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, 2019

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: 000-28386

CTI BIOPHARMA CORP.

(Exact name of registrant as specified in its charter)

Delaware	91-1533912
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
3101 Western Avenue, Suite 800 Seattle, WA	98121
(Address of principal executive offices)	(Zip Code)

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	CTIC	The Nasdaq Capital Market

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

None.

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 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 every Interactive Data File required to be submitted 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 such files). Yes ☒ No ☐

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
Emerging growth company ☐	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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, 2019, the aggregate market value of the registrant's common equity held by non-affiliates was approximately $43.7 million. Shares of common stock held by each executive officer and director and by each other person who may be deemed to be an affiliate of the registrant have been excluded from this computation. This determination of affiliate status for this purpose is not necessarily a conclusive determination for other purposes.

The number of outstanding shares of the registrant's common stock as of March 6, 2020 was 73,678,720.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2020 annual meeting of stockholders, or the 2020 Proxy Statement, are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. We expect to file the 2020 Proxy Statement 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

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Forward Looking Statements

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

- our expectations regarding sufficiency of cash resources, cash expenditures, sources of cash flows and other projections, product manufacturing and sales, research and development expenses, selling, general and administrative expenses and additional losses;
- our ability to obtain funding for our operations;
- the timing of, and our ability to develop, commercialize, and obtain regulatory approval of pacritinib and other development programs we may pursue in the future;
- the design of our clinical trials and anticipated enrollment, and the progress and potential of pacritinib and other development programs we may pursue in the future;
- the safety, effectiveness and potential benefits and indications of pacritinib and any other product candidates we may develop in the future;
- the timing of and results from clinical trials and pre-clinical development activities, including those related to pacritinib and any other product candidates we may develop in the future;
- our ability to advance product candidates, including pacritinib and any other product candidates we may develop in the future, into and successfully complete clinical trials;
- our ability to achieve profitability, including our ability to effectively implement cost reduction strategies and realize anticipated cost savings from those efforts;
- our expectations regarding federal, state and foreign regulatory requirements;
- the rate and degree of market acceptance and clinical utility of pacritinib or any other product candidates we may develop in the future;
- our and our collaborators' ability to obtain and maintain regulatory approvals for pacritinib or any other product candidates we may develop in the future, and the timing of such approvals;
- our ability to maintain and establish collaborations;
- our expectations regarding market risk, including interest rate changes and foreign currency fluctuations;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- the impact of government laws and regulations;
- our ability to negotiate, integrate, and implement collaborations, acquisitions and other strategic transactions;
- our ability to engage and retain the employees required to advance our development activities and grow our business;
- developments relating to our competitors and our industry, including the success of competing therapies that are or become available; and
- those risk factors identified in this Annual Report on Form 10-K under the heading Risk Factors and in other filings we periodically make with the U.S. Securities and Exchange Commission, or the SEC.

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, variations 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. 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 SEC.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.

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 Corp. 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 for blood-related cancers that offer a unique benefit to patients and their healthcare providers. Our goal is to build a profitable company by generating income from products we develop and commercialize, either alone or with partners. We concentrate our efforts on treatments that target blood-related cancers where there is an unmet medical need. In particular, we are focused on evaluating pacritinib, our sole product candidate currently in active development, for the treatment of adult patients with myelofibrosis.

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.

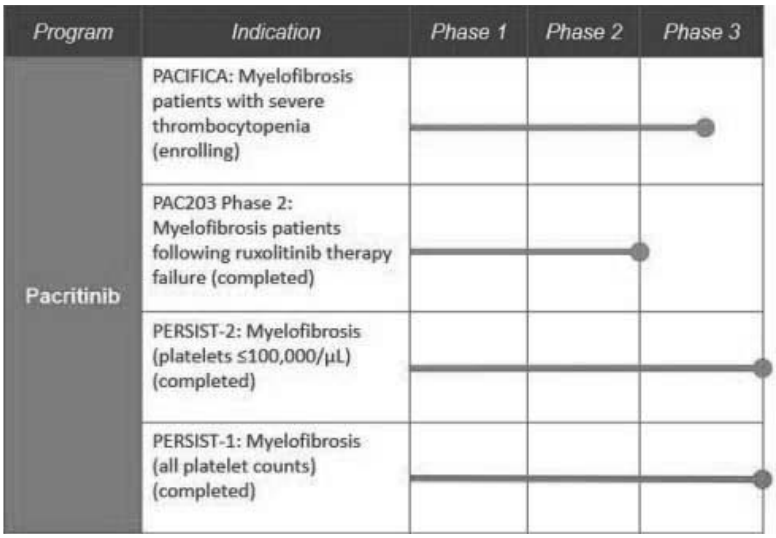
Our Strategy

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:

- **Develop Pacritinib in Myelofibrosis.** We intend to develop and commercialize pacritinib for adult patients with myelofibrosis.
- **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.** Historically, we have built our candidate pipeline using multiple approaches, including through 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 the date of this report:



Oncology Market Overview and Opportunity

According to the American Cancer Society, or ACS, cancer is the second leading cause of death in the United States, resulting in more than 600,000 deaths annually, or more than 1,600 deaths per day. Approximately 1.8 million new cases of cancer are expected to be diagnosed in 2020 in the United States. While the exact prevalence of myelofibrosis is uncertain, a U.S. study presented at the 2012 American Society of Hematology reported a prevalence rate of 5.7 myelofibrosis cases per 100,000 people, indicating that there are approximately 18,000 myelofibrosis patients in the United States. The most commonly used methods for treating patients with cancer are surgery, radiation and chemotherapy. Patients usually receive a combination of these treatments depending upon the type and extent of their disease.

We believe 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, may fill a significant unmet medical need for cancer patients.

Pacritinib

Overview

Our primary 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, MDS, chronic myelomonocytic leukemia, or CMML, prevention of GvHD, and 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 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 (low platelet counts); patients experiencing treatment-emergent thrombocytopenia on other JAK2 inhibitor therapy; or patients who are intolerant of or whose symptoms are not well controlled (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.

Pacritinib was evaluated in two Phase 3 clinical trials, collectively known as the PERSIST program, for patients with myelofibrosis. The PERSIST-1 trial evaluated pacritinib in a broad set of patients without limitations on platelet counts, and the PERSIST-2 trial evaluated pacritinib in patients with low platelet counts. 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. Currently patients with very low blood platelets, so called severe thrombocytopenia, (<50,000/μL) have limited or no effective treatment options. Myelofibrosis patients with severe thrombocytopenia have poor survival following discontinuation of therapy with the approved JAK1/JAK2 therapy. We believe pacritinib may offer effective treatment of splenomegaly and disease-related symptoms in patients with severe thrombocytopenia.

PERSIST-1 was a randomized (2:1), open-label, multi-center Phase 3 trial evaluating the efficacy and safety of pacritinib compared to BAT excluding 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 SVR from baseline to Week 24 as measured by MRI or CT, when compared with physician-specified BAT, excluding treatment with JAK2 inhibitors. The secondary endpoint was the percentage of patients achieving a 50 percent or greater reduction in 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/μL); and 16 percent of patients had platelet counts less than 50,000 per microliter (<50,000/μL); 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 was also 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.

In May 2015, data from PERSIST-1 showed that compared to BAT (exclusive of a JAK inhibitor) pacritinib therapy resulted in a significantly higher proportion of patients with SVR and control of disease-related symptoms meeting the primary endpoint of the trial.

The following table shows the proportion of patients randomized to pacritinib or BAT who achieved a ≥35 percent SVR 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/μL platelets) (33.3 percent with pacritinib vs 0 percent with BAT) (p=0.037).

Spleen Volume Reduction of ≥35 Percent at Week 24 by Platelet Levels

	Pacritinib	**BAT**	**p-value**
All Platelet Levels			
ITT*	19% (n=220)	5% (n=107)	0.0003
Evaluable**	25% (n=168)	6% (n=85)	<0.0001
<100,000/μL platelets			
ITT	17% (n=72)	0% (n=34)	0.0086
Evaluable	24% (n=51)	0% (n=24)	0.0072
<50,000/μL platelets			
ITT	23% (n=35)	0% (n=16)	0.0451
Evaluable	33% (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.*

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/μL) 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, nausea, anemia, thrombocytopenia and vomiting. Of the patients treated with pacritinib, three 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 December 2015, primarily based on the results of the PERSIST-1 trial, we submitted a NDA to the 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/μL).

The PERSIST-2 trial was a randomized (2:1), open-label, multi-center registration-directed Phase 3 trial evaluating pacritinib compared to BAT, 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 (≤100,000/μL). Patients were randomized to receive 200 mg pacritinib twice daily, 400 mg pacritinib once daily or BAT. 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 SVR 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 allowed 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.

In February 2015, we received a recommendation from the Independent Data Monitoring Committee, or IDMC, in place at the time to terminate the PERSIST-1 trial and hold enrollment of new patients in the PERSIST-2 trial. The IDMC's recommendation was based on non-statistically significant safety concerns, including mortality, in patients on pacritinib, particularly those who crossover after 24 weeks. The IDMC agreed that the recommendation would be only preliminary until we were unblinded to and could review the primary and secondary endpoint data as well as safety results from the PERSIST-1 trial. The IDMC recommendation was reviewed with the PERSIST Steering Committee, comprised of external experts and the study's principal investigators who disagreed with the IDMC's recommendation and expressed the view that the studies should continue as planned. We also asked an independent clinician and a statistician experienced in oversight of clinical trial safety to evaluate the safety profile of pacritinib in the PERSIST-1 trial. Neither was told of the recommendation reached by either the IDMC or the Steering Committee. Both experts agreed with the Steering Committee that the studies could continue. The firm that assembled the IDMC hired a second external independent statistician to review the IDMC's analyses and recommendation, who also disagreed with the IDMC recommendation and concurred with the other independent experts that the studies need not be terminated nor enrollment held. In June 2015, the IDMC made its recommendation final and we provided to the FDA the information reviewed by the IDMC, the IDMC's meeting minutes, and the written opinion of the Steering Committee co-chairs, the independent experts, and the second independent statistician. In July 2015, we requested a meeting with the FDA to confirm if we should continue the studies. The FDA assigned the request to a Type C meeting. In its written response, the FDA did not mandate any modifications to the studies or place pacritinib on clinical hold at that time, but indicated that it had not yet reviewed the data and noted the difficulty in attempting to draw meaningful conclusions from non-significant results, and that the crossover designs may confound the analysis of survival. We determined that no modifications to the ongoing trials were required. We decided to commission a new IDMC because of these concerns regarding the previous recommendation. The newly constituted IDMC met on several occasions and its recommendation was to continue PERSIST-2 as planned.

On February 8, 2016, the FDA notified us that a full clinical hold had 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 on pacritinib at the time of the hold order were required to discontinue pacritinib immediately and no new patients could 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 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 recommended that we conduct Phase 1 dose exploration studies of pacritinib in patients with myelofibrosis, submit final clinical study reports, or CSRs, 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, the SPA agreement is no longer binding for PERSIST-2, and we withdrew the NDA.

In February 2016, prior to the clinical hold we completed patient enrollment in the PERSIST-2 Phase 3 clinical trial. Under the full clinical hold, all patients participating in the PERSIST-2 clinical trial discontinued pacritinib treatment.

In August 2016, we announced the top-line results from PERSIST-2. In the PERSIST-2 trial three hundred eleven (311) patients were randomized to receive 200 mg pacritinib BID, 400 mg pacritinib QD or BAT. Two hundred twenty-one (221) patients (74 pacritinib BID; 75 pacritinib QD; 72 BAT) were enrolled at least 24 weeks prior to the full clinical hold and were potentially evaluable for the Week 24 efficacy endpoint (ITT efficacy population). In the ITT efficacy population at study entry, 46 percent (101/221) of patients had platelet counts less than 50,000 per microliter (<50,000/μL), and 59 percent (130/221) were anemic (hemoglobin <10 g/dL). Normal platelet counts range from 150,000 to 450,000 per microliter. The percentage of patients in the ITT efficacy population who received prior ruxolitinib was as follows: 41 percent (31/75) pacritinib QD; 42 percent (31/74) pacritinib BID; and 46 percent (33/72) BAT. Safety analyses were based on all patients exposed to study treatment of any duration.

The co-primary endpoints of the trial were the proportion of patients achieving a 35 percent or greater SVR from baseline to Week 24 as measured by MRI or CT scan and the proportion of patients achieving a TSS reduction of 50 percent or greater using the modified MPN-SAF TSS 2.0 diary from baseline to Week 24. The primary objective of the study was to compare pooled pacritinib arms versus BAT and the secondary objectives were to compare pacritinib BID and QD arms individually to BAT. The study was designed to evaluate its objectives with a sample size of 300. At the time of clinical hold, study enrollment was completed with three hundred eleven (311) patients randomized, but only two hundred twenty one (221) patients had the potential to be evaluated for efficacy endpoints at Week 24.

