves certain major pharmaceutical companies, Novartis may terminate the Novartis Agreement by written notice within a certain period of time to us or our successor entity.

As of December 31, 2010, we have not received any milestone payments and we will not receive any milestone payments unless Novartis elects to exercise its option to participate in the development and commercialization of Pixuvri or exercise its Development Rights for OPAXIO.

### *Financing Agreement*

In June 2006, we entered into a Step-Up Equity Financing Agreement, as amended in December 2006, with Société Générale. Subject to certain conditions, the agreement allowed us to issue to Société Générale shares of our common stock in a series of tranches over a period of 24 months beginning in January 2007 and terminating in January 2009. Under the agreement, we could issue up to 45 million worth of our common stock based on a

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pre-determined formula with the right to increase the total amount of all issuances to up to 60 million. Any issuance of our common stock pursuant to this agreement was at our election and we were not required to issue any common stock.

In January 2008, we sold 80,000 shares to Société Générale under this agreement in a registered offering at an issue price of 10.70, or approximately \$15.90, per share and we received gross proceeds of \$1.3 million. Net proceeds from the issuance were \$1.2 million.

In June 2008, we received notice from counsel for Société Générale asserting that the agreement was terminated by Société Générale effective June 6, 2008 on the basis that the going concern statement included in our Annual Report on Form 10-K, as well as the notice we received from NASDAQ on April 16, 2008 regarding our failure to comply with the minimum price requirements under the listing requirements of the NASDAQ Global Market, constituted a material adverse change under the agreement, permitting Société Générale to terminate the agreement. Upon receipt of this notice, we wrote-off capitalized offering costs of \$2.4 million, including costs associated with this agreement as well as costs related to the Italian Listing Prospectus that was published in January 2008 as an Italian regulatory requirement to issue shares under this agreement. These amounts were expensed during 2008 due to significant uncertainty regarding our ability to pursue further financings under the agreement and were included in *write-off of financing arrangement costs* for the year ended December 31, 2008.

### *Equity Line of Credit*

In July 2008, we entered into a Securities Purchase Agreement with Midsummer Investment, Ltd., or Midsummer. Pursuant to the purchase agreement, we issued to Midsummer a warrant to purchase up to the lesser of \$12.0 million in shares of our common stock or the number of shares of common stock equal to 19.9% of our outstanding common stock on July 29, 2008 (or 2.8 million shares), in order to effectuate an equity line of credit relationship. Under the agreement, as amended in August 2008, following a commencement notice by us, Midsummer was obliged (subject to customary conditions applicable to each respective closing) to exercise the warrant every three trading days for an amount of stock measured by a formula based on the trading volume of our common stock on the Milan stock exchange, or MTA, during the three trading days prior to the closing date, or the pricing period, with the issuance amount for each pricing period equal to the sum for the three prior trading days of 15% of our trading volume on the MTA for each respective trading day. We were able to suspend exercises of the warrant at our discretion and could reactivate the equity line of credit following any such suspension until the warrant had been exercised in full. The price per share for each such issuance was 85% of the volume weighted average price of our shares on the MTA for the pricing period.

Pursuant to the purchase agreement, we were deemed to have issued a commencement notice upon the signing of the purchase agreement such that the first closing date under the agreement was August 4, 2008. Under the terms of the deemed commencement notice, additional closings occurred every three trading days until August 26, 2008 at which point we suspended exercises of the warrant.

During the year ended December 31, 2008, we issued 1.5 million shares and received \$4.0 million in gross proceeds under this agreement. In December 2008, \$0.5 million in costs associated with the equity line of credit were expensed to *write-off of financing arrangement costs* based on our plans to terminate the agreement which occurred in March 2009 by mutual agreement with Midsummer.

### *Other Significant Agreements*

We have several agreements with clinical research organizations, third party manufacturers, and distributors which have a duration greater than one year for the development of our products.



**Table of Contents****13. Share-Based Compensation***Share-Based Compensation Expense*

Share-based compensation expense for all share-based payment awards made to employees and directors is measured based on the grant-date fair value estimated in accordance with generally accepted accounting principles for share-based compensation. We recognized share-based compensation using the straight-line single-award method based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period. Share-based compensation is reduced for estimated forfeitures at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. For performance-based awards that do not include market-based conditions, we record share-based compensation expense only when the performance-based milestone is deemed probable of achievement. We utilize both quantitative and qualitative criteria to judge whether milestones are probable of achievement. For awards with market-based performance conditions, we recognize the grant-date fair value of the award over the derived service period regardless of whether the underlying performance condition is met.

For the years ended December 31, 2010, 2009 and 2008, we incurred share-based compensation expense due to the following types of awards (in thousands):

	2010	2009	2008
December 2009 performance awards	\$ 13,954	\$ 1,276	\$
Restricted stock	2,908	23,259	3,274
Options	186	402	721
Total share-based compensation expense	\$ 17,048	\$ 24,937	\$ 3,995

The following table summarizes share-based compensation expense for the years ended December 31, 2010, 2009 and 2008, which was allocated as follows (in thousands):

	2010	2009	2008
Research and development	\$ 2,765	\$ 3,281	\$ 1,249
Selling, general and administrative	14,283	21,656	2,746
Share-based compensation expense included in operating expenses	\$ 17,048	\$ 24,937	\$ 3,995

Share-based compensation had a \$17.0 million, \$24.9 million and \$4.0 million effect on our net loss attributable to common shareholders and a \$(0.02), \$(0.05) and \$(0.14) effect on basic and diluted net loss per common share for the years ended December 31, 2010, 2009 and 2008, respectively. It had no effect on cash flows from operations or financing activities for the periods presented; however, during the years ended 2010 and 2009, we repurchased shares of our common stock totaling \$0.9 million and \$6.4 million, respectively, for cash in connection with the vesting of employee restricted stock awards based on taxes owed by employees due to the vesting of the awards.

As of December 31, 2010, the total remaining unrecognized compensation cost related to unvested stock options and restricted stock amounted to \$3.1 million, which will be recognized over the weighted-average remaining requisite service period of 0.8 years. The unrecognized compensation cost related to unvested options and restricted stock does not include the cost related to approximately 35.1 million performance-based restricted stock awards granted in 2010 with a grant-date fair value of \$14.2 million which, as of December 31, 2010, had not been deemed probable of achievement. As of December 31, 2010, we have not recognized any expense related to any of these performance-based award grants. In addition, unvested share-based compensation expense excludes the fair value of 150,000 restricted stock awards and 100,000 options granted to external consultants as the fair value is periodically remeasured as discussed below.

For the years ended December 31, 2010, 2009 and 2008, no tax benefits were attributed to the share-based compensation expense because a valuation allowance was maintained for substantially all net deferred tax assets.



**Table of Contents***Stock Plan*

Pursuant to our 2007 Equity Incentive Plan, as amended and restated in September 2010, or the Plan, we may grant the following types of incentive awards: (1) stock options, including incentive stock options and non-qualified stock options, (2) stock appreciation rights, (3) restricted stock, (4) restricted stock units and (5) cash awards. The Plan is administered by the Compensation Committee of the Board of Directors which has the discretion to determine which employees, consultants and directors shall be granted incentive awards. Options are typically exercisable ratably over a four-year period commencing one year from the date of grant, and expire not more than 10 years from the date of grant. As of December 31, 2010, 111.7 million shares were authorized for issuance, of which 41.0 million shares of common stock were available for future grants under the Plan. However, assuming the performance goals underlying the December 2009 performance awards (as discussed below) had been achieved as of December 31, 2010, there would have been no shares of common stock remaining for future grants under the Plan.

*Stock Options*

Fair value for employee stock options was estimated at the date of grant using the Black-Scholes pricing model, with the following weighted average assumptions:

	<b>Year Ended December 31,</b>		
	<b>2010</b>	<b>2009</b>	<b>2008</b>
Risk-free interest rates	1.3%	1.4%	2.8%
Expected dividend yield	None	None	None
Expected life (in years)	4.97	2.8	2.7
Volatility	96%	88%	79%

The risk-free interest rate used in the Black-Scholes valuation method is based on the implied yield currently available for 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 share-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 share-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. As we also recognize compensation expense for only the portion of options expected to vest, we apply estimated forfeiture rates that we derive 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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The following table summarizes stock option activity for all of the stock option plans:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (Thousands)
Outstanding January 1, 2008 (127,000 exercisable)	224,000	\$ 258.60		
Granted	122,000	\$ 4.90		
Exercised		\$		
Forfeited	(18,000)	\$ 45.30		
Cancelled and expired	(30,000)	\$ 159.70		
Outstanding December 31, 2008 (147,000 exercisable)	298,000	\$ 177.40		
Granted	404,000	\$ 1.26		
Exercised		\$		
Forfeited	(56,000)	\$ 6.41		
Cancelled and expired	(24,000)	\$ 132.37		
Outstanding December 31, 2009 (202,000 exercisable)	622,000	\$ 80.17		
Granted	485,000	\$ 0.38		
Exercised		\$		
Forfeited	(37,000)	\$ 0.94		
Cancelled and expired	(35,000)	\$ 677.61		
Outstanding December 31, 2010	1,035,000	\$ 25.30	8.4	\$ 8
Vested or expected to vest at December 31, 2010	953,000	\$ 27.40	8.3	\$ 7
Exercisable at December 31, 2010	526,000	\$ 48.94	7.7	\$ 3

The weighted average exercise price of options exercisable at December 31, 2009 and 2008 was \$241.81 and \$345.40, respectively. The weighted average fair value of options granted was \$0.28, \$0.52 and \$2.00 during 2010, 2009 and 2008, respectively.

The following table summarizes information about common stock options outstanding at December 31, 2010:

		Options Outstanding			Exercisable Options Outstanding (Without Restriction)	
		Number Outstanding	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
<b>Range of Exercise Prices</b>						
\$0.08	\$0.34	268,000	9.2	\$ 0.34	90,000	\$ 0.34
\$0.35	\$0.38	180,000	9.7	\$ 0.38		\$
\$0.39	\$1.07	205,000	8.8	\$ 1.01	186,000	\$ 1.06
\$1.08	\$5.80	240,000	8.2	\$ 2.59	110,000	\$ 3.47
\$5.81	\$1,091.80	142,000	5.1	\$ 177.11	140,000	\$ 179.26
\$0.08	\$1,091.80	1,035,000	8.4	\$ 25.30	526,000	\$ 48.94



**Table of Contents***Restricted Stock*

We issued 40.2 million, 34.1 million and 1.0 million shares of restricted common stock in 2010, 2009 and 2008, respectively. Additionally, 5.5 million, 0.3 million and 26,000 shares of restricted stock were cancelled during 2010, 2009 and 2008, respectively. The weighted average fair value of restricted shares issued during 2010, 2009 and 2008 was \$0.44, \$0.87 and \$1.70, respectively.

A summary of the status of non-vested restricted stock awards as of December 31, 2010 and changes during the period then ended, is presented below:

	Non-vested Shares	Weighted Average Grant-Date Fair Value Per Share
Non-vested at December 31, 2009	11,494,000	\$ 0.75
Granted	40,173,000	\$ 0.44
Vested	(5,622,000)	\$ 0.45
Forfeited	(5,534,000)	\$ 1.22
Non-vested at December 31, 2010	40,511,000	\$ 0.42

The total fair value of restricted stock awards vested during the year ended December 31, 2010, 2009 and 2008 was \$3.2 million, \$26.0 million and \$0.4 million, respectively.

*December 2009 Performance Awards*

In December 2009, we granted restricted stock units (which we refer to as our December 2009 performance awards) to our executive officers and directors, which vest upon milestone-based performance conditions. If one or more of the eight underlying performance-based conditions are timely achieved, the award recipient will be entitled to receive a number of shares of our common stock (subject to share limits of the Plan), determined by multiplying (i) the award percentage corresponding to that particular performance goal by (ii) the total number of outstanding shares of our common stock as of the date that the particular performance goal is achieved. The total award percentages related to all eight performance goals are 9.36% and 2.63% of shares outstanding at the time a performance goal is achieved for executive officers and directors, respectively.

The fair value of the December 2009 performance awards was estimated based on the average present value of the awards to be issued upon achievement of the performance conditions. The average present value was calculated based upon the expected date the shares of common stock underlying the performance rights will vest, or the event date, the expected stock price on the event date, and the expected shares outstanding as of the event date. The event date, stock price and the shares outstanding were estimated using a Monte Carlo simulation model, which is based on assumptions by management, including the likelihood of achieving the milestones and potential future financings. The total grant-date fair value of the December 2009 performance awards based on this calculation was \$49.8 million. In 2010, two of the eight performance criteria were amended and a portion of the restricted stock units that were converted into restricted shares of common stock. No additional share-based compensation expense was recorded as a result of these amendments. As of December 31, 2010, we have not deemed the December 2009 performance awards probable of achievement and no expense has been recognized except for the awards with an underlying market-based performance condition.

We determined that the December 2009 performance awards with the market-based performance condition have a grant-date fair value of \$15.2 million, of which we have recognized \$13.9 million and \$1.3 million in share-based compensation expense for the years ended December 31, 2010 and 2009, respectively.

*Non-Employee Share-Based Compensation*

Share-based compensation expense for awards granted to non-employees is determined using the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably



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measured. The fair value of options and restricted stock awards granted to non-employees is periodically remeasured as the underlying options or awards vest. The value of the instrument is amortized to expense over the vesting period with final valuation measured on the vesting date. At December 31, 2010, 2009 and 2008, unvested non-employee options to acquire approximately 100,000, 152,000 and 16,000 shares of common stock were outstanding, respectively. Additionally, unvested non-employee restricted stock awards totaled 150,000 and 275,000 as of December 31, 2010 and 2009, respectively. No such awards were outstanding as of December 31, 2008. We reversed previously recorded compensation expense of \$24,000 and \$5,000 in 2010 and 2008, respectively, and recorded compensation expense of \$157,000 in 2009 related to non-employee stock options and restricted stock awards.

### *Employee Stock Purchase Plan*

Under our 2007 Employee Stock Purchase Plan, as amended and restated in August 2009, or Purchase Plan, eligible employees may purchase a limited number of shares of our common stock at 85% of the lower of the subscription date fair market value and the purchase date fair market value. There are two six-month offerings per year. Under the Purchase Plan, we issued approximately 47,000, 42,000 and 8,000 shares to employees in 2010, 2009 and 2008, respectively. There are 1,525,000 shares of common stock authorized under the Purchase Plan and 1,432,000 are reserved for future purchases as of December 31, 2010.

## **14. Employee Benefit Plans**

The Company's U.S. employees participate in the Cell Therapeutics, Inc. 401(k) Plan whereby eligible employees may defer up to 80% of their compensation, up to the annual maximum allowed by the Internal Revenue Service. We may make discretionary matching contributions based on certain plan provisions. We made contributions of \$0.1 million during each of the years ended December 31, 2010, 2009 and 2008.

In connection with our merger with Novuspharma, on January 1, 2004, we assumed a defined benefit plan and related obligation for benefits owed to our Italian employees who, pursuant to Italian law, were entitled to a lump sum payment upon separation from the Company. Related costs were accrued over the employees' service periods based on compensation and years of service. In accordance with ASC 715, *Compensation-Retirement Benefits*, we elected to carry the obligation under the plan at the amount of the vested benefit obligation which is defined as the actuarial present value of the vested benefit to which the employee is entitled if the employee separates immediately. Benefits of \$0.6 million, \$0.6 million and \$0.5 million were paid to employees who separated from the Company during 2010, 2009 and 2008, respectively. As of December 31, 2009, the vested benefit obligation was \$0.6 million and was included in *current portion of long-term obligations*. We made all final defined benefit plan payments to separated employees in 2010 and no further obligation existed as of December 31, 2010 upon completion of the employee termination agreements, see Note 6, *Restructuring Activities*.

## **15. Shareholder Rights Plan**

In December 2009, CTI's Board of Directors, or the Board, approved and adopted a shareholder rights plan, or Rights Plan, in which one preferred stock purchase right was distributed for each common share held as of the close of business on January 7, 2010. Initially, the rights are not exercisable, and are attached to and trade with, all of the shares of CTI's common stock outstanding as of, and issued subsequent to January 7, 2010.

Each right, if and when it becomes exercisable, will entitle the holder to purchase a unit consisting of one ten-thousandth of a share of Series ZZ Junior Participating Cumulative Preferred Stock, no par value per share, at a cash exercise price of \$6.00 per unit, subject to standard adjustment in the Rights Plan. The rights will separate from the common stock and become exercisable if a person or group acquires 20% or more of our common stock. Upon acquisition of 20% or more of our common stock, the Board could decide that each right (except those held by a 20% shareholder, which become null and void) would become exercisable entitling the holder to



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receive upon exercise, in lieu of a number of units of preferred stock, that number of shares of our common stock having a market value of two times the exercise price of the right. In certain circumstances, including if there are insufficient shares of our common stock to permit the exercise in full of the rights, the holder may receive units of preferred stock, other securities, cash or property, or any combination of the foregoing.

In addition, if CTI is acquired in a merger or other business combination transaction, each holder of a right, except those rights held by a 20% shareholder which become null and void, would have the right to receive, upon exercise, common stock of the acquiring company having a market value equal to two times the exercise price of the right.

The Board may redeem the rights for \$0.0001 per right or terminate the Rights Plan at any time prior to an acquisition by a person or group holding 20% or more of our common stock. The Rights Plan will expire on January 7, 2013.

**16. Customer and Geographic Concentrations**

We consider our operations to be a single operating segment focused on the development, acquisition and commercialization of novel treatments for cancer. Financial results of this reportable segment are presented in the accompanying consolidated financial statements.

Product sales from Zevalin's major customers as a percentage of total product sales were as follows:

	Year Ended December 31, 2008
Customer A	77%
Customer B	5%

All sales of Zevalin during 2008 were to customers in North America.

The following table depicts long-lived assets based on the following geographic locations (in thousands):

	Year Ended December 31,	
	2010	2009
United States	\$ 21,249	\$ 21,501
Europe	5,438	5,929
	\$ 26,687	\$ 27,430

**Table of Contents****17. Net Loss Per Share**

Basic and diluted net loss per share is calculated using the weighted average number of shares outstanding as follows (in thousands, except per share amounts):

	Year Ended December 31,		
	2010	2009	2008
Net loss attributable to common shareholders	\$ (147,560)	\$ (116,763)	\$ (202,907)
Basic and diluted:			
Weighted average shares outstanding	710,754	466,352	29,383
Less weighted average restricted shares outstanding	(26,125)	(7,996)	(416)
Shares used in calculation of basic and diluted net loss per common share	684,629	458,356	28,967
Net loss per common share:			
Basic and diluted	\$ (0.22)	\$ (0.25)	\$ (7.00)

Options, warrants, unvested restricted share awards and rights, convertible debt, and convertible preferred stock aggregating 102.3 million, 34.1 million and 136.1 million common share equivalents were not included in the calculation of diluted net loss per share as their effects on the calculation are anti-dilutive as of December 31, 2010, 2009 and 2008, respectively, prior to the application of the as-if converted method for convertible securities and the treasury stock method for other dilutive securities, such as options and warrants. These amounts do not include performance or market-based awards, including options, restricted share awards and December 2009 performance awards.

