

CELL THERAPEUTICS INC

Form 10-K

March 04, 2014

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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, 2013

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)

3101 Western Avenue, Suite 600

Seattle, WA

(Address of principal executive offices)

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

91-1533912

(I.R.S. Employer Identification Number)

98121

(Zip Code)

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

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Title of each class	Name of each exchange on which registered
Common Stock, no par value	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 28, 2013, the aggregate market value of the registrant's common equity held by non-affiliates was \$106,673,063. 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 24, 2014 was 149,637,666.

### DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2014 annual meeting of shareholders, or the 2014 Proxy Statement, are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The 2014 Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

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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, as amended, 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;

any projections of revenues, operating expenses or other financial terms, and any projections of cash resources, including regarding our potential receipt of future milestone payments under any of our agreements with third parties;

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 partnerships, mergers or acquisitions; and

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

When used in this Annual Report on Form 10-K, terms such as anticipates, believes, continue, could, estimates, expects, intends, may, potential, predicts, should, or will or the negative of those terms or other comparable terms are intended to identify such forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors that may cause industry trends or actual results, level of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements expressed or implied by these statements. Our actual results may differ significantly from the results discussed in such forward-looking statements. These factors include, but are not limited to, those listed under Part I, Item 1, Business, 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.

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### 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 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 program of pacritinib for the treatment of myelofibrosis that will support regulatory submission for approval in the United States, or the U.S., and Europe.

#### *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. In May 2012, the European Commission 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 that are 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 in the E.U. for patients with multiply relapsed or refractory aggressive B-cell 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 PIX301. In connection with the conditional marketing authorization, we are conducting a required post-approval commitment trial, which compares pixantrone and rituximab with gemcitabine and rituximab in the setting of aggressive B-cell NHL.

During the fourth quarter of 2012, we began making PIXUVRI available to healthcare providers in certain countries in the E.U. and initiated our commercial operations on a country-by-country basis. As of the date of this filing, PIXUVRI was available in Austria, Denmark, Finland, Germany, Italy, France, Netherlands, Norway, Sweden and the United Kingdom, or the U.K. We have established a commercial organization, including sales, marketing and supply chain management, to commercialize PIXUVRI in the E.U. PIXUVRI is not approved in the U.S. We are pursuing potential partners for commercializing PIXUVRI in additional markets within the E.U. and other markets outside the E.U. and the U.S.

In almost all European markets, pricing and availability of prescription pharmaceuticals are subject to governmental control. Decisions by governmental authorities will impact the price and market acceptance of PIXUVRI. Accordingly, any future revenues are dependent on market acceptance of PIXUVRI, the reimbursement decisions made by the governmental authorities in each country where PIXUVRI is available for sale and other factors. In the third quarter of 2013, PIXUVRI was granted market access in Italy and France. In December 2013, we reached agreement for funding and reimbursement with the National Association of Statutory Health Insurance Funds, or the GKV-Spitzenverband, in Germany. In February 2014, the National Institute for Health and Care Excellence, or NICE, issued final guidance recommending the prescription of PIXUVRI for as long as we make the Patient Access Scheme, or PAS, available. The PAS is a confidential pricing and access agreement with the U.K.'s Department of Health. As a result of these decisions, PIXUVRI is reimbursed under varying conditions in Italy, France, Germany and England/Wales.

#### *Pacritinib*

In May 2012, we expanded our late-stage pipeline of product candidates with the acquisition of pacritinib, an oral inhibitor of both Janus Kinase 2, or JAK2, and FMS-like tyrosine kinase, or FLT3, which 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

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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, itching 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.

In November 2013, we entered into a worldwide license agreement, or the Baxter Agreement, with Baxter International, Inc., or Baxter, to develop and commercialize pacritinib. Pursuant to the Baxter Agreement, we have joint commercialization rights with Baxter for pacritinib in the U.S., while Baxter has exclusive commercialization rights for all indications outside the U.S. Under the terms of the Baxter Agreement, we received a \$60 million upfront payment, which included an equity investment of \$30 million, and we have the potential to receive \$302 million in clinical, regulatory, commercial launch and sales milestones. Additionally, if pacritinib is approved and launched, we will share U.S. profits equally and will receive royalties on net sales of pacritinib in non-U.S. markets. For additional information relating to the Baxter Agreement, see Part I, Item 1, Business License Agreements and Additional Milestones Baxter .

As part of our collaboration with Baxter, we are pursuing a broad approach to advancing pacritinib for patients with myelofibrosis by conducting two Phase 3 clinical trials: one in a broad set of patients without limitations on blood platelet counts, the PERSIST-1 trial, which was initiated in January 2013; and the other in patients with low platelet counts, the PERSIST-2 trial, which opened for enrollment in March 2014. In October 2013, we reached an agreement with the U.S. Food and Drug Administration, or FDA, on a Special Protocol Assessment, or SPA, for PERSIST-2. This trial, together with PERSIST-1, is intended to support registration in the U.S. and the E.U.

### *Other Pipeline Candidates*

Our earlier stage product candidate, tosedostat, is an oral aminopeptidase inhibitor that has demonstrated significant responses in patients with acute myeloid leukemia, or AML. It is currently being evaluated in several Phase 2 trials, which are being conducted as cooperative group sponsored and investigator-sponsored trials, or ISTs. These trials are evaluating tosedostat in combination with hypomethylating agents, or HMAs, in AML and myelodysplastic syndrome, or MDS, which are cancers of the blood and bone marrow. We anticipate that data from these signal-finding trials may be used to determine the appropriate design for a Phase 3 trial.

Although our efforts are focused on developing and commercializing treatments that target blood-related cancers, we continue to evaluate our pipeline candidate Opaxio (paclitaxel poliglumex), or Opaxio, which targets solid tumors. We are evaluating this candidate through cooperative group sponsored trials and ISTs, such as the ongoing maintenance therapy trial in patients with ovarian cancer. In addition, we continue to evaluate our other drug candidate, brostallicin.

### **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 key commercial objective is to continue our efforts to build a successful PIXUVRI franchise in Europe. PIXUVRI is currently available in Austria, Denmark, Finland, Germany, Italy, France, Netherlands, Norway, Sweden and the U.K., and we seek to expand the availability of PIXUVRI into additional geographic markets outside the E.U. and the U.S. through potential partnerships in 2014. 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 have achieved reimbursement decisions in England/Wales, France, Germany and Italy, and will continue to seek reimbursement in smaller territories in Western and Northern Europe in 2014.

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**Develop Pacritinib in Myelofibrosis and Additional Indications.** Together with Baxter, we expect to develop and commercialize pacritinib for patients with myelofibrosis. Our development program for pacritinib includes two Phase 3 registration trials in patients with myelofibrosis, and we expect to report topline data from the first Phase 3 trial in the second half of 2014. Although our efforts are focused on myelofibrosis, we are currently evaluating pacritinib in AML through an ongoing IST and intend to evaluate it in other blood cancers in the future.

**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 and Opaxio, through cooperative group sponsored trials and ISTs. Sponsoring such trials provides us with a more economical approach for further developing our investigational products.

**Enter into Product Collaborations to Accelerate Development and Commercialization.** We intend to continue to pursue additional collaborations to broaden and accelerate clinical trial development and potential commercialization of our product candidates. Collaborations have the potential to generate 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 were initially undervalued opportunities. We plan to continue to seek out additional product candidates in an opportunistic manner.

**Product and Product Candidate Portfolio**

The following table summarizes our development pipeline for PIXUVRI, pacritinib and our other late-stage product candidates as to which we have ongoing trials:

Name of Product or		
Product Candidate(1)	Indications/Intended Use	Status
<b>PIXUVRI</b>	Multiply relapsed or refractory aggressive NHL	Conditional Approval-Marketed in E.U.
<b>(pixantrone dimaleate)</b>	Aggressive NHL, 2 <sup>nd</sup> line > 1 relapse, combination with rituximab (PIX306) post-approval study	Phase 3 ongoing
<b>Pacritinib</b>	Myelofibrosis, PERSIST-1, All platelet levels	Phase 3 ongoing
	Myelofibrosis, PERSIST-2, Platelet counts $\geq 100,000/\mu\text{L}$	Phase 3 initiated(4)
	Relapsed AML	Phase 2 ongoing
<b>Tosedostat(2)</b>	First-line AML	Phase 2 ongoing
	Relapsed/Refractory AML/MDS(3)	Phase 2 ongoing
<b>Opaxio(2)</b>	Ovarian cancer, first-line maintenance (3)	Phase 3 ongoing
<b>(paclitaxel poliglumex)</b>	Newly diagnosed glioblastoma without MGMT methylation	Phase 2 ongoing
	Head and neck cancer	Phase 2 ongoing

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- (1) Our product candidate portfolio also includes brostallicin, a novel, synthetic, second-generation DNA minor groove binder. See Part I, Item 1, Business Development Candidates Brostallicin for additional information.
- (2) We support the development of these investigational agents through cooperative group sponsored trials and ISTs.
- (3) These trials have completed enrollment and the patients are being followed.
- (4) This trial opened for enrollment in March 2014.



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### **Oncology Market Overview and Opportunity**

*Overview.* According to the American Cancer Society, or ACS, cancer is the second leading cause of death in the U.S., resulting in close to 580,350 deaths annually, or more than 1,600 people per day. Approximately 1.7 million new cases of cancer were expected to be diagnosed in 2013 in the U.S. 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 that 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.

### **Commercialized 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 are often 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 often treated with the anthracycline family of anti-cancer agents. PIXUVRI is not an anthracycline and is instead a novel aza-anthracenedione with unique structural and physiochemical properties. Based on its ease of administration, anti-tumor activity and reduced risk of cardiotoxicity, we believe PIXUVRI 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. Unlike the anthracyclines, PIXUVRI does not inhibit topo-isomerase II. Also 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. This results in progressive disruption of mitosis and therefore killing of rapidly dividing cells like those found in many tumors. 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 a single-agent chemotherapy drug with 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 and commercializing PIXUVRI 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 69,740 people diagnosed with NHL in the U.S. and approximately 19,020 people would die from this disease in 2013. In Europe, the World Health Organization's International Agency for Research on Cancer's 2008 GLOBOCAN database estimates that in the E.U. approximately 79,312 people will be diagnosed with NHL and 30,691 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.

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There are many types and subtypes of NHL, although aggressive B-cell NHL is the most common and accounts for about 50 percent of NHL cases. After initial therapy for aggressive NHL with anthracycline-based combination therapy, one-third of patients typically develop progressive diseases. Approximately half of these patients are likely to be eligible for intensive second-line treatment and stem cell transplantation, although 50 percent 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. 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 U.S.

### *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 of patients in the trial who received pixantrone achieved a complete or unconfirmed complete response at end of treatment compared with 5.7 percent in the comparator group ( $p=0.021$ ). Median progression-free survival, or PFS, 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 percent) 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 percent (five patients) on the PIXUVRI arm and 2 percent (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 marketing authorization based on the results from the EXTEND pivotal trial.

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 by June 2015 aimed at confirming the clinical benefit previously observed. In this regard, our post-marketing study is an ongoing randomized, controlled Phase 3 clinical trial, known as PIX306, which 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 PIX306 trial was initiated in March 2011. In December 2013, we gained agreement from the European Medicines Agency, or the EMA, to change the primary endpoint of the PIX306 trial from overall survival to PFS. The trial is now expected to enroll approximately 220 patients versus the 350 patients previously planned. This trial is expected to complete enrollment in 2015 and is intended to support the conversion of the conditional approval for PIXUVRI in Europe to full approval and potentially support a registration application in the U.S.

### *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 U.K. Future revenues are dependent on market acceptance of PIXUVRI, the reimbursement decisions made by the governmental authorities in each country where PIXUVRI is available for sale and other factors.

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In the third quarter of 2013, PIXUVRI was granted market access in Italy and France. In December 2013, we reached agreement for funding and reimbursement with the GKV-Spitzenverband in Germany. In February 2014, NICE issued final guidance recommending the prescription of PIXUVRI for as long as we make the Patient Access Scheme, or PAS, available. The PAS is a confidential pricing and access agreement with the U.K.'s Department of Health. We have established distributors in Israel and Turkey for PIXUVRI and through a named patient program in certain countries where the drug 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.

In July 2012, we entered into an agreement with Quintiles Commercial Europe Limited, or Quintiles, under which we interview, approve for hire, train and manage a sales force and medical science liaisons for PIXUVRI in the E.U. We believe this is a cost effective way to commercialize PIXUVRI in the E.U. We currently have approximately 20 sales and medical science liaisons in the countries where PIXUVRI is reimbursed.

As discussed in Part I, Item 1, "Business" Manufacturing, Distribution and Associated Matters, we utilize third parties for the manufacture, storage and distribution of PIXUVRI, as well as for other associated supply chain requirements. Our strategy of utilizing third parties in such manner allows us to direct our resources to the development and commercialization of products rather than to the establishment of manufacturing facilities.

### *Clinical Development of PIXUVRI in the U.S.*

Although we are not currently pursuing regulatory approval of PIXUVRI in the U.S., we may reevaluate a possible resubmission strategy in the U.S. based on the data generated from the ongoing PIX306 clinical trial. Previously, in 2009, we had submitted to the FDA a completed New Drug Application, or NDA, submission for PIXUVRI, and, in 2010, the FDA issued a complete response letter. In 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 was considered a complete, Class 2 response to the FDA's 2010 complete response letter. The FDA set a Prescription Drug User Fee Act goal date of April 2012 for a decision on our resubmitted NDA. In February 2012, we voluntarily withdrew our resubmitted NDA for PIXUVRI because additional time was required to prepare the necessary information.

## **Development Candidates**

### **Pacritinib**

Pacritinib is an oral tyrosine kinase inhibitor with dual activity against JAK2 and FLT3. The JAK family of enzymes is a central component in signal transduction pathways, which are critical to normal blood cell growth and development as well as inflammatory cytokine expression and immune responses. 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 may offer an advantage over other JAK inhibitors through effective treatment of symptoms while having less treatment-emergent thrombocytopenia and anemia than has been seen in currently approved and in-development JAK inhibitors. We acquired pacritinib in May 2012 pursuant to an agreement under which we have certain royalty and milestone payment obligations. See Part I, Item 1, "Business" License Agreements and Additional Milestone Activities for additional information.

Pacritinib has been studied in two Phase 2 trials with a total of 65 myelofibrosis patients, all of whom were treated with 400 mg of once-daily pacritinib. In December 2013, an integrated analysis of these two Phase 2 trials was presented at the American Society of Hematology Annual Meeting, or ASH. During these Phase 2 trials, spleen response was assessed by physical exam and magnetic resonance imaging, or MRI, and patient-reported outcomes used the Myelofibrosis Symptom Assessment Form, or MF-SAF. Among evaluable patients, 37 percent achieved 35 percent or greater reduction in spleen volume measured by MRI and 48 percent achieved a 50 percent or greater reduction in patient-reported symptom score up to their last visit on treatment. Duration of exposure and daily dose were unaffected by baseline platelet counts. This integrated safety analysis of all 65

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patients showed the most common non-hematologic adverse events (occurring in 15 percent or more of patients overall) were gastrointestinal, predominantly diarrhea, and most were grade 1 or 2, regardless of baseline platelet counts. Of note, there were no thrombocytopenia-associated adverse events occurring at this frequency in either group.

In November 2013, we entered into the Baxter Agreement to develop and commercialize pacritinib. Pursuant to the Baxter Agreement, we have joint commercialization rights with Baxter for pacritinib in the U.S., while Baxter has exclusive commercialization rights for all indications outside the U.S. Under the terms of the Baxter Agreement, we received a \$60 million upfront payment, which included an equity investment of \$30 million, and we have the potential to receive \$302 million in clinical, regulatory, commercial launch and sales milestones. Additionally, if pacritinib is approved and launched, we will share U.S. profits equally and receive royalties on net sales of pacritinib in markets outside of the U.S.

As part of our collaboration with Baxter, we are pursuing a broad approach to advancing pacritinib for patients with myelofibrosis by conducting two Phase 3 clinical trials: one in a broad set of patients without limitations on blood platelet counts, the PERSIST-1 trial, which was initiated in January 2013; and the other in patients with low platelet counts, the PERSIST-2 trial, which opened for enrollment in March 2014.

In January 2013, we initiated clinical trial sites and began enrolling patients with myelofibrosis in a Phase 3 clinical trial known as the PERSIST-1, or PAC325, trial. PERSIST-1 is a multicenter, open-label, randomized, controlled Phase 3 trial evaluating the efficacy and safety of pacritinib with that of best available therapy in patients with primary myelofibrosis. A total of approximately 320 eligible patients are expected to be randomized 2:1 to receive either pacritinib 400 mg taken orally once daily or the best available therapy. Best available therapy includes any physician-selected treatment other than JAK inhibitors, and there is no exclusion by patient platelet count.

The primary endpoint of the PERSIST-1 trial is the percentage of patients achieving a 35 percent or greater reduction in spleen volume from baseline to Week 24 as measured by MRI or computed tomography, or CT, scan. The secondary endpoint is the percentage of patients achieving a 50 percent or greater reduction in Total Symptom Score, or TSS, from baseline to 24 weeks as measured by tracking specific symptoms on a form. At the time of initiation of the trial, PERSIST-1 utilized the original Myeloproliferative Neoplasm Symptom Assessment (MPN-SAF TSS) instrument, to measure TSS reduction. However, we have substantially concluded the process of amending the PERSIST-1 trial protocol to replace the original MPN-SAF TSS instrument with a new instrument, known as the MPN-SAF TSS 2.0, which is also being used for recording patient-reported outcomes for the PERSIST-2 trial detailed below. In connection with this amendment, we expect that enrollment in PERSIST-1 will be increased from 270 to approximately 320 patients. The trial is currently enrolling patients at clinical sites in Europe, Australia, New Zealand, Russia and the U.S. More details on the PERSIST-1 trial can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov). We anticipate reporting topline data for PERSIST-1 in the second half of 2014.

In March 2014, we opened clinical trial sites for enrollment of patients with myelofibrosis in the second Phase 3 clinical trial known as the PERSIST-2, or PAC326, trial. PERSIST-2 is a multi-center, open-label randomized, controlled clinical trial evaluating pacritinib in up to 300 patients with myelofibrosis whose platelet counts are less than or equal to 100,000/ $\mu$ L. The trial will evaluate pacritinib as compared to best available therapy, including approved JAK2 inhibitors that are dosed according to the product label for myelofibrosis patients with thrombocytopenia. Patients will be randomized (1:1:1) to receive 200 mg pacritinib twice daily, 400 mg pacritinib once daily or best available therapy. In October 2013, CTI reached an agreement with the FDA on a SPA for the PERSIST-2 trial, regarding the planned design, endpoints and statistical analysis approach of the trial to be used in support of a potential NDA submission. Under the SPA, the agreed upon co-primary endpoints are the percentage of patients achieving a 35 percent or greater reduction in spleen volume measured by MRI or CT scan from baseline to 24 weeks of treatment and the percentage of patients achieving a TSS reduction of 50 percent or greater using six key symptoms as measured by the modified MPN-SAF diary from baseline to 24 weeks. The trial is expected to enroll patients at clinical sites in the U.S., Canada, Europe, Australia and New Zealand. Additional trial details are available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

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### **Tosedostat**

Tosedostat is a selective, oral inhibitor of aminopeptidases, which are required by tumor cells to provide amino acids necessary for growth and tumor cell survival. Tosedostat has demonstrated significant anti-tumor responses in blood-related cancers and solid tumors in Phase 1 and 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 ASH. These results showed that once-daily, oral doses of tosedostat had predictable and manageable toxicities and demonstrated encouraging response rates, including a high response rate among patients who received prior hypomethylating agents, which are used to treat MDS, a precursor of AML.

In December 2013, interim results from an investigator-initiated Phase 2 clinical trial of tosedostat in combination with cytarabine or decitabine in newly diagnosed older patients with AML or high-risk MDS were presented at ASH. The Phase 2 trial was designed to test the efficacy of tosedostat in combination with low intensity therapy for older patients with previously untreated AML or high-risk MDS not considered candidates for standard intensive therapy. This presentation reported on the results of 26 patients (median age was 69) enrolled in the first dose cohort. Patients were randomized for treatment with tosedostat in combination with either cytarabine or decitabine. Fourteen out of 26 (54 percent) patients in this cohort had either a complete response (CR; n=10, 39 percent) or complete response with incomplete blood count recovery (CRi; n=4, 15 percent). The percentage of complete responses was comparable between arms. Seven (50 percent) of the 14 CR/CRi were achieved in patients with poor-risk cytogenetic features. Importantly, 10 of the 26 patients subsequently went on to receive hematopoietic stem cell transplant. The study achieved its primary objective with 21 (82 percent) patients alive at four months. Median overall survival was encouraging at approximately 12 months for both study arms. Tosedostat combination therapy was well tolerated and predominantly administered as an outpatient therapy. The primary side effects of the combination therapy, the majority of which were associated with the cytarabine arm, included febrile neutropenia (50 percent), pulmonary infections (31 percent) and sepsis (19 percent). Clinically significant non-hematological toxicities were uncommon and predominantly low grade.