The PERSIST-2 trial met one of the co-primary endpoints showing a statistically significant SVR in patients treated with pacritinib combining the once- and twice-daily arms compared to BAT. The PERSIST-2 trial did not meet the other co-primary endpoint of greater than 50 percent reduction in TSS. Although secondary objectives could not be evaluated formally due to the study not achieving one of the primary objectives, when the two pacritinib dosing arms were evaluated separately versus BAT, pacritinib given twice daily showed a higher percent of SVR and TSS responses compared to BAT; whereas, pacritinib given once daily showed only a higher percent SVR responses compared to BAT.

Spleen Volume Reduction of ≥35 Percent; Total Symptom Score Reduction of ≥50 Percent at Week 24

	Co-Primary Pacritinib BID + QD (n=149)	**Secondary Pacritinib BID (n=74)**	**Secondary Pacritinib QD (n=75)**	**BAT (n=72)**
Percent of Patients with ≥35% SVR from baseline to Week 24	18% (n=27;p=0.001)	22% (n=16;p=0.001)	15% (n=11;p=0.017)	3% (n=2)
Percent of Patients with ≥50% reduction in TSS from baseline to Week 24	25% (n=37;p=0.079)	32% (n=24;p=0.011)	17% (n=13;p=0.652)	14% (n=10)

A post-hoc analysis of TSS was conducted evaluating the response rates when the symptom fatigue was removed from calculation of patient symptom improvement. The approved JAK2 inhibitors ruxolitinib and fedratinib used this same approach for the assessment of TSS improvement in their pivotal approval studies. Once the term fatigue is removed the TSS response rates were 31% for the combined pacritinib arms (p=0.014), 35% for pacritinib BID (p=0.0075), 27% for pacritinib QD (p=0.11) and 15% for BAT.

A total of 45 percent of the BAT patients randomized received ruxolitinib at some point on the study.

There was no significant difference in overall survival, or OS, across treatment arms, censored at the time of clinical hold. Hazard ratios (95 percent confidence intervals, or CI) were, 0.9 (0.47, 1.73) for the combined pacritinib arms vs. BAT, 0.68 (0.30, 1.53) for pacritinib BID versus BAT and 1.18 (0.57, 2.44) for pacritinib QD versus BAT. Overall mortality rates at that time were comparable between arms: 9 percent BID versus 14 percent QD and 14 percent BAT.

The most common treatment-emergent AEs, occurring in 20 percent or more of patients treated with pacritinib within 24 weeks, of any grade, were gastrointestinal (generally manageable diarrhea, nausea and vomiting) and hematologic (anemia and thrombocytopenia) and were generally less frequent for BID versus QD administration. The most common serious treatment-emergent AEs (incidence of ≥5 percent reported in any treatment arm irrespective of grade) were anemia, thrombocytopenia, pneumonia and acute renal failure none of which exceeded 8 percent individually in any arm.

In January 2017, the FDA removed the full clinical hold following review of our complete response submission which included, among other items, final Clinical Study Reports for both PERSIST-1 and -2 trials and a dose-exploration clinical trial protocol that the FDA requested. At that time, the PAC203 trial was designed to enroll up to approximately 105 patients with primary myelofibrosis and who had failed prior ruxolitinib therapy across three dose regimens of pacritinib, 100 mg QD, 100 mg BID and 200 mg BID, to evaluate the dose response relationship for safety and efficacy (SVR at 12 and 24 weeks). The 200 mg BID dose was selected as the top dose based upon observations from the completed PERSIST-2 study. In PAC203, the entry criteria were modified to exclude patients with a history of cardiac and/or bleeding events and additional dose modification guidelines were implemented for the management of treatment-emergent cardiac and or bleeding events. The first patient in the PAC203 trial was enrolled in July 2017. In April 2018, we amended the protocol to expand the sample size to a maximum of 150 patients (or 50 patients per arm) to collect additional data for the safety and efficacy analyses. In July 2018, we announced that the IDMC for the PAC203 trial completed its planned interim data review of the PAC203 trial and that the IDMC did not identify any drug- or dose-related safety concerns and did not identify any concerns about cardiac or bleeding events. Following meetings with the FDA and European Medicines Agency, or EMA, and consultation with the IDMC, we eliminated the interim efficacy analysis and focused the second interim data review, and all subsequent data reviews, on an assessment of safety. The protocol was amended to reflect this change and submitted to FDA. In October 2018, we announced the continuation of the PAC203 Phase 2 study without modification, following a planned second interim data review by the IDMC. The IDMC did not identify significant drug- or dose-related safety concerns and specifically did not identify any concerns around hemorrhagic or cardiac toxicity. A complete dataset from the fully enrolled study (including efficacy, safety, pharmacokinetic and pharmacodynamic data) will be used to determine the optimal dose of pacritinib for further clinical development, as requested by the FDA. The PAC203 study was fully enrolled in December 2018. In January 2019, the IDMC completed its planned third interim safety review and recommended that the study continue without modification.

In December 2019, we announced top-line efficacy and safety data for the PAC203 trial. Pacritinib was shown to be generally well tolerated across dosing cohorts. The majority of non-hematological adverse events were mild or moderate in severity and, with the exception of diarrhea, were considered unlikely related to pacritinib. The most common non-hematologic AEs were gastrointestinal, including diarrhea (23.6%) and nausea (23.6%), and occurred more commonly in patients treated at 200 mg BID (31/54, 57.4%) than at lower doses (100 mg BID: 23/55, 41.8%, 100 mg QD: 22/52, 42.3%). These events were largely grade 1 or 2 in severity. Diarrhea was generally manageable with standard antidiarrheal agents, and only one patient (at 200mg BID) required drug discontinuation due to any gastrointestinal event (diarrhea).

The most common hematologic AEs were thrombocytopenia and anemia, both occurring at higher frequencies at the 200 mg BID dose (35.2 percent and 24.1 percent respectively); this did not, however, lead to higher rates of Grade 3/4 hemorrhage at higher doses (200 mg BID: 5.6 percent; 100 mg BID: 0 percent; 100 mg QD: 7.7 percent; all Grade 3). Similarly, the highest dose saw no excess in Grade 3/4 cardiac (200 mg BID: 3.7 percent; 100 mg BID: 7.3 percent; 100 mg QD: 5.8; all grade 3). There were 10 Grade 5 (fatal) AEs: 3 at 200 mg BID (sepsis, respiratory failure, subdural hematoma), 3 at 100 mg BID (disease progression, subdural hemorrhage, heart failure), and 4 at 100 mg QD (disease progression, general physical health deterioration, sepsis, tuberculosis).

The 200 mg BID arm had the highest observed rates of SVR ≥35 percent (200 mg BID: 9.3 percent; 100 mg BID: 1.8 percent; 100 mg QD: 0.0 percent). Of the 5 patients with SVR ≥35 percent at the 200 mg BID dose, 4 had platelet counts <50,000/μL, representing a 17 percent (4/24) response rate among patients with severe thrombocytopenia. Though a dose response relationship was not observed in total symptom score (TSS) based on the threshold of 50 percent reduction in symptom score, the median percent decrease in TSS (including fatigue) did show deeper reductions with escalating doses, with best response at 200 mg BID. At Week 24, the percent change in TSS from baseline was highest in the 200 mg pacritinib

BID group (median -27.3%) compared with the other treatment groups (100 mg pacritinib BID group: median -16.0%; 100 mg pacritinib QD group: median -3.1%). Of the TSS (including fatigue) responders, baseline cytopenias were common: 8 of 12 had hemoglobin <10g/dL, and 4 of 12 had platelet counts <50,000/μL.

In June 2019, we attended a Type B meeting with the FDA to review the results of the PAC203 study. Based on FDA feedback at that meeting, we designed a randomized Phase 3 study of pacritinib to compare the safety and efficacy of 200 mg BID of pacritinib to Physician's Choice in adult myelofibrosis patients with severe thrombocytopenia (platelet count of less than 50,000 per microliter) an indication that has been recognized by the FDA as an important unmet serious medical need. In July 2019, we received scientific advice from the EMA on the study's design.

The selection of the 200 mg BID dose and dosing schedule for the Phase 3 study was determined using the results of the PAC203 study together with dose- and exposure-response analyses using all available data from pacritinib clinical trial. In July 2019, a draft protocol for that Phase 3 study was submitted to the FDA and we received their feedback on the design in September 2019 and October 2019, which included a suggestion that we amend the design to include change in total symptom score, or TSS, as a co-primary endpoint. We completed a Type C meeting with the FDA in December 2019 and received additional input from the FDA on key elements of the design of the Phase 3 study including changes that could allow for an accelerated approval NDA filing and that we would power the study for TSS but it would remain a secondary endpoint.

In January 2020, we had a Type A meeting with the FDA and reached an agreement on the final design changes to the Phase 3 study including changes to the statistical analysis plan that would allow for an accelerated approval pathway for pacritinib. We will be amending the PACIFICA pivotal Phase 3 trial protocol to allow for the primary analysis of SVR rates on the first 168 patients, with an end-of-study analysis of TSS and OS following the full enrollment of 348 patients. If the primary endpoint of SVR is met following the planned review of data from the first 168 patients, we intend to submit an NDA under the FDA's regulations for the Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses, 21 C.F.R. subpart H, subject to review of all available efficacy and safety data. Conversion to a regular approval of pacritinib would be anticipated following a statistically significant successful end-of-study assessment of the secondary efficacy endpoint of TSS, no survival detriment for the pacritinib arm and the completion of post-marketing requirements. Based on the new trial design, we expect to report primary SVR data by the end of 2021, with a potential NDA filing in early 2022 if the SVR data is positive. Final study efficacy data is expected in 2023.

Marketing Authorization Application

The MAA for pacritinib was submitted to the EMA in February 2016 with an indication statement based on the PERSIST-1 trial data. In its initial assessment report, the CHMP determined that the original application was not approvable at that point in the review cycle because of major objections in the areas of efficacy, safety (hematological and cardiovascular toxicity) and the overall risk-benefit profile of pacritinib. Subsequent to the filing of the original MAA, data from the second Phase 3 trial of pacritinib, PERSIST-2, were reported to the EMA.

Following discussions with the EMA about how PERSIST-2 data might address the major objections and potential methods to integrate the data into the current application, we withdrew the original MAA, and submitted a new application for the treatment of patients with myelofibrosis who have thrombocytopenia (platelet counts less than 100,000 per microliter). The new MAA was validated by the EMA in July 2017. Validation confirms that the submission is complete and initiates the centralized review process by the CHMP. The CHMP review period is 210 days, excluding question or opinion response periods, after which the CHMP opinion is reviewed by the European Commission, which usually issues a final decision on EU authorization within three months. If authorized, pacritinib would be granted a marketing license valid in all 28 EU member states, Norway, Iceland and Liechtenstein.

We received the Day 120 LoQ in November 2017, which included Major Objections in areas including efficacy, safety (including hematological, cardiovascular and infectious toxicities) and other concerns including the size of the data set and the pharmacokinetic analyses of the two dosing regimens studied in PERSIST-2. A request for an extension was submitted following a clarification meeting with the rapporteur, co-rapporteur and members of the EMA to provide the EMA with data from PAC203, and in January 2018, we were granted a three-month extension for submitting our response to the Day 120 LoQs. In December 2017 a preapproval GCP inspection of the PERSIST-2 clinical study was conducted by the EMA. In February 2018, the EMA issued its final GCP inspection report, which concluded that the PERSIST-2 clinical trial was generally conducted in compliance with GCP and internationally accepted ethical standards, that the deficient safety reporting procedures identified as inspection findings did not pose a direct risk to data quality and that the results from the PERSIST-2 clinical trial can be used for the evaluation and assessment of the MAA. In July 2018, we received the Day 180 LoQs and were granted a two-month extension to allow us to submit a snapshot of clinical data from the ongoing PAC203 study with our responses to the remaining list of questions. In the third quarter of 2018, we submitted comprehensive responses to the Day

180 LoQs, which included new data from the PAC203 trial. In November 2018, we received a second round of questions related to the Day 180 List of Outstanding Issues. We submitted responses to these additional questions, which included data from the ongoing open label PAC203 trial, in December 2018. We withdrew the MAA in February 2019 following interactions with CHMP, during which we learned that CHMP was likely to formally adopt a negative opinion in its evaluation of the application. CHMP indicated that the risk-benefit profile for pacritinib for the intended indication has not been sufficiently established with the clinical data available to date.

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 broad spectrum of blood-related cancers. Pacritinib's potent inhibition of IRAK1 and CSF1R highlight its potential therapeutic utility in other diseases, such as MDS, CLL, graft versus host disease, or GvHD, autoimmune diseases and breast cancer, some of which are currently being evaluated in investigator sponsored trials, or ISTs.

In October 2016, we regained worldwide rights for the development and commercialization of pacritinib following termination of the Pacritinib License Agreement with Baxalta. For additional information relating to the termination of the Pacritinib License Agreement, see "License Agreements - Baxalta" below.

