

CTI BIOPHARMA CORP  
Form 10-K  
March 12, 2015

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, 2014

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

CTI BIOPHARMA CORP.

(Exact name of registrant as specified in its charter)

Washington  
(State or other jurisdiction of incorporation or organization) 91-1533912  
(I.R.S. Employer Identification Number)

3101 Western Avenue, Suite 600

Seattle, WA  
(Address of principal executive offices) 98121  
(Zip Code)

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

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

Title of each class                      Name of each exchange on which registered  
Common Stock, no par value    The NASDAQ Stock Market LLC

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

Preferred Stock Purchase Rights

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

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

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

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

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

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

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

As of June 30, 2014, the aggregate market value of the registrant's common equity held by non-affiliates was \$330,945,510. Shares of common stock held by each executive officer and director and by each person known to the registrant who beneficially owns more than 5% of the outstanding shares of the registrant's common stock have been excluded in that such persons may under certain circumstances be deemed to be affiliates. This determination of executive officer or affiliate status is not necessarily a conclusive determination for other purposes. The registrant has no non-voting common stock outstanding.

The number of outstanding shares of the registrant's common stock as of March 5, 2015 was 180,255,852.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2015 annual meeting of shareholders, or the 2015 Proxy Statement, are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The 2015 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.



CTI BIOPHARMA CORP.

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## Forward Looking Statements

This Annual Report on Form 10-K and the documents we incorporate by reference herein or therein may contain “forward-looking statements” within the meaning of the United States, or the U.S., federal securities laws. All statements other than statements of historical fact are forward-looking statements, including, without limitation:

- any statements regarding future operations, plans, expectations, intentions, regulatory filings or approvals;
- any statements regarding the performance, or likely performance, outcomes or economic benefit of any licensing collaboration or other arrangement;
- 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 and expected sales of PIXUVRI;
- any statements of the plans and objectives of management for future operations or programs;
- any statements concerning proposed new products;
- any statements regarding the safety and efficacy or future availability of any of our compounds;
- any statements on plans regarding proposed or potential clinical trials or new drug filing strategies, timelines or submissions;
- any significant disruptions in our information technology systems;
- any statements regarding compliance with the listing standards of The NASDAQ Stock Market and the Mercato Telematico Azionario, or the MTA, in Italy;
- any statements regarding potential future partnerships, licensing arrangements, mergers, acquisitions or other transactions;
- any statements regarding future economic conditions or performance; and
- any statements of assumption underlying any of the foregoing.

In some cases, forward-looking statements can be identified by terms such as “anticipates,” “believes,” “continue,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “projects,” “should” or “will” or the negative thereof and similar expressions. Such statements are based on management’s current expectations and are subject to risks and uncertainties, which may cause actual results to differ materially from those set forth in the forward-looking statements. In particular, this Annual Report on Form 10-K addresses top line results regarding primary endpoints of the PERSIST-1 study, and should be evaluated together with secondary endpoints, safety and additional data once such data has been more fully analyzed and is made publicly available. The statements are based on assumptions about many important factors and information currently available to us to the extent we have thus far had an opportunity to fully and carefully evaluate such information in light of all surrounding facts, circumstances, recommendations and analyses. There can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements. We urge you to carefully review the disclosures we make concerning risks and other factors that may affect our business and operating results, including those made 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 and any risk factors contained in subsequent Quarterly Reports on Form 10-Q that we file with the Securities and Exchange Commission, or the SEC.

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.

In this Annual Report on Form 10-K, all references to “we,” “us,” “our,” the “Company” and “CTI” mean CTI BioPharma Co. and our subsidiaries, except where it is otherwise made clear.



## PART I

### Item 1. Business

#### Overview

We are a biopharmaceutical company focused on the acquisition, development and commercialization of novel targeted therapies covering a spectrum of blood-related cancers that offer a unique benefit to patients and healthcare providers. 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. In particular, we are primarily focused on commercializing PIXUVRI<sup>®</sup> (pixantrone), or PIXUVRI, in the European Union, or the E.U., for the treatment of adult patients with multiply relapsed or refractory aggressive B-cell non-Hodgkin lymphoma, or NHL, and conducting a Phase 3 clinical trial program of pacritinib for the treatment of adult patients with myelofibrosis to support regulatory submission for approval in the U.S. and Europe. We are also evaluating pacritinib in earlier clinical trials as treatment for other blood-related cancers.

#### PIXUVRI

PIXUVRI is a novel aza-anthracenedione with unique structural and physiochemical properties. In May 2012, the European Commission granted conditional marketing authorization in the E.U. for PIXUVRI as a monotherapy for the treatment of adult patients with multiply relapsed or refractory aggressive B-cell 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. As part of the conditional marketing authorization, we are required to conduct a post-authorization trial, or PIX306, which compares PIXUVRI and rituximab with gemcitabine and rituximab in the setting of aggressive B-cell NHL.

PIXUVRI is currently available in Austria, Denmark, Finland, France, Germany, Israel, Italy, Netherlands, Norway, Sweden and the United Kingdom, or the U.K., and has achieved reimbursement decisions under varying conditions in England/Wales, Italy, France, Germany, the Netherlands and Spain. 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. Although we do not have and are not currently pursuing regulatory approval of PIXUVRI in the U.S., we may reevaluate a possible submission strategy in the U.S. based on the data generated from the PIX306 study.

We have established a commercial organization, including sales, marketing, supply chain management and reimbursement capabilities, to commercialize PIXUVRI in certain countries in the E.U. In September 2014, we entered into an exclusive license and collaboration agreement, or the Servier Agreement, with Les Laboratoires Servier and Institut de Recherches Internationales Servier, or collectively, Servier, with respect to the development and commercialization of PIXUVRI. Under the Servier Agreement, we retain full commercialization rights to PIXUVRI in Austria, Denmark, Finland, Germany, Israel, Norway, Sweden, Turkey, the U.K. and the U.S., while Servier has exclusive rights to commercialize PIXUVRI in all other countries. We received an upfront payment from Servier of €14.0 million (or \$17.8 million using the currency exchange rate as of the date we received the funds in October 2014), and we have the potential to receive milestone payments under the Servier Agreement of up to €89.0 million. For additional information on our collaboration with Servier, please see the discussion in Part I, Item 1, “Business – License Agreements and Additional Milestone Activities – Servier”.

## Pacritinib

Our lead development candidate, pacritinib, is an oral multikinase inhibitor with activity against Janus Kinase 2, or JAK2, and FMS-like tyrosine kinase, or FLT3, as well as other kinases, and is currently being evaluated in adult patients with myelofibrosis. 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, itching and pain. We believe 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 the currently approved JAK inhibitor.

In collaboration with Baxter International, Inc., or Baxter, pursuant to our worldwide license agreement to develop and commercialize pacritinib, or the Baxter Agreement, we are pursuing a broad approach to advancing pacritinib for adult 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; and the other in patients with low platelet counts, the PERSIST-2 trial. In October 2013, we reached an agreement with the U.S. Food and Drug Administration, or the FDA, on a Special Protocol Assessment, or SPA, for PERSIST-2.



In August 2014, pacritinib was granted Fast Track designation by the FDA for the treatment of intermediate and high risk myelofibrosis, including, but not limited, to patients with disease-related thrombocytopenia, patients experiencing treatment-emergent thrombocytopenia on other JAK2 therapy or patients who are intolerant of, or whose symptoms are sub-optimally managed on, other JAK2 therapy. The FDA's Fast Track process is designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The PERSIST-1 and PERSIST-2 clinical trials are intended to support a potential regulatory submission to the FDA or the European Medicines Agency, or the EMA.

In March 2015, we reported top-line results for the primary endpoint from PERSIST-1 for the treatment of adult patients with myelofibrosis. The primary endpoint of the trial was the proportion of patients achieving a 35 percent or greater reduction in spleen volume from baseline to Week 24 as measured by magnetic resonance imaging, or MRI, or computerized tomography, or CT, when compared with physician-specified best available therapy, excluding treatment with JAK2 inhibitors. The trial met its primary endpoint in the intent-to-treat population with statistically significant activity observed in patients irrespective of their initial platelet count, including patients with very low platelet counts at study entry. For additional information concerning the top-line results, see Part I, Item 1, "Business—Development Candidates—Pacritinib—Development in Myelofibrosis".

Under the Baxter Agreement, we share joint commercialization rights to pacritinib with Baxter in the U.S., while Baxter has exclusive commercialization rights for all indications outside the U.S. In connection with the execution 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. Of these milestones, we have received a \$20 million development milestone payment in connection with the first treatment dosing of the last patient enrolled in PERSIST-1. Additionally, we will share any U.S. profits from pacritinib equally and will receive royalties on any 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 Milestone Activities—Baxter".

#### Other Pipeline Candidates

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

#### Our Strategy

Our objective 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 to achieve these objectives are to:

- Successfully Commercialize PIXUVRI. Together with Servier, we intend to continue our efforts to build a successful PIXUVRI franchise in Europe as well as other markets. 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 available.

Develop Pacritinib in Myelofibrosis and Additional Indications. Together with Baxter, we intend to develop and commercialize pacritinib for adult patients with myelofibrosis. We also intend to continue evaluation of pacritinib in other blood-related cancers, including AML and MDS, through ongoing and planned ISTs.

·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 intend to continue to advance the development of our other pipeline candidates through cooperative group sponsored trials and ISTs. Sponsoring such trials provides us with a more economical approach for further developing our investigational products.

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- Evaluate Strategic Product Collaborations to Accelerate Development and Commercialization. Where we believe it may be beneficial, we intend to evaluate 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 Development Portfolio

The following table summarizes our current product and development portfolio:

	Indications/Intended Use	Status
PIXUVRI (pixantrone)	Multiply relapsed aggressive B-cell NHL	Conditional Marketing Authorization—Marketed in E.U.
	Aggressive NHL, 2 <sup>nd</sup> line >1 relapse, combination with rituximab (PIX306) post-approval study	Phase 3 ongoing
Pacritinib	Myelofibrosis, PERSIST-1, All platelet levels(2)	Phase 3 ongoing, Enrollment completed, Top-line results
	Myelofibrosis, PERSIST-2, Platelet counts ≤100,000/μL	Phase 3 ongoing
	Relapsed AML(1)	Phase 2 ongoing
	MDS(1)	Phase 2 initiating
	Front-line AML(1)	Phase 2 ongoing
Tosedostat	AML/MDS(1)	Phase 2 ongoing
Opaxio	Ovarian cancer, maintenance(1)(2)	Phase 3 ongoing

- (1) We support the development of these investigational agents through cooperative group sponsored trials and ISTs.
- (2) These trials have completed enrollment and the patients are being followed.

#### Oncology Market Overview and Opportunity

According to the American Cancer Society, or ACS, cancer is the second leading cause of death in the U.S., resulting in close to 589,430 deaths annually, or more than 1,620 people per day. Approximately 1.7 million new cases of cancer were expected to be diagnosed in 2015 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 our expertise in blood-related cancers, together with our ability to identify unique therapies that address unmet medical needs that are potentially less toxic and more effective at treating and curing 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 cardiotoxicity 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 but rather a novel aza-anthracenedione with unique structural and physiochemical properties. Based on its ease of administration, unique anti-tumor activity and reduced risk of cardiotoxicity, we believe PIXUVRI could gain a significant share in the relapsed aggressive NHL 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 anthracyclines, PIXUVRI does not bind to cardiac topo-isomerase II beta, a major mediator of anthracycline associated cardiotoxicity. In addition, in contrast to doxorubicin, PIXUVRI does not produce toxic free oxygen radicals in cultured cardiac cells that are thought to be responsible for early anthracycline cardiotoxicity. Also unlike anthracyclines, rather than intercalating with deoxyribonucleic acid, or DNA, PIXUVRI hydrogen bonds to and alkylates DNA, thus forming stable DNA adducts with particular specificity for CpG rich, hypermethylated sites. The result is progressive disruption of mitosis and therefore killing of rapidly dividing cells like those found in many tumors. PIXUVRI appears to impair chromosomal segregation during mitosis, thereby generating loss of genetic material in daughter cells, an abnormality, which is ultimately lethal to tumor cells. 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 resistant to other cytotoxic agents such as doxorubicin.

#### PIXUVRI for the Treatment of NHL

We are specifically developing and commercializing PIXUVRI for the treatment of aggressive NHL. NHL is caused by the abnormal proliferation of lymphocytes, which are cells key to the functioning of the immune system. NHL usually originates in lymph nodes and spreads through the lymphatic system. The ACS estimated that there would be 71,850 people diagnosed with NHL in the U.S. and approximately 19,790 people would die from this disease in 2015. The World Health Organization's International Agency for Research on Cancer's 2012 GLOBOCAN database estimates that, in the E.U., approximately 79,312 people will be diagnosed with NHL and 30,730 are estimated to die from NHL annually. NHL is the seventh most common type of cancer. NHL can be broadly classified into two main forms, each with many subtypes; aggressive NHL is a rapidly growing form of the disease that moves into advanced stages much faster than indolent NHL, which progresses more slowly.

Aggressive B-cell NHL is the most common subtype, accounting for about 55 percent of NHL cases. After initial therapy for aggressive NHL with anthracycline-based combination therapy, one-third of patients typically develop progressive disease. Approximately half of these patients are likely to be eligible for intensive second-line treatment and stem cell transplantation, although 50 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 only. PIXUVRI is the first treatment approved in the E.U. for patients with multiply relapsed or refractory aggressive B-cell NHL. Neither

PIXUVRI nor any other drugs are approved for this indication in the U.S.

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

The pivotal Phase 3 trial, or PIX301, evaluated PIXUVRI for patients with relapsed or refractory aggressive B-cell 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 PIXUVRI 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 PIXUVRI 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. The PIX301 study was published in *Lancet Oncology* in May 2012.

In May 2012, PIXUVRI was granted conditional marketing authorization by the European Commission as a monotherapy for the treatment of adult patients with multiply relapsed or refractory aggressive NHL. The European Commission granted conditional marketing authorization for PIXUVRI based, in part, on the results of the PIX301 trial.

Similar to accelerated approval regulations in the U.S., conditional marketing authorizations can be granted in the E.U. by the European Commission in exceptional circumstances in accordance with the procedures discussed in Part I, Item 1, Business—Government Regulation—Non-U.S. Regulation. A conditional marketing authorization is required to be renewed annually. In connection with the conditional marketing authorization for PIXUVRI, we are conducting the PIX306 post-marketing study, which is an ongoing randomized, controlled Phase 3 clinical trial comparing 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. Under the provisions of the conditional marketing authorization for PIXUVRI, we are required to submit the clinical study report for the post-marketing study in November 2016 to further investigate the effects of using PIXUVRI in patients who had received prior treatment with rituximab. In December 2013, we obtained an agreement from the EMA to change the primary endpoint of the PIX306 study from overall survival to PFS. PIX306 is now expected to enroll approximately 220 patients versus the 350 patients previously planned and is currently enrolling patients in sites in the U.S. and Europe. If the PIX306 study is deemed successful by the applicable European regulatory authorities, it is intended that the conditional approval for PIXUVRI would no longer be necessary in and the E.U. and instead a full marketing authorization would be granted by the European Commission. We believe that the data from the PIX306 study could 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. PIXUVRI is currently available in Austria, Denmark, Finland, France, Germany, Israel, Italy, Netherlands, Norway, Sweden and the U.K., and has achieved reimbursement decisions under varying conditions in England/Wales, Italy, France, Germany, the Netherlands and Spain. PIXUVRI is not approved in the U.S.

We have established a commercial organization, including sales, marketing, supply chain management and reimbursement capabilities, to commercialize PIXUVRI in certain countries in the E.U., and in September 2014 we entered into the Servier Agreement with respect to the development and commercialization of PIXUVRI. Under the Servier Agreement, we retain full commercialization rights to PIXUVRI in Austria, Denmark, Finland, Germany, Israel, Norway, Sweden, Turkey, the U.K. and the U.S., while Servier has exclusive rights to commercialize PIXUVRI in all other countries. We received an upfront payment from Servier of €14.0 million (or \$17.8 million using the currency exchange rate as of the date we received the funds in October 2014), and we have the potential to receive milestone payments under the Servier Agreement of up to €89.0 million. Of the foregoing potential milestone payments, we received a €1.5 million milestone payment in February 2015 relating to the attainment of reimbursement approval for PIXUVRI in Spain. For additional information on our collaboration with Servier, please see the discussion in Part I, Item 1, “Business—License Agreements and Additional Milestone Activities—Servier”.

As discussed in Part I, Item 1, “Business—Manufacturing, Distribution and Associated Operations,” we utilize third parties for the manufacture, storage and distribution of PIXUVRI, as well as for other associated supply chain operations. Our strategy of utilizing third parties in such manner allows us to direct our resources to the development and commercialization of compounds rather than to the establishment and maintenance of facilities for such operational activities.

#### Development Candidates

Pacritinib

## Development in Myelofibrosis

Our lead development candidate, pacritinib, is an oral multikinase inhibitor with activity against JAK2, FLT3 and other kinases. 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.

As part of our collaboration with Baxter, we are pursuing a broad approach to advancing pacritinib for adult 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; and the other in patients with low platelet counts, the PERSIST-2 trial.



Our PERSIST-1 trial 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 thrombocytopenia, or low platelets, and primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis. A total of 327 eligible patients were 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 JAK2 inhibitors, and there is no exclusion by patient platelet count.

The primary endpoint for PERSIST-1 was the proportion of patients achieving a 35 percent or greater reduction in spleen volume from baseline to Week 24 as measured by MRI or CT, when compared with physician-specified best available therapy, excluding treatment with JAK2 inhibitors. The secondary endpoint was the percentage of patients achieving a 50 percent or greater reduction in Total Symptom Score, or TSS, from baseline to week 24 as measured by tracking specific symptoms on a form, or Patient Reported Outcome, or PRO, instrument. At the time of initiation of the trial, PERSIST-1 utilized the Myeloproliferative Neoplasm Symptom Assessment Form, or MPN-SAF TSS, the PRO instrument developed by Mayo Clinic, to measure TSS reduction. We collaborated with Mayo Clinic and the FDA and developed a modified instrument to be used as the endpoint for pacritinib clinical development. As a result, we amended 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. In connection with this amendment, we increased patient enrollment in the PERSIST-1 study from 270 to 327 patients. The trial enrolled patients at clinical sites in Europe, Australia, New Zealand, Russia and the U.S. The PRO Consortium, of which we are an active member, was formed by the non-profit Critical Path Institute in cooperation with the FDA and the medical products industry.

In March 2015, we reported positive top-line results for the primary endpoint from PERSIST-1. The trial met its primary endpoint in the intent-to-treat population with statistically significant activity observed in patients irrespective of their initial platelet count, including patients with very low platelet counts at study entry, a condition known as severe or life-threatening thrombocytopenia. The trial demonstrated that pacritinib treatment provided a statistically significant response rate ( $p = 0.0003$ ) in spleen volume reduction in patients with myelofibrosis when compared to best available therapy, excluding treatment with JAK2 inhibitors, or BAT. Importantly, the trial results also demonstrated a significant difference among patients with platelet counts of less than 100,000 per microliter and less than 50,000 per microliter, both subgroups that were stratified at randomization. The magnitude of treatment effect was consistent with previously reported Phase 2 results, with the greatest reduction observed among the sickest patients (platelet counts  $<50,000$  per microliter). Among 50 patients who were red blood cell transfusion dependent at study entry ( $\geq 6$  units of RBC over 90 days pre entry), pacritinib therapy resulted in a clinically meaningful percentage of patients becoming transfusion independent compared to best available treatment. Seventy-nine percent (79%) of patients in the BAT arm of the study crossed over to pacritinib therapy.

The following table shows the proportion of patients randomized to pacritinib or BAT who achieved a  $\geq 35\%$  reduction in spleen volume from baseline at Week 24 or up to Week 24 in the intent-to-treat, or ITT, population or evaluable patient population. The ITT population is the primary analysis, which included all randomized patients on pacritinib,  $n=220$ , or BAT,  $n=107$ . Patients without scans at baseline or at Week 24 are considered as non-responders for this primary analysis. In contrast, the evaluable patient population includes only patients with both baseline and Week 24 scans,  $n=168$  for pacritinib and  $n=85$  for BAT.

	Pacritinib	BAT	p-value
At Week 24 (Intent-to-Treat (1))	42/220 (19.1%)	5/107 (4.7%)	0.0003
Up to Week 24 (2) (Intent-to-Treat)	52/220 (23.6%)	5/107 (4.7%)	$<0.0001$
At Week 24 (Evaluable (3))	42/168 (25.0%)	5/85 (5.9%)	0.0001

- (1) Primary analysis included all patients randomized. Patients who missed baseline and Week 24 MRI or CT scans were counted as non-responders.
- (2) Includes patients who responded before week 24.
- (3) Analysis included patients who had assessment at both baseline and at Week 24.

The safety profile in the trial was consistent with prior Phase 2 trials. While the most common treatment emergent adverse events were diarrhea, nausea and vomiting, the incidence of grade 3 events was lower than observed in Phase 2 trials. No grade 4 gastrointestinal adverse events were reported. Three patients discontinued therapy and nine patients required dose reduction for diarrhea. Preliminary analysis suggests that very few patients discontinued treatment while on pacritinib or required a dose reduction due to treatment-related anemia or thrombocytopenia. Additional data from ongoing analyses along with top-line results from PERSIST-1 will be submitted for presentation at a scientific meeting.

Our ongoing PERSIST-2 trial is a multi-center, open-label, randomized, controlled Phase 3 trial evaluating pacritinib in up to 300 patients with myelofibrosis whose platelet counts are less than or equal to 100,000 per microlitre. This ongoing study is evaluating pacritinib as compared to best available therapy, including the approved JAK1/JAK2 inhibitor dosed according to the product label for myelofibrosis patients with thrombocytopenia. Patients are being randomized (1:1:1) to receive 200 mg pacritinib twice daily, 400 mg pacritinib once daily or best available therapy.

In October 2013, we 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 regulatory 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 week 24 of treatment and the percentage of patients achieving a TSS reduction of 50 percent or greater using eight key symptoms as measured by the modified MPN-SAF TSS 2.0 diary from baseline to week 24. The trial is open for enrollment at clinical sites in the U.S., Canada, Europe, Australia, New Zealand and Russia. Additional study details are available at [www.PERSISTprogram.com](http://www.PERSISTprogram.com) or [www.clinicaltrials.gov](http://www.clinicaltrials.gov), study identifier NCT02055781; however, the information found on such website is not incorporated by reference into this Annual Report on Form 10-K.

#### Development in Other Indications

In January 2014, we announced that an international cooperative group Phase 2 clinical trial of pacritinib in adult patients with relapsed AML with mutations of the FLT3 gene. Mutation of the FLT3 gene is found in approximately one-third of AML patients and is an independent risk factor for poor prognosis. Pacritinib has demonstrated encouraging activity in preclinical models of AML with mutated FLT3 gene, including additional FLT3 mutations that confer resistance to other targeted FLT3 agents. The trial is being conducted by the AML Working Group of the National Cancer Research Institute Haematological Oncology Study Group in AML and high risk MDS under the sponsorship of Cardiff University and supported by Cancer Research UK.

#### Contractual Arrangements Relating to Pacritinib

For a discussion of our milestone and royalty payment potential and other contractual terms under the Baxter Agreement, together with a discussion of the agreement under which we originally acquired pacritinib (and under which we have certain royalty and milestone payment obligations), see Part I, Item 1, “Business—License Agreements and Additional Milestone Activities”.

