

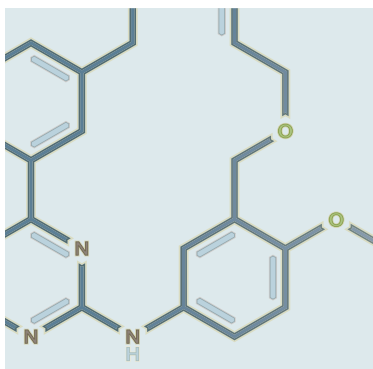
## EMERGE

biopharmaceutical  
company with a marketed  
oncology drug



late-stage pipeline that  
we believe addresses  
patient unmet medical  
needs which will  
promote and build  
shareholder value

## EXPAND



## EVOLVE

potential to become  
a fully-integrated,  
sustainable oncology  
company





treatment option among physicians in the countries where PIXUVRI is currently available. As we navigate the reimbursement process in each country, we are working with reimbursement regulators to obtain a successful outcome for patients.

During 2013, we plan to extend the availability of PIXUVRI through potential partnership(s) for market expansion outside the E.U. and the U.S.

### Dear Fellow Stockholders,

2012 was a significant year for CTI, as we achieved an important corporate milestone by obtaining conditional marketing authorization\* for PIXUVRI® (pixantrone) in the European Union (E.U.) as the first therapy for the treatment of adult patients with multiply relapsed or refractory aggressive B-cell non-Hodgkin lymphoma (NHL). We believe the approval was a transformative event for CTI, as it marked our emergence as a commercial biopharmaceutical company focused on hematology/oncology. More importantly, for patients in the E.U. with aggressive NHL and their healthcare providers, PIXUVRI provides hope and offers a new treatment standard. Prior to PIXUVRI, there were limited options for patients; namely, palliative care or clinical trials.

Although it is early in the launch, we are pleased with the interest in PIXUVRI by healthcare providers and key lymphoma opinion leaders. We currently are focused on educating physicians on the unmet medical need and building brand awareness for PIXUVRI as a

### Pacritinib—Expanded Pipeline with Strategic Acquisition

In June 2012, we expanded our pipeline with the acquisition of pacritinib, an oral, once-daily JAK2/FLT3 inhibitor being developed for the treatment of patients with myelofibrosis. Pacritinib is focused on a commercially validated target. We believe pacritinib could offer the same symptom management seen with agents that target this pathway while avoiding certain serious treatment-related side effects, such as thrombocytopenia.

In Phase 2 studies, pacritinib demonstrated the ability to reduce the symptoms of patients with myelofibrosis and did not appear to induce a clinically-relevant degree of treatment-emergent thrombocytopenia. In myelofibrosis, myelosuppression, particularly thrombocytopenia—a relative decrease of platelets in blood—is both a consequence of the disease and has emerged as a limiting treatment-related side effect of JAK1/JAK2 inhibitors. As the myelofibrosis progresses and platelet production

## 2012 SELECTED ACCOMPLISHMENTS

- European Commission granted conditional marketing authorization for PIXUVRI® (pixantrone) as a monotherapy for the treatment of patients with multiply relapsed or refractory aggressive B-cell non-Hodgkin lymphoma (NHL)
- PIXUVRI commercially available in 8 “free market access” countries in the European Union
- Acquired pacritinib, an oral JAK2/FLT3 inhibitor
- Initiated Phase 3 trial of pacritinib, known as PERSIST-1
- Received U.S. orphan drug status for Opaxio™ for newly-diagnosed glioblastoma multiforme
- Initiated investigator-sponsored trials for tosedostat in AML/MDS
- Completed \$60mm underwritten offering

\*The benefit of PIXUVRI treatment has not been established in patients when used as fifth line or greater chemotherapy in patients who are refractory to last therapy.

decreases, thrombocytopenia develops, identifying a higher-risk population than patients with myelofibrosis who have a normal platelet count.

Based on the safety profile seen in Phase 2 studies, we believe pacritinib could offer a significant advantage over the currently approved therapy in this population. In January 2013, we initiated the first of two Phase 3 clinical trials evaluating pacritinib for patients with myelofibrosis. A second Phase 3 trial in a subgroup of patients with myelofibrosis that are at a higher risk of developing thrombocytopenia, due to low blood platelet counts, is planned to begin in the second half of 2013.

In addition to myelofibrosis, we have encouraging clinical data in lymphoma and preclinical data in FLT3 resistant AML. From an intellectual property perspective, pacritinib has patent protection through 2026 and orphan drug designation in both the U.S. and Europe for myelofibrosis. We believe the acquisition of pacritinib was an excellent strategic fit for CTI, as we continue to expand our product pipeline.

### Evolve and Grow CTI

We believe CTI has the potential to become a sustainable, fully integrated oncology company. We are focused on growing sales of PIXUVRI with a positive net product contribution from PIXUVRI commercial operations. We believe pacritinib is an attractive asset, and we are in the process of looking

for an ex-U.S. partner to help expand and propel the clinical development program. At the end of the day, our intent is to evaluate those partnerships that we believe are in the best interest of our company, patients and shareholders.

This is clearly an exciting time in CTI's corporate evolution. We have an opportunity to serve patients, their caregivers, and to ensure rapid and widespread access to new, less toxic therapies that will make a difference. We take this responsibility seriously, and are committed to working diligently to make this happen.

With a prioritized product development and commercialization plan for PIXUVRI and worldwide rights to pacritinib for all indications, we believe we have established a strong foundation for continued progress.

The path ahead, much like the path we took to get here, cannot be chartered alone. We would like to thank everyone involved in bringing PIXUVRI to market in the E.U.—our dedicated and passionate employees; all of the patients who have participated in our clinical trials; our collaborators, investigators, physicians and nurses; as well as our stockholders—who support the company and share in our mission to make cancer more treatable.



**James A. Bianco**  
President and CEO  
and Shareholder

Our Mission: To acquire, develop and bring to market less toxic, more effective therapies to treat cancer.

We currently are prioritizing our resources on the commercialization of PIXUVRI® (pixantrone) in patients with aggressive B-cell NHL, and the evaluation of pacritinib, our JAK2/FLT3 inhibitor, in patients with myelofibrosis and other blood-related cancers.

## EMERGE



### PIXUVRI® (Pixantrone)

In May 2012, the European Commission granted conditional marketing authorization\* for PIXUVRI as the first pharmaceutical product for the treatment of adult patients with aggressive non-Hodgkin B-cell lymphomas (NHL) who have failed two or three prior lines of therapy. This approval was based on the results from our pivotal Phase 3 clinical trial known as EXTEND or PIX-301. In the fourth quarter of 2012, we initiated PIXUVRI commercial availability in eight countries. We began to establish a European commercial operation on a country-by-country basis in order to begin commercial sales of PIXUVRI in the E.U. in January 2013. Our focus in 2013 is to increase use and adoption of PIXUVRI in countries in the European Union where we have market access pending the completion of the reimbursement process. In connection with the approval and in agreement with the European Commission, we are conducting a post-marketing commitment trial, known as the PIX-R or PIX-306 study. This trial is intended to support the conversion of our E.U. conditional approval to a full approval.



### About Aggressive NHL

NHL is caused by the abnormal production of lymphocytes, which are cells key to the functioning of the immune system and can be broadly classified into two main forms, each with many subtypes—aggressive NHL is a rapidly growing form of the disease that moves into advanced stages much faster than indolent NHL, which progresses more slowly. Aggressive NHL is one of the more common types of NHL and accounts for about 60% of all NHL cases. Patients with aggressive B-cell NHL who have failed initial treatment with anthracyclines typically go on to receive second-line treatment consisting of intensive non-anthracycline based salvage therapy, with a small percentage going on to stem cell transplantation. Literature shows a majority of these patients will relapse after second-line therapy. Prior to PIXUVRI, there were limited options for patients; namely, palliative care or clinical trials.

\*The benefit of PIXUVRI treatment has not been established in patients when used as fifth line or greater chemotherapy in patients who are refractory to last therapy. PIXUVRI is available in the E.U. through Named Patient Programs in those countries where it is not available commercially. PIXUVRI does not have marketing approval in the United States.

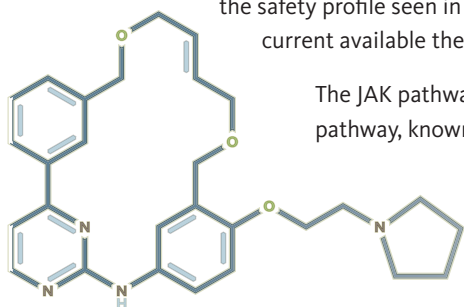
# EXPAND



## Pacritinib

In June 2012, we expanded our late-stage pipeline of product candidates with the acquisition of pacritinib, an oral, once-daily JAK2/FLT3 inhibitor that demonstrated a meaningful clinical benefit and good tolerability in myelofibrosis patients in Phase 2 clinical trials without treatment-emergent myelosuppression seen with other agents in this class.

In January 2013, we initiated the first of two planned Phase 3 clinical trials in patients with myelofibrosis, and anticipate fully enrolling the trial within 12 to 14 months. We plan to initiate a second Phase 3 trial in a subgroup of patients with myelofibrosis that are at higher risk of thrombocytopenia due to low blood platelet counts. Based on the safety profile seen in Phase 2 studies, we believe pacritinib could offer a significant advantage over current available therapy in this population.



The JAK pathway is important in many biological processes and one component of this pathway, known as JAK2, is implicated in numerous blood cancers, such as myeloproliferative neoplasms, leukemia and lymphoma. JAK2 inhibitors have shown to be effective in treating myelofibrosis and have an established regulatory approval pathway, which lowers the risk of development.

## About Myeloproliferative Neoplasms (MPNs)

MPNs are a group of diseases in which specific types of blood cells are overproduced in the body and disrupt their normal functioning. It is a chronic malignant bone marrow disorder that triggers an inflammatory response, resulting in fibrosis within the bone marrow and limiting its ability to produce blood cells. Symptoms include: enlargement of the spleen, anemia, thrombocytopenia, extreme fatigue, pain, severe itching and GI side effects. The spleen size can grow to 10 times the normal size causing great discomfort and at this stage the disease is termed myelofibrosis. It is estimated that there are approximately 30,000 people living with myelofibrosis in the United States. Myelofibrosis is typically diagnosed in people between 50 to 80 years old, but can occur at any age.



# EVOLVE

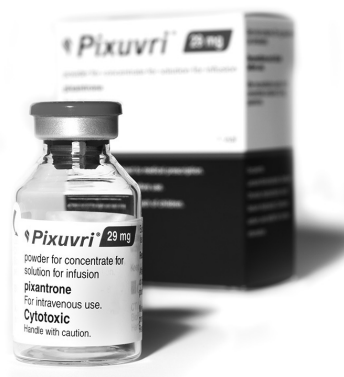


We believe that it is important to maintain a diverse pipeline to sustain our future growth. To accomplish this, we continue to advance the development of our other novel, clinical-stage product candidates, particularly tosedostat, Opaxio™ and brostallicin through investigator-sponsored trials, or ISTs. Sponsoring ISTs provides us with a more economical approach for further developing our promising investigational products.

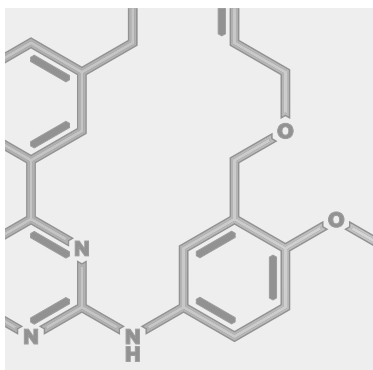
Company-Sponsored Trials	INDICATION	PHASE 1	PHASE 2	PHASE 3	MARKET
<b>PIXUVRI® (pixantrone dimaleate)*</b>					
3rd line: EXTEND Pivotal Study (PIX301)	R/R Aggressive NHL (Granted conditional approval in E.U.)*				
2nd line: PIX-R post-approval study Combination with rituximab (PIX306)	R/R Aggressive NHL				
<b>Pacritinib</b>					
PERSIST-1 All platelet levels	Myelofibrosis				
PERSIST-2 Platelet counts <100,000/μL	Myelofibrosis (study expected to initiate 2H2013)				

Select Investigator-Sponsored Trials	INDICATION	PHASE 1	PHASE 2	PHASE 3	MARKET
<b>Opaxio™ (paclitaxel poliglumex)</b>					
1st line: maintenance (GOG-0212)	Ovarian cancer				
Newly diagnosed glioblastoma without MGMT methylation	Glioblastoma multiforme				
<b>Tosedostat</b>					
1st line	AML/MDS				
<b>Brostallicin</b>					
	Metastatic triple-negative breast cancer				

\*PIXUVRI was granted conditional marketing approval in the EU in MAY 2012 as a monotherapy for the treatment of adult patients with multiply relapsed or refractory aggressive B-cell non-Hodgkin lymphoma. The benefit of pixantrone treatment has not been established in patients when used as fifth line or greater chemotherapy in patients who are refractory to last therapy.



2012



Form 10-K





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UNITED STATES  
**SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, D.C. 20549  
**FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2012

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)

91-1533912

(I.R.S. Employer Identification Number)

3101 Western Avenue, Suite 600  
Seattle, WA

(Address of principal executive offices)

98121

(Zip Code)

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

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

Title of each class

Name of each exchange on which registered

Common Stock, no par value

The NASDAQ Stock Market LLC

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

Preferred Stock Purchase Rights

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 29, 2012, the aggregate market value of the registrant's common equity held by non-affiliates was \$121,317,591. Shares of common stock held by each executive officer and director and by each person known to the registrant who beneficially owns more than 5% of the outstanding shares of the registrant's common stock have been excluded in that such persons may under certain circumstances be deemed to be affiliates. This determination of executive officer or affiliate status is not necessarily a conclusive determination for other purposes. The registrant has no non-voting common stock outstanding.

The number of outstanding shares of the registrant's common stock as of February 22, 2013 was 109,810,743.

**DOCUMENTS INCORPORATED BY REFERENCE**

None.

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**CELL THERAPEUTICS, INC.**

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## Forward Looking Statements

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

- any statements regarding future operations, plans, regulatory filings or approvals;
- any statement regarding the performance, or likely performance, or outcomes or economic benefit of any licensing or other agreement, including any agreement with Novartis International Pharmaceutical Ltd., or Novartis, or its affiliates, including whether or not such partner will elect to participate, terminate or otherwise make elections under any such agreement or whether any regulatory authorizations required to enable such agreement will be obtained;
- any projections of cash resources, revenues, operating expenses or other financial terms;
- any statements of the plans and objectives of management for future operations or programs;
- any statements concerning proposed new products or services;
- any statements on plans regarding proposed or potential clinical trials or new drug filing strategies or timelines;
- any statements regarding compliance with the listing standards of The NASDAQ Stock Market, or NASDAQ;
- any statements regarding pending or future mergers or acquisitions; and
- any statement regarding future economic conditions or performance, and any statement of assumption underlying any of the foregoing.

When used in this Annual Report on Form 10-K, terms such as “anticipates,” “believes,” “continue,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “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,” Part I, Item 1A “Risk Factors,” Part II, 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. 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.

## PART I

### Item 1. Business

#### Overview

We are a biopharmaceutical company focused on the acquisition, development, and commercialization of less toxic and more effective ways to treat cancer. Our goal is to build a profitable company by generating income from products we develop and commercialize, either alone or with one or more potential strategic partners. We are currently concentrating our efforts on treatments that target blood-related cancers where there is an unmet medical need. We are primarily focused on commercializing PIXUVRI® (pixantrone) in the European Union, or the E.U., for multiply relapsed or refractory aggressive non-Hodgkin lymphoma, or NHL, and conducting a Phase 3 clinical trial of pacritinib for the treatment of myelofibrosis.

Our most clinically advanced compound is PIXUVRI. PIXUVRI is a novel aza-anthracenedione derivative that is structurally related to anthracyclines and anthracenediones, but does not appear to be associated with the same level of cardiotoxic effects. PIXUVRI was structurally designed so that it cannot bind iron and perpetuate oxygen radical production or form a long-lived hydroxyl metabolite—both of which are the putative mechanisms for anthracycline-induced acute and chronic cardiotoxicity.

In May 2012, the European Commission, or the EC, granted conditional marketing authorization in the E.U., of PIXUVRI as a monotherapy for the treatment of adult patients with multiply relapsed or refractory aggressive NHL, a cancer 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. PIXUVRI is the first approved treatment for patients with multiply relapsed or refractory aggressive B-cell NHL. This approval was based on the results from our pivotal Phase 3 clinical trial known as EXTEND or PIX301. In connection with the conditional marketing authorization, we are required to conduct a post-approval study that is intended to confirm PIXUVRI's clinical benefit. We are currently accruing patients into a Phase 3 clinical trial comparing pixantrone and rituximab with gemcitabine and rituximab in the setting of aggressive B-cell NHL.

In September 2012, we began making PIXUVRI available for commercial sale in parts of the E.U. PIXUVRI is currently available in eight countries: Austria, Denmark, Finland, Germany, Netherlands, Norway, Sweden and the United Kingdom. We plan to extend the availability of PIXUVRI to France, Italy and Spain, as well as other European countries, in 2013. We have established commercial operations organization, including sales, marketing, supply chain management, and reimbursement capabilities, to commercialize PIXUVRI in the E.U. We are pursuing potential partners for commercializing PIXUVRI in other markets outside the E.U. and the United States (U.S.). PIXUVRI is not approved in the U.S.

In May 2012, we expanded our late-stage pipeline of product candidates with the acquisition of pacritinib, an oral, once-daily JAK2 inhibitor that demonstrated meaningful clinical benefits and good tolerability in myelofibrosis patients in Phase 2 clinical trials. Myelofibrosis is a blood-related cancer caused by the accumulation of malignant bone marrow cells that triggers an inflammatory response, scarring the bone marrow and limiting its ability to produce red blood cells prompting the spleen and liver to take over this function. Symptoms that arise from this disease include enlargement of the spleen, anemia, extreme fatigue and pain. We believe pacritinib may offer an advantage over other JAK inhibitors through effective relief of symptoms with less treatment-emergent thrombocytopenia and anemia. We initiated the first Phase 3 clinical trial in myelofibrosis in January 2013, and plan to initiate a second Phase 3 trial in the second half of 2013.

Tosedostat is an oral aminopeptidase inhibitor that has demonstrated significant responses in patients with acute myeloid leukemia, or AML, and is currently in two Phase 2 investigator-sponsored trials examining the activity of combining tosedostat with hypomethylating agents (HMAs) in AML and myelodysplastic syndrome, cancers of the blood and bone marrow. We expect data from these trials may be used to determine the appropriate design for a Phase 3 trial.



We continue to work with our other pipeline candidates targeting solid tumors including Opaxio™ (paclitaxel poliglumex), or Opaxio, and brostallicin through a cooperative group and investigator-sponsored studies.

## **Our Strategy**

Our strategy is to become a leader in the acquisition, development and commercialization of novel therapeutics for the treatment of blood-related cancers. The key elements of our strategy are to:

- **Successfully Commercialize PIXUVRI.** Our most important commercial objective is to continue our efforts to build a successful PIXUVRI franchise in Europe. PIXUVRI is currently available in eight countries in the E.U., and we plan to extend the availability to other European countries in 2013. We are currently focused on educating physicians on the unmet medical need and building brand awareness for PIXUVRI among physicians in the countries where PIXUVRI is currently available. We are also focused on achieving favorable reimbursement in the five major market European countries (France, Germany, Italy, Spain and the United Kingdom), as well as smaller territories in Western and Northern Europe, in 2013. We also seek to expand the availability of PIXUVRI into additional geographic markets in the rest of the world through one or more strategic partnerships in 2013.
- **Develop Pacritinib in Myelofibrosis.** Pacritinib has the potential to build value for us through the successful enrollment of the first of two Phase 3 registration trials in patients with myelofibrosis within 12-14 months from the initiation of the trial in January 2013. We plan to initiate a second Phase 3 trial in the second half of 2013 and anticipate patient accrual to take approximately one year. Data for each trial is expected to be available approximately six months after completion of enrollment.
- **Continue to Develop our Other Pipeline Programs.** We believe that it is important to maintain a diverse pipeline to sustain our future growth. To accomplish this, we continue to advance the development of our other novel, clinical-stage product candidates, particularly tosedostat, Opaxio and brostallicin through investigator-sponsored trials, or ISTs. Sponsoring ISTs provides us with a more economical approach for further developing our promising investigational products.
- **Enter into Strategic Product Collaborations to Generate Capital and Supplement our Internal Resources.** We enter into collaborations to broaden and accelerate clinical trial development and potential commercialization of our product candidates. Collaborations can generate significant non-equity based operating capital, supplement our own internal expertise and provide us with access to the marketing, sales and distribution capabilities of our collaborators in specific territories.
- **Identify and Acquire Additional Pipeline Opportunities.** Our current pipeline is the result of licensing and acquiring assets that we believe to be undervalued opportunities. We plan to continue to seek out additional product candidates in an opportunistic manner.

## PIXUVRI and Product Development Candidates

The following table summarizes our development pipeline for PIXUVRI and our late-stage product candidates:

Name of Product or Product Candidate	Indications/Intended Use	Status
<b>PIXUVRI</b> (pixantrone dimaleate)	Multiply relapsed or refractory aggressive NHL, EXTEND pivotal Aggressive NHL, 2 <sup>nd</sup> line > 1 relapse, combination with rituximab (PIX-R/PIX306) post-approval study	Conditional Approval- Marketed in E.U. Phase 3 ongoing
<b>Pacritinib</b>	Myelofibrosis, PERSIST-1 All platelet levels Myelofibrosis, PERSIST-2 Platelet counts <100,000/ $\mu$ L	Phase 3 ongoing Phase 3 planning to initiate in the second half of 2013
<b>Opaxio*</b> (paclitaxel poliglumex)	Ovarian Cancer, first-line maintenance Newly diagnosed glioblastoma without MGMT methylation Head and Neck Cancer	Phase 3 ongoing Phase 2 ongoing Phase 2 ongoing
<b>Tosedostat*</b>	First-line Acute Myeloid Leukemia Relapsed/Refractory Acute Myeloid Leukemia/ Myelodysplastic Syndrome	Phase 2 ongoing Phase 2 ongoing
<b>Brostallicin*</b>	Metastatic Triple-Negative Breast Cancer	Phase 2 ongoing

\* We support the development of these investigational agents through investigator-sponsored studies.

## 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 580,350 deaths annually, or more than 1,600 people per day and approximately 1.7 million new cases of cancer were expected to be diagnosed in 2013 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.

We believe developing agents which improve on the cornerstone chemotherapy classes, in addition to novel drugs designed to target biological pathways to treat specific types of cancer and cancer patients, fills a significant unmet medical need for cancer patients.

## Approved Product

### Pixuvri

*Overview.* 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 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.

PIXUVRI is being developed in an effort to improve the activity and safety in treating cancers usually initially treated with the anthracycline family of anti-cancer agents. 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 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 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 the Treatment of NHL*

We are specifically developing PIXUVRI, a novel aza-anthracenedione derivative, for the treatment of 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. The ACS estimated that there would be 70,130 people diagnosed with NHL in the U.S. and approximately 18,940 people would die from this disease 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. NHL is the seventh most common type of cancer. NHL can be broadly classified into two main forms, each with many subtypes—aggressive NHL is a rapidly growing form of the disease that moves into advanced stages much faster than indolent NHL, which progresses more slowly.

Aggressive NHL is one of the more common types of NHL and accounts for about 60% of all NHL cases. After initial therapy for aggressive NHL with anthracycline-based combination therapy, one-third of patients typically develop progressive disease. Approximately half of these patients are likely to be eligible for intensive second-line treatment and stem cell transplantation, although 50% are expected not to respond. For those patients who fail to respond or relapse following second-line treatment, treatment options are limited and usually palliative only. PIXUVRI is the first treatment approved in the E.U. for treatment of patients with multiply relapsed or refractory aggressive B-cell NHL. There are no drugs approved for this indication in the United States.

### *Clinical Trials and Conditional Marketing Approval of PIXUVRI in the E.U.*

The pivotal Phase 3 EXTEND, or PIX301, trial evaluated PIXUVRI for patients with relapsed or refractory aggressive NHL. The trial enrolled 140 patients randomized to receive either PIXUVRI or another single-agent drug currently used for the treatment of this patient population and selected by the physician. Twenty percent (20%) of patients in the trial who received pixantrone achieved a complete or unconfirmed complete response at end of treatment compared with 5.7% in the comparator group ( $p=0.021$ ). Median progression-free survival in the intent-to-treat population was also greater with pixantrone than with comparators: 5.3 versus 2.6 months ( $p=0.005$ ). PIXUVRI had predictable and manageable toxicities when administered at the proposed dose and schedule 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 trials 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. The EXTEND study was published in *Lancet Oncology* in May 2012.

In May 2012, PIXUVRI was granted conditional marketing authorization by the European Commission, or the E.C., as a monotherapy for the treatment of adult patients with multiply relapsed or refractory aggressive NHL. The E.C. granted conditional approval based on the results from the EXTEND pivotal trial. The decision authorized us to market PIXUVRI in the 27 Member States of the E.U. as well as in Iceland, Liechtenstein and Norway.

Similar to accelerated approval regulations in the U.S., conditional marketing authorizations are granted in the E.U. 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 are required to complete a post-marketing study aimed at confirming the clinical benefit previously observed.

An ongoing randomized, controlled Phase 3 clinical trial, known as PIX-R® or PIX306, compares PIXUVRI-rituximab to gemcitabine-rituximab in patients who have relapsed after one to three prior regimens for aggressive B-cell NHL and who are not eligible for autologous stem cell transplant. 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 PIX306 trial was initiated in March 2011. Planned enrollment in this study is approximately 350 patients. As a condition of approval, we have agreed to submit the results of the Phase 3 PIX-R study to the E.C. by June 2015. We plan to meet with the European regulatory authorities in 2013 in regards to the endpoint of the ongoing trial.

#### *Commercialization of PIXUVRI in the E.U.*

In September 2012, we initiated E.U. commercialization of PIXUVRI and by the end of 2012 made PIXUVRI available to healthcare providers in eight E.U. countries, including Austria, Denmark, Finland, Germany Netherlands, Norway, Sweden and the United Kingdom. We plan to extend the availability of PIXUVRI to France, Italy and Spain as well as other European countries in 2013. PIXUVRI is currently available elsewhere in the E.U. and Turkey through a named patient program where it is not otherwise commercially available. A named patient program is a mechanism through which physicians can prescribe investigational drugs under individual country-specific guidelines for patients prior to marketing approval.

We entered into an agreement with Quintiles Commercial Europe Limited, or Quintiles, in July 2012 under which we will interview, approve for hire, train and manage a sales force for PIXUVRI in the E.U. While the sales force would be dedicated to PIXUVRI, they are not our employees, but Quintiles employees. We believe this is a cost effective way to commercialize PIXUVRI in the E.U. We have also entered into a third-party logistics agreement with Movianto Nederland BV in September 2012 to provide us with warehousing, transportation, distribution, order processing and cash collection services for PIXUVRI as well as an agreement with LogixX Pharma Solutions, Ltd to act as our interim wholesaler dealers license holder while we apply for our own license.

We signed a manufacturing supply agreement with NerPharMa, S.r.l. in July 2010 for PIXUVRI drug product manufacture for both the commercial and clinical supply of PIXUVRI drug product. In July 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.

#### *Clinical Development of PIXUVRI in the United States*

We are not currently pursuing regulatory approval of PIXUVRI in the U.S., but may evaluate a possible resubmission strategy in the U.S. based on the data generated from the ongoing PIX306 clinical trial. In the U.S. we began a rolling NDA submission to the FDA in April 2009 and completed the submission in June 2009. In March 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 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 and to ask the Office of New Drugs, or the OND, to conclude that PIX301 demonstrated efficacy.

In April 2011, 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 did not believe that accelerated approval of 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.

In June 2011, we 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. Subsequently, 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.

In October 2011, we resubmitted 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. In December 2011, the DOP1 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. ODAC was scheduled to review our resubmitted NDA for PIXUVRI in February 2012, but we voluntarily withdrew our resubmitted NDA for PIXUVRI because, after communications with the FDA, we needed additional time to prepare for the review of the NDA by ODAC at its February 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 PDUFA goal date, the only way to have PIXUVRI possibly considered at a later ODAC meeting was to withdraw and later resubmit the NDA. We are not currently pursuing regulatory approval of PIXUVRI in the U.S., but may evaluate a possible resubmission strategy in the U.S. based on the data generated from the ongoing PIX306 clinical trial. 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.

Novartis International Pharmaceutical Ltd., or Novartis, has an option to negotiate a license to develop and commercialize PIXUVRI as discussed under Part I, Item 1, Business "—License Agreements and Additional Milestones — Novartis."



## Development Candidates

### Pacritinib

Pacritinib is an oral, once-daily, tyrosine kinase inhibitor, or TKI, with dual activity against JAK2 and FMS-like tyrosine kinase 3, or FLT3. Mutations in these kinases have been shown to be directly related to the development of a variety of blood related cancers including myeloproliferative neoplasms, leukemia, and lymphoma. Pacritinib has been studied in two Phase 2 trials in a total of 65 myelofibrosis patients. In these trials, 30-74% improvement in seven of the myelofibrosis symptom assessment form (MF-SAF) scores was observed relative to baseline at cycle 4, 7 or 10 (28 day cycles). Among evaluable patients, 31% achieved 35% or greater reduction in spleen volume measured by MRI. We believe these effects appear to be independent of patient platelet count. Pacritinib appears to be associated with less myelosuppression than other JAK2 inhibitors. In January 2013, we initiated the first of two planned Phase 3 clinical trials in patients with myelofibrosis. PERSIST-1 is a multicenter, randomized, controlled Phase 3 trial comparing the efficacy and safety of pacritinib with that of best available therapy in patients with primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis. A total of 270 eligible patients are planned to be randomized 2:1 to receive either pacritinib 400 mg taken orally, once daily or the best available therapy. The best available therapy includes any physician-selected treatment other than JAK inhibitors. There will be no exclusion by patient platelet count. The primary endpoint will be the percentage of patients achieving a 35% or greater reduction in spleen volume measured by MRI or CT at 24 weeks of treatment. The trial is expected to enroll patients at clinical sites in Europe, Australia and the United States.

The second Phase 3 clinical trial, PERSIST-2, is currently being planned to evaluate pacritinib compared to best available therapy, including JAK inhibitors, in patients with myelofibrosis whose platelet counts are <100,000 /  $\mu$ L. This trial is expected to initiate in the second half of 2013, and we expect it will have the same primary endpoint as PERSIST-1.

We acquired all right, title and interest of S\*Bio and assumed certain liabilities relating to, certain intellectual property and other assets related to compounds SB1518 (also referred to as “pacritinib”) and SB1578, which inhibit Janus kinase 2, commonly referred to as JAK2. Under the S\*Bio Agreement, we are solely responsible for development and commercialization activities of pacritinib worldwide and agreed to make regulatory success and sales-based milestone payments, as well as single-digit royalties on net sales.

### Opaxio (paclitaxel poliglumex)

Opaxio is our novel biologically-enhanced chemotherapeutic agent that links paclitaxel to a biodegradable polyglutamate polymer, resulting in a new chemical entity. Taxanes, including paclitaxel (Taxol®) and docetaxel (Taxotere®), are widely used for the treatment of various solid tumors, including non-small cell lung, ovarian, breast and prostate cancers. We are currently focusing our development of Opaxio through investigator-sponsored studies in the following indications: ovarian, glioblastoma multiforme, and head and neck cancers.

Opaxio was designed to deliver paclitaxel preferentially to tumor tissue. By linking paclitaxel to a biodegradable amino acid carrier, the conjugated chemotherapeutic agent is inactive in the bloodstream, sparing normal tissues the toxic side effects of chemotherapy. Once inside tumor tissue the conjugated chemotherapeutic agent is activated and released by the action of an enzyme called cathepsin B. Opaxio remains stable in the bloodstream for several days after administration; this prolonged circulation allows the passive accumulation of Opaxio in tumor tissue.

#### *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 March 2004, we entered into a clinical trial agreement with the Gynecologic Oncology Group, or



GOG, to perform a Phase 3 trial, known as the GOG-0212 trial. As such, the GOG-0212 trial is conducted and managed by the GOG. We expect the trial to enroll 1,100 patients. In February 2012, we were informed that the Data Monitoring Committee for GOG-0212 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. There are early stopping criteria for either success or futility. In January 2013, we reported that the GOG informed us that the Data Safety Monitoring Board (DSMB) recommended continuation of the GOG-0212 Phase 3 clinical trial of Opaxio for maintenance therapy in ovarian cancer with no changes following a planned interim survival analysis. Enrollment in the trial is expected to be completed in 2013.

#### *Opaxio for glioblastoma multiforme (malignant brain cancer)*

In November 2010, results were presented by the Brown University Oncology Group from a Phase 2 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 2 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. Preliminary results are expected to be available in the second half of 2013. In September 2012, Opaxio was granted orphan-drug designation by the FDA for the treatment of a type of brain cancer called glioblastoma multiforme.

#### *Opaxio for head and neck cancer*

A Phase 1-2 study of Opaxio combined with radiotherapy and cisplatin was initiated by SUNY Upstate Medical University, in patients with locally advanced head and neck cancer. Preliminary results are expected to be presented mid-2013. We acquired an exclusive worldwide license for rights to Opaxio and certain polymer technology from PG-TXL in November 1998 as discussed below in “—License Agreements and Additional Milestone Activities—PG-TXL.”

We have entered into an exclusive worldwide licensing agreement for Opaxio with Novartis as discussed below in “—License Agreements and Additional Milestone Activities—Novartis.”