There are several ongoing Phase 2 cooperative group sponsored trials and ISTs evaluating the activity of tosedostat in combination with standard agents in patients with AML or MDS. We anticipate that data from these signal-finding trials may inform the appropriate design for a Phase 3 trial.

We have an exclusive marketing and co-development agreement for tosedostat in North, Central and South America, which is discussed in more detail in Part I, Item 1, Business License Agreements and Additional Milestone Activities.

### **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 cooperative group trials and ISTs 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.

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### *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 the 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. The GOG-0212 study is a randomized, multicenter, open label Phase 3 trial of either monthly Opaxio or paclitaxel for up to 12 consecutive months compared to surveillance among women with advanced ovarian cancer who have no evidence of disease following first-line therapy with paclitaxel and carboplatin. For purposes of registration, the primary endpoint of the study is overall survival of Opaxio compared to surveillance. Secondary endpoints are PFS, safety and quality of life.

In February 2012, we were informed that the Data Monitoring Committee for GOG-0212 adopted an amendment to the study's statistical analysis plan 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 were informed that the Data Safety Monitoring Board 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. In January 2014, we were informed by the GOG that enrollment in the trial had been completed with 1,150 patients enrolled.

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

In November 2010, results 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, were presented by the Brown University Oncology Group. 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 trial 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 primary endpoints of the trial are to estimate disease free and overall survival for the two study arms. Preliminary results are expected to be available in the second quarter of 2014. 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*

In April 2008, SUNY Upstate Medical University initiated a Phase 1-2 trial of Opaxio combined with radiotherapy and cisplatin for patients with locally advanced head and neck cancer. In June 2013, results from the Phase 1-2 trial showed promising clinical activity and the combination of the two agents was tolerable. An expansion cohort of HPV negative advanced head and neck cancer patients on this protocol is in progress.

We acquired an exclusive worldwide license for rights to Opaxio and certain polymer technology from PG-TXL Company, L.P., or PG-TXL, in November 1998 as discussed below in Part I, Item 1, Business License Agreements and Additional Milestone Activities PG-TXL.

## **Brostallicin**

Brostallicin, a novel, synthetic, second-generation DNA minor groove binder, binds covalently to DNA within the DNA minor groove, interfering with DNA division and leading to tumor cell death. More than 200 patients have been treated with brostallicin in single-agent and combination studies. In June 2013, we reported on final results from a cooperative group sponsored trial and National Cancer Institute-sponsored Phase 2 clinical trial of brostallicin in combination with cisplatin for the treatment of women with metastatic triple-negative breast cancer, or mTNBC. Triple-negative breast cancer lacks progesterone and estrogen receptors and the HER2 biomarker that is present in most breast cancers, which makes standard therapy with hormone or targeted therapy

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ineffective. The rationale for the present study in TNBC is based on data that demonstrates that silencing of the breast cancer susceptibility gene(s), or BRCA, is associated with substantially enhanced sensitivity to brostallicin. BRCA is silenced or mutated in most patients with TNBC. In this study of 48 patients with heavily pretreated mTNBC, the 3-month PFS was 51 percent with 10 confirmed responses (one complete response and nine partial responses). Among the 25 patients who received a reduced brostallicin dose, the overall response rate was 28 percent, with 3-month PFS of 61.5 percent and median overall survival of 11.8 months. Adverse events were mostly hematologic (75 percent) and consistent with other treatments in this setting. The final data were presented at the 2013 American Society for Clinical Oncology Meeting.

We have worldwide rights to use, develop, import and export brostallicin pursuant to a license agreement, which is discussed in more detail in Part I, Item 1, Business License Agreements and Additional Milestone Activities.

## **Research and Development Expenses**

Research and development is essential to our business. We spent \$33.6 million, \$33.2 million and \$34.9 million in 2013, 2012 and 2011, respectively, on company-sponsored research and development activities. The development of a product candidate involves inherent risks and uncertainties, including, among other things, that we cannot predict with any certainty the pace of enrollment of our clinical trials. As a result, we are unable to provide the nature, timing and estimated costs of the efforts necessary to complete the development of pacritinib, tosedostat and Opaxio or to complete the post-approval commitment study of PIXUVRI. Further, third parties are conducting key clinical trials for tosedostat and Opaxio. 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, pacritinib, tosedostat and Opaxio to generate material net cash inflows. For additional information relating to our research and development expenses, see Part II, Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations Results of Operations Research and development expenses.

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 Part I, Item 1A, Risk Factors.

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

### *Baxter*

In November 2013, we entered into the Baxter Agreement for the development and commercialization of pacritinib for use in oncology and potentially additional therapeutic areas. Under the terms of the Baxter Agreement, we have granted to Baxter an exclusive, worldwide (subject to certain co-promotion rights for us in the U.S.), royalty-bearing, non-transferable, and (under certain circumstances outside of the U.S.) sub-licensable license to our know-how and patents relating to pacritinib. Licensed products under the Baxter Agreement consist of products in which pacritinib is an ingredient.

Baxter has granted to us a non-exclusive license in order for us to perform our rights and obligations under the Baxter Agreement, including our co-promotion rights and manufacturing obligations.

Baxter paid us an upfront payment of \$60 million, which included \$30 million to acquire 30,000 shares of our convertible preferred stock. In November 2013, Baxter converted such preferred stock into our common stock at an initial conversion price of \$1.914 per share.

We are also eligible to receive potential payments of up to \$302 million upon the successful achievement of certain development and commercialization milestones, comprised of \$112 million of potential clinical,

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regulatory and commercial launch milestone payments, and potential additional sales milestone payments of up to \$190 million. Of such milestones, \$67 million relates to clinical progress milestones. We and Baxter will jointly commercialize and share profits and losses on sales of pacritinib in the U.S.

We will be responsible for all development costs incurred prior to January 1, 2014, as well as for approximately \$96 million in U.S. and E.U. development costs incurred on or after January 1, 2014. Of such \$96 million in development costs, we anticipate that up to \$67 million will be offset through the potential receipt from Baxter through 2015 of the aforementioned clinical progress milestones. All development costs exceeding the \$96 million threshold will generally be shared as follows: (i) costs generally applicable worldwide will be shared 75 percent to Baxter and 25 percent to us, (ii) costs applicable to territories exclusive to Baxter will be 100 percent borne by Baxter and (iii) costs applicable exclusively to co-promotion in the U.S. will be shared equally between the parties, subject to certain exceptions.

Outside the U.S., we are eligible to receive tiered high single digit to mid-teen percentage royalty payments based on net sales for myelofibrosis, and higher double digit royalties for other indications, subject to reduction by up to 50 percent if (i) Baxter is required to obtain additional third party licenses, on which it is obligated to pay royalties, to fulfill its obligations under the Baxter Agreement and (ii) in any jurisdiction where there is no longer either regulatory exclusivity or patent protection.

Joint commercialization, manufacturing, development and steering committees with representatives from Baxter and from us will be established pursuant to the Baxter Agreement. The Baxter Agreement will expire when there is no longer any obligation for Baxter to pay royalties to us in any jurisdiction, at which time the licenses granted to Baxter will become perpetual and royalty-free. We or Baxter may terminate the Baxter Agreement prior to its expiration in certain circumstances. Following the one year anniversary of receipt of regulatory approval in Australia, Canada, China, France, Germany, Italy, Japan, Spain, the U.K. or the U.S., we may terminate the Baxter Agreement as to one or more particular countries if Baxter has not undertaken requisite regulatory or commercialization efforts in the applicable country and certain other conditions are met. Baxter may terminate the Baxter Agreement earlier than its expiration in certain circumstances including (i) in the event development costs for myelofibrosis for the period commencing January 1, 2014 are reasonably projected to exceed a specified threshold, (ii) as to some or all countries in the event of commercial failure of the licensed product or (iii) without cause following the one-year anniversary of the effective date of the Baxter Agreement, provided that such termination will have a lead-in period of six months before it becomes effective. Additionally, either party may terminate the Baxter Agreement prior to its expiration in events of force majeure, or the other party's uncured material breach or insolvency. In the event of a termination prior to the expiration date, rights in pacritinib will revert to us.

The Baxter Agreement also requires Baxter and us to negotiate and enter into a Manufacturing and Supply Agreement, which will provide for the manufacture of the licensed products, with an option for Baxter to finish and package encapsulated bulk product, within 180 days of the effective date of the Baxter Agreement.

### *University of Vermont*

We entered into an agreement with the University of Vermont, or UVM, in March 1995, as amended, or the UVM Agreement, 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



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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 in the event of an uncured material breach of the UVM Agreement by the other party or in the event of bankruptcy of the other party.

### *S\***BIO***

We acquired the compounds SB1518 (which is referred to as *pacritinib*) and SB1578, which inhibit JAK2, from S\***BIO** Pte Ltd, or S\***BIO**, in May 2012. Under our agreement with S\***BIO**, we are required to make milestone payments to S\***BIO** 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 compound that we acquired from S\***BIO** for use for specific diseases, infections or other conditions. At our election, we may pay up to 50 percent 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, or the Chroma License Agreement, with Chroma Therapeutics, Ltd., or Chroma, 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 are required to make a milestone payment to Chroma 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 required to pay Chroma royalties on net sales of tosedostat in any country within the Licensed Territory. Royalties commence on the first commercial sale of tosedostat in any country in the Licensed Territory and continue with respect to that country until the latest of the expiration date of the last patent claim, the expiration of all regulatory exclusivity periods for tosedostat in that country or 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 are responsible for performing the development operations and commercialization activities in the Licensed Territory, and Chroma will oversee and is responsible for performing the development operations and commercialization activities worldwide except for the Licensed Territory. Development costs may not exceed \$50.0 million for the first three years of the Chroma License Agreement unless agreed upon by the parties. We will be responsible for 75 percent of all development costs, while Chroma will be responsible for 25 percent of all development costs, subject to certain exceptions. Chroma is responsible for the manufacturing of tosedostat for development purposes in accordance with the terms of our supply agreement with Chroma. 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. As discussed in Part I, Item 3, *Legal Proceedings*, the parties have certain disputes arising under the Chroma License Agreement, although no court proceedings have commenced as of the time of this filing.

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### *Gynecologic Oncology Group*

We entered into an agreement with the GOG in March 2004, as amended, related to the GOG-0212 trial of Opaxio in patients with ovarian cancer, which the GOG is conducting. We recorded a \$0.9 million payment due to the GOG based on the 1,100 patient enrollment milestone achieved in the third quarter of 2013. In addition, we may be required to pay up to \$1.2 million upon the attainment of certain milestones, as well as other fees under certain circumstances, of which \$0.7 million has been recorded as an accrued expense in our Consolidated Financial Statements as of December 31, 2013.

### *PG-TXL*

In November 1998, we entered into an agreement, or the PG-TXL Agreement, with PG-TXL, as amended, 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 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 for any reason upon advance written notice. In addition, either party may terminate the PG-TXL Agreement upon advance written notice in the event certain license fee payments are not made; in the event of an uncured material breach of the respective material obligations and conditions of the PG-TXL Agreement; or in the event of liquidation or bankruptcy of a party.

### *Novartis*

In January 2014, we entered into a termination agreement, or the Termination Agreement, with Novartis International Pharmaceutical Ltd., or Novartis, to reacquire the rights to PIXUVRI and Opaxio, or the Compounds, previously granted to Novartis under our License and Co-Development Agreement with Novartis entered into in September 2006, as amended, or the Original Agreement. Pursuant to the Termination Agreement, the Original Agreement was terminated in its entirety, other than certain customary provisions, including those pertaining to confidentiality and indemnification, which survive termination.

Under the Termination Agreement, we agreed not to transfer, license, sublicense or otherwise grant rights with respect to intellectual property of the Compounds unless the transferee/licensee/sublicensee agrees to be bound by the terms of the Termination Agreement. We also agreed to provide potential payments to Novartis, including a percentage ranging from the low double-digits to the mid-teens, of any consideration received by us or our affiliates in connection with any transfer, license, sublicense or other grant of rights with respect to intellectual property of PIXUVRI or Opaxio, respectively; *provided* that such payments will not exceed certain prescribed ceilings in the low-single digit millions. Novartis is entitled to receive potential payments of up to \$16.6 million upon the successful achievement of certain sales milestones of the Compounds. Novartis is also eligible to receive tiered low single-digit percentage royalty payments for the first several hundred million in annual net sales, and ten percent royalty payments thereafter based on annual net sales of each Compound, subject to reduction in the event generic drugs are introduced and sold by a third party, causing the sale of PIXUVRI or Opaxio to fall by a percentage in the high double-digits. To the extent we are required to pay royalties on net sales of Opaxio pursuant to the PG-TXL Agreement, we may credit a percentage of the amount of such royalties paid to those payable to Novartis, subject to certain exceptions. Notwithstanding the foregoing,

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royalty payments for both PIXUVRI and Opaxio are subject to certain minimum floor percentages in the low single-digits.

### *Nerviano Medical Sciences*

Our license agreement with Nerviano Medical Sciences, S.r.l. for brostallicin, dated October 6, 2006, provides for the potential payment by us of up to \$80 million in milestone payments based on the achievement of certain product development results. Due to the early stage of development of brostallicin, we cannot make a determination that the milestone payments are reasonably likely to occur at this time.

### *Cephalon*

In June 2005, we entered into an acquisition agreement with Cephalon, Inc., or Cephalon. Cephalon was subsequently acquired by Teva Pharmaceutical Industries Ltd., or Teva. Under the agreement, we have the right to receive up to \$100 million in payments upon achievement by Teva of specified sales and development milestones related to TRISENOX. In November 2013, we received a \$5 million payment related to achievement of a sales milestone.

## **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 and through acquisitions. 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, pacritinib, tosedostat, Opaxio, 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 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 currently in force in Europe will expire from 2015 through 2023. Some of these European patents are subject to Supplementary Protection Certificates such that the extended patents will expire from 2020 to 2027. Although 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 additional countries in Europe, there can be no guarantee of extensions of PIXUVRI-directed or other patents 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 21 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, Distribution and Associated Matters**

Our manufacturing strategy utilizes third-party contract manufacturers for our products and product candidates. We utilize third-party contractors for raw materials, active pharmaceutical ingredients and finished drug product, as well as for labeling, packaging, storing and distributing our products and product candidates. As

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our business continues to expand, we expect that our manufacturing, distribution and associated requirements will increase correspondingly. One such requirement becoming increasingly important relates to our commercial supply needs; while we currently have a commercial supply arrangement for PIXUVRI, we do not presently have any such arrangement in place for pacritinib (or for our other product candidates). In particular, as we have continued to advance the development of pacritinib and position such product for potential commercialization, procuring a qualified commercial supplier for pacritinib has become an important objective.

Integral to our manufacturing strategy is our quality control and quality assurance program, which includes standard operating procedures and specifications with the goal that our products and product candidates are manufactured in accordance with current Good Manufacturing Practices, or cGMPs, and other applicable global regulations. The cGMP compliance includes strict adherence to regulations for quality control, quality assurance and the maintenance of records and documentation. The manufacturing facilities for products and product candidates must meet cGMP requirements, and with respect to the commercial products, must have acquired FDA, EMA and any other applicable regulatory approval. In this regard, we expect to continue to rely on contract manufacturers to produce sufficient quantities of our products and product candidates in accordance with cGMPs for use in clinical trials and distribution.

We believe our manufacturing strategy of utilizing qualified outside vendors allows us to direct our financial and managerial resources to development and commercialization activities, rather than to the establishment of a manufacturing infrastructure.

## **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 NHL; however there are other agents approved to treat aggressive NHL 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 NHL that, 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 approved in the future. Pacritinib would compete with Incyte, which markets Jakafi®, and potentially other candidates in development that target JAK inhibition to treat cancer. Tosedostat would compete with corporations such as Eisai Inc., which markets Dacogen®; Celgene Corporation, which markets Vidaza®, Revlimid®, and Thalomid®; Genzyme Corporation, which markets Clolar® and new anti-cancer drugs that may be developed and marketed. 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., which market paclitaxel and generic forms of paclitaxel; Sanofi-Aventis U.S. LLC, which markets docetaxel; Genentech, Inc., Hoffmann-La Roche Inc. and Astellas Pharma US, Inc., which market Tarceva®; Genentech, Inc. and Hoffmann-La Roche Inc., which market Avastin®; Eli Lilly & Company, which markets Alimta®; and Celgene Corporation, which markets Abraxane®.

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

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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 U.S. and other countries.

### *U.S. Regulation.*

In the U.S., 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 U.S. until such drug has received FDA approval. The steps required before a drug may be marketed in the U.S. 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

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effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA

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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

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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 U.S. 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 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 the Pharmaceutical Research and Manufacturers of America Code and FDA regulations.

### *Non-U.S. Regulation.*

Before our products can be marketed outside of the U.S., they are subject to regulatory approval similar to that required in the U.S., 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.



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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 E.U. member states, as well as in 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, 2013, we employed 106 individuals in the U.S., including two employees at our majority-owned subsidiary Aequus Biopharma, Inc., and five in Europe. Our U.S. and U.K. employees do not have a collective bargaining agreement. Two employees in Italy are 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 below, 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 the Mercato Telematico Azionario, or the 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. CTI, 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 as soon as reasonably practicable after each is electronically filed with, or furnished to, the U.S. Securities and Exchange Commission, or the SEC.

In addition, you may review a copy of this Annual Report on Form 10-K, including exhibits and any schedule filed herewith, and obtain copies of such materials at prescribed rates, at the SEC's 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, including the Company, that file electronically with the SEC.

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### **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 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**

*We expect that we will need to raise additional financing to develop our business, but additional funds may not be available on acceptable terms, or at all. Any inability to raise required capital when needed could impair our ability to make our contractually obligated payments and harm our liquidity, financial condition, business, operating results and prospects.*

We have substantial operating expenses associated with the development of our product candidates and the commercialization of PIXUVRI, and we have significant contractual payment obligations. Our available cash and cash equivalents were \$71.6 million as of December 31, 2013. At our currently planned spending rate, we believe that our present financial resources, together with pacritinib milestone payments projected to be earned and received over the course of 2014 and 2015 under our collaboration with Baxter and expected European sales from PIXUVRI, will be sufficient to fund our operations into the third quarter of 2015. Cash forecasts and capital requirements are subject to change as a result of a variety of risks and uncertainties. Changes in manufacturing, clinical trial expenses, any expansion of our sales and marketing organization in Europe and other unplanned business developments may consume capital resources earlier than planned. Additionally, we may not receive the anticipated pacritinib milestone payments or sales from PIXUVRI. Due to these and other factors, our forecast for the period for which we will have sufficient resources to fund our operations, as well as any other operational or business projection we have disclosed, or may, from time to time, disclose, may fail.

We have \$15.0 million outstanding under our senior secured term loan agreement. We are required to make monthly interest payments of approximately \$158,000, and commencing May 1, 2014 through October 1, 2016, we will be required to make monthly interest plus principal payments in the aggregate amount of approximately \$584,000. The loan agreement also requires us to comply with restrictive covenants, including those that limit our operating flexibility and ability to borrow additional funds. A failure to make a required loan payment or an uncured covenant breach could lead to an event of default, and in such case, all amounts then outstanding may become due and payable immediately.

We expect that we will need to acquire additional funds in order to develop our business, including in the event our costs are greater than anticipated or our cash inflow projections fail, or in the event we seek to expand our operations. We may seek to raise such capital through equity or 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 convertible securities is restricted by the limited number of our residual authorized shares, the difficulty of obtaining shareholder approval to increase authorized shares, and the restrictive covenants of our senior secured term loan agreement;

issuance of equity securities or convertible securities will dilute the proportionate ownership of existing shareholders;

our ability to raise debt capital is limited by our existing senior secured term loan agreement;

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some of such arrangements may require us to relinquish rights to certain assets; and

we may be required to meet additional regulatory requirements, and we may be subject to certain contractual limitations, which may increase our costs and harm our ability to obtain funding.

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, reduce our selling, general and administrative expenses and/or refrain from making our contractually required payments when due, which could 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, 2013, we had an accumulated deficit of \$1.9 billion. We are pursuing regulatory approvals for PIXUVRI, pacritinib, tosedostat and Opaxio. We will need to continue to conduct research, development, testing and regulatory compliance activities and procure manufacturing and drug supply services, the costs of which, together with projected general and administrative expenses, may result in operating losses for the foreseeable future. There can be no assurances that we will ever achieve profitability.

*If our collaboration with Baxter with respect to pacritinib or any other collaboration for our products or product candidates is not successful, or if we are unable to enter into additional collaborations, we may not be able to effectively develop and/or commercialize the applicable product(s), which could have a material adverse effect on our business.*

Under the Baxter Agreement, we rely heavily on Baxter to collaborate with us in respect of the development and global commercialization of our lead product candidate, pacritinib. As a result of our dependence on our relationship with Baxter, the eventual success or commercial viability of pacritinib is, to a certain extent, beyond our control. We are subject to a number of specific risks associated with our dependence on our collaborative relationship with Baxter, including: possible disagreements between Baxter and us as to the timing, nature and extent of our development plans, including clinical trials or regulatory approval strategy; changes in personnel at Baxter who are key to the collaboration efforts; any changes in Baxter's business strategy adverse to our interests; and possible disagreements with Baxter regarding ownership of proprietary rights. Furthermore, the contingent financial returns under our collaboration with Baxter depend in large part on the achievement of development and commercialization milestones, plus a share of revenues from any sales. Therefore, our success, and any associated future financial returns to us and our investors, will depend in large in part on the performance of both Baxter and us under the Baxter Agreement.

