

CELL THERAPEUTICS INC  
Form 10-K  
March 08, 2012  
Table of Contents

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, 2011

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:

Edgar Filing: CELL THERAPEUTICS INC - Form 10-K

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, 2011, the aggregate market value of the registrant's common equity held by non-affiliates was \$262,221,235. 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 March 2, 2012 was 226,608,687.

**DOCUMENTS INCORPORATED BY REFERENCE**

None.

**Table of Contents****CELL THERAPEUTICS, INC.****TABLE OF CONTENTS**

	<b>Page</b>
<b>PART I</b>	
ITEM 1. <u>BUSINESS</u>	2
ITEM 1A. <u>RISK FACTORS</u>	21
ITEM 1B. <u>UNRESOLVED STAFF COMMENTS</u>	43
ITEM 2. <u>PROPERTIES</u>	43
ITEM 3. <u>LEGAL PROCEEDINGS</u>	43
ITEM 4. <u>MINE SAFETY DISCLOSURES</u>	48
<b>PART II</b>	
ITEM 5. <u>MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	49
ITEM 6. <u>SELECTED FINANCIAL DATA</u>	51
ITEM 7. <u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	53
ITEM 7A. <u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	69
ITEM 8. <u>FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	70
ITEM 9. <u>CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	119
ITEM 9A. <u>CONTROLS AND PROCEDURES</u>	119
ITEM 9B. <u>OTHER INFORMATION</u>	119
<b>PART III</b>	
ITEM 10. <u>DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u>	120
ITEM 11. <u>EXECUTIVE COMPENSATION</u>	123
ITEM 12. <u>SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED SHAREHOLDER MATTERS</u>	146
ITEM 13. <u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE</u>	148
ITEM 14. <u>PRINCIPAL ACCOUNTING FEES AND SERVICES</u>	151
<b>PART IV</b>	
ITEM 15. <u>EXHIBITS, FINANCIAL STATEMENT SCHEDULES</u>	152
<u>SIGNATURES</u>	161
<u>CERTIFICATIONS</u>	

---

## Table of Contents

### **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.

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

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.

---

**Table of Contents**

**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, tosedostat, 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 or refractory aggressive non-Hodgkin's lymphoma, or NHL, who received two or more prior therapies and who were sensitive to treatment with anthracyclines. In the U.S., we initially completed our new drug application, or NDA, submission with the U.S. Food and Drug Administration, or the FDA, in June 2009. 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 and other items. We filed an appeal in December 2010 with the FDA's Center for Drug Evaluation and Research regarding the FDA's decision in April 2010 to not approve Pixuvri. The appeal was filed under the FDA's formal dispute resolution process asking the Office of New Drugs, or the OND, to conclude that PIX301 demonstrated efficacy.

The FDA responded allowing us to resubmit the NDA with additional information. Prior to resubmitting the NDA, we initiated 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. On October 25, 2011, we announced the resubmission of the NDA to the FDA's Division of Oncology Products 1, or DOP1, for accelerated approval to treat relapsed or refractory aggressive NHL in patients who failed two or more lines of prior therapy. On December 6, 2011, we announced that the FDA's DOP1 had notified us that our resubmitted NDA is considered a complete, Class 2 response to the FDA's April 2010 complete response letter. The FDA set a Prescription Drug User Fee Act, or PDUFA, goal date of April 24, 2012 for a decision on the NDA.

On January 3, 2012, we announced that the FDA's Oncologic Drugs Advisory Committee, or ODAC, was scheduled to review our resubmitted NDA for Pixuvri on February 9, 2012. On January 30, 2012, we announced that we had voluntarily withdrawn our NDA for Pixuvri. The NDA was withdrawn because, after communications with the FDA, we needed additional time to prepare for the review of the NDA by the FDA's ODAC at its February 9, 2012 meeting. Prior to withdrawing the NDA, we requested that the FDA consider rescheduling the review of the NDA to the ODAC meeting to be held in late March. The FDA was unable to accommodate our request to reschedule, and given the April 24, 2012 PDUFA date, the only way to have Pixuvri possibly considered at a later ODAC meeting was to withdraw and later resubmit the NDA. We plan to resubmit the NDA in 2012.

In Europe, we filed a Marketing Authorization Application, or MAA, for commercialization of Pixuvri, which was accepted for review by the European Medicines Agency, or the EMA, in December 2010. On February 17, 2012, Pixuvri was granted a positive opinion for conditional approval from the EMA's Committee for Medicinal Products for Human Use, or CHMP. The CHMP recommended Pixuvri for conditional approval as monotherapy for the treatment of adult patients with multiple relapsed or refractory aggressive non-Hodgkin B-cell lymphomas. The CHMP positive opinion for Pixuvri will now be reviewed by the European Commission, which has the authority to approve medicines for use in the E.U. If the CHMP's recommendation is formally adopted by the European Commission, Pixuvri would be approved for marketing in the 27 countries that are members of the E.U., as well as the European Economic Area. We are hopeful that a conditional marketing authorization for Pixuvri should be granted by the European Commission within the first half of 2012.

## Table of Contents

Similar to accelerated approval regulations in the U.S., conditional marketing authorizations are granted to medicinal products with a positive benefit/risk assessment that address unmet medical needs and whose availability would result in a significant public health benefit. A conditional marketing authorization is renewable annually. Under the provisions of the conditional marketing authorization for Pixuvri, we will be required to complete a post-marketing study aimed at confirming the clinical benefit previously observed. The CHMP has accepted PIX306 study as the study to confirm clinical benefit. As a condition of approval, we have agreed to have available the PIX306 clinical trial results by June 2015. We are working with consultants to develop a go-to-market strategy in Europe, including product messaging, positioning, staffing and resources required for Pixuvri product introduction in the E.U. If the European Commission adopts the positive opinion rendered by the CHMP for Pixuvri and if we successfully implement our go-to-market strategy, we expect to begin product launch on an E.U. country-by-country basis beginning in the second half of 2012.

Another late-stage drug candidate of ours, 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 843 patients enrolled as of December 31, 2011. OPAXIO is also being studied in follow-on phase II trial for the treatment of metastatic brain cancer based on encouraging results from a prior phase II study in this disease.

We are also developing tosedostat in collaboration with Chroma Therapeutics, Ltd., or Chroma. We entered into a co-development and license agreement with Chroma in March 2011, providing us with exclusive marketing and co-development rights to Chroma's drug candidate, tosedostat, in North, Central and South America. Tosedostat is an oral, aminopeptidase inhibitor that has demonstrated significant anti-tumor responses in blood related cancers and solid tumors in phase I-II clinical trials. Interim results from the phase II OPAL study of tosedostat in elderly patients with relapsed or refractory acute myeloid leukemia, or AML, were presented in June 2011 at the 2011 Annual Meeting of the American Society of Clinical Oncology, or ASCO. These results showed that once-daily, oral doses of tosedostat had predictable and manageable toxicities and demonstrated encouraging response rates at the interim evaluation time point including a high-response rate among patients who received prior hypomethylating agents, which are used to treat myelodysplastic syndrome, or MDS, a precursor of AML. Based on these results, and pending discussions with the FDA, we, in collaboration with Chroma, anticipate initiating a phase III study for patients with relapsed or refractory MDS in the second half of 2012.

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, or 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. Depending on our resources and priorities, we may choose to discontinue additional pre-IND work or seek to out-license the product to another third party.

We also continue to evaluate additional novel clinical stage compounds to expand our hematologic cancer product pipeline. We are interested in compounds or products that are complementary to our existing pipeline.

**Table of Contents****Product Candidates**

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/open
	Aggressive NHL, => 3 relapses, single-agent (PIX301)	III/closed
	Aggressive NHL, front-line, CPOP-R (PIX203)	II/closed
	Metastatic HER2-negative breast cancer (North Central Cancer Treatment Group)	II/closed
<b>OPAXIO</b> (paclitaxel poliglumex)	Ovarian cancer, first-line maintenance (GOG0212-Gynecologic Oncology Group)	III/open
	Metastatic brain cancer (Brown University Oncology Group)	II/open
	Head and neck cancer (SUNY Upstate Medical University)	II/open
	Esophageal cancer (Brown University Oncology Group)	II/closed
<b>Tosedostat</b>	Acute Myeloid Leukemia (HOVON)	II/open
	Acute Myeloid Leukemia, relapsed or refractory (OPAL-Chroma)	II/closed
<b>Brostallicin</b>	Metastatic triple-negative breast cancer (North Central Cancer Treatment Group)	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 577,190 deaths annually, or more than 1,500 people per day and approximately 1.6 million new cases of cancer were expected to be diagnosed in 2012 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

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

## **Table of Contents**

*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.

*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 NHL, and various other hematologic malignancies, and solid tumors. We believe a next-generation anthracycline with 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. 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

---

**Table of Contents**

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 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. NHL is the sixth most common type of cancer. The American Cancer Society's most recent estimates are that there will be 70,130 people diagnosed with NHL in the United States and approximately 18,949 people will die from this disease in the United States in 2012. In Europe, the World Health Organization's International Agency for Research on Cancer's 2008 GLOBOCAN database estimates that in the European Union approximately 74,162 people will be diagnosed with NHL and 31,371 are estimated to die from NHL annually.

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 60% 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. We began a rolling NDA submission to the FDA in April 2009 and completed the submission in June 2009.

In 2010, 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 and commercial supplies.

On March 22, 2010, the FDA's 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 and other items. We met with the FDA in August 2010 at an end of review meeting at which time the FDA informed us that the Pixuvri Investigational New Drug application, or IND, and NDA were being transferred to the newly-formed Division of Hematology Drug Products, or the DHP. We filed an appeal in December 2010 with the FDA's 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 filed under the FDA's formal dispute resolution process asked the Office of New Drugs, or the OND, to conclude that PIX301 demonstrated efficacy. In March 2011, we announced that we met with officials of the OND and presented our arguments supporting our belief that the data contained in the NDA are consistent with the conclusion that Pixuvri is effective for its planned use. At the meeting, the OND requested additional analyses related to the EXTEND clinical study which we submitted.

On May 3, 2011, we announced that the OND responded to our December 2010 appeal of the FDA's April 2010 decision to not approve Pixuvri for relapsed or refractory aggressive NHL. In its response, the OND indicated that after considering the data available in the appeal, it does not believe that accelerated approval of

---

**Table of Contents**

our NDA is necessarily out of reach based on a single controlled clinical trial, provided that two key matters can be resolved satisfactorily. First, the circumstances of stopping the PIX301 trial early must be resolved to assure that ongoing results assessment were not dictating the decision to stop. Second, ascertainment of the primary endpoint in the PIX301 study must be determined to have been sound and not subject to bias.

The OND also indicated that our request that the OND find that the data in our NDA demonstrate efficacy and return the NDA to the Office of Oncology Drug Products for consideration of safety and other issues was denied because the OND was not able to conclude that efficacy had been demonstrated. However, the OND also did not find that it could be concluded that PIX301 was a failed study, which warranted application of interim analysis statistical thresholds.

On June 14, 2011, we announced that we had met with the FDA's Division of Oncology Drug Products, or DODP, in a meeting that focused on the documents we proposed to provide regarding the circumstances of stopping the enrollment of PIX301 prior to achieving the original planned patient accrual and the make-up of the new radiology expert panel, as well as our plan to address the items noted in the FDA's complete response letter. The DODP confirmed that our NDA would be reviewed within six months from the resubmission of our NDA. On September 28, 2011, we announced that a second independent radiology assessment of response and progression endpoint data from our PIX301 clinical trial of Pixuvri was achieved with statistical significance. We believe this assessment confirmed the statistical robustness of the PIX301 efficacy data that was previously submitted by us to the FDA in our NDA for Pixuvri.

On October 25, 2011, we announced the resubmission of the NDA to the FDA's DOP1 for accelerated approval to treat relapsed or refractory aggressive NHL in patients who failed two or more lines of prior therapy. On December 6, 2011, we announced that the DOP1 had notified us that our resubmitted NDA is considered a complete, Class 2 response to the FDA's April 2010 complete response letter. The FDA set a PDUFA goal date of April 24, 2012 for a decision on our resubmitted NDA.

On January 3, 2012, we announced that ODAC was scheduled to review our resubmitted NDA for Pixuvri on February 9, 2012. On January 30, 2012, we announced that we had voluntarily withdrawn our resubmitted NDA for Pixuvri. The NDA was withdrawn because, after communications with the FDA, we needed additional time to prepare for the review of the NDA by ODAC at its February 9, 2012 meeting. Prior to withdrawing the NDA, we requested that the FDA consider rescheduling the review of the NDA to the ODAC meeting to be held in late March. The FDA was unable to accommodate our request to reschedule, and given the April 24, 2012 PDUFA date, the only way to have Pixuvri possibly considered at a later ODAC meeting was to withdraw and later resubmit the NDA. We plan to resubmit the NDA in 2012.

We believe the results of the EXTEND trial met its primary endpoint and 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 had predictable and manageable toxicities 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. Other common adverse events (any grade) included infection, anemia, 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.

In March 2011, we initiated the PIX-R trial to study Pixuvri in combination with rituximab in patients with relapsed/refractory diffuse large B-cell lymphoma, or DLBCL. The trial will compare a combination of Pixuvri plus rituximab to a combination of gemcitabine plus rituximab in patients with relapsed or refractory DLBCL.

---

**Table of Contents**

who have received one to three prior lines of therapy. The PIX-R trial utilizes overall survival, or OS, as the primary endpoint of the study, with a secondary endpoint of progression free survival, or PFS. The PIX-R trial is targeting to enroll approximately 350 patients and will include patients who have failed at least one line of previous therapy and patients who are not candidates for myeloablative chemotherapy and stem cell transplant. We had discussions with the DHP relating to a Special Protocol Assessment, or SPA, and following these discussions we determined that we would not pursue a SPA. The DHP noted that we could conduct a study utilizing PFS along with OS as co-primary endpoints which would be an acceptable design outside of the formal SPA process. At the initiation of the study, co-primary endpoints of OS and PFS were used. Subsequently, an amendment was made to the study protocol in January 2012, to make OS the sole primary endpoint, and PFS a secondary endpoint. As this study is being conducted without a SPA, regulatory acceptability will depend on the magnitude of the difference between the trial study arms as well as a risk and benefit analysis. This study could serve as either a post-approval confirmatory study, if Pixuvri were to be approved on the basis of an NDA that will be re-submitted later in 2012, or as a registration study for approval in the United States.

In Europe in July 2009, we were notified by the EMA that Pixuvri was eligible to be submitted for an 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 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.

In June 2010, the Italian Medicines Agency, or AIFA, the national authority responsible for drug regulation in Italy, approved the facility at NerPharMa DS, S.r.l. for the production of Pixuvri drug substance. In July 2010, we signed a supply agreement with NerPharMa, S.r.l. for Pixuvri drug product manufacturing. The five-year contract provides for both the commercial and clinical supply of Pixuvri drug product.

In March 2011, we received the Day 120 list of questions from the EMA's CHMP. In April 2011, we met with the co-rapporteurs and members of the EMA to discuss our proposed responses. Based on feedback and recommendation from the rapporteurs, in order to allow time for preclinical reports to be available, we requested and were granted an extension so that our responses could address the questions in the Day 120 list. In August 2011, we submitted our response to the Day 120 questions. On December 5, 2011, we announced that we had received the Day 180 list of outstanding issues from the EMA's CHMP which contained only one remaining major clinical objection to our MAA and items not deemed to be major issues. To address the remaining major objection, the CHMP required that we provide a literature review of mechanisms of rituximab resistance and analyses that demonstrate the efficacy of Pixuvri in patients with prior rituximab treatment. In addition, the CHMP required that we provide information to address some additional questions that were not deemed to be major issues and could be addressed by additional analyses of currently available data. On January 18, 2012, we presented to the CHMP an oral explanation to address outstanding questions raised by some of the member states.

---

## **Table of Contents**

On February 17, 2012, Pixuvri was granted a positive opinion for conditional approval from the EMA's CHMP. The CHMP recommended Pixuvri for conditional approval as monotherapy for the treatment of adult patients with multiple relapsed or refractory aggressive non-Hodgkin B-cell lymphomas. The CHMP positive opinion for Pixuvri will now be reviewed by the European Commission, which has the authority to approve medicines for use in the E.U. If the CHMP's recommendation is formally adopted by the European Commission, Pixuvri would be approved for marketing in the 27 countries that are members of the E.U., as well as the European Economic Area. We are hopeful that a conditional marketing authorization for Pixuvri should be granted by the European Commission within the first half of 2012.

Similar to accelerated approval regulations in the U.S., conditional marketing authorizations are granted to medicinal products with a positive benefit/risk assessment that address unmet medical needs and whose availability would result in a significant public health benefit. A conditional marketing authorization is renewable annually. Under the provisions of the conditional marketing authorization for Pixuvri, we will be required to complete a post-marketing study aimed at confirming the clinical benefit previously observed. The CHMP has accepted PIX306 study as the study to confirm clinical benefit. As a condition of approval, we have agreed to have available the PIX306 clinical trial results by June 2015.

### *Pixuvri for metastatic breast cancer*

Pixuvri has also been 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 this phase II study for enrollment. The study is closed to accrual and results are expected to be reported by the NCCTG later in 2012.

## **OPAXIO**

OPAXIO, which we have previously referred to as XYOTAX, 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, esophageal, head and neck 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 biodegradable amino acids, it is slowly metabolized by lysosomal enzymes (principally cathepsin B) inside the lysosome of the tumor cell. This metabolism releases the active chemotherapy agent, 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 10 to 20 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

## **Table of Contents**

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*

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. In April 2004, we announced that we entered into a clinical trial agreement with the GOG to perform a phase III trial, or the GOG0212 trial. We have been advised that the GOG submitted both an IND, which cross references our IND, and a SPA for the GOG0212 trial to the FDA. As such, the GOG0212 trial is conducted and managed by the GOG. The trial is expected to enroll 1,100 patients with 843 patients enrolled as of December 31, 2011. On February 21, 2012, we were informed that the Data Monitoring Committee for GOG0212 adopted an amendment to the study's statistical analysis plan, or SAP, to perform four interim analyses instead of the previously-planned single interim analysis allowing for an earlier analysis of survival results than previously noted. The first interim analysis is expected to take place when 109, versus the previously-planned 138, events occur in the control arm. There are early stopping criteria for either success or futility. The final fifth analysis would be conducted when 301, versus the previously-planned 277, events have occurred in the control arm. We understand that the GOG will attempt to amend its SPA following a discussion with the FDA. Based on feedback from the GOG, the GOG Data Monitoring Committee currently plans to conduct its first interim analysis of overall survival in 2013. 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 PFS. Based on these results, the Brown University Oncology Group has initiated a randomized, multicenter, phase II study of OPAXIO and standard radiotherapy versus TMZ and radiotherapy for newly diagnosed patients with glioblastoma with an active gene termed MGMT that reduces responsiveness to TMZ. The trial goals are to estimate disease free and overall survival for the two study arms.

### *OPAXIO for esophageal cancer*

In June 2009, we announced that, in a study released from Brown University at the 2009 ASCO 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 compared to standard therapy.

### *OPAXIO for head and neck cancer*

A phase I/II study of OPAXIO combined with radiotherapy and cisplatin was initiated by SUNY Upstate Medical University, in patients with locally advanced head and neck cancer. The results are expected to be presented in late 2012.

## **Table of Contents**

### **Tosedostat**

In March 2011, we entered into a co-development and license agreement with Chroma, providing us with exclusive marketing and co-development rights to Chroma's drug candidate, tosedostat, in North, Central and South America. Tosedostat is an oral, aminopeptidase inhibitor that has demonstrated significant anti-tumor responses in blood related cancers and solid tumors in phase I-II clinical trials. Interim results from the phase II OPAL study of tosedostat in elderly patients with relapsed or refractory AML were presented in June 2011 at the 2011 ASCO Annual Meeting. These results showed that once-daily, oral doses of tosedostat had predictable and manageable toxicities and results demonstrated encouraging response rates including a high-response rate among patients who received prior hypomethylating agents, which are used to treat myelodysplastic syndrome, or MDS, a precursor of AML. Based on these results, and pending discussions with the FDA, we, in collaboration with Chroma, anticipate initiating a phase III study for patients with relapsed or refractory MDS in the second half of 2012.

### **Brostallicin**

We are developing brostallicin through our wholly-owned subsidiary, Systems Medicine LLC, 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.

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 ASCO 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. Depending on our resources and priorities, we may choose to discontinue additional pre-IND work or seek to out-license the product to another third party.



---

**Table of Contents****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 Pharmaceuticals, 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 \$34.9 million, \$27.0 million and \$30.2 million in 2011, 2010, and 2009, 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. 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.

*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, esophageal, head and neck 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.

*Tosedostat.* Tosedostat is an oral, aminopeptidase inhibitor that has demonstrated significant anti-tumor responses in blood related cancers and solid tumors in phase I-II clinical trials. We are unable to provide the nature, timing, and estimated costs of the efforts necessary to complete the development of tosedostat because, among other reasons, we cannot predict with any certainty the pace of enrollment of our clinical trials. 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 tosedostat will be completed or when we will be able to begin commercializing tosedostat to generate material net cash inflows.

**Table of Contents**

*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 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 the dinuclear-platinum complex, or CT-47463, that we expect may be more potent than cisplatin. 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 21 of this Form 10-K: *Our financial condition may be harmed 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 and as a radiation sensitizer. ; 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**

*Chroma Therapeutics, Ltd.*

We have an agreement with Chroma, or the Chroma Agreement, under which we have an exclusive license to certain technology and intellectual property controlled by Chroma to develop and commercialize the drug candidate, tosedostat, in North, Central and South America, or the Licensed Territory. Pursuant to the terms of the Chroma Agreement, we paid Chroma an upfront fee of \$5.0 million upon execution of the agreement and will make a milestone payment of \$5.0 million upon the initiation of the first pivotal trial, which could commence in the second half of 2012. The Chroma Agreement also includes additional development- and sales-based milestone payments related to AML and certain other indications, up to a maximum amount of \$209.0 million payable by us to Chroma if all development and sales milestones are achieved.

We will also pay Chroma royalties on net sales of tosedostat in any country within the Licensed Territory, commencing on the first commercial sale of tosedostat in any country in the Licensed Territory and continuing with respect to that country until the later of (a) the expiration date of the last patent claim covering tosedostat in

---

**Table of Contents**

that country, (b) the expiration of all regulatory exclusivity periods for tosedostat in that country or (c) ten years after the first commercial sale in that country. Royalty payments to Chroma are based on net sales volumes in any country within the Licensed Territory and range from the low- to mid-teens as a percentage of net sales.

We will oversee and be responsible for performing the development operations and commercialization activities in the Licensed Territory and Chroma will oversee and be responsible for performing the development operations and commercialization activities worldwide except for the Licensed Territory, or the ROW Territory. Development costs may not exceed \$50.0 million for the first three years of the Chroma Agreement unless agreed by the parties and we will be responsible for 75% of all development costs, while Chroma will be responsible for 25% of all development costs, subject to certain exceptions. Chroma is responsible for the manufacturing of tosedostat for development purposes in the Licensed Territory and the ROW Territory in accordance with the terms of the manufacturing and supply agreement. We have the option of obtaining a commercial supply of tosedostat from Chroma or from another manufacturer at our sole discretion in the Licensed Territory. The Chroma Agreement may be terminated by us at our convenience upon 120 days written notice to Chroma. The Chroma Agreement may also be terminated by either party following a material breach by the other party subject to notice and cure periods.

*University of Vermont*

We have an agreement with the University of Vermont, or UVM, which grants us an exclusive license, with the right to sublicense, for the rights to pixantrone, or the UVM Agreement. Pursuant to the UVM Agreement, we acquired the rights to make, have made, sell and use pixantrone. Pursuant to the UVM Agreement, we are obligated to make payments to UVM based on net sales. Our royalty payments range from low-single digits to mid-single digits as a percentage of net sales. The higher royalty rate is payable for net sales in countries where specified UVM licensed patents exist, or where we have obtained orphan drug protection, until such UVM patents or such protection no longer exists. For a period of ten years after first commercialization of pixantrone, the lower royalty rate is payable for net sales in such countries after expiration of the designated UVM patents or loss of orphan drug protection, and in all other countries without such specified UVM patents or orphan drug protection. Unless otherwise terminated, the term of the UVM Agreement continues for the life of the licensed patents in those countries in which a licensed patent exists, and continues for ten years after the first sale of pixantrone in those countries where no such patents exist. We may terminate the UVM Agreement, on a country-by-country basis or on a patent-by-patent basis, at any time upon advance written notice. UVM may terminate the UVM Agreement upon advance written notice in the event royalty payments are not made. In addition, either party may terminate the UVM Agreement (a) in the event of an uncured material breach of the UVM Agreement by the other party; or (b) in the event of bankruptcy of the other party.

*PG-TXL*

We have an agreement, or the PG-TXL 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. 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

## **Table of Contents**

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 GOG related to the GOG0212 trial, which the GOG is conducting. We recorded a \$1.7 million payment due to the GOG based on the 800 patient enrollment milestone achieved in the second quarter of 2011, which is included in accounts payable as of December 31, 2011. Under this agreement, we are required to pay up to \$1.8 million in additional milestone payments related to the trial, of which \$0.5 million will become due upon receipt of the interim analysis and data transfer which may occur in 2013. There were 843 patients enrolled as of December 31, 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, or the Novartis Agreement, with Novartis International Pharmaceutical Ltd., or Novartis, 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 the 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.

---

## **Table of Contents**

Royalties for OPAXIO are based on worldwide sales volumes of OPAXIO and royalties for Pixuvri are based on sales volumes in the United States 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, 2011, 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 pending patent applications or issued patents in the U.S. and foreign countries directed to OPAXIO, Pixuvri, tosedostat, 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. The tosedostat-directed patents will expire in 2017. The brostallicin-directed patents will expire on various dates ranging from 2017 to 2021. The patent expiration ranges given above are only for U.S. issued patents. The Pixuvri-directed patents in Europe will expire in 2012 through 2015. However, these dates do not account for potential extensions that 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

## **Table of Contents**

agreements with third-party vendors to produce, test, and distribute Pixuvri, OPAXIO, tosedostat 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 signed 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 signed a manufacturing and supply agreement, or the Chroma Supply Agreement, with Chroma for our drug candidate tosedostat. The Chroma Supply Agreement is a non-exclusive agreement and provides for both the clinical and commercial drug supply of tosedostat. The Chroma Supply Agreement commenced on June 8, 2011 and expires two years from the date when tosedostat is granted first approval for commercial distribution by the applicable regulatory authority in the licensed territory. Upon expiration of the initial term, we have a one year renewal option. We have the right to terminate the Chroma Supply Agreement without cause with 90 days written notice to Chroma. Both parties have the right to terminate for breach, bankruptcy, mutual agreement, or termination of the development agreement.

## **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, Pfizer, Roche Group, Genentech, Inc., Astellas Pharma, Eli Lilly and Company, Celgene, 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 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.

## **Table of Contents**

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.

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





## **Table of Contents**

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 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 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

## **Table of Contents**

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.

## **Employees**

As of December 31, 2011, we employed 95 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 are good.

## **Table of Contents**

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 , Pixuvri 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, 2011, we had cash and cash equivalents of \$47.1 million. We do not expect that our existing cash and cash equivalents, including additional funds received to date, will provide sufficient working capital to fund our presently anticipated operations beyond the second quarter of 2012. There can be no assurance that we will have sufficient earnings, access to liquidity or cash flow in the future to meet our operating expenses and other obligations.

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 very few authorized shares of common stock available for issuance and it can be 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 harmed. 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 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 the European Union (including Italy) and the United States and we may be subject to

---

**Table of Contents**

certain contractual limitations, which may increase our costs and harm 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, tosedostat, 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, tosedostat, brostallicin and bisplatinates.

*We need to implement a reduction in expenses across our operations if we are unable to secure additional financing.*

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.

*Our common stock is listed on The NASDAQ Capital Market and the Mercato Telematico Azionario stock market in Italy, or 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. NASDAQ's 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 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 had 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

**Table of Contents**

our common stock closed at \$1.00 per share or more for a minimum of ten consecutive trading days before November 1, 2010. In addition, 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).

On May 3, 2011, we received a notice from NASDAQ stating that we had not regained compliance with NASDAQ's \$1.00 minimum bid price rule under NASDAQ Marketplace Rule 5550(a)(2). On May 5, 2011, in an effort to regain compliance with the NASDAQ listing requirements and increase the per-share trading price of our common stock, our board of directors approved a 1-for-6 reverse stock split. The reverse stock split became effective on May 15, 2011. On June 1, 2011, we announced that we received a letter from NASDAQ indicating that as of that date we had regained compliance with NASDAQ Marketplace Rule 5550(a)(2) and that as of that date we were in compliance with all applicable listing standards. As a result, our common stock will continue to be listed and traded on The NASDAQ Capital Market. However, notwithstanding our current compliance with NASDAQ listing standards, there can be no assurance that we will be able to maintain our continued listing on The NASDAQ Capital Market in the future.