#### **Tosedostat**

Tosedostat is an oral, aminopeptidase inhibitor that has demonstrated significant anti-tumor responses in blood related cancers and solid tumors in Phase 1-2 clinical trials. In December 2011, final results from the Phase 2 OPAL study of tosedostat in elderly patients with relapsed or refractory AML were presented at the American Society of Hematology 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. There are three ongoing Phase 2 investigator-sponsored trials examining the activity of tosedostat in combination with standard agents in patients with AML or MDS. We expect data from these trials may be used to determine the appropriate design for a Phase 3 trial. We have entered into an exclusive license agreement with Chroma Therapeutics, Ltd., or Chroma. Our agreement with Chroma is discussed in more detail in Part I, Item 1, Business, “—License Agreements and Additional Milestone Activities.”

#### **Brostallicin**

We are developing brostallicin through our 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.

An investigator-sponsored study of brostallicin with the North Central Cancer Treatment Group, or the NCCTG, opened for enrollment a Phase 2 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. In December 2012, preliminary results of this study were presented at the San Antonio Breast Cancer Symposium. As of the preliminary analysis, 10 of 47 evaluable patients (21%) achieved a confirmed tumor response with nine patients having a partial response (PR) and one complete response (CR). The 3-month PFS was at 51%. Adverse events were manageable. Final results are expected to be presented in 2013. We have entered into a license agreement with Nerviano Medical Sciences, S.r.l., or Nerviano. Our agreement with Nerviano is discussed in more detail in Part I, Item 1, Business, “—License Agreements and Additional Milestone Activities.”

### **Research and Development Costs**

Research and development is essential to our business. We spent \$33.2 million, \$34.9 million and \$27.0 million in 2012, 2011 and 2010, 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.

We are unable to provide the nature, timing, and estimated costs of the efforts necessary to complete the development of PIXUVRI, Opaxio, pacritinib, tosedostat and brostallicin because, among other reasons, we cannot predict with any certainty the pace of enrollment of our clinical trials. Further, third parties are conducting key clinical trials for Opaxio and brostallicin. 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 these product candidates will be completed or when we will generate material net cash inflows from PIXUVRI or be able to begin commercializing Opaxio, pacritinib, tosedostat and brostallicin to generate material net cash inflows.

The risks and uncertainties associated with completing development of our product candidates on schedule and the consequences to operations, financial position and liquidity if our research and development projects are not completed timely are discussed in more detail in the following risk factors, which begin on page 20 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 may not obtain or maintain the regulatory approvals required to commercialize some or all of our products.”*; *“Even if our drug candidates are successful in clinical trials and receive regulatory approvals, 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**

#### *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. Under the Novartis Agreement, total product and registration milestones to us for

Opaxio could amount to approximately \$270 million. Royalty payments to us for Opaxio are based on worldwide Opaxio net sales volumes and range from the low- 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 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, 2012, 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.

#### *University of Vermont*

We entered into an agreement with the University of Vermont, or UVM Agreement, in March 1995, as amended in March 2000, which grants us an exclusive license, with the right to sublicense, for the rights to PIXUVRI. Pursuant to the UVM Agreement, we acquired the rights to make, have made, sell and use PIXUVRI, and we are obligated to make royalty payments to UVM ranging 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 PIXUVRI, 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 PIXUVRI 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.

#### *S\***BIO** Pte Ltd*

Pursuant to the S\***BIO** Agreement, we acquired the compounds SB1518 (which is referred to as “pacritinib”) and SB1578, which inhibit Janus Kinase 2, commonly referred to as JAK2, and we made an initial payment of \$2 million in cash at signing. In consideration of the assets and rights acquired under the S\***BIO** Agreement, we made an additional payment of \$13 million in cash and issued 15,000 shares of our Series 16 Preferred Stock to S\***BIO**, which were automatically converted into 2.5 million shares of our common stock. The S\***BIO** Agreement also provides S\***BIO** with a contingent right to certain milestone payments from us up to an aggregate amount of \$132.5 million if certain U.S., E.U. and Japanese regulatory approvals are obtained or if certain worldwide net sales thresholds are met in connection with any pharmaceutical product containing or comprising any Seller Compound for use for specific diseases, infections or other conditions. At our election, we may pay up to 50% of any milestone payments to S\***BIO** through the issuance of shares of our common stock or shares of our preferred stock convertible into our common stock. In addition, S\***BIO** will also be entitled to receive royalty payments from us at incremental rates in the low-single digits based on certain worldwide net sales thresholds on a product-by-product and country-by-country basis.

#### *Chroma Therapeutics, Ltd.*

We entered into an agreement with Chroma, or the Chroma License Agreement, in March 2011 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 License 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. The Chroma License 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.

Under the Chroma License Agreement, we are required to 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.

Under the Chroma License Agreement, we are required to 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 License 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 License Agreement may be terminated by us at our convenience upon 120 days' written notice to Chroma. The Chroma License Agreement may also be terminated by either party following a material breach by the other party subject to notice and cure periods.

By a letter dated July 18, 2012, Chroma notified us that Chroma alleges breaches under the Chroma License Agreement. Chroma asserts that we have not complied with the Chroma License Agreement because we made decisions with respect to the development of tosedostat without the approval of the joint committees to be established pursuant to the terms of the Chroma License Agreement, did not hold meetings of those committees and have not used diligent efforts in the development of tosedostat. We dispute Chroma's allegations and intend to vigorously defend our development activities and judgments. In particular, we dispute Chroma's lack of diligence claim based in part on the appropriateness of completing the ongoing Phase 2 combination trials prior to developing a Phase 3 trial design. In addition, we believe that Chroma has failed to comply with its antecedent obligations with respect to the joint committees and failed to demonstrate an ability to manufacture tosedostat to the required standards under the terms of the Chroma License Agreement. Under the Chroma License Agreement there is a 90 day cure period for any nonpayment default, which period shall be extended to 180 days if the party is using efforts to cure. A party may terminate the Chroma License Agreement for a material breach only after arbitration in accordance with the terms of the Chroma License Agreement.

Effective September 25, 2012, we and Chroma entered into a three month standstill with respect to the parties' respective claims under the Chroma License Agreement, but otherwise reserving the parties' respective rights as of the commencement of the standstill period. Effective December 25, 2012, the standstill was subsequently extended until March 25, 2013 and is terminable by either party on one month's notice.

#### *Gynecologic Oncology Group*

We entered into an agreement with the GOG, or the GOG Agreement, in March 2004, as amended on August 2008, related to the GOG-0212 trial of Opaxio in patients with ovarian cancer, 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, of which \$0.4 million was outstanding and included in *accounts payable* as of December 31, 2012. 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 and \$0.9 million will become due upon completion of the 1,100 patient enrollment milestone, both of which may occur in 2013.

#### *PG-TXL*

In November 1998, we entered into an agreement with PG-TXL Company, L.P., or the PG-TXL Agreement (as amended in February 2006), 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 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.

#### *Nerviano Medical Sciences*

Under a license agreement entered into with Nerviano Medical Sciences for brostallicin, or the Nerviano Agreement, 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 have the right to 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.

### **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 PIXUVRI, Opaxio, pacritinib, 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 PIXUVRI-directed patents in the U.S. will expire in 2014. The Opaxio-directed U.S. patents will expire on various dates ranging from 2017 through 2018. The pacritinib-directed U.S. patents will expire from 2026 through 2029. The tosedostat-directed U.S. patents will expire in 2017. The brostallicin-directed U.S. patents will expire on various dates ranging between 2017 through 2021. The PIXUVRI-directed patents in Europe will expire from 2013 through 2023. 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 through 2027 in some countries in Europe. Supplementary Protection Certificates extending certain PIXUVRI-directed patents have been granted in Italy and Luxembourg, but there can be no guarantee of extensions in other countries. The risks and uncertainties associated with our intellectual property, including our patents, are discussed in more detail in the following risk factors, which begin on page 20 of this Annual Report on Form 10-K: “*We hold rights under numerous patents that we have acquired or licensed or 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.*”; “*If we fail to adequately protect our intellectual property, our competitive position could be harmed.*”; “*Patent litigation is widespread in the biotechnology industry, and any patent litigation could harm our business.*”; and “*We may be unable to obtain or protect our intellectual property rights and we may be liable for infringing 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.*”

### **Manufacturing**

We currently use, and expect to continue to be dependent upon, contract manufacturers and contract service providers to manufacture, test and distribute each of our product candidates and commercial product. 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 global regulations. We expect that we will need to invest in additional manufacturing development, manufacturing and supply chain resources, and may seek to enter into additional collaborative arrangements with other parties that have established manufacturing capabilities. It is likely that we will continue to rely on third-party manufacturers for our development and commercial products on a contract basis. Currently, we have agreements with third-party vendors to produce, test and distribute PIXUVRI, Opaxio, pacritinib, tosedostat and brostallicin drug supply for clinical trials and commercial product for PIXUVRI. 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 entered into 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 product, 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 entered into 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. With respect to PIXUVRI, there are no other products approved in the E.U. as monotherapy for the treatment of adult patients with multiply relapsed or refractory aggressive non-Hodgkin lymphoma; however there are other agents approved to treat aggressive non-Hodgkin lymphoma that could be used in this setting including both branded and generic anthracyclines as well as mitoxantrone. There are also other investigational candidates being tested in aggressive non-Hodgkin lymphoma which if approved could compete with PIXUVRI.

With respect to our other investigational candidates if approved they may face competition from compounds that are currently approved or may be in the future. Pacritinib would compete with Incyte, which markets Jakafi®, and potentially other candidates in development that target JAK inhibition to treat cancer. Opaxio would compete with other 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®. Tosedostat would compete with corporations such as Eisai, which markets Dacogen®; Celgene, which markets Vidaza®, Revlimid®, and Thalomid®; Genzyme which markets Clolar® and new anti-cancer drugs that may be developed and marketed.

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 or EC approval. However, cancer drugs with distinctly different mechanisms of action are often used together in combination for treating cancer, allowing several different products to target the same cancer indication or disease type. Such combination therapy is typically supported by clinical trials that demonstrate the advantage of combination therapy over that of a single-agent treatment.

We believe that our ability to compete successfully will be based on our ability to create and maintain scientifically advanced technology, develop proprietary products, attract and retain scientific personnel, obtain patent or other protection for our products, obtain required regulatory approvals and manufacture and successfully market our products, either alone or through outside parties. We will continue to seek licenses with respect to technology related to our field of interest and may face competition with respect to such efforts. See the risk factor, *“We face direct and intense competition from our competitors in the biotechnology and pharmaceutical industries, and we may not compete successfully against them.”* in Part I, Item 1A “Risk Factors” of this Annual Report on Form 10-K for additional information regarding the risks and uncertainties we face due to competition in our industry.

## **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.

### *U.S. Regulation.*

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 Investigational New Drug Application, or 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 Good Distribution Practices; 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 1 usually involves the initial introduction of the investigational product into people to evaluate its short-term safety, dosage tolerance, metabolism, pharmacokinetics and pharmacologic actions, and, if possible, to gain an early indication of its effectiveness. Phase 2 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 3 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 1, Phase 2 or Phase 3 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 trials 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 trials 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 trials, 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 trials 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 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 December 2007, we 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 term of the CIA, and the requirement that we establish a compliance committee and compliance program and adopt a formal code of conduct, expired as of December 22, 2012, however we intend to continue to abide by PhRMA Code and FDA regulations.

#### *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 E.U. members' states. Similar to accelerated approval regulations in the U.S., conditional marketing authorizations are granted in the E.U. 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 are required to complete a post-marketing study aimed at confirming the clinical benefit previously observed.

The approval of new drugs in the E.U. may be achieved using a mutual recognition procedure, which is available at the request of the applicant for all medicinal products that are not subject to the centralized procedure. These procedures apply in the EU member states, plus the European Economic Area countries, Norway and Iceland. Since the E.U. does not have jurisdiction over patient reimbursement or pricing matters in its member states, we are working or planning to work with individual countries on such matters across the region. However, there can be no assurance that our reimbursement strategy will secure reimbursement 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. See the risk factor, "*Since we use hazardous materials in our business, we may be subject to claims relating to improper handling, storage or disposal of these materials.*" in Part I, Item 1A "Risk Factors" of this Annual Report on Form 10-K for additional information regarding the risks and uncertainties we face due to the use of hazardous materials we use in our business.

## **Employees**

As of December 31, 2012, we employed 111 individuals in the United States, including two employees at our majority-owned subsidiary Aequus Biopharma, Inc., and three in Europe. Our U.S. and U.K. employees do not have a collective bargaining agreement. One employee in Italy is subject to a collective bargaining agreement. We believe our relations with our employees are good.

Information regarding our executive officers is set forth in Part III, 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. We completed our initial public offering in 1997 and our shares are listed on The NASDAQ Capital Market in the U.S. and Mercato Telematico Azionario (MTA) in Italy,



where our symbol is CTIC. Our principal executive offices are located at 3101 Western Avenue, Suite 600, Seattle, Washington 98121. Our telephone number is (206) 282-7100. Our website address is <http://www.celltherapeutics.com>. However, information found on our website is not incorporated by reference into this report. “CTT”, “PIXUVRI” and “Opaxio” are our proprietary marks. All other product names, trademarks and trade names referred to in this Form 10-K are the property of their respective owners. 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 harm our business, financial condition, operating results and prospects and the trading price of our securities.*

### **Factors Affecting Our Operating Results and Financial Condition**

*If we are unable to generate significant product revenues from the sale of PIXUVRI, we may never become profitable.*

We anticipate that, for at least the next several years, our ability to generate revenues and become profitable will depend in large part on the commercial success of our only marketed product candidate, PIXUVRI. One of the priorities of our business strategy is to successfully execute the commercial launch of PIXUVRI in Europe. PIXUVRI is not approved for marketing in the United States. In September 2012, we began making PIXUVRI available for commercial sale in the E.U. PIXUVRI is currently available in eight countries: Austria, Denmark, Finland, Germany, Netherlands, Norway, Sweden and the United Kingdom. We plan to extend the availability of PIXUVRI to France, Italy and Spain, as well as other European countries, in 2013; however, we may not be able to successfully commercialize PIXUVRI in Europe as planned. Our ability to successfully commercialize PIXUVRI will depend on several factors, including, without limitation, our ability to:

- successfully increase and maintain market demand for, and sales of, PIXUVRI in Europe through our sales and marketing efforts and by expanding our sales force;
- obtain greater acceptance of PIXUVRI by physicians and patients;
- obtain favorable reimbursement rates for PIXUVRI in Europe;
- maintain compliance with regulatory requirements;
- obtain a renewal annually of our conditional marketing authorization for PIXUVRI in the E.U. and complete a post-marketing study of PIXUVRI aimed at confirming the clinical benefit previously observed in PIXUVRI;
- establish and maintain agreements with wholesalers and distributors on commercially reasonable terms;
- maintain commercial manufacturing arrangements with third-party manufacturers as necessary to meet commercial demand for PIXUVRI, continue to manufacture commercial quantities at acceptable cost levels and build our distribution, managerial and other non-technical capabilities;
- successfully maintain intellectual property protection for PIXUVRI;



- compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain sales and marketing personnel; and
- successfully develop our own commercial organization to market PIXUVRI.

We currently have limited resources and the continued development of a commercial organization to market PIXUVRI will be expensive and time-consuming. Our subsidiary CTI Life Sciences Limited, or CTILS, has entered into a services agreement with Quintiles Commercial Europe Limited, or Quintiles, whereby CTILS has engaged Quintiles to provide a variety of services, which may include, market access services, promotion and detailing services, strategic planning, project management, pricing and reimbursement support, pharmacovigilance, medical information and other regulatory services and consultancy advice to CTILS and affiliates in relation to the commercialization of PIXUVRI in Europe. Because we rely on third parties for the manufacture, distribution and marketing and sale of PIXUVRI, we may have limited control over the efforts of these third parties and we may receive less revenue than if we commercialized these products ourselves. In the event we are unable to successfully develop our own commercial organization or collaborate with third-party organizations, we may not be able to successfully commercialize or generate meaningful sales from PIXUVRI or other product candidates. As a result, we may be unable to generate sufficient revenues to grow or sustain our business and we may never become profitable, and our business, financial condition, operating results and prospects and the trading price of our securities could be harmed.

*We need to continue to raise additional financing to operate, but additional funds may not be available on acceptable terms, or at all.*

We have substantial operating expenses associated with the development of our product candidates. Our available cash and cash equivalents were \$50.4 million as of December 31, 2012. At our currently planned spending rate, we believe that our financial resources, in addition to the expected receipts from European PIXUVRI sales, will be sufficient to fund our operations into the fourth quarter of 2013. Changes in manufacturing, clinical trial expenses, and expansion of our sales and marketing organization in Europe, may consume capital resources earlier than planned. Additionally, we may not receive the country reimbursement rates in Europe for PIXUVRI that we currently assume in planning for 2013 and 2014.

We expect we will need to raise additional funds and are currently exploring alternative sources of debt and other non-dilutive capital. We may seek to raise such capital through debt financings, partnerships, collaborations, joint ventures, disposition of assets or other sources, but our ability to do so is subject to a number of risks and uncertainties, including:

- our ability to raise capital through the issuance of additional shares of our common stock or other securities convertible into common stock is restricted by the limited number of authorized shares available for issuance, the difficulty of obtaining shareholder approval to increase the authorized number of shares, and the restrictive covenants of our credit facility;
- issuance of equity securities, or securities convertible into our equity securities, will dilute the proportionate ownership of existing shareholders;
- our ability to raise debt capital may be limited by the terms of any future indebtedness, and any such indebtedness may include restrictive covenants that limit our operating flexibility;
- arrangements that require us to relinquish rights to certain technologies, drug candidates, products and/or potential markets;
- we may be required to meet additional regulatory requirements in the European Union (including Italy) and the United States and we may be subject to certain contractual limitations, which may increase our costs and harm our ability to obtain additional funding.

However, additional funding may not be available on favorable terms or at all. 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 as well as reduce our selling, general and administrative expenses, which could materially harm our business, financial condition, operating results and prospects.

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

We were incorporated in 1991 and have incurred a net operating loss every year since our formation. As of December 31, 2012, we had an accumulated deficit of \$1.8 billion. We are pursuing regulatory approval for PIXUVRI, pacritinib, Opaxio, tosedostat and brostallicin. We will need to continue 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 PIXUVRI or other products currently in development or otherwise.

*We have in the past received and may in the future receive audit reports with an explanatory paragraph on our consolidated financial statements.*

Our independent registered public accounting firm included an explanatory paragraph in its reports on our consolidated financial statements for each of the years ended December 31, 2007 through December 31, 2011 regarding their substantial doubt as to our ability to continue as a going concern. Although our independent registered public accounting firm removed this going concern explanatory paragraph in its report on our December 31, 2012 consolidated financial statements, we expect to continue to need to raise additional financing to fund our operations and satisfy obligations as they become due. The inclusion of a going concern explanatory paragraph in future years may negatively impact the trading price of our common stock and make it more difficult, time consuming or expensive to obtain necessary financing, and we cannot guarantee that we will not receive such an explanatory paragraph in the future.

*We may not be able to maintain our listings on The NASDAQ Capital Market and the Mercato Telematico Azionario stock market in Italy, or the MTA, or trading on these exchanges may otherwise be halted or suspended, which may make it more difficult for investors to sell shares of our common stock.*

Maintaining the listing of our common stock on The NASDAQ Capital Market requires that we comply with certain listing requirements. We have in the past and may in the future fail to continue to meet one or more listing requirements. For example, in June 2012, we received a notification from The NASDAQ Stock Market LLC, or NASDAQ, indicating non-compliance with the requirement to maintain a minimum closing bid price of \$1.00 per share and would be delisted if we did not regain compliance prior to the expiration of a 180 day grace period. We regained compliance through a reverse stock split in September 2012, but we could fail to meet the continued listing requirements as a result of a decrease in our stock price or otherwise.

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, decrease the level of trading activity and make it more difficult for investors to buy or sell shares of our common stock. Our failure to maintain a listing on The NASDAQ Capital Market may constitute an event of default under any indebtedness which would accelerate the maturity date of such future debt or trigger other obligations. In addition, certain institutional investors that are not permitted to own securities of non-listed companies may be required to sell their shares adversely affecting the trading price of our common stock. If we are not listed on The NASDAQ Capital Market or if our public float falls below \$75 million, we will be limited in our ability to file new shelf registration statements on SEC Form S-3 and/or to fully use one or more registration statements on SEC Form S-3. We have relied significantly on shelf registration statements on SEC Form S-3 for most of our financings in recent years, so any such limitations may harm our ability to raise the capital we need. Delisting from NASDAQ could also affect our ability to maintain our listing or trading on the Borsa Italiana. Trading in our common stock has been halted or suspended on both NASDAQ and Borsa Italiana in the past and may also be halted or suspended in the future due to market or trading conditions at the discretion of 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). Any halt or suspension in the trading in our common stock may negatively impact the trading price of our common stock.

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

Our articles 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. Failure to meet a quorum or obtain shareholder approval can prevent us from raising capital through equity financing or otherwise taking certain actions that may be in the best interest of the company and shareholders.

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, we were unable to obtain a quorum at two scheduled annual meetings. Following that failure to obtain a 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. Obtaining a quorum at future meetings 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. 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. For example, a proposal to approve a reverse stock split failed to receive sufficient votes to pass at the March 2009 shareholders meeting. Moreover, 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 which broker discretionary voting is allowed, such as the revisions imposed in August 2010 by the Dodd-Frank Wall Street Reform and Consumer Protection 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.

*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. NASDAQ Marketplace Rules also require shareholder approval if an issuance would result in a change of control as defined under the NASDAQ Marketplace Rules and other circumstances. We have in the past and may in the future issue additional equity securities that would comprise more than 20% of the total shares of our common stock outstanding in order to fund our operations. However, we might not be successful in obtaining the required shareholder approval for any future issuance that requires shareholder approval pursuant to the NASDAQ Marketplace Rules, particularly in light of the difficulties we have experienced in obtaining a quorum and holding shareholder meetings discussed above. If we are unable to in the future, obtain financing due to shareholder approval difficulties, such failure may harm our ability to continue operations.

*We are subject to limitations on our ability to issue additional shares of our common stock or undertake other business initiatives due to Italian regulatory requirements.*

Compliance with Italian regulatory requirements may delay additional issuances of our common stock or other business initiatives. 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, subject to certain 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.

*We are subject to Italian regulatory requirements, which could result in administrative and other challenges and additional expenses.*

Because our common stock is traded on the MTA, we are required to also comply with the rules and regulations of CONSOB and the Borsa Italiana, which regulate companies listed on Italy’s public markets. Compliance with these regulations and responding to periodic information requests from Borsa Italiana and CONSOB requires us to devote additional time and resources to regulatory compliance matters, and incur additional expense of engaging additional outside counsel, accountants and other professional advisors. Actual or alleged failure to comply with Italian regulators can also subject us to regulatory investigations. For more information on current investigations, see the regulatory investigations that are discussed in more detail in Part I, Item 3 “Legal Proceedings.”

*We will incur a variety of costs and may never realize the anticipated benefits of any acquisitions we may make, including our acquisition of pacritinib.*

We evaluate and acquire assets and technologies from time to time. If appropriate opportunities become available, we may attempt to acquire other businesses and assets that we believe are a strategic fit with our business. The process of negotiating an acquisition and integrating an acquired business and assets, including the acquisition of pacritinib, may result in operating difficulties and expenditures. In addition, our acquisitions 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, including the acquisition of pacritinib. Any additional acquisitions could result in potentially dilutive issuances of equity securities, the incurrence of debt, contingent liabilities and/or amortization expenses related to intangible assets, which could harm our business, financial condition, operating results and prospects and the trading prices of our securities.

*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 was \$8.1 million and \$5.0 million as of December 31, 2012 and 2011, respectively. On April 14, 2009, December 21, 2009 and June 25, 2010, 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, 2005 and 2006 and 2007. 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, \$7.2 million, \$3.3 million and \$1.1 million converted using the currency exchange rate as of December 31, 2012, 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 final decision of lower tax courts (i.e. the Provincial Tax Court or the Regional Tax Court) or of the Supreme Court is unfavourable to us, we may be requested to pay to the ITA an amount up to €9.4 million (or approximately \$12.4 million converted using the currency exchange rate as of December 31, 2012) 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. Further information pertaining to these cases can be found in this Annual Report on Form 10-K under Item 3 "Legal Proceedings" and is incorporated by reference herein.

*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. In addition, the agreement imposes restrictions on activities relating to the development and commercialization of PIXUVRI and any actual or alleged failure to comply with the terms of the agreement could result in potential damage claims, legal expenses, loss of rights under the agreement or termination of the agreement. Novartis has the right under the agreement in its sole discretion to terminate such agreement at any time upon written notice to us.



*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:

- preclinical tests may show the product to be toxic or lack efficacy in animal models;
- clinical trial results may show the product to be less effective than desired or to have harmful or problematic side effects;
- 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;
- the product candidate is not cost effective in light of existing therapeutics; or
- 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.

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

*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 to the satisfaction of the applicable regulatory authority the safety and efficacy of the product for its intended use. We forecast the commencement and completion of clinical trials for planning purposes, but actual commencement or completion may not occur as forecasted or planned due to a number of reasons, including:

- we may not obtain authorization to permit product candidates that are already in the preclinical development phase to enter the human clinical testing phase;
- the FDA, the EMA or other regulatory authority may object to proposed protocols;
- there may be shortages of available product supplies or the materials that are used to manufacture the products or 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 for the specific indication for which they are tested and, as with many drugs, may fail to demonstrate the desired safety and efficacy characteristics in human clinical trials;



- 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;
- inadequate financing to complete a clinical trial;
- 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;
- the failure of 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, to perform or to meet applicable standards; and
- the rates of patient recruitment and enrollment of patients who meet trial eligibility criteria may be lower than anticipated as a result of factors, such as 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.

If we fail to commence or complete, or 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.

*We may not obtain or maintain the regulatory approvals required to commercialize some or all of our products.*

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 in the E.U. All of our other compounds are currently in research or development and, other than conditional marketing authorization for PIXUVRI in the E.U., have not received marketing approval for these other compounds or FDA marketing approval of PIXUVRI. 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. Each product candidate requires significant research, development and preclinical testing and extensive clinical investigation before submission of any regulatory application for marketing approval. Obtaining regulatory approval requires substantial time, effort and financial resources, and we may not be able to obtain approval of any of our products on a timely basis, or at all. The number and focus of preclinical and clinical trials that will be required for approval by the FDA, the EMA or any other foreign regulatory agency varies depending on the drug candidate, the disease or condition that the drug candidate is designed to address and the regulations applicable to any particular drug candidate. Preclinical and clinical data can be interpreted in different ways, which could delay, limit or preclude regulatory approval. The FDA, the EMA and other foreign regulatory agencies can delay, limit or deny approval of a drug candidate for many reasons, including, but not limited to:

- a drug candidate may not be shown to be safe or effective;
- a clinical trial results in negative or inconclusive results or adverse medical events occur during a clinical trial;
- they may not approve the manufacturing process of a drug candidate;
- they may interpret data from pre-clinical and clinical trials in different ways than we do; or
- they might change their approval policies or adopt new regulations.

Any delay or failure by us to obtain regulatory approvals of our products could diminish competitive advantages that we may attain and could adversely affect the marketing of our products. 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. 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. If our products are not approved quickly enough to provide net revenues to defray our operating expenses, our business, financial condition and results of operations will be harmed.

Information about the status of the regulatory approval of PIXUVRI, pacritinib, Opaxio, tosedostat, and brostallicin can be found in this Annual Report on Form 10-K under Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and is incorporated by reference herein. Except for conditional marketing authorization of PIXUVRI in Europe, none of our current product candidates have received approval for marketing in any country.

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

Even if our products are successful in clinical trials and even products that have been granted conditional marketing authorization, such as PIXUVRI, or other regulatory approvals, our products 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;
- not compete effectively with existing or future alternatives to our products;
- fail to achieve market acceptance; or
- be precluded from commercialization by proprietary rights of third parties.

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

*Even if regulatory approval is obtained, we will be subject to ongoing obligations and continued regulatory review by the FDA, the EMA and other foreign regulatory agencies, as applicable, and may be subject to additional post-marketing obligations, all of which may result in significant expense and limit commercialization of our other products, including PIXUVRI.*

Even if our other products receive regulatory approvals, we will be subject to numerous regulations and statutes regulating the manner of selling and obtaining reimbursement for those products. Regulatory approvals that we receive for our products may be subject to limitations on the indicated uses for which the product may be marketed or require potentially costly post-marketing follow-up studies. In addition, PIXUVRI is subject to extensive regulatory requirements regarding its labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping. If the FDA, the EMA or other foreign regulatory agency approves any of our other products, they will also be subject to similar extensive regulatory requirements. The subsequent discovery of previously unknown problems with PIXUVRI or any of our other products, including adverse events of unanticipated severity or frequency, or the discovery that adverse effects or unknown toxicities observed in preclinical research or clinical trials that were believed to be minor actually constitute more serious problems, may result in restrictions on the marketing of the product or withdrawal of the drug from the market. If we are

not granted full approval of PIXUVRI in the E.U. or we are unable to renew our conditional marketing authorization for PIXUVRI in the E.U., our business, financial condition and results of operations would be harmed.

*We cannot predict the outcome of our clinical trial for PIXUVRI or whether our clinical trial for PIXUVRI will serve as either a post-marketing commitment trial or as a pivotal trial.*

In March 2011, we initiated a randomized pivotal trial of PIXUVRI for the treatment of relapsed or refractory aggressive B-cell NHL. This clinical trial, referred to as PIX306, or PIX-R, will compare a combination of PIXUVRI plus rituximab to a combination of gemcitabine plus rituximab in patients who have relapsed after one to three prior regimens for aggressive B-cell NHL and who are not eligible for autologous stem cell transplant. 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 not be able to complete the PIX306 clinical trial by June 2015 or at all. If we are unable to submit the clinical trial data from our ongoing randomized Phase 3 clinical trial, PIX306, by June 2015, it may result in the withdrawal of the conditional marketing authorization by the E.U. 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. Failure to meet clinical trial deadlines can also result in the withdrawal of conditional marketing authorization.

*If we do not successfully develop our product candidates into marketable products, we may be unable to generate significant revenue or become profitable.*

Currently only our product PIXUVRI is approved for marketing in the European Union. Pacritinib, Opaxio, tosedostat and brostallicin are currently in clinical trials; 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 3 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.

*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 currently developing 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 Phase 3 clinical trial, or the GOG-0212 trial, is under the control of the Gynecologic Oncology Group, or the GOG, and is expected to enroll 1,100 patients. On January 31, 2013, the Data Safety Monitoring Board recommended continuation of the GOG-0212 trial of Opaxio for maintenance therapy in ovarian cancer with no changes following the first planned interim survival analysis. Three prior pivotal clinical trials for Opaxio have not been successful and failure of the GOG-0212 trial could delay, limit or preclude regulatory approval of Opaxio.

*We may be subject to fines, penalties, injunctions and other sanctions if we are deemed to be promoting the use of our products for non-FDA-approved, or off-label, uses.*

Our business and future growth depend on the development, use and ultimate sale of products that are subject to FDA, EMA and or other regulatory agencies regulation, clearance and approval. Under the U.S. Federal Food, Drug, and Cosmetic Act and other laws, we are prohibited from promoting our products for off-label uses. This means that in the United States, we may not make claims about the safety or effectiveness of our products and may not proactively discuss or provide information on the use of our products, except as allowed by the FDA.

Government investigations concerning the promotion of off-label uses and related issues are typically expensive, disruptive and burdensome and generate negative publicity. If our promotional activities are found to be in violation of applicable law or if we agree to a settlement in connection with an enforcement action, we would likely face significant fines and penalties and would likely be required to substantially change our sales, promotion, grant and educational activities. For example, in April 2007, we paid a civil penalty of \$10.6 million and entered into a settlement agreement with the U.S. 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.

*If we fail to establish and maintain collaborations, 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 3 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.

*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.*

Our collaborative arrangements with third parties, subject us to a number of risks, including:

- 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.

*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. We are dependent on a single vendor for manufacturing PIXUVRI and, as such, we do not have direct control over the manufacture, testing or distribution of PIXUVRI. The active pharmaceutical ingredients and drug products for our products under development, pacritinib, tosedostat and brostallicin, are manufactured by single vendors. Finished product manufacture and distribution for these products are to be manufactured and distributed by different single vendors. 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. Because we do not directly control our suppliers, these vendors may not be able to provide us with finished product when we need it. If our vendors fail to comply with regulatory requirements or we experience a delay in the manufacturing of our finished products, we may experience a delay in the distribution of our products, which may impact the related clinical trials and our commercial activities currently planned or underway.

*If our contract manufacturers and/or our products fail to comply with FDA, EMA or other applicable regulations, we may have to curtail or stop the manufacture of such products which would harm our sales.*

We are dependent upon 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. 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. Failure of our manufacturers 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, which would harm our business, financial condition and results of operations.

*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. 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. In September 2012, our wholly-owned subsidiary CTI Life Sciences Ltd., or CTILS, entered into a Logistics Agreement with Movianto Nederland BV, or Movianto, pursuant to which Movianto agreed to provide certain warehousing, transportation, distribution, order processing and cash collection services and all related activities to CTILS and its affiliates for PIXUVRI in certain agreed territories in Europe. Movianto provides a variety of services related to our sales of PIXUVRI, including the receipt, unloading and checking, warehousing and inventory control; customer order management; distribution and transportation; lot number and expiry date control; returned goods processing; return and recall; product quality assurance; reporting, credit management and debt collection. If Movianto, or other third parties we may enter into contracts with default on the 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 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 in the United States, PIXUVRI will face competition from currently marketed anthracyclines, such as mitoxantrone (Novantrone®). In addition, PIXUVRI may face competition in the United States and the European Union if new anti-cancer drugs with reduced toxicity are developed and marketed in the United States and/or the European Union.
- 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 pacritinib to market, pacritinib will face competition from ruxolitinib (Jakafi®) and new drugs targeting similar diseases that may be developed and marketed.
- 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 and technical resources and substantially larger development and marketing teams than us, as well as significantly greater experience than we do in developing, manufacturing and marketing products. As a result, products of our competitors 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.