The continued development of our other product candidates also depends on our ability to enter into and/or maintain collaborations. We have entered into a third-party service provider agreement with Quintiles Commercial Europe Limited, or Quintiles, whereby Quintiles provides a variety of services related to the commercialization of PIXUVRI in Europe. We are also pursuing potential partners for commercializing PIXUVRI in other markets outside of the U.S. and our current target E.U. markets discussed in Part II, Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations. Because we rely on third parties to manufacture, distribute, and market and sell PIXUVRI, we have limited control over the efforts of these third parties, and we may receive less revenue than if we commercialized PIXUVRI ourselves. We are also a party to other agreements with third parties for our product candidates, including an agreement with the GOG, to perform a Phase 3 trial of Opaxio in patients with ovarian cancer.

If we fail to enter into additional collaborative arrangements or to maintain existing or future arrangements and service provider relationships, we may be unable to further develop and commercialize product candidates, generate revenues to grow, sustain our business or achieve profitability, which would harm our business, financial condition, operating results and prospects.

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*Our clinical trials may take longer to complete than expected, or they may not be completed at all.*

Our business is dependent on our ability, and to the extent applicable, the ability of our collaboration partners and other third parties (such as cooperative groups and ISTs), to successfully 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. For example, our ability to develop pacritinib depends on the successful completion of two Phase 3 trials, one of which initiated in January 2013 and the second of which opened for enrollment in March 2014. 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. We forecast the commencement and completion of clinical trials for planning purposes, but actual commencement or completion may take longer than planned or not be completed at all 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 or could place a partial or full hold on any clinical trial at any time;

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 to the extent applicable, our collaboration partners, or regulatory authorities may suspend clinical trials at any time on the basis that the participants are being exposed to unacceptable health risks or for other reasons; and

the rates of patient recruitment and enrollment of patients who meet trial eligibility criteria may be lower than anticipated 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.

In addition, the failure of third parties, including, where applicable, contract research organizations, academic institutions, collaborators, cooperative groups and/or investigator sponsors, to conduct, oversee and monitor clinical trials, as well as to process clinical results, manage test requests and meet applicable standards, can affect the timing and outcome of the applicable trials. In particular, the clinical trials currently underway for tosedostat and Opaxio are being conducted as cooperative group trials and ISTs, and as such, are not under our control.

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A delay in, or failure to commence or complete, any present or planned clinical trials, or the need to perform more or larger clinical trials than planned, could result in an increase in development costs, which could harm our ability to commercialize our product candidates, and our business, financial condition, operating results or prospects.

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

The successful development of anti-cancer drugs and other pharmaceutical products is highly uncertain, and obtaining regulatory approval to market drugs to treat cancer is expensive, difficult and speculative. 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. For example, our Phase 3 clinical trials for Opaxio for the treatment of non-small cell lung cancer failed to meet their primary endpoints. In addition, in June 2013, the FDA implemented a partial clinical hold on tosedostat, which prevented new patients from entering any ongoing tosedostat clinical trials. This hold was lifted in December 2013.

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 or 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;

any 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;

the product candidate may not be cost effective compared to alternative treatments; 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.

If the development of our product candidates is delayed, our development costs may increase, the product may not reach later stages of development and/or the ability to commercialize our product candidates may be harmed, which could harm our business, financial condition, operating results or prospects.

*We or our collaboration partners 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 U.S. and by comparable agencies in other states and countries, including the EMA in the E.U. Pacritinib and all of our other compounds are currently in research or development and, other than conditional marketing authorization for PIXUVRI in the E.U., we have not received marketing approval for these other compounds or FDA marketing approval of PIXUVRI (and we are not currently pursuing FDA marketing approval of PIXUVRI). Information about the status of the regulatory approval of PIXUVRI, pacritinib, tosedostat and Opaxio can be found in Part II, Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations and is incorporated by reference herein. Our products may not be marketed in the U.S. 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



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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;

a drug candidate may fail to comply with regulatory requirements; 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 adversely affect the marketing of our products. If our products are not approved quickly enough to provide net revenues to defray our operating expenses, our business, financial condition and operating results will be harmed.

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

Pacritinib, Opaxio and tosedostat are currently in clinical trials; the development and clinical trials of these products may not be successful and, even if they are, such products may never be successfully developed into commercial products. Even if our products are successful in clinical trials or in obtaining other regulatory approvals, our products (even those that have been granted conditional marketing authorization, such as PIXUVRI) may not reach the market for a number of reasons including:

they may be found ineffective or cause harmful side effects;

they may be difficult to manufacture on a scale necessary for commercialization;

they may be uneconomical to produce;

we may fail to obtain reimbursement amount approvals or pricing that is cost effective for patients as compared to other available forms of treatment;

they may not compete effectively with existing or future alternatives to our products;



we are unable to sell marketing rights or develop commercial operations;

they may fail to achieve market acceptance; or

we may be precluded from commercialization of our products by proprietary rights of third parties.

In particular, with respect to the future potential commercialization of pacritinib, we will be heavily dependent on our collaboration partner, Baxter. Under the terms of our agreement, Baxter has exclusive commercialization rights for all indications for pacritinib outside the U.S., while Baxter and CTI share commercialization rights in the U.S.

The failure of Baxter (or any other applicable collaboration partner) to fulfill its commercialization obligations with respect to a product, or the occurrence of any of the events itemized in the foregoing list, could adversely affect the commercialization of our products. 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.

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*If users of our products are unable to obtain adequate reimbursement from third party payers, market acceptance of our products may be limited and we may not achieve anticipated revenues.*

To the extent our products are successfully introduced to market, they may not be considered cost-effective and third-party or government reimbursement might not be available or sufficient. Governmental and other third-party payors continue to attempt to contain healthcare costs by strictly controlling, directly or indirectly, pricing and reimbursement, and we expect pressures on pricing and reimbursement from both governments and private payers inside and outside the U.S. to continue. 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 is and will be determined by national regulatory authorities. A variety of factors are considered in making reimbursement decisions, including whether there is sufficient evidence to show that treatment with the product is more effective than current treatments, that the product represents good value for money for the health service it provides and that treatment with the product works at least as well as currently available treatments. Reimbursement decisions from any of the European markets may impact reimbursement decisions in other European markets. 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.

*We may never be able to generate significant product revenues from the sale of PIXUVRI.*

We anticipate that, for at least the next several years, our ability to generate revenues and become profitable will depend on the commercial success in Europe of our only marketed product candidate, PIXUVRI. PIXUVRI is not approved for marketing in the U.S. PIXUVRI is available to healthcare providers in certain countries in the E.U. See Part II, Item 7, Management's Discussion and Analysis of Financial Condition and Results of Operations for a discussion of the reimbursement status in the applicable E.U. countries. However, our ability to continue to commercialize PIXUVRI in Europe will depend on our ability to obtain an annual renewal of our conditional marketing authorization for PIXUVRI in the E.U. and to timely complete the post-marketing study of PIXUVRI aimed at confirming the clinical benefit previously observed in PIXUVRI. A failure of such study could result in a cessation of commercialization of PIXUVRI in the E.U.

In addition, the successful commercialization of PIXUVRI in the E.U. depends heavily on our ability to obtain and maintain favorable reimbursement rates for users of PIXUVRI, as well as on various additional factors, including, without limitation, our ability to:

increase and maintain demand for and sales of PIXUVRI in Europe and obtain greater acceptance of PIXUVRI by physicians and patients;

establish and maintain agreements with wholesalers and distributors on reasonable terms;

maintain, and enter into additional, commercial manufacturing arrangements with third-parties, cost-effectively manufacture necessary quantities and build distribution, managerial and other capabilities; and

further develop and maintain a commercial organization to market PIXUVRI.

If we are unable to successfully commercialize PIXUVRI in Europe as planned, our business, financial condition, operating results and prospects could be harmed.

*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



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December 31, 2012 consolidated financial statements, we expect to continue to need to raise additional financing to develop our business 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 MTA in Italy, 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 that we would be delisted if we did not timely regain compliance. 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 our senior secured term loan and any future indebtedness, which would accelerate the maturity date of such 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 The NASDAQ Capital Market could also affect our ability to maintain our listing or trading on the MTA. Trading in our common stock has been halted or suspended on both The NASDAQ Capital Market and MTA in the past and may also be halted or suspended in the future due to market or trading conditions at the discretion of The NASDAQ Stock Market LLC, 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.

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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 and necessary shareholder approvals at shareholder meetings 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 of the foregoing, we may be unable to obtain a quorum or shareholder approval of proposals, when needed, at annual or special meetings of shareholders. Even if we are able to 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. Any failure to obtain a quorum or the requisite vote on a proposal in question could harm us.

*We could fail in financing efforts if we fail to receive shareholder approval when needed.*

We are required under the NASDAQ Marketplace Rules to obtain shareholder approval for any issuance of additional equity securities that would comprise more than 20 percent 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 as well as under certain other circumstances. We have in the past and may in the future issue additional equity securities that would comprise more than 20 percent 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 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 percent 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 have in the past issued convertible preferred stock and may in the future issue convertible securities because the common stock resulting from the conversion of such securities, subject to 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 percent limitation imposed by E.U. and Italian law. However, any changes to Italian regulatory requirements, exemptions or interpretations may increase compliance costs or limit our ability to issue securities.

*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 to incur

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additional expenses 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 for and may never realize the anticipated benefits of acquisitions.*

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 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. Any 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 or prospects.

*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 \$5.7 million and \$8.1 million as of December 31, 2013 and December 31, 2012, respectively. On April 14, 2009, December 21, 2009 and June 25, 2010, the Italian Tax Authority, or the ITA, issued notices of assessment to Cell Therapeutics Inc. Sede Secondaria, or 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). 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. While we are defending ourselves against the assessments both on procedural grounds and on the merits of the case, there can be no assurances that we will be successful in such defense. Further information pertaining to these cases can be found in Part I, Item 3, Legal Proceedings and is incorporated by reference herein. If the final decision of the Supreme Court is unfavorable to us, or if, in the interim, the ITA were to make a demand for payment and we were to be unsuccessful in suspending collection efforts, we may be requested to pay to the ITA an amount up to 9.4 million (or approximately \$12.9 million converted using the currency exchange rate as of December 31, 2013) 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.

*Even if our products receive regulatory approval, 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 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. Even if a product receives regulatory approval, we may not be able to maintain compliance with regulatory requirements, which could result in the product being withdrawn from the market, product seizures, injunctions, regulatory restrictions on our business and sales activities, monetary penalties or criminal prosecution. 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

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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, operating results and prospects 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 PIX-R, or PIX306, compares 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 PIX306 or whether PIX306 will serve as either a post-marketing commitment trial or as a pivotal trial. We may not be able to demonstrate the clinical benefit of PIXUVRI in patients who had previously received rituximab or that PIXUVRI is more clinically effective than treatments currently used in clinical practice. 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 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, operating results or prospects. Failure to meet clinical trial deadlines may also result in the withdrawal of our conditional marketing authorization for PIXUVRI.

*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 U.S., 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, generate negative publicity and may result in fines or payments of settlement awards. For example, in April 2007, we paid a civil penalty of \$10.6 million and entered into a settlement agreement with the USAO for the Western District of Washington arising out of their investigation into certain of our prior marketing practices relating to TRISENOX, which was divested to Cephalon Inc. in July 2005. As part of that settlement agreement and in connection with the acquisition of Zevalin, we also entered into a corporate integrity agreement with the OIG-HHS, which required us to establish a compliance committee and compliance program and adopt a formal code of conduct. 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.

*A failure to comply with laws and regulations that govern our cross-border conduct, as well as with healthcare fraud and abuse and false claims laws and regulations, could result in substantial penalties and prosecution.*

We are subject to risks associated with doing business outside of the U.S., which exposes us to complex foreign and U.S. regulations. For example, we are subject to regulations imposed by the Foreign Corrupt

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Practices Act, or FCPA, and other anti-corruption laws that generally prohibit U.S. companies and their intermediaries from offering, promising, authorizing or making improper payments to foreign government officials for the purpose of obtaining or retaining business. The SEC and U.S. Department of Justice have increased their enforcement activities with respect to the FCPA. Internal control policies and procedures and employee training and compliance programs that we have implemented to deter prohibited practices may not be effective in prohibiting our employees, contractors or agents from violating or circumventing our policies and the law.

In addition, we are subject to various state and federal fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and federal False Claims Act. There are similar laws in other countries. These laws may impact, among other things, the sales, marketing and education programs for our drugs. The federal Anti-Kickback Statute prohibits persons from knowingly and willingly soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a federal healthcare program. The federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, or the knowing use of false statements to obtain payment from the federal government. Suits filed under the False Claims Act can be brought by any individual on behalf of the government and such individuals, commonly known as whistleblowers, may share in any amounts paid by the entity to the government in fines or settlement. Many states have also adopted laws similar to the federal Anti-Kickback Statute and False Claims Act.

We are unable to predict whether we could be subject to actions under any of the foregoing or similar laws and regulations, or the impact of such actions. If we were to be found to be in violation of these laws or regulations, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from government healthcare reimbursement programs and the curtailment or restructuring of our operations, all of which could have a material adverse effect on our business and results of operations.

*We are dependent on third-parties for the manufacture, testing and distribution of products and product candidates. Any failure or delay in manufacturing, or in obtaining a qualified vendor when needed, could delay the clinical development and commercialization of the applicable product(s) and product candidate(s) and harm our business.*

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, and we instead utilize third party vendors. In particular, we are dependent on a single vendor for the manufacturing of each of PIXUVRI, pacritinib and tosedostat. With respect to Opaxio, we are presently relying on stored inventory of the drug, as we do not presently have a manufacturing agreement in place for Opaxio. Because we do not have a manufacturing infrastructure, we are dependent upon our vendors to supply us in a timely manner with products manufactured in compliance with cGMPs or similar manufacturing standards imposed by the U.S. and/or applicable foreign regulatory authorities, including the FDA and EMA. Any of such regulatory authorities may take action against a contract manufacturer who violates 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.

With respect to commercial supply arrangements, we currently have such an arrangement in place for PIXUVRI, but we do not presently have one in place for pacritinib (or for our other product candidates). In particular, as we have continued to advance the development of pacritinib and position such product for potential commercialization, procuring a qualified commercial supplier for pacritinib has become an important objective.

Any failure or delay in the manufacturing and testing of a product or product candidate in compliance with applicable regulations, or in obtaining and maintaining qualified vendors (including qualified commercial suppliers) to provide the requisite services when needed, could delay the clinical development and commercialization of the applicable product or product candidate and harm our business.



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*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. In September 2012, our wholly-owned subsidiary CTI Life Sciences Limited, 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 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; and 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 operating results 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 and product development. We anticipate that we will face increased competition in the future as new companies enter the market. Our competitors in the U.S. and elsewhere are numerous and include, among others, major multinational pharmaceutical companies, specialized biotechnology companies and universities and other research institutions. Specifically:

In Europe, PIXUVRI faces competition from existing treatments for adults with multiply relapsed or refractory aggressive B-cell NHL. For example, patients are currently being treated with bendamustine, oxaliplatin and gemcitabine, although these particular agents do not have regulatory approval in Europe for the foregoing indication. If we were to pursue bringing PIXUVRI to market in the U.S. (which is not currently part of our near-term plan), PIXUVRI would face similar competition. In addition, PIXUVRI may face competition in the E.U. (and, if applicable in the future, the U.S.) if new anti-cancer drugs with reduced toxicity and/or increased efficacy are developed and marketed in the E.U. and/or the U.S.

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 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., which market paclitaxel and generic forms of paclitaxel; Sanofi-Aventis U.S. LLC, which markets docetaxel; Genentech, Inc., Hoffmann-La Roche Inc. and Astellas Pharma US, Inc., which market Tarceva ; Genentech, Inc. and Hoffmann-La Roche Inc., which market Avastin ; Eli Lilly & Company, which markets Alimta®; and Celgene Corporation, which markets Abraxane . In addition, other companies such as Telik, Inc. are also developing products, which could compete with Opaxio.

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

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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.

*The pharmaceutical business is subject to increasing government price controls and other restrictions on pricing, reimbursement, and access to drugs, which could affect our future revenues and profitability if new restrictive legislation is adopted.*

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. In the U.S., we are subject to substantial pricing, reimbursement and access pressures from state Medicaid programs, private insurance programs and pharmacy benefit managers, and implementation of U.S. health care reform legislation is increasing these pricing pressures. The Patient Protection and Affordable Care Act (HR 3590) instituted comprehensive health care reform in 2010 and includes provisions that, among other things, reduce and/or limit Medicare reimbursement, require all individuals to have health insurance (with limited exceptions) and impose new and/or increased taxes. These measures could significantly influence the purchase of healthcare services and products, resulting in lower prices and reducing demand for our products. In addition, many state legislative proposals could further negatively affect our pricing and reimbursement for, or access to, our products.

Globally, governments are becoming increasingly aggressive in imposing health care cost-containment measures such as:

adopting more restrictive price controls;

limiting and reducing 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;

restricting access to human pharmaceuticals based on the payers' assessments of comparative effectiveness and value;

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.

If adequate third-party or government coverage is not available, 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.

*If any of our license agreements for intellectual property underlying our compounds are terminated, we may lose the right to develop or market that product.*

We have acquired or licensed intellectual property from third parties, including patent applications and patents relating to intellectual property for PIXUVRI, pacritinib and tosedostat. 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.



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

One component of our business strategy is in-licensing drug compounds developed by other pharmaceutical and biotechnology companies or academic research laboratories. Our product candidates tosedostat and Opaxio, which are in clinical and pre-clinical development, and PIXUVRI, which is in a post-approval commitment study, have been in-licensed or acquired 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 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 and through acquisitions. 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, pacritinib, tosedostat, Opaxio 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 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 currently in force in Europe will expire from 2015 through 2023. Some of these European patents are subject to Supplementary Protection Certificates such that the extended patents will expire from 2020 to 2027. Although 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 additional countries in Europe, there can be no guarantee of extensions of PIXUVRI-directed or other patents 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 and maintain patent protection for our products or processes both in the U.S. 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 U.S. 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

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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 may not have 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, pacritinib or any of the other compounds 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.

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*We are currently and may in the future be subject to litigation proceedings that could harm our financial condition and operating results.*

We may be subject to legal claims or regulatory matters involving shareholder, consumer, regulatory and other issues. As described in Part I, Item 3, Legal Proceedings, 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, operating results and prospects could be harmed.

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 operating results 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 Part I, Item 3, Legal Proceedings, 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 is probable that CONSOB will impose a pecuniary administrative sanction for such asserted violation.

Securities class action and shareholder derivative lawsuits are often instituted against issuers, and we have been subjected to such actions. For example, on May 31, 2013, we settled a shareholder derivative lawsuit pursuant to which we agreed to implement certain corporate governance measures and were required to pay \$1.4 million in plaintiffs' attorneys' fees and reimbursement of expenses, all of which amount was covered by our insurance.

We cannot predict with certainty the eventual outcome of pending litigation. Furthermore, we may have to incur substantial expenses in connection with such lawsuits and 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. In the event of an adverse outcome under any currently pending or future lawsuit, our business could be materially harmed.

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

We have 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.

*Our operations 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, as well as the reported amounts of revenues and expenses, 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 operating results and financial condition.

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*We may be unable to obtain the raw materials necessary to produce a particular product or product candidate.*

We may not be able to purchase the materials necessary to produce a particular product or product candidate in adequate volume and quality. For example, paclitaxel, a material used to produce Opaxio, is derived from certain varieties of yew trees and the supply of paclitaxel is controlled by a limited number of companies. We purchase paclitaxel and polyglutamic acid (another material used to produce Opaxio) from single sources. If paclitaxel or polyglutamic acid, or any other raw material required to produce a product or product candidate, is insufficient in quantity or quality, if a supplier fails 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.

*Because there is a risk of product liability associated with our products, we face potential difficulties in obtaining insurance, and if product liability lawsuits were to be successfully brought against us, our business may be harmed.*

Our business exposes us to potential product liability risks inherent in the testing, manufacturing and marketing of human pharmaceutical products. In particular, as a result of the commercialization of PIXUVRI, our risk with respect to potential product liability has increased. If our insurance covering a product or product candidate 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 operating results.

*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 depend on sophisticated information technology systems to operate our business and a cyber-attack or other breach of these systems could have a material adverse effect on our business.*

We rely on information technology systems to process, transmit and store electronic information in our day-to-day operations. The size and complexity of our information technology systems makes them vulnerable to a cyber-attack, malicious intrusion, breakdown, destruction, loss of data privacy or other significant disruption. Any such successful attacks could result in the theft of intellectual property or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyber-attacks are becoming more sophisticated and frequent. We have invested in our systems and the protection of our data to reduce the risk of an intrusion or interruption, and we monitor our systems on an ongoing basis for any current or potential threats. There can be no assurance that these measures and efforts will prevent future interruptions or breakdowns. If we fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to these systems, we could have difficulty preventing, detecting and controlling fraud, have disputes with customers, physicians and other health care professionals, have regulatory sanctions or penalties imposed, have increases in operating expenses, incur

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expenses or lose revenues as a result of a data privacy breach or theft of intellectual property or suffer other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition and cash flows.