#### Tosedostat

Tosedostat is a first-in-class selective inhibitor of aminopeptidases, which are required by tumor cells to provide amino acids necessary for growth and tumor cell survival. Tosedostat has demonstrated anti-tumor responses in blood-related cancers and solid tumors in Phase 1 and 2 clinical studies. Several ongoing Phase 2 cooperative group sponsored trials and ISTs are 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 study to support potential regulatory approval. In June 2014, we announced the initiation of an international cooperative group Phase 2/3 clinical trial of tosedostat in combination with low-dose cytarabine in older patients with AML or high risk MDS. The study is being conducted by the National Cancer Research Institute Haematological Oncology Study Group under the sponsorship of Cardiff University. In this Phase 2/3 study, referred to as AML Less Intensive (LI-1), patients are being randomized to standard treatment, low dose cytarabine, versus one of five novel investigational treatments, one of which is tosedostat, each in combination with low dose cytarabine. The trial will utilize a “Pick a Winner” trial design. Overall survival will serve as the primary endpoint of this trial.

In December 2014, 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 the American Society of Hematology Annual Meeting. 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 34 patients (median age was 70) that were enrolled. Patients were randomized for treatment with tosedostat in combination with either cytarabine or decitabine. Eighteen out of 34 (41 percent) patients in this cohort had either a complete response (CR; n=14, 41 percent) or complete response with incomplete blood count recovery (CRi; n=4, 12 percent). The percentage of complete responses was comparable between arms. The study achieved its primary objective with 27 (79 percent)

patients alive at four months. Median overall survival was encouraging at approximately 16.7 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 (47 percent), pulmonary infections (32 percent) and sepsis (21 percent). Clinically significant non-hematological toxicities were uncommon and predominantly low grade.

We have an exclusive worldwide license agreement for tosedostat, as discussed in more detail in Part I, Item 1, “Business—License Agreements and Additional Milestone Activities—Chroma”

#### Opaxio

Opaxio is a novel biologically-enhanced chemotherapeutic agent that links paclitaxel to a biodegradable polyglutamate polymer, resulting in a new chemical entity. Taxanes, including paclitaxel (Taxol<sup>®</sup>) and docetaxel (Taxotere<sup>®</sup>), are widely used for the treatment of various solid tumors, including non-small cell lung, ovarian, breast and prostate 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 the drug in tumor tissue.

The 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 is being conducted and managed by the Gynecologic Oncology Group, or GOG, now part of NRG Oncology, which is one of the National Cancer Institute's funded cooperative cancer research groups focused on the study of gynecologic malignancies.

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 platinum-taxane based therapy. For purposes of registration, the primary endpoint of the study is overall survival of Opaxio compared to no maintenance therapy. Secondary endpoints are PFS, safety and quality of life. The statistical analysis plan calls for up to four interim analyses and one final analysis, each with boundaries for early closure for superior efficacy or for futility. Additional information about GOG-0212 may be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov), study identifier NCT00108745; however, the information found on such website is not incorporated by reference into this Annual Report on Form 10-K.

We acquired an exclusive worldwide license for rights to paclitaxel poligumex 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".

#### Research and Development Expenses

Research and development is essential to our business. We spent \$64.6 million, \$33.6 million and \$33.2 million in 2014, 2013 and 2012, 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 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, if ever, we will generate material net cash inflows from PIXUVRI or be able to commence commercialization of pacritinib, tosedostat and Opaxio. For additional information relating to our research and development expenses and associated risks, see Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations—Results of Operations—Years Ended December 31, 2014 and 2013—Operating costs and expenses—Research and development expenses" and Part I, Item 1A, "Risk Factors".

#### License Agreements and Additional Milestone Activities

##### Servier

In September 2014, we entered into the Servier Agreement pursuant to which we granted Servier an exclusive and sublicensable (subject to certain conditions) royalty-bearing license with respect to the development and commercialization of PIXUVRI for use in pharmaceutical products outside of the CTI Territory (defined below). We retained rights to PIXUVRI in Austria, Denmark, Finland, Germany, Israel, Norway, Sweden, Turkey, the U.K. and the U.S., or collectively, the CTI Territory.

We received an upfront payment in October 2014 of €14.0 million (or \$17.8 million using the currency exchange rate as of the date we received the funds in October 2014). In addition, subject to the achievement of certain conditions, we are eligible to receive milestone payments under the Servier Agreement in the aggregate amount of up to €89.0 million, which is comprised of the following: up to €49.0 million in potential clinical and regulatory milestone payments (of which €9.5 million is payable upon occurrence of certain enrollment events in connection with the PIX306 study for PIXUVRI); and up to €40.0 million in potential sales-based milestone payments. Of the foregoing potential milestone payments, we received a €1.5 million milestone payment in February 2015 relating to the attainment of reimbursement approval for PIXUVRI in Spain. In addition, for a number of years following the first commercial sale of a product containing PIXUVRI in the respective country, regardless of patent expiration or expiration of regulatory exclusivity rights, we are eligible to receive tiered royalty payments ranging from a low-double digit percentage up to a percentage in the mid-twenties based on net sales of PIXUVRI products, subject to certain reductions of up to mid-double digit percentages under certain circumstances.

Unless otherwise agreed by the parties, (i) certain development costs incurred pursuant to a development plan and (ii) certain marketing costs incurred pursuant to a marketing plan will be shared equally by the parties, subject to a maximum dollar obligation of each party.

The Servier Agreement will expire on a country-by-country basis upon the expiration of the royalty terms in the countries outside of the CTI Territory, at which time all licenses granted to Servier would become perpetual and royalty-free. Each party may terminate the Servier Agreement in the event of an uncured repudiatory breach (as defined under English law) of the other party's obligations. Servier may terminate the Servier Agreement without cause on a country-by-country basis upon written notice to us within a specified time period or upon written notice within a certain period of days in the event of (i) certain safety or public health issues involving PIXUVRI or (ii) cessation of certain marketing authorizations. In the event of a termination prior to the expiration date, rights granted to Servier will terminate, subject to certain exceptions.

#### 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 Baxter Agreement, we granted Baxter an exclusive, worldwide (subject to co-promotion rights discussed below), royalty-bearing, non-transferable license (which is sub-licensable under certain circumstances) relating to pacritinib. Licensed products under the Baxter Agreement consist of products in which pacritinib is an ingredient.

Baxter paid us an upfront payment of \$60 million, which included a \$30 million investment in our equity. The Baxter Agreement also provides for us to receive potential additional payments of up to \$302 million upon the successful achievement of certain development and commercialization milestones, comprised of \$112 million of potential clinical, regulatory and commercial launch milestone payments, and potential additional sales milestone payments of up to \$190 million. Of such potential milestones payments, we have received \$20 million to date relating to the achievement of a clinical milestone. We and Baxter will jointly commercialize and share any profits and losses on sales of pacritinib in the U.S.

We were responsible for all development costs incurred prior to January 1, 2014, and are responsible for approximately \$96 million in U.S. and E.U. development costs incurred thereafter, subject to potential adjustment in certain circumstances. 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 third party royalty-bearing licenses to fulfill its obligations under the Baxter Agreement and (ii) in any jurisdiction where there is no longer either regulatory exclusivity or patent protection.

The Baxter Agreement will expire when Baxter has no further obligation 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 certain countries, we may terminate the Baxter Agreement as to one or more such 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.



#### 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 sublicensable license for the rights to PIXUVRI. Pursuant to the UVM Agreement, we acquired the rights to make, have made, sell and use PIXUVRI, and we are obligated to make royalty payments to UVM ranging from low single digits to mid-single digits as a percentage of net sales. The higher royalty rate is payable for net sales in countries where specified UVM licensed patents exist, or where we have obtained orphan drug protection, until such UVM patents or such protection no longer exists. For a period of ten years after first commercialization of PIXUVRI, the lower royalty rate is payable for net sales in such countries after expiration of the designated UVM patents or loss of orphan drug protection, and in all other countries without such specified UVM patents or orphan drug protection. Unless otherwise terminated, the term of the UVM Agreement continues for the life of the licensed patents in those countries in which a licensed patent exists, and continues for ten years after the first sale of PIXUVRI in those countries where no such patents exist. We may terminate the UVM Agreement, on a country-by-country basis or on a patent-by-patent basis, at any time upon advance written notice. UVM may terminate the UVM Agreement upon advance written notice in the event royalty payments are not made. In addition, either party may terminate the UVM Agreement 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 and FLT3, 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

In October 2014, we entered into an asset purchase agreement, or the Chroma APA, with Chroma Therapeutics Limited, or Chroma, pursuant to which we acquired all of Chroma’s right, title and interest in the compound tosedostat and certain related assets. Concurrently, we and Chroma terminated our Co-Development and License Agreement relating to tosedostat, or the Chroma License Agreement, previously entered into on March 11, 2011, thereby eliminating potential future milestone payments thereunder of up to \$209.0 million, and we acquired an exclusive worldwide license with respect to tosedostat directly from Vernalis R&D Limited, or Vernalis.

As consideration under the Chroma APA, we issued an aggregate of 9,000 shares of the Company’s Series 20 convertible preferred stock, of which 7,920 have been delivered to Chroma. The remaining 1,080 shares are being held in escrow for nine months and will be applied towards any indemnification obligations of Chroma as set forth in the Chroma APA.

#### Vernalis

Concurrently with the termination of the Chroma License Agreement and the execution of the Chroma APA, we also entered into an amended and restated exclusive license agreement with Vernalis, or the Vernalis License Agreement, for the exclusive worldwide right to use certain patents and other intellectual property rights to develop, market and commercialize tosedostat and certain other compounds, as well as a deed of novation pursuant to which all rights of Chroma under its prior license agreement with Vernalis relating to tosedostat were novated to us. Under the Vernalis

License Agreement, we have agreed to make tiered royalty payments of no more than a high single digit percentage of net sales of products containing licensed compounds, with such obligation to continue on a country-by-country basis for the longer of ten years following commercial launch or the expiry of relevant patent claims.

The Vernalis License Agreement will terminate when the royalty obligations expire, although the parties have early termination rights under certain circumstances, including the following: (i) we have the right to terminate, with three months' notice, upon the belief that the continued development of tosedostat or any of the other licensed compounds is not commercially viable; (ii) Vernalis has the right to terminate in the event of our uncured failure to pay sums due; and (iii) either party has the right to terminate in event of the other party's uncured material breach or insolvency.

### Gynecologic Oncology Group (GOG)

We entered into an agreement with the GOG, now part of NRG Oncology, in March 2004, as amended, related to the GOG-0212 trial of Opaxio it is conducting in patients with ovarian cancer. Pursuant to the terms of such agreement, we paid an aggregate of \$1.2 million in milestone payments during 2014 based on certain enrollment milestones achieved. We may be required to pay up to an additional \$1.0 million upon the attainment of certain other milestones, of which \$0.5 million has been recorded in accrued expenses as of December 31, 2014.

### PG-TXL

In November 1998, we entered into an agreement, or the PG-TXL Agreement, as amended, with PG-TXL Company, L.P., or PG-TXL, which grants us an exclusive worldwide license for the rights to Opaxio and to all potential uses of PG-TXL's polymer technology. Pursuant to the PG-TXL Agreement, we acquired the rights to research, develop, manufacture, market and sell anti-cancer drugs developed using this polymer technology. 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 of 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 obligations range from low 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 of issues regarding the safety of the products licensed pursuant to the PG-TXL Agreement 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 the other party.

### Novartis

In January 2014, we entered into a termination agreement, or the Novartis 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 agreement with Novartis entered into in September 2006, as amended, or the Original Agreement. Pursuant to the Novartis Termination Agreement, the Original Agreement was terminated in its entirety, except for certain customary provisions, including those pertaining to confidentiality and indemnification, which survive termination.

Under the Novartis Termination Agreement, we agreed not to transfer, license, sublicense or otherwise grant rights with respect to intellectual property of the Compounds unless the recipient thereof agrees to be bound by the terms of the Novartis 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. As a result of having received the upfront payment under the Servier Agreement, we were obligated to pay Novartis €2.1 million (or \$2.7 million using the currency exchange rate as of the date of payment in October 2014). Novartis is entitled to receive potential payments of up to \$16.6 million upon the successful achievement of certain sales milestones of the Compounds. We are also obligated to pay Novartis 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. 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 dated October 6, 2006 with Nerviano Medical Sciences, S.r.l. for brostallicin, a synthetic DNA minor groove binding agent that has demonstrated anti-tumor activity, provides for the potential payment by us of up to \$80 million in milestone payments based on the achievement of certain product development results.

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Teva Pharmaceutical Industries Ltd.

In June 2005, we entered into an acquisition agreement with Cephalon, Inc., or Cephalon, pursuant to which we divested of the compound, TRISENOX. Cephalon was subsequently acquired by Teva Pharmaceutical Industries Ltd., or Teva. Under this 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. To date, we have received \$20.0 million of such potential milestone payments as a result of having achieved certain sales milestones.

#### 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 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 expired in 2014. While we have a pending PIXUVRI-directed U.S. patent application (which, if granted, would expire in 2023), we have to date been unable to obtain issuance of a patent for such application (and no assurances can be made that we will ever receive such patent). The tosedostat-directed patents will expire from 2017 to 2018.

The PIXUVRI-directed patents currently in force in Europe will begin to expire in late March 2015 through a portion of 2023. Some of these European patents are subject to Supplementary Protection Certificates such that the extended patents will expire from 2020 to 2027. Although we are seeking to obtain Supplementary Protection Certificates for certain other of our PIXUVRI-directed patents in Europe that could provide extensions 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 Part I, Item 1A, "Risk Factors".

#### Manufacturing, Distribution and Associated Operations

Our manufacturing strategy utilizes third party contractors for the procurement and manufacture, as applicable, of raw materials, active pharmaceutical ingredients and finished drug product, as well as for labeling, packaging, storage and distribution of our compounds and associated supply chain operations. As our business continues to expand, we expect that our manufacturing, distribution and related operational requirements will increase correspondingly. One item of increasing importance 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, procuring a qualified commercial supplier for pacritinib has become an important objective as we continue to advance the development of pacritinib and position such product for potential commercialization.

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 compounds 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. Manufacturing facilities for products and product candidates must meet cGMP requirements, and commercialized 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 compounds in

accordance with cGMPs for use in clinical trials and distribution.

We believe our operational strategy of utilizing qualified outside vendors in the foregoing manner allows us to direct our financial and managerial resources to development and commercialization activities, rather than to the establishment and maintenance of a manufacturing and distribution 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. In addition to the specific competitive factors discussed below, new anti-cancer drugs that may be developed and marketed in the future could compete with our various compounds.

With respect to PIXUVRI, while 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, 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.

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® in the U.S., and potentially other candidates in development that target JAK inhibition to treat cancer. Tosedostat would compete with currently marketed products such as Dacogen®, Vidaza®, Revlimid®, Thalomid® and Clolar®. 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 as paclitaxel and generic forms of paclitaxel, docetaxel, Tarceva®, Avastin®, Alimta®, and 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.

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. 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 European Commission 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

We are subject to extensive regulation by the FDA and other federal, state, and local regulatory agencies. The Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations set forth, among other things, requirements for the testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record keeping, reporting, distribution, import, export, advertising and promotion of our products. Our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the U.S., although there can be important differences. Additionally, some significant aspects of regulation in the E.U. are addressed in a centralized way through the EMA and the European Commission, but country-specific regulation by the competent authorities of the E.U. member states remains essential in many respects.

#### U.S. Regulation

In the U.S., the FDA regulates drugs under the FDCA and its implementing regulations, through review and approval of New Drug Applications, or NDAs. NDAs require extensive studies and submission of a large amount of data by the applicant.

#### Drug Development

**Preclinical Testing.** Before testing any compound in human subjects in the U.S., a company must generate extensive preclinical data. Preclinical testing generally includes laboratory evaluation of product chemistry and formulation, as well as toxicological and pharmacological studies in several animal species to assess the quality and safety of the product. Animal studies must be performed in compliance with the FDA's Good Laboratory Practice regulations and the U.S. Department of Agriculture's Animal Welfare Act.



IND Application. Human clinical trials in the U.S. cannot commence until an investigational new drug, or IND, application is submitted and becomes effective. A company must submit preclinical testing results to the FDA as part of the IND application, and the FDA must evaluate whether there is an adequate basis for testing the drug in initial clinical studies in human volunteers. Unless the FDA raises concerns, the IND application becomes effective 30 days following its receipt by the FDA. Once human clinical trials have commenced, the FDA may stop the clinical trials by placing them on “clinical hold” because of concerns about the safety of the product being tested, or for other reasons.

Clinical Trials. Clinical trials involve the administration of the drug to healthy human volunteers or to patients, under the supervision of a qualified investigator. The conduct of clinical trials is subject to extensive regulation, including compliance with the FDA’s bioresearch monitoring regulations and Good Clinical Practice, or GCP, requirements, which establish standards for conducting, recording data from and reporting the results of, clinical trials, and are intended to assure that the data and reported results are credible and accurate, and that the rights, safety, and well-being of study participants are protected. Clinical trials must be conducted under protocols that detail the study objectives, parameters for monitoring safety, and the efficacy criteria, if any, to be evaluated. Each protocol is reviewed by the FDA as part of the IND application. In addition, each clinical trial must be reviewed, approved, and conducted under the auspices of an institutional review board, or IRB, at the institution conducting the clinical trial. Companies sponsoring the clinical trials, investigators, and IRBs also must comply with regulations and guidelines for obtaining informed consent from the study subjects, complying with the protocol and investigational plan, adequately monitoring the clinical trial and timely reporting adverse events. Foreign studies conducted under an IND application must meet the same requirements that apply to studies being conducted in the U.S. Data from a foreign study not conducted under an IND application may be submitted in support of an NDA if the study was conducted in accordance with GCP and the FDA is able to validate the data.

A study sponsor is required to submit certain details about active clinical trials and clinical trial results to the National Institutes of Health for public posting on <http://clinicaltrials.gov>. Human clinical trials typically are conducted in three sequential phases, although the phases may overlap with one another:

- Phase 1 clinical trials include the initial administration of the investigational drug to humans, typically to a small group of healthy human subjects, but occasionally to a group of patients with the targeted disease or disorder. Phase 1 clinical trials generally are intended to determine the metabolism and pharmacologic actions of the drug, the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness.
- Phase 2 clinical trials generally are controlled studies that involve a relatively small sample of the intended patient population, and are designed to develop data regarding the product’s effectiveness, to determine dose response and the optimal dose range and to gather additional information relating to safety and potential adverse effects.
- Phase 3 clinical trials are conducted after preliminary evidence of effectiveness has been obtained, and are intended to gather the additional information about safety and effectiveness necessary to evaluate the drug’s overall risk-benefit profile, and to provide a basis for physician labeling. Generally, Phase 3 clinical development programs consist of expanded, large-scale studies of patients with the target disease or disorder to obtain statistical evidence of the efficacy and safety of the drug, or the safety, purity, and potency of a biological product, at the proposed dosing regimen.

The sponsoring company, the FDA or the IRB may suspend or terminate a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. Further, success in early-stage clinical trials does not assure success in later-stage clinical trials. Data obtained from clinical activities are not always conclusive and may be subject to alternative interpretations that could delay, limit or prevent regulatory approval.

The FDA and IND application 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.

## Drug Approval

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 there can be no assurance that any product 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 breakthrough therapy, fast track, priority review and accelerated approval that are intended to expedite or simplify the process for reviewing drugs and/or provide for approval on the basis of surrogate endpoints. Generally, drugs that may be eligible for one or more of these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs and those that provide meaningful benefit over existing treatments. We cannot be sure that any of our drugs will qualify for any of these programs, or that, if a drug does qualify, the review time will be reduced or the product will be approved.

Before approving a NDA, the FDA usually will inspect the facility or the facilities where the product is manufactured, tested and distributed and will not approve the product unless cGMP compliance is satisfactory. If the FDA evaluates the NDA and the manufacturing facilities as acceptable, the FDA may issue an approval letter, or in some cases, a complete response letter. A complete response letter contains a number of conditions that must be met in order to secure final approval of the NDA. When and if those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter. The approval letter authorizes commercial marketing of the drug for specific indications. As a condition of approval, the FDA may require post-marketing testing and surveillance to monitor the product's safety or efficacy, or impose other post-approval commitment conditions.

In some circumstances, post-marketing testing may include post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, which are used primarily to gain additional experience from the treatment of patients in the intended population, particularly for long-term safety follow-up. In addition, the FDA may require a Risk Evaluation and Mitigation Strategy, or REMS, to ensure that the benefits outweigh the risks. A REMS can include medication guides, physician communication plans and elements to assure safe use, such as restricted distribution methods, patient registries or other risk mitigation tools.

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. Future FDA inspections may identify compliance issues at manufacturing facilities 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. After approval in the U.S., we must comply with FDA's regulation of drug promotion and advertising, including restrictions on off-label promotion, and we comply with federal anti-kickback statutes, limitations on gifts and payments to physicians and reporting of payments to certain third-parties, among other requirements. In December 2007, we entered into a corporate integrity agreement with the Office of the Inspector General, Health and Human Services as part of our settlement agreement with the U.S. Attorney's Office for the Western District of Washington arising out of their investigation into certain of our prior marketing practices relating to TRISENOX, which was divested to Cephalon in July 2005. The term of the corporate integrity agreement, 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.

Failure to comply with applicable U.S. requirements may subject us to administrative or judicial sanctions, such as clinical holds, FDA refusal to approve pending NDAs or supplemental applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution.

## 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 the E.U., marketing authorizations for medicinal products can be obtained through several different procedures founded on the same basic regulatory process. The centralized procedure is mandatory for certain medicinal products, including orphan medicinal products, medicinal products derived from certain biotechnological processes, advanced therapy medicinal products and certain other new medicinal products containing a new active substance for the treatment of certain diseases. It is optional for certain other products, including medicinal products that are significant therapeutic, scientific or technical innovations, or whose authorization would be in the interest of public or animal health. The centralized procedure allows a company to submit a single application to the EMA which will provide a positive opinion regarding the application if it meets certain quality, safety, and efficacy requirements. Based on the opinion of the EMA, the European Commission takes a final decision to grant a centralized marketing authorization which is valid in all 28 E.U. Member States and three of the four European Free Trade Association states (Iceland, Liechtenstein and Norway).

Unlike the centralized authorization procedure, the decentralized marketing authorization procedure requires a separate application to, and leads to separate approval by, the competent authorities of each E.U. Member State in which the product is to be marketed. One national competent authority selected by the applicant, the Reference Member State, assesses the application for marketing authorization. Following a positive opinion by the competent authority of the Reference Member State the competent authorities of the other E.U. Member States, Concerned Member States are subsequently required to grant marketing authorization for their territory on the basis of this assessment except where grounds of potential serious risk to public health require this authorization to be refused. The mutual recognition procedure is similarly based on the acceptance by the competent authorities of the Concerned Member States of the marketing authorization of a medicinal product by the competent authorities of other Reference Member States. The holder of a national marketing authorization granted by a Reference Member State may submit an application to the competent authority of a Concerned Member State requesting that this authority mutually recognize the marketing authorization delivered by the competent authority of the Reference Member State.

Similar to accelerated approval regulations in the U.S., conditional marketing authorizations can be granted in the E.U. by the European Commission in exceptional circumstances. A conditional marketing authorization can be granted for medicinal products where a number of criteria are fulfilled; i) although comprehensive clinical data referring to the safety and efficacy of the medicinal product have not been supplied, the benefit/risk balance of the product is positive, ii) it is likely that the applicant will be in a position to provide the comprehensive clinical data, iii) unmet medical needs will be fulfilled and iv) the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorization must be renewed annually. Under the provisions of the conditional marketing authorization for PIXUVRI, we are required to complete a post-marketing study to further investigate the effects of using PIXUVRI in patients who had received prior treatment with rituximab.