*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.*

Even if we succeed in bringing any of our proposed products to market, they may not be considered cost-effective and third-party or government reimbursement might not be available or sufficient. 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. 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.

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 the United States, under the Patient Protection and Affordable Care Act (HR 3590), or the PPACA, instituted comprehensive health care reform in 2010 and we believe 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. The announcement or adoption of these proposals could significantly influence the purchase of healthcare services and products, resulting in lower prices and reducing demand for our products. In addition, in almost all European markets, pricing and choice of prescription pharmaceuticals are subject to governmental control. Therefore, the price of our products and their reimbursement in Europe will be determined by national regulatory authorities. For example, the pricing of PIXUVRI in Europe is subject to governmental control and we are focused on obtaining reimbursement in the five major market European countries (France, Germany, Italy, Spain and the United Kingdom), as well as smaller territories in Western and Northern Europe, in 2013.

If adequate third-party or government coverage is not available, or if new restrictive legislation is adopted, market acceptance of our products may be limited and we may not be able to maintain price levels sufficient to realize an appropriate return on our investment in research and product development or achieve anticipated revenues. 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 any of our license agreements for intellectual property underlying PIXUVRI, pacritinib, Opaxio, tosedostat, brostallicin, or any other products are terminated, we may lose the right to develop or market that product.*

We have licensed intellectual property from third parties, including patent applications relating to intellectual property for PIXUVRI, pacritinib, tosedostat, and brostallicin. We have also 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 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, pacritinib, Opaxio, tosedostat, and brostallicin.

*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. Our product candidates PIXUVRI, Opaxio, tosedostat, and brostallicin are in clinical and pre-clinical development and are in-licensed from third-parties.

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 hold rights under numerous patents that we have acquired or licensed or 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 United States 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 and through acquisitions. Patents have been issued on many of these applications. We have pending patent applications or issued patents in the United States and foreign countries directed to PIXUVRI, pacritinib, Opaxio, 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 pacritinib-directed U.S. patents will expire from 2026 through 2029. The PIXUVRI-directed U.S. patents will expire in 2014. The tosedostat-directed U.S. patents will expire in 2017. The brostallicin-directed U.S. patents will expire on various dates ranging between 2017 through 2021. The PIXUVRI-directed patents in Europe will expire from 2013 through 2023. 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 United States and through 2027 in some countries in Europe. Supplementary Protection Certificates extending certain PIXUVRI-directed patents have been granted in Italy and Luxembourg, but there can be no guarantee of extensions in other countries. The expiration of these patents may allow our competitors to copy the inventions that are currently protected and better compete with us.

*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.

The patent position of biopharmaceutical firms generally is highly uncertain and involves complex legal and factual questions. The U.S. Patent and Trademark Office has not established a consistent policy regarding the breadth of claims that it will allow in biotechnology patents. If it allows broad claims, the number and cost of patent interference proceedings in the United States and the risk of infringement litigation may increase. If it allows narrow claims, the risk of infringement may decrease, but the value of our rights under our patents, licenses and patent applications may also decrease. Patent applications in which we have rights may never issue as patents and the claims of any issued patents may not afford meaningful protection for our technologies or products. In addition, patents issued to us or our licensors may be challenged and subsequently narrowed, invalidated or circumvented. Litigation, interference proceedings or other governmental proceedings that we may become involved in with respect to our proprietary technologies or the proprietary technology of others could result in substantial cost to us.

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.

*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. With respect to our in-licensed patents, if we attempt to initiate a patent infringement suit against an alleged infringer, it is possible that our applicable licensor will not participate in or assist us with the suit and as a result we may not be able to effectively enforce the applicable patents against the alleged infringers.

*We may be unable to obtain or protect our intellectual property rights and we may be liable for infringing 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.*

At times, we may monitor patent filings for patents that might be relevant to some of 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 third-party 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 such 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. We do not believe that PIXUVRI or any of the products we are currently developing infringe upon the rights of any third parties nor

are they infringed upon by third parties; however, there can be no assurance that our technology will not be found in the future to infringe upon the rights of others or be infringed upon by others. In such a case, others may assert infringement claims against us, and should we be found to infringe upon their patents, or otherwise impermissibly utilize their intellectual property, we might be forced to pay damages, potentially including treble damages, if we are found to have willfully infringed on such parties' patent rights. In addition to any damages we might have to pay, we may be required to obtain licenses from the holders of this intellectual property, enter into royalty agreements, or redesign our drug candidates so as not to utilize this intellectual property, each of which may prove to be uneconomical or otherwise impossible. Conversely, we may not always be able to successfully pursue our claims against others that infringe upon our technology and the technology exclusively licensed from any third parties. Thus, the proprietary nature of our technology or technology licensed by us may not provide adequate protection against competitors.

Even if infringement claims against us are without merit, or if we challenge the validity of issued patents, lawsuits take significant time, may, even if resolved in our favor, be expensive and divert management attention from other business concerns. Uncertainties resulting from the initiation and continuation of any litigation could limit our ability to continue our operations.

*We may be subject to litigation proceedings that could harm our financial condition and results of operations.*

We may be subject to legal claims or regulatory matters involving shareholder, consumer, regulatory and other issues. As described in "Legal Proceedings" in Part I, Item 3 of this Form 10-K, we are currently engaged in a number of litigation matters. Litigation is subject to inherent uncertainties, and unfavorable rulings could occur. Adverse outcomes in some or all of such pending cases may result in significant monetary damages or injunctive relief against us. If an unfavorable ruling were to occur in any of the legal proceedings we are or may be subject to, our business, financial condition, results of operations and the trading price of our securities may be harmed for the period in which the ruling occurred or future periods.

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. 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. For example, as described in "Legal Proceedings" in Part I, Item 3 of this Form 10-K, CONSOB has not yet notified us of a resolution with respect to its claim that our disclosure related to the contents of the opinion expressed by Stonefield Josephson, Inc., an independent public accounting firm, with respect to our 2008 financial statements was late. However, based on our assessment, we believe the likelihood that it is probable that CONSOB will impose a pecuniary administrative sanction for such asserted violation.

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, we and certain of our officers and directors were 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 that we subsequently settled. We could not 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. Our insurance is subject to high deductibles 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.

Prior to when commercial sales of PIXUVRI began, we had an exclusive manufacturing contract for drug substance with a different manufacturer. 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 on November 11, 2010, 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. At the hearing on October 11, 2012, the parties informed the court about the ongoing negotiations pending between them and asked the court, accordingly, to postpone the case. At the request of the parties, the court extended the final hearing until March 21, 2013.

*If there is an adverse outcome in the shareholder derivative litigation that was filed against us, our business may be harmed.*

In April 2010, three shareholder derivative complaints were filed against us and certain of our officers and directors in the U.S. District Court for the Western District of Washington. These derivative complaints allege that defendants breached their fiduciary duties to us by making or failing to prevent the issuance of certain alleged false and misleading statements related to the FDA approval process for PIXUVRI. In May 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 (now Robbins Arroyo 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. In November 2012, co-lead counsel filed an executed Stipulation of Settlement, with attached exhibits, with the Court and derivative plaintiffs filed an Unopposed Motion for Preliminary Approval of Settlement, along with related documents. The Court issued an Order Preliminarily Approving Settlement and Providing for Notice on December 26, 2012, scheduling a settlement hearing for March 22, 2013 at 10:00 am. In February 2013, co-lead counsel filed Plaintiffs' Unopposed Motion for Final Approval of the Settlement and Plaintiffs' Application for Attorneys' Fees, Reimbursement of Expenses, and Incentive Award, seeking up to \$1.3 million in attorneys fees, reimbursement of \$58,195.07 in expenses, and an incentive award of \$1,500.00 for plaintiff Joseph Shackleton. We believe these fees and expenses will be covered by insurance. At this stage of the litigation, no probability of loss can be predicted in the event the settlement does not receive final approval.

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.

*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. If the paclitaxel or polyglutamic acid purchased from our sources is insufficient in quantity or quality, if a supplier fail to deliver in a timely fashion or at all, or if these relationships terminate, we may not be able to qualify and obtain a sufficient supply from alternate sources on acceptable terms, or at all.

*Our net operating losses may not be available to reduce future income tax liability.*

Our substantial tax loss carryforwards for U.S. federal income tax purposes, but 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, as a result of prior changes in the stock ownership of the company. Moreover, future changes



in the ownership of our stock, including those resulting from issuance of shares of our common stock upon exercise of outstanding warrants, may further limit our ability to use our net operating losses.

*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. If the insurance covering the product use in our clinical trials for our product candidates is not maintained on acceptable terms or at all, we might not have 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 could also exceed our insurance coverage and could harm our financial condition and results of operations.

*Our assets and liabilities in our European branches and subsidiaries 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 for financial reporting purposes. The carrying value of the assets and liabilities held in our European branches and subsidiaries 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.

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

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

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

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

### **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. 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. For example, during the twelve month period ended February 22, 2013, our stock price has ranged from a low of \$1.14 to a high of \$7.40 (as adjusted to reflect the one-for-five reverse stock split effective September 2, 2012). Fluctuations in the trading price or liquidity of our common stock may harm the value of your investment in our common stock. 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.

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 by us or others of serious adverse events that have occurred during treatment of patients following the grant of conditional marketing authorization for PIXUVRI in the European Union;
- announcements of technological innovations or new commercial therapeutic products by us, our collaborative partners or our present or potential competitors;
- our issuance of debt, equity or other securities, which we need to pursue to generate additional funds to cover our 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;
- our ability to realize the anticipated benefits of pacritinib;
- 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; and
- general economic and market conditions.

Securities class action lawsuits are often brought against companies after periods of volatility in the market price of their securities. Such lawsuits have been filed against us in the past, and should any new lawsuits be filed, such matters could result in substantial costs and a diversion of resources and our senior management team's attention.

*Shares of common stock are equity securities and are subordinate to any preferred stock or future indebtedness.*

Shares of our common stock rank junior to any shares of our preferred stock that we may issue in the future to any existing or future indebtedness we may incur 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. Any future indebtedness and 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.

*Future sales or other dilution of our equity may harm the market price of shares of our common stock.*

We expect to issue additional equity securities to fund our operating expenses as well as for other purposes. 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;
- 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's anti-takeover statute 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 66,000 square feet of space at 3101 Western Avenue in Seattle, Washington. The term of this lease is for a period of 120 months, which commenced on May 1, 2012. We also lease approximately 4,700 square feet of warehouse space in Seattle, Washington with a lease expiration of May 2013. Additionally, we lease 2,700 square feet in Milan, Italy with a lease expiration of December 2015 and 660 square feet in Heathrow, United Kingdom with a lease expiration of September 2013. 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 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 \$7,000 to \$659,000 converted using the currency exchange rate as of December 31, 2012, applicable to each of the two asserted violations. In July 2010, CONSOB notified us that it had begun the preliminary investigation for its decision on these administrative proceedings and provided us with a preliminary investigation report in response to the defenses we submitted in January 2010. In August 2010, we submitted further defenses that CONSOB had to evaluate before imposing any possible administrative sanctions. In March 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 us for the violation asserted in clause (ii) is probable.

On April 14, 2009, December 21, 2009 and June 25, 2010, 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, 2005 and 2006 and 2007. 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, \$7.2 million, \$3.3 million and \$1.1 million converted using the currency exchange rate as of December 31, 2012, 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 final decision of the lower tax courts (i.e. the Provincial Tax Court or the Regional Tax Court) or of the Supreme Court is unfavourable to us, we may be requested to pay to the ITA an amount up to €9.4 million, or approximately \$12.4 million converted using the currency exchange rate as of December 31, 2012, 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.

**2003 VAT.** On September 13, 2011, the Provincial Tax Court issued decision no. 229/3/2011, which (i) fully accepted the merits of our appeal, (ii) declared that no penalties can be imposed against us, and (iii) found the ITA liable to pay us €10,000, or approximately \$13,000 converted using the currency exchange rate as of December 31, 2012, as partial refund of the legal expenses we incurred for our appeal. On October 16, 2012, ITA appealed against this decision. The Regional Tax Court has scheduled a hearing for discussion of the

merits of the 2003 VAT case on May 31, 2013. We plan to defend ourselves in front of the Regional Tax Court both on procedural grounds and on the merits of the case.

**2005 VAT.** On January 13, 2011, the Provincial Tax Court issued decision No. 4/2010 which (i) partially accepted our appeal and declared that no penalties can be imposed against us, (ii) confirmed the right of the ITA 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. The ITA appealed to the higher court against the decision that no penalties could be imposed on us. We do not believe that the Provincial Tax Court has carefully reviewed all of our arguments, relevant documents and other supporting evidence that our counsel filed and presented during the hearing, including an appraisal from an independent expert. Accordingly, we also filed an appeal against the Provincial Tax Court's decision. On October 15, 2012, the Regional Tax Court issued a decision no. 127/31/2012, which (i) fully accepted the merits of our appeal and (ii) confirmed that no penalties can be imposed against us. The ITA is entitled to appeal such decision to the Italian Supreme Court within six months. We paid the required VAT deposit including interest and collection fees of €2.1 million. On January 3, 2013, the ITA refunded the VAT deposit including interest and collection fees of €2.1 million, or approximately \$2.8 million converted using the currency exchange rate as of December 31, 2012.

**2006 VAT.** On October 18, 2011, the Provincial Tax Court issued decision no. 276/21/2011 (jointly with the 2007 VAT case) in which it (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 ITA was liable to pay us €10,000, or approximately \$13,000 converted using the currency exchange rate as of December 31, 2012, as partial refund of the legal expenses incurred for the appeal. In March 2011, we paid to the ITA the required deposit in respect of the 2006 VAT for an amount of €0.4 million, or approximately \$0.6 million converted using the currency exchange as of December 31, 2012 (including 50% of the assessed VAT, interest and collection fees). After the Provincial Tax Court's decision at the end of the first quarter 2012, the ITA issued an order of refund of the deposit amount. Such refund was offset with the additional deposit payment made in April 2012 for 2005 VAT (please refer to "2005 VAT" above). The ITA appealed to the higher court against this decision. The Regional Tax Court scheduled the first hearing for November 6, 2012 (jointly with the 2007 VAT case). We defended ourselves against the ITA's appeal before the higher Regional Tax Court; to-date no court decision has been issued.

**2007 VAT.** On October 18, 2011, the Provincial Tax Court issued decision no. 276/21/2011 (jointly with the 2006 VAT case) in which the Provincial Tax Court (i) fully accepted the merits of our appeal (ii) declared that no penalties can be imposed against us, and (iii) found for 2006 and 2007 VAT cases the ITA liable to pay us €10,000, or approximately \$13,000 converted using the currency exchange rate as of December 31, 2012, as partial refund of the legal expenses incurred for the appeal. 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 (including 50% of the assessed VAT, interest and collection fees). After the Provincial Tax Court's decision at the end of the first quarter 2012, the ITA issued an order of refund of the deposit amount. Such refund has been suspended by the collection agent due to an assessment of social contribution due for an amount equal to €0.1 million, or approximately \$0.1 million converted using the currency exchange rate as of December 31, 2012. We do not believe this social contribution was due and we are in the process of resolving the issue with the social contribution authorities. The ITA appealed to the higher court against this decision. The Regional Tax Court scheduled the first hearing for November 6, 2012 (jointly with the 2006 VAT case). We defended against the ITA's appeal before the higher Regional Tax Court, but no court decision has been issued.

On August 3, 2009, Società Italiana Corticosteroidi S.R.L., or Sicor, filed a lawsuit in the Court of Milan to obtain the Court's assessment that we were bound to source a chemical compound, whose chemical name is BBR2778, 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 held on 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. At the hearing held on October 11, 2012 the parties informed the Court about the ongoing negotiations pending between the parties and asked the Court, accordingly, to postpone the case. At the request of the parties, the Court extended the final hearing until March 21, 2013. 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 our 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 PIXUVRI. The action seeks damages on behalf of purchasers of our 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, plaintiffs filed a motion for preliminary approval of the settlement, along with related documents. On March 16, 2012, the Court granted preliminary approval of the settlement, granted conditional certification to the proposed class, and approved the proposed forms of notice to the class. A settlement hearing occurred on July 20, 2012. The Court entered a Final Judgment and Order of Dismissal with Prejudice on July 25, 2012. The negotiated terms of the settlement include a \$19.0 million dollar settlement fund, which was paid by our insurance carriers. As a result, there is no estimated loss to us.

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 (now Robbins Arroyo 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*. On November 6, 2012, co-lead counsel filed an executed Stipulation of Settlement, with attached exhibits, with the Court. On November 13, 2012, derivative plaintiffs filed an Unopposed Motion for Preliminary Approval of Settlement, along with related documents. The Court issued an Order Preliminarily Approving Settlement and Providing for Notice on December 26, 2012, scheduling a settlement hearing for March 22, 2013 at 10:00 a.m. In February 2013, co-lead counsel filed Plaintiffs' Unopposed Motion for Final Approval of the Settlement and Plaintiffs' Application for Attorney's Fees, Reimbursement of Expenses, and Incentive Award, seeking up to \$1.3 million in attorney's fees, reimbursement of \$58,195.07 in expenses, and an incentive award of \$1,500.00 for plaintiff Joseph Shackleton. We believe these fees and expenses will be covered by insurance. At this stage of the litigation, no probability of loss can be predicted in the event the settlement does not receive final approval.

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 the Company, following the merger of Novuspharma into the Company 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 interest for an additional amount of €0.1 million) by January 15, 2012, or the January 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 a subsidized loan, and (ii) up to €2.5 million as a 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 subsidized 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 our 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 subsidized loan, but we never issued such Guarantee. In 2009, our Italian branch's research activities were terminated. Since we assert that the January 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 January Decree declared ineffective. However, if we are unable to successfully defend ourselves against the January 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 interest, as described above), or approximately \$0.8 million converted using the currency exchange rate as of December 31, 2012, plus counterparty's attorney's fees, litigation costs and additional default interest for the period lapsed between January 16, 2012 and the date of the effective payment. While the parties were engaged in pending settlement negotiations, (i) the Ministry interrupted the recovery process of the relevant financial support, and (ii) at the first hearing before the Court of Rome that took place on July 20, 2012, the Ministry failed to appear at the hearing, with the consequence that the Judge declared it in default of appearance, and we requested a postponement to continue the negotiations with the Ministry; the judge granted the postponement and the next hearing is now scheduled for April 5, 2013. On September 17, 2012, we were informed of a decree, dated August 27, 2012, issued by the General Director of the Ministry, or the August Decree, that is aimed at rectifying the January Decree and according to which the revocation will apply to only the portion of the relevant financial support that had never been requested by or granted to the Company (i.e., €0.2 million as subsidized loan and €0.1 million as grant for expenses, that we never received and therefore not obliged to return). Such decree dated August 27, 2012 was subject to the registration by the Court of Auditors (Corte dei Conti) that was performed on October 31, 2012. We are currently discussing with the Ministry the modalities to terminate the aforesaid legal suit, which is formally still pending before the Court of Rome. At this time, considering the contents of the aforementioned decree dated August 27, 2012, as well as its registration by the Court of Auditors, the likelihood of an unfavorable outcome of these legal proceedings is remote.

In July 2012, a complaint was filed against us in the Superior Court of Washington for King County captioned GLY Construction Inc. v. Cell Therapeutics, Inc. and Selig Holdings Company (Case No. 12-2-22742-0 SEA), naming the Company and Selig Holdings Company as defendants. The complaint asserts claims for breach of contract, unjust enrichment/quantum meruit and lien foreclosure, and alleges that we failed to pay certain amounts to plaintiffs for work performed for construction improvements totaling approximately \$4.0 million. We contend that these amounts should be offset by amounts owed under the lease agreement with Selig Holdings Company. We asserted cross-claims for breach of contract and business devastation against Selig in the above-referenced lawsuit. These cross-claims were based on Selig's refusal to pay amounts owed under the lease agreement, including amounts owed to GLY and other expenses incurred. GLY, Selig and the Company reached a settlement on all of GLY's claims on or around September 4, 2012. The settlement included a partial lump sum payment with subsequent monthly payments from both Selig and us. We still have claims against Selig for amounts owed under the lease agreement, including portions of the settlement amount paid by us to GLY and are currently negotiating potential settlement solutions.

In March 2011, we entered into a license and co-development agreement, or the Chroma License Agreement, with Chroma Therapeutics, Ltd., or Chroma, providing us with exclusive marketing and co-development rights to Chroma's drug candidate, tosedostat, in North, Central and South America. By a letter



dated July 18, 2012 Chroma notified us that Chroma alleges breaches under the Chroma License Agreement. Chroma asserts that we have not complied with the Chroma License Agreement because we made decisions with respect to the development of tosedostat without the approval of the joint committees to be established pursuant to the terms of the Chroma License Agreement, did not hold meetings of those committees and have not used diligent efforts in the development of tosedostat. We dispute Chroma's allegations and intend to vigorously defend our development activities and judgments. In particular, we dispute Chroma's lack of diligence claim based in part on the appropriateness of completing the ongoing Phase 2 combination trials prior to developing a Phase 3 trial design. In addition, we believe that Chroma has failed to comply with its antecedent obligations with respect to the joint committees and failed to demonstrate an ability to manufacture tosedostat to the required standards under the terms of the Chroma License Agreement. Under the Chroma License Agreement there is a 90 day cure period for any nonpayment default, which period shall be extended to 180 days if the party is using efforts to cure. A party may terminate the Chroma License Agreement for a material breach only after arbitration in accordance with the terms of the Chroma License Agreement. Effective September 25, 2012, we and Chroma entered into a three month standstill with respect to the parties' respective claims under the Chroma License Agreement, but otherwise reserving the parties' respective rights as of the commencement of the standstill period. Effective December 25, 2012, the standstill was extended for an additional three months. The standstill is terminable by either party on one month's notice.

On June 16, 2012, Craig W. Philips delivered notice of his intention to resign as our President, effective July 16, 2012. Mr. Philips claimed that his departure was a result of diminution of responsibilities and that he is entitled to the compensation for termination without cause as specified in his Employment Agreement. On July 16, 2012, Craig W. Philips resigned as our President. We entered into a Settlement Agreement and Full and Final Release of Claims, dated as of October 25, 2012 (the "Philips Settlement Agreement"), with Mr. Philips. Under the Philips Settlement Agreement, Mr. Philips is entitled to receive a severance payment of \$435,500, with 25% of such amount to be paid within 30 days of the effective date and the balance of such amount to be paid in twelve monthly installments thereafter. We have also agreed to pay Mr. Philips' premiums to continue his health coverage for 13 months following his termination. Mr. Philips' equity awards granted by us and Aequus Biopharma, Inc., a subsidiary of the Company, to the extent then outstanding and unvested, terminated as of June 16, 2012. Pursuant to the Philips Settlement Agreement, Mr. Philips has agreed to vote the existing shares of the Company that he owns in a manner consistent with the recommendation of our board of directors through October 13, 2013. The Philips Settlement Agreement also includes a release by Mr. Philips of claims against us and certain non-competition and other restrictive covenants by Mr. Philips in favor of us.

On November 15, 2012, Daniel G. Eramian separated from employment with us as our Executive Vice President, Corporate Communications. We agreed on December 27, 2012 to enter into a Settlement Agreement and Full and Final Release of Claims (the "Eramian Settlement Agreement") with Mr. Eramian. Under the Eramian Settlement Agreement, Mr. Eramian is entitled to receive total cash severance payments of approximately \$567,238. Of the total payments, approximately \$252,238 will be paid in May 2013, and the balance will be paid in twelve monthly installments following May 2013. We will also pay the premiums to continue Mr. Eramian's health coverage and life insurance provided by us for up to 18 months following his termination. In addition, the Eramian Settlement Agreement provides for accelerated vesting of certain equity awards granted to Mr. Eramian by us that were otherwise unvested such that he became vested in 33,712 shares of our common stock, and we may either settle a portion of such shares in cash or reacquire a portion of such shares to satisfy applicable tax withholding obligations. Any rights of Mr. Eramian to other equity awards granted by us, to the extent otherwise unvested, terminated. The Eramian Settlement Agreement also includes a mutual release of claims by the parties and certain restrictive covenants by Mr. Eramian in favor of us.

In addition to the items 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.

## 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 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 our common stock as reported on the NASDAQ Capital Market, our principal trading market.

	<u>High</u>	<u>Low</u>
<b>2011</b>		
First Quarter . . . . .	\$16.50	\$6.30
Second Quarter . . . . .	\$12.60	\$7.35
Third Quarter . . . . .	\$ 8.45	\$4.75
Fourth Quarter . . . . .	\$ 7.40	\$4.75
<b>2012</b>		
First Quarter . . . . .	\$ 8.25	\$5.00
Second Quarter . . . . .	\$ 6.75	\$2.80
Third Quarter . . . . .	\$ 3.94	\$1.77
Fourth Quarter . . . . .	\$ 2.75	\$1.14

On February 22, 2013, the last reported sale price of our common stock on The NASDAQ Capital Market was \$1.34 per share. As of February 22, 2012, there were 181 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

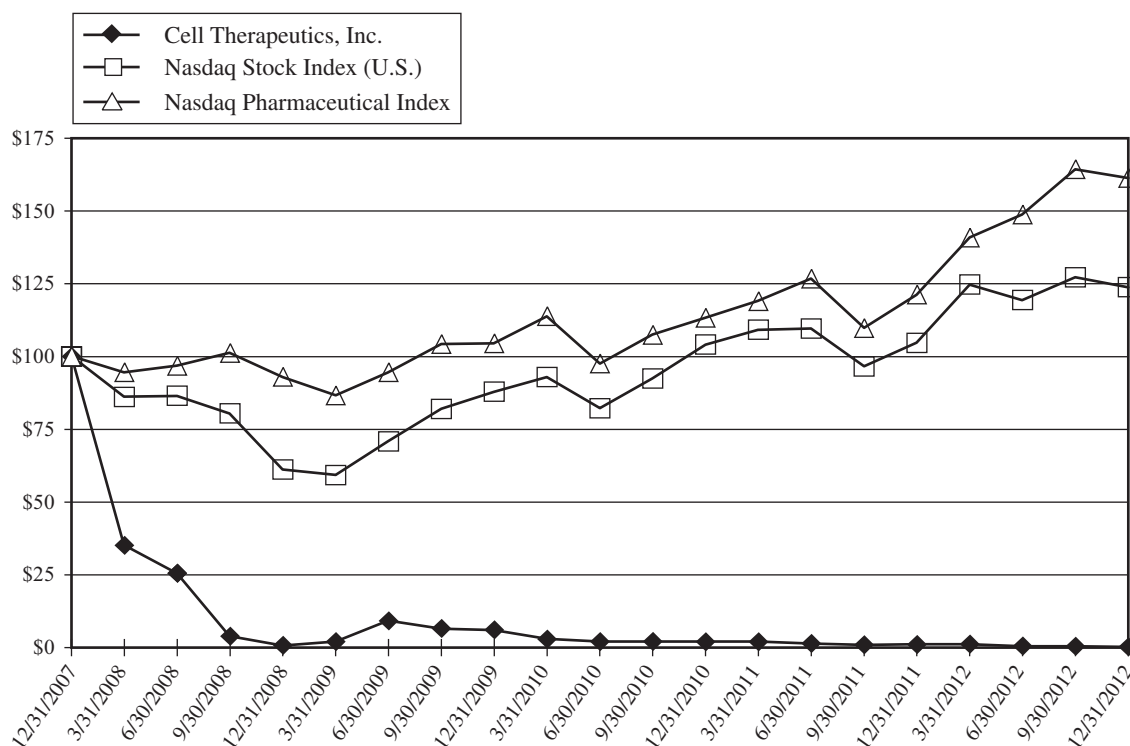
The following table sets forth information with respect to purchases of our common stock during the three months ended December 31, 2012:

<u>Period</u>	<u>Total Number of Shares Purchased (1)</u>	<u>Average Price Paid per Share</u>	<u>Total Number of Shares Purchased as Part of Publicly Announced Programs</u>	<u>Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs</u>
October 1 – October 31, 2012 . . . . .	1,549	\$1.94	—	—
November 1 – November 30, 2012 . . . . .	3,742	\$1.34	—	—
December 1 – December 31, 2012 . . . . .	—	\$ —	—	—
Total . . . . .	<u>5,291</u>	<u>\$1.51</u>	<u>—</u>	<u>—</u>

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

## 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, 2012, 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, 2007. The actual returns shown on the graph above are as follows:

	<u>3/31/08</u>	<u>6/30/08</u>	<u>9/30/08</u>	<u>12/31/08</u>
Cell Therapeutics, Inc. ....	\$ 35.11	\$ 25.53	\$ 3.89	\$ 0.75
NASDAQ Stock Index (U.S.) ....	\$ 86.11	\$ 86.54	\$ 80.48	\$ 61.17
NASDAQ Pharmaceutical Index ....	\$ 94.62	\$ 96.81	\$101.22	\$ 93.04
	<u>3/31/09</u>	<u>6/30/09</u>	<u>9/30/09</u>	<u>12/31/09</u>
Cell Therapeutics, Inc. ....	\$ 2.02	\$ 9.16	\$ 6.55	\$ 6.07
NASDAQ Stock Index (U.S.) ....	\$ 59.26	\$ 70.83	\$ 81.98	\$ 87.93
NASDAQ Pharmaceutical Index ....	\$ 86.64	\$ 94.62	\$104.30	\$104.55
	<u>3/31/10</u>	<u>6/30/10</u>	<u>9/30/10</u>	<u>12/31/10</u>
Cell Therapeutics, Inc. ....	\$ 2.88	\$ 2.02	\$ 2.08	\$ 1.97
NASDAQ Stock Index (U.S.) ....	\$ 92.95	\$ 82.22	\$ 92.45	\$104.13
NASDAQ Pharmaceutical Index ....	\$113.89	\$ 97.61	\$107.45	\$113.33
	<u>3/31/11</u>	<u>6/30/11</u>	<u>9/30/11</u>	<u>12/31/11</u>
Cell Therapeutics, Inc. ....	\$ 1.97	\$ 1.40	\$ 0.94	\$ 1.03
NASDAQ Stock Index (U.S.) ....	\$109.23	\$109.62	\$ 96.59	\$104.69
NASDAQ Pharmaceutical Index ....	\$119.02	\$126.77	\$109.78	\$121.31
	<u>3/31/12</u>	<u>6/30/12</u>	<u>9/30/12</u>	<u>12/31/12</u>
Cell Therapeutics, Inc. ....	\$ 1.17	\$ 0.51	\$ 0.43	\$ 0.23
NASDAQ Stock Index (U.S.) ....	\$124.76	\$119.42	\$127.23	\$123.85
NASDAQ Pharmaceutical Index ....	\$140.88	\$148.82	\$164.38	\$161.38

## 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,				
	2012	2011	2010	2009	2008
	(In thousands, except per share data)				
<b>Consolidated Statements of Operations Data:</b>					
Revenues:					
Product sales(1) . . . . .	\$ —	\$ —	\$ —	\$ —	\$ 11,352
License and contract revenue . . . . .	—	—	319	80	80
Total revenues . . . . .	—	—	319	80	11,432
Operating expenses, net:					
Cost of product sold(1) . . . . .	—	—	—	—	3,244
Research and development . . . . .	33,201	34,900	27,031	30,179	51,614
Selling, general and administrative . . . . .	38,244	38,290	51,546	57,725	41,607
Acquired in-process research and development(2) . . . . .	29,108	—	—	—	36
Amortization of purchased intangibles . . . . .	—	—	—	—	1,658
Restructuring charges and related gain on sale of assets, net(3) . . . . .	—	—	—	3,979	—
Gain on sale of Zevalin(1) . . . . .	—	—	—	—	(9,444)
Gain on sale of investment in joint venture(1) . . . . .	—	—	—	(10,244)	—
Settlement expense (income) . . . . .	944	(11,000)	145	4,710	3,393
Total operating expenses, net . . . . .	101,497	62,190	78,722	86,349	92,108
Loss from operations . . . . .	(101,497)	(62,190)	(78,403)	(86,269)	(80,676)
Other income (expense):					
Investment and other income (expense), net . . . . .	(478)	1,545	1,095	43	497
Interest expense . . . . .	(56)	(870)	(2,208)	(4,716)	(8,507)
Amortization of debt discount and issuance costs . . . . .	—	(546)	(768)	(5,788)	(66,530)
Foreign exchange gain (loss) . . . . .	344	(558)	(521)	33	3,637
Debt conversion expense . . . . .	—	—	(2,031)	—	—
Make-whole interest expense . . . . .	—	—	—	(6,345)	(70,243)
Gain on derivative liabilities, net . . . . .	—	—	—	7,218	69,739
Gain (loss) on exchange of convertible notes . . . . .	—	—	—	7,381	(25,103)
Equity loss from investment in joint venture . . . . .	—	—	—	(1,204)	(123)
Milestone modification expense . . . . .	—	—	—	(6,000)	—
Write-off of financing arrangement costs . . . . .	—	—	—	—	(2,846)
Net loss before noncontrolling interest . . . . .	(101,687)	(62,619)	(82,836)	(95,647)	(180,155)
Noncontrolling interest . . . . .	313	259	194	252	126
Net loss attributable to CTI . . . . .	\$(101,374)	\$ (62,360)	\$ (82,642)	\$ (95,395)	\$(180,029)
Gain on restructuring of preferred stock . . . . .	—	—	—	2,116	—
Dividends and deemed dividends on preferred stock . . . . .	(13,901)	(58,718)	(64,918)	(23,484)	(22,878)
Net loss attributable to common shareholders . . . . .	\$(115,275)	\$(121,078)	\$(147,560)	\$(116,763)	\$(202,907)
Basic and diluted net loss per common share(4) . . . . .	\$ (1.98)	\$ (3.53)	\$ (6.47)	\$ (7.64)	\$ (210.05)
Shares used in calculation of basic and diluted net loss per common share(4) . . . . .					
common share(4) . . . . .	58,125	34,294	22,821	15,279	966

	December 31,				
	2012	2011	2010	2009	2008
	(In thousands)				
<b>Consolidated Balance Sheets Data:</b>					
Cash and cash equivalents . . . . .	\$ 50,436	\$ 47,052	\$ 22,649	\$ 37,811	\$ 10,072
Restricted cash (5) . . . . .	—	—	—	—	6,640
Working capital . . . . .	37,644	33,291	(14,165)	(21,694)	(14,141)
Total assets (6) . . . . .	73,713	62,239	53,592	69,595	64,243
10% convertible senior notes . . . . .	—	—	—	—	19,784
9% convertible senior notes . . . . .	—	—	—	—	4,104
7.5% convertible senior notes . . . . .	—	—	10,215	10,102	32,601
6.75% convertible senior notes . . . . .	—	—	—	—	6,926
5.75% convertible senior notes . . . . .	—	—	12,093	11,677	23,808
4.0% convertible senior subordinated notes . . . . .	—	—	—	40,363	55,150
Current portion of long-term obligations . . . . .	393	970	1,717	1,312	757
Long-term obligations, less current portion . . . . .	4,641	2,985	4,206	1,861	2,907
Common stock purchase warrants . . . . .	13,461	13,461	13,461	626	—
Series A 3% convertible preferred stock . . . . .	—	—	—	—	417
Series B 3% convertible preferred stock . . . . .	—	—	—	—	4,031
Series C 3% convertible preferred stock . . . . .	—	—	—	—	3,221
Series D 7% convertible preferred stock . . . . .	—	—	—	—	734
Series 14 convertible preferred stock . . .	—	6,736	—	—	—
Accumulated deficit (6) . . . . .	(1,830,060)	(1,714,785)	(1,576,643)	(1,429,083)	(1,312,320)
Total shareholders' equity (deficit) . . . .	32,944	28,009	(5,145)	(18,769)	(132,061)

- (1) In 2008, we sold our product Zevalin to RIT Oncology, our 50/50 joint venture with Spectrum Pharmaceuticals, Inc., or Spectrum. We subsequently sold our 50% interest in RIT Oncology to Spectrum in March 2009.
- (2) Acquired in-process research and development in 2012 represents the purchase of assets from S\*Bio, which had not reached technological feasibility at the time of the acquisition. See Note 4 of the Notes to Consolidated Financial Statements for additional information.
- (3) The 2009 amount primarily relates to the closure of our Bresso, Italy operations as well as the termination of Zevalin-related employees.
- (4) 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-ten, one-for-six and one-for-five reverse stock splits on August 31, 2008 and May 15, 2011 and September 2, 2012, respectively. See Notes 1 and 17 of the Notes to Consolidated Financial Statements for a description of the computation of the number of shares and net loss per share.
- (5) The 2008 amount represents cash held in escrow to fund potential make-whole payments on certain of our convertible senior notes.
- (6) Effective January 1, 2011, we adopted new guidance on goodwill impairment. See Note 3 of the Notes to Consolidated Financial Statements for additional information.