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

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

The market price for securities of biopharmaceutical and biotechnology companies, including ours, historically has been highly volatile, and the market from time to time has experienced significant price and volume fluctuations that are unrelated to the operating performance of such companies. For example, during the 12-month period ended February 24, 2014, our stock price has ranged from a low of \$0.97 to a high of \$4.25. Fluctuations in the trading price or liquidity of our common stock may harm the value of your investment in our common stock.

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

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

announcements by us or others of serious adverse events that have occurred during administration of our products to patients;

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 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;

a failure to achieve previously announced goals and objectives as or when projected;

halting or suspension of trading in our common stock on The NASDAQ Capital Market by NASDAQ or on the MTA by CONSOB, or the Borsa Italiana; and

general economic and market conditions.

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

Shares of our common stock rank junior to any shares of our preferred stock that we may issue in the future and to our existing indebtedness, including our senior secured term loan agreement, or future indebtedness we

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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. Our senior secured term loan agreement restricts, and 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, dividends are payable only when and if declared by our Board of Directors or a duly authorized committee of our Board of Directors, and 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 percent or more of our common stock by a person or group, subject to certain exceptions, could result in the exercisability of the preferred stock purchase right accompanying each share of our common stock (except those held by a 20 percent 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, deterring 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.

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### **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 lease commenced on May 1, 2012 and has a term of 120 months. We also lease approximately 4,700 square feet of warehouse space in Seattle, Washington with a lease expiration of May 2014. Additionally, we lease 2,700 square feet in Milan, Italy with a lease expiration of December 2015 and 660 square feet in Heathrow, U.K. with a lease expiration of September 2014. 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, 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 sanction established by Section 193, paragraph 1 of the Italian Legislative Decree no. 58/98 for such violation could require us to pay a pecuniary administrative sanction amounting to between \$7,000 and \$689,000 upon conversion from euros as of December 31, 2013. Until CONSOB's right is barred, CONSOB may, at any time, confirm the occurrence of the asserted violation and apply a pecuniary administrative sanction within the foregoing range. To date, we have not received any such notification.

In April 2009, December 2009 and June 2010, 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). 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. We believe that the services invoiced were non-VAT taxable consultancy services and that the VAT returns are correct as originally filed. We are defending ourselves against the assessments both on procedural grounds and on the merits of the case, although we can make no assurances regarding the ultimate outcome of these cases. If the final decision of the Supreme Court is unfavorable to us, or if, in the interim, the ITA were to make a demand for payment and we were to be unsuccessful in suspending collection efforts, we may be requested to pay the ITA an amount up to 9.4 million, or approximately \$12.9 million converted using the currency exchange rate as of December 31, 2013, 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.** In September 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, as partial refund of the legal expenses we incurred for our appeal. In October 2012, the ITA appealed this decision. In June 2013, the Regional Tax Court issued decision no. 119/50/13, which accepted the appeal of the ITA and reversed the previous decision of the Provincial Tax Court. We plan to appeal such decision to the Supreme Court both on procedural grounds and on the merits of the case. On January 2, 2014, we were notified that the ITA has requested partial payment of the 2003 VAT assessment in the amount of 0.4 million (or \$0.6 million upon conversion from euros as of December 31, 2013). We paid such amount in March 2014.

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**2005 VAT.** In January 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. Both the ITA and CTI appealed to the higher court against the decision. In October 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. On April 15, 2013, the ITA appealed the decision to the Italian Supreme Court.

**2006 VAT.** In October 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 that for the 2006 and 2007 VAT cases the ITA was liable to pay us 10,000 as partial refund of the legal expenses incurred for the appeal. In December 2011, the ITA appealed this decision to the Regional Tax Court. On April 16, 2013, the Regional Tax Court issued decision no. 57/35/13 (jointly with the 2007 VAT case) in which it fully rejected the merits of the ITA's appeal, declared that no penalties can be imposed against us and found the ITA liable to pay us 12,000, as partial refund of the legal expenses we incurred for this appeal. The ITA appealed such decision in November 2013.

**2007 VAT.** In October 2011, the Provincial Tax Court issued decision no. 276/21/2011 (jointly with the 2006 VAT case described above) 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 that for 2006 and 2007 VAT cases the ITA was liable to pay us 10,000 as partial refund of the legal expenses incurred for the appeal. In December 2011, the ITA appealed this decision to the Regional Tax Court. On April 10, 2013, the ITA refunded the VAT deposit including interest and collection fees of 0.1 million. On April 16, 2013, the Regional Tax Court issued decision no. 57/35/13 (jointly with the 2006 VAT case) in which it fully rejected the merits of the ITA's appeal, declared that no penalties can be imposed against us and found the ITA liable to pay us 12,000 as partial refund of the legal expenses we incurred for this appeal. The ITA appealed such decision in November 2013.

In August 2009, SICOR 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 the chemical compound, BBR2778, from Sicor according to the terms of a supply agreement executed between Sicor and Novuspharma S.p.A, or Novuspharma, a pharmaceutical company located in Italy, on October 4, 2002. We are the successor in interest to such agreement by virtue of our merger with Novuspharma in January 2004. Sicor alleged that the agreement was not terminated according to its terms. We asserted that the supply agreement in question was properly terminated and that we have no further obligation to comply with its terms. On December 30, 2013, the Court of Milan issued its decision and rejected all of Sicor's claims; this proceeding has therefore concluded. The decision of the Court of Milan is subject to potential appeal.

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 alleged 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, the actions were consolidated as *In re Cell Therapeutics, Inc. Derivative Litigation* (Master Docket No. 2:10-cv-00564-MJP). Three more derivative complaints filed in June, July and October 2010 were also consolidated with *In re Cell Therapeutics, Inc. Derivative Litigation*. On November 6, 2012, co-lead counsel filed an executed Stipulation of Settlement. A settlement hearing occurred on May 31, 2013, and the Court entered a Final Judgment and Order of Dismissal on May 31, 2013, pursuant to which we were required to pay an aggregate of \$1.4 million in plaintiffs' attorneys' fees and reimbursement of expenses, all of which amount was covered by our insurance.

In July 2012, Chroma sent us a letter claiming that we breached the Chroma License Agreement by allegedly making decisions as to the development of tosedostat without requisite approval, failing to hold certain meetings and not using diligent efforts to develop tosedostat. We dispute the allegations. In particular, we dispute

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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 certain of Chroma's claims and failed to demonstrate an ability to manufacture tosedostat to the required standards. Under the Chroma License Agreement, there is a 90-day cure period for any nonpayment default, which period may be extended to 180 days in certain circumstances. A party may terminate the Chroma License Agreement for a material breach only after arbitration. For the period commencing September 25, 2012 through June 25, 2013, a standstill was in effect between the parties. Although the standstill period has not been renewed, court proceedings have not been initiated as of the time of this filing.

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.

### **Item 4. Mine Safety Disclosures**

Not applicable.

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

Our common stock is currently traded on The NASDAQ Capital Market under the symbol "CTIC" and the MTA in Italy, also under the 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.

	High	Low
<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
<b>2013</b>		
First Quarter	\$ 1.71	\$ 1.02
Second Quarter	\$ 1.43	\$ 1.02
Third Quarter	\$ 1.80	\$ 0.97
Fourth Quarter	\$ 2.17	\$ 1.49

On February 24, 2014, the last reported sale price of our common stock on The NASDAQ Capital Market was \$3.56 per share. As of February 24, 2014, there were 188 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, 2013:

Period	Total Number of Shares Purchased (1)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
October 1 – October 31, 2013	1,851	\$ 1.90		
November 1 – November 30, 2013	10,876	\$ 1.74		
December 1 – December 31, 2013	816	\$ 1.91		

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Total	13,543	\$ 1.77
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- (1) Represents purchases of shares in connection with satisfying tax withholding obligations on the vesting of restricted stock awards to employees.

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### 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, 2013, 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, 2008. The actual returns shown on the graph above are as follows:

	3/31/09	6/30/09	9/30/09	12/31/09
Cell Therapeutics, Inc.	\$ 271.43	\$ 1,228.33	\$ 878.57	\$ 814.29
NASDAQ Stock Index (U.S.)	\$ 96.87	\$ 115.79	\$ 134.02	\$ 143.74
NASDAQ Pharmaceutical Index	\$ 93.12	\$ 101.69	\$ 112.10	\$ 112.36
	3/31/10	6/30/10	9/30/10	12/31/10
Cell Therapeutics, Inc.	\$ 385.71	\$ 271.43	\$ 278.57	\$ 264.29
NASDAQ Stock Index (U.S.)	\$ 151.95	\$ 134.41	\$ 151.13	\$ 170.17
NASDAQ Pharmaceutical Index	\$ 122.41	\$ 104.91	\$ 115.48	\$ 121.80
	3/31/11	6/30/11	9/30/11	12/31/11
Cell Therapeutics, Inc.	\$ 264.29	\$ 188.10	\$ 126.19	\$ 138.10
NASDAQ Stock Index (U.S.)	\$ 178.51	\$ 179.14	\$ 157.85	\$ 171.08
NASDAQ Pharmaceutical Index	\$ 127.92	\$ 136.25	\$ 117.99	\$ 130.38
	3/31/12	6/30/12	9/30/12	12/31/12
Cell Therapeutics, Inc.	\$ 157.14	\$ 69.05	\$ 57.62	\$ 30.95
NASDAQ Stock Index (U.S.)	\$ 207.55	\$ 195.16	\$ 207.92	\$ 202.40
NASDAQ Pharmaceutical Index	\$ 151.42	\$ 159.95	\$ 176.67	\$ 173.46
	3/31/13	6/30/13	9/30/13	12/31/13
Cell Therapeutics, Inc.	\$ 27.38	\$ 25.00	\$ 38.57	\$ 45.48
NASDAQ Stock Index (U.S.)	\$ 219.98	\$ 229.65	\$ 254.03	\$ 281.91
NASDAQ Pharmaceutical Index	\$ 207.21	\$ 221.14	\$ 263.90	\$ 285.96



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The data set forth below should be read in conjunction with Part II, 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.

	2013	Year ended December 31,				2009
		2012	2011	2010		
		(In thousands, except per share data)				
Consolidated Statements of Operations Data:						
Revenues:						
Product sales, net(1)	\$ 2,314	\$	\$	\$	\$	
License and contract revenue(2)	32,364			319	80	
Total revenues	34,678			319	80	
Operating costs and expenses, net:						
Cost of product sold(1)	137					
Research and development	33,624	33,201	34,900	27,031	30,179	
Selling, general and administrative	42,288	38,244	38,290	51,546	57,725	
Acquired in-process research and development(3)		29,108				
Restructuring charges and related gain on sale of assets, net					3,979	
Gain on sale of investment in joint venture					(10,244)	
Settlement expense (income)	155	944	(11,000)	145	4,710	
Total operating costs and expenses, net	76,204	101,497	62,190	78,722	86,349	
Loss from operations	(41,526)	(101,497)	(62,190)	(78,403)	(86,269)	
Other income (expense):						
Investment and other income (expense), net	(546)	(478)	1,545	1,095	43	
Interest expense	(1,026)	(56)	(870)	(2,208)	(4,716)	
Amortization of debt discount and issuance costs	(513)		(546)	(768)	(5,788)	
Foreign exchange gain (loss)	61	344	(558)	(521)	33	
Debt conversion expense				(2,031)		
Make-whole interest expense					(6,345)	
Gain on derivative liabilities, net					7,218	
Gain on exchange of convertible notes					7,381	
Equity loss from investment in joint venture					(1,204)	
Milestone modification expense					(6,000)	
Net loss before noncontrolling interest	(43,550)	(101,687)	(62,619)	(82,836)	(95,647)	
Noncontrolling interest	807	313	259	194	252	
Net loss attributable to CTI	\$ (42,743)	\$ (101,374)	\$ (62,360)	\$ (82,642)	\$ (95,395)	
Gain on restructuring of preferred stock					2,116	
Dividends and deemed dividends on preferred stock	(6,900)	(13,901)	(58,718)	(64,918)	(23,484)	
Net loss attributable to common shareholders	\$ (49,643)	\$ (115,275)	\$ (121,078)	\$ (147,560)	\$ (116,763)	
Basic and diluted net loss per common share(4)	\$ (0.43)	\$ (1.98)	\$ (3.53)	\$ (6.47)	\$ (7.64)	
Shares used in calculation of basic and diluted net loss per common share(4)						
	114,195	58,125	34,294	22,821	15,279	



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	2013	2012	December 31, 2011 (In thousands)	2010	2009
<b>Consolidated Balance Sheets Data:</b>					
Cash and cash equivalents	\$ 71,639	\$ 50,436	\$ 47,052	\$ 22,649	\$ 37,811
Working capital	60,446	37,644	33,291	(14,165)	(21,694)
Total assets(5)	93,723	73,713	62,239	53,592	69,595
7.5% convertible senior notes				10,215	10,102
5.75% convertible senior notes				12,093	11,677
4.0% convertible senior subordinated notes					40,363
Current portion of long-term debt(6)	3,155				
Other current liabilities	393	393	970	1,717	1,312
Long-term debt, less current portion(6)	10,152				
Other liabilities	5,657	4,641	2,985	4,206	1,861
Common stock purchase warrants	13,461	13,461	13,461	13,461	626
Series 14 convertible preferred stock			6,736		
Accumulated deficit (5)	(1,879,703)	(1,830,060)	(1,714,785)	(1,576,643)	(1,429,083)
Total shareholders' equity (deficit)	42,758	32,944	28,009	(5,145)	(18,769)

- (1) The amounts relate to commercial sales of our product PIXUVRI.
- (2) The amount in 2013 primarily relates to the license and development services revenue recognized in connection with the collaboration agreement with Baxter. See Note 14 of the Notes to Consolidated Financial Statements for additional information.
- (3) 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 5 of the Notes to Consolidated Financial Statements for additional information.
- (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-six and one-for-five reverse stock splits on May 15, 2011 and September 2, 2012, respectively. See Notes 1 and 19 of the Notes to Consolidated Financial Statements for a description of the computation of the number of shares and net loss per share.
- (5) Effective January 1, 2011, we adopted new guidance on goodwill impairment. See Note 4 of the Notes to Consolidated Financial Statements for additional information.
- (6) In March 2013, we entered into a Loan and Security Agreement with Hercules Technology Growth Capital, Inc. for a senior secured term loan. See Note 10 of the Notes to Consolidated Financial Statements for additional information.

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### **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 Part II 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, capital raising activities 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 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 E.U., for multiply relapsed or refractory aggressive NHL, and conducting a Phase 3 clinical trial program of pacritinib for the treatment of myelofibrosis that will support regulatory submission for approval in the U.S. and Europe.

Following is a summary of our present business, including the key elements of our product and product candidate portfolio and certain financial information. For additional details pertaining to these matters, please see the discussion in Part I, Item 1, Business.

### **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. In May 2012, the European Commission 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. PIXUVRI is the first approved treatment in the E.U. for patients with multiply relapsed or refractory aggressive B-cell NHL who have failed two or three prior lines of therapy. In connection with the conditional marketing authorization, we are conducting the required post-approval commitment trial, which compares pixantrone and rituximab with gemcitabine and rituximab in the setting of aggressive B-cell NHL.

As of the date of this filing, PIXUVRI was available in Austria, Denmark, Finland, Germany, Italy, France, Netherlands, Norway, Sweden and the U.K. We have established a commercial organization, including sales, marketing, supply chain management and reimbursement capabilities to commercialize PIXUVRI in the E.U. PIXUVRI is not approved in the U.S. We are pursuing potential partners for commercializing PIXUVRI in other markets outside the E.U. and the U.S.

In almost all European markets, pricing and availability of prescription pharmaceuticals are subject to governmental control. Decisions by governmental authorities will impact the price and market acceptance of PIXUVRI. Accordingly, any future revenues are dependent on market acceptance of PIXUVRI, the

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reimbursement decisions made by the governmental authorities in each country where PIXUVRI is available for sale and other factors. In the third quarter 2013, PIXUVRI was granted market access in Italy and France. In December 2013, we reached agreement for funding and reimbursement with the National Association of Statutory Health Insurance Funds, or the GKV-Spitzenverband, in Germany. In February 2014, PIXUVRI received final guidance for funding and reimbursement from the National Institute for Health and Care Excellence, or NICE, in England/Wales.

In January 2014, we reached an agreement with Novartis to reacquire rights to PIXUVRI, as well as Opaxio. In exchange for Novartis' agreement to return such rights to us, which we had previously granted to Novartis in September 2006, we agreed to make certain potential payments to Novartis. For additional information on this agreement, please see the discussion in Part I, Item 1, Business License Agreements and Additional Milestone Activities Novartis.

### *Pacritinib*

In May 2012, we expanded our late-stage pipeline of product candidates with the acquisition of pacritinib, an oral, JAK2/FLT3 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.

In November 2013, we entered into a worldwide license agreement with Baxter to develop and commercialize pacritinib. Pursuant to the Baxter Agreement, we have joint commercialization rights with Baxter for pacritinib in the U.S., while Baxter has exclusive commercialization rights for all indications outside the U.S. Under the terms of the Baxter Agreement, we received a \$60 million upfront payment, which includes an equity investment of \$30 million, and potential to receive \$302 million in clinical, regulatory, commercial launch and sales milestones. Additionally, we will share U.S. profits equally and will receive royalties on net sales of pacritinib in the non-U.S. markets. We will be responsible for U.S. and E.U. development costs incurred on or after January 1, 2014 of approximately \$96 million, which we expect will be partially offset by up to \$67 million in potential cash milestone progress payments from Baxter through 2015, with additional success based milestone payments possible thereafter. For additional information on our agreement with Baxter, please see the discussion in Part I, Item 1, Business Overview, and Part I, Item 1, Business License Agreements and Additional Milestone Activities Baxter.

As part of the new collaboration with Baxter, we are pursuing a broad approach to advancing this therapy for myelofibrosis patients through two Phase 3 clinical trials: one in a broad set of patients without limitations on blood platelet counts, the PERSIST-1 trial, which was initiated in January 2013 and the other in patients with low platelet counts, the PERSIST-2 trial, which opened for enrollment in March 2014.

### *Financial summary*

Our product sales are currently generated solely from the sales of PIXUVRI in the E.U. We recorded \$0.5 million in total net product sales for the fourth quarter of 2013 and \$2.3 million for the full-year ended December 31, 2013. Our product sales may vary significantly from period to period as the commercialization and reimbursement negotiations for PIXUVRI progress. Our income from operations for the fourth quarter was \$10.3 million and a loss of \$41.5 million for the full-year ended December 31, 2013 compared to a loss of \$18.9 million and \$101.5 million respectively for the same periods in 2012. Our results of operations may vary substantially from year to year and from quarter to quarter and, as a result, you should not rely on them as being indicative of our future performance.

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As of December 31, 2013, we had cash and cash equivalents of \$71.6 million. See the discussion in Part II, Item 8, Financial Statements and Supplementary Data for further information relating to our senior secured term loan agreement.

## Results of Operations

Years ended December 31, 2013 and 2012.

**Product sales, net.** Net product sales for the year ended December 31, 2013 were \$2.3 million from the sales of PIXUVRI. There were no product sales of PIXUVRI for the year ended December 31, 2012, as the European Commission granted conditional marketing authorization of PIXUVRI in May 2012, and CTI was dependent on governmental authorities in each country for pricing and market acceptance of PIXUVRI. We sell PIXUVRI directly to health care providers and through a limited number of wholesale distributors in the E.U. We generally record product sales upon receipt of the product by the health care provider or distributor at which time title and risk of loss pass. Product sales are recorded net of distributor discounts, estimated government-mandated rebates, trade discounts and estimated product returns. Any future revenues are dependent on market acceptance of PIXUVRI, the reimbursement decisions made by governmental authorities in each country where PIXUVRI is available for sale and other factors.

A reconciliation of gross to net product sales for the year ended December 31, 2013 (in thousands) follows.

	2013(1)
Product sales, gross	\$ 2,935
Discounts, rebates and other adjustments	(582)
Returns reserve	(39)
Product sales, net	\$ 2,314(2)

(1) Fiscal 2012 has been omitted from this table, as there were no product sales during such year.

(2) Of our product sales, 67 percent was made to a single customer. See Note 18 to the Notes to Consolidated Financial Statements for additional information relating to our customer concentration.

As of December 31, 2013, the balance from activity in returns, discounts and rebates is reflected in *accounts receivable* and *accrued expenses*. Balances and activity for the components of our gross to net sales adjustments for the year ended December 31, 2013 are as follows (in thousands):

	Product returns	Discounts, rebates and other	Total
Balance at December 31, 2012(1)			
Provision for current year sales	39	582	621
Adjustments for prior period sales			
Payments/credits for current year sales		(405)	(405)
Payments/credits for prior period sales			
Balance at December 31, 2013	\$ 39	\$ 177	\$ 216

(1) Fiscal 2012 has been omitted from this table, as there were no product sales during such year.