License Agreements

Baxalta

In November 2013, we entered into a Development, Commercialization and License Agreement, dated as of November 14, 2013, with Baxter International Inc., or Baxter, for the development and commercialization of pacritinib for use in oncology and potentially additional therapeutic areas, or the Pacritinib License Agreement, which was subsequently amended in June 2015. Baxter assigned its rights and obligations under the Pacritinib License Agreement to Baxalta. Under the Pacritinib License Agreement, we granted to Baxter an exclusive, worldwide (subject to co-promotion rights discussed below), royalty-bearing, non-transferable, and (under certain circumstances outside of the United States) sub-licensable license to our know-how and patents relating to pacritinib.

In October 2016, we entered into the Asset Return and Termination Agreement, or the Baxalta Termination Agreement, with Baxalta. Pursuant to the Baxalta Termination Agreement, the Pacritinib License Agreement was terminated in its entirety (other than with respect to certain customary provisions that survive termination, including those pertaining to confidentiality and indemnification), the Pacritinib License Agreement has no further force or effect, and all rights and obligations of the Company and Baxalta under the Pacritinib License Agreement were terminated.

In October 2016, we resumed primary responsibility for the development and commercialization of pacritinib as a result of the Baxalta Termination Agreement and are no longer eligible to receive cost sharing or milestone payments for pacritinib's development from Baxalta. In addition, under the Baxalta Termination Agreement, we are required to make a milestone payment to Baxalta in the amount of approximately $10.3 million upon the first regulatory approval or any pricing and reimbursement approvals of a product containing pacritinib.

*S*BIO*

We acquired the compounds SB1518 (which is referred to as "pacritinib") and SB1578, which inhibit JAK2 and FLT3, from 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., EU and Japanese regulatory approvals are obtained and 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 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.

Teva Pharmaceutical Industries Ltd.

In June 2005, we entered into an acquisition agreement with Cephalon, Inc., or Cephalon, pursuant to which we divested 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 $60.0 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, or CROs, third-party manufacturers and distributors that have durations of greater than one year for the development and distribution of certain of our compounds.

Patents and Other Intellectual Property Rights

We dedicate significant resources to protecting our intellectual property, which is important to our business. We have filed numerous patent applications in the United States and various other countries seeking protection of inventions originating from our research and development, and we have also obtained rights to various patents and patent applications under licenses with third parties and through acquisitions. We have pending patent applications or issued patents in the United States and foreign countries directed to pacritinib and other product candidates. Patents for the individual products extend for varying periods according to the date of the patent filing or grant and the legal term of patents in the various countries where patent protection is obtained.

Our U.S. and foreign composition of matter patents for pacritinib expire as follows: U.S. patents expire in May 2028 (method) / January 2029 (compound) / March 2030 (salt); foreign patents expire in November 2026 (method and compound) / December 2029 (salt). We expect our U.S. and foreign patent applications for use of pacritinib for treating transplant rejection will expire in 2036.

Each patent may be eligible for future patent term restoration of up to five years under certain circumstances. Also, regulatory exclusivity tied to the protection of clinical data may be complementary to patent protection. During a period of regulatory exclusivity, competitors generally may not use the original applicant's data as the basis for a generic application. In the United States, the data protection generally runs for five years from first marketing approval of a new chemical entity, extended to seven years for an orphan drug indication. Pacritinib has orphan drug designation for myelofibrosis in the United States and the European Union.

In addition to our patent rights, we rely, to the extent possible, on trade secrets and contractual protections for our know-how and other unpatented technology. Ultimately, to the extent any of our product candidates are not protected by patent rights, our competitors would be free to use inventions embodied in our product candidates to which they have access to 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 clinical development activities continue to expand, we expect that our manufacturing, distribution and related operational requirements will increase correspondingly. Additionally, in October 2016, we resumed primary responsibility for the development and commercialization of pacritinib as a result of the termination of the Pacritinib License Agreement. The development and commercialization of a major product candidate like pacritinib without a collaborative partner has significantly increased our manufacturing, distribution and related operational requirements, and we expect such increases to continue as we advance the clinical development of pacritinib.

Each third party contractor undergoes a formal qualification process by our subject matter experts prior to our entry into any service agreement and initiating any manufacturing work. We currently have a commercial supply arrangement for pacritinib.

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.

Pacritinib may compete with Jakafi®, which is marketed by Incyte in the United States and Novartis ex-United States and Inrebic®, which is marketed by Bristol-Myers Squibb globally. If approved, we may face competition from other candidates in development that target JAK inhibition to treat cancer such as momelotinib (Sierra Oncology).

Some 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 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. In addition to FDA regulation, we are also subject to additional legal and regulatory requirements at both the federal and state levels in the United States. Our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Additionally, some significant aspects of regulation in the European Union are addressed in a centralized way through the EMA and the European Commission, but country-specific regulation by the competent authorities of the EU member states remains essential in many respects.

U.S. Regulation

In the United States, the FDA regulates drugs under the FDCA and its implementing regulations, including through review and approval of NDAs. NDAs require extensive studies and submission of a large amount of data by the applicant. There are also additional laws and regulations, administered by the FDA and other government agencies, that are applicable to the development, approval, manufacture, marketing, promotion, sale, pricing and distribution of drugs.

Drug Development

Preclinical Testing. Before testing any compound in human subjects in the United States, 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 United States 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 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 United States. 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. For additional information relating to drug development, see Part I, Item 1A, "Risk Factors" in this Annual Report on Form 10-K.

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. We are not permitted to market our drugs in the United States until we receive approval of an NDA from the FDA.

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. For additional information relating to drug development, see Part I, Item 1A, "Risk Factors" in this Annual Report on Form 10-K.

Post-Approval FDA 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. 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. For additional information relating to post-approval requirements, see Part I, Item 1A, "Risk Factors" in this Annual Report on Form 10-K.

Advertising and Promotion

Under the FDCA and other laws, we are prohibited from promoting our products for off-label uses, or uses not approved by the FDA. 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 uses of our products that are not approved by the FDA, unless otherwise allowed by the FDA by policy or other guidance. Marketing of prescription drugs is also subject to additional laws and regulations through federal and state agencies tasked with consumer protection. After approval in the U.S., we must comply with these law and regulations, as well as FDA's regulation of drug promotion and advertising, including restrictions on off-label promotion. For additional information relating to restrictions related to advertising and promotion, see Part I, Item 1A, Risk Factors in this Annual Report on Form 10-K.

Health Care Fraud and Abuse

If we receive approval for one or more of our products in the United States, our operations and business arrangements with third-parties (including but not limited to researchers, healthcare professionals, consultants, payors, and customers) will be subject to additional healthcare laws, regulations and enforcement by federal and state governments in the United States. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, price reporting, and physician sunshine laws.

Anti-Kickback Laws

The Anti-Kickback Statute prohibits companies and individuals from offering, paying, soliciting, or receiving remuneration to induce or reward referrals of business that will be paid for by federal health care programs, such as Medicare and Medicaid. We are also required to comply with other state anti-kickback statutes and other limitations on gifts and payments to physicians and reporting of payments to certain third parties, among other requirements. Failure to abide by anti-kickback statutes can result in civil and criminal enforcement actions and/or sanctions. Likewise, federal and state false claims laws, including the federal False Claims Act and similar state statutes, prohibit knowingly submitting, or causing to be submitted, false claims or false or fraudulent statements material to a false claim to government health care programs. Pharmaceutical companies are frequent targets of false claims lawsuits, which may result in treble damages, penalties, and potential exclusion from participation in government healthcare programs. The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Anti-kickback laws, false claims laws, and civil monetary penalty statutes often overlap and may also be enforced in conjunction. Some of our pre-commercial activities are subject to these laws. For additional information relating to our obligations under health care fraud and abuse laws, see Part I, Item 1A, "Risk Factors" in this Annual Report on Form 10-K.

Foreign Corrupt Practices Act

The Foreign Corrupt Practices Act of 1977, or FCPA, and similar worldwide anti-bribery laws in non-U.S. jurisdictions generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. The United States Department of Justice and Securities and Exchange Commission jointly enforce the FCPA, and those agencies have, in recent years, emphasized FCPA enforcement against pharmaceutical

companies. In some countries, we may interact with health care professionals or other officials that meet the definition of a foreign government official for the purposes of the FCPA. We are subject to the FCPA's prohibitions against unauthorized payments or offers of payments by our employees or agents. If we were determined to have violated the FCPA, we could be subject to substantial fines, penalties, and other legal or equitable sanctions. For additional information relating to our obligations under the FCPA and anti-bribery laws, see Part I, Item 1A, "Risk Factors" in this Annual Report on Form 10-K.

Third-Party Reimbursement

The coverage and reimbursement status of our products, if and when approved, is subject to significant uncertainty. Sales of and revenue from our products will depend on coverage and reimbursement decisions by third-party payors, including government health programs, managed care organizations, and private health insurers. Prices at which we or our customers seek reimbursement for our products can be subject to challenge, reduction, or denial by payors. Government health programs, private insurers, are increasingly trying to reduce the costs of pharmaceuticals, and any future legislative, regulatory, or contractual developments could affect the coverage and reimbursement status of our products, if and when approved. For additional information relating to product reimbursement, see Part I, Item 1A, "Risk Factors" in this Annual Report on Form 10-K.

Data Privacy and Protection

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and implementing regulations, create requirements relating to the privacy and security of individually identifiable health information. HIPAA regulations govern the manner in which certain health information may be used and disclosed, and require the adoption of administrative, physical, and technical safeguards to protect such information. HIPAA and HITECH requirements are applicable to covered entities, which are (1) health plans, (2) health care clearinghouses, and (3) health care providers who electronically transmit certain health information. Those requirements are also applicable, in many instances, to business associates of covered entities. In some cases, depending on our business operations and contractual agreements, including through the conduct of clinical trials, we are subject to HIPPA requirements. Non-compliance with these laws and regulations can result in significant fines, penalties, damages, loss of goodwill or business opportunities, and reputational harm. There are also additional federal, state, and local privacy laws and regulations in the U.S. that may apply to us now or in the future and that require that we take measures to protect the privacy and security of certain information we gather and use in our business. For example, in June 2018, California enacted the California Consumer Privacy Act, or CCPA, which takes effect on January 1, 2020. The law requires businesses collecting information about California consumers to disclose what personal information is collected about a consumer and the purposes for which that personal information is used, disclose what personal information is sold or shared for a business purpose, and to whom, and delete information or stop selling such information upon request (subject to exceptions). For additional information relating to our obligations under data privacy laws, see Part I, Item 1A, "Risk Factors" in this Annual Report on Form 10-K.

Non-U.S. Regulation

Before our medicinal products can be marketed outside of the United States, they must be subject to regulatory approval similar to that required in the United States. The requirements governing the conduct of clinical trials, including requirements to conduct additional clinical trials, product licensing, safety reporting, post-authorization requirements, marketing and promotion, interactions with healthcare professionals, pricing and reimbursement may vary widely from country to country. No action can be taken to market any product in a country until an appropriate approval 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.

Conduct of clinical trials in the European Union

Similar to the United States, the various phases of non-clinical and clinical research in the European Union are subject to significant regulatory controls. Although EU Clinical Trials Directive 2001/20/EC, or the Clinical Trials Directive, has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the European Union, EU Member States have transposed and applied the provisions of the Clinical Trials Directive in a manner that is not always uniform. This has led to variations in the rules governing the conduct of clinical trials in the individual EU Member States. The European Union has, therefore, adopted Regulation (EU) No 536/2014, or the Clinical Trials Regulation. The Clinical Trials Regulation, which will replace the Clinical Trials Directive, introduces a

complete overhaul of the existing regulation of clinical trials for medicinal products in the European Union, including a new coordinated procedure for authorization of clinical trials that is reminiscent of the mutual recognition procedure for marketing authorization of medicinal products, and increased obligations on sponsors to publish clinical trial results. The effectiveness of the Clinical Trials Regulation has been postponed several times due to technical difficulties with the underlying IT systems that are still ongoing. Currently it is expected to become effective sometime in 2020.

Clinical trials must currently be conducted in accordance with the requirements of the Clinical Trials Directive and applicable good clinical practice standards, as implemented into national legislation by the individual EU Member States. Under the current regime, before a clinical trial can be initiated it must be approved in each EU Member State where there is a site at which the trial is to be conducted by two separate entities: the National Competent Authority, or NCA, and one or more Ethics Committees. Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial must be reported to the NCA and to the Ethics Committees of the EU Member State where they occur.

In the European Union, pediatric data or an approved Pediatric Investigation Plan, or PIP, or deferral or waiver, must be approved by the European Medicines Agency, or EMA, prior to submission of a marketing authorization application to the EMA or to the competent authorities of the EU Member States; an application must include the results of studies as described in an approved PIP, unless the medicine is exempt because of a deferral or waiver. In most EU countries, companies are also required to have an approved PIP before enrolling pediatric patients in a clinical trial.

