

CTI BIOPHARMA CORP  
Form 10-K  
February 17, 2016

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, 2015

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

3101 Western Avenue, Suite 600 98121  
Seattle, WA (Zip Code)  
(Address of principal executive offices)

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.

Edgar Filing: CTI BIOPHARMA CORP - 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, 2015, the aggregate market value of the registrant's common equity held by non-affiliates was \$284,053,374. Shares of common stock held by each executive officer and director and by each person known to the registrant who beneficially owns more than 5% of the outstanding shares of the registrant's common stock have been excluded in that such persons may under certain circumstances be deemed to be affiliates. This determination of executive officer or affiliate status is not necessarily a conclusive determination for other purposes. The registrant has no non-voting common stock outstanding.

The number of outstanding shares of the registrant's common stock as of February 10, 2016 was 280,555,401.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive proxy statement relating to its 2016 annual meeting of shareholders, or the 2016 Proxy Statement, are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The 2016 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.  
TABLE OF CONTENTS

	Page
<u>PART I</u>	
ITEM 1. <u>BUSINESS</u>	<u>2</u>
ITEM 1A. <u>RISK FACTORS</u>	<u>22</u>
ITEM 1B. <u>UNRESOLVED STAFF COMMENTS</u>	<u>38</u>
ITEM 2. <u>PROPERTIES</u>	<u>39</u>
ITEM 3. <u>LEGAL PROCEEDINGS</u>	<u>39</u>
ITEM 4. <u>MINE SAFETY DISCLOSURES</u>	<u>41</u>
<u>PART II</u>	
ITEM 5. <u>MARKET FOR REGISTRANT’S COMMON EQUITY, RELATED SHAREHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	<u>42</u>
ITEM 6. <u>SELECTED FINANCIAL DATA</u>	<u>44</u>
ITEM 7. <u>MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	<u>46</u>
ITEM 7A. <u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	<u>56</u>
ITEM 8. <u>FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	<u>58</u>
ITEM 9. <u>CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	<u>98</u>
ITEM 9A. <u>CONTROLS AND PROCEDURES</u>	<u>99</u>
ITEM 9B. <u>OTHER INFORMATION</u>	<u>99</u>
<u>PART III</u>	
ITEM 10. <u>DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u>	<u>100</u>
ITEM 11. <u>EXECUTIVE COMPENSATION</u>	<u>100</u>
ITEM 12. <u>SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED SHAREHOLDER MATTERS</u>	<u>100</u>
ITEM 13. <u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE</u>	<u>100</u>
ITEM 14. <u>PRINCIPAL ACCOUNTING FEES AND SERVICES</u>	<u>100</u>
<u>PART IV</u>	
ITEM 15. <u>EXHIBITS, FINANCIAL STATEMENT SCHEDULES</u>	<u>101</u>
<u>SIGNATURES</u>	<u>109</u>
CERTIFICATIONS	

## 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, including our ability to get an extension for completing PIX306;
- 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 regarding expectations with respect to the potential therapeutic utility of pacritinib and the prevalence of myelofibrosis in the U.S.;
- 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 Telemarico 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 U.S. 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 health care 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 select countries in the European Union, or the E.U., for multiply relapsed or refractory aggressive B-cell non-Hodgkin lymphoma, or NHL, and evaluating pacritinib for the treatment of adult patients with myelofibrosis.

#### 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 a part of the conditional marketing authorization, we are required to conduct a post-authorization trial, which we refer to as PIX306, comparing PIXUVRI and rituximab with gemcitabine and rituximab in the setting of aggressive B-cell NHL. 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. Pursuant to our conditional marketing authorization in the E.U., we are required to submit the requisite clinical study report for PIX306 by November 2016. We plan to request an extension of such deadline.

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 United Kingdom, or the U.K., and the U.S., while Servier has exclusive rights to commercialize PIXUVRI in all other countries. 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. 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 investigational oral kinase inhibitor with specificity for JAK2, FLT3, IRAK1 and CSF1R. 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. In addition to myelofibrosis, the kinase profile of pacritinib suggests its potential therapeutic utility in conditions such as acute myeloid leukemia, or AML, myelodysplastic syndrome, or MDS, chronic myelomonocytic leukemia, or CMML, and chronic lymphocytic leukemia, or CLL, due to its inhibition of c-fms, IRAK1, JAK2 and FLT3. We believe pacritinib

has the potential to be delivered as a single agent or in combination therapy regimens.

In collaboration with Baxalta Incorporated and its affiliates, or Baxalta, pursuant to our worldwide license agreement to develop and commercialize pacritinib, we are pursuing a comprehensive 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 May 2015, we announced the final results from PERSIST-1, our pivotal Phase 3 trial of pacritinib in patients with myelofibrosis, without exclusion for low platelet counts. In December 2015, primarily based on the results of the PERSIST-1 trial, we and Baxalta submitted a New Drug Application, or NDA, to the U.S. Food and Drug Administration, or FDA, for pacritinib requesting U.S. marketing approval of pacritinib for the treatment of patients with intermediate and high-risk myelofibrosis with low platelet counts of less than 50,000 per microliter (<50,000/ $\mu$ L) for whom there are no approved

therapies. 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. In December 2015, we completed the NDA submission for pacritinib.

On February 8, 2016, the FDA notified us that a full clinical hold has been placed on pacritinib clinical studies. A full clinical hold is a suspension of the clinical work requested under the investigational new drug, or an IND, application. Under the full clinical hold, all patients currently on pacritinib must discontinue pacritinib immediately and no patients can be enrolled or start pacritinib as initial or crossover treatment. In its written notification, the FDA cited the reasons for the full clinical hold were that it noted interim overall survival results from the PERSIST-2 Phase 3 trial showing a detrimental effect on survival consistent with the results from PERSIST-1. The deaths in PERSIST-2 in pacritinib-treated patients include intracranial hemorrhage, cardiac failure and cardiac arrest. In connection with the full clinical hold, the FDA has recommended that we conduct Phase 1 dose exploration studies of pacritinib in patients with myelofibrosis, submit final study reports and datasets for PERSIST-1 and PERSIST-2, provide certain notifications, revise relevant statements in the related Investigator's Brochure and informed consent documents and make certain modifications to protocols. In addition, the FDA recommended that we request a meeting prior to submitting a response to full clinical hold. As a result of the full clinical hold of pacritinib, we have withdrawn the NDA until such time that we have reviewed the safety and efficacy data from PERSIST-2 and decide next steps.

For additional information concerning the final results of PERSIST-1, see Part I, Item 1, "Business - Development Candidates - Pacritinib - Development in Myelofibrosis". We share joint commercialization rights to pacritinib with Baxalta in the U.S., while Baxalta has exclusive commercialization rights for all indications outside the U.S.

#### 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 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 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:

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. A successful outcome from the post-authorization trial, PIX306, will enable us to potentially obtain full marketing authorization from the European Commission and expand the market potential for PIXUVRI.



Develop Pacritinib in Myelofibrosis and Additional Indications. Together with our partner, Baxalta, we intend to develop and commercialize pacritinib for adult patients with myelofibrosis.

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.

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 as of February 10, 2016:

	Indications/Intended Use	Status
PIXUVRI (pixantrone)	Multiply relapsed aggressive B-cell NHL Aggressive NHL, 2nd line >1 relapse, combination with rituximab (PIX306) post-approval study	Marketed in E.U.; Conditional Marketing Authorization Phase 3: Enrollment ongoing
Pacritinib	Myelofibrosis, PERSIST-1, All platelet levels Myelofibrosis, PERSIST-2, Platelet counts $\leq 100,000/\mu\text{L}$	Phase 3: Enrollment completed; Final results presented at medical meeting; Full FDA clinical hold Phase 3: Enrollment completed; Full FDA clinical hold
Tosedostat	AML/MDS(1)	Phase 2: Multiple studies ongoing
Opaxio	Ovarian cancer, maintenance(1)	Phase 3: Patient follow-up ongoing

(1) We support the development of these investigational agents through cooperative group sponsored trials.

#### 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 595,690 deaths annually, or more than 1,630 people per day. Approximately 1.7 million new cases of cancer were expected to be diagnosed in 2016 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

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. Similar to accelerated approval regulations in the U.S., conditional marketing authorizations can be

4

---

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. As a part of the conditional marketing authorization, we are required to conduct a post-authorization trial, PIX306, comparing PIXUVRI and rituximab with gemcitabine and rituximab in the setting of aggressive B-cell NHL. Pursuant to our conditional marketing authorization in the E.U., we are required to submit the requisite clinical study report for PIX306 by November 2016. We plan to request an extension of such deadline. PIXUVRI is not approved in the U.S., however, we believe that the data from the PIX306 study could potentially support a registration application in the U.S.

#### 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 72,580 people diagnosed with NHL in the U.S. and approximately 20,150 people would die from this disease in 2016. 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.

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

In September 2012, we initiated E.U. commercialization of PIXUVRI and in September 2014 we entered into a collaboration arrangement with Servier, under which we have 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. 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. 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 investigational oral kinase inhibitor with specificity for JAK2, FLT3, IRAK1 and CSF1R. 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. The kinase profile of pacritinib suggests its potential therapeutic utility in conditions such as AML, MDS, CMML and CLL, due to its inhibition of c-fms, IRAK1, JAK2 and FLT3.

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.

We are pursuing a comprehensive 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. Myelofibrosis is a rare blood cancer associated with significantly reduced quality of life and shortened survival. As the disease progresses, the body slows production of important blood cells and within one year of diagnosis, the incidence of disease-related thrombocytopenia (very low blood platelet counts), severe anemia and red blood cell transfusion requirements increase significantly. Among other complications, most patients with myelofibrosis present with enlarged spleens (splenomegaly), as well as many other potentially devastating physical symptoms such as abdominal discomfort, bone pain, feeling full after eating little, severe itching, night sweats and extreme fatigue. 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.

PERSIST-1 is a randomized (2:1), open-label, multi-center registration-directed Phase 3 registration-directed trial comparing the efficacy and safety of pacritinib with that of best available therapy other than JAK inhibitors, in 327 patients with myelofibrosis, without exclusion for low platelet counts. 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 study entry, 46 percent of patients were thrombocytopenic; 32 percent of patients had platelet counts less than 100,000 per microliter ( $<100,000/\mu\text{L}$ ); and 16 percent of patients had platelet counts less than 50,000 per microliter ( $<50,000/\mu\text{L}$ ); normal platelet counts range from 150,000 to 450,000 per microliter. 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 May 2015, data from PERSIST-1 showed that compared to best available therapy (exclusive of a JAK inhibitor) pacritinib therapy resulted in a significantly higher proportion of patients with spleen volume reduction and control of disease-related symptoms meeting the primary endpoint of the trial. Treatment with pacritinib resulted in improvements in severe thrombocytopenia and severe anemia, eliminating the need for blood transfusions in a quarter of patients who were transfusion dependent at the time of enrollment. Gastrointestinal symptoms were the most common adverse events and typically lasted for approximately one week. A limited number of patients discontinued treatment due to side effects. There were no Grade 4 gastrointestinal events reported. These results were presented at a late-breaking oral session at the 51st Annual Meeting of the American Society of Clinical Oncology Annual Meeting. Additionally, in June 2015, results from PERSIST-1 PRO and other quality of life measures presented at a late-breaking oral session at the 20th Congress of the European Hematology Association showed significant improvements in symptom score with pacritinib therapy compared to best available therapy (exclusive of a JAK inhibitor) across the symptoms reported in the presentation.

The following table shows the proportion of patients randomized to pacritinib or best available treatment, 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 greatest difference in treatment arms was observed in evaluable patients with the lowest platelet counts ( $< 50,000/\mu\text{L}$  platelets) (33.3 percent with pacritinib vs 0 percent with BAT) ( $p=0.037$ ).

6

---

Spleen Volume Reduction of  $\geq 35\%$  at Week 24 by Platelet Levels

	Pacritinib	BAT	p-value
All Platelet Levels			
ITT*	19.1% (n=220)	4.7% (n=107)	0.0003
Evaluable**	25.0% (n=168)	5.9% (n=85)	<0.0001
<100,000/ $\mu$ L platelets			
ITT	16.7% (n=72)	0% (n=34)	0.0086
Evaluable	23.5% (n=51)	0% (n=24)	0.0072
<50,000/ $\mu$ L platelets			
ITT	22.9% (n=35)	0% (n=16)	0.0451
Evaluable	33.3% (n=24)	0% (n=11)	0.0370

\* ITT - primary analysis included all patients randomized. Patients who missed MRI or CT scans at baseline or at Week 24 were counted as non-responders.

\*\* Evaluable - analysis included patients who had assessment at both baseline and at Week 24.

Results from PERSIST-1 PRO and other quality of life measures showed significant improvements in symptom score with pacritinib therapy compared to best available therapy (exclusive of a JAK inhibitor) across the symptoms reported in the presentation. Patients treated with pacritinib experienced greater improvement in their disease-related symptoms (ITT patient population: 24.5 percent of pacritinib-treated patients vs 6.5 percent of BAT-treated patients,  $p < 0.0001$ ; evaluable patient population: 40.9 percent of pacritinib-treated patients vs 9.9 percent of BAT-treated patients,  $p < 0.0001$ ).

Additionally, 25 percent of patients treated with pacritinib who were severely anemic and transfusion dependent - requiring at least six units of blood in the 90 days prior to study entry - became transfusion independent, compared to zero patients treated with BAT ( $p < 0.05$ ). Among patients with the lowest baseline platelets ( $< 50,000/\mu\text{L}$ ) who received treatment with pacritinib, a significant increase in platelet counts was observed over time compared to BAT ( $p = 0.003$ ) - with a 35 percent increase in platelet counts from baseline to Week 24.

The most common adverse events, occurring in 10 percent or more of patients treated with pacritinib within 24 weeks, of any grade, were: mild to moderate diarrhea (53.2 percent vs 12.3 percent with BAT), nausea (26.8 percent vs 6.6 percent with BAT), anemia (22.3 percent vs 19.8 percent with BAT), thrombocytopenia (16.8 percent vs 13.2 percent with BAT), and vomiting (15.9 percent vs 5.7 percent with BAT). Of the patients treated with pacritinib, 3 discontinued therapy and 13 patients required dose interruption (average one week) for diarrhea. Patients received a daily full dose of pacritinib over the duration of treatment. Gastrointestinal symptoms typically lasted for approximately one week and few patients discontinued treatment due to side effects. There were no Grade 4 gastrointestinal events reported.

In September 2015, following a pre-NDA meeting for pacritinib, we announced our plan to submit a rolling NDA to the FDA in the fourth quarter of 2015. In December 2015, we completed the NDA submission and requested marketing approval for the treatment of patients with intermediate and high-risk myelofibrosis with low platelet counts of less than 50,000 per microliter ( $< 50,000/\mu\text{L}$ ) for whom there are no approved therapies. We were seeking accelerated approval and the NDA was based primarily on data from the PERSIST-1 Phase 3 trial, as well as data from Phase 1 and 2 studies and additional data requested by the FDA, including a separate study report and datasets for the specific patient population with low platelet counts of less than 50,000 per microliter ( $< 50,000/\mu\text{L}$ ) for whom there are no approved therapies.



The PERSIST-2 trial is a randomized (2:1), open-label, multi-center registration-directed Phase 3 trial evaluating pacritinib compared to best available therapy, including the approved JAK inhibitor dosed according to product label, for patients with myelofibrosis whose platelet counts are less than or equal to 100,000 per microliter ( $\leq 100,000/\mu\text{L}$ ). Patients are being randomized 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 Special Protocol Assessment, or SPA, for the PERSIST-2 trial regarding the planned design, endpoints and statistical analysis approach of the trial. The SPA is a written agreement between us and the FDA regarding the design, endpoints and planned statistical analysis approach of the trial to be used in support of a NDA submission. Under the SPA, the agreed upon co-primary endpoints are the percentage of patients achieving a 35 percent or greater reduction in spleen volume measured by MRI or CT scan from baseline to 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 design of PERSIST-1 and PERSIST-2 allows for patients on the BAT arm to

crossover and receive treatment with pacritinib if their disease progresses or after they achieve the 24-week measurement endpoint. Although crossover design of clinical trials may confound evaluation of survival, such designs are frequently used in cancer studies, and the FDA has approved multiple oncology drugs that utilized crossover design in Phase 3 trials. The Independent Data Monitoring Committee, or IDMC, in place at the time for the PERSIST program recommended patients on the best available therapy arm should not crossover to receive pacritinib due to non-statistically significant safety concerns in patients who crossover after 24 weeks, which crossover confounds evaluation of survival. After receiving input from external independent experts and providing the FDA the PERSIST-1 data, IDMC's recommendation and correspondence, we and Baxalta notified the FDA of the decision to proceed per protocol. Following a written response in lieu of a Type C meeting with the FDA, we and Baxalta determined that no modifications to the ongoing trials were required. Patient enrollment in PERSIST-2 was completed in February 2016 and over 300 patients were enrolled in North America, Australia, New Zealand and Russia. In early February, the FDA notified us that a full clinical hold has been placed on pacritinib. A full clinical hold is a suspension of the clinical work requested under an investigational NDA. Under the full clinical hold, all patients currently receiving pacritinib must discontinue pacritinib, and no new patients may start pacritinib as initial or crossover treatment.

#### Development in Other Indications

In December 2014, we announced results of a preclinical analysis of kinase inhibition by pacritinib that demonstrated a unique kinome profile among agents in development for myelofibrosis and suggests potential therapeutic benefit across a spectrum of blood-related cancers. Pacritinib's potent inhibition of FLT3, c-fms, IRAK1 and c-kit highlight its potential therapeutic utility in other indications, such as AML, MDS, CMML and CLL, which are currently being evaluated in Phase 2 clinical trials. One such trial is 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. Patients currently receiving pacritinib must stop doing so as a result of the full clinical hold placed on pacritinib.

#### Full Clinical Hold on Pacritinib IND

On February 8, 2016, the FDA notified us that a full clinical hold has been placed on pacritinib clinical studies. A full clinical hold is a suspension of the clinical work requested under the investigational new drug, or an IND, application. Under the full clinical hold, all patients currently on pacritinib must discontinue pacritinib immediately and no patients can be enrolled or start pacritinib as initial or crossover treatment. In its written notification, the FDA cited the reasons for the full clinical hold were that it noted interim overall survival results from the PERSIST-2 Phase 3 trial showing a detrimental effect on survival consistent with the results from PERSIST-1. The deaths in PERSIST-2 in pacritinib-treated patients include intracranial hemorrhage, cardiac failure and cardiac arrest. In connection with the full clinical hold, the FDA has recommended that we conduct Phase 1 dose exploration studies of pacritinib in patients with myelofibrosis, submit final study reports and datasets for PERSIST-1 and PERSIST-2, provide certain notifications, revise relevant statements in the related Investigator's Brochure and informed consent documents and make certain modifications to protocols. In addition, the FDA recommended that we request a meeting prior to submitting a response to full clinical hold. As a result of the full clinical hold of pacritinib, we have withdrawn the NDA until such time that we have reviewed the safety and efficacy data from PERSIST-2 and decide next steps.