**License and contract revenue.** License and contract revenue for the year ended December 31, 2013 was related to \$27.4 million of license and development services revenue recognized in connection with the collaboration agreement with Baxter (see Note 14 to the Notes to Consolidated Financial Statements) as well as the \$5.0 million milestone payment received from Teva upon the achievement of a worldwide net sales

milestone of TRISENOX. There was no license and contract revenue for the same period in 2012.

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**Cost of product sold.** Cost of product sold for the year ended December 31, 2013 was \$0.1 million related to sales of PIXUVRI. There were no product sales or related cost of product sold for the same period in 2012. We began capitalizing costs related to the production of PIXUVRI in February 2012 upon receiving a positive opinion for conditional approval by The Committee for Medicinal Products for Human Use, or the CHMP, which is a committee of the EMA. The manufacturing costs of PIXUVRI product prior to receipt of the CHMP's positive opinion were expensed as research and development as incurred. While we tracked the quantities of individual PIXUVRI product lots, we did not track manufacturing costs prior to capitalization, and therefore, the manufacturing costs of PIXUVRI produced prior to capitalization are not reasonably determinable. Most of this reduced-cost inventory is expected to be available for us to use commercially. The timing of the sales of such reduced-cost inventory and its impact on gross margin is dependent on the level of PIXUVRI sales as well as our ability to utilize this inventory prior to its expiration date. We expect that our cost of product sold as a percentage of product sales will increase in future periods as PIXUVRI product manufactured and expensed prior to capitalization is sold. At this time, we cannot reasonably estimate the timing or rate of consumption of reduced-cost PIXUVRI product manufactured and expensed prior to capitalization.

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

	2013	2012
Compounds under development:		
PIXUVRI	\$ 3,889	\$ 8,801
Pacritinib	10,466	2,217
Opaxio	1,127	1,322
Tosedostat	985	2,824
Brostallicin	24	234
Operating expenses	16,711	17,653
Research and preclinical development	422	150
<b>Total research and development expenses</b>	<b>\$ 33,624</b>	<b>\$ 33,201</b>

Costs for our compounds 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, the EMA or other regulatory agencies outside the U.S. and Europe, as well as upfront license fees for acquired technology. Subsequent to receiving a positive opinion for conditional approval of PIXUVRI in the E.U. from the EMA's CHMP, costs associated with commercial batch production, quality control, stability testing, and certain other manufacturing costs of PIXUVRI were capitalized as inventory. Operating expenses include our personnel and an allocation of occupancy, depreciation and amortization expenses associated with developing these compounds. Research and preclinical development costs primarily include costs associated with external laboratory services associated with other compounds. We are not able to capture the total cost of each compound because we do not allocate operating expenses to all of our compounds. External direct costs incurred by us as of December 31, 2013 were \$86.2 million for PIXUVRI (excluding costs prior to our merger with Novuspharma S.p.A, a public pharmaceutical company located in Italy, in January 2004), \$12.7 million for pacritinib (excluding costs for pacritinib prior to our acquisition of certain assets from S\*Bio in May 2012 and \$29.1 million of in-process research and development expenses associated with the acquisition of certain assets from S\*Bio), \$227.0 million for Opaxio, \$10.8 million for tosedostat (excluding costs for tosedostat prior to our co-development and license agreement with Chroma) and \$9.6 million for brostallicin (excluding costs for brostallicin prior to our acquisition of Systems Medicine, LLC in July 2007).

Research and development expenses increased to \$33.6 million for the year ended December 31, 2013 from \$33.2 million for the year ended December 31, 2012. PIXUVRI costs decreased primarily due to a reduction in clinical development costs associated with the PIX306 trial, our on-going confirmatory trial in the E.U., as well as a reduction in regulatory consulting costs. These decreases were partially offset by an increase in medical affairs and pharmacovigilance activities in the E.U. Costs for pacritinib increased primarily due to clinical



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development costs associated with site initiation, patient enrollment and other costs associated with the PERSIST-1 trial, in addition to start-up costs associated with the PERSIST-2 trial. Costs associated with pacritinib manufacturing also increased between periods. Costs for our Opaxio program decreased primarily due to an adjustment in clinical development milestone activity associated with a contract amendment related to the GOG-0212 trial of Opaxio in patients with ovarian cancer, in addition to a reduction in patient enrollment in ISTs. Development costs for tosedostat decreased primarily due to the compound being placed on partial clinical hold which was lifted in December 2013. Operating expenses included in research and development expenses decreased primarily due to a reduction in occupancy costs associated with the relocation of our corporate office. This decrease was partially offset by an increase in noncash share-based compensation expense, employee termination costs and other personnel related expenses.

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 will need to commit significant time and resources to develop our current and any future product candidates. Our drug candidates pacritinib, tosedostat and Opaxio are currently in clinical development, and our product PIXUVRI, which is currently being commercialized in parts of Europe, is undergoing a post-approval commitment study. Many drugs in human clinical trials fail to demonstrate the desired safety and efficacy characteristics. We are unable to provide the nature, timing and estimated costs of the efforts necessary to complete the development of pacritinib, tosedostat and Opaxio, and to complete the post-approval commitment study of PIXUVRI, because, among other reasons, we cannot predict with any certainty the pace of patient enrollment of our clinical trials, 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. 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. We or regulatory authorities may suspend clinical trials at any time on the basis that the participants are being exposed to unacceptable health risks. Even if our drugs progress successfully through initial human testing in clinical trials, 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. For these reasons, among others, we cannot estimate the date on which clinical development of our product candidates will be completed, if ever, or when we will generate material net cash inflows from PIXUVRI or be able to begin commercializing pacritinib, Opaxio and tosedostat to generate material net cash inflows. In order to generate revenue from these products, our product candidates need to be developed to a stage that will enable us to commercialize, sell or license related marketing rights to third parties.

We also enter into collaboration agreements for the development and commercialization of our product candidates. We cannot control the amount and timing of resources our collaborators devote to product candidates, which may also result in delays in the development or marketing of products. Because of these risks and uncertainties, we cannot accurately predict when or whether we will successfully complete the development of our product candidates or the ultimate product development cost.

The risks and uncertainties associated with completing development on schedule and the consequences to operations, financial position and liquidity if the project is not timely completed are discussed in more detail in the following risk factors, which begin on page 21 of this Annual Report on Form 10-K: *We may take longer to complete our clinical trials than we expect, or they may not be completed at all. ; We or our collaboration partners 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 or our collaboration partners may not be able to successfully commercialize them. ; Even if our products receive regulatory approval, 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. ; and Our financial condition may be harmed if third parties default in the performance of contractual obligations.*

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*Selling, general and administrative expenses.* Selling, general and administrative expenses increased to \$42.3 million for the year ended December 31, 2013 from \$38.2 million for the year ended December 31, 2012. This increase was primarily due to a \$3.8 million increase in selling and marketing expenses for PIXUVRI in the E.U., a \$1.3 million increase in compensation and benefits mainly related to an increase in the average number of personnel between comparable periods and a \$0.7 million increase in noncash share-based compensation. These increases were partially offset by a \$1.0 million decrease in administrative costs and a \$0.7 million decrease in legal and patent services.

*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. There was no acquired in-process research and development expense for the corresponding period in 2013.

*Settlement expense (income).* For the year ended December 31, 2013, we recorded \$0.2 million in settlement expense related to an agreement entered into with one of our former executive officers for severance payments and related benefits upon such officer's separation from us in the prior year and attorneys' fees in connection with a shareholder lawsuit. 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.

*Investment and other income (expense), net.* The expense amount for the year ended December 31, 2013 is primarily related to the change in fair value of the warrant issued to Hercules Technology Growth Capital, Inc. and loss on disposal of property and equipment. 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.

*Interest expense.* Interest expense increased to \$1.0 million for the year ended December 31, 2013 from \$0.1 million for the year ended December 31, 2012 primarily due to interest incurred on our long-term debt issued in 2013.

*Amortization of debt discount and issuance costs.* Amortization of debt discount and issuance costs of \$0.5 million for year ended December 31, 2013 is related to our long-term debt issued in 2013. We had no similar costs for the corresponding period in 2012.

*Foreign exchange gain (loss).* Foreign exchange gain for the year ended December 31, 2013 and gain for the year ended December 31, 2012 are due to fluctuations in foreign currency exchange rates, primarily related to payables and receivables in our European branches and subsidiaries denominated in foreign currencies.

*Dividends and deemed dividends on preferred stock.* Dividends and deemed dividends on preferred stock were approximately \$6.9 million for the year ended December 31, 2013 related to the issuance of our Series 18 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.

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*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):

	2012	2011
Compounds under development:		
PIXUVRI	\$ 8,801	\$ 11,266
Pacritinib	2,217	
Opaxio	1,322	1,445
Tosedostat	2,824	6,955
Brostallicin	234	75
Operating expenses	17,653	14,975
Research and preclinical development	150	184
<b>Total research and development expenses</b>	<b>\$ 33,201</b>	<b>\$ 34,900</b>

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 IST 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. Operating expenses included in research and development 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.

*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. There was no acquired in-process research and development expense for the corresponding period in 2011.

*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 a \$0.5 million expense for the year ended December 31, 2012 as compared to \$1.5 million in income for the year ended

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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 percent 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 percent convertible senior notes in April 2011 and 5.75 percent 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 percent convertible senior notes upon maturity in April 2011. There was no amortization of debt discount and issuance costs for the corresponding period in 2012.

*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 and subsidiaries 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.

## **Liquidity and Capital Resources**

*Cash and cash equivalents.* As of December 31, 2013, we had \$71.6 million in cash and cash equivalents.

*Net cash used in operating activities.* Net cash used in operating activities totaled \$35.8 million for the year ended December 31, 2013, compared to \$62.8 million for the year ended December 31, 2012 and \$60.5 million for the year ended December 31, 2011. The decrease in net cash used in operating activities for the year ended December 31, 2013 as compared to the year ended December 31, 2012 was primarily due to the \$30.0 million upfront payment received in connection with our collaboration agreement with Baxter in 2013, the \$5.0 million milestone payment received from Teva upon achievement of a worldwide net sales milestone of TRISENOX in 2013 and cash received from sales of PIXUVRI in 2013. This decrease was primarily offset by an increase in cash paid for inventory, cash paid for commercial activities related to PIXUVRI and cash paid for interest during the year ended December 31, 2013 as compared to December 31, 2012. 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.

*Net cash used in investing activities.* Net cash used in investing activities totaled \$1.5 million, as compared to \$20.7 million for the year ended December 31, 2012 and \$2.7 million for the year ended December 31, 2011. The decrease in net cash used in investing activities for the year ended December 31, 2013 was the result of \$17.8 million paid for the acquisition of assets from S\*Bio in 2012 and a decrease in purchases of property and equipment in 2013. The increase in net cash used in investing activities for the year ended December 31, 2012 was also the result of \$17.8 million paid for the acquisition of assets from S\*Bio.

*Net cash provided by financing activities.* Net cash provided by financing activities totaled \$59.0 million for the year ended December 31, 2013, as compared to \$87.2 million for the year ended December 31, 2012 and \$87.0 million for the year ended December 31, 2011. Net cash provided by financing activities for the year ended

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December 31, 2013 was primarily due to issuances of preferred stock, long-term debt and warrants. In March 2013, we entered into a Loan and Security Agreement with Hercules Technology Growth Capital, Inc. for a senior secured term loan of up to \$15.0 million. The first \$10.0 million was funded in March 2013, and we exercised our option to borrow an additional \$5.0 million in December 2013. We received \$14.9 million in net proceeds from the issuance of our Series 18 preferred stock in September 2013. We also received approximately \$30.0 million in net proceeds from the issuance of our Series 19 preferred stock in November 2013.

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 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.

### ***Capital Resources***

Our available cash and cash equivalents were \$71.6 million as of December 31, 2013. At our currently planned spending rate, we believe that our present financial resources, together with pacritinib milestone payments projected to be earned and received over the course of 2014 and 2015 under our collaboration with Baxter, and expected European sales from PIXUVRI, will be sufficient to fund our operations into the third quarter of 2015. 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 anticipated pacritinib milestone payments or sales from PIXUVRI. Due to these and other factors, our forecast for the period for which we will have sufficient resources to fund our business may fail.

### ***Capital Requirements***

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

changes in manufacturing;

results of and other developments with respect to our clinical trials;

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potential expansion of our sales and marketing organization in Europe;

activities with respect to regulatory approvals;

the extent to which we acquire, invest or divest products/product candidates, technologies or businesses, or sell or license our assets to others;

progress in and scope of our research and development activities;

ability to find appropriate partners for development and commercialization activities;

litigation and other disputes; and

competitive market developments.

We expect that we will need to raise additional funds to develop our business. 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. If additional funds are raised by issuing equity securities, substantial dilution to existing shareholders may result. 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, reduce our selling, general and administrative expenses and/or refrain from making our contractually required payments when due, which could harm our business, financial condition, operating results and prospects.

The following table includes information relating to our contractual obligations as of December 31, 2013 (in thousands):

Contractual Obligations	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating leases:					
Facilities	\$ 20,147	\$ 2,534	\$ 4,728	\$ 4,621	\$ 8,264
Long-term debt	15,000	3,556	11,444		
Interest on long-term debt (1)	3,122	1,710	1,412		
Purchase commitments (2)	1,484	1,381	102	1	
Other obligations (3)	1,412	131	1,281		
	\$ 41,165	\$ 9,312	\$ 18,967	\$ 4,622	\$ 8,264

(1) The interest rate on our long-term debt floats at a rate per annum equal to 12.25 percent plus the amount by which the prime rate exceeds 3.25 percent. The amounts presented for interest payments in future periods assume a prime rate of 3.25 percent.

(2) Purchase commitments include obligations related to manufacturing supply, insurance and other purchase commitments.

(3) Other obligations do not include \$4.8 million deferred rent associated with our operating lease for office space.

Some of our licensing agreements obligate us to pay a royalty on net sales of licensed products. Such royalties are dependent on future product sales and are not provided for in the table above as they are not estimable. See Part I, Item 1, Business License Agreements and Additional Milestone Activities for additional information.

*Additional Milestone Activities*

In connection with our development and commercialization activities, we have entered into a number of agreements pursuant to which we have agreed to make milestone payments upon certain development, sales-based and other milestone events; assume certain development and other expenses; and pay designated royalties

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on sales, including the UVM Agreement, the S\*BIO Agreement, the Chroma License Agreement, the PG-TXL Agreement, the GOG Agreement, the Nerviano Agreement, the Termination Agreement with Novartis and our acquisition agreement with Cephalon. These agreements are discussed in more detail in Part I, Item 1, Business License Agreements and Additional Milestone Activities. As we have commenced commercial sales of PIXUVRI, we 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 Part I, 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 U.S. 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 estimates 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.

#### *Revenue Recognition*

Our license and collaboration agreements may contain multiple elements as evaluated under ASC 605-25, *Revenue Recognition Multiple-Element Arrangements*, including grants of licenses to know-how and patents relating to our product candidates as well as agreements to provide research and development services, regulatory services, manufacturing and commercialization services. Each deliverable under the agreement is evaluated to determine whether it qualifies as a separate unit of accounting based on whether the deliverable has standalone value to the customer. The arrangement's consideration that is fixed or determinable is then allocated to each separate unit of accounting based on the relative selling price of each deliverable. This evaluation requires



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subjective determinations and requires us to make judgments about the selling price of the individual elements and whether such elements are separable from the other aspects of the contractual relationship. Upfront payments for licenses are evaluated to determine if the licensee can obtain standalone value from the license separate from the value of the research and development services and other deliverables in the arrangement to be provided by us. The assessment of multiple element arrangements also requires judgment in order to determine the allocation of revenue to each deliverable and the appropriate point in time, or period of time, that revenue should be recognized. If we determine that the license does not have standalone value separate from the research and development services, the license and the services are combined as one unit of accounting and upfront payments are recorded as deferred revenue in the balance sheet and are recognized as revenue over the estimated performance period that is consistent with the term of performance obligations contained in the collaboration agreement. When standalone value is identified, the related consideration is recorded as revenue in the period in which the license or other intellectual property is delivered.

Our license and collaboration agreements may also contain milestone payments that become due to us upon achievements of certain milestones. Under the milestone method, we recognize revenue that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. A milestone is an event (i) that can be achieved in whole or in part on either our performance or on the occurrence of a specific outcome resulting from our performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due to us. A milestone payment is considered substantive when the consideration payable to us for each milestone (a) is consistent with our performance necessary to achieve the milestone or the increase in value to the collaboration resulting from our performance, (b) relates solely to our past performance and (c) is reasonable relative to all of the other deliverables and payments within the arrangement. In making this assessment, we consider all facts and circumstances relevant to the arrangement, including factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether any portion of the milestone consideration is related to future performance or deliverables.

### *Government-mandated discounts and rebates*

Our estimate for government-mandated discounts and rebates is based on actual discounts and rebates healthcare providers and distributors have claimed for reduced pricing as well as statutorily-defined discount rates.

### *Product returns and other deductions*

We offer certain distributors a limited right of return or replacement on product that is damaged in certain instances. Product returned is not resalable given the nature of our product and method of administration. We have developed estimates for product returns based upon historical industry information regarding product return rates for other specialty pharmaceutical products, inventory levels in the distribution channel and other relevant factors. To date, there have been no PIXUVRI product returns. We monitor inventory levels in the distribution channel, as well as sales of PIXUVRI by certain distributors to healthcare providers, using product-specific data provided by those distributors. If necessary, our estimates of product returns or replacements may be adjusted in the future.

For other deductions, we have written contracts with certain distributors that include terms for distribution-related discounts. We record distribution discounts based on the number of units sold to those distributors.

### *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

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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 long term performance awards, or the Long-Term Performance Awards, discussed in Note 15 of the Notes to Consolidated Financial Statements contained herein, we employ a Monte Carlo simulation model to calculate estimated grant-date fair value. For the Long-Term 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 Financial Accounting Standards Board, or 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 4, *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.

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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 was effective prospectively for reporting periods beginning after December 15, 2012. The adoption of this guidance did not have a material impact on our consolidated financial statements.

### **Recently Issued Accounting Standards**

In March 2013, the FASB issued guidance to clarify when to release cumulative foreign currency translation adjustments when an entity ceases to have a controlling financial interest in a subsidiary or group of assets within a foreign entity. The amendment is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013 and should be applied prospectively to derecognition events occurring after the effective date. Early adoption is permitted. We do not expect the adoption of this guidance to have a material impact on our consolidated financial statements.

In July 2013, the FASB issued guidance on the presentation of an unrecognized tax benefit when a net operating loss carryforward, similar tax loss or tax carryforward exists. FASB concluded that an unrecognized tax benefit should be presented as a reduction of a deferred tax asset except in certain circumstances where the unrecognized tax benefit should be presented as a liability and should not be combined with deferred tax assets. The amendment is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013, with early adoption permitted. We are currently evaluating the impact this amendment may have 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. 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 compared to the euro. As of December 31, 2013, 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 percent against the dollar, our net asset balance would decrease by approximately \$2.3 million as of this date.

#### *Interest Rate Risk*

In March 2013, we entered into our senior secured term loan, which had an outstanding balance of \$15.0 million as of December 31, 2013. The senior secured term loan bears interest at variable rates. Based on the outstanding amount under such loan at December 31, 2013 of \$15.0 million, and assuming such amount had been outstanding as of January 1, 2013, a one percent increase in interest rates would result in additional annualized interest expense of \$0.1 million. For a detailed discussion of our senior secured term loan, including a discussion of the applicable interest rate, please refer to Note 10, *Long-term Debt*, under Item 8 of Part II in this Annual Report on Form 10-K.

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

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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, 2013 and 2012, and the related consolidated statements of operations, comprehensive loss, shareholders' equity and cash flows for the years ended December 31, 2013, 2012 and 2011. 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, 2013 and 2012, and the consolidated results of its operations and cash flows for the years ended December 31, 2013, 2012 and 2011 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 Therapeutic, Inc.'s internal control over financial reporting as of December 31, 2013, based on the criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 1992 and our report dated March 4, 2014 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ Marcum LLP

San Francisco, CA

March 4, 2014

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**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 Therapeutic, Inc.'s (the "Company") internal control over financial reporting as of December 31, 2013, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 1992. 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, 2013, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 1992.

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, 2013 and 2012 and the related consolidated statements of income, shareholders' equity, and cash flows for the years ended December 31, 2013, 2012 and 2011 of the Company and our report dated March 4, 2014 expressed an unqualified opinion on those financial statements.