Marketing authorization procedures in the European Union and post-marketing obligations

In the European Union, medicinal products may only be placed on the market after a related marketing authorization, or MA, has been granted. Marketing authorizations for medicinal products can be obtained through several different procedures founded on the same basic regulatory process. These are through the centralized procedure, the mutual recognition procedure, the decentralized procedure, or a national procedure (for medicinal products sold in a single EU Member State only). 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 AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune and viral diseases. It is optional for medicinal products containing a new active substance that is not yet authorized in the European Economic Area, or the EEA, and for medicinal products that constitute significant therapeutic, scientific or technical innovations, or for which grant of a marketing authorization through the centralized procedure would be in the interest of patients or animal health at EU level. 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 positive opinion of the Committee for Medicinal Products for Human Use, or CHMP, at EMA, the European Commission has final authority for granting the marketing authorization within 67 days after receipt of the CHMP opinion to grant a centralized marketing authorization which is valid in all 28 EU Member States and three of the four European Free Trade Association, or EFTA countries (Iceland, Liechtenstein and Norway).

The decentralized authorization procedure permits companies to file identical applications for authorization to the competent authorities in several EU Member States simultaneously for a medicinal product that has not yet been authorized in any EU Member State. The competent authority of a single EU Member State, the reference member state, is appointed to review the application and provide an assessment report. The competent authorities of the other EU Member States, the concerned member states, are subsequently required to grant marketing authorization for their territories on the basis of this assessment. The only exception to this is where the competent authority of an EU Member State considers that there are concerns of potential serious risk to public health related to authorization of the product. In these circumstances the matter is submitted to the Heads of Medicines Agencies, or CMDh, for review. The mutual recognition procedure allows companies that have a medicinal product already authorized in one EU Member State to apply for this authorization to be recognized by the competent authorities in other EU Member States. The national marketing authorization procedure is founded on the same basic EU regulatory process as the other marketing authorization procedures discussed herein. The national marketing authorization procedure, which is increasingly rare, permits a company to submit an application to the competent authority of a single EU Member State and, if successful, to obtain a marketing authorization that is valid only in this EU Member State.

The maximum timeframe for the evaluation of a marketing authorization application in the European Union is 210 days, subject to extension if additional questions need to be addressed. The initial marketing authorization granted in the European Union is valid for five years. The authorization may be renewed and remain valid for an unlimited period unless the national competent authority or the European Commission decides on justified grounds to proceed with one additional five year renewal period; applications for renewal must be made to the EMA at least nine months before the five-year period

expires. The renewal of a marketing authorization is subject to a re-evaluation of the risk-benefit balance of the product by the national competent authorities or the EMA.

Similar to accelerated approval regulations in the United States, conditional marketing authorizations can be granted in the European Union by the European Commission in exceptional circumstances. A conditional marketing authorization can be granted for medicinal products where, although comprehensive clinical data referring to the safety and efficacy of the medicinal product have not been supplied, a number of criteria are fulfilled; i) 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 by the grant of the marketing authorization 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, our former product candidate, we were required to complete a post-marketing Phase 3 study to further investigate the effects of using PIXUVRI in a defined group of patients who had received prior treatment with rituximab. We submitted the related clinical study report to the EMA in November 2018.

In the European Union, innovative medicinal products that are subject to marketing authorization on the basis of a full dossier and which do not fall within the scope of the concept of global marketing authorization qualify for eight years of data exclusivity upon marketing authorization and ten years of market exclusivity. The eight years' data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data in assessing an application for authorization of a generic or biosimilar medicinal product for eight years from the data of authorization of the innovative product. After this period has expired a generic or biosimilar marketing authorization application may be submitted, and the innovator's data may be referenced in the application. However, even if the generic product or biosimilar products is authorized it cannot be marketed in the European Union during the ten year marketing exclusivity period. This market exclusivity period may be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

Pricing and reimbursement in the European Union

Even if a product is subject to a marketing authorization in the European Union, there can be no assurance that reimbursement for such product will be secured on a timely basis or at all. The EU Member States have the power to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU Member State may approve a specific price for the medicinal product. Alternatively, it may adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market.

In a number of EU Member States we may be subject to cost-cutting measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative. Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including countries representing major markets. 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; ultimately, HTA measures the added value of a new health technology compared to existing ones. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. On January 31, 2018, the European Commission adopted a proposal for a regulation on health technologies assessment. This legislative proposal is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at the EU level for joint clinical assessments in these areas. The proposal provides that EU Member States will be able to use common HTA tools, methodologies, and procedures across the European Union, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement. The European Commission has stated that the role of the draft HTA regulation is not to influence pricing and reimbursement decisions in the individual EU Member States, but there can be no assurance that the draft HTA regulation will not have effects on pricing and reimbursement decisions.

Therefore, we will need to expend significant effort and expense to establish and maintain reimbursement arrangements in the various countries comprising the European Union and may never succeed in obtaining widespread reimbursement arrangements therein.

Post-Approval Regulation

Similar to the United States, both marketing authorization holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and the competent authorities of the individual EU 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 EU laws and the related national laws of individual EU 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 EU marketing authorization for a medicinal product must also comply with EU 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 holders of marketing authorization granted through the centralized marketing authorization procedure the obligation to conduct a labor intensive collection of data regarding the risks and benefits of marketed medicinal products and to engage in ongoing assessments of those risks and benefits, including the possible requirement to conduct additional clinical studies or post-authorization safety studies to obtain further information on a medicine's safety, or to measure the effectiveness of risk-management measures, which may be time consuming and expensive and could impact our profitability. Marketing authorization holders are required to prepare Periodic Safety Update Reports in relation to medicinal products for which they hold marketing authorizations. The EMA reviews Periodic Safety Update Reports for medicinal products authorized through the centralized procedure. 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, withdrawn or varied. The Agency can advise that the marketing authorization holder be obliged to conduct post-authorization Phase IV safety studies. The EMA opinion is submitted to the European Commission for its consideration. If the Commission agrees with the opinion, it can adopt a decision varying the existing marketing authorization. Failure by the marketing authorization holder to fulfill the obligations for which the European Commission's decision provides can undermine the on-going validity of the marketing authorization.

More generally, non-compliance with pharmacovigilance 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.

The manufacturing process for medicinal products in the European Union 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 EU 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 EU cGMP standards when manufacturing medicinal products and active pharmaceutical ingredients, including the manufacture of active pharmaceutical ingredients outside of the European Union with the intention to import the active pharmaceutical ingredients into the European Union. Similarly, the distribution of medicinal products into and within the European Union is subject to compliance with the applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of the EU 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 European Commission, the competent authorities of EU Member States and other regulatory authorities. Companies may be subject to civil, criminal or administrative sanctions. These include suspension of manufacturing authorization in case of non-compliance with the EU or EU Member States' requirements governing the manufacturing of medicinal products.

Sales and Marketing Regulations

In the European Union, the advertising and promotion of our products are subject to EU 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 EU 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 European Union. The applicable laws at EU level and in the individual EU 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 European Union 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 United States 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 EU level and in the individual EU 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 European Union. Violation of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain EU 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 EU 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 the EU level with related implementing laws in individual EU Member States which impose significant compliance obligations. For example, the EU General Data Protection Regulation, which entered into force in May 2018, 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 and provides for significant monetary and other sanctions in the case of non-compliance.

As the General Data Protection Regulation entered into force recently, guidance on implementation and compliance practices are still being developed, updated or otherwise revised. Although the General Data Protection Regulation is intended to provide for a high level of harmonization across the EU, Member States may still implement certain variations, and data protection authorities may enforce the General Data Protection Regulation and national laws differently, which adds to the complexity of processing personal data in the European Union.

Furthermore, there is a trend towards the public disclosure of clinical trial data in the European Union which also adds to the complexity of processing health data from clinical trials. Such public disclosure obligations are provided in the new EU Clinical Trials Regulation (which is replacing the EU Clinical Trials Directive), EMA disclosure initiatives, and voluntary commitments by industry, among other sources. Failing to comply with these obligations could lead to government investigations, enforcement actions and significant penalties against us, harm to our reputation, and adversely impact our business and operating results. The uncertainty regarding the interplay between different regulatory frameworks, such as the Clinical Trials Regulation and the General Data Protection Regulation, further adds to the complexity that we face with regard to data protection regulation.

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, financial penalties and/or criminal prosecution.

Environmental Regulation

In connection with our research and development activities, we are subject to federal, state and local laws, rules, regulations and policies, both internationally and domestically, governing the use, generation, manufacture, storage, air

emission, effluent discharge, handling, treatment, transportation and disposal of certain materials, biological specimens and wastes and employee safety and health matters. Although we believe that we have complied with these laws, regulations and policies in all material respects and have not been required to take any significant action to correct any noncompliance, we may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our research and development involves the controlled use of hazardous materials, including, but not limited to, certain hazardous chemicals and radioactive materials. Although we believe that our safety procedures for handling and disposing of such materials comply with applicable law and regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability not covered by insurance could exceed our resources. See the risk factor, "*We may be subject to claims relating to improper handling, storage or disposal of hazardous 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, 2019, we employed 25 individuals in the United States, and all of them were full-time employees. Our employees do not have a collective bargaining agreement. We believe our relations with our employees are good.

Corporate Information

We were incorporated in the State of 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 under the symbol "CTIC". On January 24, 2018, we changed our state of incorporation from the State of Washington to the State of Delaware. Our principal executive offices are located at 3101 Western Avenue, Suite 800, Seattle, Washington 98121. Our telephone number is (206) 282-7100. Our website address is located at www.ctibiopharma.com; however, the information in, or that can be accessed through, our website is not part of this Annual Report on Form 10-K. 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. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding reports that we file or furnish electronically with them at www.sec.gov.

This Annual Report on Form 10-K includes our trademarks and registered trademarks, including "CTI BioPharma." Each other trademark, trade name or service mark appearing in this Annual Report on Form 10-K belongs to its holder.

Item 1A. Risk Factors

This report 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.

Risks Related to Our Business

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, 2019, we had an accumulated deficit of $2.3 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.

Our prospects are dependent on the successful development, regulatory approval and commercialization of pacritinib and we may be unsuccessful in such efforts.

Our business and future success depends on our ability to successfully develop, obtain regulatory approval for and commercialize pacritinib. Pacritinib, our sole product candidate in active development, has not yet received regulatory approval. Our ability to discover and develop drug candidates and to commercialize additional drug products will depend on our ability to:

- hire and retain key employees;
- identify high quality therapeutic targets;
- identify potential drug candidates;
- develop products internally or license drug candidates from others;
- identify and enroll suitable human subjects, either in the United States or abroad, for our clinical trials;
- complete laboratory testing;
- commence, conduct and complete safe and effective clinical trials on humans;
- obtain and maintain necessary intellectual property rights to our product candidates;
- obtain and maintain necessary regulatory approvals for our products, both in the United States and abroad;
- enter into arrangements with third parties to provide services or to manufacture our product candidates on our behalf;
- deploy sales and marketing resources effectively or enter into arrangements with third parties to provide these functions in compliance with all applicable laws; and
- obtain appropriate coverage and reimbursement levels for the cost of our products from governmental authorities, private health insurers and other third-party payors.

We have limited experience with many of the activities listed above and may not be successful in discovering, developing, or commercializing product candidates. Discovery and development of drug candidates are expensive, uncertain and time-consuming, and we do not know if our efforts will lead to discovery of any drug candidates that can be successfully developed and marketed. Of the compounds that we identify as potential drug products or that we may in-license from other companies, only a few, if any, are likely to lead to successful drug development programs and commercialized drug products.

In addition, obtaining regulatory approval requires substantial time, effort and financial resources, and without additional financing, we lack sufficient resources to pursue the development of pacritinib. We currently have no commitments or arrangements for any additional financing to fund the development and commercial launch of pacritinib, and we will need to seek additional funding, which may not be available or may not be available on favorable terms. The amount of financing we require is dependent on many factors, such as the number of clinical trial sites, the number of patients in the trial, the pace of patient enrollment and other matters that may impact clinical development, including changes to the trial that we may initiate or that may be requested by the FDA or other regulators, and there can be no assurance as to the amount of funding necessary to fund the development of pacritinib to completion. We could also seek another collaborative partnership for the development and commercialization of pacritinib, which may not be available on reasonable terms or at all. If we partner pacritinib, we may have to relinquish valuable economic rights and would potentially forgo additional economic benefits that could be realized if we continued the development and commercialization activities alone. Even if pacritinib receives approval from the FDA, EMA or other regulatory authorities, we would need to incur significant expenses to support the commercialization and launch of pacritinib, which investment may never be realized if sales are insufficient. As our sole product candidate in active development, our prospects are dependent upon the successful development, approval and commercialization of pacritinib. If we fail to obtain regulatory approval and successfully commercialize pacritinib, our business would be materially and adversely impacted as we have no other product candidates in active clinical development.