## 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 are a biopharmaceutical company focused on the acquisition, development, and commercialization of less toxic and more effective ways to treat cancer. Our goal is to build a profitable company by generating income from products we develop and commercialize, either alone or with one or more potential strategic partners. We are currently concentrating our efforts on treatments that target blood-related cancers where there is a high unmet medical need. We are primarily focused on commercializing PIXUVRI in the European Union, or the E.U., for multiply relapsed or refractory aggressive non-Hodgkin lymphoma, or NHL, and conducting a Phase 3 clinical trial of pacritinib for the treatment of myelofibrosis. For an overview of additional information relating to our business, including PIXUVRI and our product development programs, please see the discussion in "Item 1. Business—Overview."

Our most clinically advanced compound is PIXUVRI. PIXUVRI is a novel aza-anthracenedione derivative that is structurally related to anthracyclines and anthracenediones but does not appear to be associated with the same level of cardiotoxic effects. PIXUVRI was structurally designed so that it cannot bind iron and perpetuate oxygen radical production or form a long-lived hydroxyl metabolite—both of which are the putative mechanisms for anthracycline-induced acute and chronic cardiotoxicity.

In May 2012, we expanded our late-stage pipeline of product candidates with the acquisition of pacritinib, an oral, once-daily JAK2 inhibitor that demonstrated meaningful clinical benefits and good tolerability in myelofibrosis patients in Phase 2 clinical trials. Myelofibrosis is a blood-related cancer caused by the accumulation of malignant bone marrow cells that triggers an inflammatory response, scarring the bone marrow and limiting its ability to produce red blood cells prompting the spleen and liver to take over this function. Symptoms that arise from this disease include enlargement of the spleen, anemia, extreme fatigue and pain. We believe pacritinib may offer an advantage over other JAK inhibitors through effective relief of symptoms with less treatment-emergent thrombocytopenia and anemia. We initiated the first Phase 3 clinical trial in myelofibrosis in January 2013, and plan to initiate a second Phase 3 trial in the second half of 2013.

In May 2012, the European Commission, or the E.C., granted conditional marketing authorization in the European Union, or the E.U., of PIXUVRI as a monotherapy for the treatment of adult patients with multiply relapsed or refractory aggressive non-Hodgkin lymphoma, or NHL. PIXUVRI is the first approved treatment for patients with multiply relapsed or refractory aggressive B-cell NHL. This approval was based on the results from



our pivotal Phase 3 clinical trial known as EXTEND or PIX301. In connection with the conditional marketing authorization, we are required to conduct a post-approval trial that is intended to confirm PIXUVRI's clinical benefit. We are currently accruing patients into a Phase 3 clinical trial comparing pixantrone and rituximab with gemcitabine and rituximab in the setting of aggressive B-cell NHL.

In September 2012, we began making PIXUVRI available for commercial sale in the E.U. PIXUVRI is currently available in eight countries: Austria, Denmark, Finland, Germany, Netherlands, Norway, Sweden and the United Kingdom. We plan to extend the availability of PIXUVRI to France, Italy and Spain, as well as other European countries, in 2013. We have established a commercial organization, including sales, marketing, supply chain management, reimbursement capabilities, to commercialize PIXUVRI in the E.U. We are pursuing potential partners for commercializing PIXUVRI in other markets outside the E.U. and the United States (U.S.). PIXUVRI is not yet approved in the United States.

We began commercializing PIXUVRI in September 2012 and the commercial potential of and our ability to successfully commercialize PIXUVRI is unknown. Our success in commercializing PIXUVRI will require, among other things, effective sales, marketing, manufacturing, distribution, information systems and pricing strategies, as well as compliance with applicable laws and regulations. The E.C. granted conditional marketing authorization of PIXUVRI, which means that we are, among other things, obligated to conduct specific post-approval clinical trials to confirm patient benefit as a condition of that approval. In connection with the conditional marketing authorization, we are required to conduct a post-approval trial that is intended to confirm PIXUVRI's clinical benefit. In order to do this, we will be required to conduct an additional clinical trial and, if successful, we intend to seek additional regulatory approvals. These activities will require substantial amounts of capital and may not ultimately prove successful. Further, our other product candidate, pacritinib, is in late-stage development. PIXUVRI will require significant further development, financial resources and personnel to obtain regulatory approval and develop into commercially viable products, if at all. Accordingly, over the next several years, we expect that we will incur substantial expenses, primarily as a result of activities related to the commercialization and continued development of PIXUVRI and pacritinib. We will also continue to invest in clinical development and manufacturing of our other product candidates. Our commitment of resources to the continuing development, regulatory and commercialization activities for PIXUVRI and the research, continued development and manufacturing of our other product candidates may require us to raise substantial amounts of additional capital and our operating expenses will fluctuate as a result of such activities. In addition, we may incur significant milestone payment obligations as our product candidates progress through clinical trials towards potential commercialization.

We are very early in the product launch and our future PIXUVRI product sales revenue cannot be accurately predicted. Our sales revenue may vary significantly from period to period as the launch progresses. Our results of operations may vary substantially from year to year and from quarter to quarter and, as a result, we believe that period to period comparisons of our operating results may not be meaningful and you should not rely on them as being indicative of our future performance.

#### *Financial summary*

We began to make PIXUVRI commercially available in the E.U. during the fourth quarter of 2012, and expect to recognize revenue beginning in the first quarter of 2013. We ended 2012 with cash and cash equivalents of \$50.4 million.

## Results of Operations

Years ended December 31, 2012 and 2011.

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

	<u>2012</u>	<u>2011</u>
Compounds under development:		
PIXUVRI .....	\$ 8,801	\$11,266
Pacritinib .....	2,217	—
Opaxio .....	1,322	1,445
Tosedostat .....	2,824	6,955
Brostallicin .....	234	75
Other compounds .....	150	180
Operating expenses .....	17,653	14,975
Research and preclinical development .....	—	4
Total research and development expenses .....	<u>\$33,201</u>	<u>\$34,900</u>

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 expenses 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 expenses 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, pacritinib, Opaxio, tosedostat and brostallicin are \$82.3 million, \$2.2 million, \$225.8 million, \$9.8 million and \$9.6 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 pacritinib prior to our acquisition from S\*Bio in May 2012 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. Costs for brostallicin prior to our acquisition of SM in July 2007 are also excluded from this amount.

Research and development expenses decreased to \$33.2 million for the year ended December 31, 2012 from \$34.9 million for the year ended December 31, 2011. PIXUVRI costs decreased primarily due to a decrease in clinical development activity associated with the completion of the EXTEND and RAPID trials in addition to a decrease in manufacturing activities. Costs for pacritinib primarily relate to clinical development activity associated with the initiation of our PERSIST-1 trial. Costs for our Opaxio program decreased primarily due to a reduction in clinical development and manufacturing activities, partially offset by an increase in investigator-sponsored trial enrollment. Costs for tosedostat during 2011 primarily related to the \$5.0 million upfront payment upon execution of the co-development and license agreement with Chroma. Our share of development costs associated with activity incurred under the agreement increased during 2012 primarily due to an increase in manufacturing activities. Costs for brostallicin increased primarily due to an increase in manufacturing activity. Our operating expenses increased primarily due to an increase in the average number of personnel between periods and an increase in noncash share-based compensation expense, in addition to increases in occupancy expense and consulting activities. These increases were partially offset by a decrease in discretionary bonus expense.

Our lead drug candidates, PIXUVRI, pacritinib, 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.

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 \$38.2 million for the year ended December 31, 2012 from \$38.3 million for the year ended December 31, 2011. This decrease was in part due to a \$3.8 million decrease in legal costs primarily as a result of our settlement with The Lash Group, Inc. in 2011 and a \$3.4 million decrease related to reversal of our provision for VAT assessments associated with our CTI (Europe) operations. These decreases were partially offset by a \$4.1 million increase in consulting and other professional services mainly associated with the commercial launch of PIXUVRI in the E.U. and a \$2.3 million increase in noncash share-based compensation.

*Acquired in-process research and development.* Acquired in-process research and development for the year ended December 31, 2012 relates to charges of \$29.1 million recorded in connection with our acquisition of assets from S\*BIO in May 2012.

*Settlement expense (income).* For the year ended December 31, 2012, we recorded \$0.9 million in settlement expense related to agreements entered into with two of our former executive officers for severance payments and related benefits upon their separation from us in the year ended December 31, 2012. We recorded \$11.0 million in settlement income for the year ended December 31, 2011 resulting from our settlement with The Lash Group, Inc.

*Investment and other income (expense), net.* Investment and other income (expense) decreased to \$0.5 million expense for the year ended December 31, 2012 as compared to \$1.5 million income for the year ended December 31, 2011. The expense amount for the year ended December 31, 2012 is primarily related to the change in Series 15 warrant liability and loss on disposal of property and equipment. The income amount for the year ended December 31, 2011 is primarily related to the retirement of our 5.75% convertible senior notes in December 2011 resulting from the difference in the carrying amount and the outstanding principal balance at maturity.

*Interest expense.* Interest expense decreased to \$0.1 million for the year ended December 31, 2012 from \$0.9 million for the year ended December 31, 2011. This decrease is primarily due to maturity of our 7.5% convertible senior notes in April 2011 and 5.75% convertible senior notes in December 2011.

*Amortization of debt discount and issuance costs.* For the year ended December 31, 2011, we amortized the remaining portion of debt discount and issuance costs of our 7.5% convertible senior notes upon maturity in April 2011.

*Foreign exchange gain (loss).* Foreign exchange gain for the year ended December 31, 2012 and loss for the year ended December 31, 2011 are due to fluctuations in foreign currency exchange rates, primarily related to payables and receivables in our European branches denominated in foreign currencies.

*Dividends and deemed dividends on preferred stock.* Dividends and deemed dividends on preferred stock were approximately \$13.9 million for the year ended December 31, 2012 related to the issuances of our Series 15-1, 15-2 and 17 preferred stock. Dividends and deemed dividends on preferred stock were approximately \$58.7 million for the year ended December 31, 2011 primarily related to the redemptions of our Series 8 and 10 preferred stock in addition to the issuances of our Series 12, 13 and 14 preferred stock.

*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 were as follows (in thousands):

	<u>2011</u>	<u>2010</u>
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
Total research and development expenses .....	<u>\$34,900</u>	<u>\$27,031</u>

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 GOG-0212 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 1 and Phase 2 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 bisplatin process development work, in addition to further decreases in expenses associated with the closure of our Bresso, Italy operations.

*Selling, general and administrative expenses.* Selling, general and administrative expenses decreased to \$38.3 million for the year ended December 31, 2011 from \$51.5 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 \$3.5 million provision for VAT assessments for the year ended December 31, 2010, a \$1.6 million decrease in compensation and benefits associated with a lower average number of personnel in the year ended December 31, 2011 than the prior year, 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 the year ended December 31, 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. and a \$1.9 million increase associated with our 2011 estimated discretionary bonus accrual.

*Settlement expense (income).* We recorded \$11.0 million in settlement income for the year ended December 31, 2011 resulting from our settlement with The Lash Group, Inc.

*Investment and other income (expense), net.* Investment and other income for the year ended December 31, 2011 increased to \$1.5 million as compared to \$1.1 million for the year ended December 31, 2010. The amount for the year ended December 31, 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 the year ended December 31, 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 \$0.9 million for the year ended December 31, 2011 from \$2.2 million for the year ended December 31, 2010. This decrease is primarily due to maturity of our 4% convertible senior subordinated notes in July 2010. In addition, we fully repaid \$10.3 million of our 7.5% convertible senior notes in April 2011 and \$10.9 million of our 5.75% convertible senior 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% convertible senior subordinated notes in July 2010 and maturity of our 7.5% convertible senior notes in April 2011.

*Foreign exchange gain (loss).* Foreign exchange loss 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% convertible senior subordinated notes in May 2010 for approximately 0.1 million shares of our common stock.

*Dividends and deemed dividends on preferred stock.* Dividends and deemed dividends on preferred stock were approximately \$58.7 million for the year ended December 31, 2011 primarily related to the redemptions of our Series 8 and 10 preferred stock in addition to the issuances of our Series 12, 13 and 14 preferred stock. Dividends and deemed dividends on preferred stock were approximately \$64.9 million related to the issuances of our Series 3, 4, 5, 6 and 7 preferred stock.

## **Liquidity and Capital Resources**

*Cash and cash equivalents.* As of December 31, 2012, we had \$50.4 million in cash and cash equivalents.

*Net cash used in operating activities.* Net cash used in operating activities totaled \$62.8 million for the year ended December 31, 2012, compared to \$60.5 million for the year ended December 31, 2011 and \$63.1 million for the year ended December 31, 2010. The increase in net cash used in operating activities for the year ended December 31, 2012 as compared to the year ended December 31, 2011 was in part due to the proceeds



received from our settlement with The Lash Group, Inc. in 2011. This increase was offset by a one-time upfront payment of \$5.0 million in March 2011 related to the licensing of tosedostat, which is included in research and development expense, and a decrease in cash paid for interest on our convertible notes. The decrease in net cash used in operating activities for the year ended December 31, 2011 as compared to the year ended December 31, 2010 was also due to the proceeds received from settlement with The Lash Group, Inc. In addition, decreases in cash paid for interest primarily during the year ended December 31, 2011 as compared to the year ended December 31, 2010 and payments related to the closure of our Bresso, Italy operations made in the year ended December 31, 2010 contributed to the overall decrease in cash used in operating activities for the year ended December 31, 2011. These decreases were offset primarily by an increase in research and development expense in the year ended December 31, 2011, which included the upfront payment of \$5.0 million related to the licensing of tosedostat. In addition, we made a \$1.1 million payment in the year ended December 31, 2011 to the GOG related to the 650 patient enrollment milestone achieved in the year ended December 31, 2010.

*Net cash used in investing activities.* Net cash used in investing activities totaled \$20.7 million for the year ended December 31, 2012 as compared to \$2.7 million for the year ended December 31, 2011 and \$2.3 million for the year ended December 31, 2010. The increase in net cash used in investing activities for the year ended December 31, 2012 was the result of \$17.8 million paid for the acquisition of assets from S\*BIO. Net cash used in investing activities for the years ended December 31, 2011 and 2010 was primarily due to purchases of property and equipment.

*Net cash provided by financing activities.* Net cash provided by financing activities totaled \$87.2 million for the year ended December 31, 2012 as compared to \$87.0 million for the year ended December 31, 2011 and \$49.7 million for the year ended December 31, 2010. Net cash provided by financing activities for the year ended December 31, 2012 was primarily related to the issuance of convertible preferred stock and warrants during the period. We received approximately \$32.9 million in net proceeds from the issuances of our Series 15 preferred stock and warrants to purchase common stock in May 2012 and July 2012, collectively. In addition, we received approximately \$54.7 million in net proceeds from the issuance of our Series 17 preferred stock and warrants to purchase common stock in October 2012. These proceeds were offset by \$0.2 million of cash paid in the year ended December 31, 2012 for transaction costs associated with the issuance of Series 14 preferred stock and \$0.1 million cash paid for the repurchase of shares in connection with satisfying tax withholding obligations on the vesting of restricted stock awards to employees during the year ended December 31, 2012.

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. We received approximately \$23.2 million in net proceeds from the issuance of our Series 8 preferred stock, warrants to purchase common stock and an additional investment right to purchase shares of our Series 9 preferred stock in January 2011. We also received approximately \$23.5 million in net proceeds from the issuance of our Series 10 preferred stock, warrants to purchase common stock and an additional investment right to purchase shares of our Series 11 preferred stock in February 2011. We received approximately \$15.0 million in net proceeds from the issuance of our Series 12 preferred stock and warrants to purchase common stock in May 2011. In addition, we received approximately \$28.0 million in net proceeds from the issuance of our Series 13 preferred stock and warrants to purchase common stock in July 2011. We received approximately \$18.9 million in net proceeds from the issuance of our Series 14 preferred stock and warrants to purchase common stock in December 2011. 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% convertible senior 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 during the year ended December 31, 2011.

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 offset by repayment of outstanding convertible notes during the period. We received \$28.0 million in net proceeds from the issuance of our Series 3



preferred stock and warrants to purchase common stock in January 2010. We received \$18.6 million in net proceeds from the issuance of our Series 4 preferred stock and warrants to purchase common stock in April 2010. In addition, we received \$19.7 million in net proceeds from the issuance of our Series 5 preferred stock and warrants to purchase common stock in May 2010. We received \$3.0 million in net proceeds from the issuance of our Series 6 preferred stock and warrants to purchase common stock in July 2010. Additionally, we received \$19.9 million in net proceeds from the issuance of our Series 7 preferred stock and warrants to purchase common stock in October 2010. These proceeds were offset by a \$38.5 million payment to retire the outstanding principal balance on our 4% convertible senior subordinated notes upon maturity in July 2010. We also 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.

### ***Capital Resources***

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. In 2007, our ability to satisfy obligations upon maturity of convertible notes raised substantial doubt about our ability to continue as a going concern. Since 2007, these obligations have been satisfied.

Our available cash and cash equivalents were \$50.4 million as of December 31, 2012. At our currently planned spending rate, we believe that our financial resources, in addition to the expected receipts from European PIXUVRI sales, will be sufficient to fund our operations into the fourth quarter of 2013. Changes in manufacturing, clinical trial expenses, and expansion of our sales and marketing organization in Europe, may consume capital resources earlier than planned. Additionally, we may not receive the country reimbursement rates in Europe for PIXUVRI that we currently assume in planning for 2013 and 2014.

### ***Capital Requirements***

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

- results of our clinical trials;
- regulatory approval of our products;
- the extent to which we acquire, invest or divest products, technologies or businesses, or sell or license our products to others;
- 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;
- success in commercializing our products;
- litigation and other disputes; and
- competitive market developments.

We expect we will need to raise additional funds and are currently exploring alternative sources of debt and other non-dilutive capital. We may seek to raise such capital through debt financings, partnerships, collaborations, joint ventures or disposition of assets. Our board of directors may issue shares depending on our financial needs and market opportunities, if deemed to be in the best interest of the shareholders. However, 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 as well as reduce our selling, general and administrative expenses.

The following table includes information relating to our contractual obligations as of December 31, 2012 (in thousands):

<u>Contractual Obligations</u>	<u>Payments Due by Period</u>				
	<u>Total</u>	<u>1 Year</u>	<u>2-3 Years</u>	<u>4-5 Years</u>	<u>After 5 Years</u>
Operating leases:					
Facilities .....	\$21,861	\$2,347	\$4,532	\$4,462	\$10,520
Long-term obligations (1) .....	31	—	31	—	—
Purchase commitments (2) .....	5,118	4,316	556	246	—
	<u>\$27,010</u>	<u>\$6,663</u>	<u>\$5,119</u>	<u>\$4,708</u>	<u>\$10,520</u>

- (1) Long-term obligations do not include \$5.0 million deferred rent associated with our operating lease for office space.
- (2) Purchase commitments include manufacturing supply commitments under the NerPharMa Agreement. See Item 1, *Business* for additional information regarding the NerPharMa Agreement.

### ***Additional Milestone Activities***

In connection with our development and commercialization activities, we have entered into a number of agreements pursuant to which we agree to make milestone payments upon certain development, sales-based and other milestone events; assume certain development and other expenses; and pay designated royalties on sales, including the Novartis Agreement, the UVM Agreement, the S\*Bio Agreement, the Chroma License Agreement, the PG-TXL Agreement, the GOG Agreement, the Nerviano Agreement, and our acquisition agreement with Cephalon. These agreements are discussed in more detail in “Item 1. Business—License Agreements and Additional Milestone Activities.” Under the Novartis Agreement, Novartis also has 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 if the option is exercised. 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. As we have commenced commercial sales of PIXUVRI, we expect to pay low- or mid-single digit royalties on PIXUVRI net sales pursuant to the UVM Agreement. The UVM Agreement is discussed in more detail in “Item 1, Business—License Agreements and Additional Milestone Activities.”

### **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.

### **Critical Accounting 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.

### *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.

### *Contingencies*

We are currently involved in various claims and legal proceedings. On a quarterly basis, we review the status of each significant matter and assess its potential financial exposure. If the potential loss from any claim, asserted or unasserted, or legal proceeding is considered probable and the amount can be reasonably estimated, we accrue a liability for the estimated loss. Significant judgment is required in both the determination of probability and the determination as to whether an exposure is reasonably estimable. Because of uncertainties related to these matters, accruals are based only on the best information available at the time. As additional information becomes available, we reassess the potential liability related to pending claims and litigation and may revise our estimates. These revisions in the estimates of the potential liabilities could have a material impact on our consolidated results of operations and financial position.

### *Share-based Compensation Expense*

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

For more complex awards, such as our 2012-2014 performance awards, we employ a Monte Carlo simulation model to calculate estimated grant-date fair value. For the 2012-2014 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.

## **Recently Adopted Accounting Standards**

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 require 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 on January 1, 2011. See Note 3, *Goodwill*, for additional information.

In June 2011, the FASB issued guidance amending the presentation requirements for comprehensive income. For public entities, this guidance was effective for fiscal years, and interim periods within those years, beginning after December 15, 2011 with early adoption permitted. 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 as discussed below. Upon adoption on January 1, 2012, we had 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. We elected to present comprehensive income in two separate but consecutive statements as part of the accompanying consolidated financial statements.

## **Recently Issued Accounting Standards**

In February 2013, the FASB issued guidance requiring presentation of amounts reclassified from each component of accumulated other comprehensive income. Disclosure is required of the effects of significant reclassifications on income statement line items either on the face of the statement where net income is presented or as a separate disclosure in the notes to the financial statements. For public entities, this guidance is effective prospectively for reporting periods beginning after December 15, 2012. We do not expect 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 the translation of euro-denominated financial results and accounts into U.S. dollars for financial reporting purposes. The carrying value of the assets and liabilities held in our European branches and subsidiaries 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. As the net positions of our unhedged foreign currency transactions fluctuate, our earnings might be negatively affected. As of December 31, 2012, our foreign currency transactions were minimal and changes to the exchange rate between the U.S. dollar and foreign currencies would have an immaterial effect on our earnings. In addition, the reported carrying value of our euro-denominated assets and liabilities held in our European branches and subsidiaries will be affected by fluctuations in the value of the U.S. dollar as compared to the euro. As of December 31, 2012, 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 \$2.0 million as of this date.

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

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

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## **REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Audit Committee of the  
Board of Directors and Shareholders of  
Cell Therapeutics, Inc.

We have audited the accompanying consolidated balance sheets of Cell Therapeutics, Inc. (the “Company”) as of December 31, 2012 and 2011, and the related consolidated statements of operations, comprehensive loss, shareholders’ equity (deficit), and cash flows for the years ended December 31, 2012, 2011 and 2010. 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, 2012 and 2011 and the consolidated results of its operations and its cash flows for the years ended December 31, 2012, 2011 and 2010 in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Cell Therapeutics, Inc.’s internal control over financial reporting as of December 31, 2012, 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 February 28, 2013 expressed an unqualified opinion on the effectiveness of the Company’s internal control over financial reporting.

/s/ Marcum LLP

San Francisco, CA  
February 28, 2013



## **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, 2012, 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, 2012 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, 2012 and 2011 and the related consolidated statements of operations, comprehensive loss, shareholders' equity (deficit), and cash flows for the years ended December 31, 2012, 2011 and 2010 of Cell Therapeutics, Inc. and our report dated February 28, 2013 expressed an unqualified opinion on those financial statements.

/s/ Marcum LLP

San Francisco, CA  
February 28, 2013

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

	December 31, 2012	December 31, 2011
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents .....	\$ 50,436	\$ 47,052
Prepaid expenses and other current assets .....	9,875	4,023
Total current assets .....	60,311	51,075
Property and equipment, net .....	6,785	3,604
Other assets .....	6,617	7,560
Total assets .....	<u>\$ 73,713</u>	<u>\$ 62,239</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable .....	\$ 12,065	\$ 5,750
Accrued expenses .....	10,209	11,064
Current portion of long-term obligations .....	393	970
Total current liabilities .....	22,667	17,784
Long-term obligations, less current portion .....	4,641	2,985
Total liabilities .....	27,308	20,769
Commitments and contingencies		
Common stock purchase warrants .....	13,461	13,461
Shareholders' equity:		
Preferred stock, no par value:		
Authorized shares—333,333		
Series 14 Preferred Stock, \$1,000 stated value, 20,000 shares		
designated, 0 and 10,000 shares issued and outstanding at		
December 31, 2012 and 2011, respectively .....	—	6,736
Common stock, no par value:		
Authorized shares—150,000,000 and 76,666,666 at December 31, 2012		
and 2011, respectively		
Issued and outstanding shares—109,823,748 and 40,613,545 at		
December 31, 2012 and 2011, respectively .....	1,872,885	1,744,801
Accumulated other comprehensive loss .....	(8,273)	(8,035)
Accumulated deficit .....	(1,830,060)	(1,714,785)
Total CTI shareholders' equity .....	34,552	28,717
Noncontrolling interest .....	(1,608)	(708)
Total shareholders' equity .....	32,944	28,009
Total liabilities and shareholders' equity .....	<u>\$ 73,713</u>	<u>\$ 62,239</u>

See accompanying notes.

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

	Year Ended December 31,		
	2012	2011	2010
Revenues:			
License and contract revenue .....	\$ —	\$ —	\$ 319
Total revenues .....	—	—	319
Operating expenses, net:			
Research and development .....	33,201	34,900	27,031
Selling, general and administrative .....	38,244	38,290	51,546
Acquired in-process research and development .....	29,108	—	—
Settlement expense (income) .....	944	(11,000)	145
Total operating expenses, net .....	101,497	62,190	78,722
Loss from operations .....	(101,497)	(62,190)	(78,403)
Other income (expense):			
Investment and other income (expense), net .....	(478)	1,545	1,095
Interest expense .....	(56)	(870)	(2,208)
Amortization of debt discount and issuance costs .....	—	(546)	(768)
Foreign exchange gain (loss) .....	344	(558)	(521)
Debt conversion expense .....	—	—	(2,031)
Total other expense, net .....	(190)	(429)	(4,433)
Net loss before noncontrolling interest .....	(101,687)	(62,619)	(82,836)
Noncontrolling interest .....	313	259	194
Net loss attributable to CTI .....	(101,374)	(62,360)	(82,642)
Dividends and deemed dividends on preferred stock .....	(13,901)	(58,718)	(64,918)
Net loss attributable to common shareholders .....	<u>\$(115,275)</u>	<u>\$(121,078)</u>	<u>\$(147,560)</u>
Basic and diluted net loss per common share .....	<u>\$ (1.98)</u>	<u>\$ (3.53)</u>	<u>\$ (6.47)</u>
Shares used in calculation of basic and diluted net loss per common share .....	<u>58,125</u>	<u>34,294</u>	<u>22,821</u>

See accompanying notes.

**CELL THERAPEUTICS, INC.**  
**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**  
(In thousands)

	Year Ended December 31,		
	2012	2011	2010
Net loss before noncontrolling interest . . . . .	<u>\$(101,687)</u>	<u>\$(62,619)</u>	<u>\$(82,836)</u>
Other comprehensive income (loss):			
Foreign currency translation adjustments . . . . .	(168)	241	301
Net unrealized gain (loss) on securities available-for-sale . . . . .	<u>(70)</u>	<u>(307)</u>	<u>142</u>
Other comprehensive income (loss) . . . . .	<u>(238)</u>	<u>(66)</u>	<u>443</u>
Comprehensive loss . . . . .	<u>(101,925)</u>	<u>(62,685)</u>	<u>(82,393)</u>
Comprehensive loss attributable to noncontrolling interest . . . . .	<u>313</u>	<u>259</u>	<u>194</u>
Comprehensive loss attributable to CTI . . . . .	<u><u>\$(101,612)</u></u>	<u><u>\$(62,426)</u></u>	<u><u>\$(82,199)</u></u>

See accompanying notes.

**CELL THERAPEUTICS, INC.**

**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)**  
(In thousands)

	<u>Preferred Stock</u>		<u>Common Stock</u>		<u>Accumulated Deficit</u>	<u>Accumulated Other Comprehensive Income (Loss)</u>	<u>Noncontrolling Interest</u>	<u>Total Shareholders' Equity (Deficit)</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>				
Balance at December 31, 2009 . . . .	—	\$ —	19,676	\$1,418,931	\$(1,429,083)	\$(8,412)	\$(205)	\$(18,769)
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)	823	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)	1,333	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)	1,750	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)	387	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)	1,892	19,273	—	—	—	—
Value of beneficial conversion features related to preferred stock . . . . .	—	—	—	39,923	—	—	—	39,923
Issuance of warrants in connection with preferred stock issuances . .	—	—	—	12,741	—	—	—	12,741
Issuance of common stock in exchange for convertible notes . . . . .	—	—	143	3,879	—	—	—	3,879
Exercise or exchange of common stock purchase warrants . . . . .	—	—	17	177	—	—	—	177
Equity-based compensation . . . . .	—	—	1,155	17,048	—	—	—	17,048
Other . . . . .	—	—	(51)	(922)	—	—	—	(922)
Noncontrolling interest . . . . .	—	—	—	—	—	—	(194)	(194)
Dividends and deemed dividends on preferred stock . . . . .	—	—	—	—	(64,918)	—	—	(64,918)
Net loss for the year ended December 31, 2010 . . . . .	—	—	—	—	(82,642)	—	—	(82,642)
Other comprehensive income . . . . .	—	—	—	—	—	443	—	443
Balance at December 31, 2010 . . . .	<u>—</u>	<u>\$ —</u>	<u>27,125</u>	<u>\$1,579,866</u>	<u>\$(1,576,643)</u>	<u>\$(7,969)</u>	<u>\$(399)</u>	<u>\$ (5,145)</u>

See accompanying notes.