/s/ Marcum LLP

San Francisco, CA

March 4, 2014

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

	December 31, 2013	December 31, 2012
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 71,639	\$ 50,436
Accounts receivable	235	
Inventory	5,074	1,626
Prepaid expenses and other current assets	3,567	8,249
Total current assets	80,515	60,311
Property and equipment, net	5,478	6,785
Other assets	7,730	6,617
Total assets	\$ 93,723	\$ 73,713
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 5,051	\$ 12,065
Accrued expenses	9,469	10,209
Warrant liability	991	
Current portion of deferred revenue	1,010	
Current portion of long-term debt	3,155	
Other current liabilities	393	393
Total current liabilities	20,069	22,667
Deferred revenue, less current portion	1,626	
Long-term debt, less current portion	10,152	
Other liabilities	5,657	4,641
Total liabilities	37,504	27,308
Commitments and contingencies		
Common stock purchase warrants	13,461	13,461
Shareholders' equity:		
Common stock, no par value:		
Authorized shares 215,000,000 and 150,000,000 at December 31, 2013 and 2012, respectively		
Issued and outstanding shares 145,508,767 and 109,823,748 at December 31, 2013 and 2012, respectively	1,933,305	1,872,885
Accumulated other comprehensive loss	(8,429)	(8,273)
Accumulated deficit	(1,879,703)	(1,830,060)
Total CTI shareholders' equity	45,173	34,552
Noncontrolling interest	(2,415)	(1,608)
Total shareholders' equity	42,758	32,944
Total liabilities and shareholders' equity	\$ 93,723	\$ 73,713

See accompanying notes.





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

	Year Ended December 31,		
	2013	2012	2011
Revenues:			
Product sales, net	\$ 2,314	\$	\$
License and contract revenue	32,364		
Total revenues	34,678		
Operating costs and expenses, net:			
Cost of product sold	137		
Research and development	33,624	33,201	34,900
Selling, general and administrative	42,288	38,244	38,290
Acquired in-process research and development		29,108	
Settlement expense (income)	155	944	(11,000)
Total operating costs and expenses, net	76,204	101,497	62,190
Loss from operations	(41,526)	(101,497)	(62,190)
Other income (expense):			
Investment and other income (expense), net	(546)	(478)	1,545
Interest expense	(1,026)	(56)	(870)
Amortization of debt discount and issuance costs	(513)		(546)
Foreign exchange gain (loss)	61	344	(558)
Total other expense, net	(2,024)	(190)	(429)
Net loss before noncontrolling interest	(43,550)	(101,687)	(62,619)
Noncontrolling interest	807	313	259
Net loss attributable to CTI	(42,743)	(101,374)	(62,360)
Dividends and deemed dividends on preferred stock	(6,900)	(13,901)	(58,718)
Net loss attributable to common shareholders	\$ (49,643)	\$ (115,275)	\$ (121,078)
Basic and diluted net loss per common share	\$ (0.43)	\$ (1.98)	\$ (3.53)
Shares used in calculation of basic and diluted net loss per common share	114,195	58,125	34,294

See accompanying notes.

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**CELL THERAPEUTICS, INC.**

**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

**(In thousands)**

	<b>Year Ended December 31,</b>		
	<b>2013</b>	<b>2012</b>	<b>2011</b>
Net loss before noncontrolling interest	\$ (43,550)	\$ (101,687)	\$ (62,619)
Other comprehensive income (loss):			
Foreign currency translation adjustments	31	(168)	241
Net unrealized loss on securities available-for-sale	(187)	(70)	(307)
Other comprehensive loss	(156)	(238)	(66)
Comprehensive loss	(43,706)	(101,925)	(62,685)
Comprehensive loss attributable to noncontrolling interest	807	313	259
Comprehensive loss attributable to CTI	\$ (42,899)	\$ (101,612)	\$ (62,426)

See accompanying notes.

**Table of Contents****CELL THERAPEUTICS, INC.****CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY (DEFICIT)****(In thousands)**

	Preferred Stock		Common Stock			Accumulated Other Comprehensive	Noncontrolling Interest	Total Shareholders Equity (Deficit)
	Shares	Amount	Shares	Amount	Accumulated Deficit	Income (Loss)		
Balance at December 31, 2010		\$	27,125	\$ 1,579,866	\$ (1,576,643)	\$ (7,969)	\$ (399)	\$ (5,145)
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	10	\$ 6,736	40,614	\$ 1,744,801	\$ (1,714,785)	\$ (8,035)	\$ (708)	\$ 28,009

See accompanying notes.

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

(In thousands)

	Preferred Stock		Common Stock		Accumulated	Accumulated	Other	Noncontrolling	Total
	Shares	Amount	Shares	Amount	Deficit	Income	Comprehensive	Interest	Shareholders
						(Loss)			Equity
									(Deficit)
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
Issuance of Series 18 preferred stock, net of transaction costs	15	14,859							14,859
Conversion of Series 18 preferred stock to common stock	(15)	(14,859)	15,000	14,859					
Issuance of Series 19 preferred stock, net of transaction costs	30	29,840							29,840
Conversion of Series 19 preferred stock to common stock	(30)	(29,840)	15,674	29,840					
Value of beneficial conversion features related to preferred stock				6,900					6,900
Equity-based compensation			5,207	9,066					9,066
Noncontrolling interest								(807)	(807)
Other			(196)	(245)					(245)
Dividends and deemed dividends on preferred stock					(6,900)				(6,900)
Net loss for the year ended December 31, 2013					(42,743)				(42,743)
Other comprehensive loss						(156)			(156)

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Balance at December 31, 2013	145,509	\$ 1,933,305	\$ (1,879,703)	\$ (8,429)	\$ (2,415)	\$ 42,758
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See accompanying notes.

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

	<b>Year Ended December 31,</b>		
	<b>2013</b>	<b>2012</b>	<b>2011</b>
<b>Operating activities</b>			
Net loss	\$ (43,550)	\$ (101,687)	\$ (62,619)
Adjustments to reconcile net loss to net cash used in operating activities:			
Acquired in-process research and development		29,108	
Equity-based compensation expense	9,066	7,938	5,017
Depreciation and amortization	1,570	2,346	2,411
Noncash interest expense	513		546
Provision for VAT assessments		(3,402)	
Other	365	5	(1,958)
Changes in operating assets and liabilities:			
Accounts receivable	(227)		
Inventory	(3,254)	(1,586)	
Prepaid expenses and other current assets	4,530	(3,759)	567
Other assets	(846)	1,495	(2,452)
Accounts payable	(5,774)	3,123	(310)
Accrued expenses	(834)	(885)	(211)
Deferred revenue	2,636		
Other liabilities	(25)	4,528	(1,449)
<b>Total adjustments</b>	<b>7,720</b>	<b>38,911</b>	<b>2,161</b>
<b>Net cash used in operating activities</b>	<b>(35,830)</b>	<b>(62,776)</b>	<b>(60,458)</b>
<b>Investing activities</b>			
Purchases of property and equipment	(1,657)	(2,937)	(2,703)
Proceeds from sales of property and equipment	123		31
Cash paid for acquisition of assets from S* <i>BIO</i> Pte Ltd.		(17,764)	
<b>Net cash used in investing activities</b>	<b>(1,534)</b>	<b>(20,701)</b>	<b>(2,672)</b>
<b>Financing activities</b>			
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	(105)	54,744	
Proceeds from issuance of Series 18 preferred stock, net of issuance costs	14,859		
Proceeds from issuance of Series 19 preferred stock, net of issuance costs	29,961		
Proceeds from issuance of long-term debt, net	14,501		
Repayment of 7.5% convertible senior notes			(10,250)
Repayment of 5.75% convertible senior notes			(10,913)
Other	(244)	(214)	(424)

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Net cash provided by financing activities	58,972	87,216	87,004
Effect of exchange rate changes on cash and cash equivalents	(405)	(355)	529
Net increase in cash and cash equivalents	21,203	3,384	24,403
Cash and cash equivalents at beginning of year	50,436	47,052	22,649
Cash and cash equivalents at end of year	\$ 71,639	\$ 50,436	\$ 47,052

See accompanying notes.



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

	<b>Year Ended December 31,</b>		
	<b>2013</b>	<b>2012</b>	<b>2011</b>
<b>Supplemental disclosure of cash flow information</b>			
Cash paid during the period for interest	\$ 933	\$ 16	\$ 1,025
Cash paid for taxes	\$	\$	\$
<b>Supplemental disclosure of noncash financing and investing activities</b>			
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	\$
Conversion of Series 18 preferred stock to common stock	\$ 14,859	\$	\$
Conversion of Series 19 preferred stock to common stock	\$ 29,840	\$	\$
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*BIO 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.



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

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

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

###### *Description of Business*

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 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 adult patients with multiply relapsed or refractory aggressive non-Hodgkin lymphoma, or NHL, and conducting a Phase 3 clinical program of pacritinib for the treatment of patients with myelofibrosis. As of the date of this filing, PIXUVRI was available in Austria, Denmark, Finland, France, Germany, Italy, Netherlands, Norway, Sweden and the United Kingdom.

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

###### *Principles of Consolidation*

The consolidated financial statements include the accounts of CTI and its wholly-owned subsidiaries, which include Systems Medicine LLC, or SM, 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, 2013, 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).

###### *Capital Requirements*

We expect that we will need to raise additional funds to develop our business. 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

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best interest of the shareholders. If additional funds are raised by issuing equity securities, substantial dilution to existing shareholders may result. 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, reduce our selling, general and administrative expenses and/or refrain from making our contractually required payments when due.

### *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 reserves for sales deductions such as rebates and returns of product sold, allowances for credit losses, excess and obsolete inventory, 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 Uncertainties*

Our results of operations are subject to foreign currency exchange rate fluctuations primarily due to our activity in Europe. We report the results of our operations in U.S. dollars, while the functional currency of our foreign subsidiaries is the euro. 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 review our foreign currency risk periodically along with hedging options to mitigate such risk.

Financial instruments which potentially subject us to concentrations of credit risk consist of accounts receivable. The Company has accounts receivable from the sale of PIXUVRI from a small number of distributors and health care providers. Further, the Company does not require collateral on amounts due from its distributors and is therefore subject to credit risk. The Company has not experienced any significant credit losses to date as a result of credit risk concentration and does not consider an allowance for doubtful accounts to be necessary.

Additionally, see Note 18, *Customer and Geographic Concentrations*, for further concentration disclosure.

### *Concentrations*

We source our drug products for commercial operations and clinical trials from a concentrated group of third party contractors. 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.

### *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.

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### *Accounts Receivable*

Our accounts receivable balance includes trade receivables related to PIXUVRI sales as of December 31, 2013. We estimate an allowance for doubtful accounts based upon the age of outstanding receivables and our historical experience of collections, which includes adjustments for risk of loss for specific customer accounts. We periodically review the estimation process and make changes to our assumptions as necessary. When it is deemed probable that a customer account is uncollectible, the account balance is written off against the existing allowance. We also consider the customers' country of origin to determine if an allowance is required based on the uncertainty associated with the recent European financial crisis. As of December 31, 2013, our accounts receivable did not include any balance from a customer in a country that has exhibited financial stress that would have had a material impact on our financial results. We did not record an allowance for doubtful accounts as of December 31, 2013.

### *Value Added Tax Receivable*

Our European operations are subject to a value added tax, or VAT, which is usually applied to all goods and services purchased and sold throughout Europe. The VAT receivable is approximately \$5.7 million and \$8.1 million as of December 31, 2013 and 2012, of which \$5.6 million and \$5.1 million is included in *other assets* and \$0.1 million and \$3.0 million is included in *prepaid expenses and other current assets* as of December 31, 2013 and 2012, 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, 2013, the VAT receivable related to operations in Italy is approximately \$5.6 million. We review our VAT receivable balance for impairment whenever events or changes in circumstances indicate the carrying amount might not be recoverable.

### *Inventory*

We began capitalizing costs related to the production of PIXUVRI in February 2012 upon receiving a positive opinion for conditional approval by the EMA's Committee for Medicinal Products for Human Use, or CHMP, at which time the likelihood of receiving conditional approval to market PIXUVRI in the E.U. was deemed probable. Production costs for our other product candidates continue to be charged to research and development expense as incurred prior to regulatory approval or until our estimate for regulatory approval becomes probable. We carry inventory at the lower of cost or market. The cost of finished goods and work in process is determined using the standard-cost method, which approximates actual cost based on a first-in, first-out method. Inventory includes the cost of materials, third-party contract manufacturing and overhead costs, quality control costs and shipping costs from the manufacturers to the final distribution warehouse associated with the production and distribution of PIXUVRI. We regularly review our inventories for impairment and reserves are established when necessary. Estimates of excess inventory consider our projected sales of the product and the remaining shelf lives of product. In the event we identify excess, obsolete or unsaleable inventory, the value is written down to the net realizable value.

### *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

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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 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.

### *Fair Value Measurement*

Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Fair value measurements are based on a three-tier hierarchy that prioritizes the inputs used to measure fair value. There are three levels of inputs used to measure fair value with Level 1 having the highest priority and Level 3 having the lowest:

*Level 1* Observable inputs, such as unadjusted quoted prices in active markets for identical assets or liabilities.

*Level 2* Observable inputs other than Level 1 inputs, such as quoted prices for similar assets or liabilities, or other inputs that are observable directly or indirectly.

*Level 3* Unobservable inputs that are supported by little or no market activity, requiring an entity to develop its own assumptions.

If the inputs used to measure the financial assets and liabilities fall within more than one level described above, the categorization is based on the lowest level input that is significant to the fair value measurement of the instrument.

### *Financial Instruments*

At December 31, 2013 and 2012, the carrying value of financial instruments such as receivables and payables approximated their fair values based on the short-term maturities of these instruments. The carrying value of our long-term debt approximated its fair value at December 31, 2013 based on borrowing rates for similar loans and maturities.

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### *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 14, *Collaboration, Licensing and Milestone Agreements* and Note 21, *Legal Proceedings*, for further information regarding our current gain and loss contingencies.

### *Revenue Recognition*

We currently have conditional approval to market PIXUVRI in the E.U. Revenue is recognized when there is persuasive evidence of the existence of an agreement, delivery has occurred, prices are fixed or determinable, and collectability is assured. Where the revenue recognition criteria are not met, we defer the recognition of revenue by recording deferred revenue until such time that all criteria under the provision are met.

### Product Sales

We sell PIXUVRI directly to health care providers and through a limited number of distributors. We generally record product sales upon receipt of the product by the health care providers and certain distributors at which time title and risk of loss pass. Product sales are recorded net of distributor discounts, estimated government-mandated rebates, trade discounts, and estimated product returns. Reserves are established for these deductions and actual amounts incurred are offset against the applicable reserves. We reflect these reserves as either a reduction in the related account receivable or as an accrued liability depending on the nature of the sales deduction. These estimates are periodically reviewed and adjusted as necessary.

### Government-mandated discounts and rebates

Our products are subject to certain programs with government entities in the E.U. whereby pricing on products is discounted below distributor list price to participating health care providers. These discounts are provided to participating health care providers either at the time of sale or through a claim by the participating health care providers for a rebate. Due to estimates and assumptions inherent in determining the amount of government discounts and rebates, the actual amount of future claims may be different from our estimates, at which time we would adjust our reserves accordingly.

### Product returns and other deductions

At the time of sale, we also record estimates for certain sales deductions such as product returns and distributor discounts and incentives. We offer certain distributors a limited right of return or replacement of product that is damaged in certain instances. When we cannot reasonably estimate the amount of future product returns and/or other sales deductions, we do not recognize revenue until the risk of product return and additional sales deductions have been substantially eliminated. To date, there have been no PIXUVRI product returns.

### Collaboration agreements

We evaluate collaboration agreements to determine whether the multiple elements and associated deliverables can be considered separate units of accounting in accordance with ASC 605-25 *Revenue Recognition – Multiple-Element Arrangements*. If it is determined that the deliverables under the collaboration agreement are a single unit of accounting, all amounts received or due, including any upfront payments, are recognized as revenue over the performance obligation periods of each agreement. Following the completion of the performance obligation period, such amounts will be recognized as revenue when collectability is reasonably assured.

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The assessment of multiple element arrangements requires judgment in order to determine the allocation of revenue to each deliverable and the appropriate point in time, or period of time, that revenue should be recognized. In order to account for these agreements, we identify deliverables included within the agreement and evaluate which deliverables represent separate units of accounting based on whether certain criteria are met, including whether the delivered element has standalone value to the collaborator. The consideration received is allocated among the separate units of accounting, and the applicable revenue recognition criteria are applied to each of the separate units.

Milestone payments under the collaboration agreement are generally aggregated into three categories for reporting purposes: (i) development milestones, (ii) regulatory milestones, and (iii) sales milestones. Development milestones are typically payable when a product candidate initiates or advances into different clinical trial phases. Regulatory milestones are typically payable upon submission for marketing approval with the U.S. Food and Drug Administration, or FDA, or other countries' regulatory authorities or on receipt of actual marketing approvals for the compound or for additional indications. Sales milestones are typically payable when annual sales reach certain levels.

At the inception of each agreement that includes milestone payments, we evaluate whether each milestone is substantive and at risk to both parties on the basis of the contingent nature of the milestone. This evaluation includes an assessment of whether (a) the consideration is commensurate with either (1) the entity's performance to achieve the milestone, or (2) the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, (b) the consideration relates solely to past performance and (c) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. We evaluate factors such as the scientific, regulatory, commercial and other risks that must be overcome to achieve the respective milestone, the level of effort and investment required to achieve the respective milestone and whether the milestone consideration is reasonable relative to all deliverables and payment terms in the arrangement in making this assessment. Non-refundable development and regulatory milestones that are expected to be achieved as a result of our efforts during the period of substantial involvement are considered substantive and are recognized as revenue upon the achievement of the milestone, assuming all other revenue recognition criteria are met.

### *Cost of Product Sold*

Cost of product sold includes third party manufacturing costs, shipping costs, contractual royalties, and other costs of PIXUVRI product sold. Cost of product sold also includes any necessary allowances for excess inventory that may expire and become unsalable. We did not record an allowance for excess inventory as of December 31, 2013.

### *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



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development costs paid to the collaborator are an addition to research and development expense. We expense upfront license payments related to acquired technologies that 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 4, *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

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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.

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 was effective prospectively for reporting periods beginning after December 15, 2012. The adoption of this guidance did not have a material impact on our consolidated financial statements.

*Recently Issued Accounting Standards*

In March 2013, the Financial Accounting Standards Board, or FASB, issued guidance to clarify when to release cumulative foreign currency translation adjustments when an entity ceases to have a controlling financial interest in a subsidiary or group of assets within a foreign entity. The amendment is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013 and should be applied prospectively to derecognition events occurring after the effective date. Early adoption is permitted. We do not expect the adoption of this guidance to have a material impact on our consolidated financial statements.

In July 2013, the FASB issued guidance on the presentation of an unrecognized tax benefit when a net operating loss carryforward, similar tax loss or tax carryforward exists. FASB concluded that an unrecognized tax benefit should be presented as a reduction of a deferred tax asset except in certain circumstances the unrecognized tax benefit should be presented as a liability and should not be combined with deferred tax assets. The amendment is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013, with early adoption permitted. We are currently evaluating the impact this amendment may have on our consolidated financial statements.

*Reclassifications*

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

**2. Inventory**

The components of inventories are composed of the following as of December 31, 2013 and 2012 (in thousands):

	2013	2012
Finished goods	\$ 601	\$ 220
Work-in-process	4,473	1,406
Total inventories	\$ 5,074	\$ 1,626

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

*Property and equipment* is composed of the following as of December 31, 2013 and 2012 (in thousands):

	2013	2012
Furniture and office equipment	\$ 10,913	\$ 11,743
Leasehold improvements	5,078	5,077
Lab equipment	143	411
	16,134	17,231
Less: accumulated depreciation and amortization	(10,656)	(10,446)
	\$ 5,478	\$ 6,785

Depreciation expense of \$1.6 million, \$2.3 million and \$2.4 million was recognized during 2013, 2012 and 2011, respectively.

**4. Goodwill**

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

The following table presents the effects of the cumulative-effect application (in thousands):

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

**5. 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. 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	2,764
Total initial purchase consideration	\$ 29,108

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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.

**6. Accrued Expenses**

*Accrued expenses* consisted of the following as of December 31, 2013 and 2012 (in thousands):

	2013	2012
Clinical and investigator-sponsored trial expenses	\$ 3,360	\$ 3,301
Employee compensation and related expenses	3,035	3,904
Insurance financing and accrued interest expenses	611	598
Legal expenses	573	268
Manufacturing expenses	225	247
Rebates and royalties	186	
Other	1,479	1,891
	\$ 9,469	\$ 10,209

**7. Leases***Lease Agreements*

We lease our office space under operating leases for our U.S. and European offices. Rent expense amounted to \$2.0 million, \$2.7 million and \$1.5 million for the years ended December 31, 2013, 2012 and 2011, 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. We had no receivable related to incentives for tenant improvements as of December 31, 2013.

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

Future minimum lease commitments for non-cancelable operating leases at December 31, 2013 are as follows (in thousands):

	<b>Operating Leases</b>
2014	\$ 2,534
2015	2,508
2016	2,220
2017	2,280
2018	2,341
Thereafter	8,264
<b>Total minimum lease commitments</b>	<b>\$ 20,147</b>

*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):

	<b>2005 Activities</b>	<b>2010 Activities</b>	<b>Total Excess Facilities Liability</b>
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	\$	\$	\$

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.