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 United States and elsewhere are numerous and include, among others, major multinational pharmaceutical companies, specialized biotechnology companies and universities and other research institutions. Specifically, if we are successful in bringing pacritinib to market, pacritinib may face competition from the currently approved JAK1/JAK2 inhibitors, Jakafi® / Jakavi® and Inrebic® (fedratinib). Celgene announced FDA approval of Inrebic® for the treatment of adult patients with intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis. Pacritinib may also face competition from momelotinib, which Sierra Oncology acquired from Gilead. In June 2019, Sierra Oncology announced that momelotinib was granted fast track designation by the FDA and launched a Phase 3 clinical trial in November 2019.

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 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.

Even if pacritinib or other compounds we may develop 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 pacritinib and other compounds we may develop may not be successful and, even if they are, the resulting products may never be successfully developed into commercial products or gain market acceptance among physicians, patients, healthcare payors or the medical community. Even if we are successful in our clinical trials and in obtaining other regulatory approvals, our 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, natural disasters or other catastrophic events, inconsistency in yields or variability in product characteristics;

- they may be uneconomical to produce;

- the timing of market introduction of pacritinib and other compounds we may develop and competitive products may be inopportune;

- political and legislative changes may make the commercialization of pacritinib, or any other product candidates we may develop in the future, more difficult;

- 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.

Uncertainty and speculation continue regarding the possible repeal of all or a portion of the Patient Protection and Affordable Care Act through legislative action, as well as possible changes to the regulations implemented under the Patient Protection and Affordable Care Act by the Department of Health and Human Services. The uncertainty this causes for the healthcare industry could also 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.

If we are unable to adequately prepare the market for the potential future commercialization of a product, we may not be able to generate product revenue once marketing authorization is obtained. We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to generate product revenue.

We currently have limited commercialization expertise, including sales, marketing or distribution capabilities. Advancing pacritinib through Phase 3 development and regulatory approval will require us to begin commercialization preparation activities and incur related expenses before we obtain final trial results and know whether PACIFICA will support regulatory approval. These activities will include, among other things, the development of an in-house marketing organization and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other companies to recruit, hire, train and retain qualified marketing and sales personnel. If we are unable to adequately prepare the market for the potential future commercialization of pacritinib, we may not be able to generate product revenue once marketing authorization is obtained.

Additionally, if we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements on commercially reasonable terms, or if we are able to do so, that they will have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

Pacritinib or other compounds we may develop may cause undesirable side effects or have other properties that could halt their development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

It is possible that the FDA or foreign regulatory authorities may not agree with our assessment of the safety profile of pacritinib or other compounds we may develop in the future. Undesirable side effects caused by pacritinib could cause us, institutional review boards, our contract research organizations, or CROs, the FDA or foreign regulatory authorities to interrupt, delay or discontinue development and could result in a clinical hold on any clinical trial, or the denial of

regulatory approval by the FDA or foreign regulatory authorities for any or all targeted indications. This, in turn, could prevent us from commercializing pacritinib and generating revenues from its sale. In addition, if pacritinib or other compounds we may develop in the future cause serious or unexpected side effects or are associated with other safety risks after receiving marketing approval, a number of potential significant negative consequences could result, including, but not limited to:

- regulatory authorities may withdraw their approval of this product;
- we may be required to recall the product, change the way it is administered, conduct additional clinical trials or change the labeling of the product;
- the product may be rendered less competitive and sales may decrease;
- our reputation may suffer generally both among clinicians and patients;
- we may be exposed to potential lawsuits and associated legal expenses, including costs of resolving claims;
- regulatory authorities may require certain labeling statements, such as warnings or contraindications or limitations on the indications for use, or impose restrictions on distribution in the form of a Risk Evaluation and Mitigation Strategy in connection with approval, if any;
- we may be required to change the way the product is administered or conduct additional preclinical studies or clinical trials; or
- we may be required to change or stop other ongoing clinical studies that may negatively impact the development of the agent for other indications.

If preliminary data demonstrate that any of our product candidates has an unfavorable safety profile and is unlikely to receive regulatory approval or be successfully commercialized, we may voluntarily suspend or terminate future development of such product candidate.

Any one or a combination of these events could prevent us from obtaining approval and achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product candidate, which in turn could delay or prevent us from generating significant revenues from the sale of the product.

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

We have substantial operating expenses associated with the development of pacritinib, and we have significant contractual payment obligations. We have incurred net operating losses every year since our formation. As of December 31, 2019, we had an accumulated deficit of $2.3 billion, and we expect to continue to incur net losses for the foreseeable future. Our available cash, cash equivalents and short-term investments were $33.7 million as of December 31, 2019. In March 2020, we received approximately $59.3 million in net proceeds from our rights offering. While we believe that our present financial resources, when combined with the net proceeds we received from the rights offering, will be sufficient to fund our operations into the first quarter of 2022, cash forecasts and capital requirements are subject to change as a result of a variety of risks and uncertainties. Developments in and expenses associated with our clinical trials and other research and development activities, including regulatory approval developments, our ability to consummate appropriate collaborations for development and commercialization activities, our ability to reach milestones triggering payments under applicable contractual arrangements, receive the associated payments, 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.

We will need to acquire additional funds in order to develop our business and continue the development of pacritinib. 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 raise capital is subject to a number of risks, uncertainties, constraints and consequences, including, but not limited to, the following:

• 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 authorized shares available for issuance, the potential difficulty of obtaining stockholder approval to increase authorized shares and the restrictive covenants under our secured term loan agreement;

• issuance of equity-based securities will dilute the proportionate ownership of existing stockholders;

• our ability to obtain further funds from any potential loan arrangements is limited by our existing loan and security 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;

• 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 so long as our non-affiliate public float does not exceed $75 million, our ability to file or use shelf registration statements on Form S-3 to raise capital will be limited; and

• if we are not listed on the Nasdaq or any stock exchange, whether due to a failure to regain compliance with the minimum bid price requirement (as discussed below) or otherwise, our ability to raise capital will be adversely impacted.

For these and other reasons, additional funding may not be available on favorable terms or at all. If we raise additional funds by issuing equity or equity-linked securities, our stockholders may experience dilution. 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 may never be able to generate significant product revenues.

We anticipate that, for at least the next several years, our ability to generate significant revenues and become profitable will be dependent on our ability to obtain regulatory approval for and successfully commercialize pacritinib. If we are unable to successfully commercialize our development stage or approved products as planned, our business, financial condition, operating results and prospects could be harmed.

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 our 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 or 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 GLP and cGMP or similar standards imposed by 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, and could subject us to penalties.

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 drug supply to successor vendors, 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 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 addition, in the event pacritinib is approved, we will initially have only one commercial supplier for pacritinib. We may in the future seek to qualify an additional manufacturer of pacritinib, but the process for qualifying a manufacturer, and seeking prior regulatory approval for a new manufacturer, can be lengthy and expensive and may not occur on a timely basis or at all. The use of single vendors for core operational activities, such as clinical trial operations, manufacturing and distribution, and the resulting lack of diversification, exposes 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.

We are party to a loan and security agreement that contains operating and financial covenants that may restrict our business and financing activities and we may be required to repay the outstanding indebtedness in an event of default, which could have a material adverse effect on our business.

In November 2017, we entered into a loan and security agreement with Silicon Valley Bank, which was amended in May 2018, the proceeds of which were partially used to repay in full all outstanding indebtedness under a prior loan and security agreement.

Borrowings under this loan and security agreement are secured by substantially all of our assets except intellectual property and subject to certain other exceptions. The loan and security agreement restricts our ability, among other things, to:

- sell, transfer or otherwise dispose of any of our business assets or property, subject to limited exceptions;
- make material changes to our business or management;

- enter into transactions resulting in significant changes to the voting control of our stock;
- make certain changes to our organizational structure;
- consolidate or merge with other entities or acquire other entities;
- incur additional indebtedness or create encumbrances on our assets;
- pay dividends, other than dividends paid solely in our common shares, or make distributions on and, in certain cases, repurchase our capital stock;
- enter into certain transactions with our affiliates;
- repay subordinated indebtedness; or
- make certain investments.

In addition, we are required under our loan agreement and security agreement to comply with various affirmative covenants. The covenants and restrictions and obligations in our loan and security agreement, as well as any future financing agreements that we may enter into, may restrict our ability to finance our operations, engage in business activities or expand or fully pursue our business strategies. Our ability to comply with these covenants may be affected by events beyond our control, and we may not be able to meet those covenants. A breach of any of these covenants, including a material adverse change in our business, operations or condition (financial or otherwise) could result in a default under the loan and security agreement, which could cause all of the outstanding indebtedness under the facility to become immediately due and payable.

If we are unable to generate sufficient cash available to repay our debt obligations when they become due and payable, either when they mature, or in the event of a default, we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our business operations and financial condition.

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 stockholder 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, particularly for companies like ours that have had a history of litigation. In addition, the cost of obtaining directors and officers liability insurance recently has been increasing while applicable coverage has been decreasing and self-insured retention levels have been increasing, which requires us to pay higher premiums and reserve for higher self-insurance retention levels. 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 may encounter difficulties in managing our expected growth and in expanding our operations successfully.

Advancing our lead product candidate, pacritinib, through the product development and, if approved, commercialization process will require us to develop or expand our development, regulatory, manufacturing, medical affairs, marketing and sales capabilities or contract with third parties to provide these capabilities for us. We must also successfully integrate the employees and operations related to the development of pacritinib. Maintaining additional relationships and managing our future growth

will impose significant added responsibilities on members of our management. We must be able to manage our development efforts and clinical trials effectively, hire, train and integrate additional management, development, medical affairs, administrative and sales and marketing personnel, improve our managerial, development, operational and finance systems, and expand our facilities, all of which may impose a strain on our administrative and operational infrastructure. Our future financial performance will depend, in part, on our ability to manage this growth effectively. We may not be able to accomplish these tasks; which failure could prevent us from successfully developing and commercializing pacritinib.

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, such as pacritinib. 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 may owe additional amounts for VAT related to our operations in Europe.

Our European operations are subject to the VAT which is usually applied to all goods and services purchased and sold throughout Europe. We historically carried out research and development activities in Italy and incurred value added tax, or VAT, from Italian suppliers on the acquisition of goods and services in Italy. This VAT should be considered as an input VAT credit. We treated the majority of our sales made in Italy without output VAT (on the basis that the supplies should be considered outside the scope of Italian VAT). This resulted in the value of input VAT exceeding the value of output VAT, and accordingly we submitted a refund claim for the VAT. The Italian Tax Authority, or the ITA, has challenged the treatment of the sales transactions and claimed that the sales transactions made by us should have been subject to output VAT. Our Italian VAT receivable was $4.4 million and $4.5 million as of December 31, 2019 and 2018, respectively.

On April 14, 2009, December 21, 2009 and June 25, 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, 2006 and 2007 are €0.6 million, €2.8 million and €0.9 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. The 2005 VAT assessment was decided in favor of the Company by the Italian Supreme Court, with no further potential liabilities for the Company. Further information pertaining to these cases can be found in Part II, Item 8, "Financial Statements and Supplementary Data - Notes to Consolidated Financial Statements - Note 16. Commitments and Contingencies" 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 €4.3 million, or approximately $4.8 million converted using the currency exchange rate as of December 31, 2019, including interest and penalties for the period lapsed between the date in which the assessments were issued and the date of effective payment.

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

We are currently, and may in the future be, subject to regulatory matters and legal claims, including possible securities, derivative, consumer protection and other types of proceedings pursued by individuals, entities or regulatory bodies. See Part II, Item 8, "Financial Statements and Supplementary Data - Notes to Consolidated Financial Statements - Note 16. Commitments and Contingencies," for more information regarding the regulatory matters and legal claims in which we are currently involved. Additionally, we were previously required to supply documents in response to a subpoena from the SEC in connection with an investigation into potential federal securities law violations; however, in August 2018, the SEC staff sent a letter stating that it had concluded its investigation of us, and, based on information it had as of that date, it did not intend to recommend an enforcement action against us. Litigation and regulatory proceedings are 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 and penalties 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. 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.

We cannot predict with certainty the eventual outcome of any litigation or regulatory proceedings we are or may be party to in the future. 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.

A variety of risks associated with international operations could materially adversely affect our business.

If we engage in significant cross-border activities, we will be subject to risks related to international operations, including:

- different regulatory requirements for initiating clinical trials and maintaining approval of drugs in foreign countries and multiple, differing and changing tax laws and regulations;
- reduced protection for intellectual property rights in certain countries;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, political instability or open conflict in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations of doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in North America;
- likelihood of potential or actual violations of domestic and international anti-corruption laws, such as the U.S. Foreign Corrupt Practices Act and the U.K. Bribery Act, or of U.S. and international export control and sanctions regulations, which likelihood may increase with an increase of operations in foreign jurisdictions;
- tighter restrictions on privacy, data protection, and the collection and use of data, including genetic material, may apply in jurisdictions outside of North America; and
- business interruptions resulting from global health epidemics, including the coronavirus disease, geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

If any of these issues were to occur, 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 our company. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards, or other pre-change tax attributes, to offset U.S. federal and state taxable income and taxes may be subject to limitations. 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.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of our domestic and foreign earnings. Any new taxes could adversely affect our domestic and

international business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us.