#### Contractual Arrangements Relating to Pacritinib

Under the Pacritinib License Agreement (defined below), we share joint commercialization rights to pacritinib with Baxalta in the U.S., while Baxalta has exclusive commercialization rights for all indications outside the U.S. For additional information relating to the Pacritinib License Agreement, see Part I, Item 2, “License Agreements and Milestone Activities -Baxalta”.

#### 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. Specifically, study results presented for tosedostat in AML have shown promising complete response, or CR, rates and good tolerability. Several ongoing Phase 2 cooperative group sponsored trials and ISTs are further 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 (NCRI) Haematological Oncology Study Group under the sponsorship of Cardiff University. In this Phase 2/3 study, referred to as AML Less Intensive or LI-1, patients are being randomized to standard treatment, low dose cytarabine, versus other novel investigational treatments, one of which is tosedostat, each in combination with low dose cytarabine. The trial utilizes a “Pick a Winner” trial design. Overall survival is the primary endpoint of this trial.

In November 2015, based on the randomized Phase 2 interim analysis of the LI-1 study, the trial management group determined that tosedostat should proceed to the next stage of the study. The aim of the trial is to identify treatments that can double the 2-year survival of patients in this group. It is anticipated that an additional 110 patients will be required in such phase. A further evaluation will take place before the intended expansion to a 400 patient Phase 3 trial.

In December 2015, results from a separate investigator-sponsored Phase 2 trial of tosedostat in combination with low-dose cytarabine/Ara-C, or LDAC, in elderly patients with either primary AML or AML were presented at the American Society of Hematology Annual Meeting. The Phase 2 multicenter clinical trial was designed to assess tosedostat (orally once-daily) in combination with intermittent LDAC (twice daily) in 33 elderly patients (median age = 75 years) with either primary AML or secondary AML. This presentation reported on the results of 33 patients (median age was 75) that were enrolled. The study met the primary endpoint with an overall response rate (ORR) of 54.6 percent (n=18/33) in the ITT population. The study achieved a CR rate of 48.5 percent (n=16/33) and the median time for achieving best response was 74 days (range: 22-145 days) with 33 percent still in remission (or experiencing a CR) after a median follow-up of 506 days. Safety analysis show that tosedostat in combination with LDAC was generally well tolerated. The primary adverse events observed were pneumonitis (12 percent), cardiac (6 percent), brain hemorrhage (3 percent), and asthenia (3 percent).

## 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®) and docetaxel (Taxotere®), 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 \$76.6 million, \$64.6 million and \$33.6 million in 2015, 2014 and 2013, 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, 2015, 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, the Servier Agreement provides for us to potentially receive milestone payments thereunder 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 these potential milestone payments, we have received a €1.5 million (or \$1.7 million upon conversion from euros as of the date we received the funds) milestone payment 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 also 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.

#### Baxalta

In November 2013, we entered into a Development, Commercialization and License Agreement, dated as of November 14, 2013, between Baxter International Inc., or Baxter, and the Company, for the development and commercialization of pacritinib for use in oncology and potentially additional therapeutic areas, or the Original Pacritinib License Agreement. The Original Pacritinib License Agreement, the rights and obligations to which Baxter has assigned to Baxalta, was amended by a first amendment thereto, or the Pacritinib License Amendment, effective June 8, 2015. The Original Pacritinib License

Agreement, as amended by the Pacritinib License Amendment, is referred to herein as the “Pacritinib License Agreement”. Under the Pacritinib License Agreement, Baxalta has 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 Pacritinib License Agreement consist of products in which pacritinib is an ingredient.

We received an upfront payment of \$60 million under the Pacritinib License Agreement, which included a \$30 million investment in our equity. The Pacritinib License 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 milestone payments, we have received \$52 million to date relating to the achievement of a clinical milestone in August 2014, the PERSIST-2 Milestone (as defined below) in January 2016 and the MAA Milestone (as defined below) in February 2016.

In June 2015, we entered into the Pacritinib License Amendment. Pursuant to the Pacritinib License Amendment, two potential milestone payments in the aggregate amount of \$32.0 million from Baxalta to us were accelerated from the schedule contemplated by the original Pacritinib License Agreement relating to the following: the \$20.0 million development milestone payment payable in connection with the first treatment dosing of the 300th patient enrolled per the protocol in PERSIST-2, or the PERSIST-2 Milestone, and the \$12.0 million development milestone payment payable in connection with the regulatory submission of the Marketing Authorization Application, or the MAA, to the European Medicines Agency, or EMA, with respect to pacritinib, or the MAA Milestone. Such advances bear interest at an annual rate of 9% percent until the earlier of (i) the date of first occurrence of the respective milestone and (ii) the date that the respective advance plus accrued interest is repaid in full. In the event that pacritinib development is terminated either because of a regulatory determination that the benefit/risk profile of the drug candidate is unacceptable or due to safety concerns or certain other reasons, including the failure of pacritinib to meet certain criteria or certain endpoints, or a Milestone Failure, we would be required to repay the respective advance to Baxalta in eight quarterly installments beginning thirty days after the end of the calendar quarter of the first occurrence of a Milestone Failure and a final payment equal to the remainder of the unpaid balance, or the Repayment Terms. In January 2016 and in February 2016, we successfully achieved the \$20 million PERSIST-2 Enrollment Milestone and the \$12 million MAA Milestone, respectively.

Under the Pacritinib License Agreement, 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 by Baxalta and 25 percent by us, (ii) costs applicable to territories exclusive to Baxalta will be 100 percent borne by Baxalta and (iii) costs applicable exclusively to co-promotion in the U.S. will be shared equally between the parties, subject to certain exceptions. In the event that we do not spend a specified amount on the development of pacritinib from June 8, 2015 through February 29, 2016, payments to Baxalta in an amount equal to such deficiency may be required or credited against amounts owed to us in certain circumstances. We expect to spend the specified amount on the development of pacritinib by February 29, 2016. We and Baxalta have each been allocated up to 50% of the manufacturing (subject to certain conditions), with certain pricing adjustments based on comparative costs of supply. In addition, we may be obligated to pay the costs of certain product supplied by our manufacturer to Baxalta if the product does not meet certain prescribed standards.

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) Baxalta is required to obtain third party royalty-bearing licenses to fulfill its obligations under the Pacritinib License Agreement and (ii) in any jurisdiction where there is no longer either regulatory exclusivity or



patent protection.

The Pacritinib License Agreement will expire when Baxalta has no further obligation to pay royalties to us in any jurisdiction, at which time the licenses granted to Baxalta will become perpetual and royalty-free. We or Baxalta may terminate the Pacritinib License 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 Pacritinib License Agreement as to one or more such countries if Baxalta has not undertaken requisite regulatory or commercialization efforts in the applicable country and certain other conditions are met. Baxalta may terminate the Pacritinib License 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 Pacritinib License Agreement, provided that such termination will have a lead-in period of six months before it becomes effective. Additionally, either party may terminate the Pacritinib License 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.

#### Vernalis

We entered into an amended and restated exclusive license agreement with Vernalis (R&D) Limited, or Vernalis, in October 2014 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. 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

We entered into an agreement with the Gynecologic Oncology Group, 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, 2015.

PG-TXL

In November 1998, we entered into an agreement with 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-

12

---

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 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 (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.

#### 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 previously granted to Novartis under our agreement entered into in September 2006, as amended, or the Original Novartis Agreement. Pursuant to the Novartis Termination Agreement, the Original Novartis 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 PIXUVRI and Opaxio 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. Novartis is entitled to receive potential payments of up to \$16.6 million upon the successful achievement of certain sales milestones of PIXUVRI and Opaxio. We are also obligated to pay to 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 of PIXUVRI and Opaxio, 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.

#### 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 \$30.0 million of such potential milestone payments as a result of having achieved certain sales milestones.

Other Agreements

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

Information about Customer and Geographic Concentrations

Information about customer and geographic revenue is set forth in Part II, Item 8, "Financial Statements and Supplementary Data, Notes to Consolidated Financial Statements, Note 16. Customer and Geographic Concentrations" of this Annual Report on Form 10-K.

## 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.

Our PIXUVRI-directed patents currently in force in Europe began to expire in late March 2015 and will continue to expire through a portion of 2023. Some of these European patents are also subject to Supplementary Protection Certificates such that the extended patents will expire from 2020 to 2027. Although we are seeking to obtain a Supplementary Protection Certificate for one other PIXUVRI-directed patent in Europe that could extend through 2027, there can be no guarantee that such extension will be granted. In the United States, our PIXUVRI-directed U.S. patent will expire in 2024. 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 2030. Our U.S. and various foreign tosedostat-directed patents expire from 2017 to 2018. Our U.S. and various foreign Opaxio-directed patents primarily expire from 2017 through 2019.

In the absence of a patent we would, 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.

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. Each third party contractor will always undergo a formal qualification process by CTI subject matter experts prior to signing any service agreement and initiating any manufacturing work. 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. A qualified commercial supplier for pacritinib has been identified and commercial agreement discussions are in progress.

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 Jakafi®, which is marketed by Incyte 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 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 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

20

---

liability not covered by insurance could exceed our resources. See the risk factor, “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, 2015, we employed 149 individuals in the U.S., including two employees at our majority-owned subsidiary Aequus Biopharma, Inc., or Aequus, and six in Europe. Our U.S. and U.K. employees do not have a collective bargaining agreement. One employee in Italy is subject to a collective bargaining agreement. We believe our relations with our employees are good.

## 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 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 read and copy any materials we file with the SEC 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, liquidity, 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 expect that we will need to raise additional funds to develop our business, but additional funds may not be available on acceptable terms, or at all. Any inability to raise required capital when needed could 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 \$128.2 million as of December 31, 2015. We believe that our present financial resources, together with milestone payments projected to be received under certain of our contractual agreements and our ability to control costs, will be sufficient to fund our operations through 2017. 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 clinical trials and other research and development activities, acquisitions of compounds or other assets, our ability to generate projected sales of PIXUVRI, any expansion of our sales and marketing organization for PIXUVRI, regulatory approval developments, ability to consummate appropriate collaborations for development and commercialization activities, ability to reach milestones triggering payments under applicable contractual arrangements, receive the associated payments and satisfy the conditions necessary to retain the funds from the June 2015 accelerated milestone payment from Baxalta, litigation and other disputes, competitive market developments and other unplanned expenses or business developments may consume capital resources earlier than planned. Due to these and other factors, any 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, 2015, we had an outstanding principal balance under our senior secured term loan agreement of \$25.0 million. We are required to make monthly interest-only payments in respect thereof in the approximate amount of \$0.2 million until March 31, 2016. Following March 31, 2016, we will be required to make monthly interest plus principal payments through December 1, 2018 in the approximate amount of \$0.8 million, with the final principal payment of approximately \$3.3 million on December 1, 2018. These 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 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. In addition, with respect to the \$32.0 million accelerated milestone payment we received in June 2015 from Baxalta, certain events may trigger repayment of such advance prior to attainment of the respective milestones. On January 12, 2016 and on February 8, 2016, we successfully achieved the \$20 million PERSIST-2 Milestone and the \$12 million MAA Milestone, respectively.

We may need to acquire additional funds in order to develop 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 have in the past received and may in the future receive audit reports with an explanatory paragraph on our consolidated financial statements.

Our independent registered public accounting firm included an explanatory paragraph in its reports on our consolidated financial statements for each of the years ended December 31, 2007 through December 31, 2011 and for the year ended December 31, 2014 regarding their substantial doubt as to our ability to continue as a going concern. Although our independent registered public accounting firm removed this going concern explanatory paragraph in its report on our December 31, 2015 consolidated financial statements, we expect to continue to need to raise additional financing to fund our operations and satisfy obligations as they become due. The inclusion of a going concern explanatory paragraph in future years may negatively impact the trading price of our common stock and make it more difficult, time consuming or expensive to obtain necessary financing, and we cannot guarantee that we will not receive such an explanatory paragraph in the future.

We 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, 2015, we had an accumulated deficit of \$2.1 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 our compounds, 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 Pacritinib License Agreement, we rely heavily on the respective entities, to collaborate with us to develop and commercialize PIXUVRI and pacritinib, respectively. As a result of our dependence on our relationships with Servier and Baxalta, 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 Baxalta, 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; the ability to meet our financial and other contractual obligations under the respective agreements; and the possibility that Servier or Baxalta could elect to terminate their respective agreements with us pursuant to "at-will" termination clauses or breach their respective agreements with us. Furthermore, the contingent financial returns under our collaborations with Servier and Baxalta 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 Baxalta. 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 the applicable compounds, generate revenues to sustain or grow our business or achieve profitability, which would harm our business, financial condition, operating results and prospects.

If we are unable to address any recommendations or requirements of the FDA under the clinical hold for pacritinib to the satisfaction of the FDA on a timely basis or at all, we could be delayed or prevented from further studying pacritinib or seeking its commercialization.

On February 8, 2016, the FDA notified us that a full clinical hold had been placed on pacritinib and we subsequently withdrew our NDA for pacritinib until we have had a chance to decide next steps. A full clinical hold is a suspension of the clinical work requested under an investigational new drug application. Under the full clinical hold, all patients currently on pacritinib were required to discontinue pacritinib, and we are not permitted to enroll any new patients or start pacritinib as



initial or crossover treatment. In its written notification, the FDA noted interim overall survival results from PERSIST-2 showing a detrimental effect on survival consistent with the results from PERSIST-1, and that deaths in PERSIST-2 in pacritinib-treated patients include intracranial hemorrhage, cardiac failure and cardiac arrest. The recommendations include conducting Phase 1 dose exploration studies of pacritinib in patients with myelofibrosis, submitting final study reports and datasets for PERSIST-1 and PERSIST-2, providing certain notifications, revising relevant statements in the related Investigator's Brochure and informed consent documents and making certain modifications to protocols. In addition, the FDA recommended that we request a meeting prior to submitting a response to full clinical hold. All clinical investigators worldwide have been delivered a notice of the full clinical hold.

We plan to review the safety and efficacy data from the PERSIST-2 Phase 3 clinical trial and decide, next steps including addressing the FDA's recommendations. The FDA may not necessarily deem any information we provide or response we make sufficient to lift the full clinical hold on pacritinib or reduce it to a partial clinical hold. Additionally, the FDA may expand its information request or require us to pursue new clinical safety trials with changes to, among other things, protocol, study design or sample size before the FDA will consider modifying or lifting the clinical hold, if at all. Complying with any such requests or making any such changes may be time-consuming expensive and delay or prevent our ability to continue to study pacritinib. If we are unable to address the FDA's recommendations and requests in a manner satisfactory to the FDA, in a timely manner, or at all, we could be delayed or prevented from pursuing the further study of pacritinib and seeking its commercialization, which would prevent us from receiving future milestone or royalty payments, and otherwise significantly harm our business.

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, timely attaining process validation for particular drug products and obtaining manufacturing approval;
- pricing or 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;
- 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, from time to time we report top-line data for clinical trials. 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 are based on important assumptions, estimations, calculations and information then available to us to the extent we have had, at the time of such reporting, 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 may differ from future results, or different conclusions or considerations may qualify such results once existing data have 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. Some of 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. For instance, on February 8, 2016, the FDA placed pacritinib on full clinical hold and we subsequently withdrew our NDA for pacritinib until we have had a chance to decide next steps. The number, size, design 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;
- the clinical and other benefits of a compound may not outweigh its safety risks;
- clinical trial results may be negative or inconclusive, or adverse medical events may occur during a clinical trial;
- the results of clinical trials may not meet the level of statistical significance required by regulatory agencies for approval;
- such regulatory agencies may interpret data from pre-clinical and clinical trials in different ways than we do;
- such regulatory agencies may not approve the manufacturing process of a compound or determine that a third party contract manufacturers manufactures a compound in accordance with current good manufacturing practices, or cGMPs;
- 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 at all or quickly enough to provide net revenues to defray our operating expenses, our business, financial condition, operating results and prospects could be harmed.



In the event that we seek and the FDA does not grant accelerated approval or priority review for a drug candidate, we would experience a longer time to commercialization in the U.S., if commercialized at all, our development costs may increase and our competitive position may be harmed.

We were seeking accelerated approval and requested Priority Review of our NDA for pacritinib. However, on February 8, 2016, the FDA notified us that a full clinical hold had been placed on pacritinib and we subsequently withdrew our NDA for pacritinib until we have had a chance to decide next steps.

We may in the future decide to seek accelerated approval pathway for our compounds. The FDA may grant accelerated approval to a product designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. A surrogate endpoint under an accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. There can be no assurance that the FDA will agree that any endpoint we suggest with respect to any of our drug candidates is an appropriate surrogate endpoint. Furthermore, there can be no assurance that any application will be accepted or that approval will be granted. Even if a product candidate is granted accelerated approval, such accelerated approval is contingent on the sponsor's agreement to conduct one or more post-approval confirmatory trials. Such confirmatory trial(s) must be completed with due diligence and, in some cases, the FDA may require that the trial(s) be designed and/or initiated prior to approval. Moreover, the FDA may withdraw approval of a product candidate or indication approved under the accelerated approval pathway for a variety of reasons, including if the trial(s) required to verify the predicted clinical benefit of a product candidate fail to verify such benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the drug, or if the sponsor fails to conduct any required post-approval trial(s) with due diligence.

In the event of priority review, the FDA has a goal to (but is not required to) take action on an application within a total of eight months (rather than a goal of twelve months for a standard review). The FDA grants priority review only if it determines that a product treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness when compared to a standard application. The FDA has broad discretion whether to grant priority review, and, while the FDA has granted priority review to other oncology product candidates, our drug candidates may not receive similar designation. Moreover, receiving priority review from the FDA does not guarantee completion of review or approval within the targeted eight-month cycle or thereafter.

A failure to obtain accelerated approval or priority review would result in a longer time to commercialization of the applicable compound in the U.S., if commercialized at all, could increase the cost of development and could harm our competitive position in the marketplace.

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 experience excessive product loss due to contamination, equipment failure, inadequate transportation or storage, improper installation or operation of equipment, vendor or operator error, inconsistency in yields or variability in product characteristics;

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 any future potential commercialization of pacritinib, we will be heavily dependent on our collaboration partners, Servier and Baxalta, respectively. The failure of Servier or Baxalta (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 health care 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 health care 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 currently 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.

27

---



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 manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping regulations. These requirements include submissions of safety and other post-marketing information and reports. In addition, such products are subject to ongoing maintenance of product registration and continued compliance with cGMPs, GCPs, and good laboratory practices, or GLPs. Further, distribution of products must be conducted in accordance with good distribution practices, or GDPs. The distribution process and facilities of our third party distributors are subject to, and our wholesale distribution authorization by the UK Medicines and Healthcare Products Regulatory Agency subjects us to, continuing regulation by applicable regulatory authorities with respect to the distribution and storage of products. 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 trial 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 and are unable to obtain an extension of such deadline, or if we are otherwise unable to satisfy all applicable requirements, our conditional marketing authorization for PIXUVRI may be revoked.