Even if a product receives authorization in the E.U., there can be no assurance that reimbursement for such product will be secured on a timely basis or at all. Individual countries comprising the EU member states, rather than the EU, have jurisdiction across the region over patient reimbursement or pricing matters. Therefore, we will need to expend significant effort and expense to establish and maintain reimbursement arrangements in the various countries

comprising the E.U. and may never succeed in obtaining widespread reimbursement arrangements therein.

The national authorities of the individual E.U. Member States are free to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices and/or reimbursement of medicinal products for human use. Some E.U. Member States adopt policies according to which a specific price or level of reimbursement is approved for the medicinal product. Other E.U. Member States adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market, including volume-based arrangements and reference pricing mechanisms.

Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some E.U. Member States. These E.U. Member States include the U.K, France, Germany and Sweden. The HTA process, which is governed by the national laws of these countries, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product vary between E.U. Member States.

## Post-Approval Regulation

Similarly to the U.S., both marketing authorization holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA and the competent authorities of the individual E.U. Member States both before and after grant of the manufacturing and marketing authorizations. Failure by us or by any of our third party partners, including suppliers, manufacturers and distributors to comply with E.U. laws and the related national laws of individual E.U. Member States governing the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products and marketing of such products, both before and after grant of marketing authorization, may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials or to grant marketing authorization, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

The holder of an E.U. marketing authorization for a medicinal product must also comply with E.U. pharmacovigilance legislation and its related regulations and guidelines, which entail many requirements for conducting pharmacovigilance, or the assessment and monitoring of the safety of medicinal products. These rules can impose on central marketing authorization holders for medicinal products the obligation to conduct a labor intensive collection of data regarding the risks and benefits of marketed products and to engage in ongoing assessments of those risks and benefits, including the possible requirement to conduct additional clinical studies, which may be time consuming and expensive and could impact our profitability. Non-compliance with such obligations can lead to the variation, suspension or withdrawal of the marketing authorization for the product or imposition of financial penalties or other enforcement measures. In the E.U., PIXUVRI's label includes an inverted black triangle, which indicates that it is subject to additional monitoring, as a condition of authorization of PIXUVRI.

The manufacturing process for medicinal products in the E.U. is highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations. Manufacturing requires a manufacturing authorization, and the manufacturing authorization holder must comply with various requirements set out in the applicable E.U. laws, regulations and guidance, including Directive 2001/83/EC, Directive 2003/94/EC, Regulation (EC) No 726/2004 and the European Commission Guidelines for Good Manufacturing Practice. These requirements include compliance with E.U. cGMP standards when manufacturing medicinal products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the E.U. with the intention to import the active pharmaceutical ingredients into the E.U. Similarly, the distribution of medicinal products into and within the E.U. is subject to compliance with the applicable E.U. laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of the E.U. Member States.

We and our third party manufacturers are subject to cGMP, which are extensive regulations governing manufacturing processes, stability testing, record keeping and quality standards as defined by the EMA, the competent authorities of E.U. Member States and other regulatory authorities. The EMA reviews Periodic Safety Update Reports for medicinal products authorized in the E.U. If the EMA has concerns that the risk benefit profile of a product has varied, it can adopt an opinion advising that the existing marketing authorization for the product be suspended or varied and can advise that the marketing authorization holder be obliged to conduct post-authorization safety studies. The EMA opinion is submitted for approval by the European Commission. Failure by the marketing authorization holder to fulfill the obligations for which the approved opinion provides can undermine the on-going validity of the marketing authorization.

## Sales and Marketing Regulations

In the E.U., the advertising and promotion of our products are subject to E.U. Member States' laws governing promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair

commercial practices. In addition, other legislation adopted by individual E.U. Member States may apply to the advertising and promotion of medicinal products. These laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, as approved by the competent authorities. Promotion of a medicinal product that does not comply with the SmPC is considered to constitute off-label promotion. The off-label promotion of medicinal products is prohibited in the E.U.. The applicable laws at E.U. level and in the individual E.U. Member States also prohibit the direct-to-consumer advertising of prescription-only medicinal products. Violations of the rules governing the promotion of medicinal products in the E.U. could be penalized by administrative measures, fines and imprisonment. These laws may further limit or restrict the advertising and promotion of our products to the general public and may also impose limitations on our promotional activities with health care professionals.

#### Anti-Corruption Legislation

Our business activities outside of the U.S. are subject to anti-bribery or anti-corruption laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct or rules of other countries in which we operate, including the U.K. Bribery Act of 2010.



Interactions between pharmaceutical companies and physicians are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct developed at both E.U. level and in the individual E.U. Member States. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the E.U.. Violation of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain E.U. Member States also must be publicly disclosed. Moreover, agreements with physicians must often be the subject of prior notification and approval by the physician's employer, his/her competent professional organization, and/or the competent authorities of the individual E.U. Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

#### Data Privacy and Protection

Data protection laws and regulations have been adopted at E.U. level with related implementing laws in individual E.U. Member States which impose significant compliance obligations. For example, the E.U. Data Protection Directive, as implemented into national laws by the E.U. Member States, imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting.

Furthermore, there is a growth towards the public disclosure of clinical trial data in the E.U. which also adds to the complexity of processing health data from clinical trials. Such public disclosure obligations are provided in the new E.U. Clinical Trials Regulation, EMA disclosure initiatives, and voluntary commitments by industry. Data protection authorities from the different E.U. Member States may interpret the E.U. Data Protection Directive and national laws differently, which adds to the complexity of processing personal data in the E.U., and guidance on implementation and compliance practices are often updated or otherwise revised. Failing to comply with these laws could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results. Apart from exceptional circumstances, the E.U. Data Protection Directive prohibits the transfer of personal data to countries outside of the European Economic Area, that are not considered by the European Commission to provide an adequate level of data protection, including the U.S.

#### Consequences of Non-Compliance

Failure to comply with applicable requirements may subject us to administrative or judicial sanctions, such as clinical holds, refusal of regulatory authorities to approve or authorize pending product applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution.

#### Environmental Regulation

In connection with our research and development activities, we are subject to federal, state and local laws, rules, regulations and policies, both internationally and domestically, governing the use, generation, manufacture, storage, air emission, effluent discharge, handling, treatment, transportation and disposal of certain materials, biological specimens and wastes and employee safety and health matters. 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 applicable law and 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 not covered by insurance 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.

#### Employees

As of December 31, 2014, we employed 125 individuals in the U.S., including two employees at our majority-owned subsidiary Aequus Biopharma, Inc., or Aequus, and seven 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.

## Corporate Information

We were incorporated in Washington in 1991. In May 2014, we changed our name from “Cell Therapeutics, Inc.” to “CTI BioPharma Corp.” 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 Telemarico 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.ctibiopharma.com>. We may post information that is important to investors on our website. However, information found on our website is not incorporated by reference into this Annual Report on Form 10-K. “CTI BioPharma”, “PIXUVRI” and “Opaxio” are our proprietary marks. All other product names, trademarks and trade names referred to in this Annual Report on 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 Securities Exchange Act of 1934, as amended, or the Exchange Act, as soon as reasonably practicable after each is electronically filed with, or furnished to, 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.

### 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.

We will need to raise additional funds to operate our business, but additional funds may not be available on acceptable terms, or at all. Any inability to raise required capital when needed could harm our liquidity, financial condition, business, operating results and prospects.

We have substantial operating expenses associated with the development of our compounds and the commercialization of PIXUVRI, and we have significant contractual payment obligations. Our available cash and cash equivalents were \$70.9 million as of December 31, 2014. We believe that our present financial resources, together with additional milestone payments projected to be received under certain of our contractual agreements, our ability to control costs and expected net sales of PIXUVRI, will only be sufficient to fund our operations through mid-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, developments in and expenses associated with our research and development activities, acquisitions of compounds or other assets, any expansion of our sales and marketing organization for PIXUVRI, regulatory approval developments, ability to consummate appropriate collaborations for development and commercialization activities, litigation and other disputes, competitive market developments and other unplanned business developments may consume capital resources earlier than planned. Additionally, we may not receive anticipated milestone payments or achieve projected net 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.

As of December 31, 2014, we have \$18.5 million outstanding under our senior secured term loan agreement, and we are required to make monthly interest plus principal payments in the aggregate amount of approximately \$0.9 million through October 1, 2016. Such borrowings 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. In addition, the senior secured term loan agreement, under which we have no additional borrowing capacity, 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 will need to acquire additional funds in order to operate our business. We may seek to raise such capital through public or private equity financings, partnerships, collaborations, joint ventures, disposition of assets, debt financings or restructurings, bank borrowings or other sources of financing. However, our ability to do so is subject to a number of risks, uncertainties, constraints and consequences, 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 potential difficulty of obtaining shareholder approval to increase authorized shares and the restrictive covenants under our senior secured term loan agreement;
- issuance of equity-based securities will dilute the proportionate ownership of existing shareholders;
- our ability to obtain further funds from any potential loan arrangements is limited by our existing senior secured term loan agreement;
- certain financing arrangements may require us to relinquish rights to various assets and/or impose more restrictive terms than any of our existing or past arrangements; 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.

For these and other reasons, 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, be unable to attract and retain highly qualified personnel, refrain from making our contractually required payments when due (including debt payments) and/or be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection. Any of these consequences could harm our business, financial condition, operating results and prospects.

We received an audit report for the years ended December 31, 2007 through December 31, 2011 and December 31, 2014 containing an explanatory paragraph on our consolidated financial statements raising substantial doubt as to our ability to continue as a going concern.

We received an audit report for each of the years ended December 31, 2007 through December 31, 2011 and December 31, 2014 containing an explanatory paragraph on our consolidated financial statements raising substantial doubt as to our ability to continue as a going concern. The inclusion of a going concern explanatory paragraph may negatively impact the trading price of our common stock and make it more difficult, time consuming or expensive to obtain necessary financing. In the event our operations were to cease, you would suffer a complete loss of your investment in our securities.

We expect to 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, 2014, we had an accumulated deficit of \$2.0 billion, and we expect to continue to incur net losses. As part of our business plan, we will need to continue to conduct research, development, testing and regulatory compliance activities with respect to our compounds and ensure the procurement of manufacturing and drug supply services, the costs of which, together with projected general and administrative expenses, is expected to result in operating losses for the foreseeable future. There can be no assurances that we will ever achieve profitability.

If our development and commercialization collaborations are 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 compound(s), which could have a material adverse effect on our business.

Our business is heavily dependent on the success of our development and commercialization collaborations. In particular, under the Servier Agreement and the Baxter Agreement, we rely heavily on Servier and Baxter, respectively, to collaborate with us to develop and commercialize PIXUVRI and pacritinib. As a result of our dependence on our relationships with Servier and Baxter, the success or commercial viability of PIXUVRI and 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 Servier and Baxter, including the following: possible disagreements as to the timing, nature and extent of development plans for the respective compound, including clinical trials or regulatory approval strategy; changes in their respective personnel who are key to the collaboration efforts; any changes in their respective business strategies adverse to our interests; possible disagreements regarding ownership of proprietary rights; and the possibility that Servier or Baxter could elect to terminate their respective agreements with us pursuant to certain "at-will" termination clauses or otherwise breach their respective agreements with us. Furthermore, the contingent financial returns under our collaborations with Servier and Baxter depend in large part on the achievement of development and commercialization milestones and the ability to generate applicable product sales to trigger royalty payments. Therefore, our success, and any associated future financial returns to us and our investors, will depend in large part on the performance of each of Servier and Baxter. If our existing collaborations fail, or if we do not successfully enter into additional collaborations when needed, we may be unable to further develop and commercialize our compounds, generate revenues to sustain or grow our business or achieve profitability, which would harm our business, financial condition, operating results and prospects.

Compounds that appear promising in research and development may fail to reach later stages of development for a number of reasons, including, among others, that clinical trials may take longer to complete than expected or may not be completed at all, and top-line or preliminary clinical trial data reports may ultimately differ from actual results once existing data are more fully evaluated.

Successful development of anti-cancer and other pharmaceutical products is highly uncertain, and obtaining regulatory approval to market drugs to treat cancer is expensive, difficult and speculative. Compounds that appear promising in research and development may fail to reach later stages of development for several reasons, including,

but not limited to:

- delay or failure in obtaining necessary U.S. and international regulatory approvals, or the imposition of a partial or full regulatory hold on a clinical trial;
- difficulties in formulating a compound, scaling the manufacturing process and obtaining manufacturing approval, pricing, reimbursement issues or other factors that may make the product uneconomical to commercialize;
- production problems, such as the inability to obtain raw materials or supplies satisfying acceptable standards for the manufacture of our products, equipment obsolescence, malfunctions or failures, product quality/contamination problems or changes in regulations requiring manufacturing modifications;
- inefficient cost structure of a compound compared to alternative treatments;
- obstacles resulting from proprietary rights held by others with respect to a compound, such as patent rights;

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- lower than anticipated rates of patient enrollment as a result of factors, such as the number of patients with the relevant conditions, the proximity of patients to clinical testing centers, eligibility criteria for tests and competition with other clinical testing programs;
- preclinical or clinical testing requiring significantly more time than expected, resources or expertise than originally expected and inadequate financing, which could cause clinical trials to be delayed or terminated;
- failure of clinical testing to show potential products to be safe and efficacious, and failure to demonstrate desired safety and efficacy characteristics in human clinical trials;
- suspension of a clinical trial at any time by us, an applicable collaboration partner or a regulatory authority on the basis that the participants are being exposed to unacceptable health risks or for other reasons;
- delays in reaching or failing to reach agreement on acceptable terms with prospective clinical research organizations, or CROs, and trial sites; and
- failure of third parties, such as CROs, academic institutions, collaborators, cooperative groups and/or investigator sponsors, to conduct, oversee and monitor clinical trials and results.

In addition, while we have reported top-line data for PERSIST-1 in this Annual Report on Form 10-K and may report additional top-line data for other trials from time to time, such data are based on a preliminary analysis of then-available efficacy and safety data, and such findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. Top-line or preliminary data is based on important assumptions, estimations, calculations and information then available to us to the extent we have, at the time of such reporting, had an opportunity to fully and carefully evaluate such information in light of all surrounding facts, circumstances, recommendations and analyses. As a result, top-line results observed to date may differ from future results, or different conclusions or considerations may qualify such results once existing data has been more fully evaluated. In addition, third parties, including regulatory agencies, may not accept or agree with our assumptions, estimations, calculations or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular compound and our business in general.

If the development of our compounds is delayed or fails, or if top-line or preliminary clinical trial data reported differ from actual results, our development costs may increase and the ability to commercialize our compounds 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 develop or commercialize some or all of our compounds.

We are subject to rigorous and extensive regulation by the FDA in the U.S. and by comparable agencies in other jurisdictions, including the EMA in the E.U. Pacritinib and our other product candidates 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 our compounds. 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 jurisdictions until they have received approval from the appropriate foreign regulatory agencies. Each product candidate requires significant research, development and preclinical testing and extensive clinical investigation before submission of any regulatory application for marketing approval. Obtaining regulatory approval requires substantial time, effort and financial resources, and we may not be able to obtain approval of any of our products on a timely basis, or at all. The number and focus of preclinical and clinical trials that will be required for approval by the FDA, the EMA or any other foreign regulatory agency varies depending on the compound, the disease or condition that the compound is designed to address and the regulations applicable to any particular compound. 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 compound for many reasons, including, but not limited to:

- a compound may not be shown to be safe or effective;
- clinical trial results may be negative or inconclusive, or adverse medical events may occur during a clinical trial;



such regulatory agencies may not approve the manufacturing process of a compound and may interpret data from pre-clinical and clinical trials in different ways than we do;

· a compound may fail to comply with regulatory requirements; or

· such regulatory agencies might change their approval policies or adopt new regulations.

If our compounds are not approved quickly enough to provide net revenues to defray our operating expenses, our business, financial condition, operating results and prospects could be harmed.

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

The development and ongoing clinical trials for our compounds may not be successful and, even if they are, the resulting products may never be successfully developed into commercial products. Even if we are successful in our clinical trials and in obtaining other regulatory approvals, the respective products may not reach or remain in 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 approvals or pricing that is cost effective for patients as compared to other available forms of treatment or that covers the cost of production and other expenses;
- they may not compete effectively with existing or future alternatives;
- we may be unable to develop commercial operations and to sell marketing rights;
- they may fail to achieve market acceptance; or
- we may be precluded from commercialization of a product due to proprietary rights of third parties.

In particular, with respect to the commercialization of PIXUVRI and the future potential commercialization of pacritinib, we will be heavily dependent on our collaboration partners, Servier and Baxter, respectively. The failure of Servier or Baxter (or any other applicable collaboration partner) to fulfill its respective commercialization obligations with respect to a compound, or the occurrence of any of the events in the list above, 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.

The pharmaceutical business is subject to increasing government price controls and other restrictions on pricing, reimbursement, and access to drugs, which could adversely affect our future revenues and profitability.

To the extent our products are developed, commercialized and successfully introduced to market, they may not be considered cost-effective and third party or government reimbursement might not be available or sufficient. Globally, governmental and other third party payors are becoming increasingly aggressive in attempting to contain healthcare costs by strictly controlling, directly or indirectly, pricing and reimbursement and, in some cases, limiting or denying coverage altogether on the basis of a variety of justifications, and we expect pressures on pricing and reimbursement from both governments and private payors inside and outside the U.S. to continue. 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 instituted comprehensive health care reform, which 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. 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. Reimbursement decisions from one or more of the European markets may impact reimbursement decisions in other European markets. 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. The continuing efforts of government and insurance companies, health maintenance organizations and other payors of healthcare costs to contain or reduce costs of health care may affect our future revenues and profitability or those of our potential customers, suppliers and collaborative partners, as well as 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, in part, on our ability and that of our collaborator, Servier, to successfully commercialize our only marketed product, PIXUVRI. As disclosed elsewhere herein, PIXUVRI is not approved for marketing in the U.S., is presently available only in a limited number of countries and is reimbursed in even fewer countries.

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

- obtain an annual renewal of our conditional marketing authorization for PIXUVRI;
- increase demand for and sales of PIXUVRI and obtain greater acceptance of PIXUVRI by physicians and patients;
- establish and maintain agreements with wholesalers and distributors on reasonable terms;
- maintain, and where necessary, enter into additional, commercial manufacturing arrangements with third parties, cost-effectively manufacture necessary quantities and secure distribution, managerial and other capabilities; and
- further develop and maintain a commercial organization to market PIXUVRI.

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

Post-approval or authorization regulatory reviews and obligations often result in significant expense and marketing limitations, and any failure to satisfy such ongoing obligations, including, in particular, our post-authorization commitment trial for PIXUVRI, could negatively affect our business, financial condition, operating results or prospects.

Even if a product receives regulatory approval or authorization, as applicable, we are and will continue to be subject to numerous regulations and statutes regulating the manner of obtaining reimbursement for and selling the product, including limitations on the indicated uses for which a product may be marketed. Approved or authorized products, including PIXUVRI, are subject to extensive labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping regulations. Regulatory authorities may also impose new restrictions on continued product marketing or may require the withdrawal of a product from the market if adverse events of unanticipated severity or frequency are discovered following approval. In addition, regulatory agencies may impose post-approval/post-authorization clinical trials, such as our ongoing PIX306 study of PIXUVRI required by the EMA. We cannot predict the outcome of PIX306 or whether we will be able to complete the associated requirements in a timely manner. If we are unable to submit the requisite PIX306 clinical study report by the due date in November 2016 or are otherwise unable to satisfy all applicable requirements, our conditional marketing authorization for PIXUVRI may be revoked. A revocation of PIXUVRI's or any other product's approval or authorization or any other failure to maintain applicable regulatory approvals would result in the respective product being withdrawn from the market, product seizures, monetary penalties or possible criminal prosecution, which could negatively affect our business, financial condition, operating results or prospects.

We may be unable to obtain a quorum for meetings of our shareholders or obtain requisite shareholder approval and, consequently, be unable to take certain corporate actions.

Failure to meet the requisite quorum or obtain requisite shareholder approval can prevent us from raising capital through equity financing or otherwise taking certain actions that may be in our best interest and that of our shareholders. We have experienced such difficulties in the past.

A portion 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 recent years, certain depository banks in Italy holding shares of our common stock have facilitated book-entry transfers of their share positions at Monte Titoli

to their U.S. correspondent bank, who would then transfer the shares to an account of the Italian bank at a U.S. broker-dealer that is an affiliate of that bank. Certain of the banks we contacted to facilitate these arrangements agreed to make the share transfers pursuant to these arrangements as of the record date of the shareholder 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 may 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 do so in the future.

As a result of the foregoing or for other reasons, we may be unable to obtain a quorum 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. 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, 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 applicable rules and regulations, particularly in light of difficulties we have had in the past in obtaining a quorum and obtaining the requisite vote. If we are unable to obtain financing or our financing options are limited due to shareholder approval difficulties, such failure may harm our ability to continue operations.

We are subject to Italian regulatory requirements, which limit our ability to issue additional shares of our common stock, could result in administrative and other challenges and additional expenses and/or could limit our ability to undertake other business initiatives.

Because our common stock is traded on the MTA in Italy, 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 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 (which jointly compose a prospectus) that have to be approved by CONSOB prior to issuing common stock that is equal to or 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 issued convertible preferred stock in numerous prior offerings and may in the future issue convertible securities; 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, this exception to the prospectus requirement could change or cease to be available as a result of changes in regulations, interpretive positions, policies or otherwise. Any such change may increase compliance costs or limit our ability to issue securities. 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 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 and fines or other sanctions from time to time. For more information on a current investigation, see Part I, Item 3, Legal Proceedings.

Any of such regulatory requirements of CONSOB and the Borsa Italiana could result in administrative and other challenges and additional expenses, limit our ability to undertake other business initiatives and negatively affect our business, financial condition, operating results and prospects.

We will incur a variety of costs for, and may never realize the anticipated benefits of, acquisitions, collaborations or other strategic transactions.

We evaluate and undertake acquisitions, collaborations and other strategic transactions from time to time. The process of negotiating these transactions, as well as integrating any acquisitions and implementing any strategic alliances, may result in operating difficulties and expenditures. In addition, these transactions 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. These undertakings could also result in potentially dilutive issuances of equity securities, including common stock and preferred stock, the incurrence of debt, contingent liabilities and/or

amortization expenses related to intangible assets, and we may never realize the anticipated benefits. In addition, following the consummation of a transaction, our results of operations and the market price of our common stock may be affected by factors different from those that affected our results of operations and the market price of our common stock prior to such acquisition. Any of the foregoing consequences resulting from transactions of the type described above could harm our business, financial condition, operating results or prospects.

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, ultimate sale and use 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 U.S. Attorney's Office for the Western District of Washington arising out of their investigation into certain of our prior marketing practices relating to TRISENOX, which was divested to Cephalon in July 2005. As part of that settlement agreement and in connection with the acquisition of Zevalin, we also entered into a corporate integrity agreement with the Office of the Inspector General, Health and Human Services, 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 the numerous laws and regulations that govern our business, including those related to cross-border conduct, healthcare fraud and abuse, anti-corruption and false claims and the protection of health information, 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 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 products. 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 may also be subject to the Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act and their respective implementing regulations, or HIPAA, which established uniform standards for certain "covered entities" (healthcare providers, health plans and healthcare clearinghouses) governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of protected health information. Among other things, HIPAA's privacy and security standards are directly applicable to "business associates" — independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. In addition to possible civil and criminal penalties for violations, state attorneys general are authorized to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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 applicable 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 party service providers for a number of critical operational activities including, in particular, for clinical trial activities and for the manufacture, testing and distribution of our compounds and associated supply chain operations. Any failure or delay in these undertakings by third parties could harm our business.