**CELL THERAPEUTICS, INC.**

**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)—(Continued)**  
(In thousands)

	<u>Preferred Stock</u>		<u>Common Stock</u>		<u>Accumulated Deficit</u>	<u>Accumulated Other Comprehensive Income (Loss)</u>	<u>Noncontrolling Interest</u>	<u>Total Shareholders' Equity (Deficit)</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>				
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)	2,149	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)	2,469	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)	1,521	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)	3,529	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)	1,739	6,736	—	—	—	—
Value of beneficial conversion features related to preferred stock . . . . .	—	—	—	27,435	—	—	—	27,435
Issuance of additional investment rights in connection with preferred stock issuances . . . . .	—	—	—	7,742	—	—	—	7,742
Issuance of warrants in connection with preferred stock issuances . .	—	—	—	21,198	—	—	—	21,198
Exercise or exchange of common stock purchase warrants . . . . .	—	—	1,616	17,485	—	—	—	17,485
Equity-based compensation . . . . .	—	—	509	5,017	—	—	—	5,017
Noncontrolling interest . . . . .	—	—	—	50	—	—	(309)	(259)
Other . . . . .	—	—	(43)	(409)	—	—	—	(409)
Dividends and deemed dividends on preferred stock . . . . .	—	—	—	—	(58,718)	—	—	(58,718)
Net loss for the year ended December 31, 2011 . . . . .	—	—	—	—	(62,360)	—	—	(62,360)
Other comprehensive loss . . . . .	—	—	—	—	—	(66)	—	(66)
Balance at December 31, 2011 . . . .	<u>10</u>	<u>\$ 6,736</u>	<u>40,614</u>	<u>\$1,744,801</u>	<u>\$(1,714,785)</u>	<u>\$(8,035)</u>	<u>\$(708)</u>	<u>\$ 28,009</u>

See accompanying notes.



**CELL THERAPEUTICS, INC.**

**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT)—(Continued)**  
(In thousands)

	<b>Preferred Stock</b>		<b>Common Stock</b>		<b>Accumulated Deficit</b>	<b>Accumulated Other Comprehensive Income (Loss)</b>	<b>Noncontrolling Interest</b>	<b>Total Shareholders' Equity (Deficit)</b>
	<b>Shares</b>	<b>Amount</b>	<b>Shares</b>	<b>Amount</b>				
Conversion of Series 14 preferred stock to common stock . . . . .	(10)	(6,736)	1,739	6,736	—	—	—	—
Issuance of Series 15 preferred stock, net of transaction costs . .	35	15,442	—	—	—	—	—	15,442
Conversion of Series 15 preferred stock to common stock . . . . .	(35)	(15,442)	9,042	15,442	—	—	—	—
Issuance of Series 16 preferred stock, net of transaction costs . .	15	11,240	—	—	—	—	—	11,240
Conversion of Series 16 preferred stock to common stock . . . . .	(15)	(11,240)	2,521	11,240	—	—	—	—
Issuance of Series 17 preferred stock, net of transaction costs . .	60	54,538	—	—	—	—	—	54,538
Conversion of Series 17 preferred stock to common stock . . . . .	(60)	(54,538)	42,857	54,538	—	—	—	—
Value of beneficial conversion features related to preferred stock . . . . .	—	—	—	13,901	—	—	—	13,901
Exercise or exchange of common stock purchase warrants . . . . .	—	—	9,687	17,798	—	—	—	17,798
Equity-based compensation . . . . .	—	—	3,390	7,938	—	—	—	7,938
Noncontrolling interest . . . . .	—	—	—	587	—	—	(900)	(313)
Other . . . . .	—	—	(26)	(96)	—	—	—	(96)
Dividends and deemed dividends on preferred stock . . . . .	—	—	—	—	(13,901)	—	—	(13,901)
Net loss for the year ended December 31, 2012 . . . . .	—	—	—	—	(101,374)	—	—	(101,374)
Other comprehensive loss . . . . .	—	—	—	—	—	(238)	—	(238)
Balance at December 31, 2012 . . .	—	\$ —	109,824	\$1,872,885	\$ (1,830,060)	\$ (8,273)	\$ (1,608)	\$ 32,944

See accompanying notes.

**CELL THERAPEUTICS, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(In thousands)

	Year Ended December 31,		
	2012	2011	2010
<b>Operating activities</b>			
Net loss	\$(101,687)	\$(62,619)	\$(82,836)
Adjustments to reconcile net loss to net cash used in operating activities:			
Acquired in-process research and development	29,108	—	—
Depreciation and amortization	2,346	2,411	1,842
Equity-based compensation expense	7,938	5,017	17,048
Noncash interest expense	—	546	768
Debt conversion expense	—	—	2,031
Provision for VAT assessments	(3,402)	—	3,503
Other	5	(1,958)	(450)
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(5,345)	567	516
Other assets	1,495	(2,452)	(381)
Accounts payable	3,123	(310)	(1,403)
Accrued expenses	(885)	(211)	(3,787)
Other liabilities	4,528	(1,449)	21
Total adjustments	38,911	2,161	19,708
Net cash used in operating activities	(62,776)	(60,458)	(63,128)
<b>Investing activities</b>			
Cash paid for acquisition of assets from S*BIO Pte Ltd.	(17,764)	—	—
Purchases of securities available-for-sale	—	—	(350)
Purchases of property and equipment	(2,937)	(2,703)	(2,011)
Proceeds from sales of property and equipment	—	31	85
Net cash used in investing activities	(20,701)	(2,672)	(2,276)
<b>Financing activities</b>			
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	(170)	18,900	—
Proceeds from issuance of Series 15 preferred stock and warrants, net of issuance costs	32,856	—	—
Proceeds from issuance of Series 17 preferred stock, net of issuance costs	54,744	—	—
Cash paid for Series 16 preferred stock issuance costs	(104)	—	—
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)
Other	(110)	(424)	(928)
Net cash provided by financing activities	87,216	87,004	49,722
Effect of exchange rate changes on cash and cash equivalents	(355)	529	520
Net increase (decrease) in cash and cash equivalents	3,384	24,403	(15,162)
Cash and cash equivalents at beginning of year	47,052	22,649	37,811
Cash and cash equivalents at end of year	\$ 50,436	\$ 47,052	\$ 22,649

See accompanying notes.

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

	Year Ended December 31,		
	2012	2011	2010
<b>Supplemental disclosure of cash flow information</b>			
Cash paid during the period for interest .....	\$ 16	\$ 1,025	\$ 3,137
Cash paid for taxes .....	\$ —	\$ —	\$ —
<b>Supplemental disclosure of noncash financing and investing activities</b>			
Conversion of Series 3 preferred stock to common stock .....	\$ —	\$ —	\$ 27,761
Conversion of Series 4 preferred stock to common stock .....	\$ —	\$ —	\$ 18,621
Conversion of Series 5 preferred stock to common stock .....	\$ —	\$ —	\$ 19,464
Conversion of Series 6 preferred stock to common stock .....	\$ —	\$ —	\$ 2,970
Conversion of Series 7 preferred stock to common stock .....	\$ —	\$ —	\$ 19,273
Conversion of Series 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	\$ —
Conversion of Series 13 preferred stock to common stock .....	\$ —	\$ 19,077	\$ —
Conversion of Series 14 preferred stock to common stock .....	\$ 6,736	\$ 6,736	\$ —
Conversion of Series 15 preferred stock to common stock .....	\$ 15,442	\$ —	\$ —
Conversion of Series 16 preferred stock to common stock .....	\$ 11,240	\$ —	\$ —
Conversion of Series 17 preferred stock to common stock .....	\$ 54,538	\$ —	\$ —
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 16 preferred stock for acquisition of assets from S* <i>BIO</i> Pte. Ltd. ....	\$ 11,344	\$ —	\$ —
Issuance of common stock upon exercise or exchange of common stock purchase warrants .....	\$ 17,798	\$ 17,485	\$ —
Redemption of Series 8 and 10 preferred stock .....	\$ —	\$ 36,638	\$ —

See accompanying notes.

## CELL THERAPEUTICS, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

##### *Description of Business*

We are a biopharmaceutical company focused on the acquisition, development and commercialization of less toxic and more effective ways to treat cancer. Our goal is to build a profitable company by generating income from products we develop and commercialize, either alone or with one or more potential strategic partners. We are currently concentrating our efforts on treatments that target blood-related cancers where there is a high unmet medical need. We are primarily focused on commercializing PIXUVRI® (pixantrone) in the E.U. for multiply relapsed or refractory aggressive non-Hodgkin lymphoma, or NHL, and conducting a Phase 3 clinical trial of pacritinib for the treatment of myelofibrosis. In September 2012, we initiated the commercial launch of PIXUVRI in the E.U. PIXUVRI is currently available in eight countries: Austria, Denmark, Finland, Germany, Netherlands, Norway, Sweden and the United Kingdom. We plan to extend the availability of PIXUVRI to France, Italy and Spain, as well as other European countries, in 2013.

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 European Union 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, and CTI Life Sciences Limited, or CTILS. CTILS opened a branch in Italy in December 2009. We also retain ownership of our branch, Cell Therapeutics Inc. – Sede Secondaria, or CTI (Europe), however, we ceased operations related to this branch in September 2009. In addition, CTI Commercial LLC, a wholly-owned subsidiary, was included in the consolidated financial statements until dissolution in March 2012.

As of December 31, 2012, we also had a 61% interest in our majority-owned subsidiary, Aequus Biopharma, Inc., or Aequus. The remaining interest in Aequus not held by CTI is reported as *noncontrolling interest* in the consolidated financial statements.

All intercompany transactions and balances are eliminated in consolidation.

##### *Reverse Stock-Splits*

On May 15, 2011 and September 2, 2012, we effected one-for-six and one-for-five reverse stock splits, respectively, collectively referred to as the Stock Splits. Unless otherwise noted, all impacted amounts included in the consolidated financial statements and notes thereto have been retroactively adjusted for the Stock Splits. Unless otherwise noted, impacted amounts include shares of common stock authorized and outstanding, share issuances and cancellations, shares underlying preferred stock, convertible notes, warrants and stock options, shares reserved, conversion prices of convertible securities, exercise prices of warrants and options, and loss per share. Additionally, the Stock Splits impacted preferred stock authorized (but not outstanding because there were no shares of preferred stock outstanding as of the time of the applicable reverse stock split).

##### *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. In 2007, our ability to satisfy obligations upon maturity of convertible notes raised substantial doubt about our ability to continue as a going concern. Since 2007, these obligations have been satisfied.

Our available cash and cash equivalents were \$50.4 million as of December 31, 2012. At our currently planned spending rate, we believe that our financial resources, in addition to the expected receipts from European PIXUVRI sales, will be sufficient to fund our operations into the fourth quarter of 2013. Changes in manufacturing, clinical trial expenses, and expansion of our sales and marketing organization in Europe, may consume capital resources earlier than planned. Additionally, we may not receive the country reimbursement rates in Europe for PIXUVRI that we currently assume in planning for 2013 and 2014.

We expect we will need to raise additional funds and are currently exploring alternative sources of debt and other non-dilutive capital. We may seek to raise such capital through debt financings, partnerships, collaborations, joint ventures or disposition of assets. Our board of directors may issue shares depending on our financial needs and market opportunities, if deemed to be in the best interest of the shareholders. However, 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 as well as reduce our selling, general and administrative expenses.

#### *Use of Estimates*

The preparation of financial statements in conformity with accounting principles generally accepted in the United States 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 long-lived 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 risks.

If we are unable to obtain sufficient quantities of source materials, manufacture or distribute our products to customers from existing suppliers and service providers, or if we were unable to obtain the materials or services from other suppliers, manufacturers or distributors, certain research and development and sales activities may be delayed.

Additionally, see Note 16, *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 \$8.1 million and \$5.0 million as of December 31, 2012 and 2011, of which \$5.1 million and \$4.7 million is included in *other assets* and \$3.0 million and \$0.3 million is included in *prepaid expenses and other current assets* as of December 31, 2012 and 2011, respectively. The collection period of VAT receivable for our European operations ranges from approximately three months to five years. For our Italian VAT receivable, the collection period is approximately three to five years. As of December 31, 2012, the VAT receivable related to operations in Italy is approximately \$8.1 million, of which approximately \$2.8 million was refunded to us in January 2013 for deposits previously paid to the Italian Tax Authority, or ITA, for VAT assessments as discussed in Note 19, *Legal Proceedings* below. 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. We amortize leasehold improvements 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.

### *Leases*

We analyze leases at the inception of the agreement to classify as either an operating or capital lease. On certain of our lease agreements, the terms include rent holidays, rent escalation clauses and incentives for leasehold improvements. We recognize deferred rent relating to incentives for rent holidays and leasehold improvements and amortize the deferred rent over the term of the leases as a reduction of rent expense. For rent escalation clauses, we recognize rent expense on a straight-line basis equal to the amount of total minimum lease payments over the term of the lease.

### *Acquisitions*

We account for acquired businesses using the acquisition method of accounting, which requires that most assets acquired and liabilities assumed be recognized at fair value as of the acquisition date. Any excess of the consideration transferred over the fair value of the net assets acquired is recorded as goodwill, and the fair value of the acquired in-process research and development, or IPR&D, is recorded on the balance sheet. If the acquired net assets do not constitute a business, the transaction is accounted for as an asset acquisition and no goodwill is recognized. In an asset acquisition, the amount allocated to acquired IPR&D with no alternative future use is charged to expense at the acquisition date.

### *Financial Instruments*

At December 31, 2012 and 2011, the carrying value of financial instruments such as receivables and payables approximated their fair values based on the short-term maturities of these instruments.



### *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 12, *Collaboration, Licensing and Milestone Agreements* and Note 19, *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 Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or 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 research and development costs reimbursed by the collaborator are a reduction to research and development expense while research and development 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.

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

We record foreign currency translation adjustments and transaction gains and losses in accordance with ASC 830, *Foreign Currency Matters*. For our operations that have a functional currency other than the U.S. dollar, gains and losses resulting from the translation of the functional currency into U.S. dollars for financial statement presentation are not included in determining net loss, but are accumulated in the cumulative foreign currency translation adjustment account as a separate component of shareholders' 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 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 require 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 on January 1, 2011. See Note 3, *Goodwill*, for additional information.

In June 2011, the FASB issued guidance amending the presentation requirements for comprehensive income. For public entities, this guidance was effective for fiscal years, and interim periods within those years, beginning after December 15, 2011 with early adoption permitted. 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 as discussed below. Upon adoption on January 1, 2012, we had 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. We elected to present comprehensive income in two separate, but consecutive statements as part of the accompanying consolidated financial statements.

#### *Recently Issued Accounting Standards*

In February 2013, the FASB issued guidance requiring presentation of amounts reclassified from each component of accumulated other comprehensive income. In addition, disclosure is required of the effects of significant reclassifications on income statement line items either on the face of the statement where net income is presented or as a separate disclosure in the notes to the financial statements. For public entities, this guidance is effective prospectively for reporting periods beginning after December 15, 2012. We do not expect 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. Property and Equipment**

*Property and equipment* is composed of the following as of December 31, 2012 and 2011 (in thousands):

	<u>2012</u>	<u>2011</u>
Furniture and office equipment .....	\$ 11,743	\$ 13,375
Leasehold improvements .....	5,077	1,755
Lab equipment .....	411	411
	17,231	15,541
Less: accumulated depreciation and amortization .....	(10,446)	(11,937)
	<u>\$ 6,785</u>	<u>\$ 3,604</u>

Depreciation expense of \$2.3 million, \$2.4 million and \$1.8 million was recognized during 2012, 2011 and 2010, respectively.

### 3. 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 table presents the effects of the cumulative-effect application (in thousands):

	<u>Accumulated Deficit</u>	<u>Total Shareholders' Deficit</u>
Balance at December 31, 2010 .....	\$(1,576,643)	\$ (5,145)
Cumulative effect adjustment .....	(17,064)	(17,064)
Adjusted Balance at January 1, 2011 .....	<u>\$(1,593,707)</u>	<u>\$(22,209)</u>

### 4. Acquisitions

In April 2012, we entered into an asset purchase agreement with S\*BIO Pte Ltd., or S\*BIO, to acquire all right, title and interest in, and assume certain liabilities relating to, certain intellectual property and other assets related to compounds SB1518 (also referred to as “pacritinib”) and SB1578, or the Seller Compounds, which inhibit Janus Kinase 2, commonly referred to as JAK2. In consideration of the assets and rights acquired under the agreement, we made a payment of \$15.0 million in cash and issued 15,000 shares of Series 16 convertible preferred stock, or Series 16 Preferred Stock, to S\*BIO at closing in May 2012. Each share of Series 16 preferred stock had a stated value of \$1,000 per share. In June 2012, all outstanding shares of our Series 16 Preferred Stock were automatically converted into 2.5 million shares of our common stock at a conversion price of \$5.95 per share, subject to a 19.99% blocker provision.

The total initial purchase consideration was as follows (in thousands):

Cash .....	\$15,000
Fair value of Series 16 Preferred Stock .....	11,344
Transaction costs .....	<u>2,764</u>
Total initial purchase consideration .....	<u>\$29,108</u>

The transaction was treated as an asset acquisition as it was determined that the assets acquired did not meet the definition of a business. We determined that the acquired assets can only be economically used for the specific and intended purpose and have no alternative future use after taking into consideration further research and development, regulatory and marketing approval efforts required in order to reach technological feasibility. Accordingly, the entire initial purchase consideration of \$29.1 million was immediately expensed to *acquired in-process research and development* for the year ended December 31, 2012. The contingent consideration arrangement as discussed below will be recognized when the contingency is resolved and the consideration is paid or becomes payable.

As part of the consideration, S\*BIO also has a contingent right to certain milestone payments from us up to an aggregate amount of \$132.5 million if certain U.S., E.U. and Japanese regulatory approvals are obtained or if certain worldwide net sales thresholds are met in connection with any pharmaceutical product containing or

comprising any Seller Compound for use for specific diseases, infections or other conditions. In addition, S\*BIO will also be entitled to receive royalty payments from us at incremental rates in the low-single digits based on certain worldwide net sales thresholds on a product-by-product and country-by-country basis.

At our election, we may pay up to 50% of any milestone payments to S\*BIO through the issuance of shares of our common stock or shares of our preferred stock convertible into our common stock in lieu of cash.

## 5. Accrued Expenses

*Accrued expenses* consisted of the following as of December 31, 2012 and 2011 (in thousands):

	<u>2012</u>	<u>2011</u>
Clinical and investigator-sponsored trial expenses .....	\$ 3,301	\$ 2,807
Employee compensation and related expenses .....	3,904	4,771
Insurance financing and accrued interest expenses .....	598	587
Legal expenses .....	268	388
Manufacturing expenses .....	247	847
Co-development expenses .....	153	997
Other .....	1,738	667
	<u>\$10,209</u>	<u>\$11,064</u>

## 6. Leases

### *Lease Agreements*

We lease our office space under operating leases for our U.S. and European offices. Rent expense amounted to \$2.7 million, \$1.5 million and \$3.9 million for the years ended December 31, 2012, 2011 and 2010, respectively. Rent expense is net of sublease income and amounts offset to excess facilities charges.

In January 2012, we entered into an agreement with Selig Holdings Company LLC, or Selig, 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, which commenced on May 1, 2012. We have two five-year options to extend the term of the lease at a market rate determined according to the lease. No rent payments were due during the first five months of the lease term. The initial rent amount is based on \$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 were provided an allowance of \$3.3 million for certain tenant improvements made by us. As of December 31, 2012, we had a receivable of \$1.5 million included in *prepaid expenses and other current assets* related to the unpaid portion of incentives for tenant improvements owed to us by Selig.

### *Future Minimum Lease Payments*

Future minimum lease commitments for non-cancelable operating leases at December 31, 2012 are as follows (in thousands):

	<u>Operating Leases</u>
2013 .....	\$ 2,347
2014 .....	2,299
2015 .....	2,233
2016 .....	2,201
2017 .....	2,261
Thereafter .....	10,520
Total minimum lease commitments .....	<u>\$21,861</u>

### *Liability for Excess Facilities*

During the year ended December 31, 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.

During the year ended December 31, 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* for the year ended December 31, 2010.

The following table summarizes the changes in the liability for excess facilities during the years ended December 31, 2012 and 2011 (in thousands):

	<u>2005 Activities</u>	<u>2010 Activities</u>	<u>Total Excess Facilities Liability</u>
Balance at January 1, 2011 .....	\$ 550	\$1,410	\$ 1,960
Adjustments .....	40	102	142
Payments .....	(375)	(982)	(1,357)
Balance at December 31, 2011 .....	215	530	745
Adjustments .....	(32)	(62)	(94)
Payments .....	(183)	(468)	(651)
Balance at December 31, 2012 .....	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

We will periodically evaluate our existing needs and other future commitments to determine whether we should record additional excess facilities charges or adjustments to such charges.

## **7. Long-term Obligations**

*Long-term obligations* consisted of the following as of December 31, 2012 and 2011 (in thousands):

	<u>2012</u>	<u>2011</u>
Deferred rent .....	\$5,003	\$ 213
Excess facilities liability .....	—	745
Reserve for VAT assessments .....	—	2,947
Other long-term obligations .....	31	50
	<u>5,034</u>	<u>3,955</u>
Less current portion .....	(393)	(970)
	<u>\$4,641</u>	<u>\$2,985</u>

The balance of deferred rent as of December 31, 2012 relates to incentives for rent holidays and leasehold improvements associated with our operating lease for office space as discussed in Note 6, *Leases*. We reduced our reserve for VAT assessments in 2012 as a result of our change in estimate of the likelihood of future loss. See Note 19, *Legal Proceedings*, for additional information.

## 8. Convertible Notes

The following tables summarize the changes in the principal balances of our convertible notes during the years ended December 31, 2011 and 2010 (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 . . . . .	<u>\$21,163</u>	<u>\$ —</u>	<u>\$(21,163)</u>	<u>\$ —</u>
	Balance at January 1, 2010	Exchanged	Matured	Balance at December 31, 2010
7.5% convertible senior notes . . . . .	\$10,250	\$ —	\$ —	\$10,250
5.75% convertible senior notes . . . . .	10,913	—	—	10,913
4.0% convertible senior subordinated notes . . . . .	40,363	(1,848)	(38,515)	—
Total . . . . .	<u>\$61,526</u>	<u>\$(1,848)</u>	<u>\$(38,515)</u>	<u>\$21,163</u>

### *Convertible Notes Exchange*

In May 2010, we entered into exchange agreements with certain holders of our 4% convertible senior subordinated notes, or 4% Notes, pursuant to which we issued approximately 0.1 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.

## 9. Preferred Stock

Prior to the effective date of the Stock Splits, we completed several preferred stock transactions during the years 2010, 2011 and 2012, each of which is described below. All outstanding shares of the preferred stock issued in these transactions converted to common stock or were redeemed, in each case, prior to the effective date of the Stock Splits. Accordingly, for purposes of the descriptions of these transactions included in this Note 9, *Preferred Stock*, the number of shares of preferred stock issued, converted and redeemed and the initial stated value of shares of preferred stock issued are not adjusted to reflect the Stock Splits. 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 or exchange of the warrants in these transactions are adjusted to reflect the Stock Splits.

### *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, and warrants to purchase up to 0.3 million shares of our common stock, or the Series 3 Warrants, for gross proceeds of \$30.0 million. Issuance costs related to this transaction were \$2.2 million, including the fair value of the placement agent warrants discussed below. The Series 3 Warrants had an exercise price of \$35.40 per share of our common stock. We estimated the \$7.1 million fair value of the Series 3 Warrants using the Black-Scholes pricing model. 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 30,000 shares of our Series 3 Preferred Stock were converted into 0.8 million shares of our common stock at a conversion price of \$36.41 per share.



In July 2010, we entered into a privately negotiated exchange agreement with a certain holder of the Series 3 Warrants to exchange Series 3 Warrants to purchase up to 0.1 million shares of our common stock for the same number of warrants to purchase shares of our common stock at an exercise price of \$12.60 per share, or the Exchange Warrants. The Exchange Warrants were exercisable six months and one day after the date of issuance and expire in January 2015. In addition, the exercisability of the Exchange Warrants was subject to, and conditioned upon shareholder approval of an increase in the number of authorized shares of our common stock available for issuance, which shareholders approved in September 2010. We estimated the \$0.8 million fair value of the Exchange Warrants using the Black-Scholes pricing model. The remaining Series 3 Warrants expired in January 2011. As of December 31, 2012, the Exchange Warrants to purchase up to 0.1 million shares of our common stock remained outstanding.

In connection with this offering, we also issued warrants to purchase up to 8,230 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 \$45.51 per share and expired in January 2011.

#### *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, and warrants to purchase up to 0.7 million shares of our common stock for gross proceeds of \$20.0 million. Issuance costs related to this transaction were \$1.4 million. The warrants have an exercise price of \$18.087 per share of our common stock, were exercisable six months and one day after the date of issuance and expire in April 2014. 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 certain fundamental transactions that are outside of our control, we classified these warrants as mezzanine equity. 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 20,000 shares of our Series 4 Preferred Stock were converted into 1.3 million shares of our common stock at a conversion price of \$15.00 per share. As of December 31, 2012, warrants to purchase up to 0.7 million shares of our common stock remained outstanding.

#### *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, and warrants to purchase up to 0.9 million shares of our common stock for gross proceeds of \$21.0 million. Issuance costs related to this transaction were \$1.5 million, including the fair value of the placement agent warrants discussed below. The warrants have an exercise price of \$15.00 per share of our common stock and were exercisable six months and one day after the date of issuance and expire in November 2014. In addition, the exercisability of the warrants was subject to, and conditioned upon shareholder approval of an increase in the number of authorized shares of our common stock available for issuance, which shareholders approved in September 2010. We estimated the \$6.0 million fair value of the warrants using the Black-Scholes pricing model. As the warrants include a redemption feature that may be triggered upon certain fundamental transactions that are outside of our control, we classified these warrants as mezzanine equity. 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 21,000 shares of our Series 5 Preferred Stock were converted into 1.8 million shares of our common stock at a conversion price of \$12.00 per share. As of December 31, 2012, warrants to purchase up to 0.9 million shares of our common stock remained outstanding.

In connection with this offering, we also issued warrants to purchase up to 35,000 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 \$15.00 per share and were exercisable six months and

one day after the date of issuance and expire in May 2015. The exercisability of the warrants was subject to, and conditioned upon, our receipt of the shareholder approval as described above. As of December 31, 2012, warrants to purchase up to 35,000 shares of our common stock issued to the placement agent remained outstanding.

#### *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 and warrants to purchase up to 0.2 million shares of our common stock for gross proceeds of \$4.1 million. Issuance costs related to this transaction were \$1.1 million, including the fair value of the placement agent warrants discussed below. The warrants have an exercise price of \$12.60 per share of our common stock and were exercisable six months and one day after the date of issuance and expire in January 2015. In addition, the exercisability of the warrants was subject to, and conditioned upon receipt of shareholder approval of an increase in the number of authorized shares of our common stock available for issuance, which shareholders approved 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 certain fundamental transactions that are outside of our control, we classified these warrants as mezzanine equity. 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 4,060 shares of our Series 6 Preferred Stock were converted into 0.4 million shares of our common stock at a conversion price of \$10.50 per share. As of December 31, 2012, warrants to purchase up to 0.2 million shares of our common stock remained outstanding.

In connection with this offering, we also issued warrants to purchase up to 11,600 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 \$12.60 per share and were exercisable six months and one day after the date of issuance and expire in January 2015. The exercisability of the warrants was also subject to, and conditioned upon, our receipt of the shareholder approval as described above. As of December 31, 2012, warrants to purchase up to 11,600 shares of our common stock issued to the placement agent remained outstanding.

#### *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, and warrants to purchase up to 0.8 million shares of our common stock for gross proceeds of \$21.0 million. Issuance costs related to this transaction were \$1.7 million, including the fair value of the placement agent warrants discussed below. The warrants have an exercise price of \$13.50 per share of our common stock, were exercisable six months and one day after the date of issuance and expire in October 2015. We estimated the \$5.2 million fair value of the warrants using the Black-Scholes pricing model. 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 21,000 shares of our Series 7 Preferred Stock were converted into 1.9 million shares of our common stock at a conversion price of \$11.10 per share. As of December 31, 2012, warrants to purchase 0.8 million shares of our common stock remained outstanding.

In connection with this offering, we also issued warrants to purchase up to 37,838 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 \$13.80 per share, were exercisable six months and one day after the date of issuance and expire in October 2015. As of December 31, 2012, warrants to purchase up to 37,838 shares of our common stock issued to the placement agent remained outstanding.

#### *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 0.8 million shares of our

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. 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 \$11.634 per share of our common stock. The warrants were exercisable immediately and had an expiration date in January 2013. 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 0.8 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 in February 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 all 25,000 shares of Series 9 Preferred Stock into 2.1 million shares of our common stock at a conversion price of \$11.634 per share.

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 0.9 million shares of our 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.

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. 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 \$10.11 per share of our common stock. The warrants were exercisable immediately and had an expiration date in February 2013. 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 0.9 million shares of our 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 in March 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 all 24,957 shares of Series 11 Preferred Stock into 2.5 million shares of our common stock at a conversion price of \$10.11 per share.

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, and warrants to purchase up to 0.6 million shares of our common stock for gross proceeds of \$16.0 million. Issuance costs related to this transaction were \$1.2 million, including the fair value of the placement agent warrants discussed below. Each warrant has an exercise price of \$12.00 per share of our common stock and expires in May 2016. We estimated the \$4.1 million fair value of the warrants using the Black-Scholes pricing model. 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 15,972 shares of our Series 12 Preferred Stock were converted into 1.5 million shares of our common stock at a conversion price of \$10.50 per share. As of December 31, 2012, warrants to purchase 0.6 million shares of our common stock remained outstanding.

In connection with this offering, we also issued warrants to purchase up to 30,423 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 \$13.125 per share and expire in May 2016. As of December 31, 2012, warrants to purchase up to 30,423 shares of our common stock issued to the placement agent remained outstanding.

#### *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, and warrants to purchase up to 1.8 million shares of our common stock for gross proceeds of \$30.0

million. Issuance costs related to this transaction were \$2.5 million, including the fair value of the warrants issued to the placement agent and financial advisor discussed below. Each warrant has an exercise price of \$10.75 per share of our common stock, was exercisable beginning six months and one day from the date of issuance and expires in July 2016. We estimated the \$8.4 million fair value of the warrants using the Black-Scholes pricing model. 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 30,000 shares of our Series 13 Preferred Stock were converted into 3.5 million shares of our common stock at a conversion price of \$8.50 per share. As of December 31, 2012, warrants to purchase up to 1.8 million shares of our common stock remained outstanding.

In connection with this offering, we also issued warrants to purchase up to 70,588 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 35,294 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 \$0.2 million using the Black-Scholes pricing model. These warrants have an exercise price of \$12.25 per share, are exercisable beginning six months and one day from the date of issuance and expire in July 2016. As of December 31, 2012, warrants to purchase up to 70,588 and 35,294 shares of our common stock issued to the placement agent and financial advisor, respectively, remained outstanding.

#### *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, and warrants to purchase up to 1.4 million shares of our common stock for gross proceeds of \$20.0 million. Issuance costs related to this transaction were \$1.6 million, including the fair value of warrants issued to the placement agent and financial advisor discussed below. Each warrant has an exercise price of \$7.25 per share of our common stock, was exercisable beginning six months and one day from the date of issuance and expires in December 2016. We estimated the \$4.9 million fair value of the warrants using the Black-Scholes pricing model. 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. In December 2011, 10,000 shares of Series 14 Preferred Stock were converted into 1.7 million shares of our common stock at a conversion price of \$5.75 per share. In January 2012, the remaining 10,000 shares of Series 14 Preferred Stock automatically converted into 1.7 million shares of our common stock at a conversion price of \$5.75 per share pursuant to the terms of the Series 14 Preferred Stock. As of December 31, 2012, warrants to purchase up to 1.4 million shares of our common stock remained outstanding.

In connection with this offering, we also issued warrants to purchase up to 69,566 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 34,783 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 \$8.625 per share, were exercisable beginning six months and one day from the date of issuance and expire in December 2016. As of December 31, 2012, warrants to purchase up to 69,566 and 34,783 shares of our common stock issued to the placement agent and financial advisor, respectively, remained outstanding.

#### *Series 15-1 Preferred Stock*

In May 2012, we issued 20,000 shares of our Series 15 convertible preferred stock, or Series 15-1 Preferred Stock, and a warrant to purchase up to 2.7 million shares of our common stock, or Series 15-1 Warrant, for gross proceeds of \$20.0 million. Issuance costs related to this transaction were \$1.3 million.

Each share of our Series 15-1 Preferred Stock was convertible at the option of the holder and was entitled to a liquidation preference equal to the initial stated value of \$1,000 per share of Series 15-1 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 15-1 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 and had no voting rights except as otherwise expressly provided in our amended and restated articles of incorporation or as otherwise required by law. For the year ended December 31, 2012, we recognized \$8.5 million in *dividends and deemed dividends on preferred stock* related to the beneficial conversion feature on our Series 15-1 Preferred Stock. In May 2012, all 20,000 shares of our Series 15-1 Preferred Stock were converted into 4.0 million shares of our common stock at a conversion price of \$5.00 per share.

The Series 15-1 Warrant had an exercise price of \$5.46 per share of our common stock and had an expiration date in May 2017. The Series 15-1 Warrant contained a provision that if the price per share of our common stock was less than the exercise price of the warrant at any time while the warrant is outstanding, the warrant may be exchanged for shares of our common stock based on an exchange value derived from a specified Black-Scholes value formula, or the Exchange Value, subject to certain limitations. Upon issuance, we estimated the fair value of the Series 15-1 Warrant to be approximately \$10.3 million using the Black-Scholes pricing model. In September 2012, the holder elected to exchange a portion of the Series 15-1 Warrant to purchase 1.3 million shares with an Exchange Value of \$5.0 million. We elected to issue 2.8 million shares of our common stock as payment for the Exchange Value. In November 2012, the holder elected to exchange the remaining portion of the Series 15-1 Warrant to purchase 1.4 million shares of our common stock with an Exchange Value of \$5.4 million. We elected to issue 4.1 million shares of our common stock as payment for the Exchange Value.