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, the Commissione Nazionale per le Società e la Borsa, or CONSOB (which is the public authority responsible for regulating the Italian securities markets), or the Borsa Italiana (which ensures the development of the managed markets in Italy) 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 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

---

**Table of Contents**

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

At our Annual Meeting held on November 11, 2011, our shareholders approved a proposal to amend our articles of incorporation to reflect an increase in the total number of authorized shares from 284,999,999 to 384,999,999 and an increase in our authorized shares of common stock from 283,333,333 to 383,333,333. However, in the future, if we are unable to obtain a quorum at our shareholder meetings, including the Annual Meeting, and/or fail to obtain shareholder approval of corporation actions, such failure could harm us. Our amended and restated articles of incorporation, or our articles of incorporation, require that a quorum, generally consisting of one-third of the outstanding shares of voting stock, be represented in person, by telephone or by proxy in order to transact business at a meeting of our shareholders. In addition, amendments to our articles of incorporation, such as an amendment to increase our authorized capital stock, generally require the approval of a majority of our outstanding shares. As a result, there is a risk that we may not get shareholder approval for amendments to our articles of incorporation, including amendments to increase the number of authorized shares of common stock at a time when we need those shares to effect a future equity financing. If we do not receive shareholder approval for such increase in authorized shares, our ability to raise capital through equity financings will be significantly harmed.

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. We were able to obtain a quorum to hold special meetings of the shareholders in April 2007, January 2008, March 2009 and June 2011 and annual meetings of the shareholders in September 2007, June 2008, October 2009, September 2010 and November 2011. Nevertheless, 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 a 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.

Even if we obtain a quorum at our shareholder meetings, we may not obtain enough votes to approve matters to be resolved upon at those meetings. Under Rule 452 of the New York Stock Exchange, or Rule 452, the U.S. broker-dealer may only vote shares absent direction from the beneficial owner on certain specified routine matters, such as certain amendments to our articles of incorporation to increase authorized shares that are to be used for general corporate purposes and the ratification of our auditors. If our shareholders do not instruct their brokers on how to vote their shares on non-routine matters, then we may not obtain the necessary number of votes for approval. Non-routine matters include, for example, proposals that relate to the authorization or creation of indebtedness or preferred stock. Revisions to Rule 452 that further limit matters for

## Table of Contents

which broker discretionary voting is allowed, such as the recent revisions imposed by the Dodd-Frank Act to prohibit broker discretionary voting on matters related to executive compensation and in the election of directors, may further 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 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, 2011, we had an accumulated deficit of \$1.7 billion. We are pursuing regulatory approval for Pixuvri, OPAXIO, tosedostat, brostallicin and bisplatinates. 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.

*We may be unable to use our net operating losses to reduce future income tax liability.*

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, 2011, 2010 and 2009 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 pending 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

## Table of Contents

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 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 CONSOB and the Borsa Italiana, which ensures the development of the managed markets 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 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 registration document, securities note and summary that have to be 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 obtain and maintain a registration document, securities note or summary 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 current provisions of European Directive No. 71/2003 and, according to the current interpretations of the Committee of European Securities Regulators, is not subject to the 10% limitation imposed by E.U. and Italian law. However, there can be no assurance that these exceptions to the registration document requirement are not changed from time to time.

Moreover, 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 \$6,000 to \$649,000 converted using the currency exchange rate as of December 31, 2011, 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



**Table of Contents**

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 would have to evaluate before imposing any possible administrative sanctions. In a letter dated March 10, 2011, CONSOB notified us of a resolution confirming the occurrence of the violation asserted in clause (i) above and applied a fine in the amount of 40,000, or approximately \$55,000 converted using the foreign currency exchange rate as of March 10, 2011, which we paid on April 5, 2011. CONSOB has not yet notified us of a resolution with respect to the violation asserted in clause (ii) above, but based on our assessment, we believe the likelihood that a pecuniary administrative sanction will be imposed on us for such asserted violation (ii) 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 \$5.0 million and \$5.3 million as of December 31, 2011 and December 31, 2010, 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, \$7.1 million, \$3.3 million and \$1.1 million converted using the currency exchange rate as of December 31, 2011, 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 decisions of the Provincial Tax Court of Milan, or the Tax Court, for the different VAT cases are 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 2.9 million to 9.4 million, or approximately \$3.7 million to \$12.2 million converted using the currency exchange rate as of December 31, 2011, 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 \$2.1 million converted using the currency exchange rate as of February 2, 2011. On March 4, 2011, we paid to the ITA the required deposit in respect of the 2006 VAT in the amount of 0.4 million, or approximately \$0.6 million converted using the currency exchange rate as of March 4, 2011. On March 25, 2011, we paid to the Italian collection agent an additional 0.1 million, or approximately \$0.1 million converted using the currency exchange rate as of March 25, 2011. On September 26, 2011, we paid to the ITA the required deposit in respect of the 2007 VAT in the amount of 0.1 million or approximately \$0.1 million converted using the currency exchange rate as of September 26, 2011. Further information pertaining to these cases can be found in this Annual Report on Form 10-K under Part I, Item 3 Legal Proceedings and is incorporated by reference herein.

---

**Table of Contents**

*Our financial condition may be harmed 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 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. 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. Further information about the status of the regulatory approval for Pixuvri can be found in Risk Factors Factors Affecting Our Operating Results and Financial Condition *We cannot guarantee that we will obtain regulatory approval to manufacture or market any of our drug candidates.*

*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.

Information about the status of the regulatory approval of Pixuvri can be found in this Annual Report on Form 10-K under Part I, Item 1 Business, Overview and is incorporated by reference herein.

In March 2011, we initiated a randomized pivotal trial of Pixuvri for the treatment of relapsed or refractory DLBCL. This clinical trial, referred to as PIX306 or PIX-R, is now open to patient enrollment. PIX-R will compare a combination of Pixuvri plus rituximab to a combination of gemcitabine plus rituximab in patients with relapsed or refractory DLBCL who have received one to three prior lines of therapy. We cannot predict the outcome of PIX-R or whether PIX-R will serve as either a post-marketing commitment trial or as a pivotal trial. Moreover, the FDA may request that we conduct more clinical trials in addition to PIX-R to obtain FDA approval of our NDA for Pixuvri and we do not know what this trial will cost or how long it would take to execute this study and provide additional information to the FDA. We may also 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 Pixuvri may negatively affect our business, financial condition and results of operations.

---

**Table of Contents**

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

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 and as a radiation sensitizer. This study, the GOG0212 trial, is under the control of the GOG and is expected to enroll 1,100 patients with 843 patients enrolled as of December 31, 2011. The GOG Data Monitoring Committee plans to conduct the first interim analysis of overall survival and, based on feedback provided by the GOG, that interim analysis is currently expected in 2013. If successful, we could utilize those results to form the basis of an 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 non-small cell lung cancer, or 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 any 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.

In March 2008, we submitted an MAA to the EMA for first-line treatment of patients with advanced 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; 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 approval 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.

Information about the status of the regulatory approval of Pixuvri can be found in this Annual Report on Form 10-K under Part I, Item 1 Business, Overview and is incorporated by reference herein.

In March 2011, we initiated a randomized pivotal trial of Pixuvri for the treatment of relapsed or refractory DLBCL. This clinical trial, referred to as PIX306 or PIX-R, is now open to patient enrollment. PIX-R will compare a combination of Pixuvri plus rituximab to a combination of gemcitabine plus rituximab in patients with relapsed or refractory DLBCL who have received one to three prior lines of therapy. We cannot predict the outcome of PIX-R or whether PIX-R will serve as either a post-marketing commitment trial or as a pivotal trial. Moreover, the FDA may request that we conduct more clinical trials in addition to PIX-R to obtain FDA approval of our NDA for Pixuvri and we do not know what this trial will cost or how long it would take to execute this study and provide additional information to the FDA. We may also 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 Pixuvri may negatively affect our business, financial condition and results of operations.

---

**Table of Contents**

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 harmed.

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, labeling, advertising, promotion, distribution and export. Manufacturing processes must conform to current Good Manufacturing Practice, or cGMPs. The FDA, EMA 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.

---

**Table of Contents**

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 Celgene, which markets Abraxane . In addition, other companies such as Telik, Inc. are also developing products, which could compete with OPAXIO.

If we are successful in bringing tosedostat to market, tosedostat will face competition from currently marketed products, such as Dacogen®, Vidaza®, Clolar®, Revlimid®, Thalomid® and new anti-cancer drugs that may be developed and marketed.

If we are successful in bringing brostallicin to market, we will face direct competition from other minor groove binding agents including Yondelis®, which is currently developed by PharmaMar and has received Authorization of Commercialization from the European Commission for soft tissue sarcoma.

Many of our competitors, 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.

*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



---

## Table of Contents

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.

*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





## Table of Contents

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, tosedostat, brostallicin, bisplatinates 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, tosedostat, brostallicin and bisplatinates. 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.

*We hold rights under numerous patents that protect inventions originating from our research and development, and the expiration of any one or more of these patents may allow our competitors to copy the inventions that are currently protected.*

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 pending patent applications or issued patents in the U.S. and foreign countries directed to OPAXIO, Pixuvri, tosedostat, brostallicin and other product candidates. However, the lives of these patents are limited. 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. The tosedostat-directed patents will expire in 2017. The brostallicin-directed patents will expire on various dates ranging from 2017 to 2021. The patent expiration ranges given above are only for U.S. issued patents. The Pixuvri-directed patents in Europe will expire between 2012 and 2015. Although such patent expirations do not account for potential extensions that 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), there can be no assurance that such extensions will be obtained. The expiration of these patents may allow our competitors to copy the inventions that are currently protected and better compete with us.

*If there is an adverse outcome in the securities class actions and shareholder derivative litigation that have been filed against us, our business may be harmed.*

In March 2010, three purported securities class action complaints were filed against the Company and certain of its officers and directors in the United States District Court for the Western District of Washington. On August 2, 2010, Judge Marsha Pechman consolidated the actions, appointed lead plaintiffs, and approved lead plaintiffs' counsel. On September 27, 2010, lead plaintiff filed an amended consolidated complaint, captioned Sabbagh v. Cell Therapeutics, Inc. (Case No. 2:10-cv-00414-MJP), naming the Company, Dr. James A. Bianco, Louis A. Bianco, and Craig W. Philips as defendants. The amended consolidated complaint alleges that defendants violated the federal securities laws by making certain alleged false and misleading statements related to the FDA approval process for pixantrone. The action seeks damages on behalf of purchasers of the Company's stock during a purported class period of March 25, 2008 through March 22, 2010. On October 27, 2010,

---

**Table of Contents**

defendants moved to dismiss the amended consolidated complaint. On February 4, 2011, the Court denied in large part the defendants' motion. Defendants answered the amended consolidated complaint on March 28, 2011, and discovery commenced, with trial set for June 25, 2012. On December 14, 2011, the parties filed a letter with the Court indicating they had agreed to the general terms of a settlement, and asking the Court to remove the case deadlines from the Court calendar. On February 14, 2012, the parties filed a Motion for Preliminary Approval of the Stipulation of Settlement and related documents with the Court. The negotiated terms of the settlement include a \$19 million payment to plaintiffs.

In April 2010, three shareholder derivative complaints were filed against the Company and certain of its officers and directors in the United States District Court for the Western District of Washington. These derivative complaints allege that defendants breached their fiduciary duties to the Company by making or failing to prevent the issuance of certain alleged false and misleading statements related to the FDA approval process for pixantrone. The allegations in the derivative actions are substantially similar to those in the securities action. On May 10, 2010, Judge Marsha Pechman consolidated the shareholder derivative actions under the caption *Shackleton v. Bauer* (Case No. 2:10-cv-00414-MJP), and appointed the law firms of Robbins Umeda LLP and Federman & Sherwood as co-lead counsel for derivative plaintiffs. Three more derivative complaints were filed in June, July and October 2010, and they have also been consolidated with *Shackleton v. Bauer*. The parties have agreed to coordinate discovery in the derivative and securities actions. Pursuant to the parties' stipulation, the Court has stayed the deadline for the derivative plaintiffs to file an amended complaint until March 12, 2012 (45 days after the scheduled close of discovery in the securities class action), and briefing on any motion to dismiss will follow. The court has set a trial date of December 3, 2012 for the shareholder derivative action. The litigation is at an early stage and the company has asserted meritorious defenses, so no probability of loss can be predicted at this time.

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<sup>®</sup>, 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

## **Table of Contents**

products. In addition, patents issued to us or our licensors may be challenged and subsequently narrowed, invalidated or circumvented. Litigation, interference proceedings or other governmental proceedings that we may become involved in with respect to our proprietary technologies or the proprietary technology of others could result in substantial cost to us. Patent litigation is widespread in the biotechnology industry, and any patent litigation could harm our business. Costly litigation might be necessary to protect a patent position or to determine the scope and validity of third-party proprietary rights, and we may not have the required resources to pursue any such litigation or to protect our patent rights. Any adverse outcome in litigation with respect to the infringement or validity of any patents owned by third parties could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using a product or technology.

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

*Our products could infringe 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 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 the NASDAQ Marketplace Rules or 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.

*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.

---

**Table of Contents**

*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, EMA 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, EMA 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, tosedostat and brostallicin are 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.

*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.

---

## Table of Contents

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, tosedostat and brostallicin are currently in clinical trials and bisplatinates are in preclinical development; the development and clinical trials of these products 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

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

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

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

One component of our business strategy is in-licensing drug compounds developed by other pharmaceutical and biotechnology companies or academic research laboratories. All of our product candidates in clinical and preclinical development are in-licensed from a third-party, including Pixuvri, OPAXIO, tosedostat, brostallicin and bisplatinates.

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;

**Table of Contents**

the FDA or the EMA may object to proposed protocols;

there may be shortages of available product supplies or the materials that are used to manufacture the products;

the quality or stability of the product candidates may fall below acceptable standards;

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

the rates of patient recruitment and enrollment of patients who meet trial eligibility criteria may be lower than anticipated, 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 harmed. If delays or costs are significant, our financial results and our ability to commercialize our product candidates may be harmed.

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

We have entered into collaborative arrangements with third-parties to develop and/or commercialize product candidates and are currently seeking additional collaborations. For example, we entered into an agreement with the 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.





## Table of Contents

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 harm the development or commercialization of our products.

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

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

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

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

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

Our research and development activities involve the controlled use of hazardous materials, chemicals and various radioactive compounds. We are subject to international, federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and certain waste products. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by the regulations, the risk of accidental contamination or injury from these materials cannot be eliminated completely.

In the event of such an accident, we could be held liable for any damages that result

## Table of Contents

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 harm 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 harmed 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 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 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 harm 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

## **Table of Contents**

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 March 2, 2012, our stock price has ranged from a low of \$0.95 to a high of \$3.30. Fluctuations in the trading price or liquidity of our common stock may harm 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 2012 to generate additional funds to cover our outstanding obligations and operating expenses;

our quarterly operating results;

developments or disputes concerning patent or other proprietary rights;

developments in our relationships with collaborative partners;

acquisitions or divestitures;

litigation and government proceedings;

adverse legislation, including changes in governmental regulation;

third-party reimbursement policies;

changes in securities analysts' recommendations;

short selling;

changes in health care policies and practices;

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

economic and other external factors; and

general market conditions.

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

## **Table of Contents**

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 any outstanding shares of our 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 harmed 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 harmed 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 harm the market price of shares of our common stock.*

We are not restricted from issuing additional shares of common stock or preferred stock, including any securities that are convertible into or exchangeable for, or that represent the right to receive, shares of common stock or preferred stock, or any substantially similar securities. 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, or the perception that such sales could occur in the future.

*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;

---

**Table of Contents**

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. We notified the landlord of the warehouse space that we exercised our option to extend the term for an additional 12 months. Additionally, we lease 2,700 square feet in Milan, Italy with a lease expiration of December 2015. In January 2012, we entered into an agreement to lease approximately 66,000 square feet of office space in Seattle, Washington. The term of this lease is for a period of 120 months, commencing on the earlier of (i) May 1, 2012, or (ii) upon substantial completion of improvements we plan to perform to the premises. 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 August 10, 2011, the parties settled outstanding litigation entitled Cell Therapeutics, Inc. v. The Lash Group, Inc., et al., Case No. 07-310 (filed in the Western District of Washington), or the Litigation. The settlement is not an admission of liability by either party. Under the terms of the settlement agreement, CTI received \$11.0 million from The Lash Group, Inc.'s insurers. Of that settlement amount, CTI received a payment of approximately \$8.2 million in October 2011, which represents the settlement amount net of certain attorneys' fees, litigation costs and expenses outstanding at the time the settlement payment was made. The settlement agreement also provides for a complete, mutual and general release of all claims between CTI and The Lash Group, Inc.

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

---

**Table of Contents**

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 \$6,000 to \$649,000 converted using the currency exchange rate as of December 31, 2011, 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 had 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 converted using the currency exchange rate as of January 21, 2011, for these sanctions. On March 4, 2011, we paid the aggregate fine of 100,000 in full.

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 \$6,000 to \$649,000 converted using the currency exchange rate as of December 31, 2011, 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 had to evaluate before imposing any possible administrative sanctions. In a letter dated March 10, 2011, CONSOB notified us of a resolution confirming the occurrence of the violation asserted in clause (i) above and applied a fine in the amount of 40,000, or approximately \$55,000 converted using the currency exchange rate as of March 10, 2011, which we paid on April 5, 2011. CONSOB has not yet notified us of a resolution with respect to the violation asserted in clause (ii) above, but based on our assessment we believe the likelihood that a pecuniary administrative sanction will be imposed on the Company for the violation asserted in clause (ii) 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



**Table of Contents**

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, \$7.1 million, \$3.3 million and \$1.1 million converted using the currency exchange rate as of December 31, 2011, 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 decisions of the Provincial Tax Court of Milan, or the Tax Court, for the different VAT cases are 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 2.9 million to 9.4 million, or approximately \$3.7 million to \$12.2 million converted using the currency exchange rate as of December 31, 2011, 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 \$2.1 million converted using the currency exchange rate as of February 2, 2011. On March 4, 2011, we paid to the ITA the required deposit in respect of the 2006 VAT in the amount of 0.4 million, or approximately \$0.6 million converted using the currency exchange rate as of March 4, 2011. On March 25, 2011, we paid to the Italian collection agent an additional 0.1 million, or approximately \$0.1 million converted using the currency exchange rate as of March 25, 2011. On September 26, 2011, we paid to the ITA the required deposit in respect of the 2007 VAT in the amount of 0.1 million, or approximately \$0.1 million converted using the currency exchange rate as of September 26, 2011.

**2003 VAT.** We did not receive a notice from the ITA requesting a deposit payment for the VAT based on the 2003 assessment as of December 31, 2011. The first hearing for the discussion of the merits of the case was held on March 18, 2011 in front of the Provincial Tax Court of Milan. On September 13, 2011, the Tax Court issued decision no. 229/3/2011 in which the Tax Court (i) fully accepted the merits of our appeal, (ii) declared that no penalties can be imposed against us, and (iii) found the Tax Office liable to pay us 10,000, or approximately \$14,000 converted using the currency exchange rate as of September 13, 2011, as partial refund of the legal expenses we incurred for our appeal. The Tax Office is entitled to appeal this decision to a higher court within six months. We have not been notified of any appeal from the Tax Office.

**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, 2011. 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 \$3.4 million converted using the currency exchange rate as of December 31, 2011. On February 2, 2011, we paid the required VAT deposit of 1.5 million, or approximately \$2.1 million converted using the currency exchange rate as of February 2, 2011, prior to the due date of February 6, 2011. On March 25, 2011, we paid to the Italian collection agent an additional 0.1 million, or approximately \$0.1 million converted using the currency exchange rate as of March 25, 2011. The additional payment was for interest and collection fees during the suspension period. We do not believe this additional payment was due and we intend to pursue recovery of such payment through litigation. In July 2011, we were notified by our Italian counsel of the ITA's appeal regarding the January 2011 decision that no penalties could be imposed on the Company. 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

**Table of Contents**

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 filed an appeal with the Tax Office on July 7, 2011 and intend to 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 \$3.4 million as of December 31, 2011, of which \$2.9 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 January 10, 2011, payable in the first quarter 2011. We filed a request for suspension of the collection of such amount, which was rejected. On March 4, 2011, we paid to the ITA the required deposit in respect of the 2006 VAT in the amount of 0.4 million, or approximately \$0.6 million converted using the currency exchange rate as of March 4, 2011. The first hearing for the discussion of the merits of the case was held on May 27, 2011 (jointly with the 2007 VAT case). On October 18, 2011, the Tax Court issued decision no. 276/21/11 (jointly with the 2007 VAT case) in which the Tax Court (i) fully accepted the merits of our appeal, (ii) declared that no penalties can be imposed against us, and (iii) found for the 2006 and 2007 VAT cases the Tax Office liable to pay us 10,000, or approximately \$14,000 converted using the currency exchange rate as of October 18, 2011, as partial refund of the legal expenses we incurred for our appeal. The Tax Office has appealed to the higher court against this decision. We will defend against the Tax Office's appeal before the higher Tax Court.

**2007 VAT.** The first hearing for the discussion of the merits of the case was held on May 27, 2011 (jointly with the 2006 VAT case). On August 4, 2011, we received a notice from the ITA requiring a deposit payment for VAT to CTI (Europe) based on the 2007 assessment, including 50% of the assessed VAT, interest and collection fees for an amount of 0.1 million, or approximately \$0.1 million converted using the currency exchange rate as of August 4, 2011, payable in the third quarter 2011. On September 26, 2011, we paid to the ITA the required deposit in respect of the 2007 VAT in the amount of 0.1 million or approximately \$0.1 million converted using the currency exchange rate as of September 26, 2011. On October 18, 2011, the Tax Court issued decision no. 276/21/11 (jointly with the 2006 VAT case) in which the Tax Court (i) fully accepted the merits of our appeal, (ii) declared that no penalties can be imposed against us, and (iii) found for the 2006 and 2007 VAT cases the Tax Office liable to pay us 10,000, or approximately \$14,000 converted using the currency exchange rate as of October 18, 2011, as partial refund of the legal expenses we incurred for our appeal. The Tax Office has appealed to the higher court against this decision. We will defend against the Tax Office's appeal before the higher Tax Court.

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 to examine and discuss 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.

In March 2010, three purported securities class action complaints were filed against the Company and certain of its officers and directors in the United States District Court for the Western District of Washington. On

---

**Table of Contents**

August 2, 2010, Judge Marsha Pechman consolidated the actions, appointed lead plaintiffs, and approved lead plaintiffs' counsel. On September 27, 2010, lead plaintiff filed an amended consolidated complaint, captioned Sabbagh v. Cell Therapeutics, Inc. (Case No. 2:10-cv-00414-MJP), naming the Company, Dr. James A. Bianco, Louis A. Bianco, and Craig W. Philips as defendants. The amended consolidated complaint alleges that defendants violated the federal securities laws by making certain alleged false and misleading statements related to the FDA approval process for pixantrone. The action seeks damages on behalf of purchasers of the Company's stock during a purported class period of March 25, 2008 through March 22, 2010. On October 27, 2010, defendants moved to dismiss the amended consolidated complaint. On February 4, 2011, the Court denied in large part the defendants' motion. Defendants answered the amended consolidated complaint on March 28, 2011, and discovery commenced, with trial set for June 25, 2012. On December 14, 2011, the parties filed a letter with the Court indicating they had agreed to the general terms of a settlement, and asking the Court to remove the case deadlines from the Court calendar. On February 14, 2012, the parties filed a Motion for Preliminary Approval of the Stipulation of Settlement and related documents with the Court. The negotiated terms of the settlement include a \$19 million payment to plaintiffs, which the Company expects to be paid by the Company's insurance carriers. Because the Company expects that the negotiated settlement will be paid by the Company's insurance carriers, there is no estimated loss to the Company.

In April 2010, three shareholder derivative complaints were filed against the Company and certain of its officers and directors in the United States District Court for the Western District of Washington. These derivative complaints allege that defendants breached their fiduciary duties to the Company by making or failing to prevent the issuance of certain alleged false and misleading statements related to the FDA approval process for Pixuvri. The allegations in the derivative actions are substantially similar to those in the securities action. On May 10, 2010, Judge Marsha Pechman consolidated the shareholder derivative actions under the caption Shackleton v. Bauer (Case No. 2:10-cv-00414-MJP), and appointed the law firms of Robbins Umeda LLP and Federman & Sherwood as co-lead counsel for derivative plaintiffs. Three more derivative complaints were filed in June, July and October 2010, and they have also been consolidated with Shackleton v. Bauer. The parties have agreed to coordinate discovery in the derivative and securities actions. Pursuant to the parties' stipulation, the Court has stayed the deadline for the derivative plaintiffs to file an amended complaint until March 12, 2012 (45 days after the scheduled close of discovery in the securities class action), and briefing on any motion to dismiss will follow. The court has set a trial date of December 3, 2012 for the shareholder derivative action. We believe that the shareholder derivative action is without merit and intend to defend it vigorously. No estimate of a loss, if any, can be made at this time in the event that we do not prevail.

In December 2011, we were informed of a decree by the Italian Ministry for Education, University and Research, or the Ministry, dated July 7, 2011 revoking a financial support granted to Novuspharma S.p.A. (now CTI, following the merger of Novuspharma into CTI in January 2004) in July 2002, or the Financial Support, and requesting the repayment of the amount paid to Novuspharma as grant for the expenses (i.e.

0.5 million, plus interests for an additional amount of 0.1 million) by January 15, 2012, or the Decree. The Financial Support was granted (following a proper application by Novuspharma) for a research project about new compounds for the treatment of tumors of the gastrointestinal area, or the Project. The initial amount of the Financial Support was (i) up to 2.3 million as subsidised loan, and (ii) up to 2.5 million as grant for expenses (a portion of which, corresponding to 0.5 million, was effectively paid to Novuspharma). Following the interruption of the Project in June 2004, due to unforeseeable technical reasons not ascribable to the beneficiary company, the Financial Support was reduced (i) to

0.6 million for the subsidised loan, and (ii) to 0.6 million for the grant for expenses. In 2005, we requested the Ministry to authorize the joint ownership of the Project by both Cell Therapeutics Europe S.r.l., or CTE, and the CTI Italian branch. In May 2007, the Ministry accepted such joint ownership of the Project subject to the issuance of a guarantee, or the Guarantee, for the portion corresponding to the subsidised loan, but we never issued such Guarantee. In 2009, CTI Italian branch's research activities were terminated. Since we assert that the Decree is unlawful and that the relevant issuance represents a breach of the Ministry's duty of good faith and an abuse of right, on February 13, 2012, we served a writ of summons upon the Ministry, suing it in the civil Court of Rome in order to have the Decree declared ineffective. However, if we are unable to successfully defend ourselves against the Decree issued by the Ministry, we may be requested to pay

**Table of Contents**

0.6 million (i.e. the amount paid to Novuspharma as grant for the expenses plus interests, as described above), or approximately \$0.8 million converted using the currency exchange rate as of December 31, 2011, plus counterparty's attorney's fees, litigation costs and additional default interests for the period lapsed between January 16, 2012 and the date of the effective payment. At this time, we are not able to make a determination whether the likelihood of an unfavorable outcome is probable.

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. Mine Safety Disclosures**

Not applicable.

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

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

	High	Low
<b>2010</b>		
First Quarter	\$ 8.40	\$ 0.72
Second Quarter	\$ 4.20	\$ 1.74
Third Quarter	\$ 2.82	\$ 2.10
Fourth Quarter	\$ 2.94	\$ 2.10
<b>2011</b>		
First Quarter	\$ 3.30	\$ 1.26
Second Quarter	\$ 2.52	\$ 1.47
Third Quarter	\$ 1.69	\$ 0.95
Fourth Quarter	\$ 1.48	\$ 0.95

On March 2, 2012, the last reported sale price of our common stock on the NASDAQ Capital Market was \$1.24 per share. As of March 2, 2012, there were 186 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**

The following table sets forth information with respect to purchases of our common stock during the three months ended December 31, 2011:

Period	Total Number of Shares Purchased (1)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
October 1 - October 31, 2011	37,765	\$ 1.20		
November 1 - November 30, 2011	15,710	\$ 1.09		
December 1 - December 31, 2011		\$		

Edgar Filing: CELL THERAPEUTICS INC - Form 10-K

Total	53,475	\$ 1.17
-------	--------	---------

- (1) Represents purchases of shares in connection with satisfying tax withholding obligations on the vesting of restricted stock awards to employees.

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

The following graph sets forth the cumulative total shareholder return of our common stock during the five-year period ended December 31, 2011, as well as the NASDAQ Stock Index (U.S.) and the NASDAQ Pharmaceutical Index:

The stock performance graph assumes \$100 was invested on December 31, 2006. The actual returns shown on the graph above are as follows:

	3/31/07	6/30/07	9/30/07	12/31/07
Cell Therapeutics, Inc.	\$ 90.86	\$ 43.55	\$ 52.40	\$ 26.84
NASDAQ Stock Index (U.S.)	\$ 100.15	\$ 107.31	\$ 110.72	\$ 108.47
NASDAQ Pharmaceutical Index	\$ 97.86	\$ 102.18	\$ 106.98	\$ 105.17
	3/31/08	6/30/08	9/30/08	12/31/08
Cell Therapeutics, Inc.	\$ 9.42	\$ 6.85	\$ 1.04	\$ 0.20
NASDAQ Stock Index (U.S.)	\$ 93.42	\$ 93.87	\$ 87.29	\$ 66.35
NASDAQ Pharmaceutical Index	\$ 99.51	\$ 101.81	\$ 106.46	\$ 97.85
	3/31/09	6/30/09	9/30/09	12/31/09
Cell Therapeutics, Inc.	\$ 0.54	\$ 2.46	\$ 1.76	\$ 1.63
NASDAQ Stock Index (U.S.)	\$ 64.28	\$ 76.83	\$ 88.93	\$ 95.38
NASDAQ Pharmaceutical Index	\$ 91.12	\$ 99.51	\$ 109.69	\$ 109.95
	3/31/10	6/30/10	9/30/10	12/31/10
Cell Therapeutics, Inc.	\$ 0.77	\$ 0.54	\$ 0.56	\$ 0.53
NASDAQ Stock Index (U.S.)	\$ 100.83	\$ 89.38	\$ 100.49	\$ 113.19
NASDAQ Pharmaceutical Index	\$ 119.78	\$ 102.66	\$ 113.00	\$ 119.19
	3/31/11	6/30/11	9/30/11	12/31/11
Cell Therapeutics, Inc.	\$ 0.53	\$ 0.38	\$ 0.25	\$ 0.28
NASDAQ Stock Index (U.S.)	\$ 118.74	\$ 119.16	\$ 105.00	\$ 113.81
NASDAQ Pharmaceutical Index	\$ 125.17	\$ 133.32	\$ 115.45	\$ 127.71

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

The data set forth below should be read in conjunction with Item 7, Management's Discussion and Analysis of 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.