Any other failure to comply with applicable regulations could result in warning or untitled letters, product recalls, interruption of manufacturing and commercial supply processes, withdrawal or seizure of products, suspension of an applicable wholesale distribution authorization and/or distribution of products, operating restrictions, injunctions, suspension of licenses, revocation of the applicable product's approval or authorization, other administrative or judicial sanctions (including civil penalties and/or criminal prosecution) and/or unanticipated related expenditure to resolve shortcomings, 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, including financing activities.

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.

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.

Additionally, 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, S.p.A., the Italian central clearing agency, 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 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, and 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, 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 FDCA 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, health care 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 the FCPA, the U.K. Bribery Act 2010 and other anti-corruption laws. These laws 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 health care 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” (health care providers, health plans and health care clearinghouses) governing the conduct of certain electronic health care 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 health care 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 the manufacture, testing and distribution of our compounds and associated supply chain operations, as well as for clinical trial activities. 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 rely heavily on third parties for the manufacture and testing of our compounds. We do not have internal analytical laboratory or manufacturing facilities to allow the testing or production of compounds in compliance with GLP and cGMP. As a result, we rely on third parties to supply us in a timely manner with manufactured products/product candidates. We may not be able to adequately manage and oversee the manufacturers we choose, they may not perform as agreed or they may terminate their agreements with us. In particular, we depend on third party manufacturers to conduct their operations in compliance with

30

---

GLP and cGMP or similar standards imposed by the U.S. and/or applicable foreign regulatory authorities, including the FDA and EMA. Any of these regulatory authorities may take action against a contract manufacturer who violates GLP and cGMP. 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 may not be able to obtain sufficient quantities of our compounds if we are unable to secure manufacturers when needed, or if our designated manufacturers do not have the capacity or otherwise fail to manufacture compounds according to our schedule and specifications or fail to comply with cGMP regulations. In particular, in connection with the transition of the manufacturing of PIXUVRI and pacritinib drug supply to successor vendors, respectively, we could face logistical, scaling or other challenges that may adversely affect supply. Furthermore, in order to ultimately obtain and maintain applicable regulatory approvals, any manufacturers we utilize are required to consistently produce the respective compounds in commercial quantities and of specified quality or execute fill-finish services on a repeated basis and document their ability to do so, which is referred to as process validation. In order to obtain and maintain regulatory approval of a compound, the applicable regulatory authority must consider the result of the applicable process validation to be satisfactory and must otherwise approve of the manufacturing process. Even if our compound manufacturing processes obtain regulatory approval and sufficient supply is available to complete clinical trials necessary for regulatory approval, there are no guarantees we will be able to supply the quantities necessary to effect a commercial launch of the applicable drug, or once launched, to satisfy ongoing demand. Any compound shortage could also impair our ability to deliver contractually required supply quantities to applicable collaborators, as well as to complete any additional planned clinical trials.

We also rely on third party service providers for certain warehousing, transportation, sales, order processing, distribution and cash collection services. With regard to the distribution of our compounds, we depend on third party distributors to act in accordance with GDP, and the distribution process and facilities are subject to continuing regulation by applicable regulatory authorities with respect to the distribution and storage of products.

In addition, we depend on medical institutions and CROs (together with their respective agents) to conduct clinical trials and associated activities in compliance with 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. Furthermore, we conduct clinical trials in foreign countries, subjecting 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.

With regard to certain of the foregoing clinical trial operations and stages in the manufacturing and distribution chain of our compounds, we rely on single vendors. In particular, our current business structure contemplates, at least in the foreseeable future, use of a single commercial supplier for PIXUVRI drug substance. In addition, in the event pacritinib is approved, we are initially preparing to have only one commercial supplier for pacritinib. Although our collaborator, Baxalta, intends to qualify an additional manufacturer of pacritinib, the process for obtaining approval of a manufacturer can be lengthy. The use of single vendors for core operational activities, such as clinical trial operations, manufacturing and distribution, and the resulting lack of diversification, expose us to the risk of a material interruption in service related to these single, outside vendors. As a result, our exposure to this concentration risk could harm our business.

Although we monitor the compliance of our third party service providers performing the aforementioned services, we cannot be certain that such service providers will consistently comply with applicable regulatory requirements or that they will otherwise timely satisfy their obligations to us. Any such failure and/or any failure by us to monitor their services and to plan for and manage our short and long term requirements underlying such services could result in

shortage of the compound, delays in or cessation of clinical trials, failure to obtain or revocation of product approvals or authorizations, product recalls, withdrawal or seizure of products, suspension of an applicable wholesale distribution authorization and/or distribution of products, operating restrictions, injunctions, suspension of licenses, other administrative or judicial sanctions (including civil penalties and/or criminal prosecution) and/or unanticipated related expenditures to resolve shortcomings. Such consequences could have a significant impact on our business, financial condition, operating results or prospects.

If we are unable to recruit, retain, integrate and motivate senior management, other key personnel and directors, or if such persons are unable to perform effectively, our business could suffer.

Our future success depends, in part, on our ability to continue to attract and retain senior management, other key personnel and directors to enable the execution of our business plan and to identify and pursue new opportunities. Additionally, our productivity and the quality of our operations are dependent on our ability to integrate and train our new personnel quickly and effectively.



Directors and management of publicly traded corporations are increasingly concerned with the extent of their personal exposure to lawsuits and shareholder claims, as well as governmental, creditor and other claims that may be made against them. Due to these and other reasons, such persons are also becoming increasingly concerned with the availability of directors and officers liability insurance to pay on a timely basis the costs incurred in defending such claims. We currently carry directors and officers liability insurance. However, directors and officers liability insurance is expensive and can be difficult to obtain. If we are unable to continue to provide directors and officers sufficient liability insurance at affordable rates or at all, or if directors and officers perceive our ability to do so in the future to be limited, it may become increasingly more difficult to attract and retain management and qualified directors to serve on our Board of Directors.

The loss of the services of senior management, other key personnel or directors and/or the inability to timely attract or integrate such persons could significantly delay or prevent the achievement of our development and strategic objectives and may adversely affect our business, financial condition and operating results.

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 ibrutinib, idelalisib, lenolidimide, 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 the currently approved JAK1/JAK2 inhibitor, Jakafi®.

If we are successful in bringing tosedostat to market, we 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®, Avastin®, Alimta® and Abraxane®.

In addition to the specific competitive factors discussed above, new anti-cancer drugs that may be under development or 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 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.

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.

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.

Our PIXUVRI-directed patents currently in force in Europe began to expire in late March 2015 and will continue to expire through a portion of 2023. Some of these European patents are also subject to Supplementary Protection Certificates such that the extended patents will expire from 2020 to 2027. Although we are seeking to obtain a Supplementary Protection Certificate for one other PIXUVRI-directed patent in Europe that could extend through 2027, there can be no guarantee that such extension will be granted. In the United States, our PIXUVRI-directed U.S. patent will expire in 2024. 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 2030. Our U.S. and various foreign tosedostat-directed patents expire from 2017 to 2018. Our U.S. and various foreign Opaxio-directed patents primarily expire from 2017 through 2019.

In the absence of a patent, we would, 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 that do 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 VAT related to our operations in Europe.

Our European operations are subject to the value added tax, or VAT, which is usually applied to all goods and services purchased and sold throughout Europe. The VAT receivable was \$4.7 million and \$4.9 million as of December 31, 2015 and 2014, respectively. On April 14, 2009, December 21, 2009 and June 25, 2010, the Italian Tax Authority, or ITA, issued notices

of assessment to our branch, CTI BioPharma Corp - 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, respectively. 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 \$10.2 million upon conversion from euros as of December 31, 2015) 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 and our ability to procure or afford directors and officers liability insurance.

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 certain pending legal proceedings, including the purported class action lawsuits filed against us and certain of our current and former directors and officers in February 2016. Litigation is subject to inherent uncertainties, and we have had and may in the future have unfavorable rulings and settlements. Adverse outcomes 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. 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.

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 there is a finding of liability. 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.

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. Any expansion of our commercial operations in Europe (including with regard to sales of PIXUVRI) may increase our exposure to fluctuations in foreign currency exchange rates. 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.

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 our outstanding balance of \$32 million classified as debt as a result of the accelerated milestone payment we received from Baxalta, 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, The NASDAQ Stock Market requires listed companies to maintain a minimum closing bid price of \$1.00 per share. As of February 10, 2016, the closing bid price of our common stock was \$0.2994 per share. In the future, 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 February 10, 2016, our stock price has ranged from a low of \$0.25 to a high of \$2.94. 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, such as the imposition of a clinical trial hold;
- 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

38

---

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 expires in April 2022. We also lease approximately 4,700 square feet of warehouse space in Seattle, Washington with a lease expiration of May 2016. Additionally, we lease 2,700 square feet in Milan, Italy with a lease expiration of December 2021 and 439 square feet in Uxbridge, U.K. with a lease expiration of October 2016. 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

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 or, collectively, the VAT Assessments. 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 \$10.2 million converted using the currency exchange rate as of December 31, 2015, 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. In January 2013, our then remaining deposit for the VAT Assessments was refunded to us.

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.

**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

39

---



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.

On May 13, 2015, the Company (as nominal defendant) and our directors (as individual defendants) entered into a memorandum of understanding to settle the pending lawsuit 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, or the Settlement. On December 10, 2015, the court issued an order granting final approval to the Settlement.

The provisions of the Settlement include the following terms:

We will cancel and the non-employee directors will agree to the rescission of all currently outstanding equity awards that we previously granted to non-employee directors that included performance-based vesting metrics and as to which the performance goals remained unsatisfied as of May 13, 2015;

Our current non-employee directors will agree to hold (not transfer or sell or encumber in any way) until September 14, 2015 shares of our stock that they currently own and that we awarded to them during 2011, or at any time after 2011 to the present, and that, at the time of the award by us, was fully-vested and unrestricted;

We will cap the total annual compensation provided by it to its non-employee directors for each of 2015 and 2016. Such annual compensation cap for each non-employee director for each of 2015 and 2016 will be the greater of (i) \$375,000, plus, as to our Board Chairman, an additional \$100,000, or (ii) the 75th percentile of compensation paid by a group of peer companies to their non-employee directors (and, in the case of our Chairman, the 75th percentile of

compensation paid by such peers who have a non-employee director chair of their respective board of directors to such non-employee director chairs). The peer group for these purposes will be selected based on advice from the outside compensation consultant. For purposes of the compensation cap and the peer group comparison, compensation will be determined and measured consistent with the rules under Item 402 of Regulation S-K under the Securities Exchange Act of 1934, as amended, and based on publicly-available information at the applicable time; and We will implement, if not already implemented, within 90 days following final approval of the Settlement by the court, and maintain until at least the end of calendar year 2017 the following: an annual board discussion of non-employee director compensation philosophy; the use of a compensation consultant to advise the Compensation

Committee on material decisions concerning non-employee director compensation issues and compare our non-employee director compensation program to a group of our peers; the use of plain language in our compensation-related public filings; and obtain confirmation from our legal department and outside legal counsel advising on executive compensation matters that any contemplated non-employee director awards do not materially violate the applicable plan or materially fail to comply with applicable law.

In connection with the Settlement, to date, we paid \$0.3 million in attorneys' fees awarded to plaintiffs (net of existing insurance coverage), which was accrued for in our financial statements contained herein as of December 31, 2015.

On February 10, 2016 and February 12, 2016, similar purported class action lawsuits entitled Ahrens v. CTI Biopharma Corp. et al, Case No. 1:16-cv-01044 and McGlothlin v. CTI Biopharma Corp. et al, Case No. C16-216, respectively, were filed in the United States District Court for the Southern District of New York and the United States District Court for the Western District of Washington, respectively, on behalf of shareholders that purchased or acquired the Company's securities pursuant to our September 24, 2015 public offering and/or shareholders who otherwise acquired our stock between March 4, 2014 and February 9, 2016, inclusive. The complaints assert claims against the Company and certain of our current and former directors and officers for violations of the federal securities laws under Sections 11 and 15 of the Securities Act of 1933, as amended, or the Securities Act, and Sections 10 and 20 of the Exchange Act. Plaintiffs' Securities Act claims allege that the Company's Registration Statement and Prospectus for the September 24, 2015 public offering contained materially false and misleading statements and failed to disclose certain material adverse facts about the Company's business, operations and prospects, including with respect to the clinical trials and prospects for pacritinib. Plaintiffs' Exchange Act claims allege that the Company's public disclosures were knowingly or recklessly false and misleading or omitted material adverse facts, again with a primary focus on the clinical trials and prospects for pacritinib.

The lawsuits seek damages in an unspecified amount. We believe that the allegations contained in the complaints are without merit and intend to vigorously defend ourselves against all claims asserted therein. A reasonable estimate of the amount of any possible loss or range of loss cannot be made at this time and, as such, we have not recorded an accrual for any possible loss.

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
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
2015		
First Quarter	\$2.94	\$1.77
Second Quarter	\$2.46	\$1.65
Third Quarter	\$2.08	\$1.38
Fourth Quarter	\$1.75	\$0.80

On February 10, 2016, the last reported sale price of our common stock on The NASDAQ Capital Market was \$0.30 per share. As of February 10, 2016, there were 208 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, 2015:

Period	Total Number of Shares Purchased (1)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
October 1 – October 31, 2015	—	—	—	—

Edgar Filing: CTI BIOPHARMA CORP - Form 10-K

November 1 – November 30, 2015	13,944	1.30	—	—
December 1 – December 31, 2015	5,175	1.13	—	—
Total	19,119	1.25	—	—

(1) Represents purchases of shares in connection with satisfying tax withholding obligations on the vesting of restricted stock awards to employees and not pursuant to a publicly announced plan or program.

## Stock Performance Graph

The following graph sets forth the cumulative total shareholder return of our common stock with the cumulative total return of the NASDAQ Stock Index (U.S.) and the NASDAQ Pharmaceutical Index for the five years ended December 31, 2015. The graph assumes \$100 was invested in our common stock at the close of market on December 31, 2010. Stockholder return over the indicated period should not be considered indicative of future stockholder returns.

The actual returns shown on the graph above are as follows:

	12/31/2010	12/31/2011	12/31/2012	12/31/2013	12/31/2014	12/31/2015
CTI BioPharma Corp.	\$100.00	\$52.25	\$11.71	\$17.21	\$21.26	\$11.08
NASDAQ Stock Index (U.S.)	\$100.00	\$100.31	\$116.79	\$155.90	\$175.33	\$176.17
NASDAQ Pharmaceutical Index	\$100.00	\$117.48	\$134.31	\$182.23	\$221.99	\$234.05

The stock performance graph shall not be deemed soliciting material or to be filed with the SEC or subject to Regulation 14A or 14C under the Securities Exchange Act of 1934 or to the liabilities of Section 18 of the Exchange Act, nor shall it be incorporated by reference into any past or future filing under the Securities Act of 1933 or the Exchange Act, except to the extent we specifically request that it be treated as soliciting material or specifically incorporate it by reference into a filing under the Securities Act of 1933 or the Exchange Act.

## 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,				
	2015	2014	2013	2012	2011
	(In thousands, except per share data)				
Consolidated Statements of Operations Data:					
Revenues:					
Product sales, net(1)	\$3,472	\$6,909	\$2,314	\$—	\$—
License and contract revenue(2)	12,644	53,168	32,364	—	—
Total revenues	16,116	60,077	34,678	—	—
Operating costs and expenses, net:					
Cost of product sold(1)	1,940	895	137	—	—
Research and development	76,627	64,596	33,624	33,201	34,900
Selling, general and administrative	53,962	56,241	42,443	39,188	27,290
Acquired in-process research and development(3)	—	21,859	—	29,108	—
Other operating expense	253	2,719	—	—	—
Total operating costs and expenses, net	132,782	146,310	76,204	101,497	62,190
Loss from operations	(116,666 )	(86,233 )	(41,526 )	(101,497 )	(62,190 )
Non-operating income (expense):					
Interest expense	(2,104 )	(1,947 )	(1,026 )	(56 )	(870 )
Amortization of debt discount and issuance costs	(390 )	(729 )	(513 )	—	(546 )
Foreign exchange gain (loss)	(703 )	(4,435 )	61	344	(558 )
Debt conversion expense	(900 )	(885 )	(546 )	(478 )	1,545
Other non-operating income (expense), net	(4,097 )	(7,996 )	(2,024 )	(190 )	(429 )
Net loss before noncontrolling interest	(120,763 )	(94,229 )	(43,550 )	(101,687 )	(62,619 )
Noncontrolling interest	1,341	862	807	313	259
Net loss attributable to CTI	\$(119,422)	\$(93,367)	\$(42,743)	\$(101,374)	\$(62,360)
Dividends and deemed dividends on preferred stock	(3,200 )	(2,625 )	(6,900 )	(13,901 )	(58,718 )
Net loss attributable to common shareholders	\$(122,622)	\$(95,992)	\$(49,643)	\$(115,275)	\$(121,078)
Basic and diluted net loss per common share(4)	\$(0.65 )	\$(0.65 )	\$(0.43 )	\$(1.98 )	\$(3.53 )
Shares used in calculation of basic and diluted net loss per common share(4)	188,373	148,531	114,195	58,125	34,294

	Year ended December 31,				
	2015	2014	2013	2012	2011
	(In thousands)				
Consolidated Balance Sheets Data:					
Cash and cash equivalents	\$128,182	\$70,933	\$71,639	\$50,436	\$47,052
Working capital	62,566	44,165	60,446	37,644	33,291
Total assets(5)	144,332	92,287	93,723	73,713	62,239
Current portion of long-term debt(6)	37,371	9,014	3,155	—	—
Long-term debt, less current portion(6)	19,259	8,363	10,152	—	—
Other liabilities	4,141	5,882	5,657	4,641	2,985
Common stock purchase warrants	—	1,445	13,461	13,461	13,461
Series 14 convertible preferred stock	—	—	—	—	6,736
Accumulated deficit(5)	(2,098,317)	(1,975,695)	(1,879,703)	(1,830,060)	(1,714,785)
Total shareholders' equity (deficit)	47,413	38,478	42,758	32,944	28,009

(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 Pacritinib License Agreement and the Servier Agreement, as well as payments received from Teva upon achievement of sales-based milestones. See Part II, Item 8 "Financial Statements and Supplementary Data, Notes to Consolidated Financial Statements, Note 12. Collaboration, Licensing and Milestone Agreements" for additional information.

(3) The amounts in 2014 and 2012 represent the purchase of certain assets from Chroma and S\*BIO, respectively. These purchased assets had not reached technological feasibility at the time of such acquisitions. See Part II, Item 8 "Financial Statements and Supplementary Data, Notes to Consolidated Financial Statements, Note 4. Acquisitions" for additional information regarding the purchase of assets from Chroma.

(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 and milestone advance received from Baxalta in June 2015. See Part II, Item 8 "Financial Statements and Supplementary Data, Notes to Consolidated Financial Statements, Note 8. Long-term Debt" 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 health care 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 select countries in the E.U., for multiply relapsed or refractory aggressive B-cell NHL and evaluating pacritinib for the treatment of adult patients with myelofibrosis.