**18. Income Taxes**

We file income tax returns in the United States, Italy and the United Kingdom. Due to substantial book and tax losses from our global operations, we have reported no income tax provisions in jurisdictions in which we file returns. A substantial part of our operations takes place in the State of Washington, which does not impose an income tax as that term is defined in ASC 740, *Income Taxes*. As such, our state income tax expense or benefit, if recognized, would be immaterial to our operations. We are not currently under examination by an income tax authority, nor have we been notified that an examination is contemplated.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying values of assets and liabilities for financial reporting and income tax reporting in accordance with ASC 740. We have a valuation allowance equal to net deferred tax assets due to the uncertainty of realizing the benefits of the assets. Our valuation allowance increased \$17.8 million, decreased \$154.2 million, and increased \$17.8 million during 2010, 2009 and 2008, respectively.

The reconciliation between our effective tax rate and the income tax rate as of December 31, 2010, 2009 and 2008 is as follows:

	2010	2009	2008
Federal income tax rate	(34%)	(34%)	(34%)
Research and development tax credits	(1)	(1)	
I.R.C. Section 382 limited research and development tax credits		18	
Non-deductible debt/equity costs	18	13	20
Non-deductible executive compensation		5	
I.R.C. Section 382 limited net operating losses		125	
Valuation allowance	12	(132)	9
Expired tax attribute carryforwards	4	6	4
Other	1		1
Net effective tax rate	%	%	%



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Significant components of our deferred tax assets and liabilities as of December 31, 2010 and 2009 are as follows (in thousands):

	2010	2009
Deferred tax assets:		
Net operating loss carryforwards	\$ 141,186	\$ 121,935
Capitalized research and development	51,449	59,766
Research and development tax credit carryforwards	1,514	542
Stock based compensation	8,860	4,069
Intangible assets	532	578
Depreciation and amortization	305	270
Other deferred tax assets	2,857	1,874
<b>Total deferred tax assets</b>	<b>206,703</b>	<b>189,034</b>
Less valuation allowance	(205,826)	(188,015)
	877	1,019
Deferred tax liabilities:		
GAAP adjustments on Novuspharma merger	(208)	(208)
Deductions for tax in excess of financial statements	(669)	(811)
<b>Total deferred tax liabilities</b>	<b>(877)</b>	<b>(1,019)</b>
<b>Net deferred tax assets</b>	<b>\$</b>	<b>\$</b>

Due to our equity financing transactions, and other owner shifts as defined in Internal Revenue Code Section 382, we incurred ownership changes pursuant to the Code. These ownership changes trigger a limitation on the future use of our net operating losses and research and development credits. The annual limitation on our tax attributes is approximately \$20.7 million. The deferred tax assets and valuation allowance as of December 31, 2009 and 2010 reflect the impact of these ownership change limitations.

As of December 31, 2010, we had gross net operating losses of approximately \$851,378 million, of which \$86.7 million relates to stock compensation deductions, and gross research credit carryforwards of approximately \$21.0 million. The carryforwards began to expire in 2007.

Effective January 1, 2007, we adopted the provisions of FASB Interpretation 48, *Accounting for Uncertainty in Income Taxes*, as codified in ASC 740-10, and we have analyzed filing positions in our tax returns for all open years. We are subject to United States federal and state, Italian and United Kingdom income taxes with varying statutes of limitations. Tax years from 1996 forward remain open to examination due to the carryover of net operating losses or tax credits. Our policy is to recognize interest related to unrecognized tax benefits as interest expense and penalties as operating expenses. As of December 31, 2010, we had no unrecognized tax benefits and therefore no accrued interest or penalties related to unrecognized tax benefits. We believe that our income tax filing positions and deductions will be sustained on audit and do not anticipate any adjustments that will result in a material change to our consolidated financial position, results of operations and cash flows. Therefore, no reserves for uncertain income tax positions have been recorded.

**19. Related Party Transactions**

In the case of termination, we have severance agreements with our executive officers that provide benefits for 18 to 24 months.

In May 2007, we formed Aequus Biopharma, Inc., or Aequus, a majority owned subsidiary of which our ownership was approximately 69% as of December 31, 2010. We entered into a license agreement with Aequus

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whereby Aequus gained rights to our Genetic Polymer technology which Aequus will continue to develop. The Genetic Polymer technology may speed the manufacture, development, and commercialization of follow-on and novel protein-based therapeutics.

In May 2007, we also entered into an agreement to fund Aequus in exchange for a convertible promissory note that becomes due and payable in five years and earns interest at a rate of 6% per annum. The note can be converted into equity at any time prior to its maturity upon CTI's demand, or upon other triggering events. The number of shares of Aequus equity securities to be issued upon conversion of this note is equal to the quotient obtained by dividing (i) the outstanding balance of the note by (ii) 100% of the price per share of the equity securities. We also funded Aequus \$0.5 million, \$0.6 million and \$0.3 million during the years ended December 31, 2010, 2009 and 2008, respectively. In addition, we entered into a services agreement to provide certain administrative and research and development services to Aequus. The amounts charged for these services, if unpaid by Aequus within 30 days, will be considered additional principal advanced under the promissory note.

Our President and Chief Executive Officer, James A. Bianco, M.D. and our Executive Vice President, Chief Medical Officer, Jack W. Singer, M.D. are both minority shareholders of Aequus, each owning approximately 4.9% of the equity in the company as of December 31, 2010. Additionally, both Dr. Bianco and Dr. Singer are members of Aequus' board of directors and each have entered into a consulting agreement with Aequus. Additionally, Frederick W. Telling, Ph.D., a member of our board of directors, owns approximately 1% of Aequus as of December 31, 2010 and is also a member of Aequus' board of directors.

## **20. Legal Proceedings**

On January 22, 2007, we filed a complaint in King County Washington Superior Court against The Lash Group, Inc., or Lash, and Documedics Acquisition Co., Inc., our former third-party reimbursement expert for TRISENOX, seeking recovery of damages, including losses incurred by us in connection with our investigation, defense and settlement of claims by the United States concerning Medicare reimbursement for TRISENOX and other claims. On February 28, 2007, Lash removed the case to U.S. District Court in the Western District of Washington. On June 19, 2008, the trial judge dismissed our claims and we filed a timely notice of appeal in the Ninth Circuit Court of Appeals. An appeal hearing was held on August 31, 2009, and on November 18, 2009, the Ninth Circuit reversed the trial court and held that the False Claims Act, or the FCA, did not preclude us from seeking recovery and bringing claims against Lash for indemnification under our service agreement based upon its acts that gave rise to the government's FCA and other claims. On December 1, 2009, Lash filed a petition for rehearing with the Ninth Circuit Court of Appeals, which was formally denied on January 6, 2010. The case has been remanded for trial in the District Court. On April 30, 2010, the District Court denied a motion by Lash to strike our supplemental damages disclosure, and granted our motion for leave to amend our complaint to more fully address our claims for supplemental and independent damages. On May 21, 2010, the District Court issued a minute order setting trial and related dates. On May 24, 2010, Lash filed its answer to the amended complaint and asserted counterclaims for contractual indemnification, common law indemnification and contribution, and declaratory relief. On June 3, 2010, Lash filed a motion to bifurcate the trial to address in the first phase only its assertion that our claims are barred due to FCA liability. We opposed the motion, and on June 10, 2010, we filed our own motion to strike Lash's affirmative defense based on its FCA liability claim. On August 3, 2010, the court entered an order denying Lash's motion to bifurcate and granting our motion to strike Lash's FCA liability affirmative defense. The case is currently scheduled for trial on September 6, 2011. There is no guarantee that we will prevail at trial.

Moreover, on December 23, 2008, CONSOB sent a notice to us requesting that we issue (i) immediately, a press release providing, among other things, information about our debt restructuring plan, the current state of compliance with the relevant covenants regulating our debt and the equity line of credit agreement we entered into with Midsummer Investment Ltd. on July 29, 2008, and (ii) by the end of each month and starting from the month of December 2008, a press release providing certain information relating to our management and financial situation, updated to the previous month, or the Monthly CONSOB Press Release. On July 31, 2009, CONSOB sent us a notice asserting three violations of the provisions of Section 114, paragraph 5 of the Italian Legislative Decree no. 58/98, as follows: (a) the non-disclosure without delay of the press release described under point (i) above and the

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subsequent incomplete disclosure of the relevant information through press releases dated January 9, 2009 and January 13, 2009; (b) the non-disclosure of the Monthly CONSOB Press Release in December 2008; and (c) the incomplete disclosure of the Monthly CONSOB Press Release in January 2009. The sanctions established by Section 193, paragraph 1 of the Italian Legislative Decree no. 58/98 for such violations are pecuniary administrative sanctions amounting to between 5,000 and 500,000, or approximately \$6,700 to \$670,000 as of December 31, 2010, applicable to each one of the three asserted violations. According to the applicable Italian legal provisions, CONSOB may impose such administrative sanctions by means of a decree stating the grounds of its decision only after evaluating our possible defenses that were submitted to CONSOB on August 28, 2009 (within 30 days of July 31, 2009, the notification date of the relevant charges, according to the applicable Italian rules). On May 5, 2010, CONSOB (1) notified us that it had begun the preliminary investigation for its decision on these administrative proceedings and (2) provided us with a preliminary investigation report in response to our defenses submitted on August 28, 2009. On June 4, 2010 (within 30 days of May 5, 2010, the notification date of the beginning of the aforesaid preliminary investigation, according to the applicable Italian rules), we submitted further defenses that CONSOB will have to evaluate before imposing any possible administrative sanctions. On January 21, 2011, CONSOB notified us of a resolution confirming the occurrence of the three asserted violations and applying a fine for each of them in the following amounts: 20,000 for sanction (a) above; 50,000 for sanction (b) above; and 30,000 for sanction (c) above, for an aggregate fine of 100,000, or approximately \$136,000 as of January 21, 2011, for these sanctions. We anticipate paying the fine according to the terms and conditions established by the applicable Italian rules and prior to the deadline of March 22, 2011 (i.e., the deadline after which default interest and/or increases in the amount of the fines will be charged). We have accrued approximately \$0.1 million for this amount as of December 31, 2010, which is included in *accrued expenses*.

Separately, on December 10, 2009, CONSOB sent us a notice claiming two violations of the provisions of Section 114, paragraph 1 of the Italian Legislative Decree no. 58/98 due to the asserted late disclosure of certain information then reported, at CONSOB's request, in press releases disseminated on December 19, 2008 and March 23, 2009. Such information concerned, respectively: (i) the conversion by BAM Opportunity Fund LP of 9.66% notes into shares of common stock that occurred between October 24, 2008 and November 19, 2008; and (ii) the contents of the opinion expressed by Stonefield Josephson, Inc., an independent registered public accounting firm, with respect to our 2008 financial statements. The sanctions established by Section 193, paragraph 1 of the Italian Legislative Decree no. 58/98 for such violations are pecuniary administrative sanctions amounting to between 5,000 and 500,000, or approximately \$6,700 to \$670,000 as of December 31, 2010, applicable to each of the two asserted violations. According to the applicable Italian legal provisions, CONSOB may impose such administrative sanctions by means of a decree stating the grounds of its decision only after evaluating our possible defenses that were submitted to CONSOB on January 8, 2010 (within 30 days of December 10, 2009, the notification date of the relevant charges, according to the applicable Italian rules). On July 12, 2010, CONSOB (a) notified us that it had begun the preliminary investigation for its decision on these administrative proceedings and (b) provided us with a preliminary investigation report in response to our defenses submitted on January 8, 2010. On August 12, 2010 (within 30 days of July 12, 2010, the notification date of the beginning of the aforesaid preliminary investigation, according to the applicable Italian rules), we submitted further defenses that CONSOB will have to evaluate before imposing any possible administrative sanctions. Based on our assessment, the likelihood that these pecuniary administrative sanctions will be imposed on the Company is probable.

On April 14, 2009 and December 21, 2009, the Italian Tax Authority, or the ITA, issued notices of assessment to CTI (Europe) based on the ITA's audit of CTI (Europe)'s VAT returns for the years 2003 and 2005, respectively. On June 25, 2010, the ITA issued notices of assessment to CTI (Europe) for the years 2006 and 2007 based on similar findings for the 2003 and 2005 assessments. The ITA audits concluded that CTI (Europe) did not collect and remit VAT on certain invoices issued to non-Italian clients for services performed by CTI (Europe). The assessments, including interest and penalties, for the years 2003, 2005, 2006 and 2007 are 0.5 million, 5.5 million, 2.5 million and 0.8 million, or approximately \$0.7 million, \$7.4 million, \$3.4 million and \$1.1 million as of December 31, 2010, respectively. We believe that the services invoiced were non-VAT taxable consultancy services and that the VAT returns are correct as originally filed. We are vigorously defending ourselves against the assessments both on procedural grounds and on the merits of the case. If the

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decision of the Provincial Tax Court of Milan, or the Tax Court, is unfavorable, then we expect to appeal to the higher courts in order to further defend our interests. However, if we are unable to successfully defend ourselves against the assessments issued by the ITA, we may be requested to pay to the ITA an amount ranging from 4.9 million to 9.4 million, or approximately \$6.6 million to \$12.6 million as of December 31, 2010, plus collection fees, notification expenses and additional interest for the period lapsed between the date in which the assessments were issued and the date of effective payment. On February 2, 2011, we paid to the ITA the required deposit in respect of the 2005 VAT in the amount of 1.5 million, or approximately \$2.0 million converted using the currency exchange rate as of December 31, 2010.

**2003 VAT.** We have not received a notice from the ITA requesting a deposit payment for the VAT based on the 2003 assessment as of December 31, 2010. The Tax Court has scheduled the first hearing for the discussion of the merits of the case on March 18, 2011.

**2005 VAT.** On July 14, 2010, the ITA issued a notice requiring a deposit payment for the VAT to CTI (Europe) based on the 2005 assessment, including 50% of the assessed VAT, interest and collection fees for an amount of 1.5 million, or approximately \$2.0 million converted using the currency exchange rate as of December 31, 2010. We successfully filed a petition with the Tax Court for suspension of the 2005 notice of deposit payment. On September 28, 2010, the merits of the case for the year 2005 were discussed in a public hearing before the Tax Court. On January 13, 2011, the Tax Court issued decision no. 4/2010 in which the Tax Court (i) partially accepted our appeal and declared that no penalties can be imposed against us, (ii) confirmed the right of the Italian Tax Authorities to reassess the VAT (plus interest) in relation to the transactions identified in the 2005 notice of assessment and (iii) repealed the suspension of the notice of deposit payment. As a result of this decision, our exposure for 2005 VAT assessment is currently reduced by the waiver of penalties of 2.6 million, or approximately \$3.5 million converted using the currency exchange rate as of December 31, 2010. The ITA has the right to appeal the decision to request for confirmation of the penalties. On February 2, 2011, we paid the required VAT Deposit of 1.5 million, or approximately \$2.0 million converted using the currency exchange rate as of December 31, 2010, prior to the due date of February 6, 2011. We do not believe that the Tax Court has carefully reviewed all of our arguments, relevant documents and other supporting evidence that our counsel filed and presented during the hearing, including an appraisal from an independent expert, and, therefore, that there are grounds of appeal in order to ask the judges of the higher court to further consider all of our arguments in support of invalidating the entire notice of assessment. Accordingly, we will appeal to the Regional Tax Court and file a complaint with the European Commission.

While we contend that services invoiced were non-VAT taxable consulting services and that the VAT returns are correct as originally filed, we have recorded a reserve for VAT assessed, interest and collection fees totalling 2.6 million, or approximately \$3.5 million as of December 31, 2010 of which \$3.0 million is included in *long-term obligations, less current portion* and \$0.5 million of the reserve is accounted for as an offset to VAT receivable included in *other assets*.

**2006 VAT.** On January 10, 2011, we received a notice from the ITA requiring a deposit payment for VAT to CTI (Europe) based on the 2006 assessment, including 50% of the assessed VAT, interest and collection fees for an amount of 0.4 million, or approximately \$0.6 million converted using the currency exchange rate as of December 31, 2010, payable in the first quarter 2011. We filed a request for suspension of the collection of such amount.

**2007 VAT.** We have not received a notice from the ITA requesting a deposit payment for the VAT based on the 2007 assessment nor has the Tax Court scheduled a hearing as of December 31, 2010.

On August 3, 2009, Sicor Italia, or Sicor, filed a lawsuit in the Court of Milan to compel us to source Pixuvri from Sicor according to the terms of a supply agreement executed between Sicor and NovusPharma on October 4, 2002. Sicor alleges that the agreement was not terminated according to its terms. We assert that the supply agreement in question was properly terminated and that we have no further obligation to comply with its terms. A hearing was held on January 21, 2010 to discuss preliminary matters and set a schedule for future filings and hearings. The parties filed the authorized pleadings and submitted to the Court their requests for evidence.

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On November 11, 2010, a hearing was held aimed at examining and discussing the requests for evidence submitted by the parties in the briefs filed pursuant to article 183, paragraph 6 of the Italian code of civil procedure. At the hearing of November 11, 2010, the judge declared that the case does not require any discovery or evidentiary phase, and may be decided on the basis of the documents and pleadings already filed by the parties. A final hearing is scheduled for October 11, 2012, for the parties to definitively submit to the judge their requests. No estimate of a loss, if any, can be made at this time in the event that we do not prevail.

On March 12, 2010, a purported securities class action complaint was filed in the United States District Court for the Western District of Washington against the Company and certain of its officers and directors, styled *Cyril Sabbagh, individually and on behalf of all others similarly situated v. Cell Therapeutics, Inc., Dr. James A. Bianco, M.D., and Dr. Jack W. Singer* (Case No. 2:10-sv-00414), or the *Sabbagh* action. On March 19, 2010, a substantially similar class action complaint was filed in the same court, styled *Michael Laquidari, individually and on behalf of all others similarly situated v. Cell Therapeutics, Inc., Dr. James A. Bianco, M.D., and Dr. Jack W. Singer* (Case No. 2:10-cv-00480), or the *Laquidari* action. On March 31, 2010, a third substantially similar class action complaint was filed in the same court, styled *William Snyder, individually and on behalf of all others similarly situated v. Cell Therapeutics, Inc., James A. Bianco, Phillip M. Nudelman, Louis A. Bianco, John H. Bauer, Richard L. Love, Mary O. Mundinger, Jack W. Singer, Frederick W. Telling and Rodman & Renshaw, LLC* (Case No. 2:10-cv-00559), or the *Snyder* action. The securities actions are pending before Judge Marsha Pechman in the Western District of Washington. The securities complaints allege that the defendants violated the federal securities laws by making certain alleged false and misleading statements. The plaintiffs in the *Sabbagh* and *Laquidari* actions seek unspecified damages on behalf of a putative class of purchasers of the Company's securities from May 5, 2009 through February 8, 2010. The plaintiffs in the *Snyder* action seek unspecified damages on behalf of a putative class of purchasers of the Company's securities from May 5, 2009 through March 19, 2010, including purchasers of securities issued pursuant to or traceable to the Company's July 22, 2009 public offering. On August 2, 2010, the court consolidated the securities actions, appointed lead plaintiffs, and approved lead plaintiffs' counsel. On September 27, 2010, lead plaintiff filed an amended consolidated complaint with a purported class period of March 25, 2008 through March 22, 2010. On October 27, 2010, the defendants filed a motion to dismiss the amended consolidated complaint. Plaintiffs filed an opposition on December 3, 2010, and defendants filed their reply on December 22, 2010. The hearing on the motion to dismiss was held on January 28, 2011. On February 4, 2011, the court issued an order denying in large part the defendants' motion. Defendants must file an answer to the remaining claims in the amended consolidated complaint by February 18, 2011.