#### *Series 15-2 Preferred Stock*

In July 2012, we issued 15,000 shares of our Series 15 convertible preferred stock, or Series 15-2 Preferred Stock, and a warrant to purchase up to 3.4 million shares of our common stock, or Series 15-2 Warrant, for gross proceeds of \$15.0 million. Issuance costs related to this transaction were \$0.8 million.

Each share of our Series 15-2 Preferred Stock was convertible at the option of the holder and was entitled to a liquidation preference equal to the initial stated value of \$1,000 per share of Series 15-2 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 15-2 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 and had no voting rights except as otherwise expressly provided in our amended and restated articles of incorporation or as otherwise required by law. In July 2012, all 15,000 shares of Series 15-2 Preferred Stock were converted into 5.0 million shares of our common stock at a conversion price of \$2.97475 per share. For the year ended December 31, 2012, we recognized \$5.0 million in *dividends and deemed dividends on preferred stock* related to the beneficial conversion feature on our Series 15-2 Preferred Stock.

The Series 15-2 Warrant had substantially the same features as the Series 15-1 Warrant described above, with the exception of the exercise price of \$3.0672 per share of common stock and expiration date of July 2017. Upon issuance, we estimated the fair value of the Series 15-2 Warrant to be approximately \$7.2 million using the Black-Scholes pricing model. In September 2012, the holder elected to exchange the Series 15-2 Warrant to purchase 3.4 million shares of our common stock with an Exchange Value of \$7.4 million. We elected to issue 2.9 million shares of common stock to the holder as payment for the Exchange Value of the Series 15-2 Warrant.

#### *Series 17 Preferred Stock*

In October 2012, we issued 60,000 shares of our Series 17 convertible preferred stock, or Series 17 Preferred Stock, in an underwritten public offering for gross proceeds of \$60.0 million, before deducting underwriting commissions and discounts and other offering costs. Issuance costs related to this transaction were \$5.5 million, including \$3.9 million in underwriting commissions and discounts.



Each share of Series 17 Preferred Stock was convertible at the option of the holder and was entitled to a liquidation preference equal to the stated value of \$1,000 per share 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 holders of Series 17 Preferred Stock were not entitled to receive dividends except to share in any dividends actually paid on shares of our common stock or other junior securities and had no voting rights except as otherwise expressly provided in our amended and restated articles of incorporation or as otherwise required by law. For the year ended December 31, 2012, we recognized \$0.4 million in *dividends and deemed dividends on preferred stock* related to the beneficial conversion feature on our Series 17 Preferred Stock and all 60,000 shares of Series 17 Preferred Stock were converted into 42.9 million shares of our common stock at a conversion price of \$1.40 per share.

## 10. Common Stock

### *Common Stock Reserved*

A summary of common stock reserved for issuance is as follows as of December 31, 2012 (in thousands):

Equity incentive plans .....	3,301
Common stock purchase warrants .....	7,018
Employee stock purchase plan .....	42
	<u>10,361</u>

### *Warrants*

Warrants to purchase up to 0.1 million shares of our common stock, issued in connection with the issuance of our Series 1 Preferred Stock in April 2009, or Class B Warrants, were outstanding as of December 31, 2012. The Class B Warrants have an exercise of \$12.30 per share of common stock and expire in October 2014. We classified the Class B Warrants as mezzanine equity as they include a redemption feature that may be triggered upon certain fundamental transactions that are outside of our control.

Warrants to purchase up to 5,000 shares of common stock, issued to the placement agent in connection with our Series 1 Preferred Stock financing in April 2009, were outstanding as of December 31, 2012. These warrants have an exercise price of \$13.50 per share and expire in October 2014. These warrants are classified as mezzanine equity due to the same redemption feature of the Class B warrants as described above.

Warrants to purchase up to 0.2 million shares of our common stock, issued in connection with our registered offering of common stock in May 2009, were outstanding as of December 31, 2012. These warrants have an exercise price of \$42.00 per share and expire in May 2014.

Warrants to purchase up to 10,667 shares of our common stock, issued to the placement agent in connection with the registered offering of common stock in May 2009, were outstanding as of December 31, 2012. These warrants have an exercise price of \$46.875 per share and expire in November 2014.

Warrants to purchase up to 19,556 shares of our common stock, issued to the underwriter of our public offering of common stock in July 2009, were outstanding as of December 31, 2012. These warrants have an exercise price of \$51.00 per share and expire in April 2014.

## 11. Other Comprehensive Loss

Total accumulated other comprehensive loss consisted of the following (in thousands):

	Net Unrealized Loss on Securities Available-For-Sale	Foreign Currency Translation Adjustments	Accumulated Other Comprehensive Loss
December 31, 2011 .....	\$(165)	\$(7,870)	\$(8,035)
Current period other comprehensive loss .....	(70)	(168)	(238)
December 31, 2012 .....	<u>\$(235)</u>	<u>\$(8,038)</u>	<u>\$(8,273)</u>

## 12. Collaboration, Licensing and Milestone Agreements

### *Chroma Therapeutics, Ltd.*

We entered into an agreement with Chroma Therapeutics, Ltd., or Chroma, or the Chroma License Agreement, in March 2011 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 License Agreement, we paid Chroma an upfront fee of \$5.0 million upon execution of the agreement. *Research and development* expense attributable to the Chroma License Agreement was \$2.8 million and \$7.0 million for the years 2012 and 2011, respectively, of which \$0.2 million and \$1.0 million was included in *accrued expenses* as of December 31, 2012 and 2011, respectively. We will make a milestone payment of \$5.0 million upon the initiation of the first pivotal trial. The Chroma License 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.

Under the Chroma License Agreement, we are also required to 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.

Under the Chroma License Agreement, we are also required to 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 License 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 that we entered into with Chroma for our drug candidate tosedostat, which commenced on June 8, 2011.

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 License Agreement may be terminated by us at our convenience upon 120 days' written notice to Chroma. The Chroma License Agreement may also be terminated by either party following a material breach by the other party subject to notice and cure periods.

By a letter dated July 18, 2012 Chroma notified us that Chroma alleges breaches under the Chroma License Agreement. Chroma asserts that we have not complied with the Chroma License Agreement because we made decisions with respect to the development of tosedostat without the approval of the joint committees to be established pursuant to the terms of the Chroma License Agreement, did not hold meetings of those committees and have not used diligent efforts in the development of tosedostat. We dispute Chroma's allegations and intend to vigorously defend our development activities and judgments. In particular, we dispute Chroma's lack of diligence claim based in part on the appropriateness of completing the ongoing Phase 2 combination trials prior to developing a Phase 3 trial design. In addition, we believe that Chroma has failed to comply with its antecedent obligations with respect to the joint committees and failed to demonstrate an ability to manufacture tosedostat to the required standards under the terms of the Chroma License Agreement. Under the Chroma License Agreement there is a 90 day cure period for any nonpayment default, which period shall be extended to 180 days if the party is using efforts to cure. A party may terminate the Chroma License Agreement for a material breach only after arbitration in accordance with the terms of the Chroma License Agreement.

Effective September 25, 2012, we and Chroma entered into a three month standstill with respect to the parties' respective claims under the Chroma License Agreement, but otherwise reserving the parties' respective rights as of the commencement of the standstill period. Effective December 25, 2012, the standstill was subsequently extended until March 25, 2013 and is terminable by either party on one month's notice.

#### *S\*<sup>B</sup>IO Pte Ltd*

See Note 4, *Acquisitions*, for further information regarding contingent milestone payments related to the asset purchase agreement with S\*<sup>B</sup>IO.

#### *University of Vermont*

We entered into an agreement with the University of Vermont, or UVM Agreement, in March 1995, as amended in March 2000, which grants us an exclusive license, with the right to sublicense, for the rights to PIXUVRI, or the UVM Agreement. Pursuant to the UVM Agreement, we acquired the rights to make, have made, sell and use PIXUVRI. 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 PIXUVRI, 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 PIXUVRI 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*

In November 1998, we entered into an agreement with PG-TXL Company, L.P., or PG-TXL, as amended in February 2006, which grants us an exclusive worldwide license for the rights to Opaxio and to all potential uses of PG-TXL's polymer technology, or the PG-TXL Agreement. Pursuant to the PG-TXL Agreement, we acquired the rights to research, develop, manufacture, market and sell anti-cancer drugs developed using this polymer technology. Pursuant to the PG-TXL Agreement, we are obligated to make payments to PG-TXL upon the achievement of certain development and regulatory milestones of up to \$14.4 million. The timing of the

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

#### *Gynecologic Oncology Group*

We entered into an agreement with the GOG, or the GOG Agreement, in March 2004, as amended on August 2008, related to the GOG-0212 trial of Opaxio in patients with ovarian cancer, 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, of which \$0.4 million was outstanding and included in *accounts payable* as of December 31, 2012. 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 and \$0.9 million will become due upon completion of the 1,100 patient enrollment milestone, both of which may occur in 2013.

#### *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 have the right to 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 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, 2012, 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 contract research organizations, third party manufacturers, and distributors which have a duration greater than one year for the development and distribution of our products.

### **13. Share-Based Compensation**

#### *Share-Based Compensation Expense*

Share-based compensation expense for all share-based payment awards made to employees and directors is measured based on the grant-date fair value estimated in accordance with generally accepted accounting principles. 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, 2012, 2011 and 2010, we recognized share-based compensation expense due to the following types of awards (in thousands):

	<u>2012</u>	<u>2011</u>	<u>2010</u>
Performance rights .....	\$2,358	\$ —	\$13,954
Restricted stock .....	5,180	4,850	2,908
Options .....	400	167	186
Total share-based compensation expense .....	<u>\$7,938</u>	<u>\$5,017</u>	<u>\$17,048</u>

The following table summarizes share-based compensation expense for the years ended December 31, 2012, 2011 and 2010, which was allocated as follows (in thousands):

	<u>2012</u>	<u>2011</u>	<u>2010</u>
Research and development .....	\$1,730	\$1,126	\$ 2,765
Selling, general and administrative .....	6,208	3,891	14,283
Total share-based compensation expense .....	<u>\$7,938</u>	<u>\$5,017</u>	<u>\$17,048</u>

Share-based compensation had a \$7.9 million, \$5.0 million, and \$17.0 million effect on our net loss attributable to common shareholders, which resulted in a \$(0.14), \$(0.15) and \$(0.75) effect on basic and diluted net loss per common share for the years ended December 31, 2012, 2011 and 2010, respectively. It had no effect on cash flows from operations or financing activities for the periods presented; however, during the years ended 2012, 2011 and 2010, we repurchased 23,000, 44,000 and 52,000 shares of our common stock totaling \$0.1 million, \$0.4 million and \$0.9 million, respectively, for cash in connection with the vesting of employee restricted stock awards based on taxes owed by employees upon vesting of the awards.

As of December 31, 2012, unrecognized compensation cost related to unvested stock options and time-based restricted stock awards amounted to \$5.0 million, which will be recognized over the remaining weighted-average requisite service period of 1.6 years. The unrecognized compensation cost related to unvested options and restricted stock does not include the value of performance-based share awards.

For the years ended December 31, 2012, 2011 and 2010, 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 July 2012, 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 our board of directors, which has the discretion to determine the employees, consultants and directors who shall be granted incentive awards. Options expire 10 years from the date of grant, subject to the recipients continued service to the Company. As of December 31, 2012, 9.5 million shares were authorized for issuance, of which 3.0 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,		
	2012	2011	2010
Risk-free interest rate	0.8%	0.9%	1.3%
Expected dividend yield	None	None	None
Expected life (in years)	4.7	4.5	5.0
Volatility	88%	97%	96%

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 options 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 options, 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 options 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 our stock option plans:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (Thousands)
Outstanding at January 1, 2010 (7,000 exercisable)	20,000	\$ 2,375.08		
Granted	16,000	\$ 11.47		
Exercised	—	\$ —		
Forfeited	(1,000)	\$ 23.65		
Cancelled and expired	(1,000)	\$20,652.72		
Outstanding at December 31, 2010 (17,000 exercisable)	34,000	\$ 744.74		
Granted	126,000	\$ 5.48		
Exercised	—	\$ —		
Forfeited	(2,000)	\$ 9.91		
Cancelled and expired	(2,000)	\$ 6,740.99		
Outstanding at December 31, 2011 (59,000 exercisable)	156,000	\$ 90.07		
Granted	179,000	\$ 4.92		
Exercised	—	\$ —		
Forfeited	(23,000)	\$ 5.93		
Cancelled and expired	(5,000)	\$ 886.13		
Outstanding at December 31, 2012	307,000	\$ 33.72	8.9	\$—
Vested or expected to vest at December 31, 2012	286,000	\$ 35.94	8.5	\$—
Exercisable at December 31, 2012	105,000	\$ 89.08	8.1	\$—

The weighted average exercise price of options exercisable at December 31, 2011 and 2010 was \$228.95 and \$1,444.36, respectively. The weighted average grant-date fair value of options granted during 2012, 2011 and 2010 was \$3.28, \$3.93 and \$8.27 per option, respectively.

### *Restricted Stock*

We issued 4.3 million, 1.7 million and 1.3 million shares of restricted common stock in 2012, 2011 and 2010, respectively. The weighted average grant-date fair value of restricted shares issued during 2012, 2011 and 2010 was \$4.77, \$6.23 and \$13.11, respectively. Additionally, 0.9 million, 1.2 million and 0.2 million shares of restricted stock were cancelled during 2012, 2011 and 2010, respectively.

A summary of the status of nonvested restricted stock awards as of December 31, 2012 and changes during the period then ended, is presented below:

	<u>Nonvested Shares</u>	<u>Weighted Average Grant-Date Fair Value Per Share</u>
Nonvested at December 31, 2011 .....	1,340,000	\$6.25
Issued .....	4,308,000	\$4.77
Vested .....	(1,408,000)	\$4.38
Forfeited .....	(918,000)	\$5.75
Nonvested at December 31, 2012 .....	<u>3,322,000</u>	\$5.26

The total fair value of restricted stock awards vested during the years ended December 31, 2012, 2011 and 2010 was \$3.4 million, \$3.5 million and \$3.2 million, respectively.

### *December 2009 Performance Awards*

Share-based compensation expense for the year ended December 31, 2010 included \$13.9 million related to the portion of the restricted stock units granted to our executive officers and directors in December 2009 (which we refer to as our December 2009 performance awards) with the market-based performance condition. In December 2011, the December 2009 performance awards expired and the related shares of restricted stock were cancelled and returned to the Company as none of the performance conditions were met prior to expiration.

### *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 2012-2014 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 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 the performance goals are 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.

The fair value of the 2012-2014 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 awards 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.

In June 2012, our board of directors certified completion of the performance condition relating to approval of our marketing authorization application for PIXUVRI in the European Union and 0.4 million shares vested to our executive officers and directors. We recognized \$1.1 million in share-based compensation upon satisfaction of this performance condition for the year ended December 31, 2012. Subsequently, unvested performance awards representing rights to receive approximately 2.3% of shares outstanding at the time the respective performance goals would have been achieved were forfeited upon separation of certain executive officers from us in 2012. We determined the 2012-2014 performance awards with market-based performance conditions have a grant-date fair value of \$3.5 million, of which we recognized \$1.3 million in share-based compensation expense for the year ended December 31, 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. As of December 31, 2012, all nonemployee options and restricted stock awards have vested. As of December 31, 2011 and 2010 unvested nonemployee options to acquire approximately 2,000 and 3,000 shares of common stock were outstanding, respectively. Additionally, unvested nonemployee restricted stock awards totaled approximately 2,000 and 5,000 as of December 31, 2011 and 2010, respectively. We recorded compensation expense of \$58,000 in 2011 and reversed previously recorded compensation expense of \$1,000 and \$24,000 in 2012 and 2010, respectively 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 the 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 3,000, 3,000 and 2,000 shares to employees in 2012, 2011 and 2010, respectively. There are 50,833 shares of common stock authorized under the Purchase Plan and 41,951 shares are reserved for future purchases as of December 31, 2012.

### **14. Employee Benefit Plans**

The Company's U.S. employees participate in the Cell Therapeutics, Inc. 401(k) Plan whereby eligible employees may defer up to 80% of their compensation, up to the annual maximum allowed by the Internal Revenue Service. We may make discretionary matching contributions based on certain plan provisions. We recorded \$0.2 million, \$0.1 million and \$0.1 million related to discretionary matching contributions during each of the years ended December 31, 2012, 2011 and 2010, respectively.

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 were paid during 2010 to employees who separated from the Company. 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.

## 15. Shareholder Rights Plan

In December 2009, our board of directors 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. In 2012, our board of directors approved certain amendments to the Rights Plan.

Each right, if and when it becomes exercisable, will entitle the holder to purchase a unit consisting of one ten-thousandth of a share of Series ZZ Junior Participating Cumulative Preferred Stock, no par value per share, at a cash exercise price of \$8.00 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 we are acquired in a merger or other business combination transaction, each holder of a right, except those rights held by a 20% shareholder which become null and void, would have the right to receive, upon exercise, common stock of the acquiring company having a market value equal to two times the exercise price of the right. The Board may redeem the rights for \$0.0001 per right or terminate the Rights Plan at any time prior to an acquisition by a person or group holding 20% or more of our common stock. The Rights Plan will expire on December 3, 2015.

## 16. 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,	
	2012	2011
United States .....	\$6,570	\$3,314
Europe .....	215	290
	<u>\$6,785</u>	<u>\$3,604</u>

## 17. Net Loss Per Share

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

	Year Ended December 31,		
	2012	2011	2010
Net loss attributable to common shareholders .....	\$(115,275)	\$(121,078)	\$(147,560)
Basic and diluted:			
Weighted average shares outstanding .....	62,021	35,790	23,692
Less weighted average restricted shares outstanding .....	(3,896)	(1,496)	(871)
Shares used in calculation of basic and diluted net loss per common share .....	<u>58,125</u>	<u>34,294</u>	<u>22,821</u>
Net loss per common share:			
Basic and diluted .....	<u>\$ (1.98)</u>	<u>\$ (3.53)</u>	<u>\$ (6.47)</u>

Options, warrants, unvested restricted share awards and rights, convertible debt, and convertible preferred stock aggregating 8.6 million, 10.2 million and 3.4 million common share equivalents were not included in the calculation of diluted net loss per share as their effects on the calculation were anti-dilutive as of December 31, 2012, 2011 and 2010, 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 outstanding share-based awards with market- or performance-based vesting conditions.

## **18. Related Party Transactions**

In May 2007, we formed Aequus, a majority-owned subsidiary of which our ownership was approximately 61% as of December 31, 2012. 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 earns interest at a rate of 6% per annum and was scheduled to become due in May 2012. We are currently in negotiations with Aequus to extend the maturity date of this note, which can be converted into equity at any time prior to 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) the price per share of the Aequus equity securities. 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. We funded Aequus \$0.6 million, \$0.6 million and \$0.5 million during the years ended December 31, 2012, 2011 and 2010, respectively, including amounts advanced in association with the services agreement. The convertible promissory note balance, including accrued interest, was approximately \$4.0 million and \$3.2 million as of December 31, 2012 and 2011, respectively. This intercompany balance was eliminated in consolidation.

Our President and Chief Executive Officer, James A. Bianco, M.D. and our Executive Vice President, Global Medical Affairs and Translational Medicine, Jack W. Singer, M.D. are both minority shareholders of Aequus, each owning approximately 4.3% of the equity in Aequus as of December 31, 2012. 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 1.3% of Aequus as of December 31, 2012 and is also a member of Aequus' board of directors.

## **19. Legal Proceedings**

On August 3, 2009, Società Italiana Corticosteroidi S.R.L., or Sicor, filed a lawsuit in the Court of Milan to obtain the Court's assessment that we were bound to source a chemical compound, whose chemical name is BBR2778, from Sicor according to the terms of a supply agreement executed between Sicor and Novuspharma on October 4, 2002. We assert that the supply agreement in question was properly terminated and that we have no further obligation to comply with its terms. At the hearing of October 11, 2012, the parties informed the court about the ongoing negotiations pending between them and asked to postpone the case. Sicor alleges that the agreement was not terminated according to its terms. At the request of the parties, the court extended the final hearing until March 21, 2013. No estimate of a loss, if any, can be made at this time in the event that we do not prevail.

On December 10, 2009, CONSOB sent us a notice claiming, among other things, violation of the provisions of Section 114, paragraph 1 of the Italian Legislative Decree no. 58/98 due to the asserted late disclosure of 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 could require us to pay a pecuniary administrative sanction amounting to between \$7,000 and \$659,000 upon conversion from euros as of December 31, 2012.

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, 2005, 2006 and 2007. 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). 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. We received favorable rulings in 2012, which remain subject to further appeal, and our remaining deposit for the VAT assessments was refunded to us in January 2013. Due to the change of the position for the VAT assessment cases, we have reversed the entire reserve for VAT assessed as of December 31, 2012. If the final decisions of the lower tax courts (i.e. the Provincial Tax Court or the Regional Tax Court) or of the Supreme Court are unfavorable to us, we may incur up to \$12.4 million in losses for the VAT amount assessed including penalties, interest and fees upon conversion from euros on December 31, 2012.

In addition to the contingencies 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.

## 20. 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 decreased \$87.6 million increased \$3.6 million, and increased \$17.8 million during 2012, 2011 and 2010, respectively.

The reconciliation between our effective tax rate and the income tax rate as of December 31, 2012, 2011 and 2010 is as follows:

	<u>2012</u>	<u>2011</u>	<u>2010</u>
Federal income tax rate . . . . .	(34%)	(34%)	(34%)
Research and development tax credits . . . . .	(1)	(2)	(1)
I.R.C. Section 382 limited research and development tax credits . . . . .	2	—	—
Non-deductible debt/equity costs . . . . .	—	1	5
Non-deductible executive compensation . . . . .	1	1	—
I.R.C. Section 382 limited net operating losses . . . . .	109	21	—
Valuation allowance . . . . .	(86)	6	22
Expired tax attribute carryforwards . . . . .	7	7	7
Other . . . . .	2	—	1
Net effective tax rate . . . . .	<u>—%</u>	<u>—%</u>	<u>—%</u>



Significant components of our deferred tax assets and liabilities as of December 31, 2012 and 2011 are as follows (in thousands):

	<u>2012</u>	<u>2011</u>
Deferred tax assets:		
Net operating loss carryforwards .....	\$ 60,079	\$ 150,101
Capitalized research and development .....	36,303	43,604
Research and development tax credit carryforwards .....	686	2,556
Stock based compensation .....	10,813	9,349
Intangible assets .....	11,336	487
Depreciation and amortization .....	8	1,890
Other deferred tax assets .....	<u>3,621</u>	<u>2,138</u>
Total deferred tax assets .....	122,846	210,125
Less valuation allowance .....	<u>(121,836)</u>	<u>(209,407)</u>
	1,010	718
Deferred tax liabilities:		
GAAP adjustments on Novuspharma merger .....	(208)	(208)
Deductions for tax in excess of financial statements .....	<u>(802)</u>	<u>(510)</u>
Total deferred tax liabilities .....	(1,010)	(718)
Net deferred tax assets .....	<u>\$ —</u>	<u>\$ —</u>

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 (NOL) and research and development credits against future income. We have obtained a private letter ruling (PLR) that determines the availability of the NOL after a 2007 ownership change.

In May 2012, an “ownership change” occurred. The ownership change limits the utilization of certain tax attributes including the NOL. After the May 2012 ownership change the utilization of the NOL is limited to approximately \$6.1 million annually. At December 2012, the gross NOL carryforward is approximately \$1.1 billion. The annual NOL limitation will reduce the available NOL carryforward to approximately \$176.7 million. The deferred tax asset and valuation allowance have been reduced accordingly.

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 1998 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, 2012, 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 reflected in the various tax returns are more-likely-than not to be sustained on audit and thus there are no anticipated adjustments that would 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.

## 21. Unaudited Quarterly Data

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

	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>
<b>2012</b>				
Revenues .....	\$ —	\$ —	\$ —	\$ —
Gross profit .....	—	—	—	—
Operating expenses, net .....	(18,098)	(49,400)	(15,149)	(18,850)
Net loss attributable to CTI .....	(17,446)	(50,138)	(15,189)	(18,601)
Net loss attributable to CTI common shareholders .....	(17,446)	(58,596)	(20,203)	(19,030)
Net loss per common share—basic and diluted .....	(0.43)	(1.38)	(0.38)	(0.20)
<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 .....	(1.74)	(0.68)	(0.80)	(0.47)

*Operating expenses, net* for the fourth quarter of 2011 include income of \$11.0 million resulting from our settlement with The Lash Group, Inc. *Operating expenses, net* for the second quarter of 2012 include charges of \$29.1 million of acquired in-process research and development related to our acquisition of assets from S\*BIO, see Note 4, *Acquisitions* for additional information.

**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 2012 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, 2012 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, 2012, 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.

## 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 February 28, 2013 :

<u>Name</u>	<u>Age</u>	<u>Director Since</u>	<u>Class</u>	<u>Term Expiration</u>
John H. Bauer(3) . . . . .	72	2005	I	2013 Annual Meeting
James A. Bianco, M.D. . . . .	56	1991	II	2014 Annual Meeting
Vartan Gregorian, Ph.D.(3)(4) . . . . .	78	2001	II	2014 Annual Meeting
Richard L. Love(2)(4) . . . . .	69	2007	III	2015 Annual Meeting
Mary O. Mundinger, DrPH(2)(4) . . . . .	75	1997	III	2015 Annual Meeting
Phillip M. Nudelman, Ph.D.(1)(2)(3)(4) . . . . .	77	1994	I	2013 Annual Meeting
Jack W. Singer, M.D. . . . .	70	1991	III	2015 Annual Meeting
Frederick W. Telling, Ph.D.(2)(3) . . . . .	61	2006	II	2014 Annual Meeting
Reed V. Tuckson, M.D. . . . .	62	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 President, 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., PAREXEL

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

**Dr. Mundinger** has been one of our directors since April 1997. From 1986 to 2010, she was a dean and professor at the Columbia University School of Nursing, and an associate dean on the faculty of medicine at Columbia University. In July 2010, Dr. Mundinger was appointed the Edward M. Kennedy Professor in Health Policy and Dean Emeritus at the Columbia University School of Nursing. Dr. Mundinger 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, Global Medical Affairs and Translational Medicine. 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 as chairman of Organics, Inc. and on the board of directors of Eisai N.A., and Aequus Biopharma, Inc. (a subsidiary of the Company). Dr. Telling is also a member of the Committee for Economic Development, the EAA, and the United Hospital Fund and is a non-board emeritus of 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 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 February 28, 2013:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Steven E. Benner, M.D. . . . .	53	Executive Vice President, Chief Medical Officer
James A. Bianco, M.D. . . . .	56	President and Chief Executive Officer
Louis A. Bianco . . . . .	60	Executive Vice President, Finance and Administration
Matthew J. Plunkett, Ph.D. . . . .	41	Executive Vice President, Corporate Development
Jack W. Singer, M.D. . . . .	70	Executive Vice President, Global Medical Affairs and Translational Medicine

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."

**Dr. Benner** assumed his role as our Executive Vice President, Chief Medical Officer on June 13, 2012. Prior to joining us, Dr. Benner was Senior Vice President and Chief Medical Officer of OncoMed Pharmaceuticals from February 2007 to November 2011. From November 2002 to November 2006, Dr. Benner was Senior Vice President and Chief Medical Officer of Protein Design Labs Inc. (later PDL Biopharma). Prior to that, Dr. Benner held a series of positions of increasing responsibility at Bristol-Myers Squibb, where he held leadership roles in clinical oncology, drug development and licensing, culminating in his position as a Vice President in the company's Pharmaceutical Research Institute. Prior to his work with industry, Dr. Benner held faculty appointments at the University of North Carolina and the University of Texas M.D. Anderson Cancer Center. He received his M.D. from the University of Missouri-Columbia and earned an M.H.S. in Clinical Epidemiology from Johns Hopkins University.

**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.

**Dr. Plunkett** assumed his role as our Executive Vice President, Corporate Development in September 2012. Prior to joining us, Dr. Plunkett was the Chief Financial Officer of the California Institute for Regenerative Medicine from November 2011 to August 2012. From July 2009 to April 2011, Dr. Plunkett was the Vice President and Chief Financial Officer of iPerian, Inc. From December 2000 to July 2009, Dr. Plunkett held positions at Oppenheimer & Co. and its U.S. predecessor, CIBC World Markets, including serving as Managing Director, Head of West Coast Biotechnology from December 2008 to July 2009 and Executive Director, Head of West Coast Biotechnology from January 2008 to December 2008. He received his B.S. in chemistry from Harvey Mudd College and a Ph.D. in organic chemistry from the University of California, Berkeley.

## Audit Committee Financial Expert

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



## **Audit Committee**

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

## **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 2012 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  
3101 Western Avenue, Suite 600  
Seattle, WA 98121  
(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. (The individuals who served as executive officers of the Company during fiscal 2012 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.

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 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 early in 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 (other than Dr. Benner and Dr. Plunkett who were not employed at that time) 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 for 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 2012 Year-End” table on page 122.

In light of the general current economic climate, the Company’s compensation philosophy and objectives for fiscal year 2012 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 2012, 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 2012 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 2011 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.

#### *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 2012 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 2012. As a result, the named executive officers' base salaries for fiscal 2012 were as follows: Dr. Bianco \$650,000 (unchanged since established in 2005), Mr. Bianco \$330,000 (unchanged since established in 2005), and Dr. Singer \$340,000 (unchanged since established in 2005). The base salaries for fiscal 2012 for Mr. Philips and Mr. Eramian, each of whom terminated employment with the Company during 2012, were also unchanged from the levels in effect for fiscal 2011 and prior years.

As noted above, Dr. Benner and Dr. Plunkett each joined the Company during fiscal 2012. Their annual base salaries were set at \$380,000 and \$325,000, respectively, by the Compensation Committee based on competitive considerations and negotiations with each executive.

*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 April 2012, the Compensation Committee established the 2012 cash incentive program for the Company's named executive officers employed with the Company at that time, 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 were determined by reference to a percentage of the executive officer's base salary. For fiscal 2012 performance, the target bonus opportunities were 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 were 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 were consistent with the levels established for the 2011 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 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 2012 cash incentive program were generally subject to a requirement that the executive officer be employed by the Company on the payment date.

There were three core elements to the 2012 cash incentive program, which together comprised each executive's cash incentive opportunity: financial performance, drug development and individual performance. As indicated in the table below, a portion of each executive's bonus opportunity was allocated to each of these elements, with the percentage of the total bonus opportunity allocated to a particular element based on the executive's position and ability to affect the outcome for that particular goal. With the exception of the individual performance element, each element was composed of sub-elements as identified below. The individual performance element constituted 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 would 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 deemed appropriate.

For the financial performance element, performance for fiscal 2012 was measured based on the Company's operating capital raised. In addition, financial performance would be measured based on the Company's obtaining an agreement with its auditors to remove certain language in its SEC reports about its ability to continue as a going concern and a determination by the Commissione Nazionale per le Società e la Borsa to remove the Company from its black list. 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 2012 equals or exceeds \$75 million. The executive would be entitled to receive the maximum bonus if the Company's operating capital for fiscal 2012 equals or exceeds \$100 million. For the status change sub-element, the executive would be entitled to an additional bonus as noted in the table below.

For the drug development element, three of the performance goals established by the Compensation Committee for fiscal 2012 related to PIXUVRI. The executive would receive the portion of his bonus opportunity allocated to that particular performance goal as reflected in the table below if, during fiscal 2012, (1) the Company received approval from the European Commission of its marketing authorization application submission for PIXUVRI ("Pix EC Approval"), or (2) the Company enrolled at least 100 patients in PIXUVRI 306 trials ("Pix306 Goal"), or (3) the Company achieved 125 PIXUVRI "commercial patient starts" ("Pix Patient Starts"). In the case of Dr. Singer, however, a portion of his bonus opportunity was allocated to the initiation of a Phase III trial for Tosedostat (as opposed to the Pix Patient Starts goal established for the other executives). In addition, if, during fiscal 2012, the Company acquired one or more new products targeted for acquisition by the Company's 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		Status Changes		Pix 306 Goal	Pix EC Approval	Pix Patient Starts(1)	New Product Acquisition
	Target	Maximum	Black List Removal	Going Concern Removal				
James A. Bianco, M.D. ....	20%	40%	10%	10%	5%	15%	10%	20%
Louis A. Bianco .....	15%	25%	5%	20%	0%	1.5%	3.5%	10%
Jack W. Singer, M.D. ....	2.5%	10%	2.5%	2.5%	10%	15%	10%	10%
Craig Philips .....	5%	10%	5%	10%	10%	15%	30%	10%
Dan Eramian .....	10%	30%	5%	10%	8%	2%	0%	10%



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- (1) As noted above, this goal for Dr. Singer related to the initiation of a new trial for tosedostat (as opposed to the Pix Patient Starts goal for the other executives).

In June 2012, the Compensation Committee determined that the Company had earlier in 2012 achieved the Pix EC Approval goal and the New Product Acquisition goal (with the acquisition of pacritinib). Accordingly, the Compensation Committee approved mid-year bonuses for each executive in the following amounts (expressed as a percentage of such executive's base salary): Dr. Bianco, 35%; Mr. Bianco, 11.5%; Dr. Singer, 25%; Mr. Philips, 25%; and Mr. Eramian, 12%.