### Key Highlights

Select key recent 2016 and fiscal year 2015 highlights include:

#### Research and Development

In January 2016, we announced the completion of the rolling NDA to the FDA for pacritinib seeking U.S. marketing approval of pacritinib for the treatment of patients with intermediate and high-risk myelofibrosis with low platelet counts of less than 50,000 per microliter ( $<50,000/\mu\text{L}$ ). In February 2016, the FDA placed pacritinib's IND on a full clinical hold.

In December 2015, we reported significant data presentations on our pipeline candidates at the American Society of Hematology Annual Meeting.

In November 2015, we announced that the United Kingdom's National Cancer Research Institute (NCRI) Haematological Oncology Clinical Studies Group has chosen to advance tosedostat to the second stage of a randomized clinical trial of low-dose cytarabine plus or minus tosedostat in older patients with AML or high risk MDS.

In June 2015, PRO and other quality of life measures from the registration-directed PERSIST-1 Phase 3 trial of pacritinib in patients with myelofibrosis, without exclusion for low platelet counts, were presented at a late-breaking oral session at the 20th Congress of the European Hematology Association and showed significant improvements in symptom score with pacritinib therapy compared to best available therapy (exclusive of a JAK inhibitor) across the symptoms reported in the presentation.

In May 2015, the final results from PERSIST-1, were presented at a late-breaking oral session at the 51<sup>st</sup> Annual Meeting of the American Society of Clinical Oncology Annual Meeting. Data from PERSIST-1 showed that compared to best available therapy (exclusive of a JAK inhibitor) pacritinib therapy resulted in a significantly higher proportion of patients with spleen volume reduction and control of disease-related symptoms.

#### Corporate

In January 2016, we announced that Matthew Perry had been appointed to the Board of Directors. Mr. Perry is the President of BVF Partners L.P., or BVF, and the co-portfolio manager for the underlying funds managed by the firm. BVF is a private investment partnership that manages over \$1 billion and focuses on small-cap, value oriented investment opportunities.

In September 2015, we completed a registered direct offering and in each of October 2015 and December 2015, we completed an underwritten public offering resulting in aggregate net proceeds of approximately \$115 million.

In July 2015, Bruce J. Seeley was appointed as Executive Vice President and Chief Commercial Officer to lead all aspects of commercial operations.

In January 2015, Alan K. Burnett, M.D. was appointed Therapeutic Area Lead, Myeloid Diseases.

46

---

## 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 were \$16.1 million, \$60.1 million and \$34.7 million for the years ended December 31, 2015, 2014 and 2013, respectively. Our loss from operations was \$122.6 million, \$96.0 million and \$49.6 million for the years ended December 31, 2015, 2014 and 2013, respectively. 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.

On June 9, 2015, we and Baxalta entered into the Pacritinib License Amendment. Pursuant to the Pacritinib License Amendment, two potential milestone payments in the aggregate amount of \$32.0 million from Baxalta to us were accelerated from the schedule contemplated by the original Pacritinib License Agreement relating to the following: the \$20.0 million development milestone payment payable in connection with the PERSIST-2 Milestone, and the \$12.0 million development milestone payment payable in connection with the MAA Milestone. On January 12, 2016 and on February 8, 2016, we successfully achieved the \$20 million PERSIST-2 Milestone and the \$12 million MAA Milestone, respectively.

On September 24, 2015, we entered into a subscription agreement with BVF. Pursuant to the subscription agreement, we issued to BVF an aggregate of 10 million shares of common stock at a purchase price per share of \$1.57. The net proceeds from the offering, after deducting offering expenses, were approximately \$15.1 million. We closed the registered direct offering on September 29, 2015.

We issued 50,000 shares of Series N-1 preferred stock (which were subsequently converted into 40 million shares of common stock) for net proceeds of approximately \$46.7 million in an underwritten equity offering that closed on October 30, 2015.

We issued 55,000 shares of Series N-2 preferred stock (which were subsequently converted into approximately 50 million shares of common stock) for net proceeds of approximately \$52.8 million in an underwritten equity offering that closed on December 9, 2015.

See Part II, Item 8, "Financial Statements and Supplementary Data, Notes to Consolidated Financial Statements, Note 12. Collaboration, Licensing and Milestone Agreements" for further information relating to our collaboration agreements and offerings of preferred and common stock.

As of December 31, 2015, we had cash and cash equivalents of \$128.2 million.

## Results of Operations

### Years ended December 31, 2015, 2014 and 2013

Product sales, net. Product sales, net from PIXUVRI were \$3.5 million, \$6.9 million and \$2.3 million for the years ended December 31, 2015, 2014 and 2013, 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 parts of 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. The decrease in net product sales of \$3.4 million for the year ended December 31, 2015 compared to the year ended December 31, 2014 was primarily related to the pricing and volume variances between the periods presented as well as the decline in average exchange rate of the euro for our euro-denominated sales. The increase in net product sales of \$4.6 million for the year ended December 31, 2014 compared to the year ended December 31, 2013 was primarily due to the pricing and volume variances between the periods presented.

Any expansion of our commercial operations in E.U. (including with regard to sales of PIXUVRI) may increase our exposure to fluctuations in foreign currency exchange rates. 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.

Gross sales is defined as our contracted reimbursement price in each country. Gross sales from PIXUVRI were \$3.5

million, \$7.0 million and \$3.0 million for the years ended December 31, 2015, 2014 and 2013, respectively.

Product sales, net for the years ended December 31, 2015, 2014 and 2013 includes a provision for discounts, rebates and other of \$36,000, \$0.1 million and \$0.6 million for current period sales, respectively. The provision for discounts, rebates and other during the years ended December 31, 2015 and 2014 primarily relates to distributor discounts on PIXUVRI product sold. Such provision for the year ended December 31, 2013 primarily relates to government-mandated rebates.

The provision for product returns relates to a limited right of return or replacement that we offer to certain customers. There was no material activity related to the product returns during the periods presented.

During the periods presented, there were no material payments and credits applied towards provision for discounts, rebates and other for current or prior period sales.

As of December 31, 2015, the balances of reserve for product returns of \$13,000 and reserve for discounts, rebates and other of \$26,000, are reflected in accounts receivable and accrued expenses, respectively. As of December 31, 2014, the balances of reserve for product returns of \$10,000 and reserve for discounts, rebates and other of \$36,000 were also reflected in accounts receivable and accrued expenses, respectively.

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

	Years ended December 31,		
	2015	2014	2013
Baxalta License revenue	\$—	\$18,183	\$27,275
Development services revenue	815	2,670	89
Total Baxalta	815	20,853	27,364
Servier License revenue	1,622	17,285	—
Development services revenue	183	30	—
Royalty revenue	24	—	—
Total Servier	1,829	17,315	—
Teva Sales milestones revenue	10,000	15,000	5,000
Total Teva	10,000	\$15,000	\$5,000
Total license and contract revenue	\$12,644	\$53,168	\$32,364

#### Baxalta

The license and contract revenue under the Pacritinib License 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 Baxalta 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 Pacritinib License Agreement. The allocated amount of \$2.7 million to the development services is expected to be recognized as development service revenue through approximately 2018 based on a proportional performance method, by which revenue is recognized in proportion to the development costs incurred, including \$0.8 million recognized for the year ended December 31, 2015.

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 Pacritinib License 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.

In February 2015, we received a €1.5 million (or \$1.7 million upon conversion from euros as of the date we received the funds) milestone payment relating to the attainment of reimbursement approval for PIXUVRI in Spain, 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 Servier Agreement.

There was no such revenue for the year ended December 31, 2013.

#### Teva

During the year ended December 31, 2015, 2014 and 2013, we received \$10.0 million, \$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 is related to sales of PIXUVRI. Cost of product sold for each of the years ended December 31, 2015, 2014 and 2013 was \$1.9 million, \$0.9 million and \$0.1 million, respectively. Based on assessment of shelf lives and net realizable value of the product, a \$1.3 million reserve for excess, obsolete or unsalable inventory was recorded as of December 31, 2015, which was the primary factor in the increase in cost of product sold in 2015 compared to 2014. There was no such reserve recorded as of December 31, 2014. The increase in cost of product sold by \$0.8 million during the year ended December 31, 2014 compared to 2013 was primarily due to the increase in the quantity of inventory sold as well as the variances in the per-unit cost as discussed below. The euro experienced a decline between 2014 and 2013 which partially offset the overall increases.

We began capitalizing costs related to the production of PIXUVRI in February 2012 upon receiving a positive opinion for conditional marketing authorization by the Committee for Medicinal Products for Human Use, or the CHMP, which is a committee of the EMA. 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; however, we have reserved \$1.3 million of existing inventory expected to be unsalable. 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 may increase in future periods as PIXUVRI product manufactured and expensed prior to capitalization is sold; however, such future cost trend will ultimately depend on several factors in the near term, including, but not limited to, the consumption rate and availability of reduced cost inventory, the effect of expiring inventory and applicable manufacturing pricing structures (which will depend, in part, on the particular drug substance manufacturers we select).

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

	Years ended December 31,		
	2015	2014	2013
Compounds under development:			
PIXUVRI	\$14,465	\$7,740	\$3,889
Pacritinib	36,152	34,140	10,466
Opaxio	626	283	1,127
Tosedostat	920	645	985
Operating expenses	23,212	20,817	16,711

Edgar Filing: CTI BIOPHARMA CORP - Form 10-K

Research and preclinical development	1,252	971	446
Total research and development expenses	\$76,627	\$64,596	\$33,624

Costs for our compounds include external direct expenses such as principal investigator fees, charges from CROs, 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 Biopharma, Inc. 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, 2015 were \$108.4 million for PIXUVRI (excluding costs prior to our 2004 merger with Novuspharma S.p.A, formerly a public pharmaceutical company located in Italy), \$83.0 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), \$227.8 million for Opaxio and \$12.3 million for tosedostat (excluding costs for tosedostat prior to our co-development and license agreement with Chroma Therapeutics Limited, or 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, 2015 were \$9.6 million for brostallicin. We did not expend material resources on brostallicin during the periods presented.

Research and development expenses increased to \$76.6 million for the year ended December 31, 2015 compared to \$64.6 million for the year ended December 31, 2014. The increase of \$12.0 million was primarily attributed to a ramp-up of patients accrued in our ongoing PIX306 trial, including establishing additional sites throughout Europe; our continuing development of pacritinib for myelofibrosis, including our ongoing PERSIST-1 and PERSIST-2 Phase 3 clinical trials and operating expenses associated with supporting our research and development efforts across our portfolio of compounds.

Research and development expenses increased to \$64.6 million for the year ended December 31, 2014 compared to \$33.6 million for the year ended December 31, 2013. This \$31.0 million increase was primarily due to our continuing development of pacritinib for myelofibrosis, including the achievement of full enrollment in PERSIST-1 and progress on site openings and enrollment in PERSIST-2 Phase 3 clinical trials and operating expenses associated with supporting our research and development efforts across our portfolio of compounds.

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-authorization trial. 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-authorization PIX306 trial 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 and the availability of the compounds for use in the applicable trials. 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. For example, on February 8, 2016, the FDA placed a full clinical hold on pacritinib. 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, tosedostat or Opaxio to generate material net cash inflows. In order to generate revenue from these compounds, 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 our risk factors, which can be found in Part I, Item 1A, "Risk Factors".

Selling, general and administrative expenses. Selling, general and administrative expenses were \$54.0 million for the year ended December 31, 2015 as compared to \$56.2 million for the year ended December 31, 2014. This decrease was

50

---

primarily due to a \$5.9 million decrease in non-cash share-based compensation, partially offset by a \$1.6 million increase in personnel costs, in addition to an increase in consulting costs, legal fees and other professional services related to business development. Selling, general and administrative expenses were \$56.2 million for the year ended December 31, 2014 as compared to \$42.4 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 in 2013 and 2015.

Other operating expense. Other operating expense for the years ended December 31, 2015 and 2014 relates to the payments made to Novartis as a result of the upfront payment we received under the Servier Agreement in October 2014 and the milestone payment received under the same agreement in February 2015 relating to the attainment of reimbursement approval for PIXUVRI in Spain. We made no such payment for the year ended December 31, 2013. Certain payments are required under the Novartis Termination Agreement. See Part II, Item 8, "Financial Statements and Supplementary Data, Notes to Consolidated Financial Statements, Note 12. Collaboration, Licensing and Milestone Agreements" for further details.

#### Non-operating income and expenses

Interest expense. Interest expense for the years presented was primarily related to our senior secured term loan. Interest expense increases by \$0.2 million in 2015 and by \$0.9 million in 2014 were primarily due to interest incurred on the additional principal amounts of our senior secured term loan agreement funded in December 2013, October 2014, June 2015 and December 2015. See Part II, Item 8, "Financial Statements and Supplementary Data, Notes to Consolidated Financial Statements, Note 8. Long-term Debt for further details.

Amortization of debt discount and issuance costs. Amortization of debt discount and issuance costs for the years ended December 31, 2015 and 2014 was primarily related to our senior secured term loan.

Foreign exchange gain (loss). The foreign exchange loss for the year ended December 31, 2015 decreased by \$3.7 million compared to the foreign exchange loss for the year ended December 31, 2014 primarily due to a \$2.6 million unrealized foreign exchange loss on the intercompany balance due from our wholly owned subsidiary CTI Life Sciences Limited, which has been recorded in cumulative foreign currency translation adjustment account starting in the first quarter of 2015 as it is no longer considered to be of a short-term nature. The remaining decrease and the change from a \$0.1 million gain for the year ended December 31, 2013 to a \$4.4 million loss for the year ended 2014 were due to fluctuations in foreign currency exchange rates, primarily related to operations 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, 2015 was primarily related to a \$1.2 million loss on debt extinguishment in connection with our entry into an amendment to our senior secured term loan agreement, partially offset by the fair value adjustment of the warrant liability. See Part II, Item 8, "Financial Statements and Supplementary Data, Notes to Consolidated Financial Statements, Note 8. Long-term Debt for further details. 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 liability. 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 liability and the loss on disposal of property and equipment.

Deemed dividends on preferred stock. Deemed dividends on preferred stock were approximately \$3.2 million, \$2.6 million and \$6.9 million for the years ended December 31, 2015, 2014 and 2013, respectively, related to the issuances of our preferred stock. See Part II, Item 8, "Financial Statements and Supplementary Data, Notes to Consolidated Financial Statements, Note 9. Preferred Stock for further details.

#### Liquidity and Capital Resources

Cash and cash equivalents. As of December 31, 2015, we had \$128.2 million in cash and cash equivalents.

Net cash used in operating activities. Net cash used in operating activities totaled \$95.2 million, \$39.6 million and \$35.8 million for the years ended December 31, 2015, 2014 and 2013, respectively. The increase in net cash used in operating activities for the year ended December 31, 2015 as compared to the year ended December 31, 2014 was primarily due to an increase in research and development activities incurred in connection with our pacritinib development program and our PIX306 trial. Furthermore, in August 2014, we received a \$20.0 million milestone payment under the Pacritinib License

Agreement in connection with the first treatment dosing of the last patient enrolled in PERSIST-1, resulting in the lower amount of cash used in operating activities in 2014 compared to 2015.

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.

Net cash used in investing activities. Net cash used in investing activities totaled \$0.1 million, \$0.5 million and \$1.5 million for the years ended December 31, 2015, 2014 and 2013, respectively. The decreases in net cash used in investing activities for the years presented were primarily due to a decrease in purchases of property and equipment.

Net cash provided by financing activities. Net cash provided by financing activities totaled \$152.0 million, \$36.0 million and \$59.0 million for the year ended December 31, 2015, 2014 and 2013.

Net cash provided by financing activities for the year ended December 31, 2015 was primarily due to the acceleration of the two milestone payments received in the aggregate amount of \$32.0 million from Baxalta pursuant to the Pacritinib License Amendment discussed above, as well as due to the issuances of common and preferred stock and long-term debt. We received \$15.1 million in net proceeds from the issuance of our common stock in September 2015. We received \$46.7 million in net proceeds from the issuance of our Series N-1 preferred stock in October 2015. We received \$52.8 million in net proceeds from the issuance of our Series N-2 preferred stock in December 2015. In June 2015, we entered into the Third Amendment, or the Third Amendment, to the Loan and Security Agreement, or the Loan Agreement, with Hercules Technology Growth Capital, Inc. and certain affiliates, or collectively, Hercules. Under the Third Amendment, we received a total of \$5.8 million and we borrowed an additional \$5.0 million in December 2015 under the Fourth Amendment to the Loan Agreement, or the Fourth Amendment. These receipts were offset by repayments to Hercules of \$4.7 million made during the six months ended June 30, 2015.

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 net 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 Hercules in October 2014.

Net cash provided by financing activities for the year ended December 31, 2013 was also primarily due to issuances of preferred stock and long-term debt. In March 2013, we entered the Loan Agreement with Hercules 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.

See Part II, Item 8, "Financial Statements and Supplementary Data, Notes to Consolidated Financial Statements, Note 9. Preferred Stock and Note 8. Long-term Debt" for further details.

#### 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. We believe that our present financial resources, together with milestone payments projected to be received under certain of our contractual

agreements and our ability to control costs, will be sufficient to fund our operations through 2017. However, 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, 2015, our available cash and cash equivalents were \$128.2 million. We had an outstanding principal balance under our senior secured term loan agreement of \$25.0 million. We also had an outstanding balance of \$32.0 million classified as debt as a result of the Baxalta milestone advance received in June 2015. In January and February 2016, \$20.0 million and \$12.0 million of this balance was earned as a result of the PERSIST 2 Milestone and MAA Milestone achievement, respectively, which satisfied the full amount of the debt. Refer to the discussion above and to the Part II, Item 8, "Financial Statements and Supplementary Data, Notes to Consolidated Financial Statements, Note 8. Long-term Debt" for further details regarding these borrowings.

Financial resource forecasts are subject to change as a result of a variety of risks and uncertainties. Changes in manufacturing, developments in and expenses associated with our clinical trials and the other factors identified under "Capital Requirements" below may consume capital resources earlier than planned. Additionally, we may not receive the anticipated milestone payments or achieve projected net sales from PIXUVRI. Due to these and other factors, the foregoing forecast for the period for which we will have sufficient resources to fund our operations may fail.

### 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;
- regulatory approval developments;
- ability to execute 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, 2015 (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	\$17,296	\$2,697	\$5,387	\$5,482	\$3,730
Long-term debt (1)	25,000	5,452	19,548	—	—
Interest on long-term debt (1) (2)	6,951	4,295	2,656	—	—
Purchase commitments (3) (4)	15,322	14,827	397	96	2
Other obligations (5)	3,579	2,425	1,154	—	—
	\$68,148	\$29,696	\$29,142	\$5,578	\$3,732

The long-term debt amount includes the principal payable of \$25.0 million under our senior secured term loan. The interest rate on our senior secured term loan floats at a rate per annum equal to 10.95% plus the amount by which (1) the prime rate exceeds 3.25%. The amounts presented for interest payments in future periods assume a prime rate of 3.5%. See Part II, Item 8, "Financial Statements and Supplementary Data, Notes to Consolidated Financial Statements, Note 8. Long-term Debt" for further details.