	Year ended December 31,				
	2011	2010	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
<b>Total revenues</b>		<b>319</b>	<b>80</b>	<b>11,432</b>	<b>127</b>
Operating expenses, net:					
Cost of product sold				3,244	49
Research and development	34,900	27,031	30,179	51,614	72,019
Selling, general and administrative	38,290	48,043	57,725	41,607	35,517
Amortization of purchased intangibles				1,658	913
Restructuring charges and related gain on sale of assets, net(1)			3,979		
Gain on sale of Zevalin(2)				(9,444)	
Gain on sale of investment in joint venture(3)			(10,244)		
Gain from litigation settlement	(11,000)				
Acquired in-process research and development(4)				36	24,615
<b>Total operating expenses, net</b>	<b>62,190</b>	<b>75,074</b>	<b>81,639</b>	<b>88,715</b>	<b>133,113</b>
<b>Loss from operations</b>	<b>(62,190)</b>	<b>(74,755)</b>	<b>(81,559)</b>	<b>(77,283)</b>	<b>(132,986)</b>
Other income (expense):					
Investment and other income, net	1,713	1,221	133	549	2,430
Interest expense	(1,038)	(2,334)	(4,806)	(8,559)	(8,237)
Amortization of debt discount and issuance costs	(546)	(768)	(5,788)	(66,530)	(4,280)
Foreign exchange gain (loss)	(558)	(521)	33	3,637	4,657
Debt conversion expense		(2,031)			
Provision for VAT Assessments		(3,503)			
Make-whole interest expense			(6,345)	(70,243)	(2,310)
Gain on derivative liabilities, net			7,218	69,739	3,672
Gain (loss) on exchange of convertible notes			7,381	(25,103)	(972)
Equity loss from investment in joint venture			(1,204)	(123)	
Milestone modification expense			(6,000)		
Settlement expense, net		(145)	(4,710)	(3,393)	(160)
Write-off of financing arrangement costs				(2,846)	
<b>Net loss before noncontrolling interest</b>	<b>(62,619)</b>	<b>(82,836)</b>	<b>(95,647)</b>	<b>(180,155)</b>	<b>(138,186)</b>
Noncontrolling interest	259	194	252	126	78
<b>Net loss attributable to CTI</b>	<b>\$ (62,360)</b>	<b>\$ (82,642)</b>	<b>\$ (95,395)</b>	<b>\$ (180,029)</b>	<b>\$ (138,108)</b>
Gain on restructuring of preferred stock			2,116		
Dividends and deemed dividends on preferred stock	(58,718)	(64,918)	(23,484)	(22,878)	(10,197)
<b>Net loss attributable to common shareholders</b>	<b>\$ (121,078)</b>	<b>\$ (147,560)</b>	<b>\$ (116,763)</b>	<b>\$ (202,907)</b>	<b>\$ (148,305)</b>
<b>Basic and diluted net loss per common share(5)</b>	<b>\$ (0.71)</b>	<b>\$ (1.29)</b>	<b>\$ (1.53)</b>	<b>\$ (42.03)</b>	<b>\$ (196.43)</b>



Edgar Filing: CELL THERAPEUTICS INC - Form 10-K

Shares used in calculation of basic and diluted net loss per common share(5)	171,468	114,105	76,393	4,828	755
--	---------	---------	--------	-------	-----

**Table of Contents**

	2011	2010	December 31, 2009 (In thousands)	2008	2007
<b>Consolidated Balance Sheets Data:</b>					
Cash and cash equivalents	\$ 47,052	\$ 22,649	\$ 37,811	\$ 10,072	\$ 15,798
Restricted cash(6)				6,640	
Working capital	33,291	(14,165)	(21,694)	(14,141)	(30,909)
Total assets(7)	62,239	53,592	69,595	64,243	73,513
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
6.75% convertible senior notes				6,926	6,922
5.75% convertible senior notes		12,093	11,677	23,808	23,287
5.75% convertible senior subordinated notes					16,907
4.0% convertible senior subordinated notes			40,363	55,150	55,150
5.75% convertible subordinated notes					2,910
Current portion of long-term obligations	970	1,717	1,312	757	1,020
Long-term obligations, less current portion	2,985	4,206	1,861	2,907	9,879
Common stock purchase warrants	13,461	13,461	626		
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
Series 14 convertible preferred stock	6,736				
Accumulated deficit(7)	(1,714,785)	(1,576,643)	(1,429,083)	(1,312,320)	(1,109,413)
Total shareholders' equity (deficit)	28,009	(5,145)	(18,769)	(132,061)	(134,125)

- (1) The 2009 amount primarily relates to the closure of our Bresso, Italy operations 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, or IPRD, represents the value of Systems Medicine LLC's and Zevalin's purchased technology, which had not reached technological feasibility at the time of the acquisitions. Acquired IPRD for Systems Medicine LLC 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) The net loss per share calculation, including the number of shares used in basic and diluted net loss per share, has been adjusted to reflect one-for-four, one-for-ten and one-for-six reverse stock splits on April 15, 2007, August 31, 2008 and May 15, 2011, respectively. See Notes 1, 10 and 18 of the 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.
- (7) Effective January 1, 2011, we adopted new guidance on goodwill impairment. See Note 4 of the Notes to Consolidated Financial Statements for additional information.

**Table of Contents****Item 7. Management's Discussion and Analysis of 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, 2011, we had incurred aggregate net losses of \$1.7 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 hematologic malignancies and solid tumors. Pixuvri was studied in our PIX301 clinical trial, which is the first randomized, controlled, phase III single-agent clinical trial of Pixuvri for patients with relapsed or refractory aggressive NHL who received two or more prior therapies and who were sensitive to treatment with anthracyclines. In the U.S., we initially completed our NDA submission with the FDA in June 2009. 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 and other items. We filed an appeal in December 2010 with the FDA's Center for Drug Evaluation and Research regarding the FDA's decision in April 2010 to not approve Pixuvri. The appeal was filed under the FDA's formal dispute resolution process asking the OND to conclude that PIX301 demonstrated efficacy.

The FDA responded allowing us to resubmit the NDA with additional information. Prior to resubmitting the NDA, we initiated an additional Pixuvri clinical trial, PIX306, to study Pixuvri in combination with rituximab in patients with relapsed, aggressive NHL that received at least one prior therapy. On October 25, 2011, we announced the resubmission of the NDA to the FDA's DOP1 for accelerated approval to treat relapsed or refractory aggressive NHL in patients who failed two or more lines of prior therapy. On December 6, 2011, we announced that the FDA's DOP1 had notified us that our resubmitted NDA is considered a complete, Class 2 response to the FDA's April 2010 complete response letter. The FDA set a PDUFA goal date of April 24, 2012 for a decision on the NDA.

On January 3, 2012, we announced that the FDA's ODAC was scheduled to review our resubmitted NDA for Pixuvri on February 9, 2012. On January 30, 2012, we announced that we had voluntarily withdrawn our NDA for Pixuvri. The NDA was withdrawn because, after communications with the FDA, we needed additional

**Table of Contents**

time to prepare for the review of the NDA by the FDA's ODAC at its February 9, 2012 meeting. Prior to withdrawing the NDA, we requested that the FDA consider rescheduling the review of the NDA to the ODAC meeting to be held in late March. The FDA was unable to accommodate our request to reschedule, and given the April 24, 2012 PDUFA date, the only way to have Pixuvri possibly considered at a later ODAC meeting was to withdraw and later resubmit the NDA. We plan to resubmit the NDA in 2012.

In Europe, we filed a Marketing Authorization Application, or MAA, for commercialization of Pixuvri, which was accepted for review by the European Medicines Agency, or the EMA, in December 2010. On February 17, 2012, Pixuvri was granted a positive opinion for conditional approval from the EMA's CHMP. The CHMP recommended Pixuvri for conditional approval as monotherapy for the treatment of adult patients with multiple relapsed or refractory aggressive non-Hodgkin B-cell lymphomas. The CHMP positive opinion for Pixuvri will now be reviewed by the European Commission, which has the authority to approve medicines for use in the E.U. If the CHMP's recommendation is formally adopted by the European Commission, Pixuvri would be approved for marketing in the 27 countries that are members of the E.U., as well as the European Economic Area. We expect that a conditional marketing authorization for Pixuvri should be granted by the European Commission within the first half of 2012. We are working with consultants to develop a go-to-market strategy in Europe, including product messaging, positioning, staffing and resources required for Pixuvri product introduction in the E.U. If the European Commission adopts the positive opinion rendered by the CHMP for Pixuvri and if we successfully implement our go-to-market strategy, we expect to begin product launch on an E.U. country-by-country basis beginning in the second half of 2012.

Similar to accelerated approval regulations in the U.S., conditional marketing authorizations are granted to medicinal products with a positive benefit/risk assessment that address unmet medical needs and whose availability would result in a significant public health benefit. A conditional marketing authorization is renewable annually. Under the provisions of the conditional marketing authorization for Pixuvri, we will be required to complete a post-marketing study aimed at confirming the clinical benefit previously observed. The CHMP has accepted PIX306 study as the study to confirm clinical benefit. As a condition of approval, we have agreed to have available the PIX306 clinical trial results by June 2015.

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 GOG and is expected to enroll 1,100 patients with 843 patients enrolled as of December 31, 2011. OPAXIO is also being studied in follow-on phase II trial for the treatment of metastatic brain cancer based on encouraging results from a prior phase II study in this disease.

We are also developing tosedostat in collaboration with Chroma Therapeutics, Ltd., or Chroma. We entered into a co-development and license agreement with Chroma in March 2011, providing us with exclusive marketing and co-development rights to Chroma's drug candidate, tosedostat, in North, Central and South America. Tosedostat is an oral, aminopeptidase inhibitor that has demonstrated significant anti-tumor responses in blood related cancers and solid tumors in phase I-II clinical trials. Interim results from the phase II OPAL study of tosedostat in elderly patients with relapsed or refractory acute myeloid leukemia, or AML, were presented in June 2011 at the 2011 ASCO Annual Meeting. These results showed that once-daily, oral doses of tosedostat had predictable and manageable toxicities and demonstrated encouraging response rates at the interim evaluation time point including a high-response rate among patients who received prior hypomethylating agents, which are used to treat myelodysplastic syndrome, or MDS, a precursor of AML. Based on these results, and pending discussions with the FDA, we, in collaboration with Chroma, anticipate initiating a phase III study for patients with relapsed or refractory MDS in the second half of 2012.

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.

---

**Table of Contents**

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 outstanding convertible notes for \$7.1 million in cash and 4.0 million shares of our common stock. In addition, we exchanged of \$3.0 million of our 4% convertible senior subordinated notes, or 4% Notes, and \$1.5 million of our 6.75% convertible senior notes, or 6.75% Notes, as well as accrued and unpaid interest on these notes for 0.5 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. In May 2011, we retired \$10.3 million of our 7.5% convertible senior notes, or 7.5% Notes, and in December 2011, we retired \$10.9 million of our 5.75% convertible senior notes, or 5.75% Notes. At this time we have no convertible debt outstanding.

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 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 \$15.0 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 \$20.0 million. SMI stockholders were also entitled to receive a maximum of \$15.0 million in additional consideration (payable in cash or stock at our election, subject to certain NASDAQ limitations on issuance of stock) upon the achievement of certain FDA regulatory milestones. 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 0.9 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.

## **Table of Contents**

### *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 have reviewed goodwill for impairment annually and whenever events or changes in circumstances indicated that the carrying value may not be recoverable. Previously, goodwill was tested for impairment by comparing the fair value of our single reporting unit to its carrying value. Our estimate of fair value was based on our current market capitalization. If the implied fair value of goodwill was less than its carrying value, an impairment charge would have been recorded. Effective January 1, 2011, we adopted the accounting standards update on *Intangibles - Goodwill and Other (Topic 350)*, which provided additional guidance on when to perform Step 2 of the goodwill impairment test for reporting units with zero or negative carrying amounts. Upon adoption of the guidance, we determined that it was more likely than not that a goodwill impairment existed. On January 1, 2011, the implied fair value of goodwill for the reporting unit, after considering unrecognized in-process research and development, was zero. An impairment charge of \$17.1 million was recorded in retained earnings as a cumulative-effective adjustment.

### *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 included 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 represented 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 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.

### *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

**Table of Contents**

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 options. 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 require that we recognize compensation expense for only the portion of awards expected to vest. Therefore, we apply an estimated 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, 2011 and 2010.*

*License and contract revenue.* License and contract revenue for the year ended December 31, 2010 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 preclinical development are as follows (in thousands):

	2011	2010
Compounds under development:		
Pixuvri	\$ 11,266	\$ 7,249
OPAXIO	1,445	2,608
Tosedostat	6,955	
Brostallicin	75	115
Other compounds	180	108
Operating expenses	14,975	16,297
Research and preclinical development	4	654
<b>Total research and development expenses</b>	<b>\$ 34,900</b>	<b>\$ 27,031</b>

**Table of Contents**

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, as well as upfront license fees for acquired technology. Operating costs include our personnel and an allocation of occupancy expenses associated with developing these compounds. Research and preclinical development costs primarily include costs associated with bisplatinates development as well as external laboratory services associated with other 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, tosedostat and brostallicin are \$73.5 million, \$224.5 million, \$7.0 million and \$9.4 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. Costs for tosedostat prior to our co-development and license agreement with Chroma are also excluded from this amount.

Research and development expenses increased to \$34.9 million for the year ended December 31, 2011 from \$27.0 million for the year ended December 31, 2010. Pixuvri costs increased primarily due to an increase in clinical development activity associated with the start-up of the PIX306 study. These increases were partially offset by decreases in the EXTEND and RAPID trials related to their wind-down and by a decrease in regulatory activity primarily associated with consulting services. Costs for our OPAXIO program decreased primarily due to a reduction in clinical development activity associated with a decline in patient enrollment in our GOG0212 trial, in addition to a decrease in manufacturing activity. Costs for tosedostat relate to the upfront payment upon execution of the co-development and license agreement with Chroma, in addition to our share of development costs associated with clinical and manufacturing activity incurred under the agreement. Costs for brostallicin relate primarily to clinical development activities associated with phase I and phase II studies. Our operating expenses decreased primarily due to a reduction in occupancy costs associated with a lease adjustment, in addition to a decrease in share-based compensation expense. These decreases were partially offset by increases in our 2011 estimated discretionary bonus accrual and depreciation expense. Research and preclinical development costs declined primarily due to the completion of contracted bisplatinates process development work, in addition to further decreases in expenses associated with the closure of our Bresso, Italy operations.

Our lead drug candidates, Pixuvri, OPAXIO, tosedostat 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.



---

**Table of Contents**

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 \$38.3 million for the year ended December 31, 2011 from \$48.0 million for the year ended December 31, 2010. This decrease was primarily related to a \$10.4 million reduction in noncash share-based compensation, a \$1.6 million decrease in compensation and benefits associated with a lower average number of personnel between the periods, a \$1.2 million decrease in occupancy expense primarily related to a lease adjustment and a decrease in sales and marketing expense associated with the pre-commercial efforts for Pixuvri during 2010. These decreases were offset in part by a net increase of \$2.3 million in legal and patent services primarily related to attorney fees and related costs for litigation settlement associated with The Lash Group, Inc., see Note 20, *Legal Proceedings* in the Notes to Consolidated Financial Statement in Item 8 in this Annual Report on Form 10-K, and a \$1.9 million increase associated with our 2011 estimated discretionary bonus accrual. If we receive FDA or EMA approval for Pixuvri, we expect selling, general and administrative expenses to increase in 2012 as compared to 2011 due to increased sales and marketing expenses for Pixuvri, including increased compensation expense for our Pixuvri sales force.

*Gain from litigation settlement.* We recorded \$11.0 million gain from litigation settlement for the year ended December 31, 2011 resulting from the settlement with The Lash Group, Inc. See Note 20, *Legal Proceedings* in the Notes to Consolidated Financial Statements in Item 8 in this Annual Report on Form 10-K for additional information.

*Investment and other income, net.* Investment and other income for the year ended December 31, 2011 increased to \$1.7 million as compared to \$1.2 million for the year ended December 31, 2010. The amount in 2011 is primarily related to the retirement of our 5.75% Notes in December 2011 resulting from the difference in the carrying amount and the outstanding principal balance at maturity. 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 \$1.0 million for the year ended December 31, 2011 from \$2.3 million for the year ended December 31, 2010. This decrease is primarily due to maturity of our 4% Notes in July 2010. In addition, we fully repaid \$10.3 million on our 7.5% Notes in April 2011 and \$10.9 million on our 5.75% Notes in December 2011 upon maturity.

*Amortization of debt discount and issuance costs.* Amortization of debt discount and issuance costs decreased to \$0.5 million for the year ended December 31, 2011 as compared to \$0.8 million for the year ended December 31, 2010. The decrease is primarily due to the maturity of our 4% Notes in July 2010 and maturity of our 7.5% convertible senior notes in April 2011.

*Foreign exchange gain (loss).* Foreign exchange losses for the years ended December 31, 2011 and 2010 are due to fluctuations in foreign currency exchange rates, primarily related to payables and receivables in our European branches 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 0.7 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 included in Item 8 in this Annual Report on Form 10-K.

**Table of Contents**

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 preclinical development 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
Research and preclinical development	654	418
<b>Total research and development expenses</b>	<b>\$ 27,031</b>	<b>\$ 30,179</b>

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 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 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 associated with 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 operations as well as external consulting costs and share-based compensation expense, partially offset by an increase in discretionary bonus expense. Research and preclinical development expense increased primarily due to costs associated with contracted bisplatin process development work.

*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 noncash 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.

*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

---

**Table of Contents**

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 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 branches 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 0.7 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 in 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

## **Table of Contents**

Series E preferred stock financing and modified in July 2008 in connection with the issuance of our 18.33% convertible senior notes. The 10% convertible senior notes due 2011 were fully converted into common stock during the first quarter of 2009. The Series B Unit Warrant expired in the second quarter of 2009.

*Gain 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 4.0 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% Notes as well as accrued and unpaid interest on these notes for 0.5 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.

## **Liquidity and Capital Resources**

As of December 31, 2011, we had \$47.1 million in cash and cash equivalents.

Net cash used in operating activities totaled \$60.5 million in 2011, compared to \$63.1 million in 2010 and \$88.2 million in 2009. The decrease in net cash used in operating activities for the year ended December 31, 2011 as compared to 2010 was primarily due to the proceeds received from settlement with The Lash Group, Inc. as discussed in Note 20, *Legal Proceedings*, in the Notes to Consolidated Financial Statements in Item 8 in this Annual Report on Form 10-K. In addition, decreases in cash paid for interest during 2011 as compared to 2010 and payments related to the closure of our Bresso, Italy operations made in 2010 contributed to the overall decrease in cash used in operating activities in 2011. These decreases were offset primarily by an increase in research and development expense, which includes an upfront payment of \$5.0 million related to the licensing of tosedostat. In addition, we made a \$1.1 million payment in 2011 to the GOG related to the 650 patient enrollment milestone achieved in 2010. 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 noncash 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

---

**Table of Contents**

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.

Net cash used in investing activities totaled \$2.7 million in 2011 as compared to \$2.3 million in 2010 and net cash provided by investing activities of \$21.8 million in 2009. Net cash used in investing activities for the year ended December 31, 2011 was primarily due to purchases of property and equipment. Net cash used in investing activities 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 financing activities totaled \$87.0 million in 2011, \$49.7 million in 2010 and \$94.8 million in 2009. Net cash provided by financing activities for the year ended December 31, 2011 was primarily due to issuances of preferred stock and warrants offset by repayments of outstanding convertible notes during the period. In January 2011, we received approximately \$23.2 million in net proceeds from the issuance of our Series 8 preferred stock, warrants to purchase up to 3.8 million shares of common stock and an additional investment right to purchase shares of our Series 9 preferred stock. In February 2011, we received approximately \$23.5 million in net proceeds from the issuance of our Series 10 preferred stock, warrants to purchase up to 4.3 million shares of common stock and an additional investment right to purchase shares of our Series 11 preferred stock. In May 2011, we received approximately \$15.0 million in net proceeds from the issuance of our Series 12 preferred stock and warrants to purchase up to 3.0 million shares of common stock. In July 2011, we received approximately \$28.0 million in net proceeds from the issuance of our Series 13 preferred stock and warrants to purchase up to 8.8 million shares of common stock. In December 2011, we received approximately \$18.9 million in net proceeds from the issuance of our Series 14 preferred stock and warrants to purchase up to 7.0 million shares of common stock. These proceeds were offset by a \$10.3 million payment to retire the outstanding principal balance on our 7.5% convertible senior notes in April 2011, \$10.9 million payment to retire the outstanding principal balance on our 5.75% Notes in December 2011, and \$0.4 million cash paid for the repurchase of shares in connection with satisfying tax withholding obligations on the vesting of restricted stock awards to employees.

Net cash provided by financing activities for the year ended December 31, 2010 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 our Series 3 preferred stock and warrants to purchase up to 1.4 million shares of our common stock. In April 2010, we received \$18.6 million in net proceeds from the issuance of our Series 4 preferred stock and warrants to purchase up to 3.3 million shares of our common stock. In May 2010, we received \$19.7 million in net proceeds from the issuance of our Series 5 preferred stock and warrants to purchase up to 4.4 million shares of our common stock. In July 2010, we received \$3.0 million in net proceeds from the issuance of our Series 6 preferred stock and warrants to purchase up to 1.0 million shares of our common stock. In October 2010, we received \$19.9 million in net proceeds from the issuance of our Series 7 preferred stock and warrants to purchase up to 3.8 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 \$18.9 million in net proceeds received from the issuance of 2.7 million shares of our common stock and warrants to purchase up to 0.8 million shares of our common stock in May 2009, as well as \$40.3 million in net proceeds received from the issuance of 5.6 million shares of our common stock and warrants to purchase up to 1.4 million shares of our common stock in a public offering in July 2009. In addition, we received \$18.7 million in net proceeds from the issuance of our Series 1 preferred stock and related Class A and Class B warrants in May 2009, as well as \$3.8 million and \$4.3 million upon the exercise of the Class A and Class B warrants in May and

## Table of Contents

October 2009, respectively. We also received \$28.4 million in net proceeds from the issuance of our Series 2 preferred stock and warrants to purchase up to 0.8 million shares of our common stock in August 2009. These proceeds were offset by \$10.0 million in cash paid, net of transaction costs and in addition to 4.0 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. 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.

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, tosedostat and brostallicin.

We do not expect that our existing cash and cash equivalents are sufficient to fund our presently anticipated operations beyond the second quarter of 2012. This raises substantial doubt about our ability to continue as a going concern.

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 harm our ability to operate as a going concern.

**Table of Contents**

The following table includes information relating to our contractual obligations as of December 31, 2011 (in thousands):

Contractual Obligations	Payments Due by Period				
	Total	1 Year	2-3 Years	4-5 Years	After 5 Years
Operating leases:					
Facilities (1)	\$ 2,703	\$ 2,384	\$ 319	\$	\$
Long-term obligations (2)	262	225	37		
Purchase commitments	1,487	1,174	308	5	
	\$ 4,452	\$ 3,783	\$ 664	\$ 5	\$

- (1) The table above does not include any payments associated with the lease agreement signed in January 2012. See Note 6, *Contractual Arrangements and Commitments* in the Notes to Consolidated Financial Statement in Item 8 in this Annual Report on Form 10-K for further information regarding our contractual obligations under this lease agreement.
- (2) Long-term obligations do not include \$0.7 million related to the liability for excess facilities charges and \$2.9 million related to the reserve for VAT assessments.

***Manufacturing Supply Agreements***

We signed 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 signed the Chroma Supply Agreement for our drug candidate tosedostat. The Chroma Supply Agreement is a non-exclusive agreement and provides for both the clinical and commercial drug supply of tosedostat. The Chroma Supply Agreement commenced on June 8, 2011 and expires two years from the date when tosedostat is granted first approval for commercial distribution by the applicable regulatory authority in the licensed territory. Upon expiration of the initial term, we have a one year renewal option. We have the right to terminate the Chroma Supply Agreement without cause with 90 days written notice to Chroma. Both parties have the right to terminate for breach, bankruptcy, mutual agreement, or termination of the development agreement.

***Additional Milestone Activities******Chroma Therapeutics, Ltd.***

We have an agreement with Chroma, the Chroma Agreement, under which we have an exclusive license to certain technology and intellectual property controlled by Chroma to develop and commercialize the drug candidate, tosedostat, in the Licensed Territory. Pursuant to the terms of the Chroma Agreement, we paid Chroma an upfront fee of \$5.0 million upon execution of the agreement and will make a milestone payment of \$5.0 million upon the initiation of the first pivotal trial, which could commence in the second half of 2012. The Chroma Agreement also includes additional development- and sales-based milestone payments related to AML and certain other indications, up to a maximum amount of \$209.0 million payable by us to Chroma if all development and sales milestones are achieved.

**Table of Contents**

We will also pay Chroma royalties on net sales of tosedostat in any country within the Licensed Territory, commencing on the first commercial sale of tosedostat in any country in the Licensed Territory and continuing with respect to that country until the later of (a) the expiration date of the last patent claim covering tosedostat in that country, (b) the expiration of all regulatory exclusivity periods for tosedostat in that country or (c) ten years after the first commercial sale in that country. Royalty payments to Chroma are based on net sales volumes in any country within the Licensed Territory and range from the low- to mid-teens as a percentage of net sales.

We will oversee and be responsible for performing the development operations and commercialization activities in the Licensed Territory and Chroma will oversee and be responsible for performing the development operations and commercialization activities worldwide in the ROW Territory. Development costs may not exceed \$50.0 million for the first three years of the Chroma Agreement unless agreed by the parties and we will be responsible for 75% of all development costs, while Chroma will be responsible for 25% of all development costs, subject to certain exceptions. Chroma is responsible for the manufacturing of tosedostat for development purposes in the Licensed Territory and the ROW Territory in accordance with the terms of the Chroma Supply Agreement. We have the option of obtaining a commercial supply of tosedostat from Chroma or from another manufacturer at our sole discretion in the Licensed Territory. The Chroma Agreement may be terminated by us at our convenience upon 120 days written notice to Chroma. The Chroma Agreement may also be terminated by either party following a material breach by the other party subject to notice and cure periods.

*University of Vermont*

We have an agreement with the University of Vermont, or UVM, which grants us an exclusive license, with the right to sublicense, for the rights to pixantrone, or the UVM Agreement. Pursuant to the UVM Agreement, we acquired the rights to make, have made, sell and use pixantrone. Pursuant to the UVM Agreement, we are obligated to make payments to UVM based on net sales. Our royalty payments range from low-single digits to mid-single digits as a percentage of net sales. The higher royalty rate is payable for net sales in countries where specified UVM licensed patents exist, or where we have obtained orphan drug protection, until such UVM patents or such protection no longer exists. For a period of ten years after first commercialization of pixantrone, the lower royalty rate is payable for net sales in such countries after expiration of the designated UVM patents or loss of orphan drug protection, and in all other countries without such specified UVM patents or orphan drug protection. Unless otherwise terminated, the term of the UVM Agreement continues for the life of the licensed patents in those countries in which a licensed patent exists, and continues for ten years after the first sale of pixantrone in those countries where no such patents exist. We may terminate the UVM Agreement, on a country-by-country basis or on a patent-by-patent basis, at any time upon advance written notice. UVM may terminate the UVM Agreement upon advance written notice in the event royalty payments are not made. In addition, either party may terminate the UVM Agreement (a) in the event of an uncured material breach of the UVM Agreement by the other party; or (b) in the event of bankruptcy of the other party.

*PG-TXL*

We have an agreement with 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. 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



## Table of Contents

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 GOG related to the GOG0212 trial, which the GOG is conducting. We recorded a \$1.7 million payment due to the GOG based on the 800 patient enrollment milestone achieved in the second quarter of 2011, which is included in accounts payable as of December 31, 2011. Under this agreement, we are required to pay up to \$1.8 million in additional milestone payments related to the trial, of which \$0.5 million will become due upon receipt of the interim analysis and data transfer which may occur in 2013. There were 843 patients enrolled as of December 31, 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 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 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 the Development Rights. In the event that Novartis exercises the 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.

## **Table of Contents**

Royalties for OPAXIO are based on worldwide sales volumes of OPAXIO and royalties for Pixuvri are based on sales volumes in the United States 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, 2011, 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 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 was 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. The adoption of this guidance on January 1, 2011 did not have a material impact on our 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 was effective for fiscal years, and interim periods within those years, beginning after December 15, 2010. Upon adoption of this guidance on January 1, 2011, we performed Step 2 of the goodwill impairment test. Based on a valuation using the income, market and cost approaches, we determined that all of our \$17.1 million in goodwill was impaired. The related charge was recorded as a cumulative-effect adjustment to beginning retained earnings in the current period. See Note 4, *Goodwill*, in the Notes to Consolidated Financial Statement in Item 8 in this Annual Report on Form 10-K for additional information.