On April 1, 2010, a shareholder derivative complaint was filed in the United States District Court for the Western District of Washington, derivatively on behalf of the Company against the members of its Board of Directors, styled *Shackleton v. John A. Bauer, James A. Bianco, Vartan Gregorian, Richard L. Love, Mary O. Neil Mundinger, Phillip M. Nudelman, Jack W. Singer, and Frederick W. Telling* (Case No. 2:10-cv-564). On April 5, 2010, and April 13, 2010, substantially similar derivative actions were filed in the same court, styled, respectively, *Marbury v. James A. Bianco, et al.* (Case No. 2:10-cv-00578) and *Cyrek v. John H. Bauer, et al.* (Case No. 2:10-cv-00625). The derivative actions are also pending before Judge Marsha Pechman. The derivative complaints allege that the defendants breached their fiduciary duties to the Company under Washington law by making or failing to prevent the disclosure of certain alleged false and misleading statements. The allegations in the derivative actions are substantially similar to those in the securities actions. On May 10, 2010, pursuant to the parties' stipulation, the Court consolidated these three shareholder derivative actions and appointed the law firms Robbins Umeda LLP and Federman & Sherwood as co-lead counsel for derivative plaintiffs.

On June 1, 2010, a fourth related shareholder derivative action was filed in the Western District of Washington, *Souda v. John H. Bauer et al.* (Case No. 2:10-cv-00905). It was subsequently transferred to Judge Pechman and consolidated with the consolidated derivative actions. Plaintiff Souda filed a motion to reconsider the portion of the Court's Order dated May 10, 2010, appointing Robbins Umeda and Federman & Sherwood as co-lead derivative counsel. Souda's motion for reconsideration was denied on November 16, 2010.



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On July 27, 2010, a fifth related shareholder derivative action, *Bohland v. John H. Bauer et al.* (Case No. 2:10-cv-1213), was filed in the Western District of Washington and assigned to Judge John C. Coughenour. It was subsequently transferred to Judge Pechman. Plaintiff Bohland filed a motion to consolidate the *Bohland* action with the consolidated derivative actions and to reconsider the portion of the Court's Order dated May 10, 2010, appointing Robbins Umeda and Federman & Sherwood as co-lead derivative counsel. Bohland's motion for reconsideration was denied on November 16, 2010, and *Bohland* was ordered consolidated with the other derivative actions.

On October 4, 2010, a sixth related derivative complaint was filed in the Superior Court of Washington, County of King, *Alexander v. James A. Bianco, et al.* (Case No. 10-2-34849-2-SEA). On October 5, 2010, the complaint was removed to the Western District of Washington and assigned to Judge Pechman. On October 29, 2010, nominal defendant Cell Therapeutics, Inc. filed a Notice of Related Case in the lead derivative case, *Shackleton v. John H. Bauer, et al.*, Case No. 2:10-cv-00564 (Doc. No. 42). Cell Therapeutics notified the Court of this action and requested that it be consolidated with the Derivative Actions per the Court's May 10, 2010 Consolidation Order. On November 18, 2010, the Court issued an Order to Show Cause re Consolidation in *Alexander*. On November 26, 2010 the parties agreed and the court granted consolidation of *Alexander* and ordered that all proceedings be deferred 60 days pending the outcome of the Defendant's motion to dismiss the Securities Class Action suits. On February 4, 2011, the court lifted the stay. The lawsuits are at a preliminary stage in the proceedings. We believe that the securities class action is without merit and intend to defend it vigorously. For the shareholder derivative action, no estimate of a loss, if any, can be made at this time in the event that we do not prevail.

On July 28, 2010, the former General Manager of our Italian Branch office, CTI (Europe), initiated a Court proceeding against us to challenge the former General Manager's dismissal which occurred in 2009. The former General Manager's claims are based on the alleged unlawfulness and lack of justifications of his dismissal. The former General Manager alleged that he had suffered and requested compensation for damages ranging up to approximately 0.7 million, plus the costs of the proceedings. A hearing was scheduled to be held December 9, 2010. On November 23, 2010, we entered into a settlement agreement with the former General Manager and have paid him a settlement amount of approximately \$0.1 million including a contribution to his legal expenses as of December 31, 2010. This amount is included in *settlement expense* for 2010.

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.

**Table of Contents****21. Unaudited Quarterly Data**

The following table presents summarized unaudited quarterly financial data (in thousands, except per share data):

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
<b>2010</b>				
Revenues	\$ 20	\$ 299	\$	\$
Gross profit	20	299		
Operating expenses, net	(25,777)	(19,982)	(12,994)	(16,321)
Net loss attributable to CTI	(26,920)	(23,482)	(12,522)	(19,718)
Net loss attributable to CTI common shareholders	(44,197)	(53,639)	(15,607)	(34,117)
Net loss per common share basic and diluted	(0.07)	(0.08)	(0.02)	(0.04)
<b>2009</b>				
Revenues	\$ 20	\$ 20	\$ 20	\$ 20
Gross profit	20	20	20	20
Operating expenses, net	(6,586)	(21,720)	(27,091)	(26,242)
Net loss attributable to CTI	(14,967)	(18,027)	(35,024)	(27,377)
Net loss attributable to CIT common shareholders	(13,124)	(27,426)	(48,836)	(27,377)
Net loss per common share basic and diluted	(0.05)	(0.06)	(0.09)	(0.05)

**22. Subsequent Events**

In January 2011, we issued 25,000 shares of Series 8 non-convertible preferred stock, or Series 8 Preferred Stock, warrants to purchase up to 22,563,177 shares of common stock and an additional investment right to purchase up to 25,000 shares of the Series 9 convertible preferred stock, or Series 9 Preferred Stock, to a single life sciences institutional investor for gross proceeds of \$25.0 million. Prior to the closing of the offering, all of the warrants to purchase 22,563,177 shares of common stock and the entire additional investment right to purchase 25,000 shares of Series 9 Preferred Stock were exercised. The investor also elected to convert the 25,000 shares of Series 9 Preferred Stock into 64,466,219 shares of common stock, for a total of 87,029,396 shares of common stock issued to the Investor as a result of the full exercises of warrants and additional investment right. The exercise price for the warrants and additional investment right was paid through the issuance by the investor to us of recourse notes fully secured with marketable securities. The offering closed on January 27, 2011. As of February 16, 2011, all 25,000 shares of the Series 8 Preferred Stock are issued and outstanding.

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### **Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

None.

### **Item 9A. Controls and Procedures**

#### **(a) Evaluation of Disclosure Controls and Procedures**

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in reports filed under the Securities Exchange Act of 1934, or the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms, and that such information is accumulated and communicated to our management to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

Our management, under the supervision and with the participation of our Chief Executive Officer and Executive Vice President, Finance and Administration, or EVP of Finance, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, as of the end of the period covered by this report. Based upon that evaluation, our Chief Executive Officer and EVP of Finance have concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective.

#### **(b) Management's Annual Report on Internal Controls**

Management of Cell Therapeutics, Inc., together with its consolidated subsidiaries (the Company), is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is a process designed under the supervision of the Company's principal executive and principal financial officers to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the Company's financial statements for external reporting purposes in accordance with U.S. generally accepted accounting principles.

As of the end of the Company's 2010 fiscal year, management conducted an assessment of the effectiveness of the Company's internal control over financial reporting based on the framework established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this assessment, management has determined that the Company's internal control over financial reporting as of December 31, 2010 was effective.

The registered independent public accounting firm of Marcum LLP, as auditors of the Company's consolidated financial statements, has audited our internal controls over financial reporting as of December 31, 2010, as stated in their report, which appears herein.

#### **(c) Changes in Internal Controls**

There have been no changes to our internal control over financial reporting that occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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**Table of Contents****Item 9B. Other Information**

On February 11, 2011, the Compensation Committee of our board of directors approved cash incentive awards for 2010 for each of our named executive officers in the following amounts:

Name and Principal Position	2010 Bonus
James A. Bianco, M.D. Chief Executive Officer	\$ 585,000
Craig W. Philips President	\$ 281,400
Louis A. Bianco Executive Vice President, Finance and Administration	\$ 247,500
Jack W. Singer, M.D. Executive Vice President, Chief Medical Officer	\$ 212,500
Daniel Eramian Executive Vice President, Corporate Communications	\$ 220,500

**Table of Contents****PART III****Item 10. Directors, Executive Officers and Corporate Governance**  
**Directors**

The following table set forth certain information with respect to our directors as of December 31, 2010:

Name	Director		Class	Term Expiration
	Age	Since		
John H. Bauer(3)	70	2005	I	2013 Annual Meeting
James A. Bianco, M.D.	54	1991	II	2011 Annual Meeting
Vartan Gregorian, Ph.D.(3)(4)	76	2001	II	2011 Annual Meeting
Richard L. Love(2)	67	2007	III	2012 Annual Meeting
Mary O. Mundinger, DrPH(2)(4)	73	1997	III	2012 Annual Meeting
Phillip M. Nudelman, Ph.D.(1)(2)(3)(4)	75	1994	I	2013 Annual Meeting
Jack W. Singer, M.D.	68	1991	III	2012 Annual Meeting
Frederick W. Telling, Ph.D.(2)(3)	59	2006	II	2011 Annual Meeting

- (1) Chairman of our board of directors.
- (2) Member of the Compensation Committee.
- (3) Member of the Audit Committee.
- (4) Member of the Nominating and Governance Committee.

**Mr. Bauer** was appointed to the Board in October 2005. Mr. Bauer serves as an executive advisor and Chief Financial Officer at DigiPen Institute of Technology. He was formerly Executive Vice President for Nintendo of America Inc. from 1994 to 2004. While at Nintendo of America Inc., he had direct responsibility for all administrative and finance functions. He has also served as a consultant to Nintendo of America Inc. From 1963 to 1994, he worked for Coopers & Lybrand, including serving as the business assurance (audit) practice partner. He was also a member of Coopers & Lybrand's Firm Council, the senior policy making and governing board for the firm. Mr. Bauer is also a member of the board of directors of RIPL Corporation and Zones, Inc. Mr. Bauer received his B.S. degree in accounting from St Edward's University.

**Dr. Bianco** is our principal founder and served as our President and Chief Executive Officer and director from February 1992 to July 2008. With the addition of Craig W. Philips as President in August 2008, Dr. Bianco now serves as our Chief Executive Officer and a director. Prior to founding the Company, Dr. Bianco was an assistant professor of medicine at the University of Washington, Seattle, and an assistant member in the clinical research division of the Fred Hutchinson Cancer Research Center. From 1990 to 1992, Dr. Bianco was the director of the Bone Marrow Transplant Program at the Veterans Administration Medical Center in Seattle. Dr. Bianco currently serves on the board of directors of the Seattle Police Foundation. Dr. Bianco received his B.S. degree in biology and physics from New York University and his M.D. from Mount Sinai School of Medicine. Dr. Bianco is the brother of Louis A. Bianco, our Executive Vice President, Finance and Administration.

**Dr. Gregorian** has been one of our directors since December 2001. He is the twelfth president of Carnegie Corporation of New York, a grant-making institution founded by Andrew Carnegie in 1911. Prior to his current position, which he assumed in June 1997, Dr. Gregorian served for eight years as Brown University's sixteenth president. He was awarded a Ph.D. in history and humanities from Stanford University. A Phi Beta Kappa and a Ford Foundation Foreign Area Training Fellow, he is a recipient of numerous fellowships, including those from the John Simon Guggenheim Foundation, the American Council of Learned Societies, the Social Science Research Council, and the American Philosophical Society.

**Mr. Love** has been one of our directors since September 2007. Mr. Love is presently the manager of Translational Accelerators, LLC. Mr. Love is also a director of Applied Microarrays Inc., Ascalon, MedTrust

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OnLine, LLC, PAREXEL International, SalutarisMD Inc., was previously a director of ImaRx Therapeutics Inc., and, prior to its acquisition by us in July 2007, served as chairman of the board of Systems Medicine, Inc. He started two biopharmaceutical companies, Triton Biosciences Inc. and ILEX Oncology Inc; he served as chief executive officer for Triton Biosciences from 1983 to 1991, and as chief executive officer for ILEX Oncology 1994 to 2001. In addition, Mr. Love has served in executive positions at not-for-profit organizations, including the Cancer Therapy and Research Center, The San Antonio Technology Accelerator Initiative and the Translational Genomics Research Institute. Mr. Love received his B.S. and M.S. degrees in chemical engineering from Virginia Polytechnic Institute.

**Dr. Mundinger** has been one of our directors since April 1997. From 1986 to 2010, she was a dean and professor at the Columbia University School of Nursing, and an associate dean on the faculty of medicine at Columbia University. In July 2010, Dr. Mundinger was appointed the Edward M. Kennedy Professor in Health Policy and Dean Emeritus at the Columbia University School of Nursing. Dr. Mundinger received her doctorate in public health from Columbia's School of Public Health.

**Dr. Nudelman** has been one of our directors since March 1994. From 2000 to 2007, he served as the President and Chief Executive Officer of The Hope Heart Institute and continued to serve as a member of the board of directors for Hope Heart Institute until 2010. From 1998 to 2000, he was the Chairman of the board of Kaiser/Group Health, retiring in 2000 as Chief Executive Officer Emeritus. From 1990 to 2000, Dr. Nudelman was the President and Chief Executive Officer of Group Health Cooperative of Puget Sound, a health maintenance organization. He also currently serves on the board of directors of OptiStor Technologies, Inc. and Zynchros, Inc. Dr. Nudelman served on the White House Task Force for Health Care Reform from 1992 to 1994 and the President's advisory Commission on Consumer Protection and Quality in Health Care from 1996 to 1998. He has also served on the Pew Health Professions Commission and the AMA Task Force on Ethics, the Woodstock Ethics Commission, and currently serves as Chairman of the American Association of Health Plans. Dr. Nudelman received his B.S. degree in microbiology, zoology and pharmacy from the University of Washington, and holds an M.B.A. and a Ph.D. in health systems management from Pacific Western University.

**Dr. Singer** is one of our founders and directors and currently serves as our Executive Vice President, Chief Medical Officer. Dr. Singer has been one of our directors since our inception in September 1991. From July 1995 to January 2004, Dr. Singer was our Executive Vice President, Research Program Chairman and from April 1992 to July 1995, he served as our Executive Vice President, Research and Development. Prior to joining us, Dr. Singer was a professor of medicine at the University of Washington and a full member of the Fred Hutchinson Cancer Research Center. From 1975 to 1992, Dr. Singer was the Chief of Medical Oncology at the Veterans Administration Medical Center in Seattle. Dr. Singer received his M.D. from State University of New York, Downstate Medical College.

**Dr. Telling** has been one of our directors since December 2006. Prior to his retirement in 2007, Dr. Telling was a corporate officer of Pfizer, most recently as Vice President of Corporate Policy and Strategic Management since 1994. He joined Pfizer in 1977 and was responsible for strategic planning and policy development throughout the majority of his career. He currently serves on the board of directors of Eisai N.A., Medex, Inc., Orogenics, Inc. and our subsidiary, Aequus Biopharma, Inc. Dr. Telling is also a member of the Committee for Economic Development, IBM's Healthcare & Life Sciences Advisory Council, the March of Dimes National Foundation Board, ORBIS, the EAA, and the United Hospital Fund. Dr. Telling received his BA from Hamilton College and his Masters of Industrial and Labor Relations and Ph.D. in Economics and Public Policy from Cornell University.

**Table of Contents****Executive Officers**

The following table sets forth certain information with respect to our executive officers as of December 31, 2010:

<b>Name</b>	<b>Age</b>	<b>Position</b>
James A. Bianco, M.D.	54	Chief Executive Officer
Louis A. Bianco	58	Executive Vice President, Finance and Administration
Daniel G. Eramian	62	Executive Vice President, Corporate Communications
Craig W. Philips	50	President
Jack W. Singer, M.D.	68	Executive Vice President, Chief Medical Officer

For biographical information concerning Dr. James Bianco and Dr. Jack Singer, who are each our directors as well as executive officers, please see the discussion under the heading **Directors**.

**Mr. Bianco** is one of our founders and has been our Executive Vice President, Finance and Administration since February 1, 1992. He was also a director from our inception in September 1991 to April 1992 and from April 1993 to April 1995. From January 1989 through January 1992, Mr. Bianco was a Vice President at Deutsche Bank Capital Corporation in charge of risk management. Mr. Bianco is a Certified Public Accountant and received his M.B.A. from New York University. Mr. Bianco and Dr. Bianco are brothers.

**Mr. Eramian** joined us as Executive Vice President, Corporate Communications in March 2006. Prior to joining us, Mr. Eramian was Vice President of Communications at BIO, an industry organization representing more than 1,200 biotechnology companies, academic institutions, state biotechnology centers and related organizations. Prior to that, he was Assistant Administrator of Communications at the Small Business Administration and Director of Public Affairs at the Department of Justice and Chief Spokesman for the Attorney General of the United States of America.

**Mr. Philips** assumed his role as our President in August 2008. In that role, he manages our day-to-day drug development and commercial operations. Mr. Philips provided services to us as a consultant from April 2008 until he assumed the position of President. Prior to joining us, Mr. Philips was Vice President and General Manager of Bayer Healthcare Oncology from December 2006 to April 2008. Prior to Bayer Healthcare, Mr. Philips was Vice President and General Manager of Berlex Oncology from October 2004 to December 2006. He was also with Schering Plough from 1989 to 2003 in a variety of commercial and general management positions in the U.S., Canada, Southeast Asia and Australia. From 1984 to 1989 he was with Bristol Myers in a variety of commercial roles. Mr. Philips has also served as a member or a chair of the alliance executive committees, which included Onyx, Novartis, Genzyme, and Favrilite. Mr. Philips received his B.Sc. in marketing and M.B.A. from Ohio State University.

**Audit Committee Financial Expert**

Our board of directors has determined that Audit Committee member John Bauer is an audit committee financial expert as defined by the SEC.

**Audit Committee**

We have an Audit Committee established in accordance with Section 3(a)(58)(A) of the Exchange Act. John H. Bauer, Vartan Gregorian, Ph.D., Phillip M. Nudelman, Ph.D. and Frederick W. Telling, Ph.D., are the members of our Audit Committee. Our board of directors has determined that each of Mr. Bauer, Dr. Gregorian, Dr. Nudelman and Dr. Telling is independent within the meaning of the NASDAQ independent director standards.

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### **Section 16(a) Beneficial Ownership Reporting Compliance of the Exchange Act**

Section 16(a) of the Exchange Act requires our executive officers and directors, and persons who own more than ten percent of a registered class of our equity securities, to file with the SEC reports of ownership and reports of changes in ownership of common stock and our other equity securities. Executive officers, directors and greater than ten percent shareholders are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file. Based solely on review of this information or written representations from reporting persons that no other reports were required, we believe that, during the 2010 fiscal year, all Section 16(a) filing requirements applicable to our executive officers, directors and greater than ten percent beneficial owners complied with Section 16(a), except for one Form 4 covering one transaction for Dr. Telling.

### **Code of Ethics**

We have adopted a code of ethics for its senior executive and financial officers (including its principal executive officer and principal financial officer), as well as a code of ethics applicable to all employees and directors. Both codes of ethics are available on our website at [http://www.celltherapeutics.com/officers\\_and\\_directors](http://www.celltherapeutics.com/officers_and_directors). Shareholders may request a free copy of the codes of ethics from:

Cell Therapeutics, Inc.

Attention: Investor Relations

501 Elliott Avenue West, Suite 400

Seattle, WA 98119

(206) 282-7100

Any waivers of or amendments to our code of ethics will be posted on its website, at <http://www.celltherapeutics.com>.