The interest on long-term debt amount includes the interest on the advance received from Baxalta in June 2015 of (2) \$32.0 million related to the acceleration of two development milestone payments under the Pacritinib License Amendment. The advance bears fixed interest at an annual rate of 9%. The interest on the PERSIST-2 milestone is



accrued through January 2016 when the milestone was achieved. The interest on the MAA Milestone is accrued through February 2016 when the milestone was achieved. See Part II, Item 8, "Financial Statements and Supplementary Data, Notes to Consolidated Financial Statements, Note 8. Long-term Debt" for further details.

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

Pursuant to the Pacritinib License Agreement, we and Baxalta intend to enter into a manufacturing agreement.

(4) Upon finalizing our manufacturing agreement, we expect that Baxalta will incur the related costs under the agreement and we expect Baxalta to reimburse us or pay directly to the Contract Manufacturing Organization for the manufactured product, including the \$10.3 million included in purchase commitments above.

Other obligations include a fee in the amount of \$1.3 million payable to Hercules on the earliest to occur of October 1, 2016, or the date on which the senior secured term loan is prepaid in full or the date on which the senior secured term loan becomes due and payable in full. See Part I, Item 8, "Financial Statements and Supplementary Data, Notes to Consolidated Financial Statements, Note 8. Long-term Debt" for further details. Other obligations also include the remaining contributions we have agreed to make under certain endowment agreements in the aggregate amount of \$2.3 million in two annual installments. Other obligations do not include \$4.0 million deferred rent associated with our operating lease for office space.

Certain of our licensing agreements obligate us to pay a royalty on net sales of products utilizing licensed compounds. 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. In particular, we pay royalties on PIXUVRI net sales pursuant to each of the UVM Agreement and the Novartis Termination Agreement; These agreements are discussed in more detail in Part I, Item 1, "Business - License Agreements and Additional Milestone Activities".

#### Impact of Inflation

In the opinion of management, inflation has not had a material effect on our operations including selling prices, capital expenditures and operating expenses.

#### Critical Accounting Estimates

Management makes certain judgments and uses certain estimates and assumptions when applying accounting principles generally accepted in the U.S. in the preparation of our consolidated financial statements. We evaluate our estimates and judgments on an on-going basis and base our estimates on historical experience and on assumptions that we believe to be reasonable under the circumstances. Our experience and assumptions form the basis for our judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may vary from what we anticipate and different assumptions or estimates about the future could change our reported results. We believe the following estimates are the most critical to us, in that they are important to the portrayal of our consolidated financial statements and require our subjective or complex judgment in the preparation of our consolidated financial statements.

#### Impairment of long-lived Assets

We review our long-lived assets for impairment whenever events or changes in business circumstances indicate that the carrying amount of assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Each impairment test is based on a comparison of the undiscounted future cash flows to the recorded value of the asset. If an impairment is indicated, the asset is written down to its estimated fair value based on quoted fair market values.

#### Contingencies

54

---

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.

#### 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.

55

---

## 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 the Part II, Item 8, "Financial Statements and Supplementary Data, Notes to Consolidated Financial Statements, Note 13. Share-Based Compensation" 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.

## Recently Issued and Adopted Accounting Pronouncements

For a description of recently issued and adopted accounting pronouncements, including the expected effects on our results of operations and financial condition, refer to Part II, Item 8, "Financial Statements and Supplementary Data, Notes to Consolidated Financial Statements, Note 1. Description of Business and Summary of Significant Accounting Policies," which is incorporated herein by reference.

## 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, 2015, 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 \$1.3 million as of this date.

#### Interest Rate Risk

Our senior secured term loan bears interest at variable rates. Based on the outstanding principal balance under such loan at December 31, 2015 of \$25.0 million, a hypothetical increase of 1.0 percent in interest rates would result in additional interest expense of \$0.2 million over the next twelve months. For a detailed discussion of our senior secured term loan, including a discussion of the applicable interest rate, refer to the Part II, Item 8, "Financial Statements and Supplementary Data, Notes to Consolidated Financial Statements, Note 8. Long-term Debt". The funds advanced to us pursuant to the Pacritinib License Amendment do not bear a variable interest rate.

Item 8. Financial Statements and Supplementary Data

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	Page
<u>Reports of Marcum LLP, Independent Registered Public Accounting Firm</u>	<u>59</u>
<u>Consolidated Balance Sheets</u>	<u>61</u>
<u>Consolidated Statements of Operations</u>	<u>62</u>
<u>Consolidated Statements of Comprehensive Loss</u>	<u>63</u>
<u>Consolidated Statements of Shareholders' Equity</u>	<u>64</u>
<u>Consolidated Statements of Cash Flows</u>	<u>66</u>
<u>Notes to Consolidated Financial Statements</u>	<u>68</u>



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, 2015 and 2014, and the related consolidated statements of operations, comprehensive loss, shareholders’ equity and cash flows for the years ended December 31, 2015, 2014 and 2013. Our audits also included the financial statement schedule as of and for the years listed in the index at Item 15. These consolidated financial statements and financial statement schedule are the responsibility of the Company’s management. Our responsibility is to express an opinion on these consolidated financial statements and financial statement schedule 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, 2015 and 2014, and the consolidated results of its operations and its cash flows for the years ended December 31, 2015, 2014 and 2013 in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole presents fairly, in all material respects, the information set forth therein.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), CTI BioPharma’s internal control over financial reporting as of December 31, 2015, based on the criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 16, 2016 expressed an unqualified opinion on the effectiveness of the Company’s internal control over financial reporting.

/s/ Marcum LLP

Marcum LLP  
San Francisco, CA  
February 16, 2016

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, 2015, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying "Management Annual Report on Internal Control over Financial Reporting". Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of the inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that degree of compliance with the policies or procedures may deteriorate.

In our opinion, CTI BioPharma Corp. maintained, in all material aspects, effective internal control over financial reporting as of December 31, 2015, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets as of December 31, 2015 and 2014 and the related consolidated statements of operations, shareholders' equity, and cash flows and the related financial statement schedule for the years ended December 31, 2015, 2014 and 2013 of the Company and our report dated February 16, 2016 expressed an unqualified opinion on those financial statements and financial statement schedule.

/s/ Marcum LLP

Marcum LLP  
San Francisco, CA  
February 16, 2016

60

---

CTI BIOPHARMA CORP.  
CONSOLIDATED BALANCE SHEETS  
(In thousands, except share amounts)

	December 31, 2015	December 31, 2014
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 128,182	\$ 70,933
Accounts receivable, net	282	2,011
Inventory, net	2,845	4,182
Prepaid expenses and other current assets	3,666	3,379
Total current assets	134,975	80,505
Property and equipment, net	3,718	4,646
Other assets	5,639	7,136
Total assets	\$ 144,332	\$ 92,287
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 10,584	\$ 6,356
Accrued expenses	22,133	19,734
Current portion of deferred revenue	578	826
Current portion of long-term debt	37,371	9,014
Other current liabilities	1,743	410
Total current liabilities	72,409	36,340
Deferred revenue, less current portion	1,110	1,779
Long-term debt, less current portion	19,259	8,363
Other liabilities	4,141	5,882
Total liabilities	96,919	52,364
Commitments and contingencies		
Common stock purchase warrants	—	1,445
Shareholders' equity:		
Common stock, no par value:		
Authorized shares - 315,000,000 and 215,000,000 at December 31, 2015 and 2014, respectively		
Issued and outstanding shares - 280,461,097 and 176,761,099 at December 31, 2015 and 2014, respectively	2,157,300	2,023,949
Accumulated other comprehensive loss	(6,952)	(6,499)
Accumulated deficit	(2,098,317)	(1,975,695)
Total CTI shareholders' equity	52,031	41,755
Noncontrolling interest	(4,618)	(3,277)
Total shareholders' equity	47,413	38,478
Total liabilities and shareholders' equity	\$ 144,332	\$ 92,287

See accompanying notes.

CTI BIOPHARMA CORP.  
CONSOLIDATED STATEMENTS OF OPERATIONS  
(In thousands, except per share amounts)

	Year Ended December 31,		
	2015	2014	2013
Revenues:			
Product sales, net	\$3,472	\$6,909	\$2,314
License and contract revenue	12,644	53,168	32,364
Total revenues	16,116	60,077	34,678
Operating costs and expenses:			
Cost of product sold	1,940	895	137
Research and development	76,627	64,596	33,624
Selling, general and administrative	53,962	56,241	42,443
Acquired in-process research and development	—	21,859	—
Other operating expense	253	2,719	—
Total operating costs and expenses	132,782	146,310	76,204
Loss from operations	(116,666 )	(86,233 )	(41,526 )
Non-operating income (expense):			
Interest expense	(2,104 )	(1,947 )	(1,026 )
Amortization of debt discount and issuance costs	(390 )	(729 )	(513 )
Foreign exchange gain (loss)	(703 )	(4,435 )	61
Other non-operating expense	(900 )	(885 )	(546 )
Total non-operating expense, net	(4,097 )	(7,996 )	(2,024 )
Net loss before noncontrolling interest	(120,763 )	(94,229 )	(43,550 )
Noncontrolling interest	1,341	862	807
Net loss attributable to CTI	(119,422 )	(93,367 )	(42,743 )
Deemed dividends on preferred stock	(3,200 )	(2,625 )	(6,900 )
Net loss attributable to common shareholders	\$(122,622 )	\$(95,992 )	\$(49,643 )
Basic and diluted net loss per common share	\$(0.65 )	\$(0.65 )	\$(0.43 )
Shares used in calculation of basic and diluted net loss per common share	188,373	148,531	114,195

See accompanying notes.

## CTI BIOPHARMA CORP.

## CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(In thousands)

	Year Ended December 31,		
	2015	2014	2013
Net loss before noncontrolling interest	\$(120,763 )	\$(94,229 )	\$(43,550 )
Other comprehensive income (loss):			
Foreign currency translation adjustments	2,160	1,998	31
Unrealized foreign exchange loss on intercompany balance	(2,585 )	—	—
Net unrealized loss on securities available-for-sale	(28 )	(68 )	(187 )
Other comprehensive income (loss)	(453 )	1,930	(156 )
Comprehensive loss	(121,216 )	(92,299 )	(43,706 )
Comprehensive loss attributable to noncontrolling interest	1,341	862	807
Comprehensive loss attributable to CTI	\$(119,875 )	\$(91,437 )	\$(42,899 )

See accompanying notes.

CTI BIOPHARMA CORP.  
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY  
(In thousands)

	Preferred Stock		Common Stock		Accumulated	Accumulated Other Comprehensive Income (Loss)	Noncontrolling Interest	Total Shareholders' Equity
	Shares	Amount	Shares	Amount	Deficit			
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 issuance 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 issuance 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 )
Net loss for the year ended December 31, 2013	—	—	—	—	(42,743 )	—	—	(42,743 )
Other comprehensive loss	—	—	—	—	—	(156 )	—	(156 )
Balance at December 31, 2013	—	\$—	145,509	\$1,933,305	\$(1,879,703)	\$ (8,429 )	\$ (2,415 )	\$ 42,758
Issuance of Series 20 preferred stock, net of issuance 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 issuance costs	35	32,342	—	—	—	—	—	32,342

Edgar Filing: CTI BIOPHARMA CORP - Form 10-K

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.



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

(In thousands)

	Preferred Stock		Common Stock		Accumulated Deficit	Accumulated Other	Noncontrolling Interest	Total Shareholders' Equity
	Shares	Amount	Shares	Amount		Income (Loss)		
Issuance of common stock, net of issuance costs	—	—	10,000	15,147	—	—	—	15,147
Issuance of Series N-1 preferred stock, net of issuance costs	50	46,611	—	—	—	—	—	46,611
Conversion of Series N-1 preferred stock to common stock	(50 )	(46,611)	40,000	46,611	—	—	—	—
Issuance of Series N-2 preferred stock, net of issuance costs	55	52,409	—	—	—	—	—	52,409
Conversion of Series N-2 preferred stock to common stock	(55 )	(52,409)	50,000	52,409	—	—	—	—
Value of beneficial conversion features related to preferred stock	—	—	—	3,200	—	—	—	3,200
Expiry of exercise price provision features related to common stock purchase warrant	—	—	—	150	—	—	—	150
Equity-based compensation	—	—	3,931	14,828	—	—	—	14,828
Stock option exercises	—	—	83	156	—	—	—	156
Noncontrolling interest	—	—	—	—	—	—	(1,341 )	(1,341 )
Expiry of mezzanine equity	—	—	—	1,445	—	—	—	1,445
Other	—	—	(314 )	(595 )	—	—	—	(595 )
Deemed dividends on preferred stock	—	—	—	—	(3,200 )	—	—	(3,200 )
Net loss for the year ended December 31, 2015	—	—	—	—	(119,422 )	—	—	(119,422 )
Other comprehensive loss	—	—	—	—	—	(453 )	—	(453 )
Balance at December 31, 2015	—	\$—	280,461	\$2,157,300	\$(2,098,317)	\$ (6,952 )	\$ (4,618 )	\$ 47,413

See accompanying notes.

65

---

CTI BIOPHARMA CORP.  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
(In thousands)

	Year Ended December 31,		
	2015	2014	2013
Operating activities			
Net loss	\$(120,763 )	\$(94,229 )	\$(43,550 )
Adjustments to reconcile net loss to net cash used in operating activities:			
Acquired in-process research and development	—	21,859	—
Share-based compensation expense	14,828	20,196	9,066
Depreciation and amortization	990	1,100	1,570
Loss on debt extinguishment	1,211	—	—
Provision for expiring inventory	1,326	—	—
Noncash interest expense	390	729	513
Change in value of warrant liability	(232 )	886	—
Provision for VAT Assessments	—	600	—
Other	(409 )	(374 )	365
Changes in operating assets and liabilities:			
Accounts receivable	1,555	(1,980 )	(227 )
Inventory	(402 )	305	(3,254 )
Prepaid expenses and other current assets	(402 )	46	4,530
Other assets	826	(356 )	(846 )
Accounts payable	4,368	1,454	(5,774 )
Accrued expenses	2,426	10,250	(834 )
Deferred revenue	(918 )	(31 )	2,636
Other liabilities	3	(5 )	(25 )
Total adjustments	25,560	54,679	7,720
Net cash used in operating activities	(95,203 )	(39,550 )	(35,830 )
Investing activities			
Purchases of property and equipment	(78 )	(333 )	(1,657 )
Proceeds from sales of property and equipment	—	—	123
Other	—	(208 )	—
Net cash used in investing activities	(78 )	(541 )	(1,534 )
Financing activities			
Proceeds from issuance of Series 17 preferred stock, net of issuance costs	—	—	(105 )
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	(227 )	32,621	—
Proceeds from common stock offering, net of issuance costs	15,147	—	—
Proceeds from issuance of Series N-1 preferred stock, net of issuance costs	46,653	—	—
Proceeds from issuance of Series N-2 preferred stock, net of issuance costs	52,800	—	—
Proceeds from Baxalta milestone advance, net of issuance costs	31,922	—	—

Edgar Filing: CTI BIOPHARMA CORP - Form 10-K

Proceeds from Hercules debt, net of issuance costs	10,820	4,963	14,501	
Repayment of Hercules debt	(4,659	) (1,526	) —	
Payment of tax withholding obligations related to stock compensation	(604	) (178	) (247	)
Other	165	280	3	
Net cash provided by financing activities	152,017	36,026	58,972	
Effect of exchange rate changes on cash and cash equivalents	513	3,359	(405	)
Net increase (decrease) in cash and cash equivalents	57,249	(706	) 21,203	
Cash and cash equivalents at beginning of year	70,933	71,639	50,436	
Cash and cash equivalents at end of year	\$128,182	\$70,933	\$71,639	
See accompanying notes.				

## CONSOLIDATED STATEMENTS OF CASH FLOWS—(Continued)

(In thousands)

	Year Ended December 31,		
	2015	2014	2013
Supplemental disclosure of cash flow information			
Cash paid during the period for interest	\$2,067	\$1,894	\$933
Supplemental disclosure of noncash financing and investing activities			
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 20 preferred stock for acquisition of assets from Chroma Therapeutics Limited	\$—	\$21,600	\$—
Conversion of Series N-1 preferred stock to common stock	\$46,611	\$—	\$—
Conversion of Series N-2 preferred stock to common stock	\$52,409	\$—	\$—
Issuance of common stock upon exercise or exchange of common stock purchase warrants	\$—	\$1,877	\$—
Repayment and issuance of Hercules debt	\$13,815	\$—	\$—

See accompanying notes.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

CTI BioPharma Corp., together with its wholly-owned subsidiaries, also referred to collectively in this Annual Report on Form 10-K as “we,” “us,” “our,” the “Company” and “CTI”, 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 health care 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 select countries in the European Union, or the E.U., for multiply relapsed or refractory aggressive B-cell non-Hodgkin lymphoma, or NHL, and evaluating pacritinib for the treatment of adult patients with myelofibrosis.

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 accompanying 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. We also retain ownership of our branch, CTI BioPharma Corp.- Sede Secondaria, or CTI (Europe); however, we ceased operations related to this branch in September 2009.

As of December 31, 2015, we also had a 60% 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.

#### 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 consolidated financial statements. However, 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, tosedostat and Opaxio.

Our available cash and cash equivalents were \$128.2 million as of December 31, 2015. We believe that our present financial resources, together with milestone payments projected to be received under certain of our contractual agreements and our ability to control costs, will be sufficient to fund our operations at least through the next twelve months from the date these financial statements were issued.

We may need to acquire additional funds in order to develop 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. Furthermore, 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.

### 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, 2015 and 2014, 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 no allowance for doubtful accounts as of December 31, 2015 and \$0.1 million as of December 31, 2014.

#### 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 \$4.7 million and \$4.9 million as of December 31, 2015 and 2014, of which \$4.2 million and \$4.7 million is included in other assets and \$0.5 million and \$0.2 million is included

in prepaid expenses and other current assets as of December 31, 2015 and 2014, 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, 2015, the VAT receivable related to operations in Italy is approximately \$4.3 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 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 distribution of PIXUVRI. 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 review our inventories on a quarterly basis for impairment and reserves are established when necessary. Estimates of excess inventory consider our projected sales of the product and the remaining shelf lives of product. In the event we identify excess, obsolete or unsalable inventory, the value is written down to the net realizable value. Based on assessment of shelf lives and net realizable value of the product, a \$1.3 million reserve for excess, obsolete or unsalable inventory was recorded as of December 31, 2015. No reserve was recorded as of December 31, 2014.

#### 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, 2015 and 2014, 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, 2015 and 2014 based on borrowing rates for similar loans and maturities. See Note 8. Long-term Debt for further information regarding the fair value of our warrant liability.

#### 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 marketing authorization for 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 parts of the United Kingdom, or 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-mandated 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 customers 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 Accounting Standards Codification, or 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.

## Research and Development Expenses

Research and development costs are expensed as incurred in accordance with Financial Accounting Standards Board, or the FASB, 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. 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.