**Table of Contents**

**Recently Issued Accounting Standards**

In June 2011, the FASB issued guidance amending the presentation requirements for comprehensive income. For public entities, this guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011 with early adoption permitted. Upon adoption, we will have the option to report total comprehensive income, including components of net income and components of other comprehensive income, as a single continuous statement or in two separate but consecutive statements. Subsequently, in December 2011, the FASB deferred the effective date of the portion of the June 2011 accounting standards update requiring separate presentation of reclassifications out of accumulated other comprehensive income. We do not anticipate the adoption of this guidance will have a material impact on our consolidated financial statements.

**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, 2011, 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 will be affected by fluctuations in the value of the U.S. dollar as compared to the euro. As of December 31, 2011, we had a net asset balance, excluding intercompany payables and receivables, in our European branches and subsidiaries denominated in euros. If the euro were to weaken 20% against the dollar, our net asset balance would decrease by approximately \$1.1 million as of this date.

**Table of Contents**

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

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

	<b>Page</b>
<u>Report of Stonefield Josephson, Inc., Independent Registered Public Accounting Firm</u>	71
<u>Reports of Marcum LLP, Independent Registered Public Accounting Firm</u>	72
<u>Consolidated Balance Sheets</u>	74
<u>Consolidated Statements of Operations</u>	75
<u>Consolidated Statements of Shareholders' Equity (Deficit) and Comprehensive Loss</u>	76
<u>Consolidated Statements of Cash Flows</u>	79
<u>Notes to Consolidated Financial Statements</u>	82

**Table of Contents**

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To The Board of Directors and

Shareholders of Cell Therapeutics, Inc.

We have audited the consolidated statements of operations, shareholders' deficit and comprehensive loss, and cash flows of Cell Therapeutics, Inc. (the Company) for the year 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 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 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 audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated results of operations, shareholders' deficit and comprehensive loss, and cash flows of Cell Therapeutics, Inc. for the year 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 loss from operations over the audit period, incurred an accumulated deficit, and had 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

**Table of Contents**

**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 sheets of Cell Therapeutics, Inc. (the Company) as of December 31, 2011 and 2010, and the related consolidated statements of operations, shareholders' equity (deficit) and comprehensive loss, and cash flows for the years 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 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 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 audits provide 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, 2011 and 2010, and the consolidated results of its operations and its cash flows for the years 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 does not have sufficient liquidity to fund its presently anticipated operations beyond the second quarter of 2012. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plan in regard to these matters is also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We have also 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, 2011, based on the criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 8, 2012 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ Marcum LLP

San Francisco, CA

March 8, 2012

---

**Table of Contents**

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

To the Audit Committee of 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, 2011, 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, 2011, 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 sheets as of December 31, 2011 and 2010, and the related consolidated statements of operations, shareholders' equity (deficit) and comprehensive loss, and cash flows for the years then ended of Cell Therapeutics, Inc. and our report dated March 8, 2012 expressed an unqualified opinion, with an explanatory paragraph as to the uncertainty regarding the Company's ability to continue as a going concern, on those financial statements.

/s/ Marcum LLP

San Francisco, CA

March 8, 2012

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

	December 31, 2011	December 31, 2010
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 47,052	\$ 22,649
Prepaid expenses and other current assets	4,023	4,256
Total current assets	51,075	26,905
Property and equipment, net	3,604	3,426
Goodwill		17,064
Other assets	7,560	6,197
Total assets	\$ 62,239	\$ 53,592
<b>LIABILITIES AND SHAREHOLDERS EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 5,750	\$ 6,037
Accrued expenses	11,064	11,008
Current portion of long-term obligations	970	1,717
7.5% convertible senior notes		10,215
5.75% convertible senior notes		12,093
Total current liabilities	17,784	41,070
Long-term obligations, less current portion	2,985	4,206
Total liabilities	20,769	45,276
Commitments and contingencies		
Common stock purchase warrants	13,461	13,461
Shareholders' equity (deficit):		
Preferred stock, no par value:		
Authorized shares 1,666,666		
Series 14 Preferred Stock, \$1,000 stated value, 20,000 shares designated, 10,000 and 0 shares issued and outstanding at December 31, 2011 and 2010, respectively	6,736	
Common stock, no par value:		
Authorized shares 383,333,333 and 200,000,000 at December 31, 2011 and 2010, respectively		
Issued and outstanding shares 203,067,725 and 135,625,216 at December 31, 2011 and 2010, respectively	1,744,801	1,579,866
Accumulated other comprehensive loss	(8,035)	(7,969)
Accumulated deficit	(1,714,785)	(1,576,643)
Total CTI shareholders' equity (deficit)	28,717	(4,746)
Noncontrolling interest	(708)	(399)
Total shareholders' equity (deficit)	28,009	(5,145)
Total liabilities and shareholders' equity (deficit)	\$ 62,239	\$ 53,592

See accompanying notes.





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

	Year Ended December 31,		
	2011	2010	2009
<b>Revenues:</b>			
License and contract revenue	\$	\$ 319	\$ 80
<b>Total revenues</b>		<b>319</b>	<b>80</b>
<b>Operating expenses, net:</b>			
Research and development	34,900	27,031	30,179
Selling, general and administrative	38,290	48,043	57,725
Gain from litigation settlement	(11,000)		
Restructuring charges and related gain on sale of assets, net			3,979
Gain on sale of investment in joint venture			(10,244)
<b>Total operating expenses, net</b>	<b>62,190</b>	<b>75,074</b>	<b>81,639</b>
<b>Loss from operations</b>	<b>(62,190)</b>	<b>(74,755)</b>	<b>(81,559)</b>
<b>Other income (expense):</b>			
Investment and other income, net	1,713	1,221	133
Interest expense	(1,038)	(2,334)	(4,806)
Amortization of debt discount and issuance costs	(546)	(768)	(5,788)
Foreign exchange gain (loss)	(558)	(521)	33
Debt conversion expense		(2,031)	
Provision for VAT Assessments		(3,503)	
Make-whole interest expense			(6,345)
Gain on derivative liabilities, net			7,218
Gain on exchange of convertible notes			7,381
Equity loss from investment in joint venture			(1,204)
Milestone modification expense			(6,000)
Settlement expense		(145)	(4,710)
<b>Other expense, net</b>	<b>(429)</b>	<b>(8,081)</b>	<b>(14,088)</b>
<b>Net loss before noncontrolling interest</b>	<b>(62,619)</b>	<b>(82,836)</b>	<b>(95,647)</b>
Noncontrolling interest	259	194	252
<b>Net loss attributable to CTI</b>	<b>(62,360)</b>	<b>(82,642)</b>	<b>(95,395)</b>
Gain on restructuring of preferred stock			2,116
Dividends and deemed dividends on preferred stock	(58,718)	(64,918)	(23,484)
<b>Net loss attributable to common shareholders</b>	<b>\$ (121,078)</b>	<b>\$ (147,560)</b>	<b>\$ (116,763)</b>
<b>Basic and diluted net loss per common share</b>	<b>\$ (0.71)</b>	<b>\$ (1.29)</b>	<b>\$ (1.53)</b>
<b>Shares used in calculation of basic and diluted net loss per common share</b>	<b>171,468</b>	<b>114,105</b>	<b>76,393</b>

See accompanying notes.



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

(In thousands)

	Preferred Stock		Common Stock		Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Noncontrolling Interest	Total Shareholders Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance at December 31, 2008		\$	31,069	\$ 1,188,071	\$ (1,312,320)	\$ (7,812)	\$	\$ (132,061)
Issuance of common stock and warrants			8,289	59,233				59,233
Conversion of 10% convertible senior notes due 2011 to common stock			21,898	18,000				18,000
Conversion of 9% convertible senior notes to common stock			62	5,250				5,250
Issuance of Series F preferred stock in exchange for Series A, B, and D preferred stock	7	3,866						3,866
Conversion of Series F preferred stock to common stock	(7)	(3,866)	7,979	3,866				
Issuance of Series 1 preferred stock, net of transaction costs	20	18,537						18,537
Conversion of Series 1 preferred stock to common stock	(20)	(18,537)	11,111	18,537				
Issuance and Series 2 preferred stock, net of transaction costs	30	27,796						27,796
Conversion of Series 2 preferred stock to common stock	(30)	(27,796)	3,142	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			1,530	5,222				5,222
Exercise of Class B warrants			1,730	5,732				5,732
Issuance of common stock in exchange for convertible notes			4,589	39,523				39,523
Issuance of common stock in connection with Series A preferred stock settlement			666	509				509
Issuance of common stock in exchange for milestone modification			934	6,000				6,000
Conversion or exchange of Series A, B and D preferred stock to common stock			631	4,288				4,288
Reacquisition of BCF in connection with exchange of Series A, B and C preferred stock for Series F preferred stock				(961)				(961)
Equity-based compensation			5,637	24,937				24,937
Repurchase of shares in connection with taxes on restricted stock vesting			(894)	(6,394)				(6,394)
Employee stock purchase plan			7	36				36
Noncontrolling interest				(47)			(205)	(252)
Gain on restructuring of preferred stock					2,116			2,116
Dividends and deemed dividends on preferred stock				1	(23,484)			(23,483)
Comprehensive loss:								
Foreign currency translation loss						(601)		(601)
Unrealized gain on securities available-for-sale						1		1
Net loss for the year ended December 31, 2009					(95,395)			(95,395)

Edgar Filing: CELL THERAPEUTICS INC - Form 10-K

Comprehensive loss								(95,995)		
Balance at December 31, 2009	\$	98,380	\$ 1,418,931	\$ (1,429,083)	\$	(8,412)	\$	(205)	\$	(18,769)

See accompanying notes.

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

(In thousands)

	Preferred Stock		Common Stock		Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Noncontrolling Interest	Total Shareholders Equity (Deficit)
	Shares	Amount	Shares	Amount				
Issuance of Series 3 preferred stock, net of transaction costs	30	27,761						27,761
Conversion of Series 3 preferred stock to common stock	(30)	(27,761)	4,115	27,761				
Issuance of Series 4 preferred stock, net of transaction costs	20	18,621						18,621
Conversion of Series 4 preferred stock to common stock	(20)	(18,621)	6,667	18,621				
Issuance of Series 5 preferred stock, net of transaction costs	21	19,464						19,464
Conversion of Series 5 preferred stock to common stock	(21)	(19,464)	8,750	19,464				
Issuance of Series 6 preferred stock, net of transaction costs	4	2,970						2,970
Conversion of Series 6 preferred stock to common stock	(4)	(2,970)	1,933	2,970				
Issuance of Series 7 preferred stock, net of transaction costs	21	19,273						19,273
Conversion of Series 7 preferred stock to common stock	(21)	(19,273)	9,459	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			717	3,879				3,879
Exercise of common stock purchase warrants			86	177				177
Equity-based compensation			5,773	17,048				17,048
Repurchase of shares in connection with taxes on restricted stock vesting			(262)	(932)				(932)
Employee stock purchase plan			7	10				10
Noncontrolling interest							(194)	(194)
Dividends and deemed dividends on preferred stock					(64,918)			(64,918)
Comprehensive loss:								
Foreign currency translation gain						301		301
Unrealized gain on securities available-for-sale						142		142
Net loss for the year ended December 31, 2010					(82,642)			(82,642)
Comprehensive loss								(82,199)
Balance at December 31, 2010		\$	135,625	\$ 1,579,866	\$ (1,576,643)	\$ (7,969)	\$ (399)	\$ (5,145)

See accompanying notes.



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

(In thousands)

	Preferred Stock		Common Stock		Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Noncontrolling Interest	Total Shareholders Equity (Deficit)
	Shares	Amount	Shares	Amount				
Cumulative effect adjustment					(17,064)			(17,064)
Issuance of Series 8 preferred stock, net of transaction costs	25	18,337						18,337
Redemption of Series 8 preferred stock	(25)	(18,337)						(18,337)
Issuance of Series 9 preferred stock	25	25,000						25,000
Conversion of Series 9 preferred stock to common stock	(25)	(25,000)	10,745	25,000				
Issuance of Series 10 preferred stock, net of transaction costs	25	18,301						18,301
Redemption of Series 10 preferred stock	(25)	(18,301)						(18,301)
Issuance of Series 11 preferred stock	25	24,957						24,957
Conversion of Series 11 preferred stock to common stock	(25)	(24,957)	12,343	24,957				
Issuance of Series 12 preferred stock, net of transaction costs	16	10,647						10,647
Conversion of Series 12 preferred stock to common stock	(16)	(10,647)	7,606	10,647				
Issuance of Series 13 preferred stock, net of transaction costs	30	19,077						19,077
Conversion of Series 13 preferred stock to common stock	(30)	(19,077)	17,647	19,077				
Issuance of Series 14 preferred stock, net of transaction costs	20	13,472						13,472
Conversion of Series 14 preferred stock to common stock	(10)	(6,736)	8,696	6,736				
Value of beneficial conversion features related to preferred stock				27,435				27,435
Issuance of additional investment right in connection with preferred stock issuances				7,742				7,742
Issuance of warrants in connection with preferred stock issuances				21,198				21,198
Exercise of common stock purchase warrants			8,080	17,485				17,485
Equity-based compensation			2,547	5,017				5,017
Repurchase of shares in connection with taxes on restricted stock vesting			(222)	(405)				(405)
Noncontrolling interest				50			(309)	(259)
Dividends and deemed dividends on preferred stock					(58,718)			(58,718)
Employee stock purchase plan			13	15				15
Other			(12)	(19)				(19)
Comprehensive loss:								
Foreign currency translation gain						241		241
Unrealized loss on securities available-for-sale						(307)		(307)
Net loss for the year ended December 31, 2011					(62,360)			(62,360)
Comprehensive loss								(62,426)



Edgar Filing: CELL THERAPEUTICS INC - Form 10-K

Balance at December 31, 2011	10	\$	6,736	203,068	\$	1,744,801	\$	(1,714,785)	\$	(8,035)	\$	(708)	\$	28,009
------------------------------	----	----	-------	---------	----	-----------	----	-------------	----	---------	----	-------	----	--------

See accompanying notes.

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

(In thousands)

	Year Ended December 31,		
	2011	2010	2009
<b>Operating activities</b>			
Net loss	\$ (62,360)	\$ (82,642)	\$ (95,395)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	2,411	1,842	1,771
Equity-based compensation expense	5,017	17,048	24,937
Gain on sale of investment in joint venture			(10,244)
Noncash interest expense	546	768	5,788
Debt conversion expense		2,031	
Provision for VAT Assessment		3,503	
Gain on derivative liabilities			(7,218)
Gain on exchange of convertible notes			(7,381)
Equity loss from investment in joint venture			1,204
Milestone modification expense			6,000
Noncontrolling interest	(259)	(194)	(252)
Other	(1,958)	(450)	(487)
Changes in operating assets and liabilities:			
Restricted cash			6,640
Accounts receivable, net			991
Prepaid expenses and other current assets	567	516	(2,649)
Other assets	(2,452)	(381)	519
Accounts payable	(310)	(1,403)	(1,484)
Accrued expenses	(211)	(3,787)	(10,750)
Other liabilities	(1,449)	21	(176)
Total adjustments	1,902	19,514	7,209
Net cash used in operating activities	(60,458)	(63,128)	(88,186)
<b>Investing activities</b>			
Purchases of securities available-for-sale		(350)	
Proceeds from maturities of securities available-for-sale			600
Purchases of property and equipment	(2,703)	(2,011)	(1,478)
Proceeds from sales of property and equipment	31	85	887
Cash received for disposition of Zevalin to joint venture, net			6,844
Proceeds received from sale of investment in joint venture, net			14,987
Net cash provided by (used in) investing activities	(2,672)	(2,276)	21,840

See accompanying notes.

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

(In thousands)

	Year Ended December 31,		
	2011	2010	2009
<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 Series 8 preferred stock, additional investment right and warrants, net of issuance costs	23,213		
Proceeds from issuance of Series 10 preferred stock, additional investment right and warrants, net of issuance costs	23,530		
Proceeds from issuance of Series 12 preferred stock and warrants, net of issuance costs	14,962		
Proceeds from issuance of Series 13 preferred stock and warrants, net of issuance costs	27,986		
Proceeds from issuance of Series 14 preferred stock and warrants, net of issuance costs	18,900		
Proceeds from issuance of common stock and warrants, net of issuance costs			59,233
Proceeds from exercise of Class A warrants			3,765
Proceeds from exercise of Class B warrants			4,255
Repayment of 7.5% convertible senior notes	(10,250)		
Repayment of 5.75% convertible senior notes	(10,913)		
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	(405)	(932)	(6,394)
Payment of deemed dividends on conversion of preferred stock			(3,000)
Payment of dividends on preferred stock			(111)
Other	(19)	4	(183)
<b>Net cash provided by financing activities</b>	<b>87,004</b>	<b>49,722</b>	<b>94,775</b>
Effect of exchange rate changes on cash and cash equivalents	529	520	(690)
Net increase (decrease) in cash and cash equivalents	24,403	(15,162)	27,739
Cash and cash equivalents at beginning of year	22,649	37,811	10,072
<b>Cash and cash equivalents at end of year</b>	<b>\$ 47,052</b>	<b>\$ 22,649</b>	<b>\$ 37,811</b>
<b>Supplemental disclosure of cash flow information</b>			
Cash paid during the period for interest	\$ 1,025	\$ 3,137	\$ 12,047
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	\$

Edgar Filing: CELL THERAPEUTICS INC - Form 10-K

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 9 preferred stock to common stock	\$ 25,000	\$	\$
Conversion of Series 11 preferred stock to common stock	\$ 24,957	\$	\$
Conversion of Series 12 preferred stock to common stock	\$ 10,647	\$	\$

See accompanying notes.

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

	<b>Year Ended December 31,</b>		
	<b>2011</b>	<b>2010</b>	<b>2009</b>
Conversion of Series 13 preferred stock to common stock	\$ 19,077	\$	\$
Conversion of Series 14 preferred stock to common stock	\$ 6,736	\$	\$
Conversion of Series B 3% convertible preferred stock to common stock	\$	\$	\$ 2,317
Conversion of Series F preferred stock to common stock	\$	\$	\$ 3,866
Conversion of 10% convertible senior notes due 2011 to common stock	\$	\$	\$ 18,000
Conversion of 9% convertible senior notes to common stock	\$	\$	\$ 5,250
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 9 preferred stock	\$ 25,000	\$	\$
Issuance of Series 11 preferred stock	\$ 24,957	\$	\$
Issuance of Series F preferred stock for Series A, B and C convertible preferred stock	\$	\$	\$ 3,931
Issuance of common stock upon exercise of common stock purchase warrants	\$ 17,484	\$	\$
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
Redemption of Series 8 and 10 preferred stock	\$ 36,638	\$	\$

See accompanying notes

---

**Table of Contents**

**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 products are focused on addressing key unmet medical needs in the area of oncology. 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™ (pixantrone dimaleate), or Pixuvri, OPAXIO™ (paclitaxel poliglumex), or OPAXIO, tosedostat, 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, 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, 2011, we also had a 67% interest in our majority owned subsidiary, Aequus Biopharma, Inc., or Aequus. 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 statements of operations and shown as a component of equity in the consolidated balance sheets and consolidated statements of shareholders' equity (deficit).

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-six, one-for-ten and one-for-four reverse stock split of our common stock on May 15, 2011, August 31, 2008 and April 15, 2007, respectively. Unless otherwise noted, 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 convertible preferred stock, convertible notes, warrants and stock options, shares reserved, conversion prices of convertible securities, exercise prices of warrants or options, and loss per share. Additionally, the 2011

## **Table of Contents**

reverse stock split impacted the preferred stock authorized (but not outstanding because there were no shares of preferred stock outstanding as of the time of the reverse stock split). There was no impact on preferred stock authorized or outstanding resulting from the 2007 or 2008 reverse stock splits. See Note 10, *Reverse Stock Split*, for additional information.

### *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, tosedostat, brostallicin and bisplatinates.

Our available *cash and cash equivalents* are \$47.1 million as of December 31, 2011. Our total current liabilities were \$17.8 million as of December 31, 2011. We do not expect that we will have sufficient cash to fund our planned operations beyond the second quarter of 2012, which raises substantial doubt about our ability to continue as a going concern.

If we receive approval of Pixuvri by the EMA and/or the FDA, we would anticipate significant additional commercial expenses associated with Pixuvri operations. Accordingly, we will 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 of financing. 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 and may be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection. 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, the allocation of our operating expenses, the allocation of purchase price to acquired assets and liabilities, restructuring charges and our liability for excess facilities, our provision for loss contingencies, the useful lives of fixed assets, the fair value of our financial instruments, 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 insofar as we use U.S. dollars to make contract payments denominated in euros or vice versa. As the net positions of our unhedged foreign currency transactions fluctuate, our earnings might be negatively affected. In addition, the reported carrying value of our euro-denominated assets and liabilities that remain in our European branches and subsidiaries 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.

## **Table of Contents**

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 17, *Geographic Concentrations*, for further concentration disclosure.

### *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 are 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 \$5.0 million and \$5.3 million as of December 31, 2011 and 2010, of which \$4.7 million and \$5.2 million is included in *other assets* and \$0.3 million and \$0.1 million is included in *prepaid expenses and other current assets* as of December 31, 2011 and 2010, 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 identifiable tangible and intangible assets acquired. Goodwill 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 and 2009. In January 2011, we adopted the accounting standards update on *Intangibles – Goodwill and Other (Topic 350)*, which provided additional guidance on when to perform Step 2 of the goodwill impairment test for reporting units with zero or negative carrying amounts. See Note 4, *Goodwill*, for further information regarding our assessment of goodwill impairment upon adoption of the accounting standards update.



**Table of Contents***Other Financial Instruments*

At December 31, 2011 and 2010, 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 were determined using a discounted cash flow modeling technique. The carrying values of our convertible notes were net of accretion of debt discount and changes in the fair value of derivative liabilities, if any.

The following is a summary of the estimated fair value of our convertible notes as of December 31, 2011 and 2010 (in thousands):

	December 31,	
	2011	2010
7.5% convertible senior notes	\$	\$ 10,035
5.75% convertible senior notes	\$	\$ 9,774

*Contingencies*

We record liabilities associated with loss contingencies to the extent that we conclude the occurrence of the contingency is probable and that the amount of the related loss is reasonably estimable. We record income from gain contingencies only upon the realization of assets resulting from the favorable outcome of the contingent event. See Note 20, *Legal Proceedings*, for further information regarding our current gain and loss contingencies.

*Research and Development Expenses*

Research and development costs are expensed as incurred in accordance with ASC 730, *Research and Development*. 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. 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 completion of milestones or receipt of deliverables. In instances where we enter into cost-sharing arrangements, all costs reimbursed by the collaborator are a reduction to research and development expense while costs paid to the collaborator are an addition to research and development expense. We expense upfront license payments related to acquired technologies which have not yet reached technological feasibility and have no alternative future use.

*Advertising Costs*

The costs of advertising are expensed as incurred. We incurred advertising costs of \$0.2 million, \$0.9 million and \$1.0 million in 2011, 2010 and 2009, respectively.

*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

---

**Table of Contents**

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' equity (deficit), except for intercompany transactions that are of a short-term nature with entities that are consolidated, combined or accounted for by the equity method in our consolidated financial statements. 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 operations 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 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 was 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. The adoption of this guidance on January 1, 2011 did not have a material impact on our 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 was effective for fiscal years, and interim periods within those years, beginning after December 15, 2010. Upon adoption of this guidance on January 1, 2011, we performed Step 2 of the goodwill impairment test. Based on a valuation using the income, market and cost approaches, we determined that all of our \$17.1 million in goodwill was impaired. The related charge was recorded as a cumulative-effect adjustment to beginning retained earnings in the current period. See Note 4, *Goodwill*, for additional information.

*Recently Issued Accounting Standards*

In June 2011, the FASB issued guidance amending the presentation requirements for comprehensive income. For public entities, this guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2011 with early adoption permitted. Upon adoption, we will have the option to

**Table of Contents**

report total comprehensive income, including components of net income and components of other comprehensive income, as a single continuous statement or in two separate but consecutive statements. Subsequently, in December 2011, the FASB deferred the effective date of the portion of the June 2011 accounting standards update requiring separate presentation of reclassifications out of accumulated other comprehensive income. We do not anticipate the adoption of this guidance will have a material impact 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):

	2011	2010	2009
Net loss before noncontrolling interest	\$ (62,619)	\$ (82,836)	\$ (95,647)
Foreign currency translation gain (loss)	241	301	(601)
Net unrealized gain (loss) on securities available-for-sale	(307)	142	1
Comprehensive loss before noncontrolling interest	(62,685)	(82,393)	(96,247)
Noncontrolling interest	259	194	252
Comprehensive loss attributable to CTI	\$ (62,426)	\$ (82,199)	\$ (95,995)

Information regarding the components of accumulated other comprehensive loss as of December 31, 2011 and 2010 is as follows (in thousands):

	2011	2010
Foreign currency translation adjustment	\$ (7,870)	\$ (8,111)
Net unrealized gain (loss) on securities available-for-sale	(165)	142
Total accumulated other comprehensive loss	\$ (8,035)	\$ (7,969)

**3. Property and Equipment**

Property and equipment are composed of the following as of December 31, 2011 and 2010 (in thousands):

	2011	2010
Furniture and office equipment	\$ 13,375	\$ 13,137
Leasehold improvements	1,755	2,931
Lab equipment	411	464
	15,541	16,532
Less: accumulated depreciation and amortization	(11,937)	(13,106)

\$ 3,604      \$ 3,426

Depreciation expense of \$2.4 million, \$1.8 million and \$1.8 million was recognized during 2011, 2010, and 2009, respectively.

**Table of Contents****4. Goodwill**

In January 2011, we adopted the accounting standards update on *Intangibles – Goodwill and Other (Topic 350)*, which provided additional guidance on when to perform Step 2 of the goodwill impairment test for reporting units with zero or negative carrying amounts. Upon adoption of the guidance, we determined that it was more likely than not that a goodwill impairment existed. On January 1, 2011, the implied fair value of goodwill for the reporting unit, after considering unrecognized in-process research and development, was zero. An impairment charge of \$17.1 million was recorded in retained earnings as a cumulative-effective adjustment.

The following tables present the effects of the cumulative-effect application (in thousands):

	Goodwill	Adjustment	Net
Balance at January 1, 2011	\$ 17,064	\$	\$ 17,064
Cumulative effect adjustment		(17,064)	(17,064)
Adjusted Goodwill at January 1, 2011	\$ 17,064	\$ (17,064)	\$

	Accumulated Deficit	Accumulated Other Comprehensive Income/(Loss)	Total Shareholder s (Deficit)
Balance at December 31, 2010	\$ (1,576,643)	\$	\$ (5,145)
Cumulative effect adjustment	(17,064)		(17,064)
Adjusted Balance at January 1, 2011	\$ (1,593,707)	\$	\$ (22,209)

**5. Accrued Expenses**

Accrued expenses consisted of the following as of December 31, 2011 and 2010 (in thousands):

	2011	2010
Clinical and investigator-sponsored trial expense	\$ 2,807	\$ 4,554
Employee compensation and related expenses	4,771	3,386
Insurance financing and accrued interest expense	587	218
Legal expense	388	949
Manufacturing expense	847	776
Co-Development expenses	997	
Other	667	1,125
	\$ 11,064	\$ 11,008

**6. Contractual Arrangements and Commitments***Lease Agreements*

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 *prepaid expenses and other current assets* as of December 31, 2011 and *other assets* as of December 31, 2010. Rent expense amounted to \$1.5 million, \$3.9 million and \$3.4 million for the years ended December 31, 2011, 2010 and 2009, respectively. Rent expense is net of sublease income and amounts offset to excess facilities charges.

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

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, 2011 we had \$0.2 million accrued related to the 2005 excess facilities charge and was included in *current portion of long-term obligations*.

**Table of Contents**

During 2010, we recorded an additional 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, 2011, \$0.5 million remained accrued related to the 2010 excess facilities charge and was included in *current portion of long-term obligations*.

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 excess facilities during the years ended December 31, 2011 and 2010 (in thousands):

	2005 Activities	2010 Activities	Total Excess Facilities Liability
Balance at January 1, 2010	\$ 854	\$	\$ 854
Accrual		1,523	1,523
Adjustments	71	37	108
Payments	(375)	(150)	(525)
Balance at December 31, 2010	550	1,410	1,960
Adjustments	40	102	142
Payments	(375)	(982)	(1,357)
Balance at December 31, 2011	\$ 215	\$ 530	\$ 745

**Future Minimum Lease Payments**

Future minimum lease commitments for non-cancelable operating leases at December 31, 2011 are as follows (in thousands):

	Operating Leases
2012	\$ 2,384
2013	237
2014	82
2015	
2016	
Thereafter	
Total minimum lease commitments	\$ 2,703

In January 2012, we entered into an agreement to lease approximately 66,000 square feet of office space. The term of this lease is for a period of 120 months, commencing on the earlier of (i) May 1, 2012, or (ii) upon substantial completion of improvements we plan to perform to the premises. We have two five-year options to extend the term of the lease at a market rate determined according to the lease. No rent will be due during the first five months, so long as the Company performs all of its obligations under the lease. Rent shall be \$27.00 per square foot per annum for the remainder of the first 12 months, with rent increasing three percent over the prior year's rent amount for each year thereafter for the duration of the lease. In addition, we will be provided an allowance of up to \$50.00 per rentable square foot and \$27.50 per rentable square foot of IT/Storage Space for certain tenant improvements made by us.