### **Corporate Governance Guidelines**

We have adopted Corporate Governance Guidelines, which are available on our website at [http://www.celltherapeutics.com/officers\\_and\\_directors](http://www.celltherapeutics.com/officers_and_directors). Shareholders may request a free copy of the Corporate Governance Guidelines at the address and phone numbers set forth above.

### **Item 11. Executive Compensation Compensation Discussion and Analysis**

The Compensation Committee oversees the Board's responsibilities relating to the compensation of the Company's chief executive officer and all other executive officers of the Company with a title of executive vice president and above or who otherwise report directly to the chief executive officer. (These individuals are listed in the Summary Compensation Table below and referred to herein as the Company's named executive officers). In discharging this responsibility, the Compensation Committee evaluates and approves the Company's compensation plans, policies and programs as they affect the named executive officers.

This discussion describes and analyzes the compensation program for the named executive officers. First, it covers the Company's compensation objectives and philosophy, the cornerstone of which is pay for performance. Next, it reviews the process the Compensation Committee follows in deciding how to compensate the named executive officers and provides a brief overview of the principal components of the Company's compensation program, including a detailed discussion and analysis of the Compensation Committee's specific decisions about the compensation of the Company's named executive officers for fiscal year 2010.



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### *Compensation Objectives and Philosophy*

The Company believes that compensation of its executive officers should encourage creation of shareholder value and achievement of strategic corporate objectives. The Company attempts to align the interests of its shareholders and management by integrating compensation with the Company's short-term and long-term corporate strategic and financial objectives. In order to attract and retain the most qualified personnel, the Company intends to offer a total compensation package competitive with companies in the pharmaceutical industries, taking into account relative company size, performance and geographic location as well as individual responsibilities and performance. However, the Company believes that it is important to provide executives with performance-based incentives that are tied to key corporate goals critical to the Company's long-term success and viability.

The elements of compensation for the named executive officers include base salaries, annual cash incentives, long-term equity incentives, and perquisites, as well as severance benefits in connection with certain terminations of employment and additional benefits which are available to most other employees, including a 401(k) plan, employee stock purchase plan, health and welfare programs, and life insurance. In general, base salaries, perquisites and other benefit programs, and severance and other termination benefits are primarily intended to attract and retain highly qualified executives as they provide predictable compensation levels that reward executives for their continued service. Annual cash incentives are primarily intended to motivate executives to achieve specific strategies and operating objectives, while long-term equity incentives are primarily intended to align executives' long-term interests with those of the Company's shareholders. Executives have substantial portions of their compensation at risk for annual and long-term performance, with the largest portion at risk for the most senior executives.

In light of the general current economic climate, the Company's compensation philosophy and objectives for fiscal year 2010 continued to focus heavily on retention of the Company's senior management team through this challenging time.

### *Compensation Process*

As part of its process for determining the compensation for the named executive officers, the Compensation Committee considers competitive market data. As authorized by its charter, the Compensation Committee has engaged Milliman, Inc. ( "Milliman" ), an independent executive compensation consultant, to review the Company's compensation plans, policies and programs that affect executive officers and to provide advice and recommendations on competitive market practices and specific compensation decisions. Milliman has worked directly with the Compensation Committee to assist the Compensation Committee in satisfying its responsibilities and will undertake no projects for management except at the request of the Compensation Committee chair and in the capacity of the Compensation Committee's agent. To date, Milliman has not undertaken any projects for management or provided any services to the Company other than its services to the Compensation Committee.

In order to assess competitive market data for executive compensation, the Compensation Committee works with its compensation consultant to develop a peer group of companies with which the Company competes for executive talent (which may or may not be the same organizations that the company competes with directly on a business level). Milliman assisted the Compensation Committee in reviewing the peer group identified for 2010, focusing most closely on industry type and organization size/complexity, with the best indicators of organization size in the Company's industry being number of employees and enterprise value, although each company's revenue and net income were also considered. Following this process, the Compensation Committee selected the following peer group for fiscal 2010 compensation decisions, all of which are biotechnology organizations with an oncology focus and at a stage of company development that is comparable to the Company in the current or near-term stage: Arena Pharmaceuticals, Inc., Ariad Pharmaceuticals, Inc., Array BioPharma, Inc., Cougar Biotechnology, Inc., Dendreon Corp., IDM Pharma, Inc., Intermune, Inc., Medivation, Inc., Progenics

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Pharmaceuticals Inc., Rigel Pharmaceutical, Inc., Seattle Genetics, Inc. and Spectrum Pharmaceuticals, Inc. The peer group was the same as the group identified for fiscal 2009 compensation decisions, except that ZymoGenetics, Inc. was removed from the group as it was acquired by another company.

Once the peer group is established, the Compensation Committee then reviews the base salaries, annual cash-incentive compensation, long-term equity incentive compensation and total compensation for the Company's executive officers as compared to the compensation paid by the companies within the Company's peer group, comparing each executive officer to their counterparts in similar positions with the peer group companies. However, the Compensation Committee does not base its decisions on targeting compensation levels to specific benchmarks against the peer group. Instead, the Compensation Committee refers to the peer group compensation data as background information regarding competitive pay levels and also considers the other factors identified below in making its decisions.

In addition to consideration of the peer group data, the Compensation Committee also considers the value of each item of compensation, both separately and in the aggregate, in light of Company performance, each executive officer's position within the Company, the executive officer's performance history and potential for future advancement, and, with respect to long-term equity incentive compensation, the value of existing vested and unvested outstanding equity awards. The Compensation Committee also considers the recommendations of the Company's chief executive officer with respect to the compensation for each executive other than himself. In setting compensation, the Compensation Committee also considers, among other factors, the possible tax consequences to the Company and its executive officers, the accounting consequences and the impact on shareholder dilution. The Compensation Committee does not assign a specific weight to these factors and none of these factors by itself will compel a particular compensation decision. Instead, this information is used generally by the Compensation Committee to help inform its decision-making process. Except as noted below, decisions by the Compensation Committee are subjective, made in the exercise of the Compensation Committee's judgment.

### *Principal Elements of Compensation*

The principal elements of compensation for the Company's executive officers are composed of base salary, annual cash incentive compensation, and long-term equity incentive compensation. The Company also provides other forms of compensation, including certain perquisites and other benefits. The Compensation Committee reviews, considers and approves each element of compensation, as well as all combined elements of compensation, for the named executive officers.

*Base Salaries.* Base salaries, including merit-based salary increases, for the named executive officers are established based on the scope of their respective responsibilities, competitive market salaries and general levels of market increases in salaries, individual performance, achievement of the Company's corporate and strategic goals and changes in job duties and responsibilities.

The Compensation Committee reviewed the base salaries of the named executive officers for 2010 and determined that they are generally competitive with the market when compared to the Company's peer group despite the fact that the Company has not raised the base salaries of most of its executive officers in recent years. Given this continued competitiveness of the Company's base salaries combined with its current business situation and the current economic climate, and consistent with the Company's philosophy of providing reduced or flat levels of cash compensation while increasing equity awards during this challenging time, the Compensation Committee again determined that base salaries should not be raised in 2010. As a result, the named executive officers' base salaries for fiscal 2010 were as follows: Dr. Bianco \$650,000 (unchanged since established in 2005); Mr. Philips \$402,000 (unchanged since established in his employment agreement effective August 1, 2008), Mr. Bianco \$330,000 (unchanged since established in 2005), Dr. Singer \$340,000 (unchanged since established in 2005), and Mr. Eramian \$315,000 (unchanged since established in 2007).

*Annual Cash Incentive Compensation.* Annual cash incentives for the Company's executive officers are designed to reward performance for achieving key corporate goals, which the Company believes in turn should

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increase shareholder value. In general, the annual incentive awards for executive officers are determined based on achievement of performance objectives established by the Compensation Committee for the fiscal year and an evaluation by the Compensation Committee of the contributions made by individual executives to the Company during the course of the year, including both realization of performance goals and other notable achievements which may not have been contemplated at the time the original performance goals were established.

In August 2010, the Compensation Committee established the 2010 cash incentive program for the Company's named executive officers, including target and maximum bonus opportunities for each executive as well as performance goals that would need to be achieved in order for the executive to receive such bonuses. Both target and maximum bonus opportunities under the program are determined by reference to a percentage of the executive officer's base salary. For fiscal 2010 performance, the target bonus opportunities are 50% for Dr. Bianco, 40% for Mr. Philips, and 30% for each of Mr. Bianco, Dr. Singer and Mr. Eramian, and the maximum bonus opportunities are 125% for Dr. Bianco, 100% for Mr. Philips, and 75% for each of Mr. Bianco, Dr. Singer and Mr. Eramian. These target and maximum bonus levels are consistent with the levels established for the 2009 cash incentive program and were determined by the Compensation Committee, after consulting with Milliman, to be appropriate based on its subjective assessment of the executive's position and ability to directly impact and responsibility for the Company's performance, and its subjective assessment of general compensation practices in place at companies in the Company peer group identified above. Bonuses under the 2010 cash incentive program will be paid out in March 2011 only if the executive officer is employed by the Company on the payment date.

There are three core elements to the 2010 cash incentive program, which together comprise each executive's cash incentive opportunity: financial performance, drug development and individual performance. As indicated in the table below, a portion of each executive's bonus opportunity was allocated to each of these elements, with the percentage of the total bonus opportunity allocated to a particular element based on the executive's position and ability to affect the outcome for that particular goal. With the exception of the individual performance element, each element is composed of sub-elements as identified below. As indicated in the table below, the individual performance element constitutes only a small percentage of each executive's target bonus. Any bonus awarded under this element will be determined in the sole discretion of the Compensation Committee based on its subjective assessment of the executive's performance during the fiscal year and any other factors it deems appropriate.

For the financial performance element, performance for fiscal 2010 is measured based on the Company's operating capital raised and the percentage of the Company's then-outstanding convertible notes due in 2010 that were retired for cash or exchanged for shares or for later maturity bonds during the fiscal year (the "Company Debt Measure") compared with goals established by the Compensation Committee. The executive would generally be entitled to receive the target bonus for the operating capital sub-element if the Company's operating capital raised for fiscal 2010 is \$50 million. The executive would be entitled to receive the maximum bonus if the Company's operating capital for fiscal 2010 exceeds \$100 million (or if the Company's operating capital for fiscal 2010 is \$90 million and more than 35% of the capital is raised through means other than selling or committing stock). For the Company Debt Measure, the executive would be entitled to receive the target bonus for this sub-element if the Company Debt Measure for fiscal 2010 is retirement of 50% of the Company's 2010 convertible notes as described above, with the maximum bonus for this sub-element being payable if the Company Debt Measure for fiscal 2010 is retirement of at least 75% of the Company's 2010 convertible notes as described above.

For the drug development element, the performance goals established by the Compensation Committee for fiscal 2010 related to Pixuvri. The executive would be entitled to payment of his target bonus for this element if, during fiscal 2010, the Company either completed its marketing authorization application submission for Pixuvri or entered into Special Protocol Agreement with the U.S. Food and Drug Administration for phase III clinical trials for Pixuvri. The executive would receive his maximum bonus for this element only if both of these sub-elements were achieved.

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The following table presents the approximate relative weightings between the sub-elements of the financial and drug development components of the program described above (with the incentive opportunity for each sub-element being expressed as a percentage of the executive's base salary). The relative weightings are intended as guidelines, with the Compensation Committee having final authority to determine weightings and the appropriate final bonus amounts.

Name	Financial				Drug Development	
	Operating Capital		Company Debt		Pix 306 SPA Agreement	Pix MAA Submission
	Target	Maximum	Target	Maximum		
James A. Bianco, M.D.	10%	45%	10%	15%	25%	25%
Craig W. Philips	10%	20%	5%	5%	25%	40%
Louis A. Bianco	5%	30%	10%	20%	5%	10%
Jack W. Singer, M.D.	5%	10%	0%	5%	25%	25%
Daniel G. Eramian	5%	20%	10%	20%	10%	10%

In addition, each of the named executive officers would be eligible to receive an additional bonus if the Company applied for and received funds under the federal Therapeutic Discovery Project Program during 2010. Any additional bonus awarded to an executive under this component would be applied to the amount awarded under the 2010 cash incentive program, provided that no executive could receive more than his maximum bonus amount identified above. The maximum bonus for this component (expressed as a percentage of the executive's base salary) is 5% for Dr. Bianco and Mr. Philips and 10% for each of Mr. Bianco, Dr. Singer and Mr. Eramian.

In February 2011, the Compensation Committee determined that the Company had raised \$96 million in operating capital in 2010 and had retired 100% of its convertible notes outstanding in 2010. On that basis, the Compensation Committee awarded each executive an amount between the target and maximum levels for the operating capital sub-element and the maximum bonus level for the Company Debt Measure sub-element. In addition, the Compensation Committee noted that the Company had completed its marketing authorization application submission for Pixuvri in 2010. The Compensation Committee also determined that each executive should, based upon the Compensation Committee's subjective assessment of each executive's individual contributions during the year, receive an additional amount between 5% and 15% of the executive's base salary. While the Compensation Committee's determination of these amounts was inherently subjective, the key factors in the Compensation Committee's determination were the executives' efforts during 2010 in obtaining additional financing for the Company (and in gaining shareholder approval of authorization for the issuance of additional shares by the Company as an important step in obtaining such financing) and the Compensation Committee's subjective assessment that these bonuses were appropriate to help continue to retain the executive team. Finally, the Compensation Committee noted that the Company had applied for and received the maximum amount of funds available for four projects under the Therapeutic Discovery Project Program and awarded each of the executives the maximum bonus amount under that component.

Based on the Company's performance against the objective pre-established goals discussed above, the target and maximum bonus opportunities related to the Company's operating capital achievement, the maximum bonus opportunity related to the Company Debt Measure, the bonus opportunity related to the marketing authorization application submission for Pixuvri, the maximum bonus opportunity with respect to the Therapeutic Discovery Project Program, and the Compensation Committee's general assessment of each executive's individual performance during fiscal 2010, the Compensation Committee determined to award cash incentives to each of the named executive officers in the following amounts (expressed as a percentage of such executive's base salary): Dr. Bianco, 90%; Mr. Philips, 70%; Mr. Bianco, 75%; Dr. Singer, 62.5%; and Mr. Eramian, 70%. These amounts are reflected in the Bonus column of the Summary Compensation Table below.

*Long-Term Equity Incentive Compensation.* The Compensation Committee awards long-term equity incentive compensation to the Company's executive officers to align their interests with those of the Company's

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shareholders, to provide additional incentives to the Company's executive officers to improve the long-term performance of the Company's common stock and achieve the Company's corporate goals and strategic objectives and to retain the Company's executive officers. While stock options have been granted in the past, the Company's current practice is primarily to grant long-term incentive awards to the named executive officers in the form of shares of restricted stock or units payable in stock. In general, the restricted stock vests over a period of years following the date of grant and may be subject to the achievement within a specified period of critical corporate goals and strategic objectives established by the Compensation Committee. Thus, restricted shares are designed both to link executives' interests with those of the Company's shareholders as the shares' value is based on the value of the Company's common stock, to provide a long-term retention incentive for the vesting period as they generally have value regardless of stock price volatility and, in the case of awards subject to performance-based vesting requirements, to provide further incentives for executives to achieve goals considered critical to the Company's success.

In determining the size of the Company's long-term equity incentive awards, the Compensation Committee reviews competitive market data for similar positions in the Company's peer companies, the executive officer's performance history and/or potential for future responsibility and promotion, the chief executive officer's recommendations (with respect to executives other than himself) and the value of existing vested and unvested outstanding equity awards. The relative weight given to each of these factors will vary from individual to individual at the Compensation Committee's discretion and adjustments may be made as the Compensation Committee deems reasonable to attract candidates in the competitive environment for highly qualified employees in which the Company operates.

As described in detail in the Company's 2010 annual proxy statement, the Compensation Committee determined in 2009 that it was critical to focus management on the goal of restoring shareholder value and achieving certain regulatory approvals. Accordingly, in December 2009, the Compensation Committee decided to grant to each of the named executive officers restricted stock units that will be payable in fully vested shares of the Company's common stock upon the achievement of a particular performance goal, subject to the goal being achieved before on or December 31, 2011 and the individual's continued employment or service with the Company. (The Company refers to these awards as the December 2009 Performance Awards). The Compensation Committee believed these awards at the grant levels identified below, together with certain retention grants made to the named executive officers during 2009, would provide executives an appropriate level of incentives to help achieve the performance goals noted below and maximize and restore shareholder value and to remain with the Company over a multi-year period. For this reason, no new equity awards were granted to the named executive officers during 2010.

During 2010, the Compensation Committee approved amendments to two of the eight performance goals under the December 2009 Performance Awards. In June 2010, the Compensation Committee approved an amendment to each award to provide that a portion of the award will vest if the Company achieves a cash-flow break-even in any fiscal quarter during the term of the award (as opposed to the portion vesting only if the Company achieved a cash-flow break even for the fourth quarter of fiscal 2010). In November 2010, the Compensation Committee approved an amendment to each award to provide that a portion of the award will vest if the Company obtains approval of a marketing authorization application (MAA) for either OPAXIO or Pixuvri (as opposed to the portion vesting only if the Company obtained approval of an MAA for OPAXIO). The Compensation Committee believed that these amendments were appropriate in light of the challenging economic conditions and the Company's evolving strategic goals at the time of the amendment.

The performance goals under the December 2009 Performance Awards, as amended in 2010, are as follows:

- (a) MAA approval for either OPAXIO or Pixuvri ( OPAXIO/Pix MAA Approval );
- (b) approval of new drug application ( NDA ) for OPAXIO ( OPAXIO NDA Approval );
- (c) achievement by the Company of fiscal year sales equal to or greater than \$50,000,000 (the \$50M Sales Goal );

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- (d) achievement by the Company of fiscal year sales equal to or greater than \$100,000,000 (the \$100M Sales Goal );
- (e) Pixuvri NDA Approval ( Pix NDA Approval );
- (f) achievement by the Company of break-even cash flow in any fiscal quarter (the Fiscal Quarter Break Even );
- (g) achievement by the Company of earnings per share results in any fiscal year equal to or greater than \$0.05 per share of Company common stock (the EPS Goal ); and
- (h) achievement of a price per share of Company common stock equal to \$2.94 (the Share Appreciation Goal ).

If one or more of the performance goals are timely achieved, an award recipient will be entitled to receive a number of shares of Company common stock (subject to the applicable share limits of the Company's equity incentive plan) determined by multiplying (1) the award percentage corresponding to that particular performance goal by (2) the total number of outstanding shares of Company common stock, determined on a non-fully diluted basis, as of the date the Compensation Committee certifies that the particular performance goal has been achieved. The award percentages corresponding to the various performance goals for each of the named executive officers are set forth in the following table:

Name	Performance Goals and Applicable Award Percentages							Share Appreciation Goal
	OPAXIO/Pix MAA Approval	OPAXIO NDA Approval	\$50M Sales Goal	\$100M Sales Goal	Pix NDA Approval	Fiscal Quarter Break Even	EPS Goal	
James A. Bianco, M.D.	0.15%	0.2%	0.3%	0.6%	0.45%	0.3%	0.7%	0.75%
Louis A. Bianco	0.061%	0.081%	0.122%	0.243%	0.182%	0.122%	0.284%	0.305%
Daniel G. Eramian	0.045%	0.06%	0.09%	0.18%	0.135%	0.09%	0.21%	0.225%
Craig W. Philips	0.09%	0.12%	0.18%	0.36%	0.27%	0.18%	0.42%	0.45%
Jack W. Singer, M.D.	0.061%	0.081%	0.122%	0.243%	0.182%	0.122%	0.284%	0.305%

A performance goal will not be considered achieved unless and until the date on which the Compensation Committee certifies that it has been achieved, and as noted above, in each case the goal must be achieved on or before December 31, 2011. If a change in control of the Company occurs, and if the award recipient is then still employed by or is providing services to the Company or one of its subsidiaries, the award recipient will be entitled to receive the full award percentage with respect to any performance goal which was not otherwise achieved before the date of the change in control (as though that performance goal had been fully achieved as of the time of the change in control), except that in the case of the Share Appreciation Goal, the vesting of the award will be determined based on the Company's stock price at the time of the change in control.