In December 2012, the Compensation Committee determined that the Company had raised \$95 million in operating capital in 2012 and, accordingly, awarded each executive a bonus between the target and maximum amounts allocated to the operating capital raised sub-element of the program. In addition, the Compensation Committee determined that each executive employed with the Company through the end of 2012 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. While the Compensation Committee's determination of these amounts was inherently subjective, the key factors in the Compensation Committee's determination were the executives' successes in 2012 in making PIXUVRI available for commercial sale in eight countries in the European Union, continuing the development of tosedostat, Opaxio and other pipeline products through clinical trials, and reducing costs and expenses below the levels approved by the Board in the annual budget, 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 pre-established financial goals discussed above, the bonus opportunities related to the regulatory procedures and development involving PIXUVRI, the acquisition of pacritinib, and the Compensation Committee's general assessment of each executive's individual performance during fiscal 2012, the Compensation Committee determined to award cash incentives for fiscal 2012 to each of the named executive officers in the following amounts (expressed as a percentage of such executive's base salary and including the mid-year bonuses awarded in June 2012 identified above): Dr. Bianco, 85%; Mr. Bianco, 45%; and Dr. Singer, 45%. Mr. Philips and Mr. Eramian did not receive any bonus under the program beyond the mid-year bonuses awarded to them in June 2012 as they were not employed with the Company at the time the final bonus amounts were paid.

In connection with their joining the Company during 2012, the Company provided offer letters to Dr. Benner and Dr. Plunkett that included eligibility to receive a prorated bonus for 2012 as determined by the Compensation Committee in its discretion, with the target bonus for each executive being 30% of his base salary, and the maximum bonus being 75% of his base salary. In December 2012, the Compensation Committee awarded a 2012 bonus to Dr. Benner for \$57,000 and to Dr. Plunkett for \$32,500, each such bonus representing 30% of the executive's base salary, as pro-rated based on the portion of 2012 the executive was employed with the Company. The Compensation Committee determined, in its judgment, that these awards were appropriate based on its subjective assessment of the executive's performance during 2012.

Service Recognition Bonuses. In January 2012, the Compensation Committee approved a special bonus of \$50,000 to each of Mr. Bianco and Dr. Singer in recognition of each executive's 20 years of service with the Company. The Compensation Committee determined that these awards were appropriate in light of each executive's role as co-founder of the Company with Dr. Bianco and continuous service with the Company since its inception.

New-Hire Bonuses. The Compensation Committee approved a bonus of \$85,000 to Dr. Benner in connection with his joining the Company in June 2012 and relocating to the Seattle, Washington area. The Compensation Committee approved a new-hire bonus of \$30,000 to Dr. Plunkett in connection with his joining the Company in September 2012. These bonuses were negotiated with the executive and determined by the Compensation Committee in its judgment based on competitive considerations. The bonuses are subject to repayment to the Company if the executive terminates his employment within one year after his hire date.



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

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 goal's achievement 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 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
- (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").

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 MAA Approval	Pix NDA Approval	Opaxio NDA Approval	Market Cap Approval	\$50M Sales Goal	\$100M Sales Goal	Cash Flow Break Even	EPS 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. Philips . . . . .	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 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.

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.

On June 27, 2012, the Compensation Committee certified that the Company had received in May 2012 conditional marketing authorization from the European Commission for PIXUVRI as monotherapy for the treatment of adult patients with multiply relapsed or refractory aggressive non-Hodgkin B-cell lymphomas, that such approval constituted achievement of the "Pix MAA Approval" performance goal for purposes of the 2012-2014 Performance Awards described above and that, accordingly, the portions of those awards subject to achievement of the Pix MAA Approval performance goal vested as of the date of the Compensation Committee's certification.

New-Hire Grants. The Compensation Committee approved a grant of 100,000 shares of restricted stock to Dr. Benner in connection with his joining the Company in June 2012 and a grant of 100,000 shares of restricted stock to Dr. Plunkett in connection with his joining the Company in September 2012. The size of each grant was negotiated with the executive and determined by the Compensation Committee in its judgment based on competitive considerations.

*Perquisites and Other Benefits.* The named executive officers receive certain perquisites and other benefits provided by or paid for by the Company, as identified in the footnotes to the "Summary Compensation Table" below. 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 (other than Dr. Plunkett, who joined the Company in September 2012). 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 two years, 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 (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 Mr. Bianco and Dr. Singer 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. 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.

### *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 2012, 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. Mundinger, 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 2012. No director who served on the Compensation Committee during fiscal year 2012 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 2012.

## EXECUTIVE COMPENSATION

### Summary Compensation Table—Fiscal Years 2010-2012

The following table sets forth information concerning compensation for fiscal years 2010, 2011 and 2012 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 in office as of December 31, 2012, as well as two other individuals who served as executive officers of the Company during fiscal year 2012. Collectively, these are the "named executive officers."

Name and Principal Position	Year	Salary (\$)	Bonus \$(1)	Stock Awards \$(2)(3)	Option Awards (\$)	Non-Equity Incentive Plan Compensation (\$)	All Other Compensation \$(4)	Total(\$)
James A. Bianco, M.D. . . . . .	2012	650,000	552,500	1,318,393	—	—	292,643	2,813,536
Chief Executive Officer and	2011	650,000	767,500	2,891,120	—	—	287,018	4,595,638
President(5)	2010	650,000	585,000	—	—	—	125,967	1,360,967
Louis A. Bianco . . . . .	2012	330,000	198,500(6)	536,147	—	—	34,293	1,098,940
Executive Vice President	2011	330,000	242,550	675,836	—	—	32,928	1,281,314
Finance and Administration	2010	330,000	247,500	—	—	—	10,009	587,509
Jack W. Singer, M.D. . . . . .	2012	340,000	203,000(6)	536,147	—	—	42,579	1,121,726
Executive Vice President	2011	340,000	204,000	649,836	—	—	44,107	1,237,943
Global Medical Affairs and	2010	340,000	212,500	—	—	—	30,475	582,975
Translational Medicine								
Steven E. Benner, M.D. . . . . .	2012	210,218	142,000(7)	345,000	—	—	3,153	700,371
Executive Vice President								
Chief Medical Officer								
Matthew Plunkett, Ph.D. . . . . .	2012	106,041	62,500(7)	153,000	—	—	—	321,541
Executive Vice President								
Corporate Development								
Craig W. Philips(8) . . . . .	2012	219,296	100,500	791,036	—	—	216,892	1,327,724
Former President	2011	402,000	341,700	1,216,922	—	—	39,634	2,000,256
	2010	402,000	281,400	—	—	—	16,125	699,525
Daniel G. Eramian(9) . . . . .	2012	275,625	37,800	395,518	—	—	36,424	745,367
Former Executive Vice President	2011	315,000	226,800	649,836	—	—	11,768	1,203,404
Corporate Communications	2010	315,000	220,500	—	—	—	250	535,750

- (1) Please see the Compensation Discussion and Analysis above for a description of the cash incentive program for the named executive officers for fiscal 2012.
- (2) The amounts reported in the "Stock Awards" column of the table above for each fiscal year reflect the grant date fair value of the stock awards granted to the named executive officers during the fiscal year. These values have been determined under generally accepted accounting principles used to calculate the value of equity awards for purposes of the Company's financial statements. For a discussion of the assumptions and methodologies used to calculate the amounts reported above, please see the discussion of equity awards contained in Note 13 (Share-Based Compensation) to the Company's Consolidated Financial Statements, included as part of this Form 10-K.



- (3) The amounts reported in the “Stock Awards” column of the table above for fiscal 2012 for each of the named executive officers (other than Dr. Benner and Dr. Plunkett) include the grant-date fair value of the long-term performance awards granted to these executives in January 2012 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 2012 for these executives and the aggregate grant-date fair value of these awards assuming that the highest level of performance conditions will be achieved.

<u>Name</u>	<b>2012 Performance Awards</b>	
	<b>Aggregate Grant Date Fair Value (Based on Probable Outcome) (\$)</b>	<b>Aggregate Grant Date Fair Value (Based on Maximum Performance) (\$)</b>
James A. Bianco, M.D. ....	1,318,393	7,472,740
Louis A. Bianco ....	536,147	3,061,916
Jack W. Singer, M.D. ....	536,147	3,061,916
Craig W. Philips ....	791,036	4,482,488
Daniel G. Eramian ....	395,518	2,239,669

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

<u>Name</u>	<b>Executive Health Benefits (\$)</b>	<b>Life Insurance Premiums(\$)</b>	<b>401(k) Match (\$)</b>	<b>Other Personal Benefits\$(a)</b>	<b>Severance(\$)</b>	<b>Total (\$)</b>
James A. Bianco, M.D. ....	143,688	30,785	—	118,170(b)	—	292,643
Louis A. Bianco ....	17,378	9,532	3,750	3,633(c)	—	34,293
Jack W. Singer, M.D. ....	30,699	—	3,750	8,130(d)	—	42,579
Steven E. Benner, M.D. ....	—	—	3,153	—	—	3,153
Matthew Plunkett, Ph.D. ....	—	—	—	—	—	—
Craig W. Philips ....	9,745	—	3,289	5,224(e)	198,634	216,892
Daniel G. Eramian ....	2,426	—	—	1,912(f)	32,086	36,424

- (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) This amount includes \$62,161 for family members’ travel on commercial aircraft, \$25,500 for personal travel expenses, \$3,245 for tax preparation fees, \$4,901 for health club dues, \$20,087 for security expenses, \$1,122 for residential services and \$1,154 for miscellaneous expenses.
- (c) This amount includes \$1,860 for tax preparation fees, \$1,323 for security expenses, and \$450 for miscellaneous expenses.
- (d) This amount includes \$4,125 for tax preparation fees, \$3,235 for security expenses, and \$770 for telecommunications expenses.
- (e) This amount includes \$4,906 for automobile allowance and \$318 for security expenses.
- (f) This amount includes \$765 for tax preparation fees and \$1,147 for security expenses.
- (5) Dr. Bianco was appointed President of the Company on July 25, 2012.
- (6) These amounts include a special bonus of \$50,000 to each of Mr. Bianco and Dr. Singer in January 2012 to recognize their 20 years of continuous service with the Company since its inception.
- (7) These amounts include signing and relocation bonuses for Dr. Benner for a total of \$85,000 and a signing bonus for Dr. Plunkett of \$30,000.

- (8) Mr. Philips resigned as President of the Company on June 16, 2012, effective as of July 16, 2012. Please see “Potential Payments Upon Termination or Change in Control” below for a description of the separation agreement entered into by Mr. Philips and the Company in connection with his termination.
- (9) Mr. Eramian’s employment with the Company terminated effective November 15, 2012. Please see “Potential Payments Upon Termination or Change in Control” below for a description of the separation agreement entered into by Mr. Eramian and the Company in connection with his termination.

### **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 2012. 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.

In June 2012, the Company entered into an offer letter with Dr. Benner. The letter does not have a specified term and provides for Dr. Benner to receive an initial annualized base salary of \$380,000. Dr. Benner is eligible to receive an annual discretionary bonus, with a target bonus of 30% of base salary and a maximum bonus of 75% of base salary, and to participate in the benefit programs offered by the Company. The letter also provides for Dr. Benner to receive a signing bonus of \$50,000 and a relocation allowance of \$35,000, each of which must be repaid to the Company if Dr. Benner voluntarily terminates his employment within one year after his hire date. In addition, the letter provides for Dr. Benner to receive a grant of restricted shares as described below under “Grants of Plan-Based Awards—Fiscal 2012” and to be eligible for a 2012-2014 Performance Award grant.

In July 2012, the Company entered into an offer letter with Dr. Plunkett. The letter does not have a specified term and provides for Dr. Plunkett to receive an initial annualized base salary of \$325,000. Dr. Plunkett is eligible to receive an annual discretionary bonus, with a target bonus of 30% of base salary and a maximum

bonus of 75% of base salary, and to participate in the benefit programs offered by the Company. The letter also provides for Dr. Plunkett to receive a signing bonus of \$30,000, which must be repaid to the Company if Dr. Plunkett voluntarily terminates his employment within one year after his hire date. In addition, the letter provides for Dr. Plunkett to receive a grant of restricted shares as described below under “Grants of Plan-Based Awards—Fiscal 2012.”

Provisions of each of the foregoing agreements relating to outstanding equity incentive awards and post-termination of employment benefits are discussed below under the applicable sections of this Annual Report on Form 10-K.

## Grants of Plan-Based Awards—Fiscal 2012

The following table presents information regarding the equity awards granted to the named executive officers in fiscal 2012.

Name/Award Type	Approval Date	Grant Date	Estimated Future Payouts Under Equity Incentive Plan Awards(1)			All Other Stock Awards: Number of Shares of Stock or Units (#)	All Other Option Awards: Number of Securities Underlying Options (#)	Exercise or Base Price of Option Awards (\$/Sh)	Grant Date Fair Value of Stock and Option Awards \$(2)
			Threshold (#)	Target (#)	Maximum (#)				
James A. Bianco, M.D.									
Performance Award(3)	11/22/11	1/3/12	—	60,920	—	—	—	—	1,318,393
Performance Award(4)	11/22/11	1/3/12	—	182,761	—	—	—	—	
Performance Award(5)	11/22/11	1/3/12	—	34,521	—	—	—	—	
Performance Award(6)	11/22/11	1/3/12	—	304,601	—	—	—	—	
Performance Award(7)	11/22/11	1/3/12	—	121,841	—	—	—	—	
Performance Award(8)	11/22/11	1/3/12	—	243,681	—	—	—	—	
Performance Award(9)	11/22/11	1/3/12	—	121,841	—	—	—	—	
Performance Award(10)	11/22/11	1/3/12	—	50,361	—	—	—	—	
Louis A. Bianco									
Performance Award(3)	11/22/11	1/3/12	—	24,774	—	—	—	—	536,147
Performance Award(4)	11/22/11	1/3/12	—	73,917	—	—	—	—	
Performance Award(5)	11/22/11	1/3/12	—	13,809	—	—	—	—	
Performance Award(6)	11/22/11	1/3/12	—	123,871	—	—	—	—	
Performance Award(7)	11/22/11	1/3/12	—	49,548	—	—	—	—	
Performance Award(8)	11/22/11	1/3/12	—	98,691	—	—	—	—	
Performance Award(9)	11/22/11	1/3/12	—	49,548	—	—	—	—	
Performance Award(10)	11/22/11	1/3/12	—	24,774	—	—	—	—	
Jack W. Singer									
Performance Award(3)	11/22/11	1/3/12	—	24,774	—	—	—	—	536,147
Performance Award(4)	11/22/11	1/3/12	—	73,917	—	—	—	—	
Performance Award(5)	11/22/11	1/3/12	—	13,809	—	—	—	—	
Performance Award(6)	11/22/11	1/3/12	—	123,871	—	—	—	—	
Performance Award(7)	11/22/11	1/3/12	—	49,548	—	—	—	—	
Performance Award(8)	11/22/11	1/3/12	—	98,691	—	—	—	—	
Performance Award(9)	11/22/11	1/3/12	—	49,548	—	—	—	—	
Performance Award(10)	11/22/11	1/3/12	—	24,774	—	—	—	—	
Steven E. Benner, M.D.									
Restricted Stock	6/13/12	6/13/12	—	—	—	100,000	—	—	345,000
Matthew Plunkett, Ph.D.									
Restricted Stock	10/16/12	10/16/12	—	—	—	100,000	—	—	153,000

Name/Award Type	Approval Date	Grant Date	Estimated Future Payouts Under Equity Incentive Plan Awards(1)			All Other Stock Awards: Number of Shares of Stock or Units (#)	All Other Option Awards: Number of Securities Underlying Options (#)	Exercise or Base Price of Option Awards (\$/Sh)	Grant Date Fair Value of Stock and Option Awards (\$)(2)
			Threshold (#)	Target (#)	Maximum (#)				
Craig W. Philips									
Performance Award(3)	11/22/11	1/3/12	—	36,552	—	—	—	—	—
Performance Award(4)	11/22/11	1/3/12	—	109,656	—	—	—	—	—
Performance Award(5)	11/22/11	1/3/12	—	20,713	—	—	—	—	—
Performance Award(6)	11/22/11	1/3/12	—	182,761	—	—	—	—	791,036
Performance Award(7)	11/22/11	1/3/12	—	73,104	—	—	—	—	—
Performance Award(8)	11/22/11	1/3/12	—	146,209	—	—	—	—	—
Performance Award(9)	11/22/11	1/3/12	—	73,104	—	—	—	—	—
Performance Award(10)	11/22/11	1/3/12	—	30,054	—	—	—	—	—
Daniel G. Eramian									
Performance Award(3)	11/22/11	1/3/12	—	18,276	—	—	—	—	—
Performance Award(4)	11/22/11	1/3/12	—	54,828	—	—	—	—	—
Performance Award(5)	11/22/11	1/3/12	—	10,153	—	—	—	—	—
Performance Award(6)	11/22/11	1/3/12	—	91,380	—	—	—	—	395,518
Performance Award(7)	11/22/11	1/3/12	—	36,552	—	—	—	—	—
Performance Award(8)	11/22/11	1/3/12	—	73,104	—	—	—	—	—
Performance Award(9)	11/22/11	1/3/12	—	36,552	—	—	—	—	—
Performance Award(10)	11/22/11	1/3/12	—	15,027	—	—	—	—	—

- (1) This column reflects the 2012-2014 Performance Awards that are subject to achievement by the Company of certain performance goals (identified in the footnotes below) on or before December 31, 2014. As described in the Compensation Discussion and Analysis above, each of these awards consists of a restricted stock component and a restricted stock unit component, with the number of shares that will vest or be payable in shares of the Company's common stock, as applicable, upon achievement of the related performance goal to be determined by multiplying the payout percentage that has been assigned by the Compensation Committee to that goal for purposes of the named executive officer's award by the number of shares of the Company's common stock issued and outstanding at the time the Compensation Committee certifies that that particular goal has been achieved. For each award, the "Target" column reflects the number of shares that would vest or be issued under each award upon timely achievement of each performance goal based on the applicable payout percentages and the number of shares of the Company's common stock issued and outstanding on January 3, 2012. The actual number of shares, if any, that will vest or be issued for each award upon timely achievement of the related performance goal may be different from the number reported in the table above depending on the number of shares of the Company's common stock issued and outstanding at the time the Compensation Committee certifies that the goal has been achieved.
- (2) The amounts reported in this column reflect the grant date fair value of these awards as determined under the 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 value the awards reported in this column, please see footnote (2) to the Summary Compensation Table. With respect to equity incentive plan awards, this column reflects the grant date fair value of such awards based on the probable outcome (as of the grant date) of the performance-based conditions applicable to the awards, as determined under generally accepted accounting principles.
- (3) The vesting of these awards was subject to the Company's obtaining MAA approval of PIXUVRI on or before December 31, 2014. As noted in the Compensation Discussion and Analysis above, the Compensation Committee certified on June 27, 2012 that this performance goal had been achieved and that, accordingly, these awards vested as of the date of the Compensation Committee's certification. The number of shares that vested in connection with the achievement of this goal is included in the "Option Exercises and Stock Vested—Fiscal Year 2012" table below.
- (4) The vesting of these awards is subject to the Company's obtaining NDA approval of PIXUVRI on or before December 31, 2014.
- (5) The vesting of these awards is subject to the Company's obtaining NDA approval of OPAXIO on or before December 31, 2014.
- (6) The vesting of these awards is subject to the Company's achievement on or before December 31, 2014 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).
- (7) The vesting of these awards is subject to achievement by the Company of fiscal year sales equal to or greater than \$50 million on or before December 31, 2014.

- (8) The vesting of these awards is subject to achievement by the Company of fiscal year sales equal to or greater than \$100 million on or before December 31, 2014.
- (9) The vesting of these awards is subject to achievement by the Company of break-even cash flow in any fiscal quarter before December 31, 2014.
- (10) The vesting of these awards is subject to achievement by the Company of earnings per share results in any fiscal year equal to or greater than \$0.30 per share of Company common stock on or before December 31, 2014.

Each of the awards reported in the above table 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.

*Restricted Stock.* The awards granted to Dr. Benner and Dr. Plunkett reported in the table above represent grants of restricted stock to each of these executive officers. The vesting schedules for these awards is described in the footnotes to the Outstanding Equity Awards at Fiscal 2012 Year-End Table below. Prior to the time the shares become vested, the named executive officer generally does not have the right to dispose of the restricted shares, but does have the right to vote and receive dividends (if any) paid by the Company in respect of the restricted shares.

*Performance Awards.* The awards granted in January 2012 reported in the table above represent the 2012-2014 Performance Awards. These awards 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. See the Compensation Discussion and Analysis above for a description of the performance and other vesting conditions applicable to the awards and the footnotes to the table above for the number of shares that would be payable upon achievement of the related performance goal. The named executive officer does not have the right to vote or dispose of the awards or any other shareholder rights with respect to the awards (except the portions of the awards granted in restricted stock have voting and dividend rights).

## Outstanding Equity Awards at Fiscal 2012 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, 2012, including the vesting dates for the portions of these awards that had not vested as of that date.

Option Awards						Stock Awards			
Name/Award Type	Grant Date	Number of Shares Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)(1)	Equity Incentive Plan Awards; Number of Shares, Units or Rights That Have Not Vested (#)(2)	Equity Incentive Plan Awards; Market or Payout Value of Unearned Shares, Units or Rights That Have Not Vested (\$)(1)
James A. Bianco, M.D.									
CTI Option	12/11/03	103	—	9,720.00	12/11/13	—	—	—	—
CTI Option	12/14/05	208	—	2,832.00	12/14/15	—	—	—	—
CTI Option	1/18/07	200	—	2,040.00	1/18/17	—	—	—	—
CTI Option	12/27/07	333	—	567.00	12/27/17	—	—	—	—
CTI Restricted Stock	11/29/11	—	—	—	—	224,750(3)	292,175	—	—
CTI Performance Award(4)	1/3/12	—	—	—	—	—	—	494,207	642,469
CTI Performance Award(5)	1/3/12	—	—	—	—	—	—	93,350	121,355
CTI Performance Award(6)	1/3/12	—	—	—	—	—	—	823,678	1,070,782
CTI Performance Award(7)	1/3/12	—	—	—	—	—	—	329,471	428,313
CTI Performance Award(8)	1/3/12	—	—	—	—	—	—	658,942	856,625
CTI Performance Award(9)	1/3/12	—	—	—	—	—	—	329,471	428,313
CTI Performance Award(10)	1/3/12	—	—	—	—	—	—	136,181	177,036
Louis A. Bianco									
CTI Option	12/11/03	49	—	9,720.00	12/11/13	—	—	—	—
CTI Option	7/14/05	125	—	3,336.00	7/14/15	—	—	—	—
CTI Option	12/14/05	100	—	2,832.00	12/14/15	—	—	—	—
CTI Option	6/22/06	25	—	1,704.00	6/22/16	—	—	—	—
CTI Option	1/18/07	58	—	2,040.00	1/18/17	—	—	—	—
CTI Option	12/27/07	120	—	567.00	12/27/17	—	—	—	—
CTI Restricted Stock	11/29/11	—	—	—	—	67,424(3)	87,651	—	—
CTI Performance Award(4)	1/3/12	—	—	—	—	—	—	199,879	259,843
CTI Performance Award(5)	1/3/12	—	—	—	—	—	—	37,340	48,542
CTI Performance Award(6)	1/3/12	—	—	—	—	—	—	334,962	435,451
CTI Performance Award(7)	1/3/12	—	—	—	—	—	—	133,985	174,180
CTI Performance Award(8)	1/3/12	—	—	—	—	—	—	266,872	346,933
CTI Performance Award(9)	1/3/12	—	—	—	—	—	—	133,985	174,180
CTI Performance Award(10)	1/3/12	—	—	—	—	—	—	66,992	87,090
Aequus Restricted Stock	2/11/11	—	—	—	—	150,000(11)	19,500	—	—
Jack W. Singer									
CTI Option	12/11/03	62	—	9,720.00	12/11/13	—	—	—	—
CTI Option	7/14/05	125	—	3,336.00	7/14/15	—	—	—	—
CTI Option	12/14/05	100	—	2,832.00	12/14/15	—	—	—	—
CTI Option	6/22/06	25	—	1,704.00	6/22/16	—	—	—	—
CTI Option	1/18/07	58	—	2,040.00	1/18/17	—	—	—	—
CTI Option	12/27/07	120	—	567.00	12/27/17	—	—	—	—
CTI Restricted Stock	11/29/11	—	—	—	—	67,424(3)	87,651	—	—
CTI Performance Award(4)	1/3/12	—	—	—	—	—	—	199,879	259,843
CTI Performance Award(5)	1/3/12	—	—	—	—	—	—	37,340	48,542
CTI Performance Award(6)	1/3/12	—	—	—	—	—	—	334,962	435,451
CTI Performance Award(7)	1/3/12	—	—	—	—	—	—	133,985	174,180
CTI Performance Award(8)	1/3/12	—	—	—	—	—	—	266,872	346,933
CTI Performance Award(9)	1/3/12	—	—	—	—	—	—	133,985	174,180
CTI Performance Award(10)	1/3/12	—	—	—	—	—	—	66,992	87,090
Steven E. Benner, M.D.									
CTI Restricted Stock	6/13/12	—	—	—	—	100,000(12)	130,000	—	—



Name/Award Type	Grant Date	Option Awards				Stock Awards			
		Number of Shares Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested (\$)(1)	Equity Incentive Plan Awards; Number of Unearned Shares, Units or Rights That Have Not Vested (#)(2)	Equity Incentive Plan Awards; Market or Payout Value of Unearned Shares, Units or Rights That Have Not Vested (\$)(1)
Matthew Plunkett, Ph.D.									
CTI Restricted Stock .....	10/16/12	—	—	—		100,000(13)	130,000	—	—
Craig W. Philips .....	—	—	—	—		—	—	—	—
Daniel G. Eramian									
CTI Option .....	3/31/06	79	—	2,292.00	2/15/13	—	—	—	—
CTI Option .....	6/22/06	25	—	1,704.00	2/15/13	—	—	—	—
CTI Option .....	1/18/07	50	—	2,040.00	2/15/13	—	—	—	—
CTI Option .....	12/27/07	120	—	567.00	2/15/13	—	—	—	—
CTI Restricted Stock .....	11/29/11	—	—	—	—	33,712(14)	43,826	—	—

- (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 \$1.30 (the closing price of the Company's common stock on the last trading day of fiscal 2012) 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, 2012).
- (2) The entries in this column reflect the 2012-2014 Performance Awards that are subject to achievement by the Company of certain performance goals (identified in the footnotes below) on or before December 31, 2014. As described in the Compensation Discussion and Analysis above, each of these awards consists of a restricted stock component and a restricted stock unit component, with the number of shares that will vest or be payable in shares of the Company's common stock, as applicable, upon achievement of the related performance goal to be determined by multiplying the payout percentage that has been assigned by the Compensation Committee to that goal for purposes of the named executive officer's award by the number of shares of the Company's common stock issued and outstanding at the time the Compensation Committee certifies that that particular goal has been achieved. The table above reports the aggregate number of shares that would be vest or be issued under each award upon timely achievement of each performance goal based on the applicable payout percentages and the number of shares of the Company's common stock issued and outstanding on December 31, 2012. The actual number of shares, if any, that will vest or be issued for each award upon timely achievement of the related performance goal may be different from the number reported in the table above depending on the number of shares of the Company's common stock issued and outstanding at the time the Compensation Committee certifies that the goal has been achieved.
- (3) These awards were amended during 2012 to provide that one-half of these shares, which were originally scheduled to vest on November 29, 2012, will vest on the earlier of March 31, 2013 or two days after the filing of this Annual Report on Form 10-K. The remaining one-half of these shares are scheduled to vest on May 29, 2013, with vesting in each case being subject to continued service through the applicable vesting date.
- (4) The vesting of these awards is subject to the Company's obtaining NDA approval of PIXUVRI on or before December 31, 2014.
- (5) The vesting of these awards is subject to the Company's obtaining NDA approval of OPAXIO on or before December 31, 2014.
- (6) The vesting of these awards is subject to the Company's achievement on or before December 31, 2014 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).
- (7) The vesting of these awards is subject to achievement by the Company of fiscal year sales equal to or greater than \$50 million on or before December 31, 2014.
- (8) The vesting of these awards is subject to achievement by the Company of fiscal year sales equal to or greater than \$100 million on or before December 31, 2014.
- (9) The vesting of these awards is subject to achievement by the Company of break-even cash flow in any fiscal quarter before December 31, 2014.
- (10) The vesting of these awards is subject to achievement by the Company of earnings per share results in any fiscal year equal to or greater than \$0.30 per share of Company common stock on or before December 31, 2014.
- (11) These shares were granted to Mr. Bianco by Aequus and vest as to one-third of these shares on each of February 11, 2013, February 11, 2014 and February 11, 2015, subject to continued service with Aequus.
- (12) This award was amended during 2012 to provide that one-third of these shares, which were originally scheduled to vest on December 13, 2012, will vest on the earlier of March 31, 2013 or two days after the filing of this Annual Report on Form 10-K. The remaining two-thirds of these shares are scheduled to vest on December 13, 2013, with vesting in each case being subject to continued service through the applicable vesting date.
- (13) One-third of these shares will vest on each of September 4, 2013, September 4, 2014 and September 4, 2015, subject to continued service through the applicable vesting date.
- (14) Pursuant to the separation agreement entered into by Mr. Eramian and the Company in January 2013, these shares became vested on January 12, 2013.

## Option Exercises and Stock Vested—Fiscal Year 2012

The following table presents information regarding the vesting during fiscal year 2012 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 2012.

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. ....	—	—	228,504	742,430
Louis A. Bianco ....	—	—	68,160	191,493
Jack W. Singer, M.D. ....	—	—	68,160	191,493
Steven E. Benner, M.D. ....	—	—	—	—
Matthew Plunkett, Ph.D. ....	—	—	—	—
Craig W. Philips ....	—	—	116,268	308,995
Daniel G. Eramian ....	—	—	60,218	168,144

- (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 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.

*Other Named Executive Officers.* The Company has entered into severance agreements with each of the named executive officers currently employed with the Company (other than Dr. Bianco and Dr. Plunkett). These agreements provide that in the event the executive is discharged from employment by the Company without cause (as defined in the agreement) or resigns for good reason (as defined in the agreement, which definition includes a change in control of the Company), 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, in the case of Mr. Bianco and Dr. Singer, his outstanding stock options would remain exercisable for a period of 21 months 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 the severance agreements for Mr. Bianco and Dr. Singer 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. These executives' agreements are 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. The severance agreement for Dr. Benner does not provide for any tax reimbursements.

*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, 2012. 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)*

<u>Name</u>	<u>Cash Severance \$(1)</u>	<u>Continuation of Health/Life Benefits \$(2)</u>	<u>Equity Acceleration \$(3)</u>	<u>Totals (\$)</u>
James A. Bianco, M.D. ....	1,300,000	164,220	4,017,067	5,481,287
Louis A. Bianco ....	724,517	66,588	1,613,872	2,404,977
Jack W. Singer, M.D. ....	716,500	86,819	1,613,872	2,417,191
Steven E. Benner, M.D. ....	712,000	38,628	130,000	880,628
Matthew Plunkett, Ph.D.(4) ....	585,000	34,020	130,000	749,020

- (1) For Dr. Bianco, this amount represents two years of his base salary. 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, 2012). 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, 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 \$1.30 (the closing price of the Company's common stock on the last trading day of fiscal 2012) 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 \$1.30 (or, in the case of awards granted by Aequis, \$0.13, which Aequis determined to be the fair market value of Aequis common stock as of December 31, 2012) 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. Dr. Bianco's stock options would also remain exercisable for two years following his termination, subject to earlier termination at the end of the maximum term of the option or in connection with a change in control of the Company.
- (4) As noted above, the Company has not entered into a severance agreement with Dr. Plunkett. This line reflects the level of severance benefits provided to the other executives under the agreements described above in light of the provision in Dr. Plunkett's offer letter that he will generally be entitled to severance benefits on the same terms provided to the other senior executives.

#### *Change of Control Severance Benefits*

<u>Name</u>	<u>Cash Severance \$(1)</u>	<u>Continuation of Health Benefits \$(2)</u>	<u>Equity Acceleration \$(3)</u>	<u>Total (\$)</u>
James A. Bianco, M.D. ....	1,935,000	164,220	2,946,286	5,045,506
Louis A. Bianco ....	724,517	66,588	1,178,421	1,969,526
Jack W. Singer, M.D. ....	716,500	86,819	1,178,421	1,981,740
Steven E. Benner, M.D. ....	712,000	38,628	130,000	880,628
Matthew Plunkett, Ph.D.(4) ....	585,000	34,020	130,000	749,020

- (1) For each of the named executive officers, 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.
- (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 above, the long-term incentive awards granted to the named executive officers in January 2012 would generally vest on a change in control, except that the vesting of a portion of these awards was contingent on the Company's market capitalization and, if a change in control of the Company occurred, would be determined based on the Company's market capitalization 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, 2012, the market capitalization goal under the awards would not have been met, and the portion of the award related to market capitalization 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) See footnote (4) to the table above.

*Former Executives.* In October 2012, the Company entered into a separation agreement with Mr. Philips in connection with the termination of his employment with the Company effective July 16, 2012. Under the agreement, Mr. Philips is entitled to receive a severance payment of \$435,500, with 25% of such amount to be

paid within 30 days after the effective date of the agreement and the balance of such amount to be paid in twelve monthly installments thereafter. The Company will also pay Mr. Philips' premiums to continue his health coverage for 13 months following his termination. Mr. Philips' equity awards granted by the Company and Aequus Biopharma, Inc., a subsidiary of the Company, to the extent then outstanding and unvested, terminated as of July 16, 2012. Pursuant to the agreement, Mr. Philips has agreed to vote the existing shares of the Company that he owns in a manner consistent with the recommendation of the Company's board of directors through October 13, 2013. The separation agreement also includes a mutual release of claims by the parties and certain restrictive covenants by Mr. Philips in favor of the Company.