---

**Table of Contents****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.

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.

Of the \$16.5 million in gross proceeds, we received an initial payment of \$6.5 million in March 2009 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*

We issued a Series B Unit Warrant, or B Unit Warrant, in connection with our 13.5% convertible senior notes and other financial instruments in April 2008. We determined that the B Unit Warrant was a liability instrument that was marked to fair value with changes in value recognized through earnings at each reporting period. 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 million. The B Unit Warrant expired in the second quarter of 2009. The net change in the estimated fair value of the B Unit Warrant for the year ended December 31, 2009 was a gain of \$2.8 million and is included in *gain on derivative liabilities, net*.



**Table of Contents***Long-term obligations*

Long-term obligations consisted of the following as of December 31, 2011 and 2010 (in thousands):

	2011	2010
Accrued rent	\$ 213	\$ 628
Excess facilities liability	745	1,960
Reserve for VAT Assessments	2,947	3,042
Other long-term obligations	50	293
	3,955	5,923
Less current portion	(970)	(1,717)
	\$ 2,985	\$ 4,206

As of December 31, 2011, maturities of 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,	
2012	\$ 225
2013	23
2014	15
2015	
2016	
Thereafter	
	\$ 263

**9. Convertible Notes**

The following tables summarize the changes in the principal balances of our convertible notes during the years ended December 31, 2011, 2010 and 2009 (in thousands):

	Balance at January 1, 2011	Exchanged	Matured	Balance at December 31, 2011
7.5% convertible senior notes	\$ 10,250	\$	\$ (10,250)	\$
5.75% convertible senior notes	10,913		(10,913)	
Total	\$ 21,163	\$	\$ (21,163)	\$

	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)	

Edgar Filing: CELL THERAPEUTICS INC - Form 10-K

Total \$ 61,526 \$ (1,848) \$ (38,515) \$ 21,163

	<b>Balance at January 1, 2009</b>	<b>Converted</b>	<b>Exchanged, Extinguished or Repurchased</b>	<b>Balance at December 31, 2009</b>
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>

**Table of Contents****Exchanges of Convertible Notes***Tender Offer*

In June 2009, we completed exchange offers whereby we issued \$134.50 cash and 76 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):

	<b>Principal Amount Exchanged</b>
9% convertible senior notes	\$ 335
7.5% convertible senior notes	23,208
6.75% convertible senior notes	5,500
5.75% convertible senior notes	12,087
4% convertible senior subordinated notes	11,787
 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 4.0 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 \$0.09 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.

*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% convertible senior subordinated notes, or 4% Notes, \$1.5 million of our 6.75% convertible senior subordinated notes, or 6.75% Notes, and all accrued and unpaid interest related to these notes were exchanged for an aggregate of 0.5 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*.

*4% Notes Exchange for Common Stock*

In May 2010, we entered into exchange agreements with certain holders of our 4% Notes, pursuant to which we issued approximately 0.7 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.

**10. Reverse Stock Split**

In May 2011, our Board of Directors approved a one-for-six reverse stock split and, on May 15, 2011, the reverse stock split became effective. As a result of the reverse stock split, every six shares of our authorized and outstanding common stock were converted into one authorized and outstanding share of common stock and every six shares of our authorized preferred stock were converted into one authorized share of preferred stock; there were no shares of preferred stock outstanding so there was no impact. Fractional shares calculated in the split

**Table of Contents**

were rounded down to the nearest share and no fractional shares were issued. In lieu of fractional shares, shareholders received cash at a rate of approximately \$0.27 per whole pre-split share. The reverse stock split affected all of the holders of our common stock pro rata and did not materially affect any shareholder's percentage of ownership interest. Any shares of our common stock or shares underlying options, warrants, convertible preferred stock and convertible notes were proportionately reduced and the exercise price of any warrants or options and the conversion prices of any convertible preferred stock or convertible notes were proportionately increased in accordance with the terms of the related agreements. Unless otherwise noted, all impacted amounts included in the consolidated financial statements and notes thereto have been retroactively adjusted for the reverse stock split.

**11. Preferred Stock**

Prior to the effective date of the reverse stock split (see Note 10, *Reverse Stock Split*), we completed ten preferred stock transactions during the years 2009, 2010 and 2011, each of which are described below. All of the outstanding shares of the preferred stock issued in these transactions converted to common stock or the outstanding shares of preferred stock issued in these transactions were redeemed, in each case, prior to the effective date of the reverse stock split. Accordingly, for purposes of the descriptions of these transactions included in this Note 11, *Preferred Stock*, the number of shares of preferred stock issued and the initial stated value of shares of preferred stock issued are not adjusted to reflect the reverse stock split. However, the number of shares of common stock issued upon conversion of the preferred stock, the conversion price of common stock issued upon conversion, the exercise prices of warrants issued and the number of shares of common stock issued or issuable upon exercise of the warrants in these transactions are adjusted to reflect the reverse stock split.

*Series A 3% Convertible Preferred Stock*

During 2009, 250 shares of Series A 3% convertible preferred stock, or Series A Preferred Stock, were exchanged for \$0.1 million and 0.7 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 *dividend and deemed dividends on preferred stock* and \$0.2 million as *settlement expense* for the year ended December 31, 2009. Also, 100 shares of Series A Preferred Stock and related common stock purchase warrants were exchanged for 0.1 million shares of our common stock and we recorded \$0.1 million as *dividend and deemed dividends on preferred stock* for the year ended December 31, 2009. We exchanged 200 shares of our Series A Preferred Stock for shares of our Series F convertible preferred stock, or 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 2009, 3,000 shares of Series B 3% convertible preferred stock, or Series B Preferred Stock, were converted into 7,429 shares of our common stock in connection with our litigation settlement with Tang Capital Partners LP, or Tang. Also during 2009, 2,218 shares of Series B 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 B Preferred Stock had been converted or exchanged.

*Series C 3% Convertible Preferred Stock*

During 2009, 4,284 shares of Series C 3% convertible preferred stock, or 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.

---

**Table of Contents**

*Series D 7% Convertible Preferred Stock*

In 2009, 1,000 shares of Series D 7% convertible preferred stock, or Series D Preferred Stock, and related common stock purchase warrants were exchanged for 0.6 million shares of our common stock and we recorded \$1.1 million as *dividend and deemed dividends on preferred stock* for the year ended December 31, 2009.

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 stated value of the preferred stock to be converted, which was \$1,000 per share, by the conversion price of \$0.84. In connection with this exchange, we recorded a *gain on restructuring of preferred stock* of \$2.1 million which decreased our *net loss attributable to common shareholders* \$0.03 for the year ended December 31, 2009.

During 2009, all 6,702 shares of Series F Preferred Stock were converted into 8.0 million shares of our common stock.

*Series I Convertible Preferred Stock*

In April 2009, we issued the following in a registered offering: (a) 15,000 shares of our Series I convertible preferred stock, or Series I Preferred Stock, convertible into 8.3 million shares of our common stock at a conversion price of \$1.80 per share for a purchase price of \$1,000 per share of Series I Preferred Stock and warrants described as follows, (i) Class A warrants to purchase an additional 1.5 million shares of our common stock at an exercise price of \$2.46 per share and (ii) Class B warrants to purchase an additional 2.2 million shares of our common stock at an exercise price of \$2.46 per share. In addition, the original holder of the Series I Preferred Stock had the right to purchase up to 5,000 additional shares of Series I 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. In April 2009, the original holder exercised the right to purchase the additional 5,000 shares of Series I Preferred Stock as discussed above and we received an additional \$5.0 million in gross proceeds. Issuance costs related to this transaction were \$1.5 million, which included \$0.2 million related to the placement agent warrants as discussed below. For the year ended December 31, 2009, we recognized \$8.2 million in *dividends and deemed dividends on preferred stock* upon allocation of the proceeds to the components of this transaction. In April 2009, all shares of Series I Preferred Stock issued were converted in shares of our common stock.

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 May 2009, all of the Class A warrants were exercised for 1.5 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 1.7 million shares of our common stock and we received gross proceeds of \$4.3 million. As of December 31, 2011, Class B warrants to purchase 0.5 million shares of common stock are outstanding.

In connection with this offering, we also issued warrants to purchase 0.2 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

---

**Table of Contents**

using the Black-Scholes pricing model. These warrants have an exercise price of \$2.70 per share, became exercisable in October 2009 and expire in October 2014. In February 2010, these warrants were partially exercised. As of December 31, 2011, warrants to purchase 25,000 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 3.1 million shares of our common stock, and warrants to purchase up to 0.8 million shares of our common stock for gross proceeds of \$30.0 million. Each share of Series 2 Preferred Stock was convertible into our common stock, at the option of the holder, at a conversion price of \$9.55 per share. The warrants had an exercise price of \$10.20 per share of our common stock, were exercisable immediately upon issuance and expired nine months after the date of issuance. We estimated the \$5.5 million fair value of the warrants using the Black-Scholes pricing model. Issuance costs related to this transaction were \$2.2 million, including \$0.6 million related to the placement agent warrants as discussed below. For the year ended December 31, 2009, we recognized \$13.8 million in *dividends and deemed dividends on preferred stock* upon allocation of the proceeds to the components of this transaction. In August 2009, all shares of our Series 2 Preferred Stock were converted into shares of our common stock.

In connection with this offering, we issued warrants to purchase 0.1 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 \$11.93 per share, were exercisable immediately upon issuance and expired nine months after the date of issuance.

*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 4.1 million shares of our common stock, and warrants to purchase up to 1.4 million shares of our common stock, or Series 3 Warrants, for gross proceeds of \$30.0 million. Each share of Series 3 Preferred Stock was convertible into our common stock, at the option of the holder, at a conversion price of \$7.28 per share. The Series 3 Warrants had an exercise price of \$7.08 per share of our common stock, were exercisable immediately upon issuance and expired one year and one day after the date of issuance. We estimated the \$7.1 million fair value of the Series 3 Warrants using the Black-Scholes pricing model. Issuance costs related to this transaction were \$2.2 million, including \$0.2 million related to the placement agent warrants as discussed below. For the year ended December 31, 2010, we recognized \$17.3 million in *dividends and deemed dividends on preferred stock* upon allocation of the proceeds to the components of this transaction. In January 2010, all shares of our Series 3 Preferred Stock were converted into shares of our common stock.

In July 2010, we entered into a privately negotiated exchange agreement with a certain holder of the Series 3 Warrants to exchange 0.7 million Series 3 Warrants for the same number of warrants to purchase shares of common stock at an exercise price of \$2.52 per share, or Exchange Warrants. The Exchange Warrants 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. The exercisability of the Exchange 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, which was received in September 2010. We estimated the \$0.8 million fair value of the Exchange Warrants using the Black-Scholes pricing model, which were recorded in permanent equity. The remaining 0.7 million outstanding Series 3 Warrants expired in January 2011. None of the Exchange Warrants have been exercised as of December 31, 2011.

In connection with this offering, we also issued warrants to purchase approximately 41,000 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 had an exercise price of \$9.10 per share, were exercisable immediately upon issuance and expired one year and one day after the date of issuance.

---

**Table of Contents***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 6.7 million shares of our common stock, and warrants to purchase up to 3.3 million shares of our common stock for gross proceeds of \$20.0 million. Each share of Series 4 Preferred Stock was convertible into our common stock, at the option of the holder, at a conversion price of \$3.00 per share. The warrants have an exercise price of \$3.62 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. We estimated the \$5.6 million fair value of the warrants using the Black-Scholes pricing model. 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, 2011. Issuance costs related to this transaction were \$1.4 million. For the year ended December 31, 2010, we recognized \$15.5 million in *dividends and deemed dividends on preferred stock* upon allocation of the proceeds to the components of this transaction. In April 2010, all shares of our Series 4 Preferred Stock were converted into 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 8.8 million shares of our common stock, and warrants to purchase up to 4.4 million shares of our common stock for gross proceeds of \$21.0 million. Each share of Series 5 Preferred Stock was convertible into our common stock, at the option of the holder, at a conversion price of \$2.40 per share. The warrants have an exercise price of \$3.00 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. 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, 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. None of the warrants have been exercised as of December 31, 2011. Issuance costs related to this transaction were \$1.5 million, including \$0.2 million related to the placement agent warrants as discussed below. For the year ended December 31, 2010, we recognized \$14.6 million in *dividends and deemed dividends on preferred stock* upon allocation of the proceeds to the components of this transaction. In May 2010, all shares of our Series 5 Preferred Stock were converted into shares of our common stock.

In connection with this offering, we also issued warrants to purchase 0.2 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 \$3.00 per share and were exercisable six months and one day after the date of issuance and expire five years after the date of issuance. The exercisability of the warrants was subject to, and conditioned upon, our receipt of the shareholder approval as described above. None of the warrants have been exercised as of December 31, 2011.

*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 1.9 million shares of our common stock, and warrants to purchase up to 1.0 million shares of our common stock for gross proceeds of \$4.1 million. Each share of Series 6 Preferred Stock was convertible into our common stock, at the option of the holder, at a conversion price of \$2.10 per share. The warrants have an exercise price of \$2.52 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. 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

**Table of Contents**

stock available for issuance, which was received in September 2010. We estimated the \$1.1 million fair value of the warrants using the Black-Scholes pricing model. 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. None of the warrants have been exercised as of December 31, 2011. Issuance costs related to this transaction were \$1.1 million, including \$0.1 million related to the placement agent warrants as discussed below. For the year ended December 31, 2010, we recognized \$3.1 million in *dividends and deemed dividends on preferred stock* upon allocation of the proceeds to the components of this transaction. In July 2010, all shares of our Series 6 Preferred Stock were converted into shares of our common stock.

In connection with this offering, we also issued warrants to purchase 0.1 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 \$0.1 million using the Black-Scholes pricing model. These warrants have an exercise price of \$2.52 per share 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. The exercisability of the warrants was also subject to, and conditioned upon, our receipt of the shareholder approval as described above. None of the warrants have been exercised as of December 31, 2011.

*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 9.5 million shares of our common stock, and warrants to purchase up to 3.8 million shares of our common stock for gross proceeds of \$21.0 million. Each share of Series 7 Preferred Stock was convertible into common stock, at the option of the holder, at an initial conversion price of \$2.22 per share. The warrants have an exercise price of \$2.70 per share of our common stock, were exercisable six months and one day after the date of issuance and expire five years and one day after the date of issuance. We estimated the \$5.2 million fair value of the warrants using the Black-Scholes pricing model. None of the warrants have been exercised as of December 31, 2011. Issuance costs related to this transaction were \$1.7 million, including \$0.3 million related to the placement agent warrants as discussed below. For the year ended December 31, 2010, we recognized \$14.4 million in *dividends and deemed dividends on preferred stock* upon allocation of the proceeds to the components of this transaction. In October 2010, all shares of our Series 7 Preferred Stock were converted into shares of our common stock.

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 \$0.3 million using the Black-Scholes pricing model. These warrants have an exercise price of \$2.76 per share, were exercisable six months and one day after the date of issuance and expire five years and one day after the date of issuance. None of the warrants have been exercised as of December 31, 2011.

*Series 8 and 9 Preferred Stock*

In January 2011, we issued to an institutional investor, or the Investor, 25,000 shares of Series 8 non-convertible preferred stock, or Series 8 Preferred Stock, warrants to purchase up to 3.8 million shares of common stock and an additional investment right to purchase up to 25,000 shares of Series 9 convertible preferred stock, or Series 9 Preferred Stock, for an aggregate offering price of \$25.0 million. The aggregate offering price was reduced by a 5% commitment fee retained by the Investor for total gross proceeds received of \$23.7 million. We allocated the proceeds on a relative fair value basis, of which \$18.5 million, \$1.3 million and \$3.9 million was allocated to the Series 8 Preferred Stock, warrants and additional investment right, respectively. Issuance costs related to this transaction were approximately \$0.5 million.

The shares of Series 8 Preferred Stock accrued annual dividends at the rate of 10% from the date of issuance, payable in the form of additional shares of Series 8 Preferred Stock. Each share of our Series 8 Preferred Stock was entitled to a liquidation preference equal to the initial stated value of \$1,000 per share of our



---

**Table of Contents**

Series 8 Preferred Stock plus any accrued and unpaid dividends before any distribution of assets may be made to the holders of our common stock or any other securities ranking junior to our Series 8 Preferred Stock. The Series 8 Preferred Stock had no voting rights except as otherwise expressly provided in the Company's amended and restated articles of incorporation or as otherwise required by law. The shares of Series 8 Preferred Stock were redeemable by the Company at any time after issuance, either in cash or by offset against recourse notes fully secured with marketable securities, or Recourse Notes, which were issued by the Investor to the Company in connection with the exercise of the warrants and the additional investment right as discussed below.

Each warrant had an exercise price of \$2.3268 per share of common stock. The warrants were exercisable immediately and had an expiration date of two years from the date of issuance. The holder of the warrants had the option to pay the exercise price for the warrant either in cash or through the issuance of Recourse Notes to the Company. The Investor exercised all of the warrants to purchase 3.8 million shares of common stock for a total of \$8.8 million through the issuance of Recourse Notes by the Investor to the Company.

Each additional investment right had an exercise price of \$1,000 per share of Series 9 Preferred Stock. The additional investment right was exercisable immediately upon issuance and had an expiration date of February 11, 2011. The holder of the additional investment right had the option to pay the exercise price in cash or through issuance of Recourse Notes to the Company. The Investor exercised the entire additional investment right to purchase 25,000 shares of Series 9 Preferred Stock for a total of \$25.0 million through the issuance of Recourse Notes by the Investor to the Company. The Investor also elected to convert the 25,000 shares of Series 9 Preferred Stock into 10.7 million shares of common stock.

Each share of our Series 9 Preferred Stock was entitled to a liquidation preference equal to the initial stated value of \$1,000 per share of our Series 9 Preferred Stock plus any accrued and unpaid dividends before any distribution of assets may be made to the holders of our common stock or any other securities ranking junior to our Series 9 Preferred Stock. The Series 9 Preferred Stock was not entitled to dividends except to share in any dividends actually paid on the common stock or any pari passu or junior securities. The Series 9 Preferred Stock was convertible into common stock, at the option of the holder, at an initial conversion price of \$2.3268 per share of common stock, subject to a 9.99% blocker provision. The Series 9 Preferred Stock had no voting rights except as otherwise expressly provided in the Company's amended and restated articles of incorporation or as otherwise required by law.

In March 2011, we redeemed all 25,000 outstanding shares of Series 8 Preferred Stock (plus accrued dividends). Each share of Series 8 Preferred Stock (plus accrued dividends) was offset by \$1,350 principal amount of Recourse Notes (plus accrued interest), regardless of the issuance date of the shares of Series 8 Preferred Stock and Recourse Notes. We recognized \$0.4 million in accrued dividends on the Series 8 Preferred Stock and \$0.1 million accrued interest on the Recourse Notes through the redemption date, both of which are included in *dividends and deemed dividends on preferred stock* for the year ended December 31, 2011. Additionally, we recognized \$15.5 million in *dividends and deemed dividends on preferred stock* for the year ended December 31, 2011 upon redemption of the Series 8 Preferred Stock equal to the difference between the \$33.9 million principal balance of Recourse Notes, including accrued interest, and \$18.4 million carrying amount of Series 8 Preferred Stock, including accrued dividends.

#### *Series 10 and 11 Preferred Stock*

In February 2011, we issued to the Investor 24,957 shares of Series 10 non-convertible preferred stock, or Series 10 Preferred Stock, warrants to purchase up to 4.3 million shares of common stock and an additional investment right to purchase up to 24,957 shares of Series 11 convertible preferred stock, or Series 11 Preferred Stock, for an aggregate offering price of approximately \$25.0 million. The aggregate offering price was reduced by a 5% commitment fee retained by the Investor for total gross proceeds received of \$23.7 million. We allocated the proceeds on a relative fair value basis, of which \$18.5 million, \$1.3 million and \$3.9 million was allocated to the Series 10 Preferred Stock, warrants and additional investment right, respectively. Issuance costs related to this transaction were approximately \$0.3 million.

**Table of Contents**

The shares of Series 10 Preferred Stock accrued annual dividends at the rate of 10% from the date of issuance, payable in the form of additional shares of Series 10 Preferred Stock. Each share of our Series 10 Preferred Stock was entitled to a liquidation preference equal to the initial stated value of \$1,000 per share of our Series 10 Preferred Stock plus any accrued and unpaid dividends before any distribution of assets may be made to the holders of our common stock or any other securities ranking junior to our Series 10 Preferred Stock. The Series 10 Preferred Stock had no voting rights except as otherwise expressly provided in the Company's amended and restated articles of incorporation or as otherwise required by law. The shares of Series 10 Preferred Stock were redeemable by the Company at any time after issuance, either in cash or by offset against Recourse Notes, which were issued by the Investor to the Company in connection with the exercise of the warrants and the additional investment right as discussed below.

Each warrant had an initial exercise price of \$2.022 per share of common stock. The warrants were exercisable immediately and had an expiration date of two years from the date of issuance. The holder of the warrants had the option to pay the exercise price for the warrant either in cash or through the issuance of Recourse Notes to the Company. The Investor exercised all of the warrants to purchase 4.3 million shares of common stock for a total of \$8.7 million through the issuance of Recourse Notes by the Investor to the Company.

Each additional investment right had an exercise price of \$1,000 per share of Series 11 Preferred Stock. The additional investment right was exercisable immediately upon issuance and had an expiration date of March 19, 2011. The holder of the additional investment right had the option to pay the exercise price in cash or through issuance of Recourse Notes to the Company. The Investor exercised the entire additional investment right to purchase 24,957 shares of Series 11 Preferred Stock for a total of approximately \$25.0 million through the issuance of Recourse Notes by the Investor to the Company. The Investor also elected to convert the 24,957 shares of Series 11 Preferred Stock into 12.3 million shares of common stock.

Each share of our Series 11 Preferred Stock was entitled to a liquidation preference equal to the initial stated value of \$1,000 per share of our Series 11 Preferred Stock plus any accrued and unpaid dividends before any distribution of assets may be made to the holders of our common stock or any other securities ranking junior to our Series 11 Preferred Stock. The Series 11 Preferred Stock was not entitled to dividends except to share in any dividends actually paid on the common stock or any pari passu or junior securities. The Series 11 Preferred Stock was convertible into common stock, at the option of the holder, at an initial conversion price of \$2.022 per share of common stock, subject to a 9.99% blocker provision. The Series 11 Preferred Stock had no voting rights except as otherwise expressly provided in the Company's amended and restated articles of incorporation or as otherwise required by law.

In March 2011, we redeemed all 24,957 outstanding shares of Series 10 Preferred Stock (plus accrued dividends). Each share of Series 10 Preferred Stock (plus accrued dividends) was offset by \$1,350 principal amount of Recourse Notes (plus accrued interest), regardless of the issuance date of the shares of Series 10 Preferred Stock and Recourse Notes. We recognized \$0.1 million in accrued dividends on the Series 10 Preferred Stock and \$41,000 accrued interest on the Recourse Notes through the redemption date, both of which are included in *dividends and deemed dividends on preferred stock* for the year ended December 31, 2011. Additionally, we recognized \$15.4 million in *dividends and deemed dividends on preferred stock* for the year ended December 31, 2011 upon redemption of the Series 10 Preferred Stock equal to the difference between the \$33.7 million principal balance of Recourse Notes, including accrued interest, and \$18.3 million carrying amount of Series 10 Preferred Stock, including accrued dividends.

*Series 12 Convertible Preferred Stock*

In May 2011, we issued 15,972 shares of our Series 12 convertible preferred stock, or Series 12 Preferred Stock, which was convertible into 7.6 million shares of our common stock, and warrants to purchase up to 3.0 million shares of our common stock for gross proceeds of \$16.0 million. Issuance costs related to this transaction were \$1.2 million, including \$0.2 million related to the placement agent warrants as discussed below.

**Table of Contents**

Each share of our Series 12 Preferred Stock was entitled to a liquidation preference equal to the initial stated value of \$1,000 per share of Series 12 Preferred Stock, 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 12 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 12 Preferred Stock was convertible into our common stock, at the option of the holder, at an initial conversion price of \$2.10 per share, subject to a 4.99% blocker provision. A holder of our Series 12 Preferred Stock could have elected to increase the blocker provision to 9.99% by providing 61 days prior notice, and the maximum percentage would have automatically increased to 19.99% in the event of an automatic conversion. The Series 12 Preferred Stock had no voting rights except as otherwise expressly provided in our amended and restated articles of incorporation or as otherwise required by law.

Each warrant has an exercise price of \$2.40 per share of our common stock, was exercisable immediately on the date of issuance and expires five years and one day from the date of issuance. We estimated the \$4.1 million fair value of the warrants using the Black-Scholes pricing model. None of the warrants have been exercised as of December 31, 2011. For the year ended December 31, 2011, we recognized \$5.5 million in *dividends and deemed dividends on preferred stock* related to the beneficial conversion feature on our Series 12 Preferred Stock. In May 2011, all of our Series 12 Preferred Stock was converted into shares of our common stock.

In connection with this offering, we also issued warrants to purchase up to 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 \$2.625 per share, were exercisable immediately on the date of issuance and expire five years and one day from the date of issuance. None of the warrants have been exercised as of December 31, 2011.

*Series 13 Convertible Preferred Stock*

In July 2011, we issued 30,000 shares of our Series 13 convertible preferred stock, or Series 13 Preferred Stock, which was convertible into 17.6 million shares of our common stock, and warrants to purchase up to 8.8 million shares of our common stock for gross proceeds of \$30.0 million. Issuance costs related to this transaction were \$2.5 million, including \$0.5 million related to the placement agent warrants and financial advisor warrants as discussed below.

Each share of Series 13 Preferred Stock was entitled to a liquidation preference equal to the initial stated value of \$1,000 per share of Series 13 Preferred Stock, 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 13 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 13 Preferred Stock was convertible into common stock, at the option of the holder, at an initial conversion price of \$1.70 per share, subject to a 4.99% blocker provision. A holder of Series 13 Preferred Stock could have elected to increase the blocker provision to 9.99% by providing 61 days prior notice, and the maximum percentage would have automatically increased to 19.99% in the event of an automatic conversion. The Series 13 Preferred Stock had no voting rights except for limited protective provisions and except as is otherwise required by law.

Each warrant has an exercise price of \$2.15 per share of our common stock, is exercisable beginning six months and one day from the date of issuance and expires five years and one day from the date of issuance. We estimated the \$8.4 million fair value of the warrants using the Black-Scholes pricing model. None of the warrants have been exercised as of December 31, 2011. For the year ended December 31, 2011, we recognized \$13.0 million in *dividends and deemed dividends on preferred stock* related to the beneficial conversion feature on our Series 13 Preferred Stock. In July 2011, all of our Series 13 Preferred Stock was converted into shares of our common stock.

In connection with this offering, we also issued warrants to purchase up to 0.4 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, and warrants to purchase up to 0.2 million shares of our common stock to the financial

---

**Table of Contents**

advisor as partial compensation for its services in connection with this offering, 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 \$2.45 per share, are exercisable beginning six months and one day from the date of issuance and expire five years and one day from the date of issuance. None of the placement agent or financial advisor warrants issued in this transaction have been exercised as of December 31, 2011.

*Series 14 Convertible Preferred Stock*

In December 2011, we issued 20,000 shares of our Series 14 convertible preferred stock, or Series 14 Preferred Stock, which was initially convertible into 17.4 million shares of our common stock, and warrants to purchase up to 7.0 million shares of our common stock for gross proceeds of \$20.0 million. Issuance costs related to this transaction were \$1.6 million, including \$0.3 million related to the placement agent warrants and financial advisor warrants as discussed below.

Each share of Series 14 Preferred Stock was entitled to a liquidation preference equal to the initial stated value of \$1,000 per share of Series 14 Preferred Stock, 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 14 Preferred Stock was not entitled to dividends except to share in any dividends actually paid on the common stock or any *pari passu* or junior securities. The Series 14 Preferred Stock was convertible to common stock, at the option of the holder, at an initial conversion price of \$1.15 per share, subject to a 4.99% blocker provision. A holder of Series 14 Preferred Stock could have elected to increase the blocker provision to 9.99% by providing 61 days prior notice, and the maximum percentage would have automatically increased to 19.99% in the event of an automatic conversion. The Series 14 Preferred Stock had no voting rights except as otherwise expressly provided in the amended articles or as otherwise required by law.

Each warrant has an exercise price of \$1.45 per share of our common stock, is exercisable beginning six months and one day from the date of issuance and expires five years and one day from the date of issuance. We estimated the \$4.9 million fair value of the warrants using the Black-Scholes pricing model. None of the warrants have been exercised as of December 31, 2011. For the year ended December 31, 2011, we recognized \$8.9 million in *dividends and deemed dividends on preferred stock* related to the beneficial conversion feature on our Series 14 Preferred Stock. As of December 31, 2011, 10,000 shares of Series 14 Preferred Stock had been converted into shares of our common stock, and 10,000 shares remained outstanding. In January 2012, the remaining 10,000 shares of Series 14 Preferred Stock automatically converted into shares of our common stock pursuant to the terms of the Series 14 Preferred Stock.

In connection with this offering, we also issued warrants to purchase up to 0.3 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, and warrants to purchase up to 0.2 million shares of our common stock to the financial advisor as partial compensation for its services in connection with this offering, which were estimated to have a fair value of \$0.1 million using the Black-Scholes pricing model. These warrants have an exercise price of \$1.725 per share, are not transferrable for six months after the date of initial issuance, are exercisable beginning six months and one day from the date of issuance and expire five years and one day from the date of issuance.