In July 2010, the Compensation Committee also approved an amendment to each of the December 2009 Performance Awards granted to the named executive officers that converted a portion of the award to a grant of restricted shares. The Compensation Committee believed, particularly in light of the current economic environment, that the link between executives' interests and shareholders' interests would be further enhanced if the executives held restricted shares (whereas the December 2009 Performance Awards had provided for delivery of shares only upon the vesting of the awards). The restricted shares issued to the executives pursuant to this conversion are subject to the same performance-based vesting requirements as the December 2009 Performance Award to which they relate and will be forfeited back to the Company should these vesting requirements not be satisfied. In order to ensure that the restricted shares did not provide a benefit to the executive beyond that intended by the original December 2009 Performance Award, any restricted shares that vest in connection with the achievement of a performance goal on or before December 31, 2011 will reduce on a share-for-share basis the number of shares that would have been delivered under the original December 2009 Performance Award upon achievement of that performance goal. In furtherance of that intent, if the number of shares that would have been delivered under the original December 2009 Performance Award on achievement of a performance goal is less

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than the number of restricted shares that vest on achievement of that performance goal under the July 2010 award, a number of such restricted shares equal to the difference will be forfeited to the Company so that the executive retains no more shares related to that particular performance goal than the number of shares that would have otherwise been deliverable with respect to that goal under the original December 2009 Performance Award.

On the lines corresponding to the December 15, 2009 date of grant of these awards, the Outstanding Equity Awards at Fiscal 2010 Year-End table below reflects the number of shares that would vest or be issued to each named executive officer, as the case may be, upon timely achievement of the related performance goal based on the applicable payout percentage and the number of shares of the Company's common stock issued and outstanding on December 31, 2010. The actual number of shares that would vest or be issued for each award may be different from the share number reported in the table depending on whether the performance goal is achieved and, if achieved, the number of shares of the Company's common stock issued and outstanding at the time the Compensation Committee certifies that the related performance goal has been achieved. The grant levels for the December 2009 Performance Awards granted to each named executive officer were inherently subjective, determined by the Compensation Committee in its discretion taking into account its general assessment of each executive's overall responsibilities and contributions and the other factors noted under Long-Term Equity Incentive Compensation above.

*Perquisites and Other Benefits.* The named executive officers receive certain perquisites and other benefits provided by or paid for by the Company, including auto allowance, tax preparation fees, health club dues and reimbursement for commercial travel for family members. The named executive officers are also entitled to participate in the Company's benefit programs which are available to all Company employees, including company-sponsored health, welfare, 401(k), and employee stock purchase plans. Certain of the Company's named executive officers occasionally use a chartered aircraft for business related travel (such business purpose is approved in advance by the Chair of the Board). When space was available, certain spouses or other family members accompanied the named executive officers on such trips. In those cases, there was no additional cost to the Company of having additional passengers on such flights.

The perquisites provided to a particular named executive officer are determined by the Compensation Committee in its judgment and are considered by the Compensation Committee when it makes its subjective assessment of the appropriateness of the executive's overall compensation arrangements. The Company provides these perquisites and other benefits as a means of providing additional compensation to its named executive officers to help retain them and, in some cases, to make certain benefits available in a convenient and efficient manner in light of the demands and time constraints imposed on its executives. The Company reviews the perquisites and other benefits provided to its named executive officers periodically and, in light of the general current economic environment, determined during fiscal year 2009 that it would eliminate any tax gross-up benefits for its executives (except for the existing tax gross-ups noted below in the context of a change in control of the Company).

### *Post-Termination Protection and Payments*

The Company has entered into severance agreements with each of the named executive officers. The Compensation Committee believes these agreements are important in attracting and retaining key executive officers. Under these agreements, the executive would be entitled to severance benefits in the event of a termination of the executive's employment by the Company without cause or by the executive for good reason. The Company has determined that it is appropriate to provide each named executive officer with severance benefits under these circumstances in light of his position with the Company and as part of his overall compensation package. The severance benefits for each named executive officer are generally determined as if he continued to remain employed by the Company for 18 months following his actual termination date (or two years in the case of Dr. Bianco). Because the Company believes that a termination by an executive for good reason (or constructive termination) is conceptually the same as an actual termination by the Company without cause, the Company believes it is appropriate to provide severance benefits following such a constructive termination of the executive's employment.

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If a change in control of the Company occurs, outstanding equity awards, including awards held by the Company's named executive officers, will generally become fully vested if they are not assumed by the successor entity. In addition, the severance agreements with each of the named executive officers (other than Mr. Philips) provide for the executive to be reimbursed for the full amount of any excise taxes imposed on their severance payments and any other payments under Section 4999 of the Internal Revenue Code. Each of the named executive officers (including Mr. Philips) would also be entitled to reimbursement for any excise taxes imposed under Section 4999 upon vesting of the December 2009 Performance Awards granted to these executives as described above. The Company provides the named executive officers with a gross-up for any parachute payment excise taxes that may be imposed because the Company determined the appropriate level of benefits for each named executive officer without factoring in the adverse effects that may result from imposition of these excise taxes. The excise tax gross-up is intended to make the named executive officer whole for any adverse tax consequences they may become subject to under Section 4999 of the Internal Revenue Code, and to preserve the level of benefits that the Company has determined to be appropriate in these circumstances.

For more information regarding these severance arrangements, please see [Potential Payments upon Termination or Change in Control](#) below.

### *Tax Deductibility of Pay*

Section 162(m) of the Internal Revenue Code places a limit of \$1,000,000 on the amount of compensation that the Company may deduct in any one year with respect to the Company's chief executive officer and certain other executive officers. There is an exception to the \$1,000,000 limitation for performance-based compensation meeting certain requirements. In general, stock options granted under the Company's stock incentive plans are intended to comply with the applicable requirements for this exemption, and the Compensation Committee generally considers the limitations imposed by Section 162(m) among other factors in making its compensation decisions. However, the Compensation Committee reserves the right to design programs that recognize a full range of performance criteria important to the Company's success, even where the compensation paid under such programs may not be deductible. The Compensation Committee will continue to monitor the tax and other consequences of the Company's executive compensation program as part of its primary objective of ensuring that compensation paid to the Company's executive officers is reasonable, performance-based and consistent with the Company's goals and the goals of the Company's shareholders.

### *Risk Considerations*

The Compensation Committee has reviewed the Company's compensation programs to determine whether they encourage unnecessary or excessive risk taking and has concluded that they do not. The Compensation Committee believes that the design of the Company's annual cash and long-term equity incentives provides an effective and appropriate mix of incentives to help ensure the Company's performance is focused on long-term stockholder value creation and does not encourage the taking of short-term risks at the expense of long-term results. While the Company's performance-based cash bonuses are generally based on annual results, the amount of such bonuses are generally capped and represent only a portion of each individual's overall total compensation opportunities. The Company also generally has discretion to reduce bonus payments (or pay no bonus) based on individual performance and any other factors it may determine to be appropriate in the circumstances.

As to the Company's compensation arrangements for executive officers, the Compensation Committee takes risk into account in establishing and reviewing these arrangements and believes that the executive compensation arrangements do not encourage unnecessary or excessive risk-taking. Base salaries are fixed in amount and thus do not encourage risk-taking. While the Compensation Committee considers the achievement of specific financial and operating performance goals in determining the cash bonuses to be awarded to executives under the Company's cash incentive program, the Compensation Committee determines the actual amount of each executive's bonus based on multiple Company and individual performance criteria as described above. The Compensation Committee believes that the annual incentive program appropriately balances risk and the desire to focus executives on specific annual goals important to the Company's success, and that it does not encourage



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unnecessary or excessive risk taking. Finally, a significant portion of the compensation provided to the Company's executive officers is in the form of equity awards that further align executives' interests with those of shareholders. The Compensation Committee believes that these awards do not encourage unnecessary or excessive risk-taking since the ultimate value of the awards is tied to the Company's stock price, and since grants are generally subject to long-term vesting schedules to help ensure that executives always have significant value tied to long-term stock price performance.

### **Summary**

The Compensation Committee believes that the Company's compensation philosophy and programs are designed to foster a performance-oriented culture that aligns employees' interests with those of the Company's shareholders. The Compensation Committee believes that the compensation of the Company's executives is both appropriate and responsive to the goal of improving shareholder value.

*The following Compensation Committee Report and related disclosure shall not be deemed incorporated by reference by any general statement incorporating this Annual Report on 10-K into any filing under the Securities Act of 1933, as amended, or the Securities Act, or under the Exchange Act, except to the extent that the Company specifically incorporates this information by reference, and shall not otherwise be deemed filed under the Securities Act or the Exchange Act.*

### **Compensation Committee Report**

The Compensation Committee reviewed this Compensation Discussion and Analysis and discussed its contents with Company management. Based on this review and discussions, the Compensation Committee has recommended to the Board that this Compensation Discussion and Analysis be included in this Annual Report on Form 10-K.

Respectfully submitted by the Compensation Committee:

**Frederick W. Telling, Ph.D., Chair**

**Richard L. Love**

**Mary O. Munding, DrPH**

**Phillip M. Nudelman, Ph.D.**

### **Compensation Committee Interlocks and Insider Participation**

The directors listed at the end of the Compensation Committee Report above were each members of the Compensation Committee during all of fiscal year 2010, except for Dr. Munding who was appointed to the Compensation Committee in December 2010. No director who served on the Compensation Committee during fiscal year 2010 is or has been an executive officer of the Company or had any relationships requiring disclosure by the Company under the SEC's rules requiring disclosure of certain relationships and related-party transactions. None of the Company's executive officers served as a director or a member of a compensation committee (or other committee serving an equivalent function) of any other entity, any executive officer of which served as a member of the Board or the Compensation Committee during fiscal year 2010.

**Table of Contents****EXECUTIVE COMPENSATION****Summary Compensation Table Fiscal Years 2008-2010**

The following table sets forth information concerning compensation for services rendered to the Company by the Chief Executive Officer, or the CEO, the Executive Vice President, Finance and Administration, and the Company's next three most highly compensated executive officers for fiscal years 2008, 2009 and 2010 by each of the named executive officers. Collectively, these are the named executive officers.

Name and Principal Position	Year	Salary (\$)	Bonus \$(1)	Stock Awards \$(2)(3)	Option Awards \$(2)	Non-Equity Incentive Plan Compensation \$(1)	All Other Compensation \$(4)	Total (\$)
James A. Bianco, M.D. Chief Executive Officer	2010	650,000	585,000				125,967	1,360,967
	2009	650,000	585,000	11,275,903			81,127	12,592,030
	2008	650,000	362,793	57,000		216,645	219,718	1,506,156
Louis A. Bianco Executive Vice President, Finance and Administration	2010	330,000	247,500				10,009	587,509
	2009	330,000	204,600	4,512,112			13,249	5,059,961
	2008	330,000	99,000	28,500		66,000	16,472	539,972
Daniel G. Eramian Executive Vice President, Corporate Communications	2010	315,000	220,500				250	535,750
	2009	315,000	181,125	3,382,770			315	3,879,210
	2008	315,000	78,750	28,500		63,000	518	485,768
Craig W. Philips President	2010	402,000	281,400				16,125	699,525
	2009	402,000	241,200	6,765,543			14,775	7,423,518
	2008	167,500	22,344	147,500	23,147	44,656		405,147
Jack W. Singer, M.D. Executive Vice President, Chief Medical Officer	2010	340,000	212,500				30,475	582,975
	2009	340,000	119,000	4,512,112			40,490	5,011,602
	2008	340,000	85,000	28,500		68,000	46,748	568,248

- (1) Please see the Compensation Discussion and Analysis above for a description of the cash incentive program for the named executive officers for fiscal 2010.
- (2) The amounts reported in the Stock Awards and Option Awards columns of the table above for each fiscal year reflect the fair value on the grant date of the stock awards (including restricted stock, stock bonuses and the December 2009 Performance Awards) and option awards, respectively, granted to the named executive officers during the fiscal year. These values have been determined under generally accepted accounting principles used to calculate the value of equity awards for purposes of the Company's financial statements. For a discussion of the assumptions and methodologies used to calculate the amounts reported above, please see the discussion of equity awards contained in Note 13 (Share-Based Compensation) to the Company's Consolidated Financial Statements, included as part of this Form 10-K.
- (3) The amounts reported in the Stock Awards column of the table above for fiscal 2009 include the grant-date fair value of the December 2009 Performance Awards based on the probable outcome (as of the grant date) of the performance-based conditions applicable to the awards, as determined under generally accepted accounting principles. The following table presents the aggregate grant-date fair value of the December 2009 Performance Awards included in the Stock Awards column for fiscal 2009 and the aggregate grant-date fair value of these awards assuming that the highest level of performance conditions will be achieved. The balance of the amounts reported in the Stock Awards column above for fiscal 2009 also includes the grant-date fair value of stock bonuses awarded to the executives in July and November 2009 as described in the Company's 2010 annual proxy statement.

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Name	2009 Performance Awards	
	Aggregate Grant Date Fair Value (Based on Probable Outcome) (\$)	Aggregate Grant Date Fair Value (Based on Maximum Performance) (\$)
James A. Bianco, M.D.	4,528,069	14,821,909
Louis A. Bianco	1,841,415	6,015,644
Daniel G. Eramian	1,358,421	4,446,573
Craig W. Philips	2,716,842	8,893,145
Jack W. Singer, M.D.	1,841,415	6,015,644

- (4) The following table provides detail on the amounts reported in the All Other Compensation column of the table above for each named executive officer:

Name	Life/Health Insurance Premiums (\$)	401(k) Match (\$)	Other Personal Benefits \$(1)	Total (\$)
James A. Bianco, M.D.	47,858		78,109(2)	125,967
Louis A. Bianco	6,334	3,675		10,009
Daniel G. Eramian	250			250
Craig W. Philips	250	3,675	12,200(3)	16,125
Jack W. Singer, M.D.	26,800	3,675		30,475

- (1) Certain named executive officers were accompanied by spouses or other family members on trips using chartered aircraft where the use of the chartered aircraft was primarily for business purposes. In those cases, there was no incremental cost to the Company of having additional passengers on the chartered aircraft, and as a result, no amount is reflected in this table with respect to this benefit.
- (2) This amount includes \$66,596 for family members travel on commercial aircraft, \$6,793 for tax preparation fees, and \$4,720 for health club dues.
- (3) This amount includes \$9,000 for automobile allowance and \$3,200 for tax preparation fees.

**Compensation of Named Executive Officers**

The Summary Compensation Table above quantifies the value of the different forms of compensation earned by or awarded to the Company's named executive officers for the fiscal years indicated above. The primary elements of each named executive officer's total compensation reported in the table are base salary, an annual bonus, and long-term equity incentives consisting of awards of restricted stock and restricted stock units. Named executive officers also received the other benefits listed in the All Other Compensation column of the Summary Compensation Table, as further described in the footnotes to the table.

The Summary Compensation Table should be read in conjunction with the tables and narrative descriptions that follow. The Grants of Plan-Based Awards table provides information regarding the incentives awarded to the named executive officers in fiscal 2010. The Outstanding Equity Awards at Fiscal Year-End and Option Exercises and Stock Vested tables provide further information on the named executive officers' potential realizable value and actual value realized with respect to their equity awards. The Potential Payments upon Termination or Change in Control section provides information on the benefits the named executive officers may be entitled to receive in connection with certain terminations of their employment and/or a change in control of the Company.

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### Description of Employment Agreements Cash Compensation

In December 2008, the Company entered into an employment agreement with Dr. Bianco that replaced his original employment agreement entered into in 2005. The employment agreement has a two-year term. The agreement provides that Dr. Bianco will receive an initial annualized base salary of \$650,000, subject to review by the Compensation Committee. Based on its review, the Compensation Committee may increase (but not reduce) the base salary level. The agreement also provides for annual bonuses for Dr. Bianco with a target annual bonus of at least 50% of his base salary and for an additional bonus to be paid if certain stretch performance goals established by the Compensation Committee for the applicable year are achieved. The agreement also provides for Dr. Bianco to participate in the Company's usual benefit programs for senior executives, payment by the Company of premiums for universal life insurance with a coverage amount of not less than \$5,000,000 (up to an annual limit of \$41,500, subject to adjustment) and certain other personal benefits set forth in the agreement. Provisions of Dr. Bianco's agreement relating to outstanding equity incentive awards and post-termination of employment benefits are discussed below under the applicable sections of this Annual Report on Form 10-K.

In April 2008, the Company entered into an employment agreement with Mr. Philips. The employment agreement does not have a specified term. The agreement provides that Mr. Philips will receive an initial annualized base salary of \$402,000, subject to annual review by the Compensation Committee, and will be eligible to receive an annual bonus, with the target annual bonus being 40% of his base salary. The agreement also provides for Mr. Philips to participate in the Company's usual benefit programs for senior executives and to receive an auto allowance of \$750 per month. Provisions of Mr. Philips' agreement relating to outstanding equity incentive awards and post-termination of employment benefits are discussed below under the applicable sections of this Annual Report on Form 10-K.

### Grants of Plan-Based Awards Fiscal 2010

The following table presents information regarding the incentive awards granted to the named executive officers for fiscal 2010.

Name/Award Type	Estimated Future Payouts Under Non-Equity Incentive Plan Awards				Estimated Future Payouts Under Equity Incentive Plan Awards				All Other Stock Awards: Number of Shares of Stock or Units	All Other Option Awards: Number of Securities Underlying Options	Exercise or Base Price of Option Awards (\$/Sh)	Grant Date Fair Value of Stock and Option Awards (\$)
	Grant Date	Threshold (\$)	Target (\$)	Maximum (\$)	Threshold (#)	Target (#)	Maximum (#)					
James A. Bianco, M.D.												
Louis A. Bianco												
Daniel G. Eramian												
Craig W. Philips												
Jack W. Singer, M.D.												

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### Outstanding Equity Awards at Fiscal 2010 Year-End

The following table presents information regarding the outstanding equity awards held by each of the Company's named executive officers as of December 31, 2010, including the vesting dates for the portions of these awards that had not vested as of that date.