Our business is dependent on the performance by third parties of their responsibilities under contractual relationships. In particular, we depend on medical institutions and CROs (together with their respective employees, subcontractors and other agents, as applicable) to conduct clinical trials and associated activities in compliance with Good Clinical Practice, or GCP, and in accordance with our timelines, expectations and requirements. To the extent any such third parties are delayed in achieving or fail to meet our clinical trial enrollment expectations, fail to conduct our trials in accordance with GCP or study protocol or otherwise take actions outside of our control or without our consent, our business may be harmed. In addition, we conduct clinical trials in foreign countries, which subjects us to additional risks and challenges, including, in particular, as a result of the engagement of foreign medical institutions and foreign CROs, who may be less experienced with regard to regulatory matters applicable to us and may have different standards of medical care.

We also rely heavily on third parties for the manufacture, testing and distribution of our compounds and associated supply chain operations. We do not have internal analytical laboratory or manufacturing facilities to allow the testing or production of drug products in compliance with cGMPs. As a result, we are reliant on third parties to supply us in a timely manner with manufactured products/product candidates. We depend on these third parties to conduct their operations in compliance with cGMPs or similar 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. We also rely on third party service providers for certain warehousing, transportation, sales, order processing, distribution and cash collection services. For example, Quintiles Commercial Europe Limited provides a variety of key services to us related to the commercialization of PIXUVRI in certain countries in Europe.

With respect to certain clinical trial operations and steps in the manufacturing and distribution chain of our compounds, we rely on single vendors. The use of single vendors for these core operational activities and the resulting lack of diversification expose us to the risk of an interruption in service related to these single, outside vendors. As a result, our exposure to this concentration risk could harm our business.

If the third parties on which we depend were to default on the performance of their contractual obligations to us or otherwise fail in properly executing their duties on our behalf, including, but not limited to, those relating to the clinical trials, manufacturing, distribution and other core operational activities, our business could be harmed.

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.
- If we are successful in bringing pacritinib to market, pacritinib will face competition from ruxolitinib (Jakafi®).
- If we are successful in bringing tosedostat to market, tosedostat will face competition from currently marketed products, such as cytarabine, Dacogen®, Vidaza®, Clolar®, Revlimid® and Thalomid®.
- If we are successful in bringing Opaxio to market, we will face competition from other taxanes, epothilones, and other cytotoxic agents, which inhibit cancer cells by a mechanism similar to taxanes, or similar products such as

paclitaxel and generic forms of paclitaxel, docetaxel, Tarceva<sup>®</sup>, Avastin<sup>®</sup>, Alimta<sup>®</sup>, and Abraxane<sup>®</sup>.

In addition to the specific competitive factors discussed above, new anti-cancer drugs that may be developed and marketed in the future could compete with our various compounds.

Many of our competitors, particularly 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, commercializing, manufacturing, marketing and selling products. As a result, products of our competitors might come to market sooner or might prove to be more effective, less expensive, have fewer side effects or be easier to administer than ours. In any such case, sales of PIXUVRI or any potential future product would likely suffer and we might never recoup the significant investments we have made and will continue to make to develop and market these compounds.

If we are unable to in-license or acquire additional product candidates, our future product portfolio and potential profitability could be harmed.

One component of our business strategy is the in-licensing and acquisition of drug compounds developed by other pharmaceutical and biotechnology companies or academic research laboratories. PIXUVRI, pacritinib, tosedostat and Opaxio have all 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 or acquisition opportunities and enter into arrangements on acceptable terms, our future product portfolio and potential profitability could be harmed.

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 arrangements. 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.

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 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 patent status of our compounds follows:

· Our PIXUVRI-directed patents currently in force in Europe will begin to expire in late March 2015 through a portion of 2023. Certain of such European patents are also subject to Supplementary Protection Certificates that extend the life of the applicable patents such that they will instead expire from 2020 to 2027. In addition, we are seeking to obtain Supplementary Protection Certificates for certain other of our PIXUVRI-directed European patents that, if obtained, could provide extensions of the applicable patents through 2027. However, no assurances can be made that such extensions will be granted. Our PIXUVRI-directed U.S. patents expired in 2014, and although we have a pending PIXUVRI-directed U.S. patent application (which, if granted, would expire in 2023), we have to date been unable to obtain issuance of a patent for such application (and no assurances can be made that we will ever receive

such patent). Our PIXUVRI-directed patents outside of Europe and the U.S. expire from 2015 to 2023.

- Our U.S. and various foreign pacritinib-directed patents expire from 2026 through 2029.
- Our U.S. and various foreign tosedostat-directed patents expire from 2017 to 2018.
- Our U.S. and various foreign Opaxio-directed patents expire on various dates ranging from 2017 through 2018.
- Our U.S. and various foreign brostallicin-directed patents expire on various dates ranging between 2017 through 2021.

In the absence of a patent, as in the case of PIXUVRI in the U.S., we will, to the extent possible, need to rely on unpatented technology, know-how and confidential information. Ultimately, the lack or expiration at any given time of a patent to protect our compounds may allow our competitors to copy the underlying inventions and better compete with us.

If we fail to adequately protect our intellectual property, our competitive position and the potential for long-term success 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 pharmaceutical and biotechnology firms, including ours, 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 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 materially 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 compounds 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.

The illegal distribution and sale by third parties of counterfeit versions of a product or stolen product could have a negative impact on our reputation and business.

Third parties might illegally distribute and sell counterfeit or unfit versions of a product, which does not meet our rigorous manufacturing and testing standards. A patient who receives a counterfeit or unfit product may be at risk for a number of dangerous health consequences. Our reputation and business could suffer harm as a result of counterfeit or unfit product sold under our brand name. In addition, thefts of inventory at warehouses, plants or while in-transit, which are not properly stored and which are sold through unauthorized channels, could adversely impact patient safety, our reputation and our business.

We may owe additional amounts for value added tax, or VAT, related to our operations in Europe.

Our European operations are subject to the VAT, which is usually applied to all goods and services purchased and sold throughout Europe. The VAT receivable was \$4.9 million and \$5.5 million as of December 31, 2014 and December 31, 2013, respectively. On April 14, 2009, December 21, 2009 and June 25, 2010, the Italian Tax Authority, or the ITA, issued notices of assessment to our branch, 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 Italian 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 \$11.4 million converted using the currency exchange rate as of December 31, 2014) 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.

We are currently subject to certain regulatory and legal proceedings, and may in the future be subject to additional proceedings and/or allegations of wrong-doing, which could harm our financial condition and operating results.

We are currently, and may in the future be, subject to regulatory matters and legal claims, including possible securities, derivative, consumer protection and other types of proceedings pursued by individuals, entities or regulatory bodies. As described in Part I, Item 3, Legal Proceedings, we are currently engaged in a number of pending legal matters. Litigation is subject to inherent uncertainties, and we have had and may in the future have unfavorable rulings and settlements. Adverse outcomes in some or all of such pending cases may result in significant monetary damages or injunctive relief against us. 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, and 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.

Securities class action and shareholder derivative lawsuits are often instituted against issuers. We have been subjected to such actions and we, together with our directors and one former director, presently are subject to a derivative

lawsuit.

We cannot predict with certainty the eventual outcome of pending litigation. In addition, negative publicity resulting from any allegations of wrong-doing could harm our business, regardless of whether the allegations are valid or whether we are liable. Furthermore, we may have to incur substantial time and expense 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 negative publicity resulting from allegations of wrong-doing and/or an adverse outcome under any currently pending or future lawsuit, our business could be materially harmed.

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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.

Due to the fact that we have European branches and subsidiaries conducting operations, together with the fact that we are party to certain contractual arrangements denoting monetary amounts in foreign currencies, we are subject to 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. In addition, certain of our contractual arrangements, such as the Servier Agreement, denote monetary amounts in foreign currencies, and consequently, the ultimate financial impact to us from a U.S. dollar perspective is subject to significant uncertainty. Changes in the value of the U.S. dollar as compared to foreign currencies (in particular, the euro) might have an adverse effect on our reported operating results and financial condition.

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. If any 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 compounds, 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, marketing and sale 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 compound 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.

We may be subject to claims relating to improper handling, storage or disposal of hazardous materials.

Our research and development activities involve the controlled use of hazardous materials, chemicals and various radioactive compounds. We are subject to federal, state and local laws and regulations, both internationally and domestically, governing the use, manufacture, storage, handlings, treatment, transportation and disposal of such materials and certain waste products and employee safety and health matters. Although we believe that our safety procedures for handling and disposing of such materials comply with applicable law and 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, safety and health laws and regulations may be expensive, and

current or future environmental regulations may impair our research, development or production efforts.

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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 expenses or lose revenues or suffer other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows.

#### Risks Related To the Securities Markets

Shares of our common stock are subordinate to any preferred stock we may issue and to existing and any 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 under our senior secured term loan agreement, and any future indebtedness we may incur, as well as 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, (i) dividends are payable only when and if declared by our Board of Directors or a duly authorized committee of our Board of Directors and (ii) as a corporation, we are restricted to making dividend payments and redemption payments out of legally available assets. We have never paid a dividend on our common stock and have no current intention to pay dividends in the future. Furthermore, our common stock places no restrictions on our business or operations or on our ability to incur indebtedness or engage in any transactions, subject only to the voting rights available to our shareholders generally.

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 and consequently may negatively impact the price 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 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 market 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 in Italy. 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, CONSOB 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 market price of our common stock.

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 March 5, 2015, our stock price has ranged from a low of \$2.00 to a high of \$4.22. Fluctuations in the market price or liquidity of our common stock may harm the value of your investment in our common stock.

Factors that may have an impact, which, depending on the circumstances, could be significant, 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 by us or others relating to our ongoing development and commercialization activities;
- announcements of technological innovations or new commercial therapeutic products by us, our collaborative partners or our present or potential competitors;
- our issuance of debt or equity securities, which we expect to pursue to generate additional funds to operate our business, or any perception from time to time that we will issue such securities;
- our quarterly operating results;
- liquidity, cash position or financing needs;
- 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 our compounds;
- litigation and government proceedings;
- adverse legislation, including changes in governmental regulation;
- third party reimbursement policies;
- changes in securities analysts' recommendations;
- short selling of our securities;
- 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 or on the MTA; and
- general economic and market conditions.

Anti-takeover provisions in our charter documents, in our shareholder rights agreement, or rights plan, under Washington law and in other applicable instruments could make removal of incumbent management or an acquisition of us, which may be beneficial to our shareholders, more difficult.

Provisions of our articles of incorporation and bylaws may have the effect of deterring or delaying attempts by our shareholders to remove or replace management, to commence proxy contests, or to effect changes in control. These provisions include:

- elimination of cumulative voting in the election of directors;
- procedures for advance notification of shareholder nominations and proposals;
- the ability of our Board of Directors to amend our bylaws without shareholder approval; and
- the ability of our Board of Directors to issue shares of preferred stock without shareholder approval upon the terms and conditions and with the rights, privileges and preferences as our 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. Other existing provisions applicable to us that could have an anti-takeover effect include our executive employment agreements and certain provisions of our outstanding equity-based compensatory awards that allow for acceleration of vesting in the event of a change in control.

The foregoing provisions, alone or together, could have the effect of deterring or delaying changes in incumbent management, proxy contests or changes in control.

#### Item 1B. Unresolved Staff Comments

None.

#### Item 2. Properties

We currently lease approximately 66,000 square feet of space at 3101 Western Avenue in Seattle, Washington. The lease commenced in May 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 2015. Additionally, we lease 2,700 square feet in Milan, Italy with a lease expiration of December 2015 and 439 square feet in Uxbridge, U.K. with a lease expiration of September 2015. We believe our existing and planned facilities are adequate to meet our present requirements. We anticipate that additional space will be available, when needed, on commercially reasonable terms.

#### Item 3. Legal Proceedings

On 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 \$6,000 and \$606,000 upon conversion from euros as of December 31, 2014. 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 Italian 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 \$11.4 million converted using the currency exchange rate as of December 31, 2014, 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. Following is a summary of the status of the legal proceedings surrounding each respective VAT year return at issue:

·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. In January 2014, we appealed such decision to the Italian Supreme Court both on procedural grounds and on the merits of the case. In March 2014, we paid a deposit in respect of the 2003 VAT matter of €0.4 million, or approximately \$0.6 million upon conversion from euros as of the date of payment following the ITA's request for such payment.

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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. We, as well as the ITA, 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. In April 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 to the Italian Supreme Court 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 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 to the Italian Supreme Court in November 2013.

In July 2014, Joseph Lopez and Gilbert Soper, shareholders of the Company, filed a derivative lawsuit purportedly on behalf of the Company, which is named a nominal defendant, against all current and one past member of our Board of Directors in King County Superior Court in the State of Washington, docketed as Lopez & Gilbert v. Nudelman, et al., Case No. 14-2-18941-9 SEA. The lawsuit alleges that the directors exceeded their authority under the Company's 2007 Equity Incentive Plan, or the Plan, by improperly transferring 4,756,137 shares of the Company's common stock from the Company to themselves. It alleges that the directors breached their fiduciary duties by granting themselves fully vested shares of Company common stock, which the plaintiffs allege were not among the six types of grants authorized by the Plan, and that the non-employee directors were unjustly enriched by these grants. The lawsuit also alleges that from 2011 through 2014, the non-employee members of our Board of Directors granted themselves grossly excessive compensation, and in doing so breached their fiduciary duties and were unjustly enriched. Among other remedies, the lawsuit seeks a declaration that the specified grants of common stock violated the Plan, rescission of the granted shares, disgorgement of the compensation awards to the non-employee directors from 2011 through 2014, disgorgement of all compensation and other benefits received by the defendant directors in the course of their breaches of fiduciary duties, damages, an order for certain corporate reforms and plaintiffs' costs and attorneys' fees. Because the complaint is derivative in nature, it does not seek monetary damages from the Company. In September 2014, the director defendants moved to dismiss the complaint. The motion to dismiss was heard on November 21, 2014, and the Court entered an order denying the motion to dismiss on December 5, 2014. Defendants' answer to the complaint was filed on January 13, 2015. The trial date is currently set for August 24, 2015.

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.





## 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 under the symbol "CTIC" on each of The NASDAQ Capital Market and the MTA in Italy. 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
2013		
First Quarter	\$ 1.71	\$ 1.02
Second Quarter	\$ 1.43	\$ 1.02
Third Quarter	\$ 1.80	\$ 0.97
Fourth Quarter	\$ 2.17	\$ 1.49
2014		
First Quarter	\$ 4.25	\$ 1.99
Second Quarter	\$ 3.60	\$ 2.53
Third Quarter	\$ 3.10	\$ 2.35
Fourth Quarter	\$ 2.56	\$ 2.42

On March 5, 2015, the last reported sale price of our common stock on The NASDAQ Capital Market was \$2.72 per share. As of March 5, 2015, there were 205 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, 2014:

Period	Total Number of Shares Purchased (1)	Average Price Paid per Share	Total Number of Shares Purchased	Maximum Number of Shares that May Yet Be

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			as Part of Publicly Announced Programs	Purchased Under the Plans or Programs
October 1 – October 31, 2014	1,851	2.43	—	—
November 1 – November 30, 2014	1,255	2.17	—	—
December 1 – December 31, 2014	1,632	2.50	—	—
Total	4,738	2.39	—	—

(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, 2014, 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, 2009. The actual returns shown on the graph above are as follows:

	12/31/09	12/31/10	12/31/11	12/31/12	12/31/13	12/31/14
CTI BioPharma Corp.	\$ 100.00	\$ 32.46	\$ 16.96	\$ 3.80	\$ 5.58	\$ 6.90
NASDAQ Stock Index (U.S.)	\$ 100.00	\$ 117.55	\$ 117.91	\$ 137.29	\$ 183.26	\$ 206.09
NASDAQ Pharmaceutical Index	\$ 100.00	\$ 102.60	\$ 120.54	\$ 137.81	\$ 186.98	\$ 227.77

## Item 6. Selected Financial Data

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.

	Year ended December 31,				
	2014	2013	2012	2011	2010
(In thousands, except per share data)					
<b>Consolidated Statements of Operations Data:</b>					
<b>Revenues:</b>					
Product sales, net(1)	\$6,909	\$2,314	\$—	\$—	\$—
License and contract revenue(2)	53,168	32,364	—	—	319
Total revenues	60,077	34,678	—	—	319
<b>Operating costs and expenses, net:</b>					
Cost of product sold(1)	895	137	—	—	—
Research and development	64,596	33,624	33,201	34,900	27,031
Selling, general and administrative	56,241	42,288	38,244	38,290	51,546
Acquired in-process research and development(3)	21,859	—	29,108	—	—
Settlement expense (income)	—	155	944	(11,000 )	145
Other operating expense	2,719	—	—	—	—
Total operating costs and expenses, net	146,310	76,204	101,497	62,190	78,722
Loss from operations	(86,233 )	(41,526 )	(101,497)	(62,190 )	(78,403 )
<b>Non-operating income (expense):</b>					
Interest expense	(1,947 )	(1,026 )	(56 )	(870 )	(2,208 )
Amortization of debt discount and issuance costs	(729 )	(513 )	—	(546 )	(768 )
Foreign exchange gain (loss)	(4,435 )	61	344	(558 )	(521 )
Debt conversion expense	—	—	—	—	(2,031 )
Other non-operating income (expense), net	(885 )	(546 )	(478 )	1,545	1,095
Net loss before noncontrolling interest	(94,229 )	(43,550 )	(101,687)	(62,619 )	(82,836 )
Noncontrolling interest	862	807	313	259	194
Net loss attributable to CTI	\$(93,367 )	\$(42,743 )	\$(101,374)	\$(62,360 )	\$(82,642 )
Dividends and deemed dividends on preferred stock	(2,625 )	(6,900 )	(13,901 )	(58,718 )	(64,918 )
Net loss attributable to common shareholders	\$(95,992 )	\$(49,643 )	\$(115,275)	\$(121,078)	\$(147,560)
Basic and diluted net loss per common share(4)	\$(0.65 )	\$(0.43 )	\$(1.98 )	\$(3.53 )	\$(6.47 )
<b>Shares used in calculation of basic and diluted net loss</b>					
per common share(4)	148,531	114,195	58,125	34,294	22,821

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	Year ended December 31,				
	2014	2013	2012	2011	2010
	(In thousands)				
<b>Consolidated Balance Sheets Data:</b>					
Cash and cash equivalents	\$70,933	\$71,639	\$50,436	\$47,052	\$22,649
Working capital	44,165	60,446	37,644	33,291	(14,165 )
Total assets(5)	92,287	93,723	73,713	62,239	53,592
7.5% convertible senior notes	—	—	—	—	10,215
5.75% convertible senior notes	—	—	—	—	12,093
Current portion of long-term debt(6)	9,014	3,155	—	—	—
Long-term debt, less current portion(6)	8,363	10,152	—	—	—
Other liabilities	5,882	5,657	4,641	2,985	4,206
Common stock purchase warrants	1,445	13,461	13,461	13,461	13,461
Series 14 convertible preferred stock	—	—	—	6,736	—
Accumulated deficit (5)	(1,975,695)	(1,879,703)	(1,830,060)	(1,714,785)	(1,576,643)
Total shareholders' equity (deficit)	38,478	42,758	32,944	28,009	(5,145 )

- (1) The amounts relate to commercial sales of PIXUVRI.
- (2) The amounts primarily relate to license and development services revenue recognized in connection with the Baxter Agreement and the Servier Agreement, as well as payments received from Teva upon achievement of sales-based milestones. See note 12 of the notes to consolidated financial statements for additional information.
- (3) The amounts in 2014 and 2012 represent the purchase of certain assets from Chroma and S\*BIO, respectively, which both had not reached technological feasibility at the time of such acquisitions. See note 4 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.
- (5) Effective January 1, 2011, we adopted new guidance on goodwill impairment.
- (6) These amounts relate to our senior secured term loan agreement entered into in March 2013. See note 8 of the notes to for additional information.

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

We are a biopharmaceutical company focused on the acquisition, development and commercialization of novel targeted therapies covering a spectrum of blood-related cancers that offer a unique benefit to patients and healthcare providers. 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. In particular, we are primarily focused on commercializing PIXUVRI in the E.U. for multiply relapsed or refractory aggressive B-cell NHL, and conducting a Phase 3 clinical trial program of pacritinib for the treatment of adult patients with myelofibrosis to support regulatory submission for approval in the U.S. and Europe. We are also evaluating pacritinib in earlier clinical trials as treatment for other blood-related cancers.

### Key Highlights

In 2014, we made significant progress in commercializing PIXUVRI, advancing our product candidates in clinical trials and expanding our partnerships. Select key recent 2015 and fiscal year 2014 highlights include:

#### Commercial – PIXUVRI

- In 2014, PIXUVRI net product revenues in the E.U. increased to \$6.9 million, compared to \$2.3 million for fiscal year 2013.
- In July 2014, we announced that the Dutch Healthcare Authority and the healthcare insurance board College voor zorgverzekeringen of the Netherlands approved funding for PIXUVRI as an add-on drug for patients who need a third- or fourth-line treatment for aggressive B-cell NHL. The inclusion on the Dutch list of reimbursed drugs made PIXUVRI the first registered and reimbursed medicine for the treatment of patients with aggressive B-cell NHL in the Netherlands.
- In July 2014, we received approval from the Israeli Ministry of Health for PIXUVRI as monotherapy for the treatment of adult patients with multiply relapsed or refractory aggressive B-cell NHL who have received not more than three previous courses of treatment.
- In February 2014, we reported that the U.K.'s National Institute for Health and Care Excellence published final guidance recommending prescription of PIXUVRI as a cost-effective monotherapy for the treatment of adult patients with multiply relapsed or refractory aggressive B-cell NHL. PIXUVRI was launched in the U.K. in April 2014.

#### Research and Development

- In March 2015, we reported top-line results for the primary endpoint from the PERSIST-1 Phase 3 clinical trial of pacritinib for the treatment of adult patients with myelofibrosis. The trial met its primary endpoint in the intent-to-treat population with statistically significant activity observed in patients irrespective of their initial platelet count, including patients with very low platelet counts at study entry. The primary endpoint of the trial was the proportion of patients achieving a 35 percent or greater reduction in spleen volume from baseline to Week 24 as measured by MRI or CT, when compared with physician-specified best available therapy, excluding treatment with JAK2 inhibitors.
- In December 2014, we reported significant data presentations on our pipeline candidates at the American Society of Hematology Annual Meeting.
- In August 2014, we received a \$20 million development milestone payment from Baxter in connection with the first treatment dosing of the last patient enrolled in PERSIST-1.
- In August 2014, pacritinib was granted Fast Track designation by the FDA for the treatment of intermediate and high risk myelofibrosis, including but not limited to patients with disease-related thrombocytopenia, patients experiencing treatment emergent thrombocytopenia on other JAK2 therapy or patients who are intolerant to or whose symptoms are sub-optimally managed on other JAK2 therapy.
- In June 2014, we announced that the U.K. National Cancer Research Institute AML Cooperative Group initiated a randomized Phase 2 trial evaluating tosedostat plus cytarabine for older patients with AML or high-risk MDS.

In March 2014, we initiated our PERSIST-2 Phase 3 trial evaluating pacritinib in adult patients with myelofibrosis whose platelet counts are less than or equal to 100,000/  $\mu$ L.

In January 2014, we announced that the GOG informed us that it had completed enrollment in the GOG-0212 Phase 3 clinical trial of investigational agent Opaxio as maintenance therapy in ovarian cancer.

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## Corporate

- In October 2014, we acquired worldwide licensed rights to tosedostat.
- In September 2014, we entered into the Servier Agreement and received an upfront payment of €14.0 million (or \$17.8 million using the currency exchange rate as of the date we received the funds in October 2014).
- In January 2014, we reached an agreement with Novartis to regain rights to PIXUVRI and Opaxio.