**8. Other Liabilities**

*Other liabilities* consisted of the following as of December 31, 2013 and 2012 (in thousands):

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	2013	2012
Deferred rent	\$ 4,769	\$ 5,003
Other long-term obligations	1,281	31
	6,050	5,034
Less: other current liabilities	(393)	(393)
	\$ 5,657	\$ 4,641

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The balance of deferred rent as of December 31, 2013 and 2012 relates to incentives for rent holidays and leasehold improvements associated with our operating lease for office space as discussed in Note 7, *Leases*. The balance of other long-term obligations includes a fee in the amount of \$1.3 million payable to Hercules Technology Growth Capital. See Note 10, *Long-term Debt*, for additional information.

**9. Convertible Notes**

The following tables summarize the changes in the principal balances of our convertible notes during the year ended December 31, 2011:

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

**10. Long-term Debt**

In March 2013, we entered into a Loan and Security Agreement with Hercules Technology Growth Capital, Inc., or HTGC, for a senior secured term loan of up to \$15.0 million. The first \$10.0 million was funded in March 2013, and we exercised our option to borrow an additional \$5.0 million in December 2013. The interest rate on the term loan floats at a rate per annum equal to 12.25% plus the amount by which the prime rate exceeds 3.25%. The term loan is repayable in 30 equal monthly installments of principal and interest (mortgage style) over 42 months, including an initial interest-only period of 12 months after closing. The loan obligations are secured by a first priority security interest on substantially all of our personal property except our intellectual property and subject to certain other exceptions. We paid a facility charge of \$150,000 at closing and a fee in the amount of \$1.3 million is payable to HTGC on the date on which the term loan is paid or becomes due and payable in full. We recorded debt discount of \$2.1 million, of which \$1.7 million is unamortized as of December 31, 2013. We recorded issuance costs of \$0.3 million, of which \$0.3 million is unamortized as of December 31, 2013.

In addition, we issued a warrant to HTGC to purchase shares of common stock. The warrant is exercisable for five years from the date of issuance for 0.7 million shares of common stock. The initial exercise price of the warrant is \$1.1045 per share of common stock. The exercise price and number of shares of common stock issuable upon exercise are subject to antidilution adjustments in certain events, including if within 12 months after closing the Company issues shares of common stock or securities that are exercisable or convertible into shares of common stock in transactions not registered under the Securities Act of 1933, as amended, at an effective price per share of common stock that is less than the exercise price of the warrant, then the exercise price shall automatically be reduced to equal the price per share of common stock in such transaction and the number of shares will be increased proportionately. Since the warrant did not meet the considerations necessary for equity classification in the applicable authoritative guidance, we determined the warrant is a liability instrument that is marked to fair value with changes in fair value recognized through earnings at each reporting period. As of the issuance date and December 31, 2013, we estimated the fair value of the warrant to be \$0.5 million and \$1.0 million, respectively. We classified the warrant as Level 2 in the fair value hierarchy as the significant inputs used in determining fair value are considered observable market data. In January 2014, all of the warrant was exercised into 0.5 million shares of common stock via cashless exercise.

**11. Preferred Stock**

Prior to the effective date of the Stock Splits, we completed several preferred stock transactions during the years 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 11,





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*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 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

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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, 2013, warrants to purchase 0.6 million shares of our common stock remained outstanding.

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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, 2013, 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, 2013, 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, 2013, 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, 2013, 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, 2013, 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.

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### *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.

**Table of Contents***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.

*Series 18 Preferred Stock*

In September 2013, we issued 15,000 shares of Series 18 preferred stock, or Series 18 Preferred Stock, for gross proceeds of \$15.0 million in a registered direct offering. Issuance costs related to this transaction were \$0.1 million. Each share of Series 18 Preferred Stock was entitled to a liquidation preference equal to the initial stated value of \$1,000 per share of Series 18 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 18 Preferred Stock was not entitled to dividends except to share in any dividends actually paid on common stock or any *pari passu* or junior securities. The Series 18 Preferred Stock had no voting rights except as otherwise expressly provided in the amended articles or as otherwise required by law. For the year ended December 31, 2013, we recognized \$6.9 million in *dividends and deemed dividends on preferred stock* related to the beneficial conversion feature on our Series 18 Preferred Stock. In September 2013, all 15,000 shares of Series 18 preferred stock were converted into 15.0 million shares of common stock at a conversion price of \$1.00 per share.

*Series 19 Preferred Stock*

See Note 14, *Collaboration, Licensing and Milestone Agreements - Baxter*, for information concerning our issuance of Series 19 Preferred Stock.

**12. Common Stock***Common Stock Reserved*

A summary of common stock reserved for issuance is as follows as of December 31, 2013 (in thousands):

Equity incentive plans	10,094
Common stock purchase warrants	7,697
Employee stock purchase plan	38
	17,829

*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, 2013. 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.



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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, 2013. 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, 2013. 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, 2013. 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, 2013. These warrants have an exercise price of \$51.00 per share and expire in April 2014.

See Note 10, *Long-term Debt*, and Note 11, *Preferred Stock*, for additional information concerning our warrants.

**13. 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, 2012	\$ (235)	\$ (8,038)	\$ (8,273)
Current period other comprehensive gain (loss)	(187)	31	(156)
December 31, 2013	\$ (422)	\$ (8,007)	\$ (8,429)

**14. Collaboration, Licensing and Milestone Agreements***Baxter*

In November 2013, we entered into a Development, Commercialization and License agreement (the *Agreement*) with Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA (collectively, *Baxter*) for the development and commercialization of pacritinib (the *Compound*) for use in oncology and potentially additional therapeutic areas. Under the Agreement, we granted to Baxter an exclusive, worldwide (subject to our certain co-promotion rights in the U.S.), royalty-bearing, non-transferable, and (under certain circumstances outside of the U.S.) sub-licensable license to its know-how and patents relating to the Compound. We received an upfront payment of \$60.0 million upon execution of the Agreement, which included an equity investment of \$30 million to acquire our Series 19 Preferred Stock as discussed below.

Under the Agreement, we may receive potential clinical, regulatory and commercial launch milestone payments of up to \$112.0 million and potential additional sales-based milestone payments of up to \$190.0 million. We have determined that all of the sales-based milestone payments are contingent consideration and will be accounted for as revenue in the period in which the respective revenue recognition criteria are met. We have also determined that all of the clinical, regulatory and commercial launch milestones are substantive and will be recognized as revenue upon the achievement of the milestone, assuming all other revenue recognition criteria are met.



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Under the Agreement, the Company and Baxter will jointly commercialize and share profits and losses on sales of the Compound in the U.S. Outside the U.S., the Company is also eligible to receive tiered high single digit to mid-teen percentage royalties based on net sales for myelofibrosis, and higher double-digit royalties for other indications, subject to reduction by up to 50% if (i) Baxter is required to obtain additional third party licenses, on which it is obligated to pay royalties, to fulfill its obligations under the Agreement, and (ii) in any jurisdiction where there is no longer either regulatory exclusivity or patent protection.

Under the Agreement, the Company is responsible for all development costs incurred prior to January 1, 2014 as well as approximately up to \$96.0 million on or after January 1, 2014 for U.S. and E.U. development costs, subject to potential upward or downward adjustment in certain circumstances. All development costs exceeding such threshold will generally be shared as follows: (i) costs generally applicable worldwide will be shared 75% to Baxter and 25% to the Company, (ii) costs applicable to territories exclusive to Baxter will be 100% borne by Baxter and (iii) costs applicable exclusively to co-promotion in the U.S. will be shared equally between the parties, subject to certain exceptions.

We record the development cost reimbursements received from Baxter as *license and contract revenue* in the statements of operations, and we record the full amount of development costs as research and development expense.

Pursuant to the accounting guidance under ASC 605-25 *Revenue Recognition – Multiple-Element Arrangements*, we have determined that the following non-contingent deliverables under the Agreement meet the criteria for separation and are therefore treated as separate units of accounting:

a license from the Company to develop and commercialize the Compound worldwide (subject to certain co-promotion rights of the Company in the U.S.); and

development services provided by the Company related to jointly agreed-upon development activities with cost sharing as discussed above.

Both of the above non-contingent deliverables have no general right of return and are determined to have standalone values.

The Agreement also requires Baxter and the Company to negotiate and enter into a Manufacturing and Supply Agreement, which will provide for the manufacture of the licensed products, with an option for Baxter to finish and package encapsulated bulk product, within 180 days of the Agreement. The Manufacturing and Supply Agreement is not considered as a deliverable at the inception of the arrangement because the critical terms such as pricing and quantities are not defined and delivery of the services will be dependent on successful clinical results that are uncertain.

Also under the Agreement, joint commercialization, manufacturing, development and steering committees with representatives from the Company and Baxter will be established. We have considered whether our participation on the joint development committees may be a separate deliverable and determined that it does not represent a separate unit of accounting as the committee's activities are primarily related to governance and oversight of development activities and are therefore combined with the development services. Our participation on the joint commercialization and manufacturing committees is also determined to be a non-deliverable.

We have also considered whether our regulatory roles under the Agreement constitute a separate deliverable and determined that it should also be combined with the development services.

The Agreement will expire when there is no longer any obligation for Baxter to pay royalties to us in any jurisdiction, at which time the licenses granted to Baxter will become perpetual and royalty-free. Either party may terminate the Agreement prior to expiration in certain circumstances. The Company may terminate the Agreement if Baxter has not undertaken requisite regulatory or commercialization efforts in the applicable countries and certain other conditions are met. Baxter may terminate the Agreement prior to expiration in certain

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circumstances including (i) in the event development costs for myelofibrosis for the period commencing January 1, 2014 are reasonably projected to exceed a specified threshold, (ii) as to some or all countries in the event of commercial failure of the licensed product or (iii) without cause following the one-year anniversary of the Agreement date, provided that such termination will have a lead-in period of six months before it becomes effective. Additionally, either party may terminate the Agreement in events of force majeure, or the other party's uncured material breach or insolvency. In the event of a termination prior to the expiration date, rights in the Compound will revert to the Company.

We allocated the fixed and determinable Agreement consideration of \$30 million based on the percentage of the relative selling price of each unit of accounting. We estimated the selling price of the license using the income approach which values the license by discounting direct cash flow expected to be generated over the remaining life of the license, net of cash flow adjustments related to working capital. We estimated the selling price of the development services by discounting the estimated development expenditures to the date of arrangement which include internal estimates of personnel needed to perform the development services as well as third party costs for services and supplies. Of the \$30 million Agreement consideration, \$27.3 million was allocated to the license and \$2.7 million was allocated to the development services.

Because delivery of the license occurred upon the execution of the Agreement in November 2013 and the remaining revenue recognition criteria were met, all \$27.3 million of the allocated arrangement consideration related to the license was recognized as revenue during the year ended December 31, 2013.

The allocated amount of \$2.7 million to the development services is expected to be recognized as development service revenue through approximately 2018, with majority of development services expected to be completed through approximately 2015, based on a proportional performance method, by which revenue is recognized in proportion to the development costs incurred. During the year ended December 31, 2013, \$0.1 million was recognized as revenue, and the remaining \$2.6 million was recorded as deferred revenue in the balance sheet as of December 31, 2013.

*License and contract revenue* recognized in the statement of operations related to the Agreement were as follows (in thousands):

	Years ended December 31,		
	2013	2012	2011
License	\$ 27,275	\$	\$
Development services	89		
License and contract revenue	\$ 27,364	\$	\$

As of December 31, 2013, deferred revenue amounts related to the Agreement consisted of (in thousands):

	December 31,	
	2013	2012
Current portion of deferred revenue	\$ 1,010	\$
Deferred revenue, less current portion	1,626	
Total deferred revenue	\$ 2,636	\$

Concurrently with the execution of the Agreement, we issued 30,000 shares of Series 19 convertible preferred stock, no par value, or Series 19 Preferred Stock to Baxter for \$30.0 million. Issuance costs related to this transaction were \$0.2 million. Each share of Series 19 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 holder of Series 19 Preferred Stock was 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



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otherwise required by law. For the year ended December 31, 2013, all 30,000 shares of Series 19 Preferred Stock were converted into 15,673,981 shares of our common stock at a conversion price of \$1.914 per share. There was no beneficial conversion feature on Series 19 Preferred Stock.

### *Novartis*

In January 2014, we entered into a Termination Agreement, or the Termination Agreement, with Novartis International Pharmaceutical Ltd., or Novartis, to reacquire the rights to PIXUVRI and Opaxio, or collectively, the Compounds, previously granted to Novartis under our License and Co-Development Agreement with Novartis entered into in September 2006, as amended, or the Original Agreement. Pursuant to the Termination Agreement, the Original Agreement was terminated in its entirety, other than certain customary provisions, including those pertaining to confidentiality and indemnification, which survive termination.

Under the Termination Agreement, we agreed not to transfer, license, sublicense or otherwise grant rights with respect to intellectual property of the Compounds unless the transferee/licensee/sublicensee agrees to be bound by the terms of the Termination Agreement. We also agreed to provide potential payments to Novartis, including a percentage ranging from the low double-digits to the mid-teens, of any consideration received by us or our affiliates in connection with any transfer, license, sublicense or other grant of rights with respect to intellectual property of PIXUVRI or Opaxio, respectively; *provided* that such payments will not exceed certain prescribed ceilings in the low-single digit millions. Novartis is entitled to receive potential payments of up to \$16.6 million upon the successful achievement of certain sales milestones of the Compounds. Novartis is also eligible to receive tiered low single-digit percentage royalty payments for the first several hundred million in annual net sales, and ten percent royalty payments thereafter based on annual net sales of each Compound, subject to reduction in the event generic drugs are introduced and sold by a third party, causing the sale of PIXUVRI or Opaxio to fall by a percentage in the high double-digits. To the extent we are required to pay royalties on net sales of Opaxio pursuant to the license agreement between us and PG-TXL Company, L.P., dated as of November 13, 1998, as amended, we may credit a percentage of the amount of such royalties paid to those payable to Novartis, subject to certain exceptions. Notwithstanding the foregoing, royalty payments for both PIXUVRI and Opaxio are subject to certain minimum floor percentages in the low single-digits.

### *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.

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### *S\*BIO Pte Ltd*

See Note 5, *Acquisitions*, for further information regarding the asset purchase agreement with S\*BIO.

### *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 \$1.0 million, \$2.8 million and \$7.0 million for the years 2013, 2012 and 2011, respectively, of which \$0.1 million and \$0.2 million was included in *accrued expenses* as of December 31, 2013 and 2012, 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. 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 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.

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Effective September 25, 2012, we and Chroma entered into a 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. The standstill was extended through June 25, 2013, but has not been renewed by the parties.

### *Gynecologic Oncology Group*

We entered into an agreement with the Gynecologic Oncology Group, or GOG, in March 2004, as amended in August 2008 and August 2013, related to the GOG-0212 trial of Opaxio in patients with ovarian cancer, which the GOG is conducting. We recorded a \$0.9 million payment due to the GOG based on the 1,100 patient enrollment milestone achieved in the third quarter of 2013, which is included in *accounts payable* as of December 31, 2013. In addition, we may be required to pay up to \$1.2 million upon the attainment of certain milestones, as well as other fees under certain circumstances, of which \$0.7 million is included in *accrued expenses* as of December 31, 2013. In January 2014, we were informed by the GOG that enrollment in the trial had been completed, with 1,150 patients enrolled.

### *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.

### *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 of brostallicin, we 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 of specified sales and development milestones related to TRISENOX. In November 2013, we received \$5.0 million from Teva Pharmaceutical Industries Ltd., or Teva, upon the achievement of a worldwide net sales milestone of TRISENOX, which was included in *license and contract revenue* for the year ended December 31, 2013. TRISENOX was acquired from us by Cephalon. Cephalon was subsequently acquired by Teva. The achievement of the remaining milestones is uncertain at this time.

**Table of Contents***Other Agreements*

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

**15. 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, 2013, 2012 and 2011, we recognized share-based compensation expense due to the following types of awards (in thousands):

	2013	2012	2011
Performance rights	\$ 1,165	\$ 2,358	\$
Restricted stock	5,906	5,180	4,850
Options	1,995	400	167
Total share-based compensation expense	\$ 9,066	\$ 7,938	\$ 5,017

The following table summarizes share-based compensation expense for the years ended December 31, 2013, 2012 and 2011, which was allocated as follows (in thousands):

	2013	2012	2011
Research and development	\$ 2,178	\$ 1,730	\$ 1,126
Selling, general and administrative	6,888	6,208	3,891
Total share-based compensation expense	\$ 9,066	\$ 7,938	\$ 5,017

Share-based compensation had a \$9.1 million, \$7.9 million and \$5.0 million effect on our net loss attributable to common shareholders, which resulted in a \$(0.08), \$(0.14) and \$(0.15) effect on basic and diluted net loss per common share for the years ended December 31, 2013, 2012 and 2011, respectively. It had no effect on cash flows from operations or financing activities for the periods presented; however, during the years ended 2013, 2012 and 2011, we repurchased 200,000, 23,000 and 44,000 shares of our common stock totaling \$0.2 million, \$0.1 million and \$0.4 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, 2013, unrecognized compensation cost related to unvested stock options and time-based restricted stock awards amounted to \$8.4 million, which will be recognized over the remaining weighted-average requisite service period of 1.1 years. The unrecognized compensation cost related to unvested options and restricted stock does not include the value of performance-based share awards.





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For the years ended December 31, 2013, 2012 and 2011, 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 April 2013, 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, 2013, 21.5 million shares were authorized for issuance, of which 5.6 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:

	<b>Year Ended December 31,</b>		
	<b>2013</b>	<b>2012</b>	<b>2011</b>
Risk-free interest rate	1.4%	0.8%	0.9%
Expected dividend yield	None	None	None
Expected life (in years)	5.3	4.7	4.5
Volatility	102%	88%	97%

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.

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The following table summarizes stock option activity for all of our stock option plans:

	<b>Options</b>	<b>Weighted Average Exercise Price</b>	<b>Weighted Average Remaining Contractual Term (Years)</b>	<b>Aggregate Intrinsic Value (Thousands)</b>
Outstanding at January 1, 2011 (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 (105,000 exercisable)	307,000	\$ 33.72		
Granted	4,352,000	\$ 1.71		
Exercised		\$		
Forfeited	(112,000)	\$ 2.40		
Cancelled and expired	(28,000)	\$ 133.72		
Outstanding at December 31, 2013	4,519,000	\$ 3.04	9.53	\$ 889
Vested or expected to vest at December 31, 2013	4,241,404	\$ 3.12	9.53	\$ 842
Exercisable at December 31, 2013	1,560,000	\$ 5.39	9.54	\$ 358

The weighted average exercise price of options exercisable at December 31, 2012 and 2011 was \$89.08 and \$228.95, respectively. The weighted average grant-date fair value of options granted during 2013, 2012 and 2011 was \$1.32, \$3.28 and \$3.93 per option, respectively.

**Restricted Stock**

We issued 6.4 million, 4.3 million and 1.7 million shares of restricted common stock in 2013, 2012 and 2011, respectively. The weighted average grant-date fair value of restricted shares issued during 2013, 2012 and 2011 was \$1.21, \$4.77 and \$6.23, respectively. Additionally, 1.2 million, 0.9 million and 1.2 million shares of restricted stock were cancelled during 2013, 2012 and 2011, respectively.

A summary of the status of nonvested restricted stock awards as of December 31, 2013 and changes during the period then ended, is presented below:

	<b>Nonvested Shares</b>	<b>Weighted Average Grant-Date Fair Value Per Share</b>
Nonvested at December 31, 2012	3,322,000	\$ 5.26
Issued	6,375,000	\$ 1.21
Vested	(3,841,000)	\$ 1.83
Forfeited	(1,168,000)	\$ 3.70
Nonvested at December 31, 2013	4,688,000	\$ 2.95

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The total fair value of restricted stock awards vested during the years ended December 31, 2013, 2012 and 2011 was \$5.1 million, \$3.4 million and \$3.5 million, respectively.

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### *Long-Term Performance Awards*

In November 2011, we granted restricted stock units to our executive officers and directors that became effective on January 3, 2012, or the Long-Term Performance Awards (previously referred to as our 2012-2014 performance awards). The Long-Term Performance Awards vest upon milestone-based performance conditions. If one or more of the 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. In March 2013, certain performance criteria of the Long-Term Performance Awards were modified, two new performance goals were added, one goal was cancelled, and the expiration date was extended to December 31, 2015. The total award percentages related to all eight performance goals in effect as of December 31, 2013 are 7.0% and 2.7% of shares outstanding at the time the performance goals are achieved for the senior management and director participants, 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 Long-Term 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 0.9% and 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 2013 and 2012, respectively.

We determined the Long-Term Performance Awards with market-based performance conditions have a grant-date fair value of \$4.8 million. We determined the market-based performance condition had an incremental fair value of \$0.8 million on the modification date in March 2013, which is being recognized in addition to the unrecognized grant-date fair value as of the modification date over the remaining estimated requisite service period. We recognized \$1.2 million and \$1.3 million in share based compensation expense related to the performance awards with market-based performance conditions for the years ended December 31, 2013 and 2012, respectively.

In January 2014, the expiration date of the Long-Term Performance Awards was extended to December 31, 2016, and two new performance criteria were added to the performance awards.