Name	Grant Date	Option Awards				Stock Awards			
		Number of Shares Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Not Exercisable	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)(1)	Equity Incentive Plan Awards; Number of Unearned Shares, Units or Rights That Have Not Vested (#)(2)	Equity Incentive Plan Awards; Market or Payout Value of Unearned Shares, Units or Rights That Have Not Vested (\$)(1)
James A. Bianco, M.D.	11/30/2001	6,250		1,091.80	11/30/2011				
	7/30/2002	2,994		139.40	7/30/2012				
	12/3/2002	4,750		379.80	12/3/2012				
	12/11/2003	3,125		324.00	12/11/2013				
	12/14/2005	6,250		94.40	12/14/2015				
	1/18/2007	6,000		68.00	1/18/2017				
	12/27/2007	10,000		18.90	12/27/2017				
	3/25/2009					965,519(3)	357,242		
	12/15/2009							1,220,627(4)	451,632
	12/15/2009							1,627,503(5)	602,176
	12/15/2009							2,441,254(6)	903,264
	12/15/2009							4,882,508(7)	1,806,528
	12/15/2009							3,661,881(8)	1,354,896
	12/15/2009							2,441,254(9)	903,264
	12/15/2009							5,696,259(10)	2,107,616
	12/15/2009							6,103,135(11)	2,258,160
Louis A. Bianco	11/30/2001	1,033		1,091.80	11/30/2011				
	7/30/2002	701		139.40	7/30/2012				
	12/3/2002	1,115		379.80	12/3/2012				
	12/11/2003	1,486		324.00	12/11/2013				
	7/14/2005	3,750		111.20	7/14/2015				
	12/14/2005	3,000		94.40	12/14/2015				
	6/22/2006	750		56.80	6/22/2016				
	1/18/2007	1,750		68.00	1/18/2017				
	12/27/2007	3,600		18.90	12/27/2017				
	3/25/2009					289,655(3)	107,172		
	12/15/2009							496,388(4)	183,664
	12/15/2009							659,139(5)	243,881
	12/15/2009							992,777(6)	367,327
	12/15/2009							1,977,416(7)	731,644
	12/15/2009							1,481,027(8)	547,980
	12/15/2009							992,777(9)	367,327
	12/15/2009							2,311,054(10)	855,090
	12/15/2009							2,481,941(11)	918,318
Daniel G. Eramian	3/31/2006	2,375		76.40	3/31/2016				
	6/22/2006	750		56.80	6/22/2016				
	1/18/2007	1,500		68.00	1/18/2017				
	12/27/2007	3,600		18.90	12/27/2017				

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3/25/2009	289,655(3)	107,172		
12/15/2009			366,188(4)	135,490
12/15/2009			488,251(5)	180,653
12/15/2009			732,376(6)	270,979
12/15/2009			1,464,752(7)	541,958
12/15/2009			1,098,564(8)	406,469
12/15/2009			732,376(9)	270,979
12/15/2009			1,708,878(10)	632,285
12/15/2009			1,830,940(11)	677,448

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Name	Grant Date	Option Awards		Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Stock Awards		
		Number of Shares Underlying Unexercised Options (#)	Number of Securities Underlying Unexercised Options (#)				Market Value of Shares or Units of Stock That Have Not Vested (\$)(1)	Equity Incentive Plan Awards; Number of Shares, Units or Other Rights That Have Not Vested (#)(2)	Equity Incentive Plan Awards; Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested (\$)(1)
Craig W. Philips	6/5/2008	10,000	5,000(12)	5.80	6/5/2018				
	6/5/2008					8,333(13)	3,083		
	3/25/2009					579,311(3)	214,345		
	12/15/2009							732,376(4)	270,979
	12/15/2009							976,502(5)	361,306
	12/15/2009							1,464,752(6)	541,958
	12/15/2009							2,929,505(7)	1,083,917
	12/15/2009							2,197,129(8)	812,938
	12/15/2009							1,464,752(9)	541,958
	12/15/2009							3,417,755(10)	1,264,570
	12/15/2009							3,661,881(11)	1,354,896
Jack W. Singer, M.D.	11/30/2001	1,875		1,091.80	11/30/2011				
	7/30/2002	767		139.40	7/30/2012				
	12/3/2002	2,000		379.80	12/3/2012				
	12/11/2003	1,875		324.00	12/11/2013				
	7/14/2005	3,750		111.20	7/14/2015				
	12/14/2005	3,000		94.40	12/14/2015				
	6/22/2006	750		56.80	6/22/2016				
	1/18/2007	1,750		68.00	1/18/2017				
	12/27/2007	3,600		18.90	12/27/2017				
	3/25/2009					289,655(3)	107,172		
	12/15/2009							496,388(4)	183,664
	12/15/2009							659,139(5)	243,881
	12/15/2009							992,777(6)	367,327
	12/15/2009							1,977,416(7)	731,644
	12/15/2009							1,481,027(8)	547,980
	12/15/2009							992,777(9)	367,327
	12/15/2009							2,311,054(10)	855,090
	12/15/2009							2,481,941(11)	918,318

- (1) The dollar amounts shown in these columns are determined by multiplying the applicable number of shares or units by \$0.37 (the closing price of the Company's common stock on the last trading day of fiscal 2010).
- (2) The entries in this column reflect the December 2009 Performance Awards that are subject to achievement by the Company of certain performance goals (identified in the footnotes below) on or before December 31, 2011. As described in the Compensation Discussion and Analysis above, each of these awards consists of a restricted stock component and a restricted stock unit component, with the number of shares that will vest or be payable in shares of the Company's common stock, as applicable, upon achievement of the related performance goal to be determined by multiplying the payout percentage that has been assigned by the Compensation Committee to that goal for purposes of the named executive officer's award by the number of shares of the Company's common stock issued and outstanding at the time the Compensation Committee certifies that that particular goal has been achieved. The table above reports the aggregate number of shares that would be vest or be issued under each award upon timely achievement of each performance goal based on the applicable payout percentages and the number of shares of the Company's common stock issued and outstanding on December 31, 2010. The actual number of shares, if any, that will vest or be issued for each award upon timely achievement of the related performance goal may be different from the number reported in the table above depending on the number of shares of the Company's common stock issued and outstanding at the time the Compensation Committee certifies that the goal has been achieved.
- (3) These shares vest over two years, with one-third of the shares having vested on each of September 25, 2009 and March 25, 2010 and the remaining shares vesting on March 25, 2011, subject to continued service with the Company.
- (4) The vesting of these awards is subject to the Company's obtaining MAA approval of OPAXIO or Pixuvri on or before December 31, 2011.

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- (5) The vesting of these awards is subject to the Company's obtaining NDA approval of OPAXIO on or before December 31, 2011.
- (6) The vesting of these awards is subject to achievement by the Company of fiscal year sales equal to or greater than \$50 million on or before December 31, 2011.



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- (7) The vesting of these awards is subject to achievement by the Company of fiscal year sales equal to or greater than \$100 million on or before December 31, 2011.
- (8) The vesting of these awards is subject to the Company's obtaining NDA approval of Pixuvri on or before December 31, 2011.
- (9) The vesting of these awards is subject to achievement by the Company of break-even cash flow in any quarter of fiscal 2011.
- (10) The vesting of these awards is subject to achievement by the Company of earnings per share results in any fiscal year equal to or greater than \$0.05 per share of Company common stock on or before December 31, 2011.
- (11) The vesting of these awards is subject to the Company's achievement of a price per share of the Company's common stock equal to \$2.94 on or before December 31, 2011.
- (12) This option grant vests over three years, with one-third of the grant having vested on each of April 26, 2009 and April 26, 2010 and the remainder of the grant vesting on April 26, 2011, subject to continued service with the Company.
- (13) The shares subject to this grant vest over three years, with 8,334 shares having vested on April 26, 2009, 8,333 shares having vested on April 26, 2010 and the remaining 8,333 shares vesting on April 26, 2011, subject to continued service with the Company.

**Option Exercises and Stock Vested Fiscal Year 2010**

The following table presents information regarding the vesting during fiscal year 2010 of stock awards previously granted by the Company to the named executive officers. No executive officer exercised any stock options granted by the Company during fiscal 2010.

Name	Option Awards		Stock Awards	
	Number of Shares Acquired on Exercise (#)	Value Realized on Exercise (\$)	Number of Shares Acquired on Vesting (#)	Value Realized on Vesting \$(1)
James A. Bianco, M.D.			965,519	646,898
Louis A. Bianco			289,656	194,070
Daniel G. Eramian			289,656	194,070
Craig W. Philips			587,644	393,388
Jack W. Singer, M.D.			289,656	194,070

- (1) The dollar amounts shown in this column for stock awards are determined by multiplying the number of shares or units, as applicable, that vested by the per-share closing price of the Company's common stock on the vesting date.

**Potential Payments upon Termination or Change in Control**

The following section describes the benefits that may become payable to the named executive officers in connection with a termination of their employment and/or a change in control of the Company.

*James A. Bianco, M.D.* Pursuant to his employment agreement described above, if Dr. Bianco's employment is terminated by the Company without cause or if he resigns for good reason (as the terms "cause" and "good reason" are defined in the agreement), he will receive the following severance benefits: (i) cash severance equal to two years of his base salary, (ii) reimbursement for up to two years by the Company for COBRA premiums to continue his medical coverage and that of his eligible dependents, (iii) continued payment for up to two years by the Company of premiums to maintain life insurance paid for by the Company at the time of his termination, and (iv) a cash payment for the value of his accrued and unpaid vacation and sick leave. In addition, Dr. Bianco would be entitled to accelerated vesting of all of his then-outstanding and unvested stock-based compensation, and his outstanding stock options would remain exercisable for a period of two years following the severance date. In the event of a change of control of the Company, if Dr. Bianco is terminated without cause or resigns for good reason, he will receive cash severance in the form of a lump sum payment equal to two years of his base salary, plus an amount equal to the greater of the average of his three prior years' bonuses or thirty percent of his base salary, as well as the benefits described in clauses (ii) through (iv) above. Dr. Bianco's right to receive these severance benefits is conditioned upon his executing a release of claims in favor of the Company and complying with certain restrictive covenants set forth in the agreement. Further, if the Company is required to restate financials due to its material noncompliance with any financial reporting requirement under the U.S. securities laws during any period for which Dr. Bianco was chief executive officer of the Company or Dr. Bianco acts in a manner that would have constituted cause for his termination had he been

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employed at the time of such act, Dr. Bianco will not be entitled to any severance benefits that have not been paid, and will be required to repay any portion of the severance to the Company that has already been paid. The agreement further provides that if there is a change of control of the Company during Dr. Bianco's employment with the Company, all of his then-outstanding and unvested stock-based compensation will fully vest and all outstanding stock options will remain exercisable for a period of two years following Dr. Bianco's severance date. In addition, in the event that Dr. Bianco's benefits under the agreement are subject to the excise tax imposed under Section 280G of the Internal Revenue Code, or Section 280G, the Company will make an additional payment to him so that the net amount of such payment (after taxes) he receives is sufficient to pay the excise tax due.

*Craig W. Philips.* Pursuant to his employment agreement described above, if Mr. Philips' employment is terminated by the Company without cause or if he resigns for good cause (as the terms "cause" and "good cause" are defined in the agreement), he will receive the following severance benefits: (i) cash severance equal to 18 months of his base salary and (ii) reimbursement for up to 18 months by the Company for COBRA premiums to continue his health coverage and that of his eligible dependents. In addition, Mr. Philips would be entitled to accelerated vesting of any portion of his then-outstanding and unvested stock-based compensation that was scheduled to vest within one year following the date of his termination. If a change in control of the Company occurs and, within 12 months following the change in control, Mr. Philips' employment is terminated by the Company without cause or Mr. Philips voluntarily resigns for any reason, he would be entitled to accelerated vesting of all of his then-outstanding and unvested stock-based compensation in addition to the benefits described in clauses (i) through (iii) above. Mr. Philips' right to receive these severance benefits is conditioned upon his executing a release of claims in favor of the Company and complying with certain restrictive covenants set forth in the agreement.

If Mr. Philips' employment is terminated on account of disability, in addition to any short-term or long-term disability benefits he may be entitled to under any Company group disability plans, the Company will pay Mr. Philips a pro rata share of his target bonus for the year in which his termination occurs, and the Company will also pay Mr. Philips' COBRA premiums for the period of time he is eligible for COBRA.

*Other Named Executive Officers.* The Company has entered into severance agreements with each of Mr. Bianco, Dr. Singer and Mr. Eramian. These agreements provide that in the event the executive is discharged from employment by the Company without cause or resigns for good reason (as each such term is defined in the agreements), he will receive the following severance benefits: (i) cash severance equal to 18 months of his base salary, plus an amount equal to the greater of the average of his three prior years' bonuses or thirty percent of his base salary, (ii) reimbursement for up to 18 months by the Company for COBRA premiums to continue his medical coverage and that of his eligible dependents, (iii) continued payment for up to 18 months by the Company of premiums to maintain life insurance paid for by the Company at the time of his termination, and (iv) a cash payment for the value of his accrued and unpaid vacation. In addition, the executive would be entitled to accelerated vesting of all of his then-outstanding and unvested stock-based compensation, and his outstanding stock options would remain exercisable for a period of 21 months following the severance date. In addition, in the event that the executive's benefits under the agreement are subject to the excise tax imposed under Section 280G, the Company will make an additional payment to him so that the net amount of such payment (after taxes) he receives is sufficient to pay the excise tax due. The executive's right to receive these severance benefits is conditioned upon his executing a release of claims in favor of the Company and not breaching his inventions and proprietary information agreement with the Company.

*Quantification of Severance and Change in Control Benefits.* The tables below quantify the benefits that would have been payable to each of the named executive officers if the executive's employment had terminated under the circumstances described above and/or a change in control of the Company had occurred on December 31, 2010. The first table presents the benefits the executive would have received if such a termination had occurred outside of the context of a change in control. The second table presents the benefits the executive would have received if such a termination occurred in connection with a change in control.

**Table of Contents***Severance Benefits (Outside of Change of Control)*

Name	Cash Severance \$(1)	Continuation of Health/Life Benefits\$(2)	Cash-Out of		Total(\$)
			Accrued and Unpaid Paid Time Off(\$)	Equity Acceleration \$(3)	
James A. Bianco, M.D.	1,300,000	130,924	977,986	10,744,777	13,153,687
Louis A. Bianco	667,700	50,560	38,075	4,322,404	5,078,739
Daniel G. Eramian	627,375	40,927	28,470	3,223,433	3,920,205
Craig W. Philips	603,000	47,909(4)	46,383	6,449,949	7,147,241
Jack W. Singer, M.D.	651,667	48,553	39,229	4,322,404	5,061,853

- (1) For Dr. Bianco and Mr. Philips, this amount represents two years and 18 months of the executive's base salary, respectively. For each of the other named executive officers, this amount represents the sum of (i) 18 months of the executive's base salary, and (ii) the greater of the executive's average annual bonus for the preceding three years or 30% of the executive's base salary.
- (2) This amount represents the aggregate estimated cost of the premiums that would be charged to continue health coverage for the applicable period pursuant to COBRA for the executive and his eligible dependents (to the extent that such dependents were receiving health benefits as of December 31, 2010). For Dr. Bianco, this amount also includes the cost of continued payment by the Company of his life insurance premiums for two years. For each of the other named executive officers, except for Mr. Philips, this amount also includes the cost of continued payment by the Company of their life insurance premiums for 18 months.
- (3) This amount represents the intrinsic value of the unvested portions of the executive's awards that would have accelerated on a termination of the executive's employment as described above. For options, this value is calculated by multiplying the amount (if any) by which \$0.37 (the closing price of the Company's common stock on the last trading day of fiscal 2010) exceeds the exercise price of the option by the number of shares subject to the accelerated portion of the option. For restricted stock awards and the December 2009 Performance Awards, this value is calculated by multiplying \$0.37 by the number of shares subject to the accelerated portion of the award, based in the case of the December 2009 Performance Awards on the applicable payout percentage and the number of shares of the Company's common stock issued and outstanding on the last trading day of fiscal year 2010. As noted above, each executive would have been entitled to full acceleration of his then-outstanding equity awards on such a termination, except that Mr. Philips would have been entitled to accelerated vesting with respect to any portion of his then-outstanding equity awards that were scheduled to vest within one year of his termination. Dr. Bianco's stock options would also remain exercisable for two years following his termination, subject to earlier termination at the end of the maximum term of the option or in connection with a change in control of the Company.
- (4) As noted above, if Mr. Philips' employment terminated due to disability, he would be entitled to continued payment of his COBRA premiums for the period of time he is eligible for COBRA and a pro rata share of his target bonus for the year in which his termination occurs.

*Change of Control Severance Benefits*

Name	Cash Severance \$(1)	Continuation of Health Benefits\$(2)	Cash-Out of		Section 280G Gross-Up \$(4)	Total(\$)
			Accrued and Unpaid Paid Time Off(\$)	Equity Acceleration \$(3)		
James A. Bianco, M.D.	1,850,646	130,924	977,986	8,486,618	3,649,297	15,095,471
Louis A. Bianco	667,700	50,560	38,075	3,404,086	1,345,009	5,505,430
Daniel G. Eramian	627,375	40,927	28,470	2,545,985	963,638	4,206,395
Craig W. Philips	603,000	47,909	46,383	5,095,054		5,792,346
Jack W. Singer, M.D.	651,667	48,553	39,229	3,404,086	1,312,416	5,455,951

- (1) For each of the named executive officers, except for Mr. Philips, this amount represents the sum of (i) 18 months of the executive's base salary (or, in the case of Dr. Bianco, two years of his base salary), and (ii) the greater of the executive's average annual bonus for the preceding three years or 30% of the executive's base salary. For Mr. Philips, this amount represents 18 months of his base salary.



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- (2) See footnote (2) to the table above.
- (3) See footnote (3) to the table above. Dr. Bianco would be entitled to full acceleration of his outstanding equity awards on a change in control without regard to whether his employment terminates. Each of the other executives would be entitled to full acceleration of his outstanding equity awards on a termination of his employment in the circumstances described above. The values reported in this column are lower than the values reported in the corresponding column of the Severance Benefits (Outside of Change of Control) table above because, as noted in the discussion of the December 2009 Performance Awards in the Compensation Discussion and Analysis above, the vesting of the portion of these awards related to the Share Appreciation Goal upon a change in control of the Company will be determined based on the Company's stock price at the time of the change in control. If a change in control had occurred on December 31, 2010, the Share Appreciation Goal portion of these awards would not have vested based on the \$0.37 per-share closing price of the Company's common stock on that date and would have been cancelled on that date.
- (4) For purposes of this calculation, the Company has assumed that the executive's outstanding equity awards would be accelerated and, in the case of options, terminated in exchange for a cash payment upon a change in control that triggered excise taxes under Sections 280G and 4999 of the Internal Revenue Code. As noted above, the severance agreements for each of the named executive officers other than Mr. Philips and the award agreements for the December 2009 Performance Awards for each of the executives (including Mr. Philips) provide for a Section 280G gross-up payment.

**Table of Contents****DIRECTOR COMPENSATION****Non-Employee Director Compensation Table**

The following table presents information regarding the compensation paid for fiscal year 2010 to members of the Board of Directors who are not also employees of the Company (referred to herein as non-employee directors). The compensation paid to Dr. Bianco and Dr. Singer, who are also employed by the Company, for fiscal year 2010 is presented above in the Summary Compensation Table and the related explanatory tables. Dr. Bianco and Dr. Singer are generally not entitled to receive additional compensation for their services as directors.