During the three months ended March 31, 2015, we determined that the intercompany balance due from CTILS may no longer be considered of a short-term nature. Due to this change in accounting estimate, an unfavorable unrealized foreign exchange loss of \$2.6 million was recorded in cumulative foreign currency translation adjustment account for the year ended December 31, 2015. As of December 31, 2015, the intercompany balance due from CTILS was €27.2 million (or \$29.5 million upon conversion from euros as of December 31, 2015).

#### 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 Income (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 November 2015, the FASB issued new guidance on the balance sheet classification of deferred taxes. To simplify presentation, the new guidance requires that all deferred tax assets and liabilities, along with any related valuation allowance, be classified as noncurrent on the balance sheet. The accounting standard is effective for public business entities for annual reporting periods (including interim reporting periods within those periods) beginning after December 15, 2016. Early adoption is 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, 2017. Early adoption is permitted as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. We are



currently evaluating the impact of this accounting standard on our consolidated financial statements.

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 on our consolidated financial statements.

In April 2015, the FASB issued a new accounting standard which changes the presentation of debt issuance costs in financial statements. Under the new standard, an entity presents such costs in the balance sheet as a direct deduction from the related debt liability rather than as an asset. Amortization of the costs is reported as interest expense. The accounting standard is effective for annual reporting periods beginning after December 15, 2015 and interim periods beginning after December 15,

2016. Early adoption is allowed for all entities for financial statements that have not been previously issued. The adoption of this standard is not expected to have a material impact on our financial position or results of operations.

In July 2015, the FASB issued a new accounting guidance on simplifying the measurement of inventory which requires that inventory within the scope of the guidance be measured at the lower of cost and net realizable value. Prior to the issuance of the standard, inventory was measured at the lower of cost or market (where market was defined as replacement cost, with a ceiling of net realizable value and floor of net realizable value less a normal profit margin). The accounting guidance is effective for annual reporting periods (including interim periods within those periods) beginning after December 15, 2016. Early adoption is permitted. The adoption of this standard is not expected to have a material impact on our financial position or results of operations.

In January 2016, the FASB issued a new accounting standard on recognition and measurement of financial assets and financial liabilities. The accounting standard primarily affects the accounting for equity investments, financial liabilities under the fair value option, and the presentation and disclosure requirements for financial instruments. In addition, it includes a clarification related to the valuation allowance assessment when recognizing deferred tax assets resulting from unrealized losses on available-for-sale debt securities. The accounting guidance is effective for annual reporting periods (including interim periods within those periods) beginning after December 15, 2017. Early adoption is permitted for the provision to record fair value changes for financial liabilities under the fair value option resulting from instrument-specific credit risk in other comprehensive income. The adoption of this standard is not expected to have a material impact on our financial position or results of operations.

#### 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, 2015 and 2014 (in thousands):

	2015	2014
Finished goods	\$724	\$850
Work-in-process	3,386	3,332
Inventory, gross	\$4,110	\$4,182
Reserve for expiring inventory	\$(1,265)	) \$—
Inventory, net	\$2,845	\$4,182

#### 3. Property and Equipment

Property and equipment are composed of the following as of December 31, 2015 and 2014 (in thousands):

	2015	2014
Furniture and office equipment	\$6,484	\$11,020
Leasehold improvements	5,078	5,078
Lab equipment	203	209
	11,765	16,307
Less: accumulated depreciation and amortization	(8,047)	) (11,661)
Property and equipment, net	\$3,718	\$4,646

Depreciation expense of \$1.0 million, \$1.1 million and \$1.6 million was recognized during 2015, 2014 and 2013, respectively.

4. Acquisitions

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

74

---

related assets. Concurrently, we and Chroma terminated our Co-Development and License Agreement relating to tosedostat, or the Chroma License Agreement, previously entered into in March 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 were delivered to Chroma. The remaining 1,080 shares, which were converted into shares of common stock as discussed below and held in escrow for nine months from the initial issuance date, were released to Chroma in 2015. 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, 2015 and 2014 (in thousands):

	2015	2014
Clinical and investigator-sponsored trial expenses	\$8,976	\$7,554
Employee compensation and related expenses	5,498	5,930
Manufacturing expenses	921	2,043
Legal expenses	1,274	885
Accrued selling expenses	1,697	759
Insurance financing	679	695
Accrued other taxes	—	386
Accrued interest expenses	1,817	186
Other	1,271	1,296
Total accrued expenses	\$22,133	\$19,734

## 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 for each of the years ended December 31, 2015, 2014 and 2013. 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, 2015 are as follows (in thousands):

	Operating Leases
2016	\$2,697
2017	2,683
2018	2,703
2019	2,708
2020	2,773
Thereafter	3,730
Total minimum lease commitments	\$17,294

## 7. Other Liabilities

Other liabilities consisted of the following as of December 31, 2015 and 2014 (in thousands):

2015	2014
------	------

Edgar Filing: CTI BIOPHARMA CORP - Form 10-K

Deferred rent, less current portion	\$3,538	\$4,006
Other long-term obligations	603	1,876
Total other liabilities	\$4,141	\$5,882

76

---

The balance of deferred rent as of December 31, 2015 and 2014 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 as of December 31, 2014 included a fee in the amount of \$1.3 million payable to Hercules Technology Growth Capital Inc. and certain affiliates, or collectively, Hercules, which was reclassified and included in Other current liabilities as of December 31, 2015. See Note 8. Long-term Debt for additional information.

## 8. Long-term Debt

### Hercules

In March 2013, we entered into a Loan and Security Agreement, or the Loan Agreement, with Hercules, providing for a senior secured term loan of up to \$15.0 million, or the Term Loan. 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 \$5.0 million in October 2014. The interest rate on the Term Loan floated at a rate per annum equal to 12.25% plus the amount by which the prime rate would exceed 3.25%. The Term Loan was 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 was payable to Hercules on the date on which the term loan would be paid or become due and payable in full.

In addition, in March 2013, we issued a warrant to Hercules 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. In such an event, the exercise price will automatically be reduced to equal the price per share of common stock in such transaction, and the number of shares issuable upon conversion of the warrant will be increased proportionately. Since the warrant did not meet the considerations necessary for equity classification in the applicable authoritative guidance, we determined the warrant 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. 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 to the Loan Agreement, or the First Amendment. The First Amendment modified certain terms applicable to the loan balance then-outstanding of \$15.0 million, as described above, 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 First 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 First Amendment. Pursuant to the First Amendment, the interest-only period of the Term 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 Term Loan was, upon Hercules' receipt of evidence of the achievement of positive Phase 3 data in connection with our PERSIST-1 clinical trial for pacritinib, to be reduced from 12.25% to 11.25% plus the amount by which the prime rate would exceed 3.25%. The interest on the 2014 Term Loan floated at a rate per annum equal to 10.00% plus the amount by which the prime rate would exceed 3.25%. The modified terms were not considered substantially different pursuant to ASC 470-50, Modification and Extinguishment.

In June 2015, we entered into a Third Amendment to the Loan Agreement, or the Third Amendment. Under the Third Amendment, Hercules agreed to provide term loans in an aggregate principal amount of up to \$25.0 million, inclusive of the principal balance outstanding immediately prior to closing of the Third Amendment of \$13.8 million, or collectively, the Term Loan Borrowings. We drew \$6.2 million upon closing of the Third Amendment, resulting in a then-outstanding principal balance of \$20.0 million under the Term Loan Borrowings. The remaining \$5.0 million is available for borrowing at our option through June 30, 2016, subject to certain conditions. In connection with the Third Amendment, we paid a commitment fee of \$15,000 and a facility charge of \$0.3 million. The provision under the Loan Agreement requiring us to pay a fee to Hercules of \$1.3 million on the date of repayment of the borrowings thereunder was amended pursuant to the Third Amendment, such that the fee will now be payable on the earliest to occur of (1) October 1, 2016, (2) the date on which the Term Loan Borrowings are prepaid in full or (3) the date on which the Term Loan Borrowings become due and payable in full.



Pursuant to the Third Amendment, the interest rate on the Term Loan Borrowings floats at a rate per annum equal to 10.95% plus the amount by which the prime rate exceeds 3.25%. We were initially required to make interest payments only on a monthly basis, followed by the 36 equal monthly installments of principal and interest (mortgage style) commencing on January 1, 2016. The interest-only period may be extended by up to six months at our option if we achieve certain milestones by certain specified deadlines.

In connection with the Third Amendment, we issued a warrant to Hercules to purchase shares of common stock. The warrant is exercisable for five years from the date of issuance for 0.3 million shares of common stock at an initial exercise price is \$1.71 per share. Since the warrant contains the exercise price adjustment provision similar to the one in the March 2013 warrant as discussed above, it does not meet the considerations necessary for equity classification under the applicable authoritative guidance. As such, we determined the warrant is a liability instrument that is marked to fair value with changes in fair value recognized through earnings at each reporting period. The warrant was categorized as Level 2 in the fair value hierarchy as the significant inputs used in determining fair value are considered observable market data. As of the issuance date, we estimated the fair value of the warrant to be \$0.4 million. Upon expiry of the exercise price adjustment provision in December 2015, the then-estimated fair value of the warrant of \$0.2 million was reclassified from liability to equity.

The modified terms under the Third Amendment were considered substantially different as compared to the terms of the Loan Agreement immediately prior to the Third Amendment, pursuant to ASC 470-50, Modification and Extinguishment. As such, the Third Amendment was accounted for as a debt extinguishment, resulting in a loss on debt extinguishment of \$1.2 million which is included in other non-operating expense for the year ended December 31, 2015.

In December 2015, we entered into a Fourth Amendment to the Loan Agreement, or the Fourth Amendment, pursuant to which Hercules funded the remaining \$5.0 million term loan available under the facility, resulting in a then-outstanding principal balance of \$25.0 million under the Term Loan Borrowings. Under the Fourth Amendment, the applicable milestone event that we were required to satisfy to extend the interest-only period under the Third Amendment was amended such that such milestone would be satisfied upon receipt by Hercules on or before March 31, 2016 of satisfactory evidence that we have submitted to the FDA the fully completed new drug application for pacritinib and the FDA has confirmed in writing acceptance of the new drug application. Subject to the achievement of such milestone by the new deadline, we will be required to make interest payments only on a monthly basis, followed by the 30 equal monthly installments of principal and interest (mortgage style) commencing on July 1, 2016. The Term Loan Borrowings will mature on December 1, 2018.

We may elect to prepay some or all of the Term Loan Borrowings at any time subject to a prepayment fee, if any, pursuant to the terms of the Fourth Amendment. Under certain circumstances, we may be required to prepay the Term Loan Borrowings with proceeds of asset dispositions. The Term Loan 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 connection with the transactions described above, we recorded a total debt discount of \$2.2 million and the issuance costs of \$0.3 million during the year ended December 31, 2014. In connection with the Third and Fourth Amendments, we recorded a total debt discount of \$0.4 million and the issuance costs of \$0.1 million during the year ended December 31, 2015. As of December 31, 2015 and 2014, unamortized debt discount was \$0.4 million and \$1.1 million, unamortized issuance costs were \$0.1 million and \$0.2 million, and the outstanding principal balance was \$25.0 million and \$18.5 million, respectively.

In November 2013, we entered into a Development, Commercialization and License agreement, or the Pacritinib License Agreement, with Baxter International Inc., or Baxter, for the development and commercialization of pacritinib for use in oncology and potentially additional therapeutic areas. Baxalta Incorporated and its affiliates, or Baxalta, have been assigned Baxter's rights and obligations under the Pacritinib License Agreement. In June 2015, we entered into the First Amendment to the Pacritinib License Agreement, or the Pacritinib License Amendment. Pursuant to the Pacritinib License Amendment, two potential milestone payments in the aggregate amount of \$32.0 million from Baxalta to us were accelerated from the schedule contemplated by the original Pacritinib License Agreement relating to the following: the \$12.0 million development milestone payment payable in connection with the regulatory submission of the Marketing Authorization Application, or the MAA, to the EMA with respect to pacritinib, or the MAA Milestone, and the \$20.0 million development milestone payment payable in connection with the first treatment dosing of the 300th patient enrolled per the protocol in PERSIST-2, or the PERSIST-2 Milestone. Under the Pacritinib License Amendment, each of the two milestone advances bears interest at an annual rate of 9% until the earlier of the date of the first occurrence of the respective milestone or the date that the respective advance plus accrued interest is repaid in full.

In the event that pacritinib development is terminated due to certain specified reasons or the milestones are not achieved by respective deadlines (December 31, 2016 for the PERSIST-2 Milestone and March 31, 2017 for the MMA Milestone), we would be required to repay the respective advance to Baxalta in eight quarterly installments of \$1.5 million relating to the MMA Milestone and \$2.5 million relating to the PERSIST-2 Milestone, in each case beginning 30 days after the end of the calendar quarter of the first occurrence of such event, and a final payment equal to the remainder of the unpaid balance. Repayment of the advances will be accelerated in the event of the commencement of insolvency proceedings and certain other events of default. Additionally, in the event that we do not spend a specified amount on the development of pacritinib from the date of the amendment through February 29, 2016, payments to Baxalta in an amount equal to such deficiency may be required or credited against amounts owed to us under certain circumstances. We expect to spend the specified amount on the development of pacritinib by February 29, 2016. As of December 31, 2015, the outstanding balance of such advance was \$32.0 million. In January 2016 and February 2016, we successfully achieved the \$20 million PERSIST-2 Milestone and the \$12.0 million MAA Milestone, respectively.

Refer to the Note 12. Collaboration, Licensing and Milestone Agreements for further details regarding the Baxalta Agreement.

#### 9. Preferred Stock

##### 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.

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. 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.

##### Series 19 Preferred Stock

See Note 12. Collaboration, Licensing and Milestone Agreements - Baxalta for information concerning our issuance of Series 19 Preferred Stock.

##### Series 20 Preferred Stock

See Note 4. Acquisitions - Chroma Asset Purchase Agreement, 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.

#### Series N-1 Preferred Stock

In October 2015, in an underwritten public offering, we issued 50,000 shares of our Series N-1 convertible preferred stock, or Series N-1 Preferred Stock, for gross proceeds of \$50.0 million before deducting underwriting commissions and discounts and other offering costs. Issuance costs related to this transaction were approximately \$3.4 million, including \$3.0 million in underwriting commissions and discounts.

Each share of Series N-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 N-1 Preferred Stock, 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 N-1 Preferred Stock. The Series N-1 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 N-1 Preferred Stock had no voting rights, except as otherwise expressly provided in the amended articles or as otherwise required by law.

In October 2015, all 50,000 shares of Series N-1 Preferred Stock were converted into 40.0 million shares of common stock at a conversion price of \$1.25 per share. For the year ended December 31, 2015, we recognized \$3.2 million in deemed dividends on preferred stock related to the beneficial conversion feature on our Series N-1 Preferred Stock.

#### Series N-2 Preferred Stock

In December 2015, in an underwriting public offering, we issued 55,000 shares of the Company's Series N-2 Preferred Stock, or Series N-2 Preferred Stock, for gross proceeds of \$55.0 million before deducting underwriting commissions and discounts and other offering costs. Issuance costs related to this transaction were approximately \$2.6 million, including \$2.2 million in underwriting commissions and discounts.

Each share of Series N-2 Preferred Stock was convertible at the option of the holder (subject to a limited exception) and was entitled to a liquidation preference equal to the initial stated value of \$1,000 per share of Series N-1 Preferred Stock, 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 N-2 Preferred Stock. The Series N-2 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 N-2 Preferred Stock had no voting rights, except as otherwise expressly provided in the amended articles or as otherwise required by law.

In December 2015, all 55,000 shares of Series N-2 Preferred Stock were converted into 50.0 million shares of common stock at a conversion price of \$1.10 per share. There was no beneficial conversion feature on Series N-2 Preferred Stock.

### 10. Common Stock

#### Common Stock Authorized

In February 2015, the Company's Amended and Restated Articles of Incorporation were amended to increase the total number of authorized shares of common stock from 215 million to 315 million.

Common Stock Issued

In September 2015, we entered into a subscription agreement with certain affiliates of BVF Partners L.P., or collectively, BVF. Pursuant to the subscription agreement, we issued to BVF an aggregate of 10.0 million shares of common stock at a purchase price per share of \$1.57. The shares of common stock were offered directly to BVF without a placement agent or underwriter. The net proceeds from the offering, after deducting offering expenses, were approximately \$15.1 million.

## Common Stock Reserved

A summary of common stock reserved for issuance is as follows as of December 31, 2015 (in thousands):

Equity incentive plans	24,766
Common stock purchase warrants	4,297
Employee stock purchase plan	1,976
Total common stock reserved	31,039

## Warrants

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. We classified these warrants as mezzanine equity as they included a redemption feature that may be triggered upon certain fundamental transactions that are outside of our control. 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 of our common stock 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. These warrants were also classified as mezzanine equity due to the same redemption feature as that of Series 5 Warrants as described above. These warrants expired in May 2015 and were no longer outstanding as of December 31, 2015.

Warrants to purchase up to 0.1 million shares of our common stock with an exercise price of \$12.60 per share, issued in connection with warrant exchange in July 2010, were outstanding as of December 31, 2014. These warrants expired in January 2015 and were no longer outstanding as of December 31, 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. Warrants to purchase up to 11,600 shares of our common stock with an exercise price of \$12.60 per share issued to the placement agent for the Series 6 Preferred Stock transaction were also outstanding as of December 31, 2014. These warrants were classified as mezzanine equity due to the same redemption feature as that of Series 5 Warrants as described above. These warrants expired in January 2015 and were no longer outstanding as of December 31, 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. Warrants to purchase up to 37,838 shares of our common stock with an exercise price of \$13.80 per share issued to the placement agent for the Series 7 Preferred Stock transaction were also outstanding as of December 31, 2014. These warrants expired in October 2015 and were no longer outstanding as of December 31, 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, 2015 and 2014. Warrants to purchase up to 30,423 shares of our common stock 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, 2015 and 2014. 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, 2015 and 2014. Warrants to purchase up to 70,588 shares of our common stock 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, 2015 and 2014. 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, 2015 and 2014. Warrants to purchase up to 69,566 shares of our common stock 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, 2015 and 2014. These warrants expire in December 2016.

See Note 8. Long-term Debt for additional information concerning our warrants.

81

---



## 11. Other Comprehensive Loss

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

	Net Unrealized Loss on Securities Available-For-Sale	Foreign Currency Translation Adjustments	Unrealized Foreign Exchange Loss on Intercompany Balance	Accumulated Other Comprehensive Loss
December 31, 2014	\$ (490 )	\$ (6,009 )	\$—	\$ (6,499 )
Current period other comprehensive income (loss)	(28 )	2,160	(2,585 )	(453 )
December 31, 2015	\$ (518 )	\$ (3,849 )	\$ (2,585 )	\$ (6,952 )

## 12. Collaboration, Licensing and Milestone Agreements

## Baxalta

In November 2013, we entered into the Pacritinib License Agreement with Baxter, for the development and commercialization of pacritinib for use in oncology and potentially additional therapeutic areas. Baxalta has been assigned Baxter's rights and obligations under the Pacritinib License Agreement. Under the Pacritinib License 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 Pacritinib License Agreement, which included an equity investment of \$30 million to acquire our Series 19 Preferred Stock as discussed below.