**12. Common Stock**

In May 2009, we entered into a securities purchase agreement pursuant to which we issued 2.7 million shares of our common stock and warrants to purchase up to 0.8 million shares of common stock in a registered offering. The purchase price for one share of common stock and a warrant exercisable for 0.3 shares of common stock was \$7.50 and we received gross proceeds of \$20.0 million. Each warrant to purchase a share of our common stock has an exercise price of \$8.40 per share, was immediately exercisable and terminates on May 11, 2014. In connection with this offering, we also issued warrants to purchase 0.1 million shares of our common stock to the placement agent. These warrants have an exercise price of \$9.38 per share, were exercisable as of

**Table of Contents**

November 2009 and expire in November 2014. None of the warrants issued in connection with this offering have been exercised and all remain outstanding as of December 31, 2011. 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.

In July 2009, we issued 5.6 million shares of our common stock and warrants to purchase up to 1.4 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 \$7.80. Each warrant to purchase a share of our common stock had an exercise price of \$10.20 per share, 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 0.1 million shares of our common stock at an exercise price of \$10.20 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. Warrants to purchase 0.1 million shares of common stock issued to the underwriter of the offering remained outstanding as of December 31, 2011. We also issued a warrant to purchase up to 0.1 million shares of our common stock at an exercise price of \$9.36 per share for certain financial advisory services related to the offering. This warrant was exercisable beginning in January 2010 and expired in April 2010. 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.

*Common Stock Reserved*

A summary of common stock reserved for issuance is as follows as of December 31, 2011:

Convertible preferred stock	8,695,652
Equity incentive plans	18,459,434
Common stock purchase warrants	35,088,958
Employee stock purchase plan	225,974
Restricted share rights	65
	62,470,083

**13. Significant Agreements***Collaboration, Licensing and Milestone Agreements**Chroma Therapeutics, Ltd.*

During 2011, we entered into an agreement with Chroma Therapeutics, Ltd., or Chroma, or the Chroma Agreement, under which we have an exclusive license to certain technology and intellectual property controlled by Chroma to develop and commercialize the drug candidate, tosedostat, in North, Central and South America, or the Licensed Territory. Pursuant to the terms of the Chroma Agreement, we paid Chroma an upfront fee of \$5.0 million upon execution of the agreement. *Research and development* expense attributable to the Chroma Agreement was \$7.0 million for the year ended 2011, of which \$1.0 million was included in *accrued expenses* as of December 31, 2011. We will make a milestone payment of \$5.0 million upon the initiation of the first pivotal trial. The Chroma Agreement also includes additional development- and sales-based milestone payments related to acute myeloid leukemia, or AML, and certain other indications, up to a maximum amount of \$209.0 million payable by us to Chroma if all development and sales milestones are achieved.

We will also pay Chroma royalties on net sales of tosedostat in any country within the Licensed Territory, commencing on the first commercial sale of tosedostat in any country in the Licensed Territory and continuing with respect to that country until the later of (a) the expiration date of the last patent claim covering tosedostat in that country, (b) the expiration of all regulatory exclusivity periods for tosedostat in that country or (c) ten years after the first commercial sale in that country. Royalty payments to Chroma are based on net sales volumes in any country within the Licensed Territory and range from the low- to mid-teens as a percentage of net sales.

---

**Table of Contents**

We will oversee and be responsible for performing the development operations and commercialization activities in the Licensed Territory and Chroma will oversee and be responsible for performing the development operations and commercialization activities worldwide except for the Licensed Territory, or the ROW Territory. Development costs may not exceed \$50.0 million for the first three years of the Chroma Agreement unless agreed by the parties and we will be responsible for 75% of all development costs, while Chroma will be responsible for 25% of all development costs, subject to certain exceptions. Chroma is responsible for the manufacturing of tosedostat for development purposes in the Licensed Territory and the ROW Territory in accordance with the terms of the manufacturing and supply agreement. We have the option of obtaining a commercial supply of tosedostat from Chroma or from another manufacturer at our sole discretion in the Licensed Territory. The Chroma Agreement may be terminated by us at our convenience upon 120 days' written notice to Chroma. The Chroma Agreement may also be terminated by either party following a material breach by the other party subject to notice and cure periods.

*University of Vermont*

We have an agreement with the University of Vermont, or UVM, which grants us an exclusive license, with the right to sublicense, for the rights to pixantrone, or the UVM Agreement. Pursuant to the UVM Agreement, we acquired the rights to make, have made, sell and use pixantrone. Pursuant to the UVM Agreement, we are obligated to make payments to UVM based on net sales. Our royalty payments range from low-single digits to mid-single digits as a percentage of net sales. The higher royalty rate is payable for net sales in countries where specified UVM licensed patents exist, or where we have obtained orphan drug protection, until such UVM patents or such protection no longer exists. For a period of ten years after first commercialization of pixantrone, the lower royalty rate is payable for net sales in such countries after expiration of the designated UVM patents or loss of orphan drug protection, and in all other countries without such specified UVM patents or orphan drug protection. Unless otherwise terminated, the term of the UVM Agreement continues for the life of the licensed patents in those countries in which a licensed patent exists, and continues for ten years after the first sale of pixantrone in those countries where no such patents exist. We may terminate the UVM Agreement, on a country-by-country basis or on a patent-by-patent basis, at any time upon advance written notice. UVM may terminate the UVM Agreement upon advance written notice in the event royalty payments are not made. In addition, either party may terminate the UVM Agreement (a) in the event of an uncured material breach of the UVM Agreement by the other party; or (b) in the event of bankruptcy of the other party.

*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.

## **Table of Contents**

### *Gynecologic Oncology Group*

We have an agreement with the GOG related to the GOG0212 trial, which the GOG is conducting. We recorded a \$1.7 million payment due to the GOG based on the 800 patient enrollment milestone achieved in the second quarter of 2011, which is included in *accounts payable* as of December 31, 2011. Under this agreement we are required to pay up to \$1.8 million in additional milestone payments related to the trial, of which \$0.5 million will become due upon receipt of the interim analysis and data transfer which may occur in 2013. There were 843 patients enrolled as of December 31, 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, or the Novartis Agreement, with Novartis International Pharmaceutical Ltd., or Novartis, 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 the 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 United States 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

**Table of Contents**

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, 2011, 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.

*Other 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.

**14. 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, 2011, 2010 and 2009, we incurred share-based compensation expense due to the following types of awards (in thousands):

	2011	2010	2009
December 2009 performance awards	\$	\$ 13,954	\$ 1,276
Restricted stock	4,850	2,908	23,259
Options	167	186	402
Total share-based compensation expense	\$ 5,017	\$ 17,048	\$ 24,937



**Table of Contents**

The following table summarizes share-based compensation expense for the years ended December 31, 2011, 2010 and 2009, which was allocated as follows (in thousands):

	2011	2010	2009
Research and development	\$ 1,126	\$ 2,765	\$ 3,281
Selling, general and administrative	3,891	14,283	21,656
Share-based compensation expense included in operating expenses	\$ 5,017	\$ 17,048	\$ 24,937

Share-based compensation had a \$5.0 million, \$17.0 million and \$24.9 million effect on our net loss attributable to common shareholders and a \$(0.03), \$(0.15) and \$(0.33) effect on basic and diluted net loss per common share for the years ended December 31, 2011, 2010 and 2009, respectively. It had no effect on cash flows from operations or financing activities for the periods presented; however, during the years ended 2011, 2010 and 2009, we repurchased shares of our common stock totaling \$0.4 million, \$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, 2011, the total remaining unrecognized compensation cost related to unvested stock options and restricted stock amounted to \$7.9 million, which will be recognized over the remaining weighted-average requisite service period of 1.7 years. The unrecognized compensation cost related to unvested options and restricted stock does not include the cost related to approximately 0.2 million performance-based restricted stock awards. As of December 31, 2011, unrecognized compensation expense related to performance-based restricted stock awards was \$0.5 million, which will be recognized upon achievement of the underlying performance condition. In addition, unvested share-based compensation expense excludes the fair value of approximately 8,000 restricted stock awards and approximately 8,000 options granted to external consultants as the fair value is periodically remeasured as discussed below.

For the years ended December 31, 2011, 2010 and 2009, no tax benefits were attributed to the share-based compensation expense because a valuation allowance was maintained for substantially all net deferred tax assets.

*Stock Plan*

Pursuant to our 2007 Equity Incentive Plan, as amended and restated in October 2011, 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 the employees, consultants and directors who 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, 2011, 32.6 million shares were authorized for issuance, of which 17.7 million shares of common stock were available 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:

	Year Ended December 31,		
	2011	2010	2009
Risk-free interest rates	0.9%	1.3%	1.4%
Expected dividend yield	None	None	None
Expected life (in years)	4.54	4.97	2.8
Volatility	97%	96%	88%

**Table of Contents**

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 options. 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.

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, 2009 (24,000 exercisable)	50,000	\$ 1,063.69		
Granted	67,000	\$ 7.58		
Exercised		\$		
Forfeited	(9,000)	\$ 37.57		
Cancelled and expired	(4,000)	\$ 784.73		
Outstanding December 31, 2009 (34,000 exercisable)	104,000	\$ 479.59		
Granted	80,000	\$ 2.29		
Exercised		\$		
Forfeited	(6,000)	\$ 5.33		
Cancelled and expired	(6,000)	\$ 4,073.49		
Outstanding December 31, 2010 (88,000 exercisable)	172,000	\$ 151.16		
Granted	629,000	\$ 1.10		
Exercised		\$		
Forfeited	(10,000)	\$ 2.01		
Cancelled and expired	(9,000)	\$ 1,352.69		
Outstanding December 31, 2011	782,000	\$ 18.40	9.4	\$ 43
Vested or expected to vest at December 31, 2011	674,000	\$ 21.14	9.3	\$ 38
Exercisable at December 31, 2011	294,000	\$ 46.78	8.7	\$ 20

The weighted average exercise price of options exercisable at December 31, 2010 and 2009 was \$292.54 and \$1,414.14, respectively. The weighted average fair value of options granted was \$0.79, \$1.65 and \$3.12 per option during 2011, 2010 and 2009, respectively.

*Restricted Stock*

We issued 8.4 million, 6.7 million and 5.7 million shares of restricted common stock in 2011, 2010 and 2009, respectively. The weighted average fair value of restricted shares issued during 2011, 2010 and 2009 was \$1.25, \$2.62 and \$5.24, respectively. Additionally, 5.8 million, 1.0 million and 0.1 million shares of restricted stock were cancelled during 2011, 2010 and 2009, respectively.



**Table of Contents**

A summary of the status of nonvested restricted stock awards as of December 31, 2011 and changes during the period then ended, is presented below:

	Nonvested Shares	Weighted Average Grant-Date Fair Value Per Share
Nonvested at December 31, 2010	6,752,000	\$ 2.50
Granted	8,357,000	\$ 1.25
Vested	(2,599,000)	\$ 1.80
Forfeited	(5,810,000)	\$ 2.45
<b>Nonvested at December 31, 2011</b>	<b>6,700,000</b>	<b>\$ 1.25</b>

The total fair value of restricted stock awards vested during the years ended December 31, 2011, 2010 and 2009 was \$3.5 million, \$3.2 million and \$26.0 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 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, 2011, 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. The performance goals were not achieved as of December 31, 2011. As a result, the December 2009 performance awards expired and the related shares of restricted stock were cancelled and returned to the Company.

*2012-2014 Performance Awards*

In November 2011, we granted restricted stock units to our executive officers and directors that became effective on January 3, 2012 (which we refer to as our 2012 performance awards). Similar to the December 2009 performance awards, the 2012 performance awards 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

**Table of Contents**

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 7.5% and 2.5% of shares outstanding at the time a performance goal is achieved for executive officers and directors, respectively. A portion of each of these awards was granted in the form of restricted shares of common stock issued on January 3, 2012.

*Nonemployee Share-Based Compensation*

Share-based compensation expense for awards granted to nonemployees is determined using the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured. The fair value of options and restricted stock awards granted to nonemployees 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, 2011, 2010 and 2009, unvested nonemployee options to acquire approximately 8,000, 17,000 and 25,000 shares of common stock were outstanding, respectively. Additionally, unvested nonemployee restricted stock awards totaled approximately 8,000, 25,000 and 46,000 as of December 31, 2011, 2010 and 2009, respectively. We recorded compensation expense of \$58,000 and \$157,000 in 2011 and 2009, respectively, and reversed previously recorded compensation expense of \$24,000 in 2010, related to nonemployee 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 13,000, 8,000 and 6,000 shares to employees in 2011, 2010 and 2009, respectively. There are 254,166 shares of common stock authorized under the Purchase Plan and 225,974 are reserved for future purchases as of December 31, 2011.

**15. 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 recorded \$0.1 million related to discretionary matching contributions during each of the years ended December 31, 2011, 2010 and 2009.

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 and \$0.6 million were paid to employees who separated from the Company during 2010 and 2009, respectively. We made all final defined benefit plan payments to separated employees in 2010 and no further obligation existed upon completion of the employee termination agreements.

**16. 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.

**Table of Contents**

Each right, if and when it becomes exercisable, will entitle the holder to purchase a unit consisting of six ten-thousandth of a share of Series ZZ Junior Participating Cumulative Preferred Stock, no par value per share, at a cash exercise price of \$36.00 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 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 \$0.0006 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.

**17. 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.

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

	Year Ended December 31,	
	2011	2010
United States	\$ 3,314	\$ 21,249
Europe	290	5,438
	\$ 3,604	\$ 26,687

**18. 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,		
	2011	2010	2009
Net loss attributable to common shareholders	\$ (121,078)	\$ (147,560)	\$ (116,763)
Basic and diluted:			
Weighted average shares outstanding	178,951	118,459	77,725
Less weighted average restricted shares outstanding	(7,483)	(4,354)	(1,332)
Shares used in calculation of basic and diluted net loss per common share	171,468	114,105	76,393
Net loss per common share:			
Basic and diluted	\$ (0.71)	\$ (1.29)	\$ (1.53)



---

**Table of Contents**

Options, warrants, unvested restricted share awards and rights, convertible debt, and convertible preferred stock aggregating 51.0 million, 17.0 million and 5.7 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, 2011, 2010 and 2009, 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 the December 2009 performance awards.

**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, a majority owned subsidiary of which our ownership was approximately 67% as of December 31, 2011. 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 \$0.6 million, \$0.5 million and \$0.6 million during the years ended December 31, 2011, 2010 and 2009, 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. The convertible promissory note balance, including accrued interest, was approximately \$3.2 million and \$2.5 million as of December 31, 2011 and 2010, respectively. This intercompany balance was eliminated in consolidation.

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 4.8% of the equity in Aequus as of December 31, 2011. Both Dr. Bianco and Dr. Singer are members of Aequus' board of directors. Additionally, Frederick W. Telling, Ph.D., a member of our board of directors, owns approximately 1.4% of Aequus as of December 31, 2011 and is also a member of Aequus' board of directors.

**20. Legal Proceedings**

On August 10, 2011, the parties settled outstanding litigation entitled Cell Therapeutics, Inc. v. The Lash Group, Inc., et al., Case No. 07-310 (filed in the Western District of Washington), or the Litigation. The settlement is not an admission of liability by either party. Under the terms of the settlement agreement, CTI received \$11.0 million from The Lash Group, Inc.'s insurers. Of that settlement amount, CTI received a payment of approximately \$8.2 million in October 2011, which represents the settlement amount net of certain attorneys' fees, litigation costs and expenses outstanding at the time the settlement payment was made. The settlement agreement also provides for a complete, mutual and general release of all claims between CTI and The Lash Group, Inc.

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



---

**Table of Contents**

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 \$6,000 to \$649,000 converted using the currency exchange rate as of December 31, 2011, 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 had 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 converted using the currency exchange rate as of January 21, 2011, for these sanctions. On March 4, 2011, we paid the aggregate fine of 100,000 in full.

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 \$6,000 to \$649,000 converted using the currency exchange rate as of December 31, 2011, 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 had to evaluate before imposing any possible administrative sanctions. In a letter dated March 10, 2011, CONSOB notified us of a resolution confirming the occurrence of the violation asserted in clause (i) above and applied a fine in the amount of 40,000, or approximately \$55,000 converted using the currency exchange rate as of March 10, 2011, which we paid on April 5, 2011. CONSOB has not yet notified us of a resolution with respect to the violation asserted in clause (ii) above, but based on our assessment we believe the likelihood that a pecuniary administrative sanction will be imposed on the Company for the violation asserted in clause (ii) is probable.

**Table of Contents**

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, \$7.1 million, \$3.3 million and \$1.1 million converted using the currency exchange rate as of December 31, 2011, 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 decisions of the Provincial Tax Court of Milan, or the Tax Court, for the different VAT cases are 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 2.9 million to 9.4 million, or approximately \$3.7 million to \$12.2 million converted using the currency exchange rate as of December 31, 2011, 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 \$2.1 million converted using the currency exchange rate as of February 2, 2011. On March 4, 2011, we paid to the ITA the required deposit in respect of the 2006 VAT in the amount of 0.4 million, or approximately \$0.6 million converted using the currency exchange rate as of March 4, 2011. On March 25, 2011, we paid to the Italian collection agent an additional 0.1 million, or approximately \$0.1 million converted using the currency exchange rate as of March 25, 2011. On September 26, 2011, we paid to the ITA the required deposit in respect of the 2007 VAT in the amount of 0.1 million, or approximately \$0.1 million converted using the currency exchange rate as of September 26, 2011.

**2003 VAT.** We did not receive a notice from the ITA requesting a deposit payment for the VAT based on the 2003 assessment as of December 31, 2011. The first hearing for the discussion of the merits of the case was held on March 18, 2011 in front of the Provincial Tax Court of Milan. On September 13, 2011, the Tax Court issued decision no. 229/3/2011 in which the Tax Court (i) fully accepted the merits of our appeal, (ii) declared that no penalties can be imposed against us, and (iii) found the Tax Office liable to pay us 10,000, or approximately \$14,000 converted using the currency exchange rate as of September 13, 2011, as partial refund of the legal expenses we incurred for our appeal. The Tax Office is entitled to appeal this decision to a higher court within six months. We have not been notified of any appeal from the Tax Office.

**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, 2011. 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 \$3.4 million converted using the currency exchange rate as of December 31, 2011. On February 2, 2011, we paid the required VAT deposit of 1.5 million, or approximately \$2.1 million converted using the currency exchange rate as of February 2, 2011, prior to the due date of February 6, 2011. On March 25, 2011, we paid to the Italian collection agent an additional 0.1 million, or approximately \$0.1 million converted using the currency exchange rate as of March 25, 2011. The additional payment was for interest and collection fees during the suspension period. We do not believe this additional payment was due and we intend to pursue recovery of such payment through litigation. In July 2011, we were notified by our Italian counsel of the ITA's appeal regarding the January 2011 decision that no penalties could be imposed on the Company. 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

**Table of Contents**

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 filed an appeal with the Tax Office on July 7, 2011 and intend to 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 \$3.4 million as of December 31, 2011, of which \$2.9 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 January 10, 2011, payable in the first quarter 2011. We filed a request for suspension of the collection of such amount, which was rejected. On March 4, 2011, we paid to the ITA the required deposit in respect of the 2006 VAT in the amount of 0.4 million, or approximately \$0.6 million converted using the currency exchange rate as of March 4, 2011. The first hearing for the discussion of the merits of the case was held on May 27, 2011 (jointly with the 2007 VAT case). On October 18, 2011, the Tax Court issued decision no. 276/21/11 (jointly with the 2007 VAT case) in which the Tax Court (i) fully accepted the merits of our appeal, (ii) declared that no penalties can be imposed against us, and (iii) found for the 2006 and 2007 VAT cases the Tax Office liable to pay us 10,000, or approximately \$14,000 converted using the currency exchange rate as of October 18, 2011, as partial refund of the legal expenses we incurred for our appeal. The Tax Office has appealed to the higher court against this decision. We will defend against the Tax Office's appeal before the higher Tax Court.

**2007 VAT.** The first hearing for the discussion of the merits of the case was held on May 27, 2011 (jointly with the 2006 VAT case). On August 4, 2011, we received a notice from the ITA requiring a deposit payment for VAT to CTI (Europe) based on the 2007 assessment, including 50% of the assessed VAT, interest and collection fees for an amount of 0.1 million, or approximately \$0.1 million converted using the currency exchange rate as of August 4, 2011, payable in the third quarter 2011. On September 26, 2011, we paid to the ITA the required deposit in respect of the 2007 VAT in the amount of 0.1 million or approximately \$0.1 million converted using the currency exchange rate as of September 26, 2011. On October 18, 2011, the Tax Court issued decision no. 276/21/11 (jointly with the 2006 VAT case) in which the Tax Court (i) fully accepted the merits of our appeal, (ii) declared that no penalties can be imposed against us, and (iii) found for the 2006 and 2007 VAT cases the Tax Office liable to pay us 10,000, or approximately \$14,000 converted using the currency exchange rate as of October 18, 2011, as partial refund of the legal expenses we incurred for our appeal. The Tax Office has appealed to the higher court against this decision. We will defend against the Tax Office's appeal before the higher Tax Court.

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 to examine and discuss 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.

**Table of Contents**

In March 2010, three purported securities class action complaints were filed against the Company and certain of its officers and directors in the United States District Court for the Western District of Washington. On August 2, 2010, Judge Marsha Pechman consolidated the actions, appointed lead plaintiffs, and approved lead plaintiffs' counsel. On September 27, 2010, lead plaintiff filed an amended consolidated complaint, captioned *Sabbagh v. Cell Therapeutics, Inc.* (Case No. 2:10-cv-00414-MJP), naming the Company, Dr. James A. Bianco, Louis A. Bianco, and Craig W. Philips as defendants. The amended consolidated complaint alleges that defendants violated the federal securities laws by making certain alleged false and misleading statements related to the FDA approval process for pixantrone. The action seeks damages on behalf of purchasers of the Company's stock during a purported class period of March 25, 2008 through March 22, 2010. On October 27, 2010, defendants moved to dismiss the amended consolidated complaint. On February 4, 2011, the Court denied in large part the defendants' motion. Defendants answered the amended consolidated complaint on March 28, 2011, and discovery commenced, with trial set for June 25, 2012. On December 14, 2011, the parties filed a letter with the Court indicating they had agreed to the general terms of a settlement, and asking the Court to remove the case deadlines from the Court calendar. On February 14, 2012, the parties filed a Motion for Preliminary Approval of the Stipulation of Settlement and related documents with the Court. The negotiated terms of the settlement include a \$19 million payment to plaintiffs, which the Company expects to be paid by the Company's insurance carriers. Because the Company expects that the negotiated settlement will be paid by the Company's insurance carriers, there is no estimated loss to the Company.

In April 2010, three shareholder derivative complaints were filed against the Company and certain of its officers and directors in the United States District Court for the Western District of Washington. These derivative complaints allege that defendants breached their fiduciary duties to the Company by making or failing to prevent the issuance of certain alleged false and misleading statements related to the FDA approval process for Pixuvri. The allegations in the derivative actions are substantially similar to those in the securities action. On May 10, 2010, Judge Marsha Pechman consolidated the shareholder derivative actions under the caption *Shackleton v. Bauer* (Case No. 2:10-cv-00414-MJP), and appointed the law firms of Robbins Umeda LLP and Federman & Sherwood as co-lead counsel for derivative plaintiffs. Three more derivative complaints were filed in June, July and October 2010, and they have also been consolidated with *Shackleton v. Bauer*. The parties have agreed to coordinate discovery in the derivative and securities actions. Pursuant to the parties' stipulation, the Court has stayed the deadline for the derivative plaintiffs to file an amended complaint until March 12, 2012 (45 days after the scheduled close of discovery in the securities class action), and briefing on any motion to dismiss will follow. The court has set a trial date of December 3, 2012 for the shareholder derivative action. We believe that the shareholder derivative action is without merit and intend to defend it vigorously. No estimate of a loss, if any, can be made at this time in the event that we do not prevail.

In December 2011, we were informed of a decree by the Italian Ministry for Education, University and Research, or the Ministry, dated July 7, 2011 revoking a financial support granted to Novuspharma S.p.A. (now CTI, following the merger of Novuspharma into CTI in January 2004) in July 2002, or the Financial Support, and requesting the repayment of the amount paid to Novuspharma as grant for the expenses (i.e.

0.5 million, plus interests for an additional amount of 0.1 million) by January 15, 2012, or the Decree. The Financial Support was granted (following a proper application by Novuspharma) for a research project about new compounds for the treatment of tumors of the gastrointestinal area, or the Project. The initial amount of the Financial Support was (i) up to 2.3 million as subsidised loan, and (ii) up to 2.5 million as grant for expenses (a portion of which, corresponding to 0.5 million, was effectively paid to Novuspharma). Following the interruption of the Project in June 2004, due to unforeseeable technical reasons not ascribable to the beneficiary company, the Financial Support was reduced (i) to

0.6 million for the subsidised loan, and (ii) to 0.6 million for the grant for expenses. In 2005, we requested the Ministry to authorize the joint ownership of the Project by both Cell Therapeutics Europe S.r.l., or CTE, and the CTI Italian branch. In May 2007, the Ministry accepted such joint ownership of the Project subject to the issuance of a guarantee, or the Guarantee, for the portion corresponding to the subsidised loan, but we never issued such Guarantee. In 2009, CTI Italian branch's research activities were terminated. Since we assert that the Decree is unlawful and that the relevant issuance represents a breach of the Ministry's duty of good faith and an abuse of right, on February 13, 2012, we served a writ of summons upon the

**Table of Contents**

Ministry, suing it in the civil Court of Rome in order to have the Decree declared ineffective. However, if we are unable to successfully defend ourselves against the Decree issued by the Ministry, we may be requested to pay 0.6 million (i.e. the amount paid to Novuspharma as grant for the expenses plus interests, as described above), or approximately \$0.8 million converted using the currency exchange rate as of December 31, 2011, plus counterparty's attorney's fees, litigation costs and additional default interests for the period lapsed between January 16, 2012 and the date of the effective payment. At this time, we are not able to make a determination whether the likelihood of an unfavorable outcome is probable.

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.

**21. Income Taxes**

We file income tax returns in the United States, Italy and the United Kingdom. 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 \$3.6 million, increased 17.8 million, and decreased \$154.2 million during 2011, 2010 and 2009, respectively.

The reconciliation between our effective tax rate and the income tax rate as of December 31, 2011, 2010 and 2009 is as follows:

	2011	2010	2009
Federal income tax rate	(34%)	(34%)	(34%)
Research and development tax credits	(2)	(1)	(1)
I.R.C. Section 382 limited research and development tax credits			22
Non-deductible debt/equity costs	1	5	8
Non-deductible executive compensation	1		6
I.R.C. Section 382 limited net operating losses	21		153
Valuation allowance	6	22	(162)
Expired tax attribute carryforwards	7	7	7
Other		1	1
Net effective tax rate	%	%	%

**Table of Contents**

Significant components of our deferred tax assets and liabilities as of December 31, 2011 and 2010 are as follows (in thousands):

	2011	2010
Deferred tax assets:		
Net operating loss carryforwards	\$ 150,101	\$ 141,186
Capitalized research and development	43,604	51,449
Research and development tax credit carryforwards	2,556	1,514
Stock based compensation	9,349	8,860
Intangible assets	487	532
Depreciation and amortization	1,890	305
Other deferred tax assets	2,138	2,857
<b>Total deferred tax assets</b>	<b>210,125</b>	<b>206,703</b>
Less valuation allowance	(209,407)	(205,826)
	718	877
Deferred tax liabilities:		
GAAP adjustments on Novuspharma merger	(208)	(208)
Deductions for tax in excess of financial statements	(510)	(669)
<b>Total deferred tax liabilities</b>	<b>(718)</b>	<b>(877)</b>
Net deferred tax assets	\$	\$

Due to our equity financing transactions, and other owner shifts as defined in Internal Revenue Code Section 382 (the "Code"), we incurred ownership changes pursuant to the Code. These ownership changes trigger a limitation on our ability to utilize our net operating losses and research and development credits against future income. We will submit a private letter ruling (PLR) request to the Internal Revenue Service with respect to one of the ownership changes in the first quarter 2012. If granted, the PLR will allow us to utilize more of our tax attributes in the future. As of December 31, 2011, we had gross net operating losses of approximately \$916.7 million, of which \$90.3 million relates to stock compensation deductions, and gross research credit carryforwards of approximately \$21.8 million. The carryforwards began to expire in 2007

Based on our Section 382 analysis and assuming a favorable ruling in the PLR, our net operating loss carryforwards are limited to approximately \$441.5 million. The deferred tax assets and valuation allowance as of December 31, 2011 reflect the impact of these ownership change limitations.

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 1997 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, 2011, 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.

**Table of Contents****22. 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>2011</b>				
Revenues	\$	\$	\$	\$
Gross profit				
Operating expenses, net	(20,070)	(16,919)	(15,290)	(9,911)
Net loss attributable to CTI	(19,734)	(16,997)	(16,662)	(8,967)
Net loss attributable to CTI common shareholders	(51,017)	(22,508)	(29,685)	(17,868)
Net loss per common share basic and diluted	(0.35)	(0.14)	(0.16)	(0.09)
<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	(0.44)	(0.48)	(0.13)	(0.27)

---

**Table of Contents**

**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 2011 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, 2011 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, 2011, 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.

**Item 9B. Other Information**

None.