Name	Fees Earned or Paid in Cash (\$)	Stock Awards \$(1)(2)(3)	Option Awards \$(1)(2)(3)	Non-Equity Incentive Plan Compensation (\$)	Change in Pension Value and Nonqualified Deferred Compensation Earnings (\$)	All Other Compensation (\$)	Total (\$)
John H. Bauer	117,250	7,600	8,715				133,565
Vartan Gregorian, Ph.D.	101,250	7,600	8,715				117,565
Richard L. Love	91,750	7,600	8,715				108,065
Mary O. Mundinger, DrPH	93,500	7,600	8,715				109,815
Phillip M. Nudelman, Ph.D.	144,750	7,600	8,715				161,065
Frederick W. Telling, Ph.D.	116,750	7,600	8,715				133,065

- (1) The amounts reported in the Stock Awards and Option Awards columns of the table above reflect the fair value on the grant date of the stock awards and option awards, respectively, granted to the Company's non-employee directors during fiscal year 2010 as determined under generally accepted accounting principles used to calculate the value of equity awards for purposes of the Company's financial statements. For a discussion of the assumptions and methodologies used to calculate the amounts reported above, please see the discussion of equity awards contained in Note 13 (Share-Based Compensation) to the Company's Consolidated Financial Statements, included as part of this Form 10-K.
- (2) The table below presents the number of outstanding and unexercised option awards and the number of shares subject to unvested stock awards (including the December 2009 Performance Awards) held by each of the Company's non-employee directors as of December 31, 2010. This table includes the December 2009 Performance Awards granted to each of the non-employee directors under the Company's equity grant program. As described in the Compensation Discussion and Analysis above, these awards will be payable in shares of the Company's common stock if certain performance goals are achieved on or before December 31, 2011, with the number of shares payable upon achievement of the related performance goal to be determined by multiplying the payout percentage that has been assigned by the Board of Directors to that goal for purposes of the non-employee director's award by the number of shares of the Company's common stock issued and outstanding at the time that particular goal is achieved. In July 2010, each of these awards was amended to convert a portion of each award to a grant of restricted shares. These restricted shares are subject to the same performance-based vesting requirements as the December 2009 Performance Awards to which they relate and will be forfeited back to the Company should these vesting requirements not be satisfied. In order to ensure that the restricted shares did not provide a benefit to the non-employee director beyond that intended by the original December 2009 Performance Award, any restricted shares that vest in connection with the achievement of a performance goal on or before December 31, 2011 will reduce on a share-for-share basis the number of shares that would have been delivered under the original December 2009 Performance Award upon achievement of that performance goal. In furtherance of that intent, if the number of shares that would have been delivered under the original December 2009 Performance Award on achievement of a performance goal is less than the number of restricted shares that vest on achievement of that performance goal under the July 2010 amendment, a number of such restricted shares equal to the difference will be forfeited to the Company so that the director retains no more shares related to that particular performance goal than the number of shares that would have otherwise been deliverable with respect to that goal under the original December 2009 Performance Award. The table below reflects the aggregate number of shares that would vest or be issued, as the case may be, upon timely achievement of all

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of the performance goals based on the applicable payout percentages and the number of shares of the Company's common stock issued and outstanding on December 31, 2010. The actual number of shares issued for each award upon timely achievement of the related performance goal may be different from the number reported in the table below depending on the number of shares of the Company's common stock issued and outstanding at the time the goal is achieved.

Director	Number of Shares Subject to Outstanding Options as of 12/31/2010	Number of Unvested Restricted Shares/Units as of 12/31/2010
John H. Bauer	65,400	3,315,693
Vartan Gregorian, Ph.D.	66,525	3,315,693
Richard L. Love	65,400	3,315,693
Mary O. Mundinger, DrPH	66,500	3,315,693
Phillip M. Nudelman, Ph.D.	66,725	4,971,677
Frederick W. Telling, Ph.D.	65,100	3,315,693

- (3) On September 16, 2010, each of the non-employee directors was granted an award of 20,000 restricted shares and an option to purchase 30,000 shares pursuant to the Company's non-employee director compensation program described below. Each of the restricted stock awards had a grant-date fair value of \$7,600, and each of the options had a grant-date fair value of \$8,715. See footnote (1) above for the assumptions used to value each of these awards.

**Non-Employee Director Compensation**

*Equity Grants.* Under the Company's Revised Director Compensation Policy, as approved by the Board effective July 1, 2009, the Company's non-employee directors receive compensation as follows: (i) each new non-employee director is granted 108,000 shares of restricted stock and options to purchase 36,000 shares of the Company's common stock upon joining the Board, each such grant to vest over three years in substantially equal annual installments, subject to the non-employee director's continued service to the Company through the applicable vesting date; and (ii) on the date of each Annual Meeting, each continuing non-employee director is granted an award of 20,000 shares of restricted stock and an option to purchase 30,000 shares of the Company's common stock, each such grant to vest in full upon the earlier of (x) the one-year anniversary of the date of grant, and (y) the date immediately preceding the date of the Annual Meeting for the year following the year of grant for the award, subject to the non-employee director's continued service to the Company through the vesting date.

*Retainers and Meeting Fees.* In addition, non-employee directors are entitled under the Revised Director Compensation Policy to annual retainers and fees for attending Board and committee meetings as set forth in the following table:

	Annual Cash Retainer (\$)	Meeting Fees (\$)	
		Board	Committee
Board Member, other than Chairman of the Board	40,000	2,750	
Chairman of the Board	75,000	2,750	
Audit Committee Member			1,250
Audit Committee Chair	12,500		1,250
Compensation Committee Member			1,250
Compensation Committee Chair	12,500		1,250
Nominating and Governance Committee Member			1,250
Nominating and Governance Committee Chair	12,500		1,250

All non-employee directors are also reimbursed for their expenses incurred in attending Board meetings and committee meetings, as well as other Board-related travel expenses.

**Table of Contents****Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters**  
**Security Ownership of Certain Beneficial Owners and Management**

The following table provides certain information regarding beneficial ownership of common stock as of February 1, 2011, by (1) each shareholder known by us to be the beneficial owner of more than 5% of our outstanding shares of common stock, (2) each of our directors, (3) each of our principle executive officer, or the PEO, principal financial officer, or PFO, and the three most highly compensated executive officers other than the PEO and PFO who were still serving as executive officers as of December 31, 2010, and (4) all directors and executive officers as a group:

Name and Address of Beneficial Owner(1)	Number of Shares Beneficially Owned(2)	Common Stock Shares Subject to	
		Convertible Securities(3)	Percentage Ownership(2)
James A. Bianco, M.D.** (4)	12,288,029	39,369	1.4%
John H. Bauer** (5)	1,840,208	35,400	*
Louis A. Bianco (6)	5,828,552	17,185	*
Daniel G. Eramian (7)	4,425,124	8,225	*
Vartan Gregorian, Ph.D.** (5)	1,906,458	36,525	*
Richard L. Love** (5)	2,338,173	35,400	*
Mary O. Mundinger, DrPH** (5)	1,906,349	36,500	*
Phillip M. Nudelman, Ph.D.** (8)	2,311,590	36,725	*
Craig W. Philips (9)	9,318,206	10,000	1.0%
Jack W. Singer, M.D.** (6)	6,088,194	19,367	*
Frederick W. Telling, Ph.D.** (5)	1,623,007	35,100	*
All directors and executive officers as a group (11 persons) (10)	49,873,890	309,796	5.5%

\* Less than 1%.

\*\* Denotes director of the Company.

(1) The address of the individuals listed is 501 Elliott Avenue West, Suite 400, Seattle, Washington 98119.

(2) Beneficial ownership generally includes voting or investment power with respect to securities and is calculated based on 900,727,566 shares of our common stock outstanding as of February 1, 2011. This table is based upon information supplied by officers, directors and other investors including information from Schedules 13D, 13G and 13F and Forms 3 and 4 filed with the SEC. Shares of common stock subject to options, warrants or other securities convertible into common stock that are currently exercisable or convertible, or exercisable or convertible within 60 days of February 1, 2011, are deemed outstanding for computing the percentage of the person holding the option, warrant or convertible security but are not deemed outstanding for computing the percentage of any other person. Except as indicated in the footnotes to this table and pursuant to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of stock beneficially owned.

(3) Shares subject to convertible securities included in this column reflects all options, warrants and convertible debt held by the holder exercisable within 60 days after February 1, 2011. These shares are also included in the column titled Number of Shares Beneficially Owned.

(4) Number of shares beneficially owned includes 10,932,129 shares of unvested restricted stock, 9,966,610 of which have contingent vesting terms and will vest based on the achievement of certain performance goals as described in footnote (11) below. Includes 20 shares held by Dr. Bianco's wife and two shares held by Dr. Bianco's wife as custodian.

(5) Number of shares beneficially owned includes 1,016,661 shares of unvested restricted stock, 996,661 of which have contingent vesting terms and will vest based on the achievement of certain performance goals as described in footnote (11) below.



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- (6) Number of shares beneficially owned includes 4,331,482 shares of unvested restricted stock, 4,041,827 of which have contingent vesting terms and will vest based on the achievement of certain performance goal as described in footnote (11) below. Includes 1,118 shares held by Mr. Bianco in trust for his children.
- (7) Number of share beneficially owned includes 3,279,638 shares of unvested restricted stock, 2,989,983 of which have contingent vesting terms and will vest based on the achievement of certain performance goals as described in footnote (11) below.
- (8) Number of shares beneficially owned includes 1,518,559 shares of unvested restricted stock, 1,498,559 of which have contingent vesting terms and will vest based on the achievement of certain performance goals as described in footnote (11) below.
- (9) Number of shares beneficially owned includes 6,567,611 shares of unvested restricted stock, 5,979,967 of which have contingent vesting terms and will vest based on the achievement of certain performance goals as described in footnote (11) below.
- (10) Number of shares beneficially owned includes 36,044,206 shares of unvested restricted stock for all directors and executive officers as a group, of which 33,502,078 shares are contingent and would vest as described in the above footnotes.
- (11) Shares beneficially owned include unvested restricted stock which have contingent vesting terms based on the achievement of the following five performance goals, subject to the goal s being achieved before December 31, 2011 and the individuals continued employment or service with us: the OPAXIO NDA Approval, \$50M Sales Goal, \$100M Sales Goal, Pix NDA Approval and a cash-flow break-even in any fiscal quarter. In the event that one of the above-mentioned corporate goals is achieved prior to December 31, 2011, the following shares of restricted stock would vest as of the date of the achievement of such goal:

Name	Number of Shares of Restricted Stock Granted				
	OPAXIO NDA Approval	\$50M Sales Goal	\$100M Sales Goal	Pix NDA Approval	Cash Flow Break Even
James A. Bianco, M.D.	1,426,963	2,140,444	1,048,092	3,210,667	2,140,444
John H. Bauer	142,697	214,044	104,809	321,067	214,044
Louis A. Bianco	577,920	870,447	424,477	1,298,536	870,447
Daniel G. Eramian	428,089	642,133	314,428	963,200	642,133
Vartan Gregorian, Ph.D.	142,697	214,044	104,809	321,067	214,044
Richard L. Love	142,697	214,044	104,809	321,067	214,044
Mary O. Munding, DrPH.	142,697	214,044	104,809	321,067	214,044
Phillip M. Nudelman, Ph.D.	214,044	321,067	157,214	485,167	321,067
Craig W. Philips	856,178	1,284,267	628,855	1,926,400	1,284,267
Jack W. Singer, M.D.	577,920	870,447	424,477	1,298,536	870,447
Frederick W. Telling, Ph.D.	142,697	214,044	104,809	321,067	214,044

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

The following table gives information about our common stock that may be issued upon the exercise of options, warrants and rights under all of our existing compensation plans as of December 31, 2010, including the 2007 Equity Plan, 1994 Equity Incentive Plan and the 2007 Employee Stock Purchase Plan, as amended, or the ESPP.

Plan Category	(a) Number of		(c) Number of
	Securities to be Issued		Securities Remaining
	Upon Exercise of		Available for
	Outstanding Options,		Future
	Warrants and Rights	(b) Weighted Average	Issuance Under Equity
		Exercise Price of	Compensation Plans
		Outstanding Options,	(Excluding Securities
		Warrants, and Rights	Reflected in Column
			(a)
Plans Approved by Shareholders	1,034,815(1)	\$ 25.30	1,432,491(2)
Plan Not Approved by Shareholders		\$	
Totals	1,034,815	\$ 25.30	1,432,491

- (1) Of these shares, 1,009,095 were subject to options then outstanding under the 2007 Equity Plan, and 25,720 were subject to options then outstanding under the 1994 Equity Incentive Plan. As described above, the Compensation Committee approved the December 2009 Performance Awards under the 2007 Equity Plan that would be payable in shares of the Company's common stock upon satisfaction of the performance and other requirements imposed on the award and, in July 2010, approved amendments to convert a portion of each award to a grant of restricted shares. These restricted shares are subject to the same performance-based vesting requirements as the December 2009 Performance Awards to which they relate, and any restricted shares that vest in connection with the achievement of a performance goal will reduce on a share-for-share basis the number of shares that would have been delivered under the original December 2009 Performance Award upon achievement of that performance goal. Columns (a) and (b) of this table are presented without giving effect to the December 2009 Performance Awards as (1) the restricted shares subject to the July 2010 amendments were issued and outstanding as of December 31, 2010, and (2) the remaining number of shares that would be issuable in payment of these awards depends on the Company's total issued and outstanding shares at the time of payment and was therefore not determinable as of December 31, 2010.
- (2) Of the shares reported in Column (c), no shares were available for issuance under the 2007 Equity Plan, and 1,432,491 were available for issuance under the ESPP. The Company's authority to grant new awards under the 1994 Equity Incentive Plan has terminated. Column (c) is presented after giving effect to the December 2009 Performance Awards (based on the number of shares of the Company's common stock issued and outstanding as of December 31, 2010 and assuming the performance goals applicable to these awards were achieved). As of December 31, 2010, 41,013,297 shares of the Company's common stock were available for award grant purposes under the 2007 Equity Plan (before giving effect to the December 2009 Performance Awards) and all of these shares would have been used to pay the December 2009 Performance Awards if the performance goals applicable to these awards had been achieved. If the December 2009 Performance Awards become payable and sufficient shares are not available under the 2007 Equity Plan (after reserving sufficient shares to cover the other awards then outstanding under the 2007 Equity Plan), the number of shares payable with respect to the December 2009 Performance Awards will be proportionately reduced such that the share limits of the 2007 Equity Plan will not be exceeded.

**Item 13. Certain Relationships and Related Transactions, and Director Independence**

**Related Party Transactions**

Pursuant to our Code of Business Conduct and Ethics and our Amended and Restated Charter for the Audit Committee of our board of directors, any potential related party transaction must be fully disclosed to our Chief Financial Officer. Upon review, if our Chief Financial Officer determines that the transaction is material to us, then our Audit Committee must review and approve in writing in advance such related party transaction. Item 404(a) of Regulation S-K requires us to disclose in its Annual Report on Form 10-K any transaction

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involving more than \$120,000 in which we are a participant and in which any related person has or will have a direct or indirect material interest. A related person is any executive officer, director, nominee for director, or holder of 5% or more of our common stock, or an immediate family member of any of those persons.

### **Certain Transactions with Related Persons**

In May 2007, we formed Aequus Biopharma, Inc., or Aequus, a majority owned subsidiary of which our ownership was approximately 69% as of December 31, 2010. We entered into a license agreement with Aequus whereby Aequus gained rights to our Genetic Polymer technology which Aequus will continue to develop. The Genetic Polymer technology may speed the manufacture, development, and commercialization of follow-on and novel protein-based therapeutics.

In May 2007, we also entered into an agreement to fund Aequus in exchange for a convertible promissory note that becomes due and payable in five years and earns interest at a rate of 6% per annum. The note can be converted into equity at any time prior to its maturity upon CTI's demand, or upon other triggering events. The number of shares of Aequus equity securities to be issued upon conversion of this note is equal to the quotient obtained by dividing (i) the outstanding balance of the note by (ii) 100% of the price per share of the equity securities. We funded Aequus \$0.5 million, \$0.6 million and \$0.3 million during the years ended December 31, 2010, 2009 and 2008, respectively. In addition, we entered into a services agreement to provide certain administrative and research and development services to Aequus. The amounts charged for these services, if unpaid by Aequus within 30 days, will be considered additional principal advanced under the promissory note.

Our President and Chief Executive Officer, James A. Bianco, M.D. and our Executive Vice President, Chief Medical Officer, Jack W. Singer, M.D. are both minority shareholders of Aequus, each owning approximately 4.9% of the equity in Aequus. Additionally, both Dr. Bianco and Dr. Singer are members of Aequus' board of directors and each has entered into a consulting agreement with Aequus. Additionally, Frederick W. Telling, Ph.D., a member of our board of directors, owns approximately 1% of Aequus and is also a member of Aequus' board of directors.

We own a minority interest in DiaKine Therapeutics, Inc., or DiaKine, based upon the information last provided to us. Louis A. Bianco and Jack W. Singer, M.D. resigned from the board of directors of DiaKine in August 2010 and December 2009, respectively. In 2005, we entered into a license agreement with DiaKine for the exclusive license of Lisofylline material to DiaKine. In connection with the license agreement, we also entered into a joint representation letter with DiaKine and a law firm for legal services provided by the law firm with respect to the Lisofylline material. Pursuant to the license agreement, DiaKine agreed to pay all fees of legal services provided by the law firm with respect to the Lisofylline material. Pursuant to the joint representation letter, we agreed to be jointly responsible to the law firm with DiaKine for the payment of such fees to the law firm. In 2009, DiaKine failed to pay certain amounts payable to the law firm pursuant to the joint representation letter. In February 2010, we severed the joint representation letter with DiaKine and paid the outstanding third-party payables owed to the law firm in the amount of \$206,000. In connection, DiaKine issued to us an unregistered convertible subordinated note due February 2013 in the amount of \$206,000. The note is convertible into equity of DiaKine upon the occurrence of certain events, including certain financings of DiaKine and a sale of DiaKine.

On June 17, 2010, we terminated the license agreement due to the insolvency of DiaKine, and requested that DiaKine arrange for the return of all confidential material, intellectual property, materials and other records and reports. On August 17, 2010, we delivered an additional notice to DiaKine reiterating the termination of the license agreement due to material breach of the provisions of the license agreement by DiaKine. In addition, Mr. Bianco resigned from the board of directors of DiaKine on August 17, 2010.

On August 24, 2010, we received a letter from Brian C. Purcell, Esq., counsel to DiaKine, alleging that the termination of the license agreement pursuant to the June 17, 2010 and August 17, 2010 letters was invalid and

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that DiaKine remains in full compliance with the license agreement. On December 20, 2010, we delivered a letter to DiaKine confirming the termination but offering to enter into a new license agreement, on substantially the same terms and conditions as the terminated license agreement, for the exclusive license of Lisofylline material to DiaKine in the event that DiaKine were able to either obtain financing or sell the company within 180 days on terms and conditions acceptable to us. On January 10, 2011, we received an additional letter from Mr. Purcell reiterating DiaKine's contention that the termination of the license agreement pursuant to our June 17, 2010 and August 17, 2010 letters was invalid. Following the receipt of this letter from DiaKine's counsel, we are discussing with counsel our options with respect to DiaKine and the license agreement.

Phillip M. Nudelman serves on the board of directors of OptiStor Technologies, Inc., or OptiStor. We made payments of \$331,000 to OptiStor for hardware and software in 2010.

Corey Masten-Legge, a stepson of James A. Bianco, M.D., is employed as a corporate attorney in our legal department. Mr. Masten-Legge received approximately \$174,000 in base salary and bonus in 2010 and also received a grant during the year of 100,000 shares of restricted stock, with a grant-date fair value (based on the assumptions used to value equity awards in our financial reporting) of \$66,000.

### **Director Independence**

Our board of directors has adopted standards concerning director independence which meet the NASDAQ independence standards and, with respect to the Audit Committee, the rules of the SEC.