We could be subject to additional income tax liabilities.

We are subject to income taxes in the United States and certain foreign jurisdictions. We use significant judgment in evaluating our worldwide income-tax provision. During the ordinary course of business, we conduct many transactions for which the ultimate tax determination is uncertain. For example, our effective tax rates could be adversely affected by earnings being lower than anticipated in countries where we have lower statutory rates and higher than anticipated in countries where we have higher statutory rates, by changes in currency exchange rates, by changes in the valuation of our deferred tax assets and liabilities or by changes in the relevant tax, accounting and other laws, regulations, principles and interpretations. We are subject to audit in various jurisdictions, and such jurisdictions may assess additional income tax against us. Although we believe our tax estimates are reasonable, the final determination of tax audits and any related litigation could be materially different from our historical income-tax provisions and accruals. The results of an audit or litigation could have a material effect on our operating results or cash flows in the period or periods for which that determination is made.

We are subject to risk regarding currency exchange rate fluctuations associated with the translation of monetary amounts in foreign currencies into U.S. dollars.

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, will be affected by fluctuations in the value of the U.S. dollar as compared to the euro. Certain of our transactions 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. Furthermore, the referendum in the United Kingdom in June 2016, in which the majority of voters voted in favor of an exit from the European Union has resulted in increased volatility in the global financial markets and caused severe volatility in global currency exchange rate fluctuations that resulted in the strengthening of the U.S. dollar against the euro. 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.

Because there is a risk of product liability associated with developing and commercializing pharmaceuticals, 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. 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.

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 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 and third parties on which we rely, including our CROs and other service providers, depend on information technology systems to process, transmit and store electronic information in our day-to-day operations. The size and complexity of such information technology systems makes them vulnerable to damage from a cyber-attack, computer virus, malicious intrusion, breakdown, destruction, loss of data privacy or other significant disruption. Any such attacks or disruptions could result in the theft of intellectual property or other misappropriation of assets, result in the loss or disclosure of personal data, 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. We anticipate needing to make further investments in protecting against these matters going forward. There can be no assurance that these measures and efforts will prevent future interruptions, breakdowns, security breach or other incidents. If we or the third parties on which we rely 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 find it necessary or advisable to need to notify individuals, government agencies, or others, have difficulty preventing, detecting and controlling fraud, have disputes with customers, physicians and other health care professionals, face private litigation, be subject to negative publicity and harm to our reputation, face regulatory investigations and have regulatory sanctions or penalties imposed, have increases in operating expenses, incur expenses or lose revenues, be exposed to increased costs including remediation costs, disruption of operations, or increased cybersecurity protection costs, 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. Further, any security breach, interruption, or other breakdown may take longer than anticipated to remediate or otherwise address. The third parties on which we rely, including our CROs and other service providers, face similar risks with respect to interruptions, breakdowns, and other security incidents, and any incidents suffered by our service providers can result in similar impacts upon our business, results of operations, financial condition, prospects and cash flows.

While we maintain insurance, our insurance may be insufficient to cover all liabilities incurred by any security incidents. We also cannot be certain that our insurance coverage will be adequate for liabilities actually incurred, that insurance will continue to be available to us on economically reasonable terms, or at all, or that any insurer will not deny coverage as to any future claim. The successful assertion of one or more large claims against us that exceed available insurance coverage, or the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could have a material adverse effect on our business, including our financial condition, operating results, and reputation.

In addition, any security incident could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, including state data protection regulations and the EU General Data Protection Regulation and other regulations, the breach of which could result in significant penalties.

If we or the third parties upon whom we depend are be adversely affected by natural disasters or other events, our business continuity and disaster recovery plans may not adequately protect us from such interruptions.

Our headquarters are located in Seattle, Washington. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, power shortage, power outage, telecommunication failure, or other natural or man-made accidents or incidents could disrupt our operations. If a natural disaster or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We may not carry sufficient business interruption insurance to compensate us for all losses that may occur. The disaster recovery and business continuity plans we have in place may not be adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of a natural disaster or other event, which could have a material adverse effect on our business, and we could potentially lose valuable data and other items. The occurrence of any of the foregoing could have a material adverse effect on our business.

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.

Risks Related to the Development, Clinical Testing and Regulatory Approval of Our Product Candidates

The regulatory approval process for pacritinib has been subject to delay and uncertainty associated with clinical holds placed on pacritinib clinical trials in February 2016 and the withdrawal of the MAA in Europe. While the full clinical hold on pacritinib trials has been removed and the dose-exploration trial for pacritinib has been completed, further registration clinical trials for pacritinib could be subject to further delay or we could be prevented from further studying pacritinib or seeking its commercialization, which could have a material adverse effect on our business.

On February 8, 2016, the FDA notified us that a full clinical hold had been placed on pacritinib clinical trials. A full clinical hold is a suspension of the clinical work requested under an IND application. Under the full clinical hold, all patients on pacritinib at the time of the hold order were required to discontinue pacritinib immediately, and no new patients could be enrolled or start pacritinib as initial or crossover treatment. In January 2017, the full clinical hold was removed following review of our complete response submission which included, among other items, final Clinical Study Reports for both PERSIST-1 and 2 trials and FDA agreement on a proposed study design for a dose-exploration clinical trial. In July 2017, we enrolled the first patient in the PAC203 Phase 2 trial, which evaluated the safety and efficacy of three dosing schedules over 24 weeks in patients with myelofibrosis previously treated with ruxolitinib. In October 2018, we announced the continuation of the PAC203 Phase 2 trial without modification, following a planned second interim data review by the independent data monitoring committee, or IDMC. Following meetings with the FDA and EMA and in consultation with the IDMC, we eliminated the interim efficacy analysis and focused the second IDMC review, and all subsequent data reviews, on an assessment of safety. We completed a Type C meeting with the FDA in December 2018 and received input on key elements of the design of the PACIFICA Phase 3 trial in adult patients with myelofibrosis (primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis) and who have severe thrombocytopenia (platelet counts of less than 50,000/μL). In June 2019, we met with the FDA for a Type B, End-of-Phase 2a meeting regarding the continued development of pacritinib, and in September 2019, we initiated patient enrollment in a Phase 3 clinical trial, which we refer to as the PACIFICA Phase 3 trial. The current PACIFICA Phase 3 trial protocol provides for the comparison of the safety and efficacy of 200mg of pacritinib administered twice daily to physician's choice in adult patients with myelofibrosis and severe thrombocytopenia who are treatment-naïve or intolerant to ruxolitinib. The current PACIFICA Phase 3 protocol provides for the evaluation of 348 adult patients. Although the IDMC completed its fourth and final interim safety review in May 2019 and recommended that the PAC203 Phase 2 trial continue without modification, we cannot be certain that the PACIFICA Phase 3 trial will be sufficient for regulatory approval. Under the current protocol for the PACIFICA Phase 3 trial, the primary endpoint is the percentage of patients who achieve at least 35 percent reduction in spleen volume at Week 24 and secondary endpoints include, among others, the efficacy of pacritinib versus physician's choice therapy as assessed by the proportion of patients achieving at least a 50 percent reduction in total symptom score between baseline and Week 24. The primary analysis of SVR rates will be conducted once the 168th randomized patient has reached week 24, and this analysis will be used as the basis for an accelerated approval filing. An end-of-study efficacy analysis of the secondary endpoints TSS and OS will be conducted once the 348th randomized patient has reached week 24. Even if the current primary endpoint of the PACIFICA Phase 3 trial is achieved, the FDA may determine that the benefit/risk profile of pacritinib at the dose selected for the PACIFICA Phase 3 trial does not support approval based on the results of such trial, previously identified FDA concerns regarding safety and dosing limitations of pacritinib, including FDA concerns identified in connection with our previous PERSIST-1 and 2 trials, or otherwise. We also cannot be certain of the anticipated timing of the results from the PACIFICA Phase 3 trial. The FDA may request additional information regarding pacritinib or require us to pursue new clinical safety trials with changes to, among other things, protocol, study design or sample size, which could cause significant delays in completion of these studies.

Additionally, in July 2019 we announced an expanded access program, or EAP, for pacritinib for patients in the PAC203 Phase 2 trial. To facilitate the EAP, we have extended the PAC203 Phase 2 trial to enable trial participants to continue receiving pacritinib through the launch of our EAP. Patients who receive access to unapproved drugs through compassionate use or expanded access programs have life-threatening illnesses and generally have exhausted all other available therapies. The risk

for serious adverse events, including those which may be unrelated to pacritinib, in this patient population is high and could have a negative impact on the safety profile of pacritinib, which could cause significant delays or impair our ability to obtain regulatory approval for pacritinib.

Further, in the EMA's initial assessment report regarding our original MAA, the CHMP determined that the current application was not approvable because of major objections in the areas of efficacy, safety (hematological and cardiovascular toxicity) and the overall risk-benefit profile of pacritinib. After the filing of the original MAA, data from the second phase 3 trial of pacritinib, PERSIST-2, were reported. Following discussions with the EMA about how PERSIST-2 data might address the major objections and how to integrate the data into the current application, we withdrew the original MAA, and submitted a new application for the treatment of patients with myelofibrosis who have thrombocytopenia (platelet counts less than 100,000 per microliter). The new MAA was validated by the EMA in July 2017; however, we withdrew the MAA in February 2019 following interactions with CHMP, during which we learned that CHMP was likely to formally adopt a negative opinion in its evaluation of the application. CHMP indicated that the risk-benefit profile for pacritinib for the intended indication has not been sufficiently established with the clinical data available to date. For additional information regarding the status of our clinical development efforts, see Part I, Item 1. "Business".

The submission of new marketing applications, complying with any additional requests for information from the FDA or EMA or making any changes to study design or sample size may be time-consuming, expensive and delay or prevent our ability to continue to study pacritinib. If we are unable to adequately address any previous or further recommendations, concerns, requests, or objections in a manner satisfactory to the FDA or EMA, as applicable, in a timely manner, or at all, we could be delayed or prevented from seeking commercialization of pacritinib.

From time to time we may amend the clinical protocols for our product candidates to include additional objectives that could produce important clinical trial results critical to our overall development strategy. The protocol amendment process requires review and approval by several review bodies, including regulatory agencies and scientific, regulatory and ethics boards. These protocol amendments may not be accepted by the review bodies in the form submitted, or at all, which may delay our planned enhancements to the clinical development program and/or limit or change the type of information we may gather from our studies.

In early October 2019, we received correspondence from the FDA asking us to consider incorporating change in TSS at week 24 as a co-primary endpoint for the PACIFICA Phase 3 trial. In January 2020, we reached agreement on an accelerated approval pathway for pacritinib. We will be amending the PACIFICA pivotal Phase 3 trial protocol to allow for the primary analysis of SVR rates on the first 168 patients, with an end-of-study analysis of TSS and OS following the full enrollment of 348 patients. Such a change to the trial protocol will require an increase in the number of patients evaluated over the course of the trial, as well as the costs and time required to complete the trial. Making any changes to clinical protocols may be time-consuming, expensive and delay or prevent our ability to continue to study pacritinib. If we are unable to adequately address any previous or further recommendations, concerns, requests, or objections in a manner satisfactory to the FDA or EMA, as applicable, in a timely manner, or at all, we could be delayed or prevented from seeking commercialization of pacritinib.

An epidemic of the coronavirus disease is ongoing in China and other parts of the world and may result in significant disruptions to our clinical trials, which could have a material adverse effect on our business.

An epidemic of the coronavirus disease is ongoing in China and other parts of the world. As the outbreak is still evolving, much of its impact remains unknown. As of this filing, it is impossible to predict the effect and potential spread of the coronavirus disease in China and globally. The coronavirus disease may cause significant disruptions to our clinical trials. The patient populations that are eligible for our clinical trials are immune-compromised and are at higher risk for becoming infected with the coronavirus disease. If the coronavirus disease affects the parts of the world where we are conducting our clinical trials, and the patients involved with these clinical trials become infected with the coronavirus disease, we may have more AEs and deaths in our clinical trials as a result. We may also face difficulties enrolling patients in our clinical trials if the patient populations that are eligible for our clinical trials are impacted by the coronavirus disease. Additionally, if our clinical trial patients are unable to travel to our clinical trial sites as a result of quarantines or other restrictions resulting from the coronavirus disease, we may experience higher drop-out rates or delays in our clinical trials.

Additionally, travel restrictions have been implemented with respect to certain countries in an effort to contain the coronavirus disease, and several countries have expanded screenings of travelers. As travel restrictions are increasingly implemented and extended to other countries, we and our CROs may be unable to visit our foreign clinical trial sites and record the results of our clinical trials on a timely basis.

Any one or a combination of these events could have an adverse effect on the operation of and results from our clinical trials, which could prevent or delay us from obtaining approval for pacritinib.

If development and commercialization collaborations we enter into 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.