## Financial summary

Our revenues are generated from a combination of PIXUVRI sales and collaboration and license agreements. Collaboration revenues reflect the earned amount of upfront payments and milestone payments under our product collaborations. Total revenues increased to \$60.1 million in 2014, compared to \$34.7 million in 2013. This increase primarily reflects an increase in collaboration and license agreement revenues and increased net product sales. We recorded \$2.5 million in total net product sales for the fourth quarter of 2014 and \$6.9 million for the full-year ended December 31, 2014. Our product sales may vary significantly from period to period as the commercialization and reimbursement negotiations for PIXUVRI progress. Our loss from operations was \$39.4 million for the fourth quarter of 2014 and \$86.2 million for the full-year ended December 31, 2014 compared to an income of \$10.3 million and a loss of \$41.5 million, respectively, for the same periods in 2013. 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.

As of December 31, 2014, we had cash and cash equivalents of \$70.9 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, 2014 and 2013.

Product sales, net. Net product sales from PIXUVRI for the year ended December 31, 2014 and 2013 were \$6.9 million and \$2.3 million, respectively. We sell PIXUVRI through a limited number of wholesale distributors and directly to health care providers in Austria, Denmark, Finland, Germany, Norway, Sweden and the U.K. Servier is responsible for distribution of PIXUVRI in the respective countries in its territory. 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 discounts and 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, 2014 and 2013 (in thousands) is as follows where gross sales is defined as our contracted reimbursement price in each country:

	2014	2013
Product sales, gross	\$7,000	\$2,935
Discounts, rebates and other adjustments	(115 )	(582 )
Returns reserve	24	(39 )

Product sales, net	\$6,909	\$2,314
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As of December 31, 2014 and 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, 2014 and 2013 are as follows (in thousands):

	Discounts, rebates		
	Product returns	and other	Total
Balance at December 31, 2012	\$ —	\$ —	\$—
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 year sales	—	—	—
Balance at December 31, 2013	\$ 39	\$ 177	\$216
Provision for current year sales	10	115	125
Adjustments for prior period sales	(39 )	—	(39 )
Payments/credits for current year sales	—	(115 )	(115)
Payments/credits for prior year sales	—	(141 )	(141)
Balance at December 31, 2014	\$ 10	\$ 36	\$46

Provision for product returns relates to a limited right of return or replacement that we offer to certain customers. The provision for discounts, rebates and other decreased by \$0.5 million for the year ended December 31, 2014 as compared to the amount for the year ended December 31, 2013 due to a decline in rebates and discounts offered on products sold. Provision for discounts and other during the year-ended December 31, 2014 and 2013 primarily relates to distributor discounts; government-mandated rebates on PIXUVRI product sold were applicable during the year-ended December 31, 2013. Adjustments made during the year ended December 31, 2014 have been de minimus. All rebate payments made during the year ended December 31, 2014 relate to 2013 sales activity.

Please refer to note 1 of the notes to the consolidated financial statements for further information on significant accounting policies regarding product returns, discounts, rebates and other.

License and contract revenue. License and contract revenue are as follows (in thousands):

	Years ended December 31,	
	2014	2013
Baxter License revenue	\$18,183	\$27,275
Development services revenue	2,670	89
Total Baxter	20,853	27,364
Servier License revenue	17,285	—
Development services revenue	30	—
Total Servier	17,315	—
Other	15,000	5,000
Total license and contract revenue	\$53,168	\$32,364

Baxter

The license and contract revenue under the Baxter Agreement for the year ended December 31, 2014 includes \$18.2 million of license revenue and \$2.7 million of development services revenue. In August 2014, we received a \$20 million milestone payment from Baxter in connection with the first treatment dosing of the last patient enrolled in PERSIST-1, which was allocated to license revenue and development services revenue in the table above based on the relative-selling-price percentages originally used to allocate the arrangement consideration under the Baxter Agreement. The license and contract revenue for the year ended December 31, 2013 includes \$27.3 million of license revenue and \$0.1 million of development services revenue recognized from the upfront payment we received in connection with the Baxter Agreement.

Servier

The license and contract revenue under the Servier Agreement for the year ended December 31, 2014 includes \$17.3 million of license revenue and \$30,000 of development services revenue recognized from the upfront payment we received in connection with the execution of the Servier Agreement in September 2014. There was no such revenue for the year ended December 31, 2013.

## Other

During the year ended December 31, 2014 and 2013, we received \$15.0 million and \$5.0 million, respectively, in milestone payments from Teva upon the achievement of worldwide net sales milestones of TRISENOX.

## Operating costs and expenses

Cost of product sold. Cost of product sold for the year ended December 31, 2014 and 2013 was \$0.9 million and \$0.1 million, respectively, related to sales of PIXUVRI. 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 cost of PIXUVRI produced prior to capitalization is 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, and we are unable to provide our estimate of cost of goods sold as a percentage of product revenue once such inventory is exhausted.

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

	2014	2013
Compounds under development:		
PIXUVRI	\$7,740	\$3,889
Pacritinib	34,140	10,466
Opaxio	283	1,127
Tosedostat	645	985
Operating expenses	20,817	16,711
Research and preclinical development	971	446
Total research and development expenses	\$64,596	\$33,624

Costs for our compounds include external direct expenses such as principal investigator fees, CRO 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 the compound licensed to and under development by Aequus. 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, 2014 were \$93.9 million for PIXUVRI (excluding costs prior to our merger with Novuspharma S.p.A, a public pharmaceutical company located in Italy, in January 2004), \$46.8 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), \$227.3 million for Opaxio, \$11.4 million for tosedostat (excluding costs for tosedostat prior to our co-development and license agreement with Chroma in 2011 and \$21.9 million of in-process research and development expenses associated with the acquisition of certain assets from Chroma). External direct costs incurred by us as of December 31, 2014 for brostallicin was 9.6 million. We did not expend material resources on Brostallicin during 2014 or 2013.

Research and development expenses increased to \$64.6 million for the year ended December 31, 2014 from \$33.6 million for the year ended December 31, 2013. This \$31.0 million increase was primarily due to costs incurred in connection with our late stage pacritinib program, our post-authorization PIX306 trial for PIXUVRI and operating expenses. The increase in the pacritinib program is primarily due to the achievement of full enrollment in PERSIST-1 and progress on site openings and enrollment in PERSIST-2. The increase in PIXUVRI research and development expenses is primarily associated with our on-going PIX306 trial. The increase in operating expenses is attributed to non-cash equity compensation, personnel costs and expenses in support of our clinical trials.

Regulatory agencies, including the FDA and EMA, regulate many aspects of a product candidate's life cycle, including research and development and preclinical and clinical testing. We will need to commit significant time and resources to develop our current and any future product candidates. Our product 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 risk factors discussed in Part I, Item 1A, "Risk Factors".

**Selling, general and administrative expenses.** Selling, general and administrative expenses increased to \$56.2 million for the year ended December 31, 2014 from \$42.3 million for the year ended December 31, 2013. This increase was primarily due to a \$9.9 million increase in non-cash share-based compensation, in addition to costs associated with pre-commercial activity and professional services costs related to business development and an increase in taxes and provision for tax assessments.

**Acquired in-process research and development.** Acquired in-process research and development for the year ended December 31, 2014 relates to charges of \$21.9 million recorded in connection with our acquisition of certain assets from Chroma in October 2014. There was no acquired in-process research and development expense for the corresponding period in 2013.

**Settlement expense.** For the year ended December 31, 2013, we recorded \$0.2 million in settlement expense related to agreements entered into with one of our former executive officers for severance payments and related benefits upon such officer's separation from us in the year prior to the year ended December 31, 2013 and attorneys' fees in connection with a shareholder lawsuit. We had no settlement expense during the year ended December 31, 2014.

**Other operating expense.** Other operating expense for the year ended December 31, 2014 relates to the payment made to Novartis as a result of the upfront payment we received under the Servier Agreement. We had no such amount for

the year ended December 31, 2013. Certain payments are required under the Novartis Termination Agreement. See note 12 of the notes to the consolidated financial statements, Collaboration, Licensing and Milestone Agreements – Novartis, for further details.

Non-operating income and expenses

Interest expense. Interest expense is related to our senior secured term loan originally issued in March 2013. Interest expense increased to \$1.9 million for the year ended December 31, 2014 from \$1.0 million for the year ended December 31, 2013 primarily due to interest incurred on the additional principal amounts of our senior secured term loan agreement entered into December 2013 and October 2014.

Amortization of debt discount and issuance costs. Amortization of debt discount and issuance costs of \$0.7 million and \$0.5 million for year ended December 31, 2014 and 2013 is related to our senior secured term loan agreement.



Foreign exchange gain (loss). The foreign exchange loss of \$4.4 million and gain of \$0.1 million for the years ended December 31, 2014 and 2013, respectively, are due to fluctuations in foreign currency exchange rates. The fluctuations are primarily related to payables and receivables in our European branches and subsidiaries denominated in foreign currencies.

Other non-operating expense. Other non-operating expense of \$0.9 million for the year ended December 31, 2014 is primarily related to the change in fair value of the warrant issued to Hercules Technology Growth Capital, Inc., or HTGC. Other non-operating expense of \$0.5 million for the year ended December 31, 2013 is primarily related to the change in fair value of the warrant issued to HTGC and the loss on disposal of property and equipment.

Deemed dividends on preferred stock. Deemed dividends on preferred stock were approximately \$2.6 million for the year ended December 31, 2014 related to the issuance of our Series 21 preferred stock. 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.

Years ended December 31, 2013 and 2012.

Product sales, net. There were no product sales of PIXUVRI for the year ended December 31, 2012. For Fiscal 2013 information, please see Years ended December 31, 2014 and 2013 above.

License and contract revenue. There was no license and contract revenue for the year ended December 31, 2012. For Fiscal 2013 information, please see Years ended December 31, 2014 and 2013 above.

Operating costs and expenses

Cost of product sold. There were no product sales or related cost of product sold for the year ended December 31, 2012. For Fiscal 2013 information, please see Years ended December 31, 2014 and 2013 above.

Research and development expenses. Our research and development expenses for compounds under development and preclinical development 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
Operating expenses	16,711	17,653
Research and preclinical development	446	384
Total research and development expenses	\$33,624	\$33,201

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 study, 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 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.

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. 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.

#### Non-operating income and expenses

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 senior secured term loan agreement entered into 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 senior secured term loan agreement entered into in 2013. We had no similar costs for the corresponding period in 2012.

Foreign exchange gain (loss). The foreign exchange gain of \$0.1 million and \$0.3 million for the years ended December 31, 2013 and 2012, respectively, are due to fluctuations in foreign currency exchange rates. The fluctuations are primarily related to payables and receivables in our European branches and subsidiaries denominated in foreign currencies.

Other non-operating expense. Other non-operating expense of \$0.5 million for the year ended December 31, 2013 is primarily related to the change in fair value of the warrant issued to HTGC and the loss on disposal of property and equipment. Other non-operating expense of \$0.5 million for the year ended December 31, 2012 is primarily related to the change in Series 15 warrant liability and the loss on disposal of property and equipment.

Deemed dividends on preferred stock. 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. 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.

#### Liquidity and Capital Resources

Cash and cash equivalents. As of December 31, 2014, we had \$70.9 million in cash and cash equivalents.

Net cash used in operating activities. Net cash used in operating activities totaled \$39.6 million for the year ended December 31, 2014, compared to \$35.8 million for the year ended December 31, 2013 and \$62.8 million for the year ended December 31, 2012. The increase in net cash used in operating activities for the year ended December 31, 2014 as compared to the year ended December 31, 2013 was primarily due to an increase in research and development activities related to pacritinib for the year ended December 31, 2014 as compared to December 31, 2013. This increase was offset by the \$20.0 million milestone payment received from Baxter in the third quarter of 2014, \$17.8 million

upfront payment received from Servier in the fourth quarter of 2014 and \$15.0 million milestone payment received from Teva in the fourth quarter of 2014 upon achievement of worldwide net sales milestones of TRISENOX in 2014. 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.

Net cash used in investing activities. Net cash used in investing activities totaled \$0.5 million for the year ended December 31, 2014, as compared to \$1.5 million for the year ended December 31, 2013 and \$20.7 million for the year ended December 31, 2012. The decrease in net cash used in investing activities for the year ended December 31, 2014 as compared to December 31, 2013 was primarily due to a decrease in purchases of property and equipment in 2014. The decrease in net cash used in investing activities for the year ended December 31, 2013 as compared to December 31, 2012 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.

Net cash provided by financing activities. Net cash provided by financing activities totaled \$36.0 million for the year ended December 31, 2014, as compared to \$59.0 million for the year ended December 31, 2013 and \$87.2 million for the year ended December 31, 2012. Net cash provided by financing activities for the year ended December 31, 2014 was primarily due to issuances of preferred stock and long-term debt. We received \$32.6 million in proceeds from the issuance of our Series 21 preferred stock in November 2014. We also exercised our option to borrow an additional \$5.0 million from HTGC in October 2014.

Net cash provided by financing activities for the year ended 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 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. 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.

#### Capital Resources

We have prepared our financial statements assuming that we will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business. However, we believe that our present financial resources, together with additional milestone payments projected to be received under certain of our contractual agreements, our ability to control costs and expected net sales of PIXUVRI, will only be sufficient to fund our operations through mid-third quarter of 2015. This raises substantial doubt about our ability to continue as a going concern. Further, we have incurred net losses since inception and expect to generate losses for the next few years primarily due to research and development costs for PIXUVRI, pacritinib, Opaxio and tosedostat. We have historically funded our operations through equity financings, borrowings and funds obtained under product collaborations, any or all of which may not be available to us in the future. As of December 31, 2014, our available cash and cash equivalents were \$70.9 million, and we had an outstanding principal balance under our senior secured term loan agreement of \$18.5 million. We do not have any borrowing capacity under our senior secured loan agreement. For a discussion of such loan agreement, including applicable interest rates, covenants and events of default, please see our Current Reports on Form 8-K filed on each of March 28, 2013 and December 18, 2013, respectively, which are incorporated herein by reference (excluding Item 7.01 thereof).

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 milestone payments or achieve projected net sales from PIXUVRI. These and other factors, may negatively impact our current cash projection.

#### Capital Requirements

We will need to raise additional funds to operate our business. We may seek to raise such capital through public or private equity financings, partnerships, collaborations, joint ventures, disposition of assets, debt financings or restructurings, bank borrowings or other sources of financing. However, we have a limited number of authorized shares of common stock available for issuance and additional funding may not be available on favorable terms or at

all. If additional funds are raised by issuing equity securities, substantial dilution to existing shareholders may result. If we fail to obtain additional capital when needed, our ability to operate as a going concern will be harmed, and 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, be unable to attract and retain highly qualified personnel, refrain from making our contractually required payments when due (including debt payments) and/or may be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection.

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

- changes in manufacturing;
- developments in and expenses associated with our research and development activities;
- acquisitions of compounds or other assets;
- ability to generate sales of PIXUVRI and any expansion of our sales and marketing organization for PIXUVRI;

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- regulatory approval developments;
- ability to consummate appropriate collaborations for development and commercialization activities;
- ability to reach milestones triggering payments under certain of our contractual arrangements;
- litigation and other disputes;
- competitive market developments; and
- other unplanned business developments.

The following table includes information relating to our contractual obligations as of December 31, 2014 (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	\$ 18,144	\$ 2,600	\$ 4,639	\$ 4,884	\$ 6,021
Long-term debt	18,474	9,583	8,891	—	—
Interest on long-term debt(1)	2,172	1,680	492	—	—
Purchase commitments(2)	4,621	4,580	41	—	—
Other obligations(3)	1,276	—	1,276	—	—
	\$44,687	\$ 18,443	\$ 15,339	\$ 4,884	\$ 6,021

(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 include a fee in the amount of \$1.3 million payable to HTGC on the date on which the senior secured term loan is paid or becomes due and payable in full. Other obligations do not include \$4.4 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 on sales, including the UVM Agreement, the S\*<sup>B</sup>IO Agreement, the PG-TXL Agreement, the GOG Agreement, the Nerviano Agreement, the Novartis Termination Agreement 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.” In particular, we pay royalties on PIXUVRI net sales pursuant to each of the UVM Agreement and the Novartis Termination Agreement; see Part I, Item 1, “Business—License Agreements and Additional Milestone Activities—for additional information concerning such royalties.

### 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 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.

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### 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. 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 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 13 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.

### Going Concern

Our financial statements are prepared using U.S. GAAP applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. The audit report for the year ended December 31, 2014 contains an explanatory paragraph raising substantial doubt as to our ability to continue as a

going concern.

#### Recently Adopted Accounting Standards

In March 2013, the Financial Accounting Standards Board, or 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. The adoption of this guidance did not have an impact on our consolidated financial statements.

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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. The 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. The adoption of this guidance did not have an impact on our consolidated financial statements.

#### Recently Issued Accounting Standards

In May 2014, the FASB issued a new financial accounting standard which outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes current revenue recognition guidance. The accounting standard is effective for annual reporting periods (including interim reporting periods within those periods) beginning after December 15, 2016. Early adoption is not permitted. We are currently evaluating the impact of this accounting standard.

In August 2014, the FASB issued a new accounting standard which requires management to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern for each annual and interim reporting period and to provide related footnote disclosures in certain circumstances. The accounting standard is effective for annual reporting periods (including interim reporting periods within those periods) beginning after December 15, 2016. Early adoption is permitted. We are currently evaluating the impact of this accounting standard.

#### 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. In addition, certain of our contractual arrangements, such as the Servier Agreement, denote monetary amounts in foreign currencies, and consequently, the ultimate financial impact to us from a U.S. dollar perspective is subject to significant uncertainty. Changes in the value of the U.S. dollar as compared to applicable foreign currencies (in particular, 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, 2014, 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 \$2.0 million as of this date.

#### Interest Rate Risk

Our senior secured term loan bears interest at variable rates. Based on the outstanding amount under such loan at December 31, 2014 of \$18.5 million, and assuming such amount had been outstanding as of January 1, 2014, a 1.0 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 8 of the notes to consolidated financial statements under Item 8 of Part II in this Annual Report on Form 10-K.



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

CTI BioPharma Corp.

We have audited the accompanying consolidated balance sheets of CTI BioPharma Corp. (the “Company”) as of December 31, 2014 and 2013, and the related consolidated statements of operations, comprehensive loss, shareholders’ equity and cash flows for the years ended December 31, 2014, 2013 and 2012. 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 CTI BioPharma Corp. as of December 31, 2014 and 2013, and the consolidated results of its operations and its cash flows for the years ended December 31, 2014, 2013 and 2012 in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred losses since its inception and does not have sufficient liquidity to fund its presently anticipated operations beyond the third quarter of 2015. These conditions raise substantial doubt about the Company’s ability to continue as a going concern. Management’s plan in regard to these matters is also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), CTI BioPharma Corp.’s internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013 and our report dated March 12, 2015 expressed an unqualified opinion on the effectiveness of the Company’s internal control over financial reporting.

/s/ Marcum llp

San Francisco, CA

March 12, 2015





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

CTI BioPharma Corp.

We have audited CTI BioPharma Corp.'s (the "Company") internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013. 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, CTI BioPharma Corp. maintained, in all material aspects, effective internal control over financial reporting as of December 31, 2014, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013.

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, 2014 and 2013 and the related consolidated statements of operations, comprehensive loss, shareholders' equity, and cash flows for the years then ended of the Company and our report dated March 12, 2015 expressed an unqualified opinion, with an explanatory paragraph as to the uncertainty regarding the Company's ability to continue as a going concern, on those financial statements.

/s/ Marcum llp

San Francisco, CA

March 12, 2015

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## CTI BIOPHARMA CORP.

## CONSOLIDATED BALANCE SHEETS

(In thousands, except share amounts)

	December 31, 2014	December 31, 2013
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$70,933	\$71,639
Accounts receivable, net	2,011	235
Inventory	4,182	5,074
Prepaid expenses and other current assets	3,379	3,567
Total current assets	80,505	80,515
Property and equipment, net	4,646	5,478
Other assets	7,136	7,730
Total assets	\$92,287	\$93,723
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$6,356	\$5,051
Accrued expenses	19,734	9,469
Warrant liability	—	991
Current portion of deferred revenue	826	1,010
Current portion of long-term debt	9,014	3,155
Other current liabilities	410	393
Total current liabilities	36,340	20,069
Deferred revenue, less current portion	1,779	1,626
Long-term debt, less current portion	8,363	10,152
Other liabilities	5,882	5,657
Total liabilities	52,364	37,504
Commitments and contingencies		
Common stock purchase warrants	1,445	13,461
Shareholders' equity:		
Common stock, no par value:		
Authorized shares - 215,000,000		
Issued and outstanding shares - 176,761,099 and 145,508,767 at		
December 31, 2014 and 2013, respectively	2,023,949	1,933,305
Accumulated other comprehensive loss	(6,499 )	(8,429 )
Accumulated deficit	(1,975,695)	(1,879,703)
Total CTI shareholders' equity	41,755	45,173
Noncontrolling interest	(3,277 )	(2,415 )
Total shareholders' equity	38,478	42,758
Total liabilities and shareholders' equity	\$92,287	\$93,723

See accompanying notes.



## CTI BIOPHARMA CORP.

## CONSOLIDATED STATEMENTS OF OPERATIONS

(In thousands, except per share amounts)

	Year Ended December 31,		
	2014	2013	2012
<b>Revenues:</b>			
Product sales, net	\$6,909	\$2,314	\$—
License and contract revenue	53,168	32,364	—
Total revenues	60,077	34,678	—
<b>Operating costs and expenses:</b>			
Cost of product sold	895	137	—
Research and development	64,596	33,624	33,201
Selling, general and administrative	56,241	42,288	38,244
Acquired in-process research and development	21,859	—	29,108
Settlement expense	—	155	944
Other operating expense	2,719	—	—
Total operating costs and expenses	146,310	76,204	101,497
Loss from operations	(86,233 )	(41,526 )	(101,497 )
<b>Non-operating income (expense):</b>			
Interest expense	(1,947 )	(1,026 )	(56 )
Amortization of debt discount and issuance costs	(729 )	(513 )	—
Foreign exchange gain (loss)	(4,435 )	61	344
Other non-operating expense	(885 )	(546 )	(478 )
Total non-operating expense, net	(7,996 )	(2,024 )	(190 )
Net loss before noncontrolling interest	(94,229 )	(43,550 )	(101,687 )
Noncontrolling interest	862	807	313
Net loss attributable to CTI	(93,367 )	(42,743 )	(101,374 )
Deemed dividends on preferred stock	(2,625 )	(6,900 )	(13,901 )
Net loss attributable to common shareholders	\$(95,992 )	\$(49,643 )	\$(115,275 )
Basic and diluted net loss per common share	\$(0.65 )	\$(0.43 )	\$(1.98 )
Shares used in calculation of basic and diluted net loss per			
common share	148,531	114,195	58,125

See accompanying notes.

CTI BIOPHARMA CORP.

## CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

	Year Ended December 31,		
	2014	2013	2012
Net loss before noncontrolling interest	\$(94,229)	\$(43,550)	\$(101,687)
Other comprehensive income (loss):			
Foreign currency translation adjustments	1,998	31	(168 )
Net unrealized loss on securities available-for-sale	(68 )	(187 )	(70 )
Other comprehensive income (loss)	1,930	(156 )	(238 )
Comprehensive loss	(92,299)	(43,706)	(101,925)
Comprehensive loss attributable to noncontrolling interest	862	807	313
Comprehensive loss attributable to CTI	\$(91,437)	\$(42,899)	\$(101,612)

See accompanying notes.