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

Under the Pacritinib License 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 Baxalta and 25% to the Company, (ii) costs applicable to territories exclusive to Baxalta will be 100% borne by Baxalta 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 Baxalta 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 Pacritinib License 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 Pacritinib License Agreement also required Baxalta 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 Pacritinib License 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 Pacritinib License Agreement, joint commercialization, manufacturing, development and steering committees with representatives from the Company and Baxalta 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 Pacritinib License Agreement constitute a separate deliverable and determined that it should also be combined with the development services.

The Pacritinib License Agreement will expire when Baxalta has no further obligation to pay royalties to us in any jurisdiction, at which time the licenses granted to Baxalta will become perpetual and royalty-free. Either party may terminate the Pacritinib License Agreement prior to expiration in certain circumstances. The Company may terminate the Pacritinib License Agreement if Baxalta has not undertaken requisite regulatory or commercialization efforts in the applicable countries and certain other conditions are met. Baxalta may terminate the Pacritinib License 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 Pacritinib License 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 Pacritinib License 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 Pacritinib License 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 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 Pacritinib License 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 based on a proportional performance method, by which revenue is recognized in proportion to the development costs incurred. During the year ended December 31, 2015, 2014 and 2013, \$0.8 million, \$0.8 million and \$0.1 million of development services was recognized as revenue, respectively, and the

remaining \$1.0 million and \$1.8 million was recorded as deferred revenue in the balance sheet as of December 31, 2015 and 2014, respectively.

Concurrently with the execution of the Pacritinib License 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.

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.

In June 2015, we entered into the Pacritinib License Amendment to the Pacritinib License Agreement. Pursuant to the Pacritinib License Amendment, two potential milestone payments in the aggregate amount of \$32.0 million from Baxalta to us were accelerated from the schedule contemplated by the original Pacritinib License Agreement. Refer to the Note 8. Long-term Debt for further details regarding these milestone advances received.

#### 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 €89.0 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 post-authorization trial, which we refer to as PIX306, for PIXUVRI); and up to €40.0 million in potential sales-based milestone payments. 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. Of the foregoing potential milestone payments, we received a €1.5 million (or \$1.7 million upon conversion from euros as of the date we received the funds) milestone payment in February 2015 relating to the attainment of reimbursement approval for PIXUVRI in Spain. We allocated the milestone payment based on the relative-selling-price percentages originally used to allocate the arrangement consideration under the Servier Agreement. This revenue was accounted for under the milestone method of accounting since this milestone was determined to be substantive at the inception of the arrangement.

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 the date of the Servier Agreement) to Novartis International Pharmaceutical Ltd., or Novartis, which was recorded in Other operating expense for the year ended December 31, 2014. Furthermore, in connection with the milestone payment received in February 2015, we paid €0.2 million (or \$0.3 million using the currency exchange rate as of the date of the payment) to Novartis, which is recorded in Other operating expense for the year ended December 31, 2015.

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.

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 sublicensable 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 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, 2015 and 2014, \$1.6 million and \$18,000 of development services was recognized as revenue, respectively, and the remaining \$0.7 million and \$0.8 million was recorded as deferred revenue in the balance sheet as of December 31, 2015 and 2014, respectively.

#### Novartis

In January 2014, we entered into a Termination Agreement, or the Novartis 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 Novartis Agreement. Pursuant to the Novartis Termination Agreement, the Original Novartis Agreement was terminated in its entirety, other than 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 transferee/licensee/sublicensee 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 the Compounds, 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 the Compounds 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., or PG-TXL, 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 the Compounds are subject to certain minimum floor percentages in the low single-digits.

#### University of Vermont

In March 1995, the University of Vermont, or UVM, entered into an agreement which, as amended in March 2000, 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.

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% 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, the Chroma License Agreement was terminated in connection with the Chroma APA. See Note 4. Acquisitions - Chroma Asset Purchase Agreement, for further information.

#### Vernalis

Concurrently with the termination of the Chroma License Agreement 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

We entered into an agreement with the Gynecologic Oncology Group, or GOG, now part of NRG Oncology, in March 2004, as amended, related to the GOG-212 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 each of December 31, 2015 and December 31, 2014.

### PG-TXL

In November 1998, we entered into an agreement with 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. in October 2006, 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.

### Teva

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. Cephalon was subsequently acquired by Teva Pharmaceutical Industries Ltd., or Teva. During the years ended December 31, 2015, 2014 and 2013, we received \$10.0 million, \$15.0 million and \$5.0 million, respectively, from Teva, upon the achievement of worldwide net sales milestones of TRISENOX, which was included in license and contract revenue. 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, 2015, 2014 and 2013, we recognized share-based compensation expense which consisted of the following types of awards (in thousands):

	2015	2014	2013
Performance rights	\$3,017	\$1,549	\$1,165
Restricted stock	8,656	14,749	5,906
Options	3,155	3,898	1,995
Total share-based compensation expense	\$14,828	\$20,196	\$9,066

The following table summarizes share-based compensation expense for the years ended December 31, 2015, 2014 and 2013, which was allocated as follows (in thousands):

	2015	2014	2013
Research and development	\$3,964	\$3,437	\$2,178
Selling, general and administrative	10,864	16,759	6,888
Total share-based compensation expense	\$14,828	\$20,196	\$9,066

Share-based compensation had a \$14.8 million, \$20.2 million and \$9.1 million effect on our net loss attributable to common shareholders, which resulted in a \$(0.08), \$(0.14) and \$(0.08) effect on basic and diluted net loss per common share for the years ended December 31, 2015, 2014 and 2013, respectively. It had no effect on cash flows from operations or financing activities for the periods presented; however, during the years ended 2015, 2014 and 2013, we repurchased 321,200, 57,000 and 200,000 shares of our common stock totaling \$0.6 million, \$0.2 million and \$0.2 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, 2015, unrecognized compensation cost related to unvested stock options and time-based restricted stock awards and restricted stock units amounted to \$15.2 million, which will be recognized over the remaining weighted-average requisite service period of 2.9 years. The unrecognized compensation cost related to unvested options and restricted stock does not include the value of performance-based awards.

For the years ended December 31, 2015, 2014 and 2013, no tax benefits were attributed to the share-based compensation expense because a valuation allowance was maintained for all net deferred tax assets.

#### Stock Plan

In September 2015, the Company's 2015 Equity Incentive Plan, or the 2015 Plan, was approved by the Company's shareholders and no additional awards will be granted under the 2007 Equity Incentive Plan, as amended and restated, or the 2007 Plan.

In addition, the Company's 2007 Employee Stock Purchase Plan, as amended and restated in August 2009 and September 2015, or the Purchase Plan, was amended in September 2015 to increase the maximum number of shares of the Company's common stock authorized for issuance by 1.9 million shares. Refer to Employee Stock Purchase Plan below for further details regarding the Purchase Plan.

Pursuant to our 2015 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 2015 Plan is administered by the Compensation Committee of our Board of Directors, which has the discretion to determine the employees and consultants who shall be granted incentive awards. The Board retained sole authority under the 2015 Plan with respect to non-employee directors' awards, although the Compensation Committee has authority

88

---

under its charter to make recommendations to the Board concerning such awards. Options expire 10 years from the date of grant, subject to the recipients continued service to the Company.

As of December 31, 2015, 44.5 million shares were authorized for issuance, of which 8.8 million shares of common stock were available for future grants, under the 2015 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,			
	2015	2014	2013	
Risk-free interest rate	1.7	% 1.7	% 1.4	%
Expected dividend yield	None	None	None	
Expected life (in years)	5.3	5.2	5.3	
Volatility	80	% 97	% 102	%

The risk-free interest rate used in the Black-Scholes valuation method is based on the implied yield currently available for U.S. Treasury securities at maturity with an equivalent term. We have not declared or paid any dividends on our common stock and do not currently expect to do so in the future. The expected term of options represents the period that our options are expected to be outstanding and was determined based on historical weighted average holding periods and projected holding periods for the remaining unexercised options. Consideration was given to the contractual terms of our options, vesting schedules and expectations of future employee behavior. Expected volatility is based on the annualized daily historical volatility, including consideration of the implied volatility and market prices of traded options for comparable entities within our industry.

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

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

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (Thousands)
Outstanding at 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 (3,174,000 exercisable)	4,918,000	\$3.14		
Granted	11,492,000	\$1.39		
Exercised	(83,000 )	\$1.40		
Forfeited	(623,000 )	\$2.17		
Cancelled and expired	(115,000 )	\$5.62		
Outstanding at December 31, 2015	15,589,000	\$1.75	9.10	\$9,000
Vested or expected to vest at December 31, 2015	14,838,000	\$1.76	9.05	\$9,000
Exercisable at December 31, 2015	4,361,000	\$2.57	7.32	\$9,000

The weighted average exercise price of options exercisable at December 31, 2014 and 2013 was \$3.42 and \$5.39, respectively. The weighted average grant-date fair value of options granted during 2015, 2014 and 2013 was \$0.92, \$2.59 and \$1.32 per option, respectively.

#### Restricted Stock

We issued 5.7 million, 4.4 million and 6.4 million shares of restricted stock awards in 2015, 2014 and 2013, respectively. The weighted average grant-date fair value of restricted stock awards issued during 2015, 2014 and 2013 was \$2.06, \$3.23 and \$1.21, respectively. Additionally, 1.8 million, 0.3 million and 1.2 million shares of restricted stock awards were cancelled during 2015, 2014 and 2013, respectively.

The total fair value of restricted stock awards vested during the years ended December 31, 2015, 2014 and 2013 was \$7.3 million, \$18.0 million and \$5.1 million, respectively.

A summary of the status of nonvested restricted stock awards as of December 31, 2015 and changes during the period then ended, is presented below:

	Nonvested Shares	Weighted Average Grant-Date Fair Value Per Share
Nonvested at December 31, 2014	3,054,000	\$ 4.35
Issued	5,699,000	\$ 2.06
Vested	(4,320,000 )	\$ 2.34
Forfeited	(1,768,000 )	\$ 5.07



Nonvested at December 31, 2015	2,665,000	\$ 2.23
--------------------------------	-----------	---------

We issued 0.5 million restricted stock units and 0.1 million restricted stock units were cancelled during 2015. The weighted average grant-date fair value of restricted stock units issued during 2015 was \$1.57. There were no restricted stock units issued or cancelled during 2014 and 2013.

90

---

A summary of the status of nonvested restricted stock units as of December 31, 2015 and changes during the period then ended, is presented below:

	Nonvested Units	Weighted Average Grant-Date Fair Value Per Unit
Nonvested at December 31, 2014	—	\$ —
Issued	461,000	\$ 1.57
Vested	—	\$ —
Forfeited	(127,000	) \$ 1.57
Nonvested at December 31, 2015	334,000	\$ 1.57

#### 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 2007 Plan or 2015 Plan, as applicable), 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. In September 2015, one of the performance conditions was achieved as discussed below.

In December 2015, the Long-Term Performance Awards were modified so that as to any particular performance goal that is achieved after December 23, 2015 and on or before December 31, 2016, the executive officers will be granted a stock option with respect to the number of shares determined under the formula described above (as opposed to receiving or retaining such number of fully-vested shares of our common stock). Each option will have an exercise price equal to the closing price of the Company's common stock on the grant date (which will be the date the Compensation Committee of our Board of Directors certifies the performance goal is achieved) and will be scheduled to vest in semi-annual installments over a period of three years following the grant date. To the extent the executive officers have been issued any restricted shares pursuant to their Long-Term Performance Awards that have not yet vested, they have agreed to forfeit those shares to the Company.

The aggregate of the award percentages related to all ten performance goals in effect as of December 31, 2015 is 9.2%, all of which is attributable to the executive officers.

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, 2013.

In September 2015, our Board of Directors certified completion of the performance condition relating to Pacritinib Phase III trial result that satisfies the primary point set forth in the statistical plan then in effect and an aggregate of 1.6 million shares vested to our executive officers and directors. We recognized \$2.8 million in share-based compensation upon satisfaction of this performance condition for the year ended December 31, 2015.

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.

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. The December 2015 modification discussed above did not result in any incremental fair value. In December 2015, we reversed the total share-based compensation expense of \$1.0 million, which was previously recorded for awards granted to directors who agreed to forfeit their Long-Term Performance Awards as part of the derivative lawsuit settlement. See Note 19, Legal Proceedings for further information. We recognized \$0.3 million, \$1.4 million and \$1.2 million in share based compensation expense related to the performance awards with a market-based performance condition for the years ended December 31, 2015, 2014 and 2013, 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, unvested nonemployee options to acquire approximately 78,000 shares of common stock were outstanding. Additionally, unvested nonemployee restricted stock awards totaled approximately 21,000 as of December 31, 2014. As of December 31, 2015, all nonemployee options and restricted stock awards had vested and no compensation expense related to nonemployee options and restricted stock was recorded. We recorded compensation expense related to nonemployee options and restricted stock of \$0.3 million each in 2014 and 2013, respectively.

#### Employee Stock Purchase Plan

Under 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 7,100, 4,000 and 3,000 shares of our common stock to employees in the years ended December 31, 2015, 2014 and 2013, respectively. There are 2.0 million shares of common stock authorized under the Purchase Plan and approximately 2.0 million shares are reserved for future purchases as of December 31, 2015.

#### 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 related to discretionary matching contributions during each of the years ended December 31, 2015, 2014 and 2013.

#### 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.

In December 2015, our Board of Directors approved certain amendments to the Rights Plan to extend the final expiration date to December 2, 2018 (rather than 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 the years presented were in Europe. Product sales from PIXUVRI's major customers as a percentage of total product sales were as follows:

	Year Ended December 31,			
	2015	2014	2013	
Customer A	42	% 27	% —	%
Customer B	41	% 57	% 67	%

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

	Year Ended December 31,	
	2015	2014
United States	\$3,657	\$4,512
Europe	61	134
Total long-lived assets	\$3,718	\$4,646

#### 17. Net Loss Per Share

The numerator for both basic and diluted loss per share, or EPS, is net loss. The denominator for basic EPS (referred to as basic shares) is the weighted average number of common shares outstanding during the period, whereas the denominator for diluted EPS (referred to as diluted shares) also takes into account the dilutive effect of outstanding stock options and restricted stock awards using the treasury stock method. Basic and diluted shares for the years ended December 31, 2015, 2014 and 2013 are as follows (in thousands, except per share amounts):

	Year Ended December 31,		
	2015	2014	2013
Net loss attributable to common shareholders	\$(122,622 )	\$(95,992 )	\$(49,643 )
Basic and diluted:			
Weighted average shares outstanding	193,244	153,467	119,042
Less weighted average restricted shares outstanding	(4,871 )	(4,936 )	(4,847 )
Shares used in calculation of basic and diluted net loss per common share	188,373	148,531	114,195
Net loss per common share: Basic and diluted	\$(0.65 )	\$(0.65 )	\$(0.43 )

Equity awards, warrants, and unvested share rights aggregating 14.7 million shares, 14.8 million shares and 11.8 million shares for the year ended December 31, 2015, 2014 and 2013, respectively, prior to the application of the treasury stock method, are excluded from the calculation of diluted EPS because they are anti-dilutive.



## 18. Related Party Transactions

### Aequus

In May 2007, we formed Aequus, a majority-owned subsidiary of which our ownership was approximately 60% as of December 31, 2015. 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 \$2.3 million, \$2.0 million and \$1.5 million during the years ended December 31, 2015, 2014 and 2013, respectively, including amounts advanced in association with the services agreement. The Aequus note balance, including accrued interest, was approximately \$11.0 million and \$8.1 million as of December 31, 2015 and 2014, respectively. This intercompany balance was eliminated in consolidation.

Our President and Chief Executive Officer, James A. Bianco, M.D., and our Executive Vice President, Global Medical Affairs and Translational Medicine, Jack W. Singer, M.D., are both minority shareholders of Aequus, each owning approximately 4.3% of the equity in Aequus as of December 31, 2015. 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 3.8% of Aequus as of December 31, 2015 and is also a member of Aequus' Board of Directors.

### BVF Partners L.P.

In September 2015, as discussed in Note 10. Common Stock, we entered into a subscription agreement with BVF pursuant to which we issued 10.0 million shares of our common stock. Further, in December 2015, as discussed in Note 9. Preferred Stock, we completed an underwritten public offering of 55,000 shares of our Series N-2 Preferred Stock, no par value per share. BVF purchased 30,000 shares of our Series N-2 Preferred Stock in such offering, which were converted into approximately 27.3 million shares of our common stock.

Primarily as a result of these transactions, BVF beneficially owned approximately 15.6% of our outstanding common stock as of December 31, 2015. In connection with the Series N-2 Preferred Stock offering, we entered into a letter agreement with BVF, or the Letter Agreement, pursuant to which we granted BVF a one-time right, subject to certain conditions, to nominate not more than two individuals to serve as members of our Board, subject to the Board's consent, which is not to be unreasonably withheld and which consent shall be deemed automatically given with respect to two individuals specified in such Letter Agreement. One of such nominees (the "Independent Nominee") must (i) qualify as an "independent" director as defined under the applicable rules and regulations of the U.S. Securities and Exchange Commission, or the SEC, and NASDAQ and (ii) must not be considered an "affiliate" of BVF as such term is defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act. We have agreed, for the period hereinafter described and subject to a limited exception, to include the nominated directors in the slate of nominees for election to the Board at each annual or special meeting at which directors are to be elected, recommend



that shareholders vote in favor of the election of such nominees and support such nominees for election in a manner no less favorable than how we support our own nominees. This obligation will terminate with respect to: (x) the Independent Nominee, and such Independent Nominee must tender his or her resignation to the Board, if requested, promptly upon BVF ceasing to beneficially own at least 11% of the issued and outstanding common stock or voting power of the Company (determined on an as-converted basis that gives effect to the conversion of all outstanding preferred stock), and (y) each of the Independent Nominee and the other individual nominated by BVF shall tender their resignation to the Board, promptly upon the earlier to occur of (a) BVF and its affiliates ceasing to beneficially own at least 5% of the issued and outstanding common stock or voting power of the Company (determined on an as-converted basis that gives effect to the conversion of all outstanding preferred stock), (b) BVF ceasing to beneficially own at least 50% of the shares of the common stock beneficially owned by BVF immediately after consummation of the Series N-2 Preferred Stock offering (on an as-converted basis), (c) the continuation of such nomination right would cause any violation of the applicable listing rules of NASDAQ, (d) such time as BVF informs us in writing that wishes to terminate the foregoing nomination right, or (e) any breach of the Letter Agreement by BVF.

## 19. Legal Proceedings

In April 2009, December 2009 and June 2010, the Italian Tax Authority, or the ITA, issued notices of assessment to CTI (Europe) based on the ITA's audit of CTI (Europe)'s VAT returns for the years 2003, 2005, 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 although we can make no assurances regarding the ultimate outcome of these cases. Following is a summary of the status of the legal proceedings surrounding each respective VAT year return at issue:

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 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 2013 VAT matter of €0.4 million (or \$0.6 million upon conversion from euros as of the date of payment), following the ITA's request for such payment.