Historically, we have entered into development and commercialization collaborations to help advance the development of our product candidates. We evaluate collaboration opportunities from time to time and if we enter into such collaborations in the future, our business may become increasingly dependent on the success of such collaborations. Additionally, 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.

Compounds that appear promising in research and development may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities, and top-line or preliminary clinical trial data reports may ultimately differ from actual results once existing data are more fully evaluated, which could have a material adverse effect on our business.

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 failure of clinical testing to show potential products to be safe and efficacious, failure to demonstrate desired safety and efficacy characteristics in human clinical trials, and failure to demonstrate a benefit/risk profile sufficient to justify approval in the view of applicable regulatory authorities.

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 pacritinib 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 pacritinib may be harmed, which could harm our business, financial condition, operating results or prospects.

Pacritinib or other compounds we may develop may cause undesirable side effects or have other properties that could halt their development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.

It is possible that the FDA or foreign regulatory authorities may not agree with any assessment of the safety profile of pacritinib or other compounds we may develop in the future. Undesirable side effects caused by pacritinib could cause us, institutional review boards, our CROs, the FDA or foreign regulatory authorities to interrupt, delay or discontinue development and could result in a clinical hold on any clinical trial, or the denial of regulatory approval by the FDA or foreign regulatory authorities for any or all targeted indications. This, in turn, could prevent us from commercializing pacritinib and generating revenues from its sale. In addition, if pacritinib or other compounds we may develop in the future cause serious or unexpected side effects or are associated with other safety risks after receiving marketing approval, a number of potential significant negative consequences could result, including, but not limited to:

- regulatory authorities may withdraw their approval of this product;
- we may be required to recall the product, change the way it is administered, conduct additional clinical trials or change the labeling of the product;
- the product may be rendered less competitive and sales may decrease;

- our reputation may suffer generally both among clinicians and patients;
- we may be exposed to potential lawsuits and associated legal expenses, including costs of resolving claims;
- regulatory authorities may require certain labeling statements, such as warnings or contraindications or limitations on the indications for use, or impose restrictions on distribution in the form of a Risk Evaluation and Mitigation Strategy in connection with approval, if any;
- we may be required to change the way the product is administered or conduct additional preclinical studies or clinical trials; or
- we may be required to change or stop other ongoing clinical studies that may negatively impact the development of the agent for other indications.

If preliminary data demonstrate that any of our product candidates has an unfavorable safety profile and is unlikely to receive regulatory approval or be successfully commercialized, we may voluntarily suspend or terminate future development of such product candidate.

Any one or a combination of these events could prevent us from obtaining approval and achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product candidate, which in turn could delay or prevent us from generating significant revenues from the sale of the product.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including that we often face lengthy preparatory periods prior to the activation of clinical trial sites, the patient populations that are eligible for our clinical trials are small and unique and we must comply with specific regulatory requirements and timelines in each country in which we conduct our clinical trials. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. The enrollment of patients depends on many factors, including, but not limited to:

- the number and size of clinical trials for other product candidates in the same therapeutic area that are currently in clinical development, and our ability to compete with such trials for patients and clinical trial sites;
- the patient eligibility criteria defined in the protocols;
- the size of the specific patient populations such as those whose have low platelet counts, if required, or other defined subsets of a larger patient population;
- the risk that disease progression will result in death or clinical deterioration before the patient can enroll in clinical trials or before sufficient data has been collected such that the patient contributes no meaningful information for the clinical trial in which the patient is enrolled;
- the proximity and availability of clinical trial sites for prospective patients;
- the design of the trials, including the inclusion of a placebo or comparator arm in a trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

Our clinical trials compete with other clinical trials for product candidates that are in the same therapeutic area as our product candidate. This competition reduces the number and types of patients and qualified clinical investigators available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors or clinical trial sites may not allow us to conduct our clinical trial at such site if competing trials

are already being conducted there. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. We may also encounter difficulties finding a clinical trial site at which to conduct our trials. Moreover, because our product candidates are experimental, potential patients and their doctors may be inclined to use conventional therapies, such as surgery, radiation and chemotherapy, rather than enroll patients in any one of our clinical trials.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our planned clinical trials, which could prevent completion of these clinical trials and adversely affect our ability to advance the development of pacritinib or other compounds we may develop in the future.

We may be required to suspend, repeat or terminate our clinical trials if they are not conducted in accordance with regulatory requirements, the results are negative or inconclusive, or the trials are not well-designed.

Regulatory agencies, IRBs or data safety monitoring boards may at any time recommend the temporary or permanent discontinuation of our clinical trials or request that we cease using investigators in the clinical trials if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, or that they present an unacceptable safety risk to participants. Clinical trials must be conducted in accordance with Good Clinical Practices, or GCPs, or other applicable foreign regulatory authority guidelines. Clinical trials are subject to oversight by the FDA, foreign regulatory authorities and IRBs at the study sites where the clinical trials are conducted. In addition, clinical trials must be conducted with product candidates produced in accordance with applicable current Good Manufacturing Practices, or cGMPs. Clinical trial data may be rejected by the FDA or foreign regulatory authorities or clinical trials may be suspended by the FDA, foreign regulatory authorities, or us for various reasons, including, but not limited to:

- deficiencies in the conduct of the clinical trials, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols or to obtain or maintain clinical trial data in accordance with applicable regulatory requirements;
- deficiencies in the clinical trial operations or trial sites;
- the product candidate may have unforeseen adverse side effects;
- deficiencies in the trial designs necessary to demonstrate efficacy;
- fatalities or other adverse events arising during a clinical trial due to medical problems that may or may not be related to clinical trial treatments;
- the product candidates may not appear to be more effective than current therapies;
- the quality or stability of the product candidates may fall below acceptable standards; or
- failure to adequately demonstrate study conduct oversight, ensure data integrity, and that clinical study sites complied with the principles of GCPs.

On February 8, 2016, clinical studies under the IND for pacritinib were placed on a full clinical hold issued by the FDA. The FDA removed the full clinical hold in January 2017. Although we have not been asked by a regulatory agency, IRB or data safety monitoring board to temporarily or permanently discontinue a clinical trial since that clinical hold was removed, if we elect or are forced to suspend or terminate a clinical trial of any of our current or future product candidates, the commercial prospects for that product will be harmed and our ability to generate product revenue from that product may be delayed or eliminated. Furthermore, any of these events could prevent us or our partners from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our product candidates and impair our ability to generate revenue from the commercialization of these products either by us or by our collaboration partners.

If we are unable to expedite the regulatory approval process for pacritinib, we may be required to pursue strategic alternatives for the development of pacritinib and/or our company, which could have a material adverse effect on our business.

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 accelerated approval will be granted on any basis. Even if a product candidate is granted accelerated approval based on a surrogate endpoint, such accelerated approval is contingent on the sponsor's agreement to conduct one or more post-approval confirmatory trials that demonstrate a clinical benefit. 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 promptly conduct any required post-approval trial(s) with due diligence.

A priority review designation will direct the FDA's overall attention and resources to the evaluation of applications for drugs that, if approved, would be significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications. The FDA decides on the review designation for every application, and an applicant may also expressly request priority review. The FDA informs the applicant of a Priority Review designation within 60 days of the receipt of an original NDA. The FDA has a goal to (but is not required to) take action on an application designated as priority within six months after it has accepted an application for filing (rather than a goal of ten months for a standard review). 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, designation of a drug as priority does not alter the scientific/medical standard for approval or quality of evidence necessary for approval and does not affect the length of the clinical trial period. Also, receiving priority review from the FDA does not guarantee completion of review or approval within the targeted six-month cycle or thereafter.

As described above, in early October 2019, we received correspondence from the FDA asking us to consider incorporating change in total symptom score, or TSS, at week 24 as a co-primary endpoint for the PACIFICA Phase 3 trial. In January 2020, we reached agreement on an accelerated approval pathway for pacritinib. We will be amending the PACIFICA pivotal Phase 3 trial protocol to allow for the primary analysis of SVR rates on the first 168 patients, with an end-of-study analysis of TSS and OS following the full enrollment of 348 patients. If the primary endpoint of SVR is met following the planned review of data from the first 168 patients, we intend to submit an NDA under the FDA's regulations for the Accelerated Approval of New Drugs for Serious or Life-Threatening Illnesses, 21 C.F.R. subpart H, subject to review of all available efficacy and safety data. Conversion to a regular approval of pacritinib would be anticipated following the successful end-of-study assessment of the secondary efficacy endpoints, and the completion of post-marketing requirements. Based on the new trial design, we expect to report primary SVR data by the end of 2021, with a potential NDA filing in early 2022 if the SVR data is positive. Final study efficacy data is expected in 2023.

We or any collaboration partners we may work with may not obtain or maintain the regulatory approvals required to develop or commercialize pacritinib or any other compounds we may develop in the future, which could have a material adverse effect on our business.

We are subject to rigorous and extensive regulation by the FDA in the United States and by comparable agencies in other jurisdictions, including the EMA in the European Union. Pacritinib is currently in clinical development. Pacritinib may not be marketed in the United States until it has been approved by the FDA and may not be marketed in other jurisdictions until it has received approval from the appropriate foreign regulatory agencies, and requires development 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 pacritinib or any other product candidate on a timely basis, or at all. For instance, in February 2016, the FDA placed pacritinib on full clinical hold and the clinical hold was not removed until January 2017. 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. For example, in June 2019, we met with the FDA for a Type B, End-of-Phase 2a meeting regarding the continued development of pacritinib and, in September 2019, we initiated patient enrollment in a Phase 3 clinical trial, which we refer to as the PACIFICA Phase 3 trial. The current PACIFICA Phase 3 trial protocol provides for the comparison of the safety and efficacy of 200mg of pacritinib administered twice daily to physician's choice in adult patients with myelofibrosis and severe thrombocytopenia who are treatment-naïve or intolerant to ruxolitinib. The current PACIFICA Phase 3 protocol provides for the evaluation of 348 adult

patients. Although the IDMC completed its fourth and final interim safety review in May 2019 and recommended that the PAC203 Phase 2 trial continue without modification, we cannot be certain that the PACIFICA Phase 3 trial will be sufficient for regulatory approval. Under the current protocol for the PACIFICA Phase 3 trial, the primary endpoint is the percentage of patients who achieve at least 35 percent reduction in spleen volume at Week 24 and secondary endpoints include, among others, the efficacy of pacritinib versus physician's choice therapy as assessed by the proportion of patients achieving at least a 50 percent reduction in total symptom score between baseline and Week 24. The primary analysis of SVR rates will be conducted once the 168th patient has reached week 24, and this analysis will be used as the basis for an accelerated approval filing. An end-of-study efficacy analysis of the secondary endpoints TSS and OS will be conducted once the 348th patient has reached week 24. Even if the current primary endpoint of the PACIFICA Phase 3 trial is achieved, the FDA may determine that the benefit/risk profile of pacritinib at the dose selected for the PACIFICA Phase 3 trial does not support approval based on the results of such trial, previously identified FDA concerns regarding safety and dosing limitations of pacritinib, including FDA concerns identified in connection with our previous PERSIST-1 and 2 trials, or otherwise. 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 cGMPs;
- a compound may fail to comply with regulatory requirements; or
- such regulatory agencies might change their approval policies or adopt new regulations.

In particular, if pacritinib is 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.

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 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 United States to continue. In the United States, 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 and impose new and/or increased taxes. In addition, members of the Trump administration, including the President, have made public statements criticizing pricing practices within the pharmaceutical industry, indicating that they may seek to increase pricing pressures on the pharmaceutical industry.

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 governments and insurance companies, health

maintenance organizations and other payors of health care costs, to contain or reduce costs of health care may affect the availability of capital, as well as our future revenues and profitability or those of our potential customers, suppliers and collaborative partners.

Post-approval or authorization regulatory reviews and obligations often result in significant expense and marketing limitations, and any failure to satisfy such ongoing obligations 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, promoted and advertised. Approved or authorized products 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 for post-approval studies. 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 the PIX306 trial of PIXUVRI required by the EMA. In July 2018, we and Les Laboratoires Servier and Institut de Recherches Internationales Servier, or collectively, Servier, announced that PIXUVRI plus rituximab did not show a statistically significant improvement in progression-free survival compared to gemcitabine plus rituximab; in February 2019, we and Servier mutually agreed to terminate our collaborative agreement; and in September 2019, we transferred and assigned all of our rights and responsibilities for PIXUVRI globally to Servier pursuant to an Amended and Restated Asset Purchase Agreement, or the Asset Purchase Agreement, which eliminates our ability to receive future payments and royalties related to PIXUVRI. For more information on the termination of our agreement with Servier, see Part I, Item 1, “Business - License Agreements - Servier” of our Annual Report on Form 10-K for the year ended December 31, 2018.

Any other failure to comply with applicable regulations could result in warning or untitled letters from the FDA, 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 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, or uses not approved by the FDA. This means that in the United States, we may not make claims about the safety or effectiveness of our products and may not proactively discuss or provide information on the uses of our products that are not approved by the FDA, unless otherwise allowed by the FDA by policy or other guidance.