## CTI BIOPHARMA CORP.

## CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

(In thousands)

	Preferred Stock		Common Stock		Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Noncontrolling Interest	Total Shareholders' Equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2011	10	\$6,736	40,614	\$1,744,801	\$(1,714,785)	\$ (8,035 )	\$ (708 )	\$ 28,009
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	—	—	—	13,901	—	—	—	13,901



## Edgar Filing: CTI BIOPHARMA CORP - Form 10-K

preferred stock								
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 )
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 )
Deemed dividends on preferred stock	—	—	—	—	(6,900 )	—	—	(6,900 )
	—	—	—	—	(42,743 )	—	—	(42,743 )

Net loss for the year ended December 31, 2013								
Other comprehensive loss	—	—	—	—	—	(156 )	—	(156 )
Balance at December 31, 2013	—	\$—	145,509	\$1,933,305	\$(1,879,703 )	\$ (8,429 )	\$ (2,415 )	\$42,758

See accompanying notes.

## CTI BIOPHARMA CORP.

## CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY—(Continued)

(In thousands)

	Preferred Stock		Common Stock		Accumulated	Accumulated Other Comprehensive Income (Loss)	Noncontrolling Interest	Total Shareholders' Equity
	Shares	Amount	Shares	Amount	Deficit	(Loss)	Interest	Equity
Issuance of Series 20 preferred stock, net of								
transaction costs	9	21,486	—	—	—	—	—	21,486
Conversion of Series 20 preferred stock to								
common stock	(9 )	(21,486)	9,000	21,486	—	—	—	—
Issuance of Series 21 preferred stock, net of								
transaction costs	35	32,342	—	—	—	—	—	32,342
Conversion of Series 21 preferred stock to								
common stock	(35)	(32,342)	17,500	32,342	—	—	—	—
Value of beneficial conversion features related to								
preferred stock	—	—	—	2,625	—	—	—	2,625
Exercise of common stock purchase warrants	—	—	491	1,877	—	—	—	1,877
Equity-based compensation	—	—	4,130	20,196	—	—	—	20,196
Stock option exercises	—	—	183	272	—	—	—	272
Noncontrolling interest	—	—	—	—	—	—	(862 )	(862 )
Expiry of mezzanine equity	—	—	—	12,016	—	—	—	12,016
Other	—	—	(52 )	(170 )	—	—	—	(170 )
Deemed dividends on preferred stock	—	—	—	—	(2,625 )	—	—	(2,625 )

Net loss for the year ended December 31, 2014	—	—	—	—	(93,367 )	—	—	(93,367 )
Other comprehensive loss	—	—	—	—	—	1,930	—	1,930
Balance at December 31, 2014	—	\$—	176,761	\$2,023,949	\$(1,975,695 )	\$(6,499 )	\$(3,277 )	\$38,478

See accompanying notes.

## CTI BIOPHARMA CORP.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,		
	2014	2013	2012
<b>Operating activities</b>			
Net loss	\$(94,229)	\$(43,550)	\$(101,687)
Adjustments to reconcile net loss to net cash used in operating activities:			
Acquired in-process research and development	21,859	—	29,108
Share-based compensation expense	20,196	9,066	7,938
Depreciation and amortization	1,100	1,570	2,346
Noncash interest expense	729	513	—
Change in value of warrant liability	886	—	—
Provision for VAT assessments	600	—	(3,402)
Other	(374)	365	5
Changes in operating assets and liabilities:			
Accounts receivable	(1,980)	(227)	—
Inventory	305	(3,254)	(1,586)
Prepaid expenses and other current assets	46	4,530	(3,759)
Other assets	(356)	(846)	1,495
Accounts payable	1,454	(5,774)	3,123
Accrued expenses and other	10,250	(834)	(885)
Deferred revenue	(31)	2,636	—
Other liabilities	(5)	(25)	4,528
Total adjustments	54,679	7,720	38,911
Net cash used in operating activities	(39,550)	(35,830)	(62,776)
<b>Investing activities</b>			
Purchases of property and equipment	(333)	(1,657)	(2,937)
Proceeds from sales of property and equipment	—	123	—
Cash paid for acquisition of assets from S*BIO Pte Ltd.	—	—	(17,764)
Other	(208)	—	—
Net cash used in investing activities	(541)	(1,534)	(20,701)
<b>Financing activities</b>			
Cash paid for Series 14 preferred stock issuance costs	—	—	(170)
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	(28)	29,961	—
Cash paid for Series 20 preferred stock issuance costs	(106)	—	—
Proceeds from issuance of Series 21 preferred stock, net of issuance costs	32,621	—	—
Issuance of long-term debt, net	4,963	14,501	—
Repayment of long-term debt	(1,526)	—	—

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Other	102	(244 )	(214 )
Net cash provided by financing activities	36,026	58,972	87,216
Effect of exchange rate changes on cash and cash equivalents	3,359	(405 )	(355 )
Net increase (decrease) in cash and cash equivalents	(706 )	21,203	3,384
Cash and cash equivalents at beginning of year	71,639	50,436	47,052
Cash and cash equivalents at end of year	\$70,933	\$71,639	\$50,436

See accompanying notes.

CTI BIOPHARMA CORP.

## CONSOLIDATED STATEMENTS OF CASH FLOWS—(Continued)

(In thousands)

	Year Ended December 31,		
	2014	2013	2012
<b>Supplemental disclosure of cash flow information</b>			
Cash paid during the period for interest	\$1,894	\$933	\$16
<b>Supplemental disclosure of noncash financing and investing activities</b>			
Conversion of Series 14 preferred stock to common stock	\$—	\$—	\$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	\$—
Conversion of Series 20 preferred stock to common stock	\$21,486	\$—	\$—
Conversion of Series 21 preferred stock to common stock	\$32,342	\$—	\$—
Issuance of Series 16 preferred stock for acquisition of assets from S*BIO Pte. Ltd.	\$—	\$—	\$11,344
Issuance of Series 20 preferred stock for acquisition of assets from Chroma Therapeutics Limited	\$21,600	\$—	\$—
Issuance of common stock upon exercise or exchange of common stock purchase warrants	\$1,877	\$—	\$17,798

See accompanying notes.

CTI BIOPHARMA CORP.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

CTI BioPharma Corp., also referred to in this Annual Report on Form 10-K as CTI, the “Company,” “we,” “us” or “our,” is a biopharmaceutical company focused on the acquisition, development and commercialization of novel targeted therapies covering a spectrum of blood-related cancers that offer a unique benefit to patients and healthcare providers. 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. In particular, we are primarily focused on commercializing PIXUVRI® (pixantrone), or PIXUVRI, in the European Union, or the E.U., for multiply relapsed or refractory aggressive B-cell non-Hodgkin lymphoma, and conducting a Phase 3 clinical trial program of pacritinib for the treatment of adult patients with myelofibrosis to support regulatory submission for approval in the United States, or the U.S., and Europe. We are also evaluating pacritinib in earlier clinical trials as treatment for other blood-related cancers.

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 the FDA, in the U.S., the European Medicines Agency, or the EMA, in the E.U. and comparable agencies in other countries. Obtaining approval for a new therapeutic product is never certain, 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 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, 2014, 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 September 2, 2012, we effected a one-for-five reverse stock split, referred to as the Stock Split. Unless otherwise noted, all impacted amounts included in the consolidated financial statements and notes thereto have been retroactively adjusted for the Stock Split. 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 Split impacted preferred stock authorized (but not outstanding because there were no shares of preferred stock outstanding as of the time of the applicable reverse stock split).

#### Liquidity



The accompanying consolidated financial statements have been prepared assuming that we will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business for the twelve-month period following the date of these condensed consolidated financial statements. However, we believe that our present financial resources, together with additional milestone payments projected to be received under certain of our contractual agreements, our ability to control costs and expected net sales of PIXUVRI, will only be sufficient to fund our operations through mid-third quarter of 2015. This raises substantial doubt about our ability to continue as a going concern. Further, we have incurred net losses since inception and expect to generate losses for the next few years primarily due to research and development costs for pacritinib, PIXUVRI, Opaxio and tosedostat. Our available cash and cash equivalents were \$70.9 million as of December 31, 2014.

Accordingly, we will need to raise additional funds. We may seek to raise such capital through public or private equity financings, partnerships, collaborations, joint ventures, disposition of assets, debt financings or restructurings, bank borrowings or other sources of financing. However, we have a limited number of authorized shares of common stock available for issuance and additional funding may not be available on favorable terms or at all. If additional funds are raised by issuing equity securities, substantial dilution to existing shareholders may result. If we fail to obtain additional capital when needed, we may be required to delay, scale back or eliminate some or all of our research and development programs, reduce our selling, general and administrative expenses, be unable to attract and retain highly qualified personnel, refrain from making our contractually required payments when due (including debt payments) and/or may be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection. The accompanying condensed consolidated financial statements do not include any adjustments that may result from the outcome of this uncertainty.

#### Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S. 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.

Additionally, see Note 16, 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.

### Accounts Receivable

Our accounts receivable balance includes trade receivables related to PIXUVRI sales. 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. We continue to monitor economic conditions, including the volatility associated with international economies, the sovereign debt crisis in certain European countries and associated impacts on the financial markets and our business. As of December 31, 2014 and 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 recorded an allowance for doubtful accounts of \$0.1 million as of December 31, 2014. There was no 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 \$4.9 million and \$5.5 million as of December 31, 2014 and 2013, of which \$4.7 million and \$5.4 million is included in other assets and \$0.2 million and \$0.1 million is included in prepaid expenses and other current assets as of December 31, 2014 and 2013, 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, 2014, the VAT receivable related to operations in Italy is approximately \$4.8 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, 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 obsolescence 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 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.

At December 31, 2014 and 2013, the carrying value of financial instruments such as receivables and payables approximated their fair values due to their short-term maturities. The carrying value of our long-term debt approximated its fair value at December 31, 2014 and 2013 based on borrowing rates for similar loans and maturities.

## Contingencies

We record liabilities associated with loss contingencies to the extent that we conclude the occurrence of the contingency is probable and that the amount of the related loss is reasonably estimable. We record income from gain contingencies only upon the realization of assets resulting from the favorable outcome of the contingent event. See Note 12, Collaboration, Licensing and Milestone Agreements and Note 19, Legal Proceedings, for further information regarding our current gain and loss contingencies.

## 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 through a limited number of distributors and directly to health care providers in Austria, Denmark, Finland, Germany, Norway, Sweden and the U.K. 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.

#### 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.

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 FDA, or with the regulatory authorities of other countries, 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, 2014 and 2013.

## Research and Development Expenses

Research and development costs are expensed as incurred in accordance with Financial Accounting Standards Board, or the FASB, Accounting Standards Codification, or ASC 730, Research and Development. Research and development expenses include related salaries and benefits, clinical trial and related manufacturing costs, contract and other outside service fees, and facilities and overhead costs related to our research and development efforts. Research and development expenses also consist of costs incurred for proprietary and collaboration research and development and include activities such as product registries and investigator-sponsored trials. In instances where we enter into agreements with third parties for research and development activities, we may prepay fees for services at the initiation of the contract. We record the prepayment as a prepaid asset and amortize the asset into research and development expense over the period of time the contracted research and development services are performed. Other types of arrangements with third parties may be fixed fee or fee for service, and may include monthly payments or payments upon completion of milestones or receipt of deliverables. In instances where we enter into cost-sharing arrangements, all research and development costs reimbursed by the collaborator are a reduction to research and development expense while research and development costs paid to the collaborator are an addition to research and development expense. We expense upfront license payments related to acquired technologies 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 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, with early adoption permitted. The adoption of this guidance did not have an 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. The 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 adoption of this guidance did not have an impact on our consolidated financial statements.

### Recently Issued Accounting Standards

In May 2014, the FASB issued a new financial accounting standard which outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes current revenue recognition guidance. The accounting standard is effective for annual reporting periods (including interim reporting periods within those periods) beginning after December 15, 2016. Early adoption is not permitted. We are currently evaluating the impact of this accounting standard.

In August 2014, the FASB issued a new accounting standard which requires management to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern for each annual and interim reporting period and to provide related footnote disclosures in certain circumstances. The accounting standard is effective for annual reporting periods (including interim reporting periods within those periods) beginning after December 15, 2016. Early adoption is permitted. We are currently evaluating the impact of this accounting standard.

### 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, 2014 and 2013 (in thousands):

	2014	2013
Finished goods	\$850	\$601
Work-in-process	3,332	4,473
Total inventories	\$4,182	\$5,074

### 3. Property and Equipment

Property and equipment is composed of the following as of December 31, 2014 and 2013 (in thousands):

	2014	2013
Furniture and office equipment	\$11,020	\$10,913
Leasehold improvements	5,078	5,078
Lab equipment	209	143
	16,307	16,134
Less: accumulated depreciation and amortization	(11,661)	(10,656)
Property and equipment, net	\$4,646	\$5,478

Depreciation expense of \$1.1 million, \$1.6 million and \$2.3 million was recognized during 2014, 2013 and 2012, respectively.

#### 4. Acquisitions

##### S\*BIO Asset Purchase Agreement

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

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.

#### Chroma Asset Purchase Agreement

In October 2014, we entered into an Asset Purchase Agreement, or the Chroma APA, with Chroma Therapeutics Limited, or Chroma, pursuant to which we acquired all of Chroma's right, title and interest in the compound tosedostat and certain related assets. Concurrently, we and Chroma terminated our Co-Development and License Agreement relating to tosedostat, or the Chroma License Agreement, previously entered into on March 11, 2011, thereby eliminating potential future milestone payments thereunder of up to \$209.0 million, and we acquired an exclusive worldwide license with respect to tosedostat directly from Vernalis R&D Limited, or Vernalis (as discussed below).

As consideration under the Chroma APA, we issued an aggregate of 9,000 shares of our Series 20 Preferred Stock convertible into shares of common stock, or the Series 20 Preferred Stock, of which 7,920 shares have been delivered to Chroma. The remaining 1,080 shares are being held in escrow for nine months and will be applied towards any indemnification obligations of Chroma as set forth in the Chroma APA. Each share of Series 20 Preferred Stock had a stated value of \$2,370 per share and was convertible into shares of common stock at a conversion price of \$2.37 per share. Shares of the Series 20 Preferred Stock would receive dividends in the same amount as any dividends declared and paid on shares of common stock, but were entitled to a liquidation preference over the common stock in certain liquidation events.

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

Fair value of Series 20 Preferred Stock	\$21,600
Transaction costs	259
Total initial purchase consideration	\$21,859

All outstanding shares of Series 20 Preferred stock were converted into 9.0 million shares of common stock in October 2014. There was no beneficial conversion feature as the Series 20 Preferred Stock was recorded at fair value as of the acquisition date.

The transaction was treated as an asset acquisition because 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 \$21.9 million was expensed to acquired in-process research and development for the year ended December 31, 2014.

Concurrently with the termination of the Chroma License Agreement and the execution of the Chroma APA, we also entered into an amended and restated license agreement with Vernalis, or the Vernalis License Agreement, for the exclusive worldwide right to use certain patents and other intellectual property rights to develop, market and commercialize tosedostat and certain other compounds, as well as deed of novation pursuant to which all rights of Chroma under its prior license agreement with Vernalis relating to tosedostat were novated to us. Under the Vernalis License Agreement, we have agreed to make tiered royalty payments of no more than a high single digit percentage of net sales of products containing licensed compounds, with such obligation to continue on a country-by-country basis for the longer of ten years following commercial launch or the expiry of relevant patent claims.

The Vernalis License Agreement will terminate when the royalty obligations expire, although the parties have early termination rights under certain circumstances, including the following: (i) we have the right to terminate, with three months' notice, upon the belief that the continued development of tosedostat or any of the other licensed compounds is not commercially viable; (ii) Vernalis has the right to terminate in the event of our uncured failure to pay sums due; and (iii) either party has the right to terminate in event of the other party's uncured material breach or insolvency.

## 5. Accrued Expenses

Accrued expenses consisted of the following as of December 31, 2014 and 2013 (in thousands):

	2014	2013
Clinical and investigator-sponsored trial expenses	\$7,554	\$3,360
Employee compensation and related expenses	5,930	3,035
Manufacturing expenses	2,043	225
Legal expenses	885	573
Accrued selling expenses	759	562
Insurance financing	695	611
Accrued other taxes	386	236
Accrued interest expenses	186	133
Rebates and royalties	139	186
Other	1,157	548
Total accrued expenses	\$19,734	\$9,469

## 6. 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, \$2.0 million and \$2.7 million for the years ended December 31, 2014, 2013 and 2012, 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 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.

### Future Minimum Lease Payments

Future minimum lease commitments for non-cancelable operating leases at December 31, 2014 are as follows (in thousands):



	Operating Leases
2015	\$ 2,600
2016	2,289
2017	2,349
2018	2,411
2019	2,474
Thereafter	6,021
Total minimum lease commitments	\$ 18,144

#### Liability for Excess Facilities

During the year ended December 31, 2005, we reduced our workforce in the U.S. 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 U.S. 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 year ended December 31, 2012 (in thousands):

	2005	2010	Total
	Activities	Activities	Excess
			Facilities
			Liability
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.

#### 7. Other Liabilities

Other liabilities consisted of the following as of December 31, 2014 and 2013 (in thousands):

	2014	2013
Deferred rent, less current portion	\$4,006	\$4,376
Other long-term obligations	1,876	1,281
Total other liabilities	\$5,882	\$5,657

The balance of deferred rent as of December 31, 2014 and 2013 relates to incentives for rent holidays and leasehold improvements associated with our operating lease for office space as discussed in Note 6, Leases. The balance of other long-term obligations includes a fee in the amount of \$1.3 million payable to Hercules Technology Growth Capital Inc., or HTGC, for the years ended December 31, 2014 and 2013. See Note 8, Long-term Debt, for additional information.

#### 8. Long-term Debt

In March 2013, we entered into a Loan and Security Agreement with HTGC providing for a senior secured term loan of up to \$15.0 million, and we amended the arrangement in March 2014 thereby providing us an option to borrow an additional \$5.0 million. The first \$10.0 million was funded in March 2013, we exercised our option to borrow an additional \$5.0 million in December 2013, and we borrowed an additional \$5.0 million in October 2014. 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. 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.

In addition, in March 2013, we issued a warrant to HTGC to purchase shares of common stock. The warrant was exercisable for five years from the date of issuance for 0.7 million shares of common stock. The initial exercise price of the warrant was \$1.1045 per share of common stock. The exercise price and number of shares of common stock issuable upon exercise were subject to antidilution adjustments in certain events, including if within 12 months after closing the Company issued shares of common stock or securities that were 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 would be increased proportionately. Since the warrant did not meet the considerations necessary for equity classification in the applicable authoritative guidance, we determined the warrant was a liability instrument that is marked to fair value with changes in fair value recognized through earnings at each reporting period. The warrant was categorized as Level 2 in the fair value hierarchy as the significant inputs used in determining fair value were considered observable market data. 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. In January 2014, all of the warrant was exercised into 0.5 million shares of common stock via cashless exercise.

In March 2014, we entered into a First Amendment, or the Amendment, to Loan and Security Agreement, or the Original Loan Agreement (and as amended by the Amendment, the Loan Agreement). The Amendment modified certain terms applicable to the loan balance then-outstanding of \$15.0 million, or the Original Loan, as described below and provided us with the option to borrow an additional \$5.0 million, or the 2014 Term Loan, through October 31, 2014, subject to certain conditions. We exercised such option and received the funds in October 2014. In connection with the Amendment, we paid a facility charge of \$72,500 of which \$35,000 was refunded to us in October 2014 pursuant to the terms of the Amendment.

Pursuant to the Amendment, the interest-only period of the Original Loan was extended by six months such that the 24 equal monthly installments of principal and interest (mortgage style) commenced on November 1, 2014 (rather than May 1, 2014). In addition, the interest rate on the Original Loan (which is currently 12.25% plus the amount by which the prime rate exceeds 3.25%) will, upon Hercules' receipt of evidence of the achievement of positive Phase 3 data in connection with our PERSIST-1 clinical trial for pacritinib, be reduced to 11.25% plus the amount by which the prime rate exceeds 3.25%. The modified terms were not considered substantially different pursuant to ASC 470-50, Modification and Extinguishment.

The interest on the 2014 Term Loan floats at a rate per annum equal to 10.00% plus the amount by which the prime rate exceeds 3.25%. The 2014 Term Loan is repayable in 24 equal monthly installments of principal and interest (mortgage style) commencing on November 1, 2014.

Subject to certain exceptions, all loan obligations under the Loan Agreement are secured by a first priority security interest on substantially all of our personal property (excluding our intellectual property).

In connection with the transactions described above, we recorded a total debt discount of \$2.2 million and the issuance costs of \$0.3 million. As of December 31, 2014 and 2013, unamortized debt discount was \$1.1 million and \$1.7 million, unamortized issuance costs were \$0.2 million and \$0.3 million, and the outstanding principal balance was \$18.5 million and \$15.0 million, respectively.

## 9. Preferred Stock

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

### Series 15-1 Preferred Stock

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

Each share of our Series 15-1 Preferred Stock was convertible at the option of the holder and was entitled to a liquidation preference equal to the initial stated value of \$1,000 per share of Series 15-1 Preferred Stock, plus any

accrued and unpaid dividends before the holders of our common stock or any other junior securities receive any payments upon such liquidation. The Series 15-1 Preferred Stock was not entitled to dividends except to share in any dividends actually paid on our common stock or any pari passu or junior securities and had no voting rights except as otherwise expressly provided in our amended and restated articles of incorporation or as otherwise required by law. For the year ended December 31, 2012, we recognized \$8.5 million in dividends and deemed dividends on preferred stock related to the beneficial conversion feature on our Series 15-1 Preferred Stock. In May 2012, all 20,000 shares of our Series 15-1 Preferred Stock were converted into 4.0 million shares of our common stock at a conversion price of \$5.00 per share.

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

#### Series 15-2 Preferred Stock

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

Each share of our Series 15-2 Preferred Stock was convertible at the option of the holder and was entitled to a liquidation preference equal to the initial stated value of \$1,000 per share of Series 15-2 Preferred Stock, plus any accrued and unpaid dividends before the holders of our common stock or any other junior securities receive any payments upon such liquidation. The Series 15-2 Preferred Stock was not entitled to dividends except to share in any dividends actually paid on our common stock or any pari passu or junior securities and had no voting rights except as otherwise expressly provided in our amended and restated articles of incorporation or as otherwise required by law. In July 2012, all 15,000 shares of Series 15-2 Preferred Stock were converted into 5.0 million shares of our common stock at a conversion price of \$2.97475 per share. For the year ended December 31, 2012, we recognized \$5.0 million in dividends and deemed dividends on preferred stock related to the beneficial conversion feature on our Series 15-2 Preferred Stock.

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

#### Series 16 Preferred Stock

See Note 4, Acquisitions—S\**BIO* Asset Purchase Agreement, for information concerning our issuance of Series 16 Preferred Stock.

#### 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 12, Collaboration, Licensing and Milestone Agreements—Baxter, for information concerning our issuance of Series 19 Preferred Stock.

#### Series 20 Preferred Stock

See Note 4, Acquisitions—Chroma APA, for information concerning our issuance of Series 20 Preferred Stock.

#### Series 21 Preferred Stock

In November 2014, we issued 35,000 shares of our Series 21 convertible preferred stock, or Series 21 Preferred Stock, in an underwritten public offering for gross proceeds of \$35.0 million, before deducting underwriting commissions and discounts and other offering costs. Issuance costs related to this transaction were \$2.7 million, including \$2.1 million in underwriting commissions and discounts.