**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, 2011:

Name	Age	Director Since	Class	Term Expiration
John H. Bauer(3)	71	2005	I	2013 Annual Meeting
James A. Bianco, M.D.	55	1991	II	2014 Annual Meeting
Vartan Gregorian, Ph.D.(3)(4)	77	2001	II	2014 Annual Meeting
Richard L. Love(2)(4)	68	2007	III	2012 Annual Meeting
Mary O. Munding, DrPH(2)(4)	74	1997	III	2012 Annual Meeting
Phillip M. Nudelman, Ph.D.(1)(2)(3)(4)	76	1994	I	2013 Annual Meeting
Jack W. Singer, M.D.	69	1991	III	2012 Annual Meeting
Frederick W. Telling, Ph.D.(2)(3)	60	2006	II	2014 Annual Meeting
Reed V. Tuckson, M.D.	60	2011	I	2013 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** has been one of our directors since 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 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 a manager of Translational Accelerators, LLC. Mr. Love is also a director of Applied Microarrays Inc., Ascalon, PAREXEL International, SalutarisMD Inc., was previously a director of ImaRx Therapeutics Inc., and, prior to its



**Table of Contents**

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 has served on the board of directors of United Health Group and Gentiva Health Services and is an elected member of the Institute of Medicine of the National Academies, the American Academy of Nursing and the New York Academy of Medicine. 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. 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., Oragenics, Inc. and Aequeus Biopharma, Inc., a subsidiary of the Company. Dr. Telling is also a member of the Committee for Economic Development, IBM's Healthcare & Life Sciences Advisory Council, the EAA, and the United Hospital Fund and is a non-board emeritus at ORBIS. Dr. Telling received his B.A. degree from Hamilton College and his Masters of Industrial and Labor Relations and Ph.D. in Economics and Public Policy from Cornell University.

**Dr. Tuckson** has been one of our directors since September 2011. Dr. Tuckson is the Executive Vice President and Chief of Medical Affairs of UnitedHealth Group and has served in that capacity since December 2006. Prior to his position at UnitedHealth Group, from January 2006 to December 2006, Dr. Tuckson served as Senior Vice President, Professional Standards, for the American Medical Association. He has also served as President of the Charles R. Drew University of Medicine and Science in Los Angeles, Senior Vice President for Programs of the March of Dimes Birth Defects Foundation and Commissioner of Public Health for the District of

**Table of Contents**

Columbia. He currently serves on the board of directors of the Alliance for Health Reform, the American Telemedicine Association, the National Patient Advocate Foundation, Project Sunshine, and the Arnold P. Gold Foundation and the Advisory Committee to the Director of the National Institute of Health. Dr. Tuckson received his B.S. degree in Zoology from Howard University and his medical doctor degree from the Georgetown University School of Medicine, and completed the Hospital of the University of Pennsylvania's General Internal Medicine Residency and Fellowship programs.

**Executive Officers**

The following table sets forth certain information with respect to our executive officers as of December 31, 2011:

<b>Name</b>	<b>Age</b>	<b>Position</b>
James A. Bianco, M.D.	55	Chief Executive Officer
Louis A. Bianco	59	Executive Vice President, Finance and Administration
Daniel G. Eramian	63	Executive Vice President, Corporate Communications
Craig W. Philips	51	President
Jack W. Singer, M.D.	69	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.

## **Table of Contents**

### **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.

### **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 2011 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).

### **Code of Ethics**

We have adopted a code of ethics for our senior executive and financial officers (including our 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**

### *Executive Summary*

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.



---

## **Table of Contents**

The Company's executive compensation program is guided by the principle that the compensation of the executive officers should encourage creation of shareholder value and achievement of strategic corporate objectives. In furtherance of this principle, the Company's executive compensation program includes a number of features intended to reflect best practices in the market and help ensure that the program reinforces shareholder interests. These features are described in more detail below in this Compensation Discussion and Analysis and include the following:

The Company has not increased base salaries for its executive officers since 2005 (or, in the case of two executives who joined the Company after 2005, has not increased their base salaries since they joined the Company).

Executives' bonuses under the Company's annual incentive program are principally based on the achievement of specific performance objectives established at the beginning of the fiscal year by the Compensation Committee.

Vesting of a substantial percentage of executives' equity awards is contingent on the achievement of specific performance goals established by the Compensation Committee. In 2009, the Company approved long-term incentive awards for each of the named executive officers that would vest if the Company achieved certain performance goals by December 31, 2011. The 2009 awards with goals that were not achieved by December 31, 2011 expired on December 31, 2011. In connection with the expiration of these awards, the Company approved new long-term incentive grants, effective January 3, 2012, to each of the named executive officers that will vest based on the Company's achievement of specific operational and financial performance goals by December 31, 2014, or the 2012-2014 Performance Awards. These awards and the related performance goals are discussed in detail below in this Compensation Discussion and Analysis.

Effective 2012, the Compensation Committee approved arrangements for each of the named executive officers that eliminated any tax gross-up payment for parachute payment taxes under Section 280G of the U.S. Internal Revenue Code.

### *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. The at risk nature of the Company's long-term compensation program is evidenced by the substantial forfeiture of long-term compensation opportunities on December 31, 2011 that were previously granted by the Company for the 2009-2011 performance period, as noted in more detail below and following the Outstanding Equity Awards at Fiscal 2011 Year-End table on page 138.

## **Table of Contents**

In light of the general current economic climate, the Company's compensation philosophy and objectives for fiscal year 2011 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., or 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 2011, 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 2011 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 Pharmaceuticals Inc., Rigel Pharmaceutical, Inc., Seattle Genetics, Inc. and Spectrum Pharmaceuticals, Inc. The peer group was the same as the group identified for fiscal 2010 compensation decisions.

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.



---

**Table of Contents***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 2011 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 relatively flat target 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 2011. As a result, the named executive officers' base salaries for fiscal 2011 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 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 March 2011, the Compensation Committee established the 2011 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 2011 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 2010 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 2011 cash incentive program were paid out early in 2012 and were subject to a requirement that the executive officer is employed by the Company on the payment date.

There are three core elements to the 2011 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

**Table of Contents**

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. The individual performance element constitutes only a small percentage of each executive's target bonus, with each executive being eligible to receive up to 10% (or 15% in the case of Dr. Bianco and Dr. Singer) of his base salary under this element. 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 2011 is measured based on the Company's operating capital raised and the Company's total operating expenses 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 2011 equals or exceeds \$75 million. The executive would be entitled to receive the maximum bonus if the Company's operating capital for fiscal 2011 equals or exceeds \$90 million. For the operating expenses sub-element, the Compensation Committee established a goal that the Company's total operating expenses for 2011 would not exceed \$64.7 million (which is the level approved by our board of directors for the Company's budget for fiscal 2011). For purposes of the 2011 cash incentive program, the Company's total operating expenses are calculated excluding stock-based compensation expense, expenses incurred in connection with the acquisition of new products by the Company and certain legal expenses. The executive would generally be entitled to receive the target bonus for the operating expenses sub-element if the Company's total operating expenses are 100% or less of the goal established by the Compensation Committee, with the maximum bonus for this sub-element being payable if the Company's total operating expenses are 90% or less of this goal.

For the drug development element, two of the performance goals established by the Compensation Committee for fiscal 2011 related to Pixuvri. If, during fiscal 2011, the Company received an opinion rendered by the Committee for Medicinal Products for Human Use (CHMP) on its marketing authorization application submission for Pixuvri that supported a recommendation for approval to the EMA or if the U.S. Food and Drug Administration (FDA) agreed to use PIX306 as a clinical trial for Pixuvri, the executive would receive the portion of his bonus opportunity allocated to that particular performance goal as reflected in the table below. In addition, if, during fiscal 2011, the Company acquired one or more new products targeted for acquisition by our board of directors, the executive would receive the applicable portion of his bonus opportunity noted below.

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		Operating Expenses		Pix SPA Agreement	Positive Pix	
	Target	Maximum	Target	Maximum		CHMP Opinion	New Product Acquisition
James A. Bianco, M.D.	20%	40%	5%	20%	5%	25%	20%
Craig W. Philips	10%	10%	5%	15%	20%	25%	20%
Louis A. Bianco	20%	30%	5%	20%	2.5%	2.5%	10%
Jack W. Singer, M.D.	2.5%	5%	0%	5%	10%	25%	15%
Daniel G. Eramian	10%	30%	5%	15%	5%	5%	10%

In January 2012, the Compensation Committee determined that the Company had raised \$116 million in operating capital in 2011 and incurred total operating expenses (adjusted as described above) of approximately \$49.3 million (which represented approximately 76% of the operating expenses target for 2011 established by the Compensation Committee). On that basis, the Compensation Committee awarded each executive the maximum

**Table of Contents**

bonus amounts for the two financial sub-elements of the program. In addition, the Compensation Committee noted that the Company had largely met the goals described above during 2011 when the FDA agreed to use PIX306 as a post-marketing commitment study and we acquired a new targeted product (tosedostat). The Compensation Committee also noted that the CHMP was expected to issue an opinion early in 2012 on the Pixuvri marketing authorization application that supports a recommendation for approval to the EMA and that this opinion had been scheduled for delivery in December 2011 and was delayed as a result of EMA workflow considerations and not any action by the Company. (This opinion was in fact obtained by the Company from the CHMP in February 2012.) 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 his maximum amount under the individual performance element as identified above, except that the Compensation Committee determined that no amount would be awarded to Dr. Bianco under this element of the bonus program in light of the service award he received in November 2011 as described below. 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 2011 in acquiring and developing tosedostat, achieving a favorable outcome in certain litigation and achieving a quorum in and holding two meetings of shareholders, as well as the Compensation Committee's subjective assessment that these bonuses were appropriate to help continue to retain the executive team.

Based on the Company's performance against the objective pre-established goals discussed above, the maximum bonus opportunities related to the Company's financial achievements, the bonus opportunities related to the regulatory procedures involving Pixuvri, the acquisition of tosedostat, and the Compensation Committee's general assessment of each executive's individual performance during fiscal 2011, 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, 95%; Mr. Philips, 85%; Mr. Bianco, 73.5%; Dr. Singer, 60%; and Mr. Eramian, 72%.

In November 2011, the Compensation Committee approved a discretionary bonus of \$150,000 to Dr. Bianco in recognition of his 20 years of service to the Company. The Compensation Committee determined that this amount was appropriate in light of Dr. Bianco's role as principal founder of the Company and length of service as its Chief Executive Officer.

*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 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

**Table of Contents**

Committee deems reasonable to attract candidates in the competitive environment for highly qualified employees in which the Company operates.

**Retention Grants.** The Compensation Committee approved grants of restricted stock to each of the named executive officers during 2011. In March 2011, Dr. Bianco received a grant of 416,666 restricted shares, and each of the other named executive officers received a grant of 41,666 shares. Each of these grants vests in two six-month installments following the date of grant. In addition, the Compensation Committee approved grants of restricted stock in November 2011 to each of the named executive officers in the following amounts: Dr. Bianco - 1,685,626 shares; Mr. Philips - 1,011,376 shares; Mr. Bianco - 505,688 shares; Dr. Singer - 505,688 shares; and Mr. Eramian - 505,688 shares. Each of these grants vests in three semi-annual installments following the date of grant. The Compensation Committee determined that it was appropriate to award these grants in March and November 2011 to provide additional retention incentives for the executive team. The sizes of the awards were determined by the Compensation Committee in its judgment based on the general compensation levels of the executives and to provide meaningful retention incentives. In addition, the sizes of the November 2011 awards were similar to the three-year vesting retention awards granted by the Company in 2009, and the Committee intended the November 2011 grants to replace the retention incentives previously provided by the 2009 retention awards (which have vested in accordance with their terms). The Compensation Committee determined that it was appropriate in the case of these grants to treat all of the executives (other than Dr. Bianco and, as to the November 2011 grant, Mr. Philips) equally, with Dr. Bianco's grant set at a higher level than the other executives to reflect his position of overall responsibility for the Company and Mr. Philips's November 2011 grant set at a high level than the other executives (other than Dr. Bianco) to reflect his additional responsibilities as President of the Company.

**2012-2014 Performance Awards.** The Compensation Committee had previously granted equity awards to each of the named executive officers that would vest upon the Company's achievement of certain performance goals, subject to the goals being achieved by December 31, 2011. These 2009 awards expired on December 31, 2011 as the goals were not achieved. In connection with the expiration of these awards, the Compensation Committee granted new equity awards, effective January 3, 2012, with similar performance-based vesting requirements as outlined in detail below. (The Company refers to these awards as the 2012-2014 Performance Awards). The Compensation Committee believed these awards at the grant levels identified below, together with the retention grants made to the named executive officers during 2011 described above, would provide executives an appropriate level of incentives to help achieve the performance goals noted below so as to maximize and restore shareholder value and to remain with the Company over a multi-year period.

The performance goals under the 2012-2014 Performance Awards are as follows:

- (a) approval of marketing authorization application for Pixuvri ( Pix MAA Approval );
- (b) approval of new drug application ( NDA ) for Pixuvri ( Pix NDA Approval );
- (c) approval of NDA for OPAXIO ( Opaxio NDA Approval );
- (d) achievement of a market capitalization of \$1.2 billion or greater based on the average of the closing prices of the Company's common stock over a period of five consecutive days (the Market Cap Goal );
- (e) achievement by the Company of fiscal year sales equal to or greater than \$50,000,000 (the \$50M Sales Goal );
- (f) achievement by the Company of fiscal year sales equal to or greater than \$100,000,000 (the \$100M Sales Goal );
- (g) achievement by the Company of break-even cash flow in any fiscal quarter (the Cash Flow Break Even ); and

Edgar Filing: CELL THERAPEUTICS INC - Form 10-K

- (h) achievement by the Company of earnings per share results in any fiscal year equal to or greater than \$0.30 per share of Company common stock (the "EPS Goal").

**Table of Contents**

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 (subject to reduction for any restricted shares that vest upon attainment of that performance goal as described below). 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							
	Pix	Pix	Opaxio	Market	\$50M	\$100M	Cash Flow	EPS
	MAA	NDA	NDA	Cap	Sales	Sales	Break	Goal
James A. Bianco, M.D.	0.15%	0.45%	0.085%	0.75%	0.3%	0.6%	0.3%	0.124%
Louis A. Bianco	0.061%	0.182%	0.034%	0.305%	0.122%	0.243%	0.122%	0.061%
Daniel G. Eramian	0.045%	0.135%	0.025%	0.225%	0.09%	0.18%	0.09%	0.037%
Craig W. Phillips	0.09%	0.27%	0.051%	0.45%	0.18%	0.36%	0.18%	0.074%
Jack W. Singer, M.D.	0.061%	0.182%	0.034%	0.305%	0.122%	0.243%	0.122%	0.061%

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, 2014. 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 generally 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). With respect to the Market Cap Goal, however (to the extent the goal was not otherwise achieved before the date of the change in control), the recipient will receive the full number of shares allocated to the Market Cap Goal only if the Company's market capitalization based on the price per share of Company common stock in the change in control transaction (or, if there is no such price in the transaction, the closing price of a share of Company common stock on the last trading day preceding the date of the change in control) equals or exceeds \$1.2 billion. If the Company's market capitalization is less than \$1.2 billion on the date of the change in control, the recipient will not be entitled to receive or retain any of the shares allocated to the Market Cap Goal.

In approving the 2012-2014 Performance Awards for the named executive officers, the Compensation Committee determined that it would be appropriate to grant a portion of each award in the form of restricted shares issued on the effective date of grant. 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 (as opposed to a right to receive shares only upon the vesting of the awards). These restricted shares will be forfeited back to the Company should the performance-based vesting requirements described above not be satisfied. In order to ensure that the restricted shares do not provide the executive the right to receive any shares beyond the payout levels described above, any restricted shares that vest in connection with the achievement of a performance goal on or before December 31, 2014 will reduce on a share-for-share basis the number of shares that would otherwise have been delivered under the award percentages indicated in the table above upon achievement of that performance goal. In furtherance of that intent, if the number of shares that would have been delivered under the applicable award percentage on achievement of a performance goal is less than the number of restricted shares that vest on achievement of that performance goal, 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 applicable award percentage.

---

**Table of Contents**

The grant levels for the 2012-2014 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. As noted above, the 2012-2014 Performance Awards became effective January 3, 2012. Accordingly, these awards are considered part of each executive's compensation for 2012 under SEC rules and are therefore not reflected in the tables that follow this Compensation Discussion and Analysis.

**Subsidiary Grants.** Aequus Biopharma, Inc., or Aequus, is a majority-owned subsidiary of the Company. Mr. Bianco and Mr. Philips provide certain consulting services to Aequus, including financial guidance, business development and strategic planning services, for which they each received a grant of restricted shares of Aequus common stock during 2011 with a grant date fair value of \$26,000. The size of these grants was determined by the board of directors of Aequus in its discretion, and each of these grants is subject to a four-year vesting schedule.

**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. In addition, the Company maintains executive health programs for the benefit of the named executive officers, and these executives are also entitled to participate in the Company's benefit programs which are available to all Company employees, including the Company's 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.

**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. 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.

During the past year, the Compensation Committee has approved arrangements with each of the named executive officers that eliminate the executive's right to be reimbursed for any excise taxes imposed on his severance payments and any other payments under Sections 280G and 4999 of the Internal Revenue Code

**Table of Contents**

(generally referred to as parachute payments ). In March 2011, the Company entered into a new employment agreement with Dr. Bianco that eliminated the right he had under his prior employment agreement to be reimbursed for any parachute payment excise taxes. In January 2012, the Company entered into award agreements with each of the named executive officers to evidence the 2012-2014 Performance Awards described above. Each of these agreements provides that the executive will not be entitled to reimbursement for any excise taxes imposed on parachute payments received from the Company, whether the payment is made pursuant to the executive's 2012-2014 Performance Award or another Company plan or agreement.

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 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 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.



---

**Table of Contents**

*2011 Say-on-Pay Vote*

At the Annual Meeting held in November 2011, shareholders had the opportunity to cast an advisory vote on the compensation paid to the Company's named executive officers as disclosed in the proxy statement. The proposal to approve the executives' compensation was approved by approximately 77% of the total number of votes actually cast (disregarding abstentions and broker non-votes). The Compensation Committee, which is responsible for designing and administering the Company's executive compensation program, believes this result affirms shareholders' support of the Company's approach to executive compensation. Accordingly, the Company continued its approach to executive compensation in 2011, and its emphasis on performance-based compensation in particular, by implementing a long-term equity incentive program for 2012-2014 that is similar in structure to the 2009-2011 program. In order to help conform the program to best practices, the Compensation Committee also determined to eliminate the executives' rights to be reimbursed for parachute payment excise taxes as noted above.

**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 Form 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 2011. No director who served on the Compensation Committee during fiscal year 2011 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 2011.

**Table of Contents****EXECUTIVE COMPENSATION****Summary Compensation Table Fiscal Years 2009-2011**

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 2009, 2010 and 2011 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)	Non-Equity Incentive		All Other Compensation \$(5)	Total (\$)
					Option Award \$(2)	Plan Compensation \$(1)		
James A. Bianco, M.D. Chief Executive Officer	2011	650,000	767,500	2,891,120			287,018	4,595,638
	2010	650,000	585,000				125,967	1,360,967
	2009	650,000	585,000	11,275,903(3)			81,127	12,592,030
Louis A. Bianco Executive Vice President, Finance and Administration	2011	330,000	242,550	675,836(4)			32,928	1,281,314
	2010	330,000	247,500				10,009	587,509
	2009	330,000	204,600	4,512,112(3)			13,249	5,059,961
Daniel G. Eramian Executive Vice President, Corporate Communications	2011	315,000	226,800	649,836			11,768	1,203,404
	2010	315,000	220,500				250	535,750
	2009	315,000	181,125	3,382,770(3)			315	3,879,210
Craig W. Philips President	2011	402,000	341,700	1,216,922(4)			39,634	2,000,256
	2010	402,000	281,400				16,125	699,525
	2009	402,000	241,200	6,765,543(3)			14,775	7,423,518
Jack W. Singer, M.D. Executive Vice President, Chief Medical Officer	2011	340,000	204,000	649,836			44,107	1,237,943
	2010	340,000	212,500				30,475	582,975
	2009	340,000	119,000	4,512,112(3)			40,490	5,011,602

- (1) Please see the Compensation Discussion and Analysis above for a description of the cash incentive program for the named executive officers for fiscal 2011.
- (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 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 14 (Share-Based Compensation) to the Company's Consolidated Financial Statements, included as part of this Form 10-K.

**Table of Contents**

- (3) The amounts reported in the **Stock Awards** column of the table above for fiscal 2009 include the grant-date fair value of the long-term performance awards granted to the named executive officers in December 2009 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 these 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. As noted above, these performance awards expired on December 31, 2011 without payment as the performance goals were not 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.

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) These amounts include \$26,000, which represents the grant date fair value (as determined under generally accepted accounting principles) of an award of 200,000 restricted shares of Aequus, made to each of these executives in February 2011. The value of the Aequus shares subject to these awards was determined to be \$0.13 per share as of the grant date. Other than these shares and the related payment described in footnote 5(b) below, the executives did not receive any other compensation in 2011 for their services to Aequus.
- (5) 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	Executive	Life	401(k)	Other	Tax	Total (\$)
	Health Benefits(\$)	Insurance Premiums(\$)	Match (\$)	Personal Benefits\$(a)	Reimbursement\$(b)	
James A. Bianco, M.D.	169,593	28,060		89,365(c)		287,018
Louis A. Bianco	20,696	1,107	3,675	2,450(d)	5,000	32,928
Daniel G. Eramian	4,996			6,772(e)		11,768
Craig W. Philips	14,416		3,675	16,543(f)	5,000	39,634
Jack W. Singer, M.D.	36,683		3,675	3,749(g)		44,107

- (a) 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.
- (b) These amounts represent a payment by Aequus to the executive as partial reimbursement of his tax obligations in connection with the award by Aequus of restricted shares referred to in footnote (4) above.
- (c) This amount includes \$54,084 for family members' travel on commercial aircraft, \$5,000 for tax preparation fees, \$5,196 for health club dues, and \$25,085 for security expenses.
- (d) This amount includes \$1,761 for tax preparation fees and \$689 for security expenses.
- (e) This amount includes \$750 for tax preparation fees and \$6,022 for security expenses.
- (f) This amount includes \$3,200 for tax preparation fees, \$9,000 for automobile allowance and \$4,343 for security expenses.
- (g) This amount includes \$3,500 for tax preparation fees and \$249 for security expenses.

**Table of Contents****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 2011. 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.

**Description of Employment Agreements - Cash Compensation**

In March 2011, the Company entered into an employment agreement with Dr. Bianco that replaced his original employment agreement entered into in 2008. The employment agreement has a two-year term, with automatic one-year renewals unless either party gives notice that the term will not be extended. 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 that his annual bonus may be up to 125% of his base salary 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 disability insurance premiums and premiums for universal life insurance with a coverage amount of not less than \$5,000,000 (up to an aggregate annual limit for such premiums of \$50,000, 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.

**Table of Contents****Grants of Plan-Based Awards Fiscal 2011**

The following table presents information regarding the equity awards granted to the named executive officers in fiscal 2011.

Name/Award Type	Grant Date	Estimated Future Payouts Under Non-Equity Incentive Plan Awards			Estimated Future Payouts Under Equity Incentive Plan Awards			All Other Stock Awards: Number of Shares 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 (\$)
		Threshold (\$)	Target (\$)	Maximum (\$)	Threshold (#)	Target (#)	Maximum (#)				
James A. Bianco, M.D.											
CTI Restricted Stock	3/21/11							416,666			1,087,498
CTI Restricted Stock	11/29/11							1,685,626			1,803,620
Louis A. Bianco											
CTI Restricted Stock	3/21/11							41,666			108,748
CTI Restricted Stock	11/29/11							505,688			541,086
Aequus Restricted Stock	2/11/11							200,000			26,000
Daniel G. Eramian											
CTI Restricted Stock	3/21/11							41,666			108,748
CTI Restricted Stock	11/29/11							505,688			541,086
Craig W. Philips											
CTI Restricted Stock	3/21/11							41,666			108,748
CTI Restricted Stock	11/29/11							1,011,376			1,082,172
Aequus Restricted Stock	2/11/11							200,000			26,000
Jack W. Singer, M.D.											
CTI Restricted Stock	3/21/11							41,666			108,748
CTI Restricted Stock	11/29/11							505,688			541,086

Each of the awards reported in the above table represents a grant of restricted stock to the named executive officer. The vesting dates for these grants are reported in the footnotes to the Outstanding Equity Awards at 2011 Fiscal-Year End table below. Except for the restricted stock awards granted by Aequus to Messrs. Bianco and Philips, each of these awards was granted under, and is subject to, the terms of the Company's 2007 Equity Incentive Plan, or the 2007 Plan. The 2007 Plan is administered by the Compensation Committee. The Compensation Committee has authority to interpret the plan provisions and make all required determinations under the plan. Awards granted under the plan are generally only transferable to a beneficiary of a named executive officer upon his death or, in certain cases, to family members for tax or estate planning purposes.

Under the terms of the 2007 Plan, if there is a change in control of the Company, each named executive officer's outstanding awards granted under the plan will generally become fully vested and, in the case of options, exercisable, unless the Compensation Committee provides for the substitution, assumption, exchange or other continuation of the outstanding awards. Any options that become vested in connection with a change in control generally must be exercised prior to the change in control, or they will be cancelled in exchange for the right to receive a cash payment in connection with the change in control transaction. If the Compensation Committee provides for awards to be assumed or otherwise continue following the change in control, the award will become fully vested if the holder's employment is terminated by the successor corporation or one of its affiliates within 12 months following the change in control for any reason other than misconduct.

In addition, each named executive officer may be entitled to accelerated vesting of his outstanding equity-based awards upon certain terminations of his employment with the Company and/or a change in control of the Company. The terms of this accelerated vesting are described in this section and in the Potential Payments Upon a Termination or Change in Control section below.

**Table of Contents****Outstanding Equity Awards at Fiscal 2011 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, 2011, including the vesting dates for the portions of these awards that had not vested as of that date.

Name	Grant Date	Option Awards			Option Expiration Date	Stock Awards		Equity Incentive Plan Awards; or Payout Value of Unearned Shares, or Rights That Have Not Vested
		Number of Shares of Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)		Number of Shares of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)(1)	
<b>James A. Bianco, M.D.</b>								
CTI Option	7/30/2002	499		836.40	7/30/2012			
CTI Option	12/3/2002	790		2,278.80	12/3/2012			
CTI Option	12/11/2003	520		1,944.00	12/11/2013			
CTI Option	12/14/2005	1,041		566.40	12/14/2015			
CTI Option	1/18/2007	1,000		408.00	1/18/2017			
CTI Option	12/27/2007	1,666		113.40	12/27/2017			
CTI Restricted Stock	3/21/2011					208,333(2)	241,666	
CTI Restricted Stock	11/29/2011					1,685,626(3)	1,955,326	
<b>Louis A. Bianco</b>								
CTI Option	7/30/2002	116		836.40	7/30/2012			
CTI Option	12/3/2002	185		2,278.80	12/3/2012			
CTI Option	12/11/2003	247		1,944.00	12/11/2013			
CTI Option	7/14/2005	625		667.20	7/14/2015			
CTI Option	12/14/2005	500		566.40	12/14/2015			
CTI Option	6/22/2006	125		340.80	6/22/2016			
CTI Option	1/18/2007	291		408.00	1/18/2017			
CTI Option	12/27/2007	600		113.40	12/27/2017			
CTI Restricted Stock	3/21/2011					20,833(2)	24,166	
CTI Restricted Stock	11/29/2011					505,688(3)	586,598	
Aequus Restricted Stock	2/11/11					200,000(4)	26,000	
<b>Daniel G. Eramian</b>								
CTI Option	3/31/2006	395		458.40	3/31/2016			
CTI Option	6/22/2006	125		340.80	6/22/2016			
CTI Option	1/18/2007	250		408.00	1/18/2017			
CTI Option	12/27/2007	600		113.40	12/27/2017			
CTI Restricted Stock	3/21/2011					20,833(2)	24,166	
CTI Restricted Stock	11/29/2011					505,688(3)	586,598	
<b>Craig W. Philips</b>								
CTI Option	6/5/2008	2,500		34.80	6/5/2018			
CTI Restricted Stock	3/21/2011					20,833(2)	24,166	
CTI Restricted Stock	11/29/2011					1,011,376(3)	1,173,196	
Aequus Restricted Stock	2/11/11					200,000(4)	26,000	
<b>Jack W. Singer, M.D.</b>								
CTI Option	7/30/2002	127		836.40	7/30/2012			

Edgar Filing: CELL THERAPEUTICS INC - Form 10-K

CTI Option	12/3/2002	332	2,278.80	12/3/2012		
CTI Option	12/11/2003	312	1,944.00	12/11/2013		
CTI Option	7/14/2005	625	667.20	7/14/2015		
CTI Option	12/14/2005	500	566.40	12/14/2015		
CTI Option	6/22/2006	125	340.80	6/22/2016		
CTI Option	1/18/2007	291	408.00	1/18/2017		
CTI Option	12/27/2007	600	113.40	12/27/2017		
CTI Restricted Stock	3/21/2011				20,833(2)	24,166
CTI Restricted Stock	11/29/2011				505,688(3)	586,598

**Table of Contents**

- (1) The dollar amounts shown in these columns for awards granted by the Company are determined by multiplying the applicable number of shares or units by \$1.16 (the closing price of the Company's common stock on the last trading day of fiscal 2011) or, in the case of the shares granted by Aequus, by multiplying the applicable number of shares by \$0.13 (the fair market value of Aequus' common stock as of December 31, 2011).
- (2) These shares vest on March 21, 2012, subject to continued service with the Company.
- (3) These shares vest over 18 months, with one-third of the shares vesting on each of May 29, 2012, November 29, 2012 and May 29, 2013, subject to continued service with the Company.
- (4) These shares were granted to the executive by Aequus as described in footnote (5) to the Summary Compensation Table above and vest over four years, with one-fourth of the shares vesting on each of February 11, 2012, February 11, 2013, February 11, 2014 and February 11, 2015, subject to continued service with Aequus.