We, our Nominating and Governance Committee and our board of directors are involved in the process for determining the independence of acting directors and director nominees. We solicit relevant information from directors and director nominees via a questionnaire, which covers material relationships, compensatory arrangements, employment and any affiliation with us. In addition to reviewing information provided in the questionnaire, we ask our executive officers on an annual basis regarding their awareness of any existing or currently proposed transactions, arrangements or understandings involving us in which any director or director nominee has or will have a direct or indirect material interest. We share our findings with our Nominating and Governance Committee and our board of directors regarding the NASDAQ and SEC independence requirements and any information regarding the director or director nominee that suggest that such individual is not independent. Our board of directors discusses all relevant issues, including consideration of any transactions, relationships or arrangements which are not required to be disclosed under Item 404(a) of Regulation S-K, prior to making a determination with respect to the independence of each director.

In making independence determinations, the following relationships were considered:

Dr. Nudelman serves on the board of directors of the Hope Heart Institute and Dr. Nudelman's son, Mark Nudelman, serves as its President and Chief Executive Officer. We have committed to making a charitable donation to the Hope Heart Institute for 2010, however the amount falls within NASDAQ prescribed limits.

Based on the review described above, our board of directors affirmatively determined that:

A majority of the directors are independent, and all members of the Audit, Compensation and Nominating and Governance Committees are independent, under the NASDAQ standard and, in the case of the Audit Committee, the SEC standard.

All of the non-management directors of our board of directors are independent under the NASDAQ standard. The independent directors are: John H. Bauer, Vartan Gregorian, Ph.D, Richard L. Love, Mary O. Munding, Dr. PH, Phillip M. Nudelman, Ph.D., and Frederick W. Telling, Ph.D.

James A. Bianco, M.D. and Jack W. Singer, M.D are not independent by virtue of their positions as our Chief Executive Officer and Executive Vice President, Chief Medical Officer, respectively.

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Other than as described above, in 2010, there were no transactions, relationships or arrangements not disclosed as related person transactions that were considered by our board of directors in determining that the applicable independence standards were met by each of the directors.

**Item 14. Principal Accounting Fees and Services**

The following table provides the aggregate fees billed for professional services rendered by our principal accountants during each of the past two fiscal years ended December 31:

Services Rendered	2010	2009
Audit Fees (1)	\$ 450,000	\$ 521,000
Audit-Related Fees (2)		
Tax Fees (3)		
All Other Fees (4)		

- (1) *Audit Fees.* This category includes fees for professional services provided in conjunction with the audit of our financial statements and with the audit of management's assessment of internal control over financial reporting and the effectiveness of internal control over financial reporting, review of our quarterly financial statements, assistance and review of documents filed with the SEC, consents, and comfort letters and attestation services provided in connection with statutory and other regulatory filings and engagements.
- (2) *Audit Related Fees.* This category includes fees for assurance and related professional services associated with due diligence related to mergers and acquisitions, consultation on accounting standards or transactions, internal control reviews and assistance with internal control reporting requirements, services related to the audit of employee benefit plans, and other attestation services not required by statute or regulation.
- (3) *Tax Fees.* This category includes fees for professional services provided related to tax compliance, tax planning and tax advice.
- (4) *Other Fees.* There were no other fees for services not included above.

**Pre-Approval Policy**

Pursuant to the amended and restated charter for our Audit Committee, our Audit Committee pre-approves all auditing services and non-audit services to be performed by our independent auditors. Our Audit Committee also pre-approves all associated fees, except for de minimus amounts for non-audit services, which are approved by the Audit Committee prior to the completion of the audit.

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**PART IV**

**Item 15. Exhibits, Financial Statement Schedules**

(a) Financial Statements and Financial Statement Schedules

(i) Financial Statements

Report of Stonefield Josephson, Inc, Independent Registered Public Accounting Firm

Reports of Marcum LLP, Independent Registered Public Accounting Firm

Consolidated Balance Sheets

Consolidated Statements of Operations

Consolidated Statements of Shareholders' Deficit and Comprehensive Loss

Consolidated Statements of Cash Flows

Notes to Consolidated Financial Statements

(ii) Financial Statement Schedules

All schedules have been omitted since they are either not required, are not applicable, or the required information is shown in the financial statements or related notes.

(iii) Exhibits

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
2.1	Agreement and Plan of Merger by and between Cell Therapeutics, Inc. and Novuspharma, S.p.A., dated as of June 16, 2003.	Incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K, filed on June 17, 2003 (Commission No. 001-12465).
2.2	Acquisition Agreement by and among Cell Therapeutics, Inc., Cell Technologies, Inc. and Cephalon, Inc., dated June 10, 2005.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on June 14, 2005.
2.3	Acquisition Agreement among Cell Therapeutics, Inc., Cactus Acquisition Corp., Saguaro Acquisition Company LLC, Systems Medicine, Inc. and Tom Hornaday and Lon Smith, dated July 24, 2007.	Incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K, filed on July 27, 2007.
2.4	Purchase and Formation Agreement by and among Cell Therapeutics, Inc., Spectrum Pharmaceuticals, Inc. and RIT Oncology, LLC, dated as of November 26, 2008.	Incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K, filed on December 19, 2008.

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The schedules to this exhibit have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A description of the omitted schedules appears in the Table of Exhibits of Exhibit 2.1. The Registrant hereby agrees to furnish a copy of any omitted schedule to the Commission upon request.

3.1 Amended and Restated Articles of Incorporation.

Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-3 (File No. 333-153358), filed on September 5, 2008.

3.2 Articles of Amendment to Amended and Restated Articles of Incorporation.

Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on February 9, 2009.



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<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
3.3	Amendment to Amended and Restated Articles of Incorporation.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on March 27, 2009.
3.4	Articles of Amendment to Amended and Restated Articles of Incorporation.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on April 13, 2009.
3.5	Articles of Amendment to Amended and Restated Articles of Incorporation.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on August 21, 2009.
3.6	Articles of Amendment to Amended and Restated Articles of Incorporation.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-A, filed on December 28, 2009.
3.7	Articles of Amendment to Amended and Restated Articles of Incorporation.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on January 19, 2010.
3.8	Articles of Amendment to Amended and Restated Articles of Incorporation.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on April 5, 2010.
3.9	Articles of Amendment to Amended and Restated Articles of Incorporation.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on May 27, 2010.
3.10	Articles of Amendment to Amended and Restated Articles of Incorporation.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on July 27, 2010.
3.11	Amendment to Amended and Restated Articles of Incorporation.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on September 17, 2010.
3.12	Articles of Amendment to Amended and Restated Articles of Incorporation.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on October 22, 2010.
3.13	Articles of Amendment to Amended and Restated Articles of Incorporation.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on January 18, 2011.
3.14	Articles of Amendment to Amended and Restated Articles of Incorporation.	Incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed on January 18, 2011.
3.15	Second Amended and Restated Bylaws.	Incorporated by reference to the Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed on February 22, 2010.
4.1	Indenture between Cell Therapeutics, Inc. and U.S. Bank National Association as trustee, dated June 23, 2003.	Incorporated by reference to Exhibit 4.5 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2003, filed on August 6, 2003.

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<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
4.2	Indenture between Cell Therapeutics, Inc. and U.S. Bank National Association as Trustee, dated April 27, 2006.	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on April 28, 2006.
4.3	Indenture between Cell Therapeutics, Inc. and U.S. Bank National Association as Trustee, dated December 12, 2007.	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on December 13, 2007.
4.4	Form of Warrant issued July 27, 2007.	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed on July 27, 2007.
4.5	Form of Warrant issued December 3, 2007.	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed on December 3, 2007.
4.6	Form of Warrant issued December 21, 2007.	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on December 27, 2007.
4.7	Form of Warrant issued March 4, 2008.	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed on March 5, 2008.
4.8	Class B Common Stock Purchase Warrant, dated April 13, 2009.	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on April 13, 2009.
4.9	Common Stock Purchase Warrant, dated April 13, 2009.	Incorporated by reference to Exhibit 4.2 to the Registrant's Quarterly Report on Form 10-Q, filed on August 6, 2009.
4.10	Common Stock Purchase Warrant, dated May 11, 2009.	Incorporated by reference to Exhibit 4.3 to the Registrant's Quarterly Report on Form 10-Q, filed on August 6, 2009.
4.11	Form of Common Stock Purchase Warrant, dated July 28, 2009.	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on July 28, 2009.
4.12	Form of Common Stock Purchase Warrant, dated July 28, 2009.	Incorporated by reference to Exhibit 4.2 to the Registrant's Quarterly Report on Form 10-Q, filed on November 5, 2009.
4.13	Form of Common Stock Purchase Warrant, dated August 19, 2009.	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on August 21, 2009.
4.14	Shareholder Rights Agreement, dated December 28, 2009, between the Registrant and Computershare Trust Company, N.A.	Incorporated by reference to Exhibit 4.1 to the Registrant's Form 8-A, filed on December 28, 2009.
4.15	Form of Common Stock Purchase Warrant, dated January 19, 2010.	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on January 19, 2010.
4.16	Form of Common Stock Purchase Warrant, dated April 6, 2010.	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed on April 5, 2010.

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<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
4.17	Form of Common Stock Purchase Warrant, dated May 27, 2010.	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed on May 27, 2010.
4.18	Form of Common Stock Purchase Warrant, dated July 27, 2010.	Incorporated by reference to Exhibit 4.6 to the Registrant's Quarterly Report on Form 10-Q, filed on August 6, 2010.
4.19	Form of Common Stock Purchase Warrant, dated October 22, 2010.	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed on October 22, 2010.
4.20	Form of Series 8 Preferred Stock Certificate.	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on January 18, 2011.
4.21	Form of Common Stock Purchase Warrant, dated January 12, 2011.	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed on January 18, 2011.
10.1	Sublease Agreement between F5 Networks, Inc. and the Registrant, dated March 30, 2001, as amended April 13, 2001.	Incorporated by reference to Exhibit 10.21 to the Registrant's amended Annual Report on Form 10-K/A for the year ended December 31, 2001, filed on April 30, 2002.
10.2	Third Amendment to Sublease Agreement between F5 Networks, Inc. and the Registrant, dated December 22, 2005.	Incorporated by reference to Exhibit 10.6 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2006, filed on March 16, 2007.
10.3	Lease agreement between Elliott Park LLC and the Registrant, dated August 20, 2002.	Incorporated by reference to Exhibit 10.7 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002, filed on March 27, 2003 (Commission No. 001-12465).
10.4*	Employment Agreement between Cell Therapeutics, Inc. and James A. Bianco, dated as of December 31, 2008.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on January 6, 2009.
10.5*	Form of Strategic Management Team Severance Agreement.	Incorporated by reference to Exhibit 10.5 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2008, filed on March 16, 2009.
10.6*	Form of Amendment to Strategic Management Team Severance Agreement.	Incorporated by reference to Exhibit 10.6 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2008, filed on March 16, 2009.
10.7*	Severance Agreement and General Release between Cell Therapeutics, Inc. and Scott Stromatt, dated April 3, 2008.	Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, filed on May 12, 2008.

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<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
10.8*	Employment Agreement between Cell Therapeutics, Inc. and Craig Philips, dated April 23, 2008	Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, filed on August 18, 2008.
10.9*	Consulting Agreement between Cell Therapeutics, Inc. and Craig Philips, dated April 23, 2008.	Incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2008, filed on August 18, 2008.
10.10*	Amendment to Employment Agreement between Cell Therapeutics, Inc. and Craig Philips, dated December 31, 2008.	Incorporated by reference to Exhibit 10.10 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2008, filed on March 16, 2009.
10.11*	Form of Indemnification Agreement.	Incorporated by reference to Exhibit 10.19 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2001, filed on March 29, 2002 (Commission No. 001-12465).
10.12*	Form of Italian Indemnity Agreement	Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K, filed on December 17, 2009.
10.13*	1994 Equity Incentive Plan, as amended.	Incorporated by reference to Exhibit 99.1 to the Registrant's Registration Statement on Form S-8, filed on July 24, 2002.
10.14*	2007 Equity Incentive Plan, as amended and restated.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on September 17, 2010.
10.15*	2007 Employee Stock Purchase Plan, as amended and restated.	Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed on October 23, 2009.
10.16*	Form of Notice of Grant of Stock Options and Option Agreement for option grants under the Registrant's 2007 Equity Incentive Plan, as amended.	Incorporated by reference to Exhibit 10.19 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2004, filed on March 4, 2005.
10.17*	Form of Notice of Grant of Award and Award Agreement for grants of restricted stock under the Registrant's 2007 Equity Incentive Plan, as amended.	Incorporated by reference to Exhibit 10.18 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2004, filed on March 4, 2005.
10.18*	Cell Therapeutics, Inc. Novuspharma S.p.A. Stock Option Plan.	Incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-8, filed on February 13, 2004.
10.19*	Form of Nonqualified Stock Option Agreement for option grants under the Registrant's Novuspharma S.p.A. Stock Option Plan.	Incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form 10, filed on April 29, 1996.
10.20*	Revised Director Compensation Policy.	Incorporated by reference to Exhibit 10.20 to the Registrant's Annual Report on Form 10-K, filed on February 26, 2010.

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<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
10.21*	English Translation of Severance Agreement, dated May 13, 2009.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on May 20, 2009.
10.22*	Form of Equity/Long-Term Incentive Award Agreement for Directors, dated December 15, 2009.	Incorporated by reference to Exhibit 10.22 to the Registrant's Annual Report on Form 10-K, filed on February 26, 2010.
10.23*	Form of Equity/Long-Term Incentive Award Agreement for Employees, dated December 15, 2009.	Incorporated by reference to Exhibit 10.23 to the Registrant's Annual Report on Form 10-K, filed on February 26, 2010.
10.24*	Form of Amendment to Amendment to Equity/Long-Term Incentive Award Agreement for Employees and Directors, dated November 30, 2010.	Filed herewith.
10.25*	Form of 2007 Equity Incentive Plan Restricted Stock Award Agreement for Directors, dated July 12, 2010.	Incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q, filed on October 28, 2010.
10.26*	Form of 2007 Equity Incentive Plan Restricted Stock Award Agreement for Employees, dated July 12, 2010.*	Incorporated by reference to Exhibit 10.7 to the Registrant's Quarterly Report on Form 10-Q, filed on October 28, 2010.
10.27	License Agreement between Cell Therapeutics, Inc. and PG-TXL Company, dated as of November 13, 1998.	Incorporated by reference to Exhibit 10.27 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1998, filed on March 31, 1999 (Commission No. 001-12465).
10.28	Amendment No. 1 to the License Agreement between the Registrant and PG-TXL Company, L.P., dated as of February 1, 2006.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on February 7, 2006.
10.29	Second Amendment to the Acquisition Agreement, dated as of August 6, 2009, by and among the Registrant and each of Tom Hornaday and Lon Smith, in their capacities as Stockholder Representatives.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on August 7, 2009.
10.30	Drug Product Manufacturing Supply Agreement, dated July 13, 2010, by and between NerPharMa, S.r.l. and the Registrant.	Incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q, filed on August 6, 2010.
10.31	Form of Exchange Agreement between Cell Therapeutics, Inc. and certain other parties thereto, dated December 12, 2007.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on December 13, 2007.
10.32	Termination of Securities Purchase Agreement between Cell Therapeutics, Inc. and Midsummer Investment, Ltd., dated March 5, 2009.	Incorporated by reference to Exhibit 10.44 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2008, filed on March 16, 2009.

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<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
10.33	Letter Agreement with Midsummer Investment, Ltd., SCO Capital Partners, LLC, Context Opportunistic Master Fund, LP, Context Capital Management, LLC, ALTMA Fund SICAV PLC in Respect of the Grafton Sub Fund, Rockmore Investment Mater Fund Ltd., TRUK Opportunity Fund, LLC, TRUK International Fund, LP, McMahan Securities Co., L.P., Tewksbury Investment Fund Ltd., Whitebox Hedged High Yield Partners, LP and Whitebox Combined Partners, LP, dated January 29, 2009.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on February 9, 2009.
10.34	Letter Agreement with RHP Master Fund Ltd., dated February 4, 2009.	Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed on February 9, 2009.
10.35	Exchange Agreement, dated April 7, 2009, between the Registrant and Milfam I L.P.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on April 17, 2009.
10.36	Exchange Agreement, dated April 7, 2009, between the Registrant and CD Investment Partners Ltd.	Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed on April 17, 2009.
10.37	Securities Purchase Agreement, dated April 13, 2009.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on April 13, 2009.
10.38	Securities Purchase Agreement, dated May 11, 2009.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on May 12, 2009.
10.39	Form of Securities Purchase Agreement.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on August 21, 2009.
10.40	Form of Securities Purchase Agreement.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on January 19, 2010.
10.41	Form of Securities Purchase Agreement.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on April 5, 2010.
10.42	Form of Securities Purchase Agreement.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on May 27, 2010.
10.43	Form of Securities Purchase Agreement, dated July 25, 2010.	Incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, filed on August 6, 2010.
10.44	Form of Warrant Exchange Agreement, dated July 25, 2010.	Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q, filed on August 6, 2010.

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Exhibit Number	Exhibit Description	Location
10.45	Form of Securities Purchase Agreement, dated October 19, 2010.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on October 22, 2010.
10.46	Form of Securities Purchase Agreement, dated January 12, 2011.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on January 18, 2011.
12.1	Statement Re: Computation of Ratio of Earnings to Fixed Charges.	Filed herewith.
16.1	Letter from Stonefield Josephson, Inc. to the Securities and Exchange Commission dated October 25, 2010.	Incorporated by reference to Exhibit 16.1 to the Registrant's Current Report on Form 8-K/A, filed on October 6, 2010.
21.1	Subsidiaries of the Registrant.	Filed herewith.
23.1	Consent of Stonefield Josephson, Inc., Independent Registered Public Accounting Firm.	Filed herewith.
23.2	Consent of Marcum LLP, Independent Registered Public Accounting Firm.	Filed herewith.
24.1	Power of Attorney. Contained in the signature page of this Annual Report on Form 10-K and incorporated herein by reference.	Filed herewith.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith.

\* Indicates management contract or compensatory plan or arrangement.  
Portions of these exhibits have been omitted pursuant to a request for confidential treatment.

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

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Seattle, State of Washington, on February 16, 2011.

Cell Therapeutics, Inc.

By: /s/ James A. Bianco  
**James A. Bianco, M.D.**  
 Chief Executive Officer

**POWER OF ATTORNEY**

KNOW BY ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints James A. Bianco and Louis A. Bianco, and each of them his attorney-in-fact, with the power of substitution, for him in any and all capacities, to sign any amendment of post-effective amendment to this Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the SEC, hereby ratifying and confirming all that said attorney-in-fact, or his substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Phillip M. Nudelman	Chairman of the Board and Director	February 16, 2011
<b>Phillip M. Nudelman, Ph.D.</b>		
/s/ James A. Bianco	Chief Executive Officer and Director (Principal Executive Officer)	February 16, 2011
<b>James A. Bianco, M.D.</b>		
/s/ Louis A. Bianco	Executive Vice President, Finance and Administration (Principal Financial Officer and Principal Accounting Officer)	February 16, 2011
<b>Louis A. Bianco</b>		
/s/ John H. Bauer	Director	February 16, 2011
<b>John H. Bauer</b>		
/s/ Vartan Gregorian	Director	February 16, 2011
<b>Vartan Gregorian, Ph.D.</b>		
/s/ Richard L. Love	Director	February 16, 2011
<b>Richard Love</b>		
/s/ Mary O. Munding	Director	February 16, 2011
<b>Mary O. Munding, DrPH</b>		



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/s/ Jack W. Singer

Director

February 16, 2011

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

/s/ Frederick W. Telling

Director

February 16, 2011

**Frederick Telling, Ph.D.**