Each share of Series 21 Preferred Stock was convertible at the option of the holder and was entitled to a liquidation preference equal to the initial stated value of such holder's Series 21 Preferred Stock of \$1,000 per share, plus any declared and unpaid dividends and any other payments that may be due on such shares, before any distribution of assets may be made to holders of capital stock ranking junior to the Series 21 Preferred Stock.

The Series 21 Preferred Stock was not entitled to dividends except to share in any dividends actually paid on the common stock or any pari passu or junior securities. The Series 21 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, 2014, we recognized \$2.6 million in deemed dividends on preferred stock related to the beneficial conversion feature on our Series 21 Preferred Stock, and all 35,000 shares of Series 21 Preferred Stock were converted into 17.5 million shares of our common stock at a conversion price of \$2.00 per share.

#### 10. Common Stock

##### Common Stock Reserved

A summary of common stock reserved for issuance is as follows as of December 31, 2014 (in thousands):



Equity incentive plans	16,781
Common stock purchase warrants	5,183
Employee stock purchase plan	34
Total common stock reserved	21,998

## Warrants

Warrants to purchase up to 0.1 million shares of our common stock with an exercise price of \$12.30 per share, 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. We classified the Class B Warrants as mezzanine equity as they included a redemption feature that may be triggered upon certain fundamental transactions that are outside of our control. These warrants expired in October 2014 and were no longer outstanding as of December 31, 2014. Warrants to purchase up to 5,000 shares of common stock with an exercise price of \$13.50 per share, issued to the placement agent for the Series 1 Preferred Stock transaction were outstanding as of December 31, 2013. These warrants were also classified as mezzanine equity due to the same redemption feature as that of the Class B warrants. These warrants expired in October 2014 and were no longer outstanding as of December 31, 2014.

Warrants to purchase up to 0.2 million shares of our common stock with an exercise price of \$42.00 per share, issued in connection with our registered offering of common stock in May 2009, were outstanding as of December 31, 2013. These warrants expired in May 2014 and were no longer outstanding as of December 31, 2014.

Warrants to purchase up to 10,667 shares of our common stock with an exercise price of \$46.875 per share, 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 expired in November 2014 and were no longer outstanding as of December 31, 2014.

Warrants to purchase up to 19,556 shares of our common stock with an exercise price of \$51.00 per share, issued to the underwriter of our public offering of common stock in July 2009, were outstanding as of December 31, 2013. These warrants expired in April 2014 and were no longer outstanding as of December 31, 2014.

Warrants to purchase up to 0.7 million shares of our common stock with an exercise price of \$18.09 per share, issued in connection with the issuance of our Series 4 Preferred Stock in April 2010, or Series 4 Warrants, were outstanding as of December 31, 2013. The Series 4 Warrants were classified as mezzanine equity due to the same redemption feature as that of the Class B warrants as described above. The Series 4 Warrants expired in April 2014 and were no longer outstanding as of December 31, 2014.

Warrants to purchase up to 0.9 million shares of our common stock with an exercise price of \$15.00 per share, issued in connection with the issuance of our Series 5 Preferred Stock in May 2010, or Series 5 Warrants, were outstanding as of December 31, 2013. These warrants were classified as mezzanine equity due to the same redemption feature as that of the Class B warrants as described above. The Series 5 Warrants expired in November 2014 and were no longer outstanding as of December 31, 2014. Warrants to purchase up to 35,000 shares with an exercise price of \$15.00 per share issued to the placement agent for the Series 5 Preferred Stock transaction were outstanding as of December 31, 2014 and 2013 and will expire in May 2015. These warrants are also classified as mezzanine equity due to the same redemption feature as that of the Class B warrants as described above.

Warrants to purchase up to 0.1 million shares with an exercise price of \$12.60 per share issued in July 2010 were outstanding as of December 31, 2014 and 2013. These warrants expired in January 2015.

Warrants to purchase up to 0.2 million shares of our common stock with an exercise price of \$12.60 per share, issued in connection with the issuance of our Series 6 Preferred Stock in July 2010, were outstanding as of December 31, 2014 and 2013. Warrants to purchase up to 11,600 shares with an exercise price of \$12.60 per share issued to the placement agent for the Series 6 Preferred Stock transaction were outstanding as of December 31, 2014 and 2013. These warrants are classified as mezzanine equity due to the same redemption feature as that of the Class B warrants as described above. These warrants expired in January 2015.

Warrants to purchase up to 0.8 million shares of our common stock with an exercise price of \$13.50 per share, issued in connection with the issuance of our Series 7 Preferred Stock in October 2010, were outstanding as of December 31, 2014 and 2013. Warrants to purchase up to 37,838 shares with an exercise price of \$13.80 per share issued to the placement agent for the Series 7 Preferred Stock transaction were outstanding as of December 31, 2014 and 2013. These warrants expire in October 2015.

Warrants to purchase up to 0.6 million shares of our common stock with an exercise price of \$12.00 per share, issued in connection with the issuance of our Series 12 Preferred Stock in May 2011, were outstanding as of December 31, 2014 and 2013. Warrants to purchase up to 30,423 shares with an exercise price of \$13.125 per share issued to the placement agent for the Series 12 Preferred Stock transaction were outstanding as of December 31, 2014 and 2013. These warrants expire in May 2016.

Warrants to purchase up to 1.8 million shares of our common stock with an exercise price of \$10.75 per share, issued in connection with the issuance of our Series 13 Preferred Stock in July 2011, were outstanding as of December 31, 2014 and 2013. Warrants to purchase up to 70,588 shares with an exercise price of \$12.25 per share and warrants to purchase up to 35,294 shares with an exercise price of \$12.25 per shares, issued to the placement agent and to the financial advisor, respectively were outstanding as of December 31, 2014 and 2013. These warrants expire in July 2016.

Warrants to purchase up to 1.4 million shares of our common stock with an exercise price of \$7.25 per share, issued in connection with the issuance of our Series 14 Preferred Stock in December 2011, were outstanding as of December 31, 2014 and 2013. Warrants to purchase up to 69,566 shares with an exercise price of \$8.625 per share and warrants to purchase up to 34,783 shares with an exercise price of \$8.625 per shares, issued to the placement agent and to the financial advisor, respectively were outstanding as of December 31, 2014 and 2013. These warrants expire in December 2016.

See Note 8, Long-term Debt, and Note 9, Preferred Stock, for additional information concerning our warrants.

#### 11. Other Comprehensive Loss

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

	Net Unrealized	Foreign	Accumulated
	Loss on Securities	Currency	Other
	Available-For-Sale	Translation	Comprehensive
	Adjustments	Loss	
December 31, 2013	\$ (422 )	\$ (8,007 )	\$ (8,429 )
Current period other comprehensive income (loss)	(68 )	1,998	1,930
December 31, 2014	\$ (490 )	\$ (6,009 )	\$ (6,499 )

#### 12. Collaboration, Licensing and Milestone Agreements

##### Baxter

In November 2013, we entered into a Development, Commercialization and License agreement, or Baxter Agreement, with Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA, or collectively, Baxter, for the development and commercialization of pacritinib for use in oncology and potentially additional therapeutic areas. Under the Baxter 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 pacritinib. We received an upfront payment of \$60.0 million upon execution of the Baxter Agreement, which included an equity investment of \$30 million to acquire our Series 19 Preferred Stock as discussed below.

Under the Baxter 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.

Under the Baxter Agreement, the Company and Baxter will jointly commercialize and share profits and losses on sales of pacritinib 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 third party royalty-bearing licenses to fulfill its obligations under the Baxter Agreement, and (ii) in any jurisdiction where there is no longer either regulatory exclusivity or patent protection.

Under the Baxter 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 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 Baxter Agreement meet the criteria for separation and are therefore treated as separate units of accounting:

- a license from the Company to develop and commercialize pacritinib 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 Baxter Agreement also required Baxter and the Company to negotiate and enter into a manufacturing and supply agreement providing for the manufacture of the licensed products. The manufacturing and supply agreement contemplated under the Baxter Agreement was not considered as a deliverable at the inception of the arrangement because the critical terms such as pricing and quantities were not defined and delivery of the services would be dependent on successful clinical results that are uncertain.

Also under the Baxter Agreement, joint commercialization, manufacturing, development and steering committees with representatives from the Company and Baxter will be established. We considered whether our participation on the joint development committees may be a separate deliverable and determined that it did 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 was also determined to be a non-deliverable.

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

The Baxter Agreement will expire when Baxter has no further obligation 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 Baxter Agreement prior to expiration in certain circumstances. The Company may terminate the Baxter 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 Baxter Agreement prior to 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 Baxter 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 Baxter 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 pacritinib will revert to the Company.

We allocated the fixed and determinable Baxter 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 Baxter 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, 2014 and 2013, \$0.8 million and \$0.1 million of development services was recognized as revenue, and the remaining \$1.8 million and \$2.6 million was recorded as deferred revenue in the balance sheet as of December 31, 2014 and 2013, respectively.

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Concurrently with the execution of the Baxter 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 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.

In August 2014, we received a \$20 million milestone payment from Baxter in connection with the first treatment dosing of the last patient enrolled in PERSIST-1. Of the \$20 million milestone payment recorded in license and contract revenue, \$18.2 million was allocated to the license and \$1.8 million was allocated to the development services based on the relative-selling price percentages used to allocate the arrangement consideration discussed above.

#### Servier

In September 2014, we entered into an Exclusive License and Collaboration Agreement, or the Servier Agreement, with Les Laboratoires Servier and Institut de Recherches Internationales Servier, or collectively, Servier. Under the Servier Agreement, we granted Servier an exclusive and sublicensable (subject to certain conditions) royalty-bearing license with respect to the development and commercialization of PIXUVRI for use in pharmaceutical products outside of the CTI Territory (defined below). We retained rights to PIXUVRI in Austria, Denmark, Finland, Germany, Israel, Norway, Sweden, Turkey, the U.K. and the U.S., or collectively, the CTI Territory.

In October 2014, we received a non-refundable, non-creditable cash upfront payment of €14.0 million. Subject to the achievement of certain conditions, we are eligible to receive milestone payments under the Servier Agreement in the approximate aggregate amount of up to €89.0 million, which is comprised of the following: up to €49.0 million in potential clinical and regulatory milestone payments (of which €9.5 million is payable upon occurrence of certain enrollment events in connection with the PIX306 study for PIXUVRI); and up to €40.0 million in potential sales-based milestone payments. Of the foregoing potential milestone payments, we received a €1.5 million milestone payment in February 2015 relating to the attainment of reimbursement approval for PIXUVRI in Spain. We have determined that all of the clinical and regulatory milestones are substantive and will be recognized as revenue upon achievement of the milestone, assuming all other revenue recognition criteria are met. We have also determined that the sales-based milestone payments are contingent consideration and will be recognized as revenue in the period in which the respective revenue recognition criteria are met. For a number of years following the first commercial sale of a product containing PIXUVRI in the respective country, regardless of patent expiration or expiration of regulatory exclusivity rights, we are eligible to receive tiered royalty payments ranging from a low double digit percentage up to a percentage in the mid-twenties based on net sales of PIXUVRI products, subject to certain reductions of up to mid-double digit percentages under certain circumstances. As previously disclosed, we owe royalties on net sales of PIXUVRI products as well as other payments to certain third parties, including the €2.1 million payment (or \$2.7 million using the currency exchange rate as of September 16, 2014, the date of Servier Agreement) to Novartis International Pharmaceutical Ltd., or Novartis, which is recorded in Other operating expense for the year ended December 31, 2014.

Unless otherwise agreed by the parties, (i) certain development costs incurred pursuant to a development plan and (ii) certain marketing costs incurred pursuant to a marketing plan will be shared equally by the parties, subject to a maximum dollar obligation of each party. We record reimbursements received from Servier as revenue and record the full amount of costs as operating expenses in the statements of operations.



The Servier Agreement will expire on a country-by-country basis upon the expiration of the royalty terms in the countries outside of the CTI Territory, at which time all licenses granted to Servier would become perpetual and royalty-free. Each party may terminate the Servier Agreement in the event of an uncured repudiatory breach (as defined under English law) of the other party's obligations. Servier may terminate the Servier Agreement without cause on a country-by-country basis upon written notice to us within a specified time period or upon written notice within a certain period of days in the event of (i) certain safety or public health issues involving PIXUVRI or (ii) cessation of certain marketing authorizations. In the event of a termination prior to the expiration date, rights granted to Servier will terminate, subject to certain exceptions.

Pursuant to accounting guidance under ASC 605-25 Revenue Recognition – Multiple-Element Arrangements, we identified the following non-contingent deliverables with standalone value at the inception of the Servier Agreement:

- a license with respect to the development and commercialization of PIXUVRI in certain countries; and
- development services under the development plans.

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We have determined that our regulatory, commercial, and manufacturing and supply responsibilities, as well as our joint committee obligations also have standalone value but are insignificant.

The license deliverable has standalone value because it is sublicenseable and can be used for its intended purpose without the receipt of the remaining deliverables. The service deliverables have standalone value because these services are not proprietary in nature, and other vendors could provide the same services to derive value from the license. Further, there is no general right of return associated with these deliverables. As such, the deliverables meet the criteria for separation and qualify as separate units of accounting.

We allocated the arrangement consideration of \$18.1 million (€14.0 million converted into U.S. dollar using the currency exchange rate as of September 16, 2014, the date of the Servier Agreement) based on the percentage of the relative selling price of each unit of accounting as follows (in thousands):

License	\$17,277
Development and other services	852
Total upfront payment	\$18,129

We estimated the selling price of the license using the income approach that 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. The estimates and assumptions include, but are not limited to, estimated market opportunity, expected market share, and contractual royalty rates. We estimated the selling price of the development services deliverable, which includes personnel costs as well as third party costs for applicable services and supplies, by discounting estimated expenditures for services to the date of the Servier Agreement. We concluded that a change in the key assumptions used to determine the best estimate of selling price for the license deliverable would not have a significant effect on the allocation of the arrangement consideration.

During the year ended December 31, 2014, we recognized \$17.3 million of the arrangement consideration allocated to the license as revenue since the delivery of the license occurred upon the execution of the Servier Agreement in September 2014 and the remaining revenue recognition criteria were satisfied. The amount allocated to the development and other services is expected to be recognized as revenue through approximately 2022 on a straight-line basis. During the year ended December 31, 2014, \$18,000 of development services was recognized as revenue, and the remaining \$0.5 million was recorded as deferred revenue in the balance sheet as of December 31, 2014.

#### Novartis

In January 2014, we entered into a Termination Agreement, or the Termination Agreement, with 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, or the UVM Agreement, with the University of Vermont, or UVM, in March 1995, as amended in March 2000, which grants us an exclusive, sublicensable license 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.

#### S\*BIO Pte Ltd.

See Note 4, Acquisitions—S\*BIO Asset Purchase Agreement, for further information regarding the asset purchase agreement with S\*BIO.

#### Chroma

In October 2014, the Chroma Licensing Agreement was terminated in connection with the Chroma APA. See Note 4, Acquisitions—Chroma APA, for further information.

#### Vernalis

Concurrently with the termination of the Co-Development and Licensing Agreement with Chroma and the execution of the Chroma APA, we also entered into (i) the Vernalis License Agreement for the exclusive worldwide right to use certain patents and other intellectual property rights to develop, market and commercialize tosedostat and certain other compounds and (ii) a deed of novation pursuant to which all rights of Chroma under Chroma's prior license agreement with Vernalis relating to tosedostat were novated to us. Under the Vernalis License Agreement, we have agreed to make tiered royalty payments of no more than a high single digit percentage of net sales of products containing licensed compounds, with such obligation to continue on a country-by-country basis for the longer of ten years following commercial launch or the expiry of relevant patent claims. The Vernalis License Agreement will terminate when the royalty obligations expire, although the parties have early termination rights under certain circumstances, including the following: (i) we have the right to terminate, with three months' notice, upon the belief that the continued development of tosedostat or any of the other licensed compounds is not commercially viable; (ii) Vernalis has the right to terminate in the event of our uncured failure to pay sums due; and (iii) either party has the right to terminate in event of the other party's uncured material breach or insolvency.

#### Gynecologic Oncology Group (GOG)

We entered into an agreement with the GOG, now part of NRG Oncology, 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 obligation due to the GOG based on the 1,100 patient enrollment milestone achieved in the third quarter of 2013 which was subsequently paid in the first half of 2014. In the first quarter of 2014, we also recorded a \$0.3 million

obligation to the GOG as required under the agreement based on the additional 50 patients enrolled, with such amount being paid in April 2014. We may be required to pay up to an additional \$1.0 million upon the attainment of certain other milestones, of which \$0.5 million has been recorded in accrued expenses as of December 31, 2014.

## 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. During the year ended December 31, 2014 and 2013, we received \$15.0 million and \$5.0 million, respectively, from Teva Pharmaceutical Industries Ltd., or Teva, upon the achievement of worldwide net sales milestones of TRISENOX, which was included in license and contract revenue. TRISENOX was acquired from us by Cephalon. Cephalon was subsequently acquired by Teva. The achievement of the remaining milestones is uncertain at this time.

## Other Agreements

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

## 13. Share-Based Compensation

### Share-Based Compensation Expense

Share-based compensation expense for all share-based payment awards made to employees and directors is measured based on the grant-date fair value estimated in accordance with generally accepted accounting principles. We

recognize 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, 2014, 2013 and 2012, we recognized share-based compensation expense which consisted of the following types of awards (in thousands):

	2014	2013	2012
Performance rights	\$1,549	\$1,165	\$2,358
Restricted stock	14,749	5,906	5,180
Options	3,898	1,995	400
Total share-based compensation expense	\$20,196	\$9,066	\$7,938

The following table summarizes share-based compensation expense for the years ended December 31, 2014, 2013 and 2012, which was allocated as follows (in thousands):

	2014	2013	2012
Research and development	\$3,437	\$2,178	\$1,730
Selling, general and administrative	16,759	6,888	6,208
Total share-based compensation expense	\$20,196	\$9,066	\$7,938

Share-based compensation had a \$20.2 million, \$9.1 million and \$7.9 million effect on our net loss attributable to common shareholders, which resulted in a \$(0.14), \$(0.08) and \$(0.14) effect on basic and diluted net loss per common share for the years ended December 31, 2014, 2013 and 2012, respectively. It had no effect on cash flows from operations or financing activities for the periods presented; however, during the years ended 2014, 2013 and 2012, we repurchased 57,000, 200,000 and 23,000 shares of our common stock totaling \$0.2 million, \$0.2 million and \$0.1 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, 2014, unrecognized compensation cost related to unvested stock options and time-based restricted stock awards amounted to \$6.3 million, which will be recognized over the remaining weighted-average requisite service period of 1.02 years. The unrecognized compensation cost related to unvested options and restricted stock does not include the value of performance-based share awards.

For the years ended December 31, 2014, 2013 and 2012, 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, 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, 2014, 32.5 million shares were authorized for issuance, of which 11.9 million shares of common stock were available for future grants, under the Plan.

### Stock Options

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

	Year Ended December 31,		
	2014	2013	2012
Risk-free interest rate	1.7%	1.4%	0.8%
Expected dividend yield	None	None	None



Expected life (in years)	5.2	5.3	4.7
Volatility	97 %	102 %	88 %

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.

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Our stock price volatility and option lives involve management's best estimates, both of which impact the fair value of options calculated under the Black-Scholes methodology and, ultimately, the expense that will be recognized over the life of the option. As we also recognize compensation expense for only the portion of options expected to vest, we apply estimated forfeiture rates that we derive from historical employee termination behavior. If the actual number of forfeitures differs from our estimates, additional adjustments to compensation expense may be required in future periods.

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

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (Thousands)
Outstanding at January 1, 2012 (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 (1,560,000 exercisable)	4,519,000	\$ 3.04		
Granted	1,015,000	\$ 3.49		
Exercised	(183,000 )	\$ 1.49		
Forfeited	(356,000 )	\$ 2.25		
Cancelled and expired	(77,000 )	\$ 9.86		
Outstanding at December 31, 2014	4,918,000	\$ 3.14	8.83	\$ 2,480
Vested or expected to vest at December 31, 2014	4,759,000	\$ 3.15	8.82	\$ 2,436
Exercisable at December 31, 2014	3,174,000	\$ 3.42	8.73	\$ 1,925

The weighted average exercise price of options exercisable at December 31, 2013 and 2012 was \$5.39 and \$89.08, respectively. The weighted average grant-date fair value of options granted during 2014, 2013 and 2012 was \$2.59, \$1.32 and \$3.28 per option, respectively.

#### Restricted Stock

We issued 4.4 million, 6.4 million and 4.3 million shares of restricted common stock in 2014, 2013 and 2012, respectively. The weighted average grant-date fair value of restricted shares issued during 2014, 2013 and 2012 was \$3.23, \$1.21 and \$4.77, respectively. Additionally, 0.3 million, 1.2 million and 0.9 million shares of restricted stock were cancelled during 2014, 2013 and 2012, respectively.

A summary of the status of nonvested restricted stock awards as of December 31, 2014 and changes during the period then ended, is presented below:

	Nonvested Shares	Weighted Average Grant-Date Fair Value Per Share
Nonvested at December 31, 2013	4,688,000	\$ 2.95
Issued	4,426,000	\$ 3.23
Vested	(5,764,000)	\$ 2.42
Forfeited	(296,000 )	\$ 3.00
Nonvested at December 31, 2014	3,054,000	\$ 4.35

The total fair value of restricted stock awards vested during the years ended December 31, 2014, 2013 and 2012 was \$18.0 million, \$5.1 million and \$3.4 million, respectively.

#### 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. The Long-Term Performance Awards vest upon achievement of milestone-based performance conditions. (There were eight of such performance conditions, one of which is a market-based performance condition). 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 June 2012, one of the performance conditions was achieved as discussed below. In March 2013, certain performance criteria of the Long-Term Performance Awards were modified, two new performance-based awards were granted, one performance-based award was cancelled, and the expiration date was extended to December 31, 2015. In January 2014, the expiration date of the Long-Term Performance Awards was further extended to December 31, 2016, and two new performance-based awards were granted.

The aggregate of the award percentages related to all ten performance goals in effect as of December 31, 2014 is 12.0%, of which 8.8% and 3.2% are attributable to the executive officers 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 E.U. 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.

We determined the Long-Term Performance Awards with a market-based performance condition had a grant-date fair value of \$3.6 million for the current executive officers and director participants. We determined that the market-based performance condition had an incremental fair value of \$0.8 million on the first modification date in March 2013 and an additional incremental fair value of \$1.8 million on the second modification date in January 2014 for the current executive officers and director participants, which are 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 \$1.4 million, \$1.2 million and \$1.3 million in share based compensation expense related to the performance awards with a market-based performance condition for the years ended December 31, 2014, 2013 and 2012, respectively.

#### 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, 2014 and 2013 unvested nonemployee options to acquire approximately 78,000 and 157,000 shares of common stock were outstanding, respectively. Additionally, unvested nonemployee restricted stock awards totaled approximately 21,000 and 163,000 as of December 31, 2014 and 2013, respectively. As of December 31, 2012, all nonemployee options and restricted stock awards had vested. We recorded compensation expense of \$317,000 and \$310,000 in 2014 and 2013, 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 4,000, 3,000, 3,000 shares to employees in each year ended December 31, 2014, 2013 and 2012. There are 50,833 shares of common stock authorized under the Purchase Plan and 34,149 shares are reserved for future purchases as of December 31, 2014.

## 14. Employee Benefit Plans

The Company's U.S. employees participate in the CTI BioPharma Corp. 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 \$0.2 million related to discretionary matching contributions during each of the years ended December 31, 2014, 2013 and 2012, respectively.