### *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, 2013 and 2011 unvested nonemployee options to acquire approximately 157,000 and 2,000 shares of common stock were outstanding, respectively. Additionally, unvested nonemployee restricted stock awards totaled approximately

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163,000 and 2,000 as of December 31, 2013 and 2011, respectively. As of December 31, 2012, all nonemployee options and restricted stock awards had vested. We recorded compensation expense of \$310,000 and \$58,000 in 2013 and 2011, respectively, and reversed previously recorded compensation expense of \$1,000 in 2012 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 shares to employees in each year ended December 31, 2013, 2012 and 2011. There are 50,833 shares of common stock authorized under the Purchase Plan and 38,631 shares are reserved for future purchases as of December 31, 2013.

## **16. 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, \$0.2 million and \$0.1 million related to discretionary matching contributions during each of the years ended December 31, 2013, 2012 and 2011, respectively.

## **17. 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.

## **18. Customer and Geographic Concentrations**

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

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All sales of PIXUVRI during 2013 were in Europe. Product sales from PIXUVRI's major customers as a percentage of total product sales were as follows:

	Year Ended December 31, 2013
Customer A	67%
Customer B	4%
Customer C	3%

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

	Year Ended December 31, 2013	2012
United States	\$ 5,336	\$ 6,570
Europe	142	215
	\$ 5,478	\$ 6,785

**19. 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,		
	2013	2012	2011
Net loss attributable to common shareholders	\$ (49,643)	\$ (115,275)	\$ (121,078)
Basic and diluted:			
Weighted average shares outstanding	119,042	62,021	35,790
Less weighted average restricted shares outstanding	(4,847)	(3,896)	(1,496)
Shares used in calculation of basic and diluted net loss per common share	114,195	58,125	34,294
Net loss per common share: Basic and diluted	\$ (0.43)	\$ (1.98)	\$ (3.53)

Options, warrants, unvested restricted share awards and rights, convertible debt, and convertible preferred stock aggregating 15.4 million, 8.6 million and 10.2 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, 2013, 2012 and 2011, 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.

**20. Related Party Transactions**

In May 2007, we formed Aequus, a majority-owned subsidiary of which our ownership was approximately 61% as of December 31, 2013. 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.

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In May 2007, we also entered into an agreement to fund Aequus in exchange for a convertible promissory note. The terms of the note provide that (i) interest accrues at a rate of 6% per annum until maturity, (ii) in the event the note balance is not paid on or before the maturity date, interest accrues at a rate of 10% per annum and

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(iii) prior to maturity, the note is convertible into a number of shares of Aequus equity securities equal to the quotient obtained by dividing (a) the outstanding balance of the note by (b) the price per share of the Aequus equity securities. The note matured and was due and payable in May 2012, although it has not yet been repaid. We are currently in negotiations with Aequus to, among other things, extend the maturity date of the note. 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 \$1.5 million, \$0.6 million and \$0.6 million during the years ended December 31, 2013, 2012 and 2011, respectively, including amounts advanced in association with the services agreement. The Aequus note balance, including accrued interest, was approximately \$5.8 million and \$4.0 million as of December 31, 2013 and 2012, 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, 2013. 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, 2013 and is also a member of Aequus Board of Directors.

## **21. Legal Proceedings**

In August 2009, SICOR 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 the chemical compound, BBR2778, from Sicor according to the terms of a supply agreement executed between Sicor and Novuspharma S.p.A, or Novuspharma, a pharmaceutical company located in Italy, on October 4, 2002. We are the successor in interest to such agreement by virtue of our merger with Novuspharma in January 2004. Sicor alleged that the agreement was not terminated according to its terms. We asserted that the supply agreement in question was properly terminated and that we have no further obligation to comply with its terms. On December 30, 2013, the Court of Milan issued its decision and rejected all of Sicor's claims; this proceeding has therefore concluded. The decision of the Court of Milan is subject to potential appeal.

On December 10, 2009, CONSOB sent us a notice claiming, among other now resolved claims, 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 sanction established by Section 193, paragraph 1 of the Italian Legislative Decree no. 58/98 for such violation could require us to pay a pecuniary administrative sanction amounting to between \$7,000 and \$689,000 upon conversion from euros as of December 31, 2013. Until CONSOB's right is barred, CONSOB may, at any time, confirm the occurrence of the asserted violation and apply a pecuniary administrative sanction within the foregoing range. To date, we have not received any such notification.

### *VAT Assessments*

The Italian Tax Authority, or 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 (collectively, the VAT Assessments). The ITA audits concluded that CTI (Europe) did not collect and remit VAT on certain invoices issued to non-Italian clients for services performed by CTI (Europe). We believe that the services invoiced were non-VAT taxable consultancy services and that the VAT returns are correct as originally filed. We are 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 then remaining deposit for the VAT Assessments was refunded to us in January 2013. Due to the change of the position for the VAT Assessments, we reversed the entire reserve for VAT assessed as of December 31, 2012.



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In June 2013, the Regional Tax Court issued decision no. 119/50/13 in regards to the 2003 VAT assessment, which accepted the appeal of the ITA and reversed the previous decision of the Provincial Tax Court. We believe that such decision has not carefully taken into account our arguments and the documentation we filed, and we therefore plan to appeal such decision in front of the Supreme Court both on procedural grounds and on the merits of the case. In January 2014, we were notified that the ITA has requested partial payment of the 2003 VAT assessment in the amount of \$593,000 upon conversion from euros as of December 31, 2013. We paid such amount in March 2014.

If the final decisions of the Supreme Court for the VAT Assessments are unfavorable to us, we may incur up to \$12.9 million in losses for the VAT amount assessed including penalties, interest and fees upon conversion from euros as of December 31, 2013.

**22. Income Taxes**

We file income tax returns in the United States, Italy and the United Kingdom. A substantial part of our operations takes place in the State of Washington, which does not impose an income tax as that term is defined in ASC 740, *Income Taxes*. As such, our state income tax expense or benefit, if recognized, would be immaterial to our operations. We are not currently under examination by an income tax authority, nor have we been notified that an examination is contemplated.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying values of assets and liabilities for financial reporting and income tax reporting in accordance with ASC 740. We have a valuation allowance equal to net deferred tax assets due to the uncertainty of realizing the benefits of the assets. Our valuation allowance increased \$11.3 million, decreased \$113.5 million and increased \$3.6 million during 2013, 2012 and 2011, respectively.

The reconciliation between our effective tax rate and the income tax rate as of December 31, 2013, 2012 and 2011 is as follows:

	2013	2012	2011
Federal income tax rate	(34%)	(34%)	(34%)
Research and development tax credits	(3)		(2)
I.R.C. Section 382 limited research and development tax credits		1	
Non-deductible debt/equity costs			1
Non-deductible executive compensation	1	1	1
I.R.C. Section 382 limited net operating losses	3	134	21
Valuation allowance	27	(111)	6
Expired tax attribute carryforwards		7	7
Foreign tax rate differential	6	1	
Other		1	
Net effective tax rate	%	%	%

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Significant components of our deferred tax assets and liabilities as of December 31, 2013 and 2012 were as follows (in thousands):

	2013	2012
Deferred tax assets:		
Net operating loss carryforwards	\$ 49,777	\$ 34,655
Capitalized research and development	31,046	36,303
Research and development tax credit carryforwards	1,486	223
Stock based compensation	12,097	10,813
Intangible assets	10,518	11,336
Depreciation and amortization	96	8
Other deferred tax assets	3,062	3,621
<b>Total deferred tax assets</b>	<b>108,082</b>	<b>96,959</b>
Less valuation allowance	(107,271)	(95,949)
	811	1,010
Deferred tax liabilities:		
GAAP adjustments on Novuspharma merger	(208)	(208)
Deductions for tax in excess of financial statements	(603)	(802)
<b>Total deferred tax liabilities</b>	<b>(811)</b>	<b>(1,010)</b>
<b>Net deferred tax assets</b>	<b>\$</b>	<b>\$</b>

Due to our equity financing transactions, and other owner shifts as defined in Internal Revenue Code Section 382 (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 October 2012, an ownership change occurred. The ownership change limits the utilization of certain tax attributes including the NOL. After the October 2012 ownership change the utilization of the NOL is limited to approximately \$4.3 million annually. At December 2013, the gross NOL carryforward was approximately \$1.0 billion. The annual NOL limitation will reduce the available NOL carryforward to approximately \$146.4 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, 2013, 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.

In July 2013, the FASB issued guidance on the presentation of an unrecognized tax benefit when a net operating loss carryforward, similar tax loss or tax carryforward exists. FASB concluded that an unrecognized tax benefit should be presented as a reduction of a deferred tax asset except in certain circumstances the unrecognized tax benefit should be presented as a liability and should not be combined with deferred tax assets. The amendment is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013, with early adoption permitted. The Company will adopt this standard in the first quarter of 2014 and does not expect the adoption of this standard to have an impact on its consolidated financial statements.

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### 23. Unaudited Quarterly Data

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

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
<b>2013</b>				
Total revenues (1)	\$ 1,126	\$ 306	\$ 362	\$ 32,884
Product sales, net	1,126	306	362	520
Gross profit	1,071	270	349	487
Operating costs and expenses	(19,553)	(18,158)	(15,942)	(22,551)
Net income (loss) attributable to CTI	(19,384)	(18,011)	(15,544)	10,196
Net income (loss) attributable to CTI common shareholders	(19,384)	(18,011)	(22,444)	10,196
Net income (loss) per common share basic	(0.18)	(0.17)	(0.20)	0.08
Net income (loss) per common share diluted	(0.18)	(0.17)	(0.20)	0.08
<b>2012</b>				
Total revenues	\$	\$	\$	\$
Product sales, net				
Gross profit				
Operating costs and expenses (2)	(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	(0.43)	(1.38)	(0.38)	(0.20)
Net loss per common share diluted	(0.43)	(1.38)	(0.38)	(0.20)

- (1) Total revenues for the fourth quarter of 2013 include \$27.4 million of *license and contract revenue* recognized in connection with the collaboration agreement with Baxter in November 2013 and \$5.0 million of *license and contract revenue* from Teva in November 2013 upon the achievement of a worldwide net sales milestone of TRISENOX. See Note 14, *Collaboration, Licensing and Milestone Agreements*, for additional information.
- (2) Operating costs and expenses 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 5, *Acquisitions*, for additional information.

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

None.

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

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

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

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

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

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

As of the end of the Company's 2013 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 (1992) 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, 2013 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, 2013, 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 fourth fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

### **Item 9B. Other Information**

None.

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**PART III**

**Item 10. Directors, Executive Officers and Corporate Governance**

The information required by this Item is incorporated herein by reference from the Company's 2014 definitive proxy statement (which will be filed with the SEC within 120 days after December 31, 2013 in connection with the solicitation of proxies for the Company's 2014 annual meeting of shareholders) ( "2014 Proxy Statement" ) under the captions "Proposal 2 Election of Directors," "Other Information Executive Officers," and "Other Information Beneficial Ownership Reporting Compliance under Section 16(a) of the Exchange Act."

**Item 11. Executive Compensation**

The information required by this Item is incorporated herein by reference from the Company's 2014 Proxy Statement under the captions "Executive Compensation" and "Non-Employee Director Compensation."

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Shareholder Matters**

The information required by this Item is incorporated herein by reference from the Company's 2014 Proxy Statement under the captions "Other Information Security Ownership of Certain Beneficial Owners and Management" and "Other Information Equity Compensation Plan Information."

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

The information required by this Item is incorporated herein by reference from the Company's 2014 Proxy Statement under the captions "Other Information Related Party Transactions Overview," "Other Information Certain Transactions with Related Persons" and "Proposal 2 - Election of Directors."

**Item 14. Principal Accounting Fees and Services**

The information required by this Item is incorporated herein by reference from the Company's 2014 Proxy Statement under the caption "Proposal 4 Ratification of the Selection of Independent Auditors."

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**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

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
2.1	Agreement and Plan of Merger by and between  Cell Therapeutics, Inc. and Novuspharma, S.p.A., dated as of June 16, 2003.	Incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K, filed on June 17, 2003.
2.2	Acquisition Agreement by and among Cell  Therapeutics, Inc., Cell Technologies, Inc. and  Cephalon, Inc., dated June 10, 2005.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on June 14, 2005.
2.3	Acquisition Agreement among Cell Therapeutics, Inc., Cactus Acquisition Corp., 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.

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2.4	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.
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.
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.

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<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
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 Registration Statement 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.



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<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.

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<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	Amendment to Amended and Restated Articles of Incorporation of Cell Therapeutics, Inc.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on June 26, 2013.
3.30	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 18 Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on September 18, 2013.
3.31	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 19 Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on November 15, 2013.
3.32	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 Registration Statement on 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.

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<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
4.7	Form of Common Stock Purchase Warrant, dated April 6, 2010.	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed on April 5, 2010.
4.8	Form of Common Stock Purchase Warrant, dated May 27, 2010.	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed on May 27, 2010.
4.9	Form of Common Stock Purchase Warrant, dated July 27, 2010.	Incorporated by reference to Exhibit 4.6 to the Registrant's Quarterly Report on Form 10-Q, filed on August 6, 2010.
4.10	Form of Common Stock Purchase Warrant, dated October 22, 2010.	Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K, filed on October 22, 2010.
4.11	Form of Common Stock Purchase Warrant, dated 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.
4.16	Warrant Agreement, dated March 26, 2013, by and between Cell Therapeutics, Inc. and Hercules Technology Growth Capital, Inc.	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on March 28, 2013.
10.1	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 for the year ended December 31, 2011, filed on March 8, 2012.
10.2*	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.
10.3*	Amendment to Employment Agreement between the Registrant and James A. Bianco, dated as of March 21, 2013	Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q, filed on May 2, 2013.
10.4*	Offer Letter, by and between Cell Therapeutics, Inc. and Matthew Plunkett, dated July 31, 2012.	Incorporated by reference to Exhibit 10.24 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2012, filed on February 28, 2013.

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<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
10.5*	Offer Letter, by and between Cell Therapeutics, Inc. and Steven Benner, M.D., dated June 12, 2012.	Incorporated by reference to Exhibit 10.22 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2012, filed on February 28, 2013.
10.6*	Form of Strategic Management Team Severance Agreement.	Incorporated by reference to Exhibit 10.5 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2008, filed on March 16, 2009.
10.7*	Form of Amendment to Strategic Management Team Severance Agreement.	Incorporated by reference to Exhibit 10.6 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2008, filed on March 16, 2009.
10.8*	Severance Agreement, dated as of March 21, 2013, between the Company and Matthew Plunkett.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on March 22, 2013.
10.9*	Severance Agreement, dated as of July 19, 2012, between the Company and Steven Benner, M.D.	Incorporated by reference to Exhibit 10.23 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2012, filed on February 28, 2013.
10.10*	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.
10.11*	Form of Indemnification Agreement.	Incorporated by reference to Exhibit 10.19 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2001, filed on March 29, 2002.
10.12*	Form of Italian Indemnity Agreement	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on December 17, 2009.
10.13*	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 June 26, 2013.
10.14*	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.
10.15*	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.
10.16*	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.

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<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
10.17*	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.
10.18*	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.
10.19*	Form of Restricted Stock Award Agreement for grants of restricted shares under the Registrant's 2007 Equity Incentive Plan, as amended.	Incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, filed on October 30, 2013.
10.20*	Form of Stock Option Agreement for option grants under the Registrant's 2007 Equity Incentive Plan, as amended.	Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed on October 30, 2013.
10.21*	Form of Stock Award Agreement for grants of fully vested shares under the Registrant's 2007 Equity Incentive Plan, as amended.	Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed on October 30, 2013.
10.22*	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.
10.23*	Form of Equity/Long-Term Incentive Award Agreement for James A. Bianco, Louis A. Bianco and Jack W. Singer.	Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q, filed on April 20, 2012.
10.24*	Form of Equity/Long-Term Incentive Award Agreement for Stephen E. Benner and Matthew J. Plunkett	Incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q, filed on May 2, 2013.
10.25*	Amendment to Form of Equity/Long-Term Incentive Award Agreement, dated as of March 21, 2013, for James A. Bianco, Louis A. Bianco, Jack W. Singer and the Registrant's Directors.	Incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q, filed on May 2, 2013.
10.26*	Amendment to Form of Equity/Long-Term Incentive Award Agreement, dated as of January 30, 2014, for the Registrant's Executive Officers and Directors.	Filed herewith.
10.27	License Agreement between Cell Therapeutics, Inc. and PG-TXL Company, dated as of November 13, 1998.	Incorporated by reference to Exhibit 10.27 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 1998, filed on March 31, 1999.
10.28	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.

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<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
10.29	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.
10.30	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	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.
10.32	Development, Commercialization and License Agreement dated as of November 14, 2013 between Cell Therapeutics, Inc., Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA.	Filed herewith.
10.33	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.
10.34	Master Services Agreement, dated July 9, 2012, between Quintiles Commercial Europe Limited and CTI Life Sciences Ltd.	Incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q, filed on August 2, 2012.
10.35	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 Quarterly Report on Form 10-Q, filed on August 2, 2012.
10.36	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 Quarterly Report on Form 10-Q, filed on November 1, 2012.
10.37	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.
10.38	Settlement Agreement and Full and Final Release of Claims dated as of January 4, 2013, by and between Cell Therapeutics, Inc. and Daniel Eramian.	Incorporated by reference to Exhibit 10.49 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2012, filed on February 28, 2013.
10.39	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.
10.40	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.

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Exhibit Number	Exhibit Description	Location
10.41	Registration Rights Agreement, among Cell Therapeutics, Inc. and Baxter Healthcare SA, dated November 14, 2013.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on November 15, 2013.
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	Form of Securities Purchase Agreement, dated September 12, 2013.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on September 18, 2013.
10.44	Loan and Security Agreement, dated March 26, 2013, by and among Cell Therapeutics, Inc., Systems Medicine LLC and Hercules Technology Growth Capital, Inc.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on March 28, 2013.
10.45	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.
10.46	Stipulation of Settlement, dated November 6, 2012.	Incorporated by reference to Exhibit 99.2 to the Registrant's Current Report on Form 8-K, filed on March 27, 2013.
10.47	Wholesale Distribution Agreement, dated as of March 26, 2013, by and between CTI Life Sciences Limited and Max Pharma GmbH.	Incorporated by reference to Exhibit 10.7 to the Registrant's Quarterly Report on Form 10-Q, filed on May 2, 2013.
10.48	Amendment No. 1 to Wholesale Distribution Agreement, effective June 10, 2013, by and between CTI Life Sciences Limited and Max Pharma GmbH.	Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed on July 31, 2013.
10.49	Amendment No. 2 to Wholesale Distribution Agreement, effective June 25, 2013, by and between CTI Life Sciences Limited and Max Pharma GmbH.	Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed on July 31, 2013.
10.50	Amendment No. 3 to Wholesale Distribution Agreement, effective July 9, 2013, by and between CTI Life Sciences Limited and Max Pharma GmbH.	Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q, filed on October 30, 2013.
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.

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<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Location</b>
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.
99.1	Notice of Pendency and Proposed Settlement of Action.	Incorporated by reference to Exhibit 99.1 to the Registrant's Current Report on Form 8-K, filed on March 27, 2013.
101.INS	XBRL Instance	Filed herewith.
101.SCH	XBRL Taxonomy Extension Schema	Filed herewith.
101.CAL	XBRL Taxonomy Extension Calculation	Filed herewith.
101.DEF	XBRL Taxonomy Extension Definition	Filed herewith.
101.LAB	XBRL Taxonomy Extension Labels	Filed herewith.
101.PRE	XBRL Taxonomy Extension Presentation	Filed herewith.

\* Indicates management contract or compensatory plan or arrangement.

Portions of these exhibits have been omitted pursuant to a request for confidential treatment.



**Table of Contents****SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Seattle, State of Washington, on March 4, 2014.

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.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Phillip M. Nudelman	Chairman of the Board and Director	March 4, 2014
<b>Phillip M. Nudelman, Ph.D.</b>		
/s/ James A. Bianco	President, Chief Executive Officer and Director (Principal Executive Officer)	March 4, 2014
<b>James A. Bianco, M.D.</b>		
/s/ Louis A. Bianco	Executive Vice President, Finance and Administration (Principal Financial Officer and Principal Accounting Officer)	March 4, 2014
<b>Louis A. Bianco</b>		
/s/ John H. Bauer	Director	March 4, 2014
<b>John H. Bauer</b>		
/s/ Vartan Gregorian	Director	March 4, 2014
<b>Vartan Gregorian, Ph.D.</b>		
/s/ Karen Ignagni	Director	March 4, 2014
<b>Karen Ignagni</b>		
/s/ Richard L. Love	Director	March 4, 2014
<b>Richard Love</b>		
/s/ Mary O. Munding	Director	March 4, 2014
<b>Mary O. Munding, DrPH</b>		

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/s/ Jack W. Singer	Director	March 4, 2014
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**Jack W. Singer, M.D.**

/s/ Frederick W. Telling	Director	March 4, 2014
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**Frederick Telling, Ph.D.**

/s/ Reed V. Tuckson.	Director	March 4, 2014
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**Reed V. Tuckson, M.D.**