In January 2013, the Company entered into a separation agreement with Mr. Eramian in connection with the termination of his employment with the Company effective November 15, 2012. Under the agreement, Mr. Eramian is entitled to receive total cash severance payments of approximately \$567,238. Of the total payments, approximately \$252,238 will be paid in May 2013, and the balance will be paid in twelve monthly installments following May 2013. The Company will also pay the premiums to continue Mr. Eramian's health coverage and life insurance provided by the Company for up to 18 months following his termination. In addition, the agreement provides for accelerated vesting of certain equity awards granted to Mr. Eramian by the Company that were otherwise unvested such that he became vested in 33,712 shares of Company common stock. Any rights of Mr. Eramian to other equity awards granted by the Company, to the extent otherwise unvested, terminated. The agreement also includes a mutual release of claims by the parties and certain restrictive covenants by Mr. Eramian in favor of the Company.

## DIRECTOR COMPENSATION

### Non-Employee Director Compensation Table—Fiscal 2012

The following table presents information regarding the compensation paid for fiscal year 2012 to members of the Company's 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 2012 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 \$(1)	Stock Awards \$(2)(3)(4)	Option Awards \$(3)	Non-Equity Incentive Plan Compensation (\$)	Change in Pension Value and Nonqualified Deferred Compensation Earnings (\$)	All Other Compensation (\$)	Total (\$)
John H. Bauer .....	137,500	243,323	—	—	—	—	380,823
Vartan Gregorian, Ph.D. ....	132,000	243,323	—	—	—	—	375,323
Richard L. Love .....	122,500	243,323	—	—	—	—	365,823
Mary O. Mundinger, DrPH .....	122,500	243,323	—	—	—	—	365,823
Phillip M. Nudelman, Ph.D. ....	178,750	339,984	—	—	—	—	518,734
Frederick W. Telling, Ph.D.(5) ..	152,500	243,323	—	—	—	—	395,823
Reed V. Tuckson, M.D. ....	95,750	243,323	—	—	—	—	339,073

- (1) The amounts reported in the "Fees Earned or Paid in Cash" column of the table above reflect the payment during 2012 of the director's retainer and meeting fees for 2012 and retainer fees for the first six months of 2013. The director is not entitled to any additional retainer fee for the first six months of 2013.
- (2) The amounts reported in the "Stock Awards" and "Option Awards" columns of the table above reflect the grant date fair value of the stock awards and option awards, respectively, granted to the Company's non-employee directors during fiscal year 2012 as determined under generally accepted accounting principles used to calculate the value of equity awards for purposes of the Company's financial statements. For a discussion of the assumptions and methodologies used to calculate the amounts reported above, please see the discussion of equity awards contained in Note 13 (Share-Based Compensation) to the Company's Consolidated Financial Statements, included as part of this Form 10-K.
- (3) The table below presents the number of outstanding and unexercised option awards and the number of shares subject to unvested stock awards held by each of the Company's non-employee directors as of December 31, 2012. This table includes the 2012-2014 Performance Awards granted to each of the non-employee directors under the Company's equity grant program and described in more detail under "Non-Employee Director Compensation" below. The table below reflects the aggregate number of shares that would be issued upon timely achievement of all of the performance goals based on the applicable payout percentages for these awards and the number of shares of the Company's common stock issued and outstanding on December 31, 2012. The actual number of shares issued for each award upon timely achievement of the related performance goal may be different from the number reported in the table above depending on the number of shares of the Company's common stock issued and outstanding at the time the goal is achieved.

Director	Number of Shares Subject to Outstanding Options as of 12/31/2012	Number of Unvested Restricted Shares/ Units as of 12/31/2012
John H. Bauer .....	3,179	319,587
Vartan Gregorian, Ph.D. ....	3,200	319,587
Richard L. Love .....	3,180	319,587
Mary O. Mundinger, DrPH .....	3,207	319,587
Phillip M. Nudelman, Ph.D. ....	3,214	479,381
Frederick W. Telling, Ph.D. ....	3,169	319,587
Reed V. Tuckson, M.D. ....	2,200	321,987



- (4) On December 3, 2012, each of the non-employee directors (other than Dr. Nudelman) was granted 71,429 fully-vested shares with a grant-date fair value of \$100,000, and Dr. Nudelman was granted 89,286 fully-vested shares with a grant-date fair value of \$125,000. Effective January 3, 2012, each of the non-employee directors was granted a 2012-2014 Performance Award under the Company's equity grant program as described below under "Non-Employee Director Compensation." The amounts reported in the "Stock Awards" column of the table above for each of the non-employee directors include a grant-date fair value of these performance awards of \$143,323 (or \$214,984 in the case of Dr. Nudelman's award) 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 aggregate grant-date fair value of these awards for each director assuming that the highest level of performance conditions will be achieved is \$971,020 (or \$1,459,290 in the case of Dr. Nudelman's award). See footnote (2) above for the assumptions used to value each of these awards granted to the non-employee directors in 2012.
- (5) For Dr. Telling, the "Fees Earned or Paid in Cash" column of the table above includes \$7,500 fees for his service on the board of directors of Aequus. Dr. Telling did not receive any other compensation in 2012 for his services to Aequus. Dr. Telling holds 8,333 shares of Aequus common stock that were unvested as of December 31, 2012.

### **Non-Employee Director Compensation**

*Equity Grants.* Under the Company's Director Compensation Policy, the Company's non-employee directors receive an equity award each year. Effective June 27, 2012, the Company's board of directors amended the policy to provide that the level of these grants would be a fixed dollar amount (as opposed to a fixed number of shares). Under the amended policy, non-employee directors will receive stock awards as follows: (i) each new non-employee director will be granted an award of fully vested shares of the Company's common stock in connection with joining the Board, with the number of shares to equal \$100,000 divided by the closing price of a share of the Company's common stock on the date of grant of the award; and (ii) in connection with each annual meeting of shareholders commencing with the 2012 Annual Meeting, each continuing non-employee director will be granted an award of fully vested shares of the Company's common stock, with the number of shares to equal \$100,000 (\$125,000 in the case of a non-employee director who is serving, after such annual meeting of shareholders, as the Chair of the Board) divided by the closing price of a share of the Company's common stock on the date of grant of the award. Each grant will be rounded to the nearest whole share. In accordance with this policy, each non-employee director received a stock grant in December 2012 as described in note (4) to the table above. 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 achievement 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.

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(1)	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%

- (1) As noted in the Compensation Discussion and Analysis above with respect to the 2012-2014 Performance Awards granted to named executive officers, the Board of Directors certified on June 27, 2012 that the Pix MAA Approval performance goal had been achieved and that, accordingly, the portion of these awards allocated to this goal vested as of the date of the Board of Directors' certification.

*Retainers and Meeting Fees.* In addition, non-employee directors are entitled under the Director Compensation Policy to annual retainers and fees for attending Board and committee meetings as set forth in the following table:

	Annual Cash Retainer (\$)	Meeting Fees (\$)	
		Board	Committee
Board Member, other than Chairman of the Board . . . . .	40,000	2,750	—
Chairman of the Board . . . . .	75,000	2,750	—
Audit Committee Member . . . . .	—	—	1,250
Audit Committee Chair . . . . .	12,500	—	1,250
Compensation Committee Member . . . . .	—	—	1,250
Compensation Committee Chair . . . . .	12,500	—	1,250
Nominating and Governance Committee Member . . . . .	—	—	1,250
Nominating and Governance Committee Chair . . . . .	12,500	—	1,250

All non-employee directors are also reimbursed for their expenses incurred in attending Board meetings and committee meetings, as well as other Board-related travel expenses.

## 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 15, 2013 by (1) each shareholder known by us to be the beneficial owner of more than 5% of the outstanding shares of our common stock, (2) each of our directors, (3) each of the principal executive officer, or the PEO, principal financial officer, or the PFO, and our three most highly compensated executive officers other than the PEO and PFO who served as executive officers during the fiscal year ended December 31, 2012, and (4) all directors and executive officers as a group:

Name and Address of Beneficial Owner	Common Stock		
	Number of Shares Beneficially Owned(1)	Shares Subject to Convertible Securities(2)	Percentage Ownership(1)
<b>5% or More Shareholders:</b>			
Entities affiliated with FMR LLC(3) .....	7,331,357	176,400	6.7%
<b>Directors and named executive officers:(4)</b>			
John H. Bauer**(5) .....	252,591	3,179	*
Steven E. Benner, M.D.(6) .....	100,000	—	*
James A. Bianco, M.D.**(7) .....	1,057,403	844	*
Louis A. Bianco(8) .....	443,105	477	*
Daniel G. Eramian(9) .....	82,818	—	*
Vartan Gregorian, Ph.D.**(10) .....	239,382	3,200	*
Richard L. Love**(11) .....	266,690	3,180	*
Mary O. Munding, DrPH**(12) .....	254,787	3,207	*
Phillip M. Nudelman, Ph.D.**(13) .....	301,629	3,214	*
Craig W. Philips(14) .....	414	—	*
Matthew J. Plunkett, Ph.D.(15) .....	100,000	—	*
Jack W. Singer, M.D.**(16) .....	495,994	490	*
Frederick W. Telling, Ph.D.**(17) .....	226,477	3,169	*
Reed V. Tuckson, M.D.**(18) .....	223,307	1,400	*
All directors and executive officers as a group (14 persons)(19) ...	4,044,597	22,360	3.68%

\* Less than 1%.

\*\* Denotes director of the Company.

- (1) Beneficial ownership generally includes voting or investment power with respect to securities and is calculated based on 109,810,743 shares of our common stock outstanding as of February 15, 2013. 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 15, 2013, 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.
- (2) 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 15, 2013. These shares are also included in the column titled "Number of Shares Beneficially Owned."
- (3) As reflected in the Schedule 13G/A filed on February 14, 2013 by FMR LLC ("FMR") and Edward C. Johnson. Fidelity Management & Research Company ("Fidelity Management"), a wholly-owned subsidiary of FMR LLC and an investment advisor registered under Section 203 of the Investment Advisers Act of 1940, is the beneficial owner of 7,331,357 shares and this amount beneficially owned includes

176,400 shares, as adjusted to reflect our one-for-five reverse stock split that was effective on September 2, 2012, of our common stock issuable upon exercise of warrants. The ownership of one investment company, Fidelity Select Biotechnology Portfolio (“Fidelity Select”) amounted to 6,843,029 of the shares.

Mr. Johnson and FMR, through its control of Fidelity Management, and the funds each has sole power to dispose of the shares. Neither FMR nor Mr. Johnson has the sole power to vote or direct the voting of the shares, which power resides with the funds’ Board of Trustees. Fidelity Management carries out the voting of the shares under written guidelines established by the funds’ Board of Trustees. The address of Fidelity Management and Fidelity Select is 82 Devonshire Street, Boston MA 02109.

- (4) The address of our current directors and executive officers listed is 3101 Western Avenue, Suite 600, Seattle, Washington 98121.
- (5) Number of shares beneficially owned includes 86,413 shares of unvested restricted stock, all of which have contingent vesting terms and will vest based on the achievement of certain performance goals as described in footnote (19) below.
- (6) Number of shares beneficially owned includes 100,000 shares of unvested restricted stock.
- (7) Number of shares beneficially owned includes 976,529 shares of unvested restricted stock, 751,779 of which have contingent vesting terms and will vest based on the achievement of certain performance goals as described in footnote (19) below.
- (8) Number of shares beneficially owned includes 372,456 shares of unvested restricted stock, 305,032 of which have contingent vesting terms and will vest based on the achievement of certain performance goals as described in footnote (19) below. Includes 37 shares held by Mr. Bianco in trust for his children.
- (9) Mr. Eramian, our former Executive Vice President, Corporate Communications, separated from the Company effective as of November 15, 2012.
- (10) Number of shares beneficially owned includes 86,413 shares of unvested restricted stock, all of which have contingent vesting terms and will vest based on the achievement of certain performance goals as described in footnote (19) below.
- (11) Number of shares beneficially owned includes 86,413 shares of unvested restricted stock, all of which have contingent vesting terms and will vest based on the achievement of certain performance goals as described in footnote (19) below.
- (12) Number of shares beneficially owned includes 86,413 shares of unvested restricted stock, all of which have contingent vesting terms and will vest based on the achievement of certain performance goals as described in footnote (19) below.
- (13) Number of shares beneficially owned includes 129,809 shares of unvested restricted stock, all of which have contingent vesting terms and will vest based on the achievement of certain performance goals as described in footnote (19) below.
- (14) Mr. Philips resigned as President on June 16, 2012, effective as of July 16, 2012.
- (15) Number of shares beneficially owned includes 100,000 shares of unvested restricted stock.
- (16) Number of shares beneficially owned includes 372,456 shares of unvested restricted stock, 305,032 of which have contingent vesting terms and will vest based on the achievement of certain performance goals as described in footnote (19) below.
- (17) Number of shares beneficially owned includes 86,413 shares of unvested restricted stock, all of which have contingent vesting terms and will vest based on the achievement of certain performance goals as described in footnote (19) below.
- (18) Number of shares beneficially owned includes 88,813 shares of unvested restricted stock, 86,413 of which have contingent vesting terms and will vest based on the achievement of certain performance goals as described in footnote (19) below.
- (19) Number of shares beneficially owned includes 2,572,128 shares of unvested restricted stock for all directors and executive officers as a group, of which 2,010,130 shares are contingent and would vest as described in the above footnotes. 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 five performance goals, subject to the goal’s achievement before December 31, 2014 and the individual’s continued employment or service with us: 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 NDA Approval	Opaxio NDA Approval	Market Cap Goal	\$50M Sales Goal	\$100M Sales Goal
James A. Bianco, M.D. ....	168,562	31,741	280,937	112,375	158,164
John H. Bauer ....	28,093	3,174	28,093	11,237	15,816
Louis A. Bianco ....	68,174	12,855	114,248	45,699	64,056
Vartan Gregorian, Ph.D. ....	28,093	3,174	28,093	11,237	15,816
Richard L. Love ....	28,093	3,174	28,093	11,237	15,816
Mary O. Munding, DrPH. ....	28,093	3,174	28,093	11,237	15,816
Phillip M. Nudelman, Ph.D. ....	42,328	4,761	42,140	16,856	23,724
Jack W. Singer, M.D. ....	68,174	12,855	114,248	45,699	64,056
Frederick W. Telling, Ph.D. ....	28,093	3,174	28,093	11,237	15,816
Reed V. Tuckson ....	28,093	3,174	28,093	11,237	15,816

### 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, 2012, 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 .....	307,329(1)	\$33.72	41,951(2)
Plan Not Approved by Shareholders .....	—	—	—
Totals .....	307,329	\$33.72	41,951

- (1) Of these shares, 307,316 were subject to options then outstanding under the 2007 Equity Plan, and 13 were subject to options then outstanding under the 1994 Equity Incentive Plan. As described in the Compensation Discussion and Analysis above, the Compensation Committee approved the 2012-2014 Performance Awards under the 2007 Equity Plan that would be payable in fully-vested shares of our common stock upon satisfaction of the performance and other requirements imposed on the award, with a portion of each such award being granted in the form of restricted shares that would vest upon achievement of the related performance goal and the balance of each such award being granted as a contingent right to receive additional shares upon achievement of the performance goal based on our total outstanding shares at the time such goal is achieved. Columns (a) and (b) of this table are presented without giving effect to the 2012-2014 Performance Awards as (1) the restricted shares subject to these awards were issued and outstanding as of December 31, 2012, and (2) the remaining number of shares that would be issuable in payment of these awards depends on our total issued and outstanding shares at the time of payment and was therefore not determinable as of December 31, 2012.
- (2) Of these shares, no shares were available for issuance under the 2007 Equity Plan, and 41,951 were available for issuance under the ESPP. Our authority to grant new awards under the 1994 Equity Incentive Plan has terminated. This number of shares is presented after giving effect to the 2012-2014 Performance Awards (based on the number of shares of our common stock issued and outstanding as of December 31, 2012 and assuming the performance goals applicable to these awards were achieved). As of December 31,



2012, 2,993,930 shares of our common stock were available for award grant purposes under the 2007 Equity Plan (giving effect only to the portion of the 2012-2014 Performance Awards granted in the form of restricted shares as described in footnote (1) above), and all of these shares would have been used to pay the 2012-2014 Performance Awards if the performance goals applicable to these awards had been achieved. If the 2012-2014 Performance Awards become payable and sufficient shares are not available under the 2007 Equity Plan (after reserving sufficient shares to cover the other awards then outstanding under the 2007 Equity Plan), the number of shares payable with respect to the 2012-2014 Performance Awards will be proportionately reduced such that the share limits of the 2007 Equity Plan will not be exceeded.

### **Item 13. Certain Relationships and Related Transactions, and Director Independence**

#### **Related Party Transactions**

Pursuant to our Code of Business Conduct and Ethics and our Amended and Restated Charter for the Audit Committee of our board of directors, any potential related party transaction must be fully disclosed to our Chief Financial Officer. Upon review, if our Chief Financial Officer determines that the transaction is material to us, then our Audit Committee must review and approve in writing in advance such related party transaction. Item 404(a) of Regulation S-K requires us to disclose in its Annual Report on Form 10-K any transaction 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 61% as of December 31, 2012. 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 number of shares of Aequus equity securities to be issued upon conversion of this note is equal to the quotient obtained by dividing (i) the outstanding balance of the note by (ii) 100% of the price per share of the equity securities. We funded Aequus \$0.5 million, \$0.6 million and \$0.5 million during the years ended December 31, 2012, 2011 and 2010, 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 \$4.0 million and \$3.3 million as of December 31, 2012 and 2011, respectively.

Our President and Chief Executive Officer, James A. Bianco, M.D. and our Executive Vice President, Global Medical Affairs and Translational Medicine, Jack W. Singer, M.D. are both minority shareholders of Aequus, each owning approximately 4.3% of the equity in Aequus as of December 31, 2012, 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 1.3% of Aequus as of December 31, 2012, 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. Of the 100,000 restricted shares of Aequus granted to Dr. Telling, 8,333 shares were unvested as of December 31, 2012. In addition, in 2012, Dr. Telling earned \$7,500 in fees for his service on the board of directors of Aequus (of which \$5,000 was paid



in 2012). Dr. Telling did not receive any other compensation in 2012 for his services to Aequus. Our Executive Vice President, Finance and Administration, Louis A. Bianco provides certain consulting services to Aequus, including financial guidance business development services, for which he received a grant of restricted shares of Aequus common stock during 2011 with a grant date fair value of \$26,000 and a cash payment of \$5,000 as partial reimbursement for taxes associated with such restricted shares. Prior to his resignation as our President in July 2012, Craig W. Philips provided certain consulting services to Aequus, including strategic planning services, for which he received a grant of restricted shares of Aequus common stock during 2011 with a grant date fair value of \$26,000. The size of the grants to each of Mr. Bianco and Mr. Philips 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. Upon Mr. Philips resignation, 75% of his grant was forfeited.

We formerly owned a minority interest in DiaKine Therapeutics, Inc., or DiaKine. 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 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 was acquired by Islet Sciences, Inc., or Islet, on March 14, 2012. In connection with the closing of the acquisition, we (i) converted the note into equity of DiaKine, which was exchanged (along with the our other equity interests in DiaKine) at the closing of the acquisition for Series C Preferred Shares of Islet and (ii) rescinded the termination of the license agreement. Our Series C Preferred Shares of Islet automatically converted into common shares of Islet on April 26, 2012.

Corey Masten-Legge, a stepson of James A. Bianco, M.D., is employed as a corporate attorney in our legal department. In 2012, Mr. Masten-Legge received \$219,503 in base salary and bonus, approximately \$3,293 in 401k Plan matching funds, a grant of 6,000 shares of restricted stock and a grant of stock options for 1,600 shares, with grant-date fair values (based on the assumptions used to value equity awards in our financial reporting) of \$36,300 and \$6,457, 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 relationship was considered:

- Dr. Nudelman's son, Mark Nudelman, serves as the President and Chief Executive Officer of the Hope Heart Institute. We made charitable donations to the Hope Heart Institute in 2012; however, the amount falls within NASDAQ prescribed limits.

Based on the review described above, our board of directors affirmatively determined that:

- A majority of the directors are independent, and all members of the Audit, Compensation and Nominating and Governance Committees are independent, under the NASDAQ standard and, in the case of the Audit Committee, the SEC standard.
- All of the non-management directors of our board of directors are independent under the NASDAQ standard. The independent directors are: John H. Bauer, Vartan Gregorian, Ph.D., Richard L. Love, Mary O. 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 President and Chief Executive Officer, and Executive Vice President, Global Medical Affairs and Translational Medicine, respectively.

Other than as described above, in 2012, 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:

<u>Services Rendered</u>	<u>2012</u>	<u>2011</u>
Audit Fees (1) . . . . .	\$588,000	\$590,000
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.

## PART IV

### Item 15. Exhibits, Financial Statement Schedules

#### (a) Financial Statements and Financial Statement Schedules

##### (i) Financial Statements

Reports of Marcum LLP, Independent Registered Public Accounting Firm  
 Consolidated Balance Sheets  
 Consolidated Statements of Operations  
 Consolidated Statements of Comprehensive Loss  
 Consolidated Statements of Shareholders' Equity (Deficit)  
 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

Exhibit Number	Exhibit Description	Location
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., Saguaro Acquisition Company LLC, Systems Medicine, Inc. and Tom Hornaday and Lon Smith dated July 24, 2007.	Incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K, filed on July 27, 2007.
2.4†	Purchase and Formation Agreement by and among Cell Therapeutics, Inc., Spectrum Pharmaceuticals, Inc. and RIT Oncology, LLC, dated as of November 26, 2008.	Incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K, filed on December 19, 2008.  The schedules to this exhibit have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A description of the omitted schedules appears in the Table of Exhibits of Exhibit 2.1. The Registrant hereby agrees to furnish a copy of any omitted schedule to the Commission upon request.
3.1	Amended and Restated Articles of Incorporation.	Incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-3 (File No. 333-153358), filed on September 5, 2008.
3.2	Articles of Amendment to Amended and Restated Articles of Incorporation; 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.

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
3.3	Amendment to Amended and Restated Articles of Incorporation.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on March 27, 2009.
3.4	Articles of Amendment to Amended and Restated Articles of Incorporation; 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.
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.

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
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	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 15-1 Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on May 31, 2012.
3.24	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 16 Preferred Stock.	Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed on June 5, 2012.
3.25	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 15-2 Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on August 1, 2012.
3.26	Amendment to Amended and Restated Articles of Incorporation.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on August 31, 2012.



<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
3.27	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 4, 2012.
3.28	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 17 Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on October 11, 2012.
3.29	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	Shareholder Rights Agreement, dated December 28, 2009, between Cell Therapeutics, Inc. 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.
4.2	First Amendment to Shareholder Rights Agreement, dated as of August 31, 2012, between Cell Therapeutics, Inc. and Computershare Trust Company, N.A., as Rights Agent.	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on September 4, 2012.
4.3	Second Amendment to Shareholder Rights Agreement, dated as of December 6, 2012, between Cell Therapeutics, Inc. and Computershare Trust Company, N.A., as Rights Agent.	Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed on December 7, 2012.
4.4	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.
4.5	Common Stock Purchase Warrant, dated April 13, 2009.	Incorporated by reference to Exhibit 4.2 to the Registrant's Quarterly Report on Form 10-Q, filed on August 6, 2009.
4.6	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.
4.7	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.

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
4.11	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.
4.12	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.
4.13	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.
4.14	Form of Warrant to Purchase Common Stock, dated May 29, 2012.	Incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K, filed on May 31, 2012.
4.15	Form of Warrant to Purchase Common Stock, dated July 30, 2012.	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on August 1, 2012.
10.1	Sublease Agreement between F5 Networks, Inc. and Cell Therapeutics, Inc., 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 Cell Therapeutics, Inc., dated December 22, 2005.	Incorporated by reference to Exhibit 10.6 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2006, filed on March 16, 2007.
10.3	Lease agreement between Elliott Park LLC and Cell Therapeutics, Inc., 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.	Incorporated by reference to Exhibit 10.4 to the Registrant's Annual Report on Form 10-K, filed on March 8, 2012.
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*	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.

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
10.9*	Form of Italian Indemnity Agreement	Incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K, filed on December 17, 2009.
10.10*	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).
10.11*	2007 Equity Incentive Plan, as amended and restated.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on September 4, 2012.
10.12*	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.
10.13*	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.
10.14*	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.
10.15*	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.
10.16*	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.
10.17*	2007 Equity Incentive Plan Restricted Stock Award Agreement, dated April 8, 2011, by and between Cell Therapeutics, Inc. 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.
10.18*	Amendment to Restricted Stock Award Agreement, dated September 20, 2011, by and between Cell Therapeutics, Inc. 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.
10.19*	Form of Equity/Long-Term Incentive Award Agreement for the Registrant's Directors.	Incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, filed on April 20, 2012.
10.20*	Form of Equity/Long-Term Incentive Award Agreement for the Registrant's Executive Officers.	Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q, filed on April 20, 2012.
10.21*	Director Compensation Policy.	Incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q, filed on August 2, 2012.

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
10.22*	Offer Letter, by and between Cell Therapeutics, Inc. and Steven Benner, M.D., dated June 12, 2012.	Filed herewith.
10.23*	Severance Agreement and General Release, by and between Cell Therapeutics, Inc. and Steven Benner, M.D., dated July 19, 2012.	Filed herewith.
10.24*	Offer Letter, by and between Cell Therapeutics, Inc. and Matthew Plunkett, dated July 31, 2012.	Filed herewith.
10.25†	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.
10.26†	Amendment No. 1 to the License Agreement between Cell Therapeutics, Inc. 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.
10.27†	License and Co-Development, dated September 15, 2006, by and among Cell Therapeutics, Inc., 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.
10.28	Second Amendment to the Acquisition Agreement, dated as of August 6, 2009, by and among Cell Therapeutics, Inc. 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.
10.29†	Drug Product Manufacturing Supply Agreement, dated July 13, 2010, by and between NerPharMa, S.r.l. and Cell Therapeutics, Inc.	Incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q, filed on August 6, 2010.
10.30†	Co-Development and License Agreement, dated March 11, 2011, by and between Chroma Therapeutics Ltd. and Cell Therapeutics, Inc.	Incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q, filed on April 26, 2011.
10.31	Form of Exchange Agreement between Cell Therapeutics, Inc. and certain other parties thereto, dated December 12, 2007.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on December 13, 2007.
10.32	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.

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
10.33	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.
10.34	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.
10.35	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.
10.36	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.
10.37	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.
10.38	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.
10.39	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.
10.40†	Asset Purchase Agreement, dated April 18, 2012, between S*BIO Pte Ltd. and Cell Therapeutics, Inc.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on April 24, 2012.
10.41†	Form of Registration Rights Agreement, by and between Cell Therapeutics, Inc., S*BIO Pte Ltd. and each Holder Permitted Transferee.	Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed on April 24, 2012.
10.42	Form of Securities Purchase Agreement, dated May 28, 2012.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on May 31, 2012.
10.43	Registration Rights Agreement, by and between Cell Therapeutics, Inc., S*BIO Pte Ltd. and each Holder Permitted Transferee, dated May 31, 2012.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on June 5, 2012.
10.44†	Master Services Agreement, dated July 9, 2012, between Quintiles Commercial Europe Limited CTI Life Sciences Ltd.	Incorporated by reference to Exhibit 10.6 to the Registrant's Current Report on Form 10-Q, filed on August 2, 2012.
10.45	Letter of Guarantee, dated July 1, 2012, between Cell Therapeutics, Inc. and Quintiles Commercial Europe Limited.	Incorporated by reference to Exhibit 10.7 to the Registrant's Current Report on Form 10-Q, filed on August 2, 2012.
10.46†	Logistics Agreement, dated September 1, 2012, between Movianto Nederland BV and CTI Life Sciences Limited.	Incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 10-Q, filed on November 1, 2012.

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
10.47	Settlement Agreement and Full and Final Release of Claims, dated as of October 25, 2012, by and between Cell Therapeutics, Inc. and Craig W. Philips.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on October 31, 2012.
10.48	Stipulation of Settlement, dated November 6, 2012.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on December 31, 2012.
10.49	Settlement Agreement and Full and Final Release of Claims dated as of January 4, 2013, by and between Cell Therapeutics, Inc. and Daniel Eramian.	Filed herewith.
12.1	Statement Re: Computation of Ratio of Earnings to Fixed Charges.	Filed herewith.
21.1	Subsidiaries of the Registrant.	Filed herewith.
23.1	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.



## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Seattle, State of Washington, on February 28, 2013.

Cell Therapeutics, Inc.

By: /s/ James A. Bianco

James A. Bianco, M.D.

*President and 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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
/s/ Phillip M. Nudelman <b>Phillip M. Nudelman, Ph.D.</b>	Chairman of the Board and Director	February 28, 2013
/s/ James A. Bianco <b>James A. Bianco, M.D.</b>	President, Chief Executive Officer and Director (Principal Executive Officer)	February 28, 2013
/s/ Louis A. Bianco <b>Louis A. Bianco</b>	Executive Vice President, Finance and Administration (Principal Financial Officer and Principal Accounting Officer)	February 28, 2013
/s/ John H. Bauer <b>John H. Bauer</b>	Director	February 28, 2013
/s/ Vartan Gregorian <b>Vartan Gregorian, Ph.D.</b>	Director	February 28, 2013
/s/ Richard L. Love <b>Richard Love</b>	Director	February 28, 2013
/s/ Mary O. Munding <b>Mary O. Munding, DrPH</b>	Director	February 28, 2013
/s/ Jack W. Singer <b>Jack W. Singer, M.D.</b>	Director	February 28, 2013
/s/ Frederick W. Telling <b>Frederick Telling, Ph.D.</b>	Director	February 28, 2013
/s/ Reed V. Tuckson. <b>Reed V. Tuckson, M.D.</b>	Director	February 28, 2013

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## Management Team

James A. Bianco, M.D.  
*President and Chief Executive Officer*

Steven E. Benner, M.D., M.H.S.  
*Executive Vice President,  
Chief Medical Officer*

Matthew J. Plunkett, Ph.D.  
*Executive Vice President,  
Corporate Development*

Jack W. Singer, M.D.  
*Executive Vice President,  
Global Medical Affairs and  
Translational Medicine*

Louis A. Bianco  
*Executive Vice President,  
Finance and Administration*

## Board of Directors

John H. Bauer  
*Executive Advisor and  
Chief Financial Officer,  
DigiPen Institute of Technology*

James A. Bianco, M.D.  
*President and Chief Executive Officer,  
Cell Therapeutics*

Vartan Gregorian, Ph.D.  
*President, Carnegie Corporation*

Richard Love  
*Managing Partner,  
Translational Accelerator, LLC*

Mary O'Neil Mundinger, DrPH, R.N.  
*Former Dean of School of Nursing,  
Columbia University*

Phillip M. Nudelman, Ph.D.  
*Chairman of the Board,  
Former President and CEO,  
Hope Heart Institute*

Jack W. Singer, M.D.  
*Executive Vice President,  
Global Medical Affairs and  
Translational Medicine*

Frederick W. Telling, Ph.D.  
*Former Vice President of Corporate  
Policy and Strategic Management,  
Pfizer, Inc.*

Reed V. Tuckson, M.D., F.A.C.P.  
*Former Executive Vice President  
and Chief of Medical Affairs,  
United Healthcare Group*

## Corporate Headquarters

Cell Therapeutics, Inc.  
3101 Western Ave.  
Seattle, WA 98121  
Telephone: (206) 282-7100  
[www.celltherapeutics.com](http://www.celltherapeutics.com)

## Transfer Agent and Stockholder Services

Computershare Investor Services  
250 Royall St.  
Canton, MA 02021  
Telephone: (800) 736-3001  
Outside U.S.: (781) 575-3100  
[www.computershare.com](http://www.computershare.com)

## Independent Auditors

Marcum LLP  
San Francisco, CA

## Stockholder Information

The Company's common stock trades on The NASDAQ Stock Market and Mercato Telematico Azionario (MTA) stock market in Italy under the symbol CTIC. Anyone wishing more information about CTI should direct their inquiries to:

Investor Relations  
Cell Therapeutics, Inc.  
3101 Western Ave.  
Seattle, WA 98121.

## Annual Shareholder Meeting

Wednesday, June 26, 2012 at  
10:00 a.m. Pacific Daylight Time  
at CTI's corporate headquarters.

## Additional Information

CTI's current quarterly and annual reports, news releases and other information regarding the company and its products and technologies are available at [www.celltherapeutics.com](http://www.celltherapeutics.com).

This Annual Report on Form 10-K includes forward-looking statements including that CTI may not be able to continue to raise capital as needed to fund its operations in general, and other risks, including, without limitation, competitive factors, technological developments, costs of developing, producing, and selling PIXUVRI or the CTI's other drug candidates and the risk factors listed or described from time to time in CTI's filings with the Securities and Exchange Commission including, without limitation, CTI's most recent filings on Forms 10-K, 10-Q and 8-K. Except as may be required by law, CTI does not intend to update or alter its forward-looking statements whether as a result of new information, future events, or otherwise.

CTI is a biopharmaceutical company headquartered in Seattle, Washington, with offices in London and Milan; we are publicly traded on NASDAQ and the MTA under the symbol CTIC.