## 15. Shareholder Rights Plan

In December 2009, our Board of Directors approved and adopted a shareholder rights plan, or Rights Plan, in which one preferred stock purchase right was distributed for each common share held as of the close of business on January 7, 2010. Initially, the rights are not exercisable, and are attached to and trade with, all of the shares of CTI's common stock outstanding as of, and issued subsequent to January 7, 2010. In 2012, our Board of Directors approved certain amendments to the Rights Plan.

Each right, if and when it becomes exercisable, will entitle the holder to purchase a unit consisting of one ten-thousandth of a share of Series ZZ Junior Participating Cumulative Preferred Stock, no par value per share, at a cash exercise price of \$8.00 per unit, subject to standard adjustment in the Rights Plan. The rights will separate from the common stock and become exercisable if a person or group acquires 20% or more of our common stock. Upon acquisition of 20% or more of our common stock, the Board could decide that each right (except those held by a 20% shareholder, which become null and void) would become exercisable entitling the holder to receive upon exercise, in lieu of a number of units of preferred stock, that number of shares of our common stock having a market value of two times the exercise price of the right. In certain circumstances, including if there are insufficient shares of our common stock to permit the exercise in full of the rights, the holder may receive units of preferred stock, other securities, cash or property, or any combination of the foregoing.

In addition, if we are acquired in a merger or other business combination transaction, each holder of a right, except those rights held by a 20% shareholder which become null and void, would have the right to receive, upon exercise, common stock of the acquiring company having a market value equal to two times the exercise price of the right. The Board may redeem the rights for \$0.0001 per right or terminate the Rights Plan at any time prior to an acquisition by a person or group holding 20% or more of our common stock. The Rights Plan will expire on December 3, 2015.

#### 16. 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.

All sales of PIXUVRI during 2014 and 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,		
	2014	2013	2012
Customer A	57%	67%	-
Customer B	27%	-	-

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

	Year Ended	
	December 31,	
	2014	2013
United States	\$4,512	\$5,336
Europe	134	142
Total long-lived assets	\$4,646	\$5,478

#### 17. Net Loss Per Share

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

	Year Ended December 31,		
	2014	2013	2012
Net loss attributable to common shareholders	\$(95,992 )	\$(49,643 )	\$(115,275 )
Basic and diluted:			
Weighted average shares outstanding	153,467	119,042	62,021
Less weighted average restricted shares outstanding	(4,936 )	(4,847 )	(3,896 )
Shares used in calculation of basic and diluted net loss per common share	148,531	114,195	58,125
Net loss per common share: Basic and diluted	\$(0.65 )	\$(0.43 )	\$(1.98 )

Equity awards, warrants, and unvested share rights aggregating 14.8 million shares, 11.8 million shares and 8.5 million shares for the year ended December 31, 2014, 2013 and 2012, respectively, prior to the application of the treasury stock method, are excluded from the calculation of diluted net loss per share because they are anti-dilutive.

#### 18. Related Party Transactions

In May 2007, we formed Aequus, a majority-owned subsidiary of which our ownership was approximately 61% as of December 31, 2014. We entered into a license agreement with Aequus whereby Aequus gained rights to our Genetic Polymer™ technology which Aequus will continue to develop. The Genetic Polymer technology may speed the manufacture, development, and commercialization of follow-on and novel protein-based therapeutics.

In May 2007, we also entered into an agreement to fund Aequus in exchange for a convertible promissory note. 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 (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 \$2.0 million, \$1.5 million and \$0.6 million during the years ended December 31, 2014, 2013 and 2012, respectively, including amounts advanced in association with the services agreement. The Aequus note balance, including accrued interest, was approximately \$8.1 million and \$5.8 million as of December 31, 2014 and 2013, 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 4.4% of the equity in Aequus as of December 31, 2014. 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, 2014 and is also a member of Aequus' Board of Directors.

#### 19. 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 and is not subject to appeal.

On December 10, 2009, the Commissione Nazionale per le Società e la Borsa (which is the public authority responsible for regulating the Italian securities markets), or CONSOB, sent us a notice claiming, among other things, violation of the provisions of Section 114, paragraph 1 of the Italian Legislative Decree no. 58/98 due to the asserted late disclosure of the contents of the opinion expressed by Stonefield Josephson, Inc., an independent registered public accounting firm, with respect to our 2008 financial statements. The sanctions established by Section 193, paragraph 1 of the Italian Legislative Decree no. 58/98 for such violations could require us to pay a pecuniary administrative sanction amounting to between \$6,000 and \$606,000 upon conversion from euros as of December 31, 2014. 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.

The Italian Tax Authority, or the ITA, issued notices of assessment to CTI (Europe) based on the ITA's audit of CTI (Europe)'s VAT returns for the years 2003, 2005, 2006 and 2007, or, 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. As of December 31, 2012, we reversed the entire reserve we had previously recorded relating to the VAT Assessments after having received favorable court rulings. In January 2013, our then remaining deposit for the VAT Assessments was refunded to us. The current status of the legal proceedings surrounding each respective VAT year return at issue is as follows:

2003. 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. In January 2014, we were notified that the ITA requested partial payment of the 2003 VAT assessment in the amount of €0.4 million translated to \$0.6 million which we paid in March 2014. We believe that the decision of the Regional Tax Court did not carefully take into account our arguments and the documentation we filed, and in January 2014, we appealed such decision to the Italian Supreme Court both on procedural grounds and on the merits of the case.

2005, 2006 and 2007. The ITA has appealed to the Italian Supreme Court the decisions of the respective appellate court with respect to each of the 2005, 2006 and 2007 VAT returns.

If the final decisions of the Italian Supreme Court for the VAT Assessments are unfavorable to us, we may incur up to \$11.4 million in losses for the VAT amount assessed including penalties, interest and fees upon conversion from euros as of December 31, 2014.

In July 2014, Joseph Lopez and Gilbert Soper, shareholders of the Company, filed a derivative lawsuit purportedly on behalf of the Company, which is named a nominal defendant, against all current and one past member of the Company's Board of Directors in King County Superior Court in the State of Washington, docketed as Lopez & Gilbert v. Nudelman, et al., Case No. 14-2-18941-9 SEA. The lawsuit alleges that the directors exceeded their authority under the Plan by improperly transferring 4,756,137 shares of the Company's common stock from the Company to themselves. It alleges that the directors breached their fiduciary duties by granting themselves fully vested shares of Company common stock, which the plaintiffs allege were not among the six types of grants

authorized by the Plan, and that the non-employee directors were unjustly enriched by these grants. The lawsuit also alleges that from 2011 through 2014, the non-employee members of the Board of Directors granted themselves grossly excessive compensation, and in doing so breached their fiduciary duties and were unjustly enriched. Among other remedies, the lawsuit seeks a declaration that the specified grants of common stock violated the Plan, rescission of the granted shares, disgorgement of the compensation awards to the non-employee directors from 2011 through 2014, disgorgement of all compensation and other benefits received by the defendant directors in the course of their breaches of fiduciary duties, damages, an order for certain corporate reforms and plaintiffs' costs and attorneys' fees. Because the complaint is derivative in nature, it does not seek monetary damages from the Company. In September 2014, the director defendants moved to dismiss the complaint. The motion to dismiss was heard on November 21, 2014, and the Court entered an order denying the motion to dismiss on December 5, 2014. Defendants' answer to the complaint was filed on January 13, 2015. The trial date is currently set for August 24, 2015. At this stage of the litigation, no probability of loss can be predicted.

## 20. Income Taxes

We file income tax returns in the U.S., 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.

In 2014, 2013 and 2012, we had losses from operations before income taxes from domestic operations of \$86.7 million, \$42.1 million and \$111.1 million; and from foreign operations of \$9.3 million, \$7.6 million and \$4.2 million, respectively.

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 \$28.0 million, increased \$11.3 million, decreased \$113.5 million during 2014, 2013 and 2012, respectively.

The reconciliation between our effective tax rate and the income tax rate as of December 31, 2014, 2013 and 2012 is as follows:

	2014	2013	2012
Federal income tax rate	(34 %)	(34 %)	(34 %)
Research and development tax credits	(3 )	(3 )	—
I.R.C. Section 382 limited research and development tax credits	—	—	1
Non-deductible executive compensation	3	1	1
I.R.C. Section 382 limited net operating losses	—	3	134
Valuation allowance	30	27	(111)
Expired tax attribute carryforwards	—	—	7
Foreign tax rate differential	3	6	1
Other	1	—	1
Net effective tax rate	— %	— %	— %

Significant components of our deferred tax assets and liabilities as of December 31, 2014 and 2013 were as follows (in thousands):

	December 31,	
	2014	2013
Deferred tax assets:		
Net operating loss carryforwards	\$63,983	\$49,777
Capitalized research and development	34,936	31,046
Research and development tax credit carryforwards	3,968	1,486
Stock based compensation	12,809	12,097
Intangible assets	17,007	10,518
Depreciation and amortization	191	96

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Other deferred tax assets	3,072	3,062
Total deferred tax assets	135,966	108,082
Less valuation allowance	(135,293)	(107,271)
	673	811
Deferred tax liabilities:		
GAAP adjustments on Novuspharma merger	(208 )	(208 )
Deductions for tax in excess of financial statements	(465 )	(603 )
Total deferred tax liabilities	(673 )	(811 )
Net deferred tax assets	\$—	\$—

Due to our equity financing transactions, and other owner shifts as defined in Internal Revenue Code Section 382, or 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, or NOL, and research and development credits against future income. We have obtained a private letter ruling that determines the availability of the NOL after a 2007 ownership change.

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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 2014, the gross NOL carryforward was approximately \$1.1 billion. The annual NOL limitation will reduce the available NOL carryforward to approximately \$188.2 million expiring from 2018 to 2024. The deferred tax asset and valuation allowance have been reduced accordingly.

At December 2014, the NOL carryforward in the United Kingdom was approximately \$20.9 million which be carried forward indefinitely. The NOL carryforward for the United Kingdom is not included in our schedule of deferred tax assets nor our effective tax rate reconciliation because the net impact on our financial statements is not material. NOLs in Italy are not material.

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 U.S. 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, 2014, 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 adoption of this standard did not have an impact on its consolidated financial statements.

## 21. Unaudited Quarterly Data

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

	First	Second	Third	Fourth
	Quarter	Quarter	Quarter	Quarter
<b>2014</b>				
Total revenues (1), (2)	\$ 1,411	\$ 1,343	\$ 39,534	\$ 17,789
Product sales, net	1,268	1,148	2,021	2,472
Gross profit (3)	1,123	946	1,769	2,176
Net income (loss) attributable to CTI	(29,002)	(27,399)	4,603	(41,569)
Net income (loss) attributable to CTI common shareholders	(29,002)	(27,399)	4,603	(44,194)
Net income (loss) per common share—basic	(0.20 )	(0.19 )	0.03	(0.27 )
Net income (loss) per common share—diluted	(0.20 )	(0.19 )	0.03	(0.27 )
<b>2013</b>				
Total revenues (4)	\$ 1,126	\$ 306	\$ 362	\$ 32,884

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Product sales, net	1,126	306	362	520
Gross profit (3)	1,071	270	349	487
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

(1) Total revenues for the third quarter of 2014 include \$17.3 million of license and contract revenue recognized in connection with the collaboration agreement with Servier in September 2014 and \$20.0 million of license and contract revenue for a milestone payment received under the collaboration agreement with Baxter. See Note 12, Collaboration, Licensing and Milestone Agreements, for additional information.

(2) Total revenues for the fourth quarter of 2014 include \$15.0 million of milestone payments received from Teva in November 2014 upon the achievement of worldwide net sales milestones of TRISENOX. See Note 12, Collaboration, Licensing and Milestone Agreements, for additional information.

(3) Gross profit is computed by subtracting cost of product sold from net product sales.

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(4) 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 12, Collaboration, Licensing and Milestone Agreements, for additional information.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure  
None.

Item 9A. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in reports filed under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the Securities Exchange Commission 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 Exchange Act as of the end of the period covered by this Annual Report on Form 10-K. 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 Annual Report on Form 10-K, our disclosure controls and procedures were effective.

(b) Management's Annual Report on Internal Controls

Management of the Company, including its consolidated subsidiaries, 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 2014 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" (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management has determined that the Company's internal control over financial reporting as of December 31, 2014 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, 2014, 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 2015 definitive proxy statement (which will be filed with the SEC within 120 days after December 31, 2014 in connection with the solicitation of proxies for the Company's 2015 annual meeting of shareholders) ("2015 Proxy Statement") under the captions "Proposal 1—Election of Directors," "Other Information—Executive Officers," and "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 2015 Proxy Statement under the captions "Executive Compensation" and "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 2015 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 2015 Proxy Statement under the captions "Other Information—Related Party Transactions Overview," "Other Information—Certain Transactions with Related Persons" and "Director Attributes and Independence."

Item 14. Principal Accounting Fees and Services

The information required by this Item is incorporated herein by reference from the Company's 2015 Proxy Statement under the caption "Proposal 4—Ratification of the Selection of Independent Auditors."

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

Consolidated Statements of Cash Flows

Notes to Consolidated Financial Statements

(ii) Financial Statement Schedules

All schedules have been omitted since they are either not required, are not applicable, or the required information is shown in the financial statements or related notes.

(iii) Exhibits

Exhibit Number	Exhibit Description	Location
2.1	Agreement and Plan of Merger by and between the Registrant 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.
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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|-----|---|--|
| 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.              |

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Exhibit Number	Exhibit Description	Location
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.
3.15	Form of 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	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.

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| 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.    |

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Exhibit Number	Exhibit Description	Location
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.
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.	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	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 22, 2014.
3.33	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 2, 2014.
3.34	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 20 Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on October 27, 2014.
3.35	Articles of Amendment to Amended and Restated Articles of Incorporation; Designation of Preferences, Rights and Limitations of Series 21 Preferred Stock.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on November 13, 2014.

3.37	Amendment to Amended and Restated Articles of Incorporation.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on February 27, 2015.
3.36	Amended and Restated Bylaws.	Incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed on June 2, 2014.
4.1	Shareholder Rights Agreement, dated December 28, 2009, between the Registrant and Computershare Trust Company, N.A.	Incorporated by reference to Exhibit 4.1 to the Registrant's 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 the Registrant 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 the Registrant 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 December 7, 2012.



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Exhibit Number	Exhibit Description	Location
4.4	Specimen Common Stock Certificate.	Incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form S-3 (File No. 333-200452), filed on November 21, 2014.
4.5	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.
4.6	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.
4.7	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.
4.8	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.
4.9	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.
4.10	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.
4.11	Form of Warrant to Purchase Common Stock, dated July 30, 2012 (expiry date on May 27, 2015).	Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K, filed on August 1, 2012.
4.12	Warrant Agreement, dated March 26, 2013, by and between the Registrant 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 the Registrant 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 the Registrant 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*		Filed herewith.

Amendment No. 2 to Employment Agreement  
between the Registrant and James A. Bianco,  
dated as of January 6, 2015.

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| 10.5* | Offer Letter, by and between the Registrant and Matthew Plunkett, dated July 30, 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. |
| 10.6* | Form of Severance Agreement for the Registrant's Executive Officers other than James A. Bianco (as in effect as of January 6, 2015). | Filed herewith.   |

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Exhibit Number	Exhibit Description	Location
10.7*	Form of Severance Agreement for Louis A. Bianco and Jack W. Singer, as amended by Form of Amendment (in each case, as in effect prior to January 6, 2015).	Incorporated by reference to Exhibit 10.5 and 10.6, respectively, 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 Registrant and Matthew Plunkett (as in effect prior to January 6, 2015).	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on March 22, 2013.
10.9*	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.
10.10*	Form of Indemnity Agreement for the Registrant's Executive Officers and Directors.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on June 2, 2014.
10.11*	Form of Italian Indemnity Agreement for certain of the Registrant's Executive Officers.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on December 17, 2009.
10.12*	2007 Employee Stock Purchase Plan, as amended and restated.	Incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed on October 23, 2009.
10.13*	2007 Equity Incentive Plan, as amended and restated.	Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed on October 31, 2014.
10.14*	Form of 2007 Equity Incentive Plan Restricted Stock Award Agreement.	Filed herewith.
10.15*	Global Form of 2007 Equity Incentive Plan Restricted Stock Unit Award Agreement.	Filed herewith.
10.16*	Global Form of 2007 Equity Incentive Plan Stock Option Agreement.	Filed herewith.
10.17*	Form of 2007 Equity Incentive Plan Restricted Stock Award Agreement for the Registrant's directors (relating to applicable awards granted prior to December 17, 2014).	Incorporated by reference to Exhibit 10.7 to the Registrant's Quarterly Report on Form 10-Q, filed on April 26, 2011.
10.18*	Form of 2007 Equity Incentive Plan Restricted Stock Award Agreement (relating to applicable awards granted prior to December 17, 2014).	Incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, filed on October 30, 2013.
10.19*	Form of 2007 Equity Incentive Plan Restricted Stock Award Agreement for employees (relating to	Incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q, filed on

applicable awards granted prior to December 17, 2014). April 26, 2011.

- 10.20\* Form of 2007 Equity Incentive Plan Stock Option Agreement for the Registrant's directors and officers (relating to applicable awards granted prior to December 17, 2014). Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed on October 30, 2013.
- 10.21\* 2007 Equity Incentive Plan Restricted Stock Award Agreement, dated April 8, 2011, by and between the Registrant and James Bianco. Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q, filed on July 28, 2011.

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Exhibit Number	Exhibit Description	Location
10.22*	Amendment to Restricted Stock Award Agreement, dated September 20, 2011, by and between the Registrant and James Bianco.	Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q, filed on October 25, 2011.
10.23*	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.
10.24*	Form of Equity/Long-Term Incentive Award Agreement for James A. Bianco, Louis A. Bianco and Jack W. Singer.	Incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, filed on April 20, 2012.
10.25*	Form of Equity/Long-Term Incentive Award Agreement for the Registrant's directors.	Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q, filed on April 20, 2012.
10.26*	Form of Equity/Long-Term Incentive Award Agreement for 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.
10.27*	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.
10.28*	Amendment to Form of Equity/Long-Term Incentive Award Agreement, dated as of January 30, 2014, for the Registrant's directors and officers.	Incorporated by reference to Exhibit 10.26 to the Registrant's Annual Report on Form 10-K, filed on March 4, 2014.
10.29	Acquisition Agreement by and among the Registrant, 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.
10.30	Acquisition Agreement among the Registrant, 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.
10.31	Second Amendment to the Acquisition Agreement, dated as of August 6, 2009, by and among the Registrant and each of Tom Hornaday and Lon Smith, in their capacities as Stockholder Representatives.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on August 7, 2009.
10.32†	License Agreement between the Registrant 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.

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| 10.33† | Amendment No. 1 to the License Agreement between the Registrant and PG-TXL Company, L.P., dated as of February 1, 2006.       | Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on February 7, 2006.  |
| 10.34† | Termination Agreement, effective January 3, 2014, by and among Novartis International Pharmaceutical Ltd. and the Registrant. | Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed on April 29, 2014. |

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Exhibit Number	Exhibit Description	Location
10.35†	Asset Purchase Agreement, dated April 18, 2012, between S*BIO Pte Ltd. and the Registrant.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on April 24, 2012.
10.36†	Asset Purchase Agreement, dated October 24, 2014, by and between Chroma Therapeutics Limited and the Registrant.	Incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K/A, filed on November 6, 2014.
10.37†	Exclusive License and Collaboration Agreement by and between the Registrant, CTI Life Sciences Limited, Laboratoires Servier and Institut de Recherches Internationales Servier dated as of September 16, 2014.	Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed on October 31, 2014.
10.38†	Development, Commercialization and License Agreement dated as of November 14, 2013 between the Registrant, Baxter International Inc., Baxter Healthcare Corporation and Baxter Healthcare SA.	Incorporated by reference to Exhibit 10.32 to the Registrant's Annual Report on Form 10-K, filed on March 4, 2014.
10.39†	Amended and Restated Exclusive License Agreement, dated October 24, 2014, by and between Vernalis (R&D) Ltd. and the Registrant.	Incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K/A, filed on November 6, 2014.
10.40†	Drug Product Manufacturing Supply Agreement, dated July 13, 2010, by and between NerPharMa, S.r.l. and the Registrant.	Incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q, filed on August 6, 2010.
10.41†	Manufacturing and Supply Agreement, dated as of April 15, 2014, by and between the Registrant and DSM Fine Chemicals Austria Nfg GmbH & Co KG.	Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed on August 4, 2014.
10.42†	Master Services Agreement, dated July 9, 2012, between Quintiles Commercial Europe Limited CTI Life Sciences Ltd.	Incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q, filed on August 2, 2012.
10.43	Letter of Guarantee, dated July 1, 2012, between the Registrant 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.
10.44	Registration Rights Agreement, among the Registrant 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.

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| 10.45 | Registration Rights Agreement, among the Registrant and Chroma Therapeutics Limited, dated October 24, 2014.  | Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on October 27, 2014.  |
| 10.46 | Loan and Security Agreement, dated March 26, 2013, by and among the Registrant, 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.    |
| 10.47 | First Amendment to Loan and Security Agreement, dated March 25, 2014, by and among the Registrant, Systems Medicine LLC and Hercules Technology Growth Capital, Inc.  | Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed on April 29, 2014. |
| 10.48 | Second Amendment to Loan and Security Agreement, dated October 22, 2014, by and among the Registrant, Systems Medicine LLC, Hercules Technology Growth Capital, Inc. and Hercules Capital Funding Trust 2012-1. | Filed herewith.   |



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Exhibit Number	Exhibit Description	Location
10.49	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.
10.50	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.
12.1	Statement Re: Computation of Ratio of Earnings to Fixed Charges.	Filed herewith.
21.1	Subsidiaries of the Registrant.	Filed herewith.
23.1	Consent of Marcum LLP, Independent Registered Public Accounting Firm.	Filed herewith.
24.1	Power of Attorney. Contained in the signature page of this Annual Report on Form 10-K and incorporated herein by reference.	Filed herewith.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
101.INS	XBRL Instance	Filed herewith.
101.SCH	XBRL Taxonomy Extension Schema	Filed herewith.
101.CAL	XBRL Taxonomy Extension Calculation	Filed herewith.
101.DEF	XBRL Taxonomy Extension Definition	Filed herewith.
101.LAB	XBRL Taxonomy Extension Labels	Filed herewith.
101.PRE	XBRL Taxonomy Extension Presentation	Filed herewith.

\*Indicates management contract or compensatory plan or arrangement.

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



SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Seattle, State of Washington, on March 12, 2015.

CTI BioPharma Corp.

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.

Signature	Title	Date
/s/ Phillip M. Nudelman	Chairman of the Board and Director	March 12, 2015
Phillip M. Nudelman, Ph.D.		
/s/ James A. Bianco	President, Chief Executive Officer and Director (Principal Executive Officer)	March 12, 2015
James A. Bianco, M.D.		
/s/ Louis A. Bianco	Executive Vice President, Finance and Administration (Principal Financial Officer and Principal Accounting Officer)	March 12, 2015
Louis A. Bianco		

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/s/ John H. Bauer                      Director    March 12, 2015

John H. Bauer

/s/ Karen Ignagni                      Director    March 12, 2015

Karen Ignagni

/s/ Richard L. Love                      Director    March 12, 2015

Richard Love

/s/ Mary O. Munding                      Director    March 12, 2015

Mary O. Munding, DrPH

/s/ Jack W. Singer                      Director    March 12, 2015

Jack W. Singer, M.D.

/s/ Frederick W. Telling                      Director    March 12, 2015

Frederick Telling, Ph.D.

/s/ Reed V. Tuckson.                      Director    March 12, 2015

Reed V. Tuckson, M.D.