As noted in the Compensation Discussion and Analysis above, the Company granted equity awards to each of the named executive officers in December 2009 that would vest upon the Company's achievement of certain performance goals, subject to the goals being achieved by December 31, 2011. The 2009 awards are described in more detail in the Compensation Discussion and Analysis portion of the Company's Proxy Statement for its 2011 Annual Meeting of Shareholders. In general, the number of shares that the executive would have been entitled to receive upon achievement of a particular performance goal was stated as a percentage of the Company's total number of outstanding shares on the date the goal was achieved. These 2009 awards expired on December 31, 2011 as the goals were not achieved, and, accordingly, these awards are not reflected in the table above. Based on the Company's outstanding shares as of December 31, 2011, the number of shares subject to the awards forfeited by the named executive officers on that date (assuming the payouts that would have occurred had all of the applicable performance goals been achieved on that date) were as follows: Dr. Bianco 7,198,473 shares; Mr. Bianco 2,921,119 shares; Mr. Eramian 2,159,542 shares; Mr. Philips 4,319,084 shares; and Dr. Singer 2,921,119 shares.

**Option Exercises and Stock Vested Fiscal Year 2011**

The following table presents information regarding the vesting during fiscal year 2011 of stock awards granted by the Company to the named executive officers. No executive officer exercised any stock options granted by the Company during fiscal 2011.

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.			369,252	579,395
Louis A. Bianco			69,108	131,317
Daniel G. Eramian			69,108	131,317
Craig W. Philips			118,772	244,667
Jack W. Singer, M.D.			69,108	131,317

- (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. In addition, as noted in the Compensation Discussion and Analysis above, the 2012-2014 Performance Awards granted to the named executive officers, which were effective as of January 3, 2012, would generally vest if a change in control of the Company occurs (subject to certain limitations with respect to the Market Cap Goal as described above).

*James A. Bianco, M.D.* As described above, Dr. Bianco entered into a new employment agreement with the Company in March 2011. Pursuant to his employment agreement, 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





**Table of Contents**

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 and (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. 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) and (iii) 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 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. As noted above, Dr. Bianco is not entitled to any tax gross-up payments from the Company under his new employment agreement.

*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, and (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. 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.

**Table of Contents**

following the severance date. 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. Although these severance agreements provide for the executive to be reimbursed for any excise tax imposed under Section 280G of the Internal Revenue Code on these benefits, each of these executives has entered into an agreement with the Company, effective January 3, 2012, that provides he will not be entitled to any such tax reimbursement. Each executive's agreement is included in the award agreement evidencing the executive's 2012-2014 Performance Award and applies to taxes imposed under Section 280G on any payments or benefits received from the Company, whether the payment is made pursuant to the executive's 2012-2014 Performance Award or another Company plan or agreement.

*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, 2011. 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.

*Severance Benefits (Outside of Change of Control)*

Name	Cash	Continuation	Equity	Total(\$)
	Severance (\$)(1)	of Health/Life Benefits(\$)(2)	Acceleration (\$)(3)	
James A. Bianco, M.D.	1,300,000	124,269	10,547,221	11,971,490
Louis A. Bianco	700,700	52,772	4,025,263	4,778,735
Daniel G. Eramian	653,625	42,614	3,115,833	3,812,072
Craig W. Philips	603,000	51,111(4)	5,822,935	6,477,046
Jack W. Singer, M.D.	671,500	50,765	3,999,263	4,721,528

- (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, 2011). 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 \$1.16 (the closing price of the Company's common stock on the last trading day of fiscal 2011) exceeds the exercise price of the option by the number of shares subject to the accelerated portion of the option. For restricted stock awards, this value is calculated by multiplying \$1.16 (or, in the case of awards granted by Aequus, \$0.13, which Aequus determined to be the fair market value of Aequus common stock as of December 31, 2011) by the number of shares subject to the accelerated portion of the award. 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.

**Table of Contents**

- (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	Continuation	Equity	Section	Total(\$)
	Severance	of	Acceleration	280G	
	(\$)(1)	Health	(\$)(3)	Gross-Up	
		Benefits(\$)(2)		(\$)(4)	
James A. Bianco, M.D.	1,883,146	124,269	8,731,954		10,739,369
Louis A. Bianco	700,700	52,772	3,287,054	1,086,717	5,127,243
Daniel G. Eramian	653,625	42,614	2,571,253		3,267,492
Craig W. Philips	603,000	51,111	5,144,339		5,798,450
Jack W. Singer, M.D.	671,500	50,765	3,261,054	1,061,176	5,044,495

- (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.
- (2) See footnote (2) to the table above.
- (3) See footnote (3) to the table above. Except as expressly provided under the terms of the award, Dr. Bianco would generally be entitled to full acceleration of his outstanding equity awards on a change in control without regard to whether his employment terminates, and each of the other executives would generally be entitled to full acceleration of his outstanding equity awards on a termination of his employment in the circumstances described above. As described in the Compensation Discussion and Analysis included in the Company's 2011 proxy statement, the long-term incentive awards granted to the named executive officers in December 2009 would generally vest on a change in control, except that the vesting of a portion of these awards was contingent on appreciation in the Company's stock price and, if a change in control of the Company occurred, would be determined based on the Company's stock price at the time of the change in control (notwithstanding any acceleration provisions of the executive's employment or severance agreement). If a change in control had occurred on December 31, 2011, the stock price goal under the awards would not have been met, and the portion of the award related to stock price appreciation would have been cancelled on that date. Accordingly, 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.
- (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, Dr. Bianco is not entitled to a Section 280G gross-up payment pursuant to his March 2011 employment agreement. Because the agreements for the 2012-2014 Performance Awards did not become effective until January 2012, each of the other named executive officers would have been entitled to a Section 280G gross-up payment as of December 31, 2011 under the performance award agreements they entered into with the Company in December 2009 (which expired as of December 31, 2011).

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

The following table presents information regarding the compensation paid for fiscal year 2011 to members of our board of directors who are not also employees of the Company, or the non-employee directors. The compensation paid to Dr. Bianco and Dr. Singer, who are also employed by the Company, for fiscal year 2011 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	107,500	258,777	4,397				370,474
Vartan Gregorian, Ph.D.	99,750	258,777	4,397				362,724
Richard L. Love	100,250	258,777	4,397				363,224
Mary O. Mundinger, DrPH	97,500	258,777	4,397				360,474
Phillip M. Nudelman, Ph.D.	146,500	358,778	4,397				509,675
Frederick W. Telling, Ph.D.(4)	118,750	271,577	4,397			2,500	397,224
Reed V. Tuckson, M.D. (5)	5,500	221,842	8,929				236,271

- 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 2011 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 14 (Share-Based Compensation) to the Company's Consolidated Financial Statements, included as part of this Form 10-K.
- The table below presents the number of CTI shares subject to outstanding and unexercised option awards and the number of CTI shares subject to unvested stock awards held by each of the Company's non-employee directors as of December 31, 2011.

Director	Number of Shares Subject to Outstanding Options as of 12/31/2011	Number of Unvested Restricted Shares/ Units as of 12/31/2011
	John H. Bauer	15,899
Vartan Gregorian, Ph.D.	16,022	13,749
Richard L. Love	15,900	13,749
Mary O. Mundinger, DrPH	16,059	13,749
Phillip M. Nudelman, Ph.D.	16,096	13,749
Frederick W. Telling, Ph.D.	15,849	13,749
Reed V. Tuckson, M.D.	11,000	21,333

- On March 21, 2011, each of the non-employee directors (other than Dr. Tuckson) received a grant of 20,833 restricted shares, with a grant-date fair value of \$54,375. In connection with his appointment to our board of directors, Dr. Tuckson was granted on September 22, 2011, an award of 18,000 restricted shares, with a grant-date fair value of \$17,640, and an option to purchase 6,000 shares, with a grant-date fair value of \$4,532. On November 11, 2011, each of the non-employee directors was granted an award of 3,333 restricted

Edgar Filing: CELL THERAPEUTICS INC - Form 10-K

shares and an option to purchase 5,000 shares pursuant to the Company's non-employee director compensation program described below. Each of these restricted stock awards had a grant-date fair value of

**Table of Contents**

\$3,800, and each of these options had a grant-date fair value of \$4,397. On November 29, 2011, each of the non-employee directors (other than Dr. Nudelman) was granted 187,292 fully-vested shares with a grant-date fair value of \$200,402, and Dr. Nudelman was granted 280,938 fully-vested shares with a grant-date fair value of \$300,604. See footnote (1) above for the assumptions used to value each of these awards granted to the non-employee directors in 2011.

- (4) For Dr. Telling, the Fees Earned or Paid in Cash column of the table above includes \$2,500 fees for his service on the board of directors of Aequus; the Stock Awards column includes \$13,000, which represents the grant date fair value (as determined under generally accepted accounting principles) of an award of 100,000 restricted shares of Aequus granted to him in February 2011; and the amount in the All Other Compensation column represents a payment by Aequus as partial reimbursement of his tax obligations in connection with this award. Of the 100,000 restricted shares of Aequus granted to Dr. Telling, 58,333 shares were unvested as of December 31, 2011.

Dr. Telling did not receive any other compensation in 2011 for his services to Aequus.

- (5) Dr. Tuckson was appointed to our board of directors, effective September 22, 2011.

**Non-Employee Director Compensation**

*Equity Grants.* Under the Company's Revised Director Compensation Policy, the Company's non-employee directors receive equity compensation as follows: (i) each new non-employee director is granted 18,000 shares of restricted stock and options to purchase 6,000 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 of shareholders, each continuing non-employee director is granted an award of 3,333 shares of restricted stock and an option to purchase 5,000 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 of shareholders 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. The Company's non-employee directors are also eligible to receive discretionary grants of equity awards under the 2007 Equity Plan from time to time.

As described in the 2012-2014 Performance Awards section of the Compensation Discussion and Analysis above, the Compensation Committee had previously granted equity awards in 2009 to each of the named executive officers that would vest if the Company achieved certain performance goals by December 31, 2011. At the same time, our board of directors approved grants of similar awards to each of the non-employee directors (other than Dr. Tuckson who was not on our board of directors at that time). The 2009 awards granted to the executives and directors expired on December 31, 2011 as the goals were not achieved. As described above, the Compensation Committee approved the grants of the 2012-2014 Performance Awards to the named executive officers that will be payable in fully vested shares of Company common stock if the Company achieves certain financial and operational performance goals by December 31, 2014. In connection with the expiration of the 2009 awards, our board of directors also approved the grant, effective January 3, 2012, to each non-employee director of a 2012-2014 Performance Award that will be payable in fully vested shares of the Company's common stock upon the achievement of the performance goals identified for the named executive officers' awards in the Compensation Discussion and Analysis above, subject to the goal's being achieved before December 31, 2014 and the director's continued service with the Company. As with the awards granted to the executives, a portion of each non-employee director's 2012-2014 Performance Award was granted in the form of restricted stock. The number of shares that will be payable in respect of each award will be determined based on the applicable payout percentage assigned to that particular goal and the number of the Company's issued and outstanding shares at the time the goal is achieved, subject to reduction on a share-for-share basis for any shares of restricted stock that vest in connection with the achievement of that particular goal and subject also to the applicable share limits of the Company's equity incentive plan.

**Table of Contents**

The award percentages corresponding to the various performance goals for each of the non-employee directors are set forth in the following table:

Name	Performance Goals and Applicable Award Percentages							
	Pix MAA Approval	Pix NDA Approval	Opaxio NDA Approval	Market Cap Goal	\$50M Sales Goal	\$100M Sales Goal	Cash Flow Break Even	EPS Goal
Phillip M. Nudelman, Ph.D.	0.068%	0.113%	0.013%	0.1125%	0.045%	0.09%	0.045%	0.018%
All Other Non-Employee Directors	0.045%	0.075%	0.008%	0.075%	0.03%	0.06%	0.03%	0.013%

As noted above, the 2012-2014 Performance Awards became effective January 3, 2012. Accordingly, these awards are considered part of each director's compensation for 2012 under SEC rules and are therefore not reflected in Non-Employee Director Compensation Table above (as the table reflects compensation for fiscal year 2011).

*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:

	Meeting Fees (\$)		
	Annual Cash Retainer (\$)	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**

The following table provides certain information regarding beneficial ownership of common stock as of February 16, 2012, by (1) each shareholder known by the Company to be the beneficial owner of more than 5% of the outstanding shares of the Company's common stock, (2) each of the directors of the Company, (3) each of the principal executive officer, or the PEO, principal financial officer, or the PFO, and the three most highly compensated executive officers of the Company other than the PEO and PFO who were still serving as executive officers as of December 31, 2011, 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)	6,157,183	5,516	2.72%
John H. Bauer**(5)	873,409	10,899	*
Louis A. Bianco(6)	2,461,276	2,689	1.09%
Daniel G. Eramian(7)	1,973,309	1,370	*
Vartan Gregorian, Ph.D.**(5)	884,386	11,022	*
Richard L. Love**(5)	943,904	10,900	*
Mary O. Munding, DrPH**(5)	884,409	11,059	*
Phillip M. Nudelman, Ph.D.**(8)	1,215,329	11,096	*
Craig W. Philips(9)	3,990,934	2,500	1.76%
Jack W. Singer, M.D.**(6)	2,500,878	2,912	1.10%
Frederick W. Telling, Ph.D.**(5)	837,209	10,849	*
Reed V. Tuckson, M.D.**(10)	724,985		*
All directors and executive officers as a group (12 persons)(11)	23,447,211	80,812	10.34%

\* 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 226,585,253 shares of our common stock outstanding as of February 16, 2012. 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 sixty (60) days of February 16, 2012, 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 sixty (60) days after February 16, 2012. These shares are also included in the column titled "Number of Shares Beneficially Owned."

(4) Number of shares beneficially owned includes 5,933,802 shares of unvested restricted stock, 4,039,843 of which have contingent vesting terms and will vest based on the achievement of certain performance goals as described in footnote (12) below. Includes 3 shares held by Dr. Bianco's wife.

(5) Number of shares beneficially owned includes 530,109 shares of unvested restricted stock, 516,360 of which have contingent vesting terms and will vest based on the achievement of certain performance goals as described in footnote (12) below.

(6) Number of shares beneficially owned includes 2,165,935 shares of unvested restricted stock, 1,639,414 of which have contingent vesting terms and will vest based on the achievement of certain performance goals as described in footnote (12) below. Includes 186 shares held by Mr. Bianco in trust for his children.

**Table of Contents**

- (7) Number of share beneficially owned includes 1,738,474 shares of unvested restricted stock, 1,211,953 of which have contingent vesting terms and will vest based on the achievement of certain performance goals as described in footnote (12) below.
- (8) Number of shares beneficially owned includes 790,160 shares of unvested restricted stock, 776,411 of which have contingent vesting terms and will vest based on the achievement of certain performance goals as described in footnote (12) below.
- (9) Number of shares beneficially owned includes 3,456,115 shares of unvested restricted stock, 2,423,906 of which have contingent vesting terms and will vest based on the achievement of certain performance goals as described in footnote (12) below.
- (10) Number of shares beneficially owned includes 537,693 shares of restricted stock, 516,360 of which have contingent vesting terms and will vest based on the achievement of certain performance goals as described in footnote (12) below.
- (11) Number of shares beneficially owned includes 19,438,659 shares of unvested restricted stock for all directors and executive officers as a group, of which 14,829,101 shares are contingent and would vest as described in the above footnotes.
- (12) Shares beneficially owned include unvested restricted stock which, as described in the Compensation Discussion and Analysis in Item 11 above, have contingent vesting terms based on the achievement of the following six performance goals, subject to the goal s being achieved before December 31, 2014 and the individual s continued employment or service with us: Pix MAA Approval, Pix NDA Approval, Opaxio NDA Approval, Market Cap Goal, \$50M Sales Goal and \$100M Sales Goal. In the event that a particular performance goal is achieved prior to December 31, 2014, the following shares of restricted stock would vest as of the date of certification by the Compensation Committee of the achievement of such goal:

Name	Number of Shares of Restricted Stock Granted					
	Pix MAA Approval	Pix NDA Approval	Opaxio NDA Approval	Market Cap Goal	\$50M Sales Goal	\$100M Sales Goal
James A. Bianco, M.D.	280,938	842,813	158,707	1,404,689	561,875	790,821
John H. Bauer	84,281	140,469	15,871	140,469	56,188	79,082
Louis A. Bianco	114,248	340,871	64,276	571,240	228,496	320,283
Daniel G. Eramian	84,281	252,844	47,612	421,407	168,563	237,246
Vartan Gregorian, Ph.D.	84,281	140,469	15,871	140,469	56,188	79,082
Richard L. Love	84,281	140,469	15,871	140,469	56,188	79,082
Mary O. Munding, DrPH.	84,281	140,469	15,871	140,469	56,188	79,082
Phillip M. Nudelman, Ph.D.	127,358	211,640	23,806	210,703	84,281	118,623
Craig W. Philips	168,563	505,688	95,224	842,813	337,125	474,493
Jack W. Singer, M.D.	114,248	340,871	64,276	571,240	228,496	320,283
Frederick W. Telling, Ph.D.	84,281	140,469	15,871	140,469	56,188	79,082
Reed V. Tuckson	84,281	140,469	15,871	140,469	56,188	79,082

**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, 2011, 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 Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights	(b) Weighted Average Exercise Price of Outstanding Options, Warrants, and Rights	(c) Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))
Plans Approved by Shareholders	781,626(1)	\$ 18.40	17,903,782(2)
Plan Not Approved by Shareholders			
Totals	781,626	\$ 18.40	17,903,782

- (1) Of these shares, 779,311 were subject to options then outstanding under the 2007 Equity Plan, and 2,315 were subject to options then outstanding under the 1994 Equity Incentive Plan.
- (2) Of these shares, 17,677,808 shares were available for issuance under the 2007 Equity Plan, and 225,974 were available for issuance under the ESPP. The Company's authority to grant new awards under the 1994 Equity Incentive Plan has terminated. As described in the Compensation Discussion and Analysis above, the Company granted long-term performance awards in December 2009 that were subject to forfeiture on December 31, 2011 to the extent that the performance goals applicable to the awards were not achieved. In connection with the termination of these awards, the Company granted new long-term performance awards that became effective on January 3, 2012 and relate to performance goals established for the three-year period ending on December 31, 2014. Column (c) is presented after giving effect to the forfeiture of the performance awards granted in December 2009 and without taking into account the new performance awards that became effective January 3, 2012.

**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 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 67% as of December 31, 2011. 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 our demand,

or upon other triggering events. The

---

**Table of Contents**

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 \$0.6 million, \$0.5 million and \$0.6 million during the years ended December 31, 2011, 2010 and 2009, 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 4.8% of the equity in Aequus as of December 31, 2011, and are members of the board of directors of Aequus. Additionally, Frederick W. Telling, Ph.D., a member of our board of directors, owns approximately 1.4% of Aequus as of December 31, 2011, which includes the restricted shares described in the next sentence, and is also a member of the board of directors of Aequus. In 2011, Dr. Telling was granted an award of 100,000 restricted shares of Aequus common stock with a grant-date fair value (as determined under generally accepted accounting principles) of \$13,000 and payment of \$2,500 was made by Aequus as partial reimbursement of Dr. Telling's tax obligations in connection with this award. In addition, in 2011, Dr. Telling received \$2,500 in fees for his service on the board of directors of Aequus. Of the 100,000 restricted shares of Aequus granted to Dr. Telling, 58,333 shares were unvested as of December 31, 2011. Dr. Telling did not receive any other compensation in 2011 for his services to Aequus. Our Executive Vice President, Finance and Administration, Louis A. Bianco and our President, Craig W. Philips provide certain consulting services to Aequus, including financial guidance business development and strategic planning services, for which they each received a grant of restricted shares of Aequus common stock during 2011 with a grant date fair value of \$26,000. The size of these grants was determined by the board of directors of Aequus in its discretion, and each of these grants is subject to a four-year vesting schedule.

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 exchange, DiaKine issued to us an unregistered convertible subordinated note due February 2013 in the amount of \$206,000. The note was 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 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

---

**Table of Contents**

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.

On February 29, 2012, DiaKine and its shareholders, including us, entered into a Share Exchange Agreement pursuant to which DiaKine will be acquired by Islet Sciences, Inc. The acquisition is expected to close by March 9, 2012. In connection with the acquisition, the Company (i) intends to rescind the termination of the license agreement at the closing of the acquisition and (ii) agreed to convert the note into equity of DiaKine, which will be exchanged (along with our other equity interest in DiaKine) at the closing of the acquisition for Series C Preferred Shares of Islet Sciences, Inc.

Phillip M. Nudelman serves on the board of directors of OptiStor Technologies, Inc., or OptiStor. We made payments of approximately \$140,000 to OptiStor for hardware and software upgrades, maintenance and support in 2011.

Corey Masten-Legge, a stepson of James A. Bianco, M.D., is employed as a corporate attorney in our legal department. In 2011, Mr. Masten-Legge received approximately \$191,000 in base salary and bonus, \$2,871 in 401k Plan matching funds, a grant of 39,000 shares of restricted stock and a grant of stock options for 10,000 shares, with grant-date fair values (based on the assumptions used to value equity awards in our financial reporting) of \$43,290 and \$7,738, respectively.

**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 OptiStor and was granted stock options of OptiStor when he joined the board of directors in 2002. However, Dr. Nudelman is not a controlling shareholder or employee of OptiStor.

Dr. Nudelman's son, Mark Nudelman, serves as the President and Chief Executive Officer of the Hope Heart Institute. We made a charitable donation to the Hope Heart Institute in 2011; 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.

**Table of Contents**

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. Mundinger, DrPH, Phillip M. Nudelman, Ph.D., Frederick W. Telling, Ph.D. and Reed V. Tuckson, M.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.

Other than as described above, in 2011, 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	2011	2010
Audit Fees (1)	\$ 590,000	\$ 450,000
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.

**Table of Contents****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' Equity (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.
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., Saguro 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.



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.

**Table of Contents**

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
3.2	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series F Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on February 9, 2009.
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; Designation of Preferences, Rights and Limitations of Series 1 Preferred Stock.	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; Designation of Preferences, Rights and Limitations of Series 2 Preferred Stock.	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; Certificate of Designation, Preferences and Rights of Series ZZ Junior Participating Cumulative Preferred Stock.	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; Designation of Preferences, Rights and Limitations of Series 3 Preferred Stock.	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; Designation of Preferences, Rights and Limitations of Series 4 Preferred Stock.	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; Designation of Preferences, Rights and Limitations of Series 5 Preferred Stock.	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; Designation of Preferences, Rights and Limitations of Series 6 Preferred Stock.	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; Designation of Preferences, Rights and Limitations of Series 7 Preferred Stock.	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; Designation of Preferences, Rights and Limitations of Series 8 Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on January 18, 2011.

**Table of Contents**

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
3.14	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 9 Preferred Stock.	Incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed on January 18, 2011.
3.15	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 10 Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on February 24, 2011.
3.16	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 11 Preferred Stock.	Incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed on February 24, 2011.
3.17	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 12 Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on May 2, 2011.
3.18	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 18, 2011.
3.19	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 June 17, 2011.
3.20	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 13 Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on July 6, 2011.
3.21	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 November 15, 2011.
3.22	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 14 Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on December 14, 2011.
3.23	Second Amended and Restated Bylaws.	Incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed on February 22, 2010.
4.1	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.
4.2	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.
4.3	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.

**Table of Contents**

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
4.4	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.
4.5	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.
4.6	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.
4.7	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.
4.8	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.
4.9	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.
4.10	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.
4.11	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.
4.12	Form of Common Stock Purchase Warrant, dated February 17, 2011.	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed on February 24, 2011.
4.13	Form of Common Stock Purchase Warrant, dated May 3, 2011.	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed on May 2, 2011.
4.14	Form of Common Stock Purchase Warrant, dated July 5, 2011.	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed on July 6, 2011.
4.15	Form of Common Stock Purchase Warrant, dated December 13, 2011.	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed on December 14, 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.

**Table of Contents**

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
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.
10.4	Office Lease, dated as of January 27, 2012, by and between Cell Therapeutics, Inc. and Selig Holdings Company LLC.	Filed herewith.
10.5*	Employment Agreement between Cell Therapeutics, Inc. and James A. Bianco, dated as of March 10, 2011.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on March 15, 2011.
10.6*	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.
10.7*	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.
10.8*	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.
10.9*	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.
10.10*	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.
10.11*	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.
10.12*	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.
10.13*	Form of Italian Indemnity Agreement	Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K, filed on December 17, 2009.
10.14*	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 (File No. 333-97015).

**Table of Contents**

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
10.15*	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 November 15, 2011.
10.16*	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.
10.17*	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.
10.18*	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.
10.19*	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 (File No. 333-112791).
10.20*	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 10.20 to the Registrant's Annual Report on Form 10-K, filed on March 4, 2005.
10.21*	Revised Director Compensation Policy.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on September 26, 2011.
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 Equity/Long-Term Incentive Award Agreement for Employees and Directors, dated November 30, 2010.	Incorporated by reference to Exhibit 10.24 to the Registrant's Annual Report on Form 10-K, filed on February 16, 2011.
10.25*	Form of Equity/Long-Term Incentive 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 Equity/Long-Term Incentive 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*	Form of 2007 Equity Incentive Plan Restricted Stock Award Agreement for Employees.	Incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q, filed on April 26, 2011.
10.28*	Form of 2007 Equity Incentive Plan Restricted Stock Award Agreement for Directors.	Incorporated by reference to Exhibit 10.7 to the Registrant's Quarterly Report on Form 10-Q, filed on April 26, 2011.

**Table of Contents**

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
10.29*	2007 Equity Incentive Plan Restricted Stock Award Agreement, dated April 8, 2011, by and between the Registrant and James Bianco.	Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q, filed on July 28, 2011.
10.30*	Amendment to Restricted Stock Award Agreement, dated September 20, 2011, by and between the Registrant and James Bianco.	Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q, filed on October 25, 2011.
10.31	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.
10.32	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.
10.33	License and Co-Development, dated September 15, 2006, by and among the Registrant, Cell Therapeutics Europe S.r.l. and Novartis International Pharmaceutical Ltd.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on September 18, 2006.
10.34	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.
10.35	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.
10.36	Co-Development and License Agreement, dated March 11, 2011, by and between Chroma Therapeutics Ltd. and the Registrant.	Incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q, filed on April 26, 2011.
10.37	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.
10.38	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.
10.39	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.

**Table of Contents**

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
10.40	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.
10.41	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.
10.42	Exchange Agreement, dated April 7, 2009, between the Registrant and CD Investment Partners Ltd.	Incorporated by reference to the Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed on April 17, 2009.
10.43	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.
10.44	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.
10.45	Form of Securities Purchase Agreement, dated May 23, 2010.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on May 27, 2010.
10.46	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.
10.47	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.
10.48	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.
10.49	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.
10.50	Form of Securities Purchase Agreement, dated February 17, 2011.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on February 24, 2011.
10.51	Form of Securities Purchase Agreement, dated April 27, 2011.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on May 2, 2011.
10.52	Form of Securities Purchase Agreement, dated June 29, 2011.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on July 6, 2011.
10.53	Form of Securities Purchase Agreement, dated December 8, 2011.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on December 14, 2011.
10.54	Stipulation of Settlement, dated February 13, 2012.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on February 15, 2012.



**Table of Contents**

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
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.
101.INS	XBRL Instance	Filed herewith.
101.SCH	XBRL Taxonomy Extension Schema	Filed herewith.
101.CAL	XBRL Taxonomy Extension Calculation	Filed herewith.
101.DEF	XBRL Taxonomy Extension Definition	Filed herewith.
101.LAB	XBRL Taxonomy Extension Labels	Filed herewith.
101.PRE	XBRL Taxonomy Extension Presentation	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 March 8, 2012.

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.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Phillip M. Nudelman	Chairman of the Board and Director	March 8, 2012
<b>Phillip M. Nudelman, Ph.D.</b>		
/s/ James A. Bianco	Chief Executive Officer and Director (Principal Executive Officer)	March 8, 2012
<b>James A. Bianco, M.D.</b>		
/s/ Louis A. Bianco	Executive Vice President, Finance and Administration (Principal Financial Officer and Principal Accounting Officer)	March 8, 2012
<b>Louis A. Bianco</b>		
/s/ John H. Bauer	Director	March 8, 2012
<b>John H. Bauer</b>		
/s/ Vartan Gregorian	Director	March 8, 2012
<b>Vartan Gregorian, Ph.D.</b>		
/s/ Richard L. Love	Director	March 8, 2012
<b>Richard Love</b>		
/s/ Mary O. Munding	Director	March 8, 2012
<b>Mary O. Munding, DrPH</b>		
/s/ Jack W. Singer	Director	March 8, 2012
<b>Jack W. Singer, M.D.</b>		

Edgar Filing: CELL THERAPEUTICS INC - Form 10-K

/s/ Frederick W. Telling

Director

March 8, 2012

**Frederick Telling, Ph.D.**

/s/ Reed V. Tuckson.

Director

March 8, 2012

**Reed V. Tuckson, M.D.**

161