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 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 \$10.2 million converted using the currency exchange rate as of December 31, 2015, 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. In January 2013, our then remaining deposit for the VAT Assessments was refunded to us.

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.

On May 13, 2015, the Company (as nominal defendant) and our directors (as individual defendants) entered into a memorandum of understanding to settle the pending lawsuit 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, or the Settlement. On

December 10, 2015, the court issued an order granting final approval to the Settlement.

The provisions of the Settlement include the following terms:

We will cancel and the non-employee directors will agree to the rescission of all currently outstanding equity awards that we previously granted to non-employee directors that included performance-based vesting metrics and as to which the performance goals remained unsatisfied as of May 13, 2015;

Our current non-employee directors will agree to hold (not transfer or sell or encumber in any way) until September 14, 2015 shares of our stock that they currently own and that we awarded to them during 2011, or at any time after 2011 to the present, and that, at the time of the award by us, was fully-vested and unrestricted;

We will cap the total annual compensation provided by it to its non-employee directors for each of 2015 and 2016. Such annual compensation cap for each non-employee director for each of 2015 and 2016 will be the greater of (i) \$375,000, plus, as to our Board Chairman, an additional \$100,000, or (ii) the 75th percentile of compensation paid by a group of peer companies to their non-employee directors (and, in the case of our Chairman, the 75th percentile of compensation paid by such peers who have a non-employee director chair of their respective board of directors to such non-employee director chairs). The peer group for these purposes will be selected based on advice from the outside compensation consultant. For purposes of the compensation cap and the peer group comparison, compensation will be determined and measured consistent with the rules under Item 402 of Regulation S-K under the Securities Exchange Act of 1934, as amended, and based on publicly-available information at the applicable time; and We will implement, if not already implemented, within 90 days following final approval of the Settlement by the court, and maintain until at least the end of calendar year 2017 the following: an annual board discussion of non-employee director compensation philosophy; the use of a compensation consultant to advise the Compensation Committee on material decisions concerning non-employee director compensation issues and compare our non-employee director compensation program to a group of our peers; the use of plain language in our compensation-related public filings; and obtain confirmation from our legal department and outside legal counsel advising on executive compensation matters that any contemplated non-employee director awards do not materially violate the applicable plan or materially fail to comply with applicable law.

In connection with the Settlement, to date, we paid \$0.3 million in attorneys' fees awarded to plaintiffs (net of existing insurance coverage), which was accrued for in our financial statements contained herein as of December 31, 2015.

On February 10, 2016 and February 12, 2016, similar purported class action lawsuits entitled Ahrens v. CTI Biopharma Corp. et al, Case No. 1:16-cv-01044 and McGlothlin v. CTI Biopharma Corp. et al, Case No. C16-216, respectively, were filed in the United States District Court for the Southern District of New York and the United States District Court for the Western District of Washington, respectively, on behalf of shareholders that purchased or acquired the Company's securities pursuant to our September 24, 2015 public offering and/or shareholders who otherwise acquired our stock between March 4, 2014 and February 9, 2016, inclusive. The complaints assert claims against the Company and certain of our current and former directors and officers for violations of the federal securities laws under Sections 11 and 15 of the Securities Act of 1933, as amended, or the Securities Act, and Sections 10 and 20 of the Exchange Act. Plaintiffs' Securities Act claims allege that the Company's Registration Statement and Prospectus for the September 24, 2015 public offering contained materially false and misleading statements and failed to disclose certain material adverse facts about the Company's business, operations and prospects, including with respect to the clinical trials and prospects for pacritinib. Plaintiffs' Exchange Act claims allege that the Company's public disclosures were knowingly or recklessly false and misleading or omitted material adverse facts, again with a primary focus on the clinical trials and prospects for pacritinib.

The lawsuits seek damages in an unspecified amount. We believe that the allegations contained in the complaints are without merit and intend to vigorously defend ourselves against all claims asserted therein. A reasonable estimate of the amount of any possible loss or range of loss cannot be made at this time and, as such, we have not recorded an accrual for any possible loss.

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.

## 20. Income Taxes

We file income tax returns in the United States, Italy and the U.K. 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.

For the years ended December 31, 2015, 2014 and 2013, we had net losses before income taxes from our domestic companies totalling \$110.9 million, \$84.9 million and \$36.0 million; and from our foreign subsidiaries totalling \$9.9 million, \$9.3 million and \$7.6 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 by \$38.7 million, \$28.0 million and \$11.3 million during the years ended December 31, 2015, 2014 and 2013, respectively.

The reconciliation between our effective tax rate and the income tax rate as of December 31, 2015, 2014 and 2013 is as follows:

	2015		2014		2013	
Federal income tax rate	(34	)%	(34	)%	(34	)%
Research and development tax credits	(3	)	(3	)	(3	)
I.R.C. Section 382 limited research and development tax credits	—		—		—	
Non-deductible executive compensation	1		3		1	
I.R.C. Section 382 limited net operating losses	—		—		3	
Valuation allowance	32		30		27	
Expired tax attribute carryforwards	—		—		—	
Foreign tax rate differential	3		3		6	
Other	1		1		—	
Net effective tax rate	—	%	—	%	—	%

Significant components of our deferred tax assets and liabilities as of December 31, 2015 and 2014 were as follows (in thousands):

	December 31,	
	2015	2014
Deferred tax assets:		
Net operating loss carryforwards	\$94,024	\$63,983
Capitalized research and development	39,537	34,936
Research and development tax credit carryforwards	6,685	3,968
Stock based compensation	15,242	12,809
Intangible assets	15,694	17,007
Depreciation and amortization	260	191
Other deferred tax assets	3,180	3,072
Total deferred tax assets	174,622	135,966
Less valuation allowance	(173,947	) (135,293
	675	673
Deferred tax liabilities:		
GAAP adjustments on Novuspharma merger	(208	) (208
Deductions for tax in excess of financial statements	(467	) (465
Total deferred tax liabilities	(675	) (673
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 the NOL, and research and development credits against future income. We have obtained a private letter ruling, or the PLR, that determines the availability of the NOL after a 2007 ownership change.

In October 2012, an “ownership change” occurred. The ownership change limits the utilization of certain tax attributes including the NOL. After the October 2012 ownership change the utilization of the NOL is limited to approximately \$4.3 million annually. At December 2014, the gross NOL carryforward was approximately \$1.2 billion. The annual NOL limitation will reduce the available NOL carryforward to approximately \$276.5 million expiring from 2018 to

2035. The deferred tax asset and valuation allowance have been reduced accordingly.

At December 31, 2015, the NOL carryforward in the U.K. was approximately \$28.5 million which can be carried forward indefinitely. The NOL carryforward for the U.K. 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. The NOL in Italy are not material.

97

---

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 U.K. 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, 2015, 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 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 Quarter	Second Quarter	Third Quarter	Fourth Quarter
2015				
Total revenues (1)	\$2,728	\$1,100	\$964	\$11,324
Product sales, net	805	849	740	1,078
Gross profit (2)	615	666	(91)	342
Net loss attributable to CTI	(28,597)	(32,596)	(32,592)	(25,637)
Net loss attributable to CTI common shareholders	(28,597)	(32,596)	(32,592)	(28,837)
Net loss per common share—basic	(0.16)	(0.19)	(0.19)	(0.13)
Net loss per common share—diluted	(0.16)	(0.19)	(0.19)	(0.13)
2014				
Total revenues (3), (4)	\$1,411	\$1,343	\$39,534	\$17,789
Product sales, net	1,268	1,148	2,021	2,472
Gross profit (2)	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)

Total revenues for the fourth quarter of 2015 include \$10.0 million of milestone payments received from Teva in (1) November 2015 upon the achievement of worldwide net sales milestones of TRISENOX. See Note 12.

Collaboration, Licensing and Milestone Agreements for additional information.

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

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 (3) contract revenue for a milestone payment received under the collaboration agreement with Baxalta. See Note 12.

Collaboration, Licensing and Milestone Agreements for additional information.

(4) 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.

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

None.

98

---

## 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 SEC rules and forms, and that such information is accumulated and communicated to our management to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

Our management, under the supervision and with the participation of our Chief Executive Officer and Executive Vice President, Finance and Administration, or EVP of Finance, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the 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 2015 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, 2015 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, 2015, 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.



## PART III

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

We have adopted a code of ethics for our senior executive and financial officers (including our principal executive officer and principal financial officer), as well as a code of business conduct and ethics applicable to all officers, directors and employees, or collectively, the "Codes." The Codes are available on our website at <http://www.ctibiopharma.com>. Any amendments to, or waivers from, the Codes for our executive officers and directors will be posted on our website at <http://www.ctibiopharma.com> to the extent required by applicable SEC and NASDAQ rules.

The additional information required by this Item is incorporated herein by reference from the Company's 2016 definitive proxy statement (which will be filed with the SEC within 120 days after December 31, 2015 in connection with the solicitation of proxies for the Company's 2016 annual meeting of shareholders) ("2016 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 2016 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 2016 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 2016 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 2016 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

Schedule II. Valuation and Qualifying Accounts

Valuation and qualifying accounts include the following (in thousands):

Description	Balance at 1/1/2015	Additions		(3) Deductions	Balance at 12/31/2015
		(1) Charged to costs and expenses	(2) Charged to other accounts		
Inventory reserve	\$—	\$1,326	\$(25 )	\$(36 )	\$1,265

(1) We review our inventories on a quarterly basis for impairment and reserves are established when necessary.

(2) We record inventory in euros and we record foreign currency translation gains and losses from recurring measurement of our inventory in Accumulated other comprehensive income in our consolidated balance sheets.

(3) The amount of inventory reserve is adjusted for the items disposed of during the period.

Refer to the Part II "Financial Statements and Supplementary Data, Notes to Consolidated Financial Statements, Note 1. Description of Business and Summary of Significant Accounting Policies" for further details regarding our accounting policy for inventory and foreign currency translation.

All other 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

Edgar Filing: CTI BIOPHARMA CORP - Form 10-K

Exhibit Number	Exhibit Description	Location
3.1	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 23, 2015.
3.2	Articles of Amendment to Amended and Restated Articles of Incorporation, dated October 29, 2015 (Series N Preferred Stock).	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on October 30, 2015.
3.3	Articles of Amendment to Amended and Restated Articles of Incorporation, dated October 29, 2015 (Series N-1 Preferred Stock).	Incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed on October 30, 2015.
3.4	Articles of Amendment to Amended and Restated Articles of Incorporation, dated December 8, 2015 (Series N-2 Preferred Stock).	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on December 9, 2015.
3.5	Amended and Restated Bylaws.	Incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on December 3, 2015.
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.
4.4	Third Amendment to Shareholder Rights Agreement, dated as of December 1, 2015, 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 1, 2015.

4.5	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.
4.6	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.
4.7	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.
4.8	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.
4.9	Warrant Agreement, dated June 9, 2015, by and between 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 June 10, 2015.

Edgar Filing: CTI BIOPHARMA CORP - Form 10-K

Exhibit Number	Exhibit Description	Location
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, 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*	Amendment No. 2 to Employment Agreement between the Registrant and James A. Bianco, dated as of January 6, 2015.	Incorporated by reference to Exhibit 10.4 to the Registrant's Annual Report on Form 10-K, filed on March 12, 2015.
10.5*	Amendment No. 3 to Employment Agreement between the Registrant and James A. Bianco, dated as of December 23, 2015.	Filed herewith.
10.6*	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, filed on February 28, 2013.
10.7*	Offer Letter, by and between the Registrant and Bruce J. Seeley, dated as of July 2, 2015.	Incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, filed on August 6, 2015.
10.8*	Form of Severance Agreement for the Registrant's Executive Officers other than James A. Bianco (as in effect as of January 6, 2015).	Incorporated by reference to Exhibit 10.6 to the Registrant's Annual Report on Form 10-K, filed on March 12, 2015.
10.9*	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, filed on March 16, 2009.
10.10*	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.



Edgar Filing: CTI BIOPHARMA CORP - Form 10-K

- |        |  |   |
|--------|--|---|
| 10.11* | Severance Agreement, dated as of July 27, 2015, between the Registrant and Bruce J. Seeley | Filed herewith.   |
| 10.12* | Director Compensation Policy.  | Filed herewith.   |
| 10.13* | 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.      |
| 10.14* | 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. |

103

---

Edgar Filing: CTI BIOPHARMA CORP - Form 10-K

Exhibit Number	Exhibit Description	Location
10.15*	2007 Employee Stock Purchase Plan, as amended and restated.	Incorporated by reference to Appendix B to the Registrant's Definitive Proxy Statement on Schedule 14A filed on July 29, 2015.
10.16*	CTI BioPharma Corp. 2015 Equity Incentive Plan, effective as of September 23, 2015.	Incorporated by reference to Exhibit 4.1 to the Registrant's Form S-8, filed on September 28, 2015.
10.17*	Form of 2015 Equity Incentive Plan Restricted Stock Award Agreement.	Incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q, filed on November 5, 2015.
10.18*	Global Form of 2015 Equity Incentive Plan Restricted Stock Unit Award Agreement.	Incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q, filed on November 5, 2015.
10.19*	Global Form of 2015 Equity Incentive Plan Stock Option Agreement.	Incorporated by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q, filed on November 5, 2015.
10.20*	Global Form of 2015 Equity Incentive Plan Stock Bonus Award Agreement.	Incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q, filed on November 5, 2015.
10.21*	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.
10.22*	Form of 2007 Equity Incentive Plan Restricted Stock Award Agreement.	Incorporated by reference to Exhibit 10.14 to the Registrant's Annual Report on Form 10-K, filed on March 12, 2015.
10.23*	Global Form of 2007 Equity Incentive Plan Restricted Stock Unit Award Agreement.	Incorporated by reference to Exhibit 10.15 to the Registrant's Annual Report on Form 10-K, filed on March 12, 2015.
10.24*	Global Form of 2007 Equity Incentive Plan Stock Option Agreement.	Incorporated by reference to Exhibit 10.16 to the Registrant's Annual Report on Form 10-K, filed on March

12, 2015.

- |        |  |   |
|--------|--|---|
| 10.25* | 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.   |
| 10.26* | 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. |

Edgar Filing: CTI BIOPHARMA CORP - Form 10-K

Exhibit Number	Exhibit Description	Location
10.27*	Form of 2007 Equity Incentive Plan Restricted Stock Award Agreement for employees (relating to applicable awards granted prior to December 17, 2014).	Incorporated by reference to Exhibit 10.6 to the Registrant's Quarterly Report on Form 10-Q, filed on April 26, 2011.
10.28*	Form of 2007 Equity Incentive Plan 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.
10.29*	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.
10.30*	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.
10.31*	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.
10.32*	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.
10.33*	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.
10.34*	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.
10.35*	Form of Equity/Long-Term Incentive Award Agreement for Bruce J. Seeley.	Filed herewith.
10.36*	Form of Amendment to Form of Equity/Long-Term Incentive Award Agreement, dated as of December 23, 2015, for James A. Bianco, Louis A. Bianco and Jack W. Singer.	Filed herewith.

- 10.37\* Form of Amendment to Form of Equity/Long-Term Incentive Award Agreement, dated as of December 23, 2015, for Matthew J. Plunkett and Bruce J. Seeley. Filed herewith.
- 10.38 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.

105

---

Edgar Filing: CTI BIOPHARMA CORP - Form 10-K

Exhibit Number	Exhibit Description	Location
10.39	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.
10.40	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.
10.41†	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, filed on March 31, 1999.
10.42†	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.
10.43†	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.
10.44†	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.
10.45†	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.
10.46	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.
10.47†	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.
10.48†	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.

10.49†	First Amendment to the Development, Commercialization and License Agreement by and among the Registrant, Baxalta Incorporated, Baxalta US Inc. and Baxalta GmbH, effective June 8, 2015.	Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q, filed on August 6, 2015.
10.50†	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.
10.51†	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.

Edgar Filing: CTI BIOPHARMA CORP - Form 10-K

Exhibit Number	Exhibit Description	Location
10.52†	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.
10.53	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.
10.54	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.
10.55	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.
10.56	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.	Incorporated by reference to Exhibit 10.48 to Registrant's Annual Report of Form 10-K, filed on March 12, 2015.
10.57	Third Amendment to Loan and Security Agreement, dated June 9, 2015, by and among Hercules Technology Growth Capital, Inc. (and certain of its affiliates), the Registrant and Systems Medicine LLC.	Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on June 10, 2015.
10.58	Fourth Amendment to Loan and Security Agreement, dated December 11, 2015, by and among the Registrant, Systems Medicine LLC, Hercules Capital Funding Trust 2014-1 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 December 11, 2015.
10.59	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.
10.60	Stipulation of Settlement, dated November 6, 2012.	Incorporated by reference to Exhibit 99.2 to the Registrant's Current Report on Form 8-K, filed on March 27, 2013.
10.61	Stipulation of Settlement	Incorporated by reference to Exhibit 99.2 to the Registrant's Current Report



Edgar Filing: CTI BIOPHARMA CORP - Form 10-K

on Form 8-K, filed on September 29, 2015.

10.62 Form of Subscription Agreement for Common Stock.

Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on September 29, 2015.

10.63 Letter Agreement, dated December 9, 2015, by and between CTI BioPharma Corp. and BVF Partners L.P.

Incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on December 9, 2015.

12.1 Statement Re: Computation of Ratio of Earnings to Fixed Charges.

Filed herewith.

107

---

Edgar Filing: CTI BIOPHARMA CORP - Form 10-K

Exhibit Number	Exhibit Description	Location
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.	Furnished herewith.
101.INS	XBRL Instance	Filed herewith.
101.SCH	XBRL Taxonomy Extension Schema	Filed herewith.
101.CAL	XBRL Taxonomy Extension Calculation	Filed herewith.
101.DEF	XBRL Taxonomy Extension Definition	Filed herewith.
101.LAB	XBRL Taxonomy Extension Labels	Filed herewith.
101.PRE	XBRL Taxonomy Extension Presentation	Filed herewith.

\* Indicates management contract or compensatory plan or arrangement.

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

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Seattle, State of Washington, on February 16, 2016.

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 Phillip M. Nudelman, Ph.D.	Chairman of the Board and Director	February 16, 2016
/s/ James A. Bianco James A. Bianco, M.D.	President, Chief Executive Officer and Director (Principal Executive Officer)	February 16, 2016
/s/ Louis A. Bianco Louis A. Bianco	Executive Vice President, Finance and Administration (Principal Financial Officer and Principal Accounting Officer)	February 16, 2016
/s/ Richard L. Love Richard L. Love	Director	February 16, 2016
/s/ Mary O. Mundinger Mary O. Mundinger, DrPH	Director	February 16, 2016
/s/ Matthew D. Perry Matthew D. Perry	Director	February 16, 2016
/s/ Jack W. Singer Jack W. Singer, M.D.	Director	February 16, 2016

/s/ Frederick W. Telling  
Frederick W. Telling, Ph.D.

Director

February 16, 2016

/s/ Reed V. Tuckson  
Reed V. Tuckson, M.D.

Director

February 16, 2016

109