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. 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.

We are subject to numerous laws and regulations related to health care fraud and abuse, false claims, anti-bribery and anti-corruption laws, such as the U.S. Anti-Kickback Statute and Foreign Corrupt Practices Act of 1977, in which violations of these laws could result in substantial penalties and prosecution.

In the United States, 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. Any allegation, investigation, or violation of these domestic health care fraud and abuse laws could result in government or internal investigations, significant diversion of resources, exclusion from government health care reimbursement programs and the curtailment or restructuring of our operations, significant fines, penalties, or other financial consequences, any of which may ultimately have a material adverse effect on our business.

For our sales and operations outside the United States, we are similarly subject to various heavily-enforced anti-bribery and anti-corruption laws, such as the FCPA, as amended, U.K. Bribery Act, and similar laws around the world. These laws generally prohibit U.S. companies and their employees and intermediaries from offering, promising, authorizing or making improper payments to foreign government officials for the purpose of obtaining or retaining business or gaining any advantage. We face significant risks if we, which includes our third parties, fail to comply with the FCPA and other anti-corruption and anti-bribery laws.

We leverage various third parties to sell our products and conduct our business abroad. We, our commercial partners and our other third-party intermediaries, including collaborators and licensees, may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities (such as in the context of obtaining government approvals, registrations, or licenses or sales to government owned or controlled health care facilities, universities, institutes, clinics, etc.) and may be held liable for the corrupt or other illegal activities of these third-party business partners and intermediaries, our employees, representatives, contractors, partners, collaborators, licensees and agents, even if we do not explicitly authorize such activities. In many foreign countries, particularly in countries with developing economies, it may be a local custom that businesses engage in practices that are prohibited by the FCPA or other applicable laws and regulations. To that end, while we have adopted and implemented internal control policies and procedures and employee training and compliance programs to deter prohibited practices, such compliance measures ultimately may not be effective in prohibiting our employees, representatives, contractors, partners, collaborators, licensees, agents and other third parties or intermediaries from violating or circumventing our policies and/or the law.

Any violation of the FCPA, other applicable anti-bribery, anti-corruption laws, and anti-money laundering laws could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and, in the case of the FCPA, suspension or debarment from U.S. government contracts, which could have a material and adverse effect on our reputation, business, operating results and prospects. In addition, responding to any enforcement action or related investigation may result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees.

Our employees, collaborators and other personnel may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading, which could have a material adverse impact on our business.

We are exposed to the risk of fraud or other misconduct by our employees, collaborators, vendors, principal investigators, consultants and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA, EMA and other regulators, providing inaccurate or misleading information to the FDA, EMA and other regulators, failure to comply with data privacy and security and healthcare fraud and abuse laws and regulations in the United States and abroad, reporting inaccurate financial information or clinical data or failing to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices.

Various laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Any misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, officers, directors, agents and representatives, including consultants, but it is not always possible to identify and deter misconduct, and the precautions we

take to detect and prevent misconduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

We are subject to a variety of laws regarding data privacy and protection, which carry potentially significant penalties for non-compliance.

Laws regarding data privacy and protection may impose obligations with respect to safeguarding the privacy, use, security, transmission and other processing of individually identifiable health information and other personal data that we may collect, retain, and otherwise process.

In the United States, these laws include HIPAA and HITECH. In addition to possible civil and criminal penalties imposed by federal authorities for HIPAA violations, state attorneys general are authorized to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' 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. In some instances, individuals also may file civil actions related to alleged data privacy and protection violations, seeking damages, injunctions, attorneys' fees, costs, and other relief.

As the General Data Protection Regulation entered into force recently, guidance on implementation and compliance practices are still being developed, updated or otherwise revised. Although the General Data Protection Regulation is intended to provide for a high level of harmonization across the European Union, Member States may still implement certain variations, and data protection authorities may enforce the General Data Protection Regulation and national laws differently, which adds to the complexity of processing personal data in the European Union.

Furthermore, there is a trend towards the public disclosure of clinical trial data in the European Union, which also adds to the complexity of processing health data from clinical trials. Such public disclosure obligations are provided in the new EU Clinical Trials Regulation (which is replacing the EU Clinical Trials Directive), EMA disclosure initiatives, and voluntary commitments by industry, among other sources.

The uncertainty regarding the interplay between different regulatory frameworks, such as the Clinical Trials Regulation and the General Data Protection Regulation, further adds to the complexity that we face with regard to data protection regulation.

Failing to comply with these obligations could lead to government investigations and enforcement actions and significant penalties against us, harm to our reputation, and adversely impact our business and operating results. For example, the General Data Protection Regulation provides for significant penalties that may be assessed in the event of noncompliance, up to the greater of 20 million or 4% of worldwide annual revenues. We may be subject to negative publicity, have increases in operating expenses, incur expenses or lose revenues, be exposed to increased costs including remediation costs and disruption of operations, 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.

Additionally, we rely on the use of standard contractual clauses approved by the European Commission in order to transfer personal data from the European Union to the United States. These standard contractual clauses are subject to legal challenge in the European Union, and it is possible that they will be invalidated or modified. In such event, we could need to implement alternative measures to transfer personal data from the European Union to the United States, which we may be unable to do in a commercially reasonable manner or at all.

Risks Related to Our Intellectual Property

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

We have acquired or licensed intellectual property from third parties, including patent applications and patents relating to pacritinib and other product candidates. Some of our product development programs depend on our ability to maintain rights under license agreements relating to this licensed intellectual property. Each licensor of this intellectual property has the power to terminate its agreement with us if we fail to meet our obligations under that agreement. We may

not be able to meet all of our obligations under each of these agreements. If we default under any of these agreements, we may lose our right to market and sell any products based on the intellectual property licensed under these agreements and may be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection. Bankruptcy may result in the termination of these agreements.

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 would enable our competitors to use the inventions that are the subject of such patents in competition with us.

We dedicate significant resources to protecting our intellectual property, which is important to our business. We have filed numerous patent applications in the United States and various other countries seeking protection of inventions originating from our research and development, and we have also obtained rights to various patents and patent applications under licenses with third parties and through acquisitions. We have pending patent applications or issued patents in the United States and foreign countries directed to pacritinib and other product candidates. Patents for the individual products extend for varying periods according to the date of the patent filing or grant and the legal term of patents in the various countries where patent protection is obtained.

Our U.S. and foreign method and composition of matter patents for pacritinib expire as follows: U.S. patents expire in May 2028 (method) / January 2029 (compound) / March 2030 (salt); foreign patents expire in November 2026 (method and compound) / December 2029 (salt). We expect our U.S. and foreign patent applications for use of pacritinib for treating transplant rejection will expire in 2036.

Each patent may be eligible for future patent term restoration of up to five years under certain circumstances. However, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before such candidates are commercialized which may prevent us from obtaining any regulatory extensions if all the patents covering our candidates are expired prior to regulatory approval of the corresponding product candidate. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Also, regulatory exclusivity tied to the protection of clinical data may be complementary to patent protection. During a period of regulatory exclusivity, competitors generally may not use the original applicant's data as the basis for a generic application. In the United States, the data protection generally runs for five years from first marketing approval of a new chemical entity, extended to seven years for an orphan drug indication. Pacritinib has orphan drug designation for myelofibrosis in the United States and the European Union.

In addition to our patent rights, we rely, to the extent possible, trade secret and contractual protections for our know-how and other unpatented technology. Ultimately, to the extent any of our product candidates are not protected by patent rights our competitors would be free to use inventions embodied in our product candidates to which they have access to 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, including the inventions embodied in our product candidates. Our success depends in part on our ability to:

- obtain and maintain patent protection for our product candidates and technologies both in the United States and other countries;
- maintain our know-how, unpatented technologies and trade secrets; and
- prevent others from infringing on our patent and other intellectual 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, the U.S. PTO, has not established a consistent policy regarding the breadth of claims that it will allow in pharmaceutical and biotechnology patents. If the U.S. PTO allows broad claims in patents that are issued, the number and cost of patent interference or derivation proceedings in the United States and the risk of infringement litigation may increase. If the U.S. PTO 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 product candidates or technologies. In addition, patents issued to us or our licensors may be challenged and subsequently narrowed, invalidated, circumvented or found unenforceable. Litigation, interference or derivation proceedings or other governmental proceedings that we may become involved in with respect to our patent rights or our proprietary technologies or the proprietary technologies of others could result in substantial cost to us.

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

Patent litigation is widespread in the pharmaceutical and biotechnology industry, and any patent litigation in which we become involved could harm our business.

Costly litigation might be necessary for us 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 product candidates in an effort to guide the design and development of our products to avoid infringement, but we may not conduct a search or, if we do, it may not be 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 pacritinib infringes upon the rights of any third parties of which we are aware nor do we believe that third parties are materially infringing any of our owned or licensed patents; however, there can be no assurance that our product candidates or technologies 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 that are asserted against us, lawsuits in which such claims could be asserted or challenges could be made take significant time, may, even if resolved in our favor, be expensive and divert management attention from other business activities requiring attention. Uncertainties resulting from the initiation and continuation of any litigation relating to intellectual property could limit our ability to continue our operations.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our employees' former employers.

Many of our employees were previously employed at universities or other life sciences companies, including our competitors or potential competitors. Although no claims against us are currently pending, we or our employees may be subject

to claims that we or these employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of the former employers of these employees. Litigation may be necessary to defend against these claims. If we are unsuccessful in our defense of such claims, in addition to paying monetary damages, we may lose the right to use valuable intellectual property rights relating to our product candidates or technologies. A loss of key research personnel work product could hamper or prevent our ability to commercialize certain potential products, which could severely harm our business. Even if we are successful in defending against these claims, the litigation involving these claims could result in substantial costs and be a distraction to management.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

Our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve technological and legal complexity, and obtaining and enforcing patents is costly, time consuming, and inherently uncertain. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our and our licensors' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts, and the U.S. PTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our and our licensors' ability to obtain new patents or to enforce existing patents and patents we and our licensors or may obtain in the future.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting, enforcing and defending patents on our product or product candidates in all countries throughout the world would be prohibitively expensive, and our or our licensors' intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we and our licensors may not be able to prevent third parties from practicing our and our licensors' inventions in all countries outside the United States, or from selling or importing products made using our and our licensors' inventions in and into the United States or other jurisdictions. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we and our licensors have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product and product candidates and our and our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us and our licensors to stop the infringement of our and our licensors' patents or marketing of competing products in violation of our and our licensors' proprietary rights generally. Proceedings to enforce our and our licensors' patent rights in foreign jurisdictions could result in substantial costs and divert our and our licensors' efforts and attention from other aspects of our business, could put our and our licensors' patents at risk of being invalidated or interpreted narrowly and our and our licensors' patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors. We or our licensors may not prevail in any lawsuits that we or our licensors initiate and the damages or other remedies awarded, if any, may not be commercially meaningful.

Risks Related to Our Common Stock

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

The market price for securities of biopharmaceutical and biotechnology companies, including ours, historically has been highly volatile, and the market from time to time has experienced significant price and volume fluctuations that are unrelated to the operating performance of such companies. For example, during the 12-month period ended March 5, 2020, our stock price ranged from a low of $0.63 to a high of $1.93. 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 or required amendments to our clinical trial protocols;

•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;

•halting or suspension of trading in our common stock on the Nasdaq;

•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; and

•general economic and market conditions.

We may not be able to maintain our listing on the Nasdaq Capital Market, or the Nasdaq, or trading on the Nasdaq 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.

We regained compliance in December 2019 with the minimum $1.00 bid price requirement, after receiving notice of non-compliance from the Nasdaq in June 2019.

We have in the past and may in the future fail to comply with the Nasdaq requirements. If our common stock ceases to be listed for trading on the Nasdaq for failure to comply with the minimum $1.00 per share closing bid price requirement or for any other 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 may constitute an event of default under our loan and security agreement 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, our ability to raise capital will be adversely impacted. Additionally, for

so long as our non-affiliate public float does not exceed $75 million, the amount of securities that we may sell pursuant to registration statements on Form S-3 will be limited to the equivalent of one-third of our public float, which will limit our ability to file or use shelf registration statements on Form S-3 and further limit our ability to raise capital. We have relied significantly on shelf registration statements on 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. Trading in our common stock has been halted or suspended on the Nasdaq in the past and may also be halted or suspended in the future on the Nasdaq due to market or trading conditions at the discretion of the Nasdaq. Any halt or suspension in the trading in our common stock may negatively impact the market price of our common stock.

Future financing, strategic and other activities may require us to increase the number of authorized shares in our certificate of incorporation. An inability to secure requisite stockholder approval for such increases could materially and adversely impact our ability to fund our operations.

At our 2018 annual meeting of stockholders, we sought and received approval of an amendment to our certificate of incorporation to increase the total number of authorized shares and the total number of authorized shares of our common stock by 20 million. We proposed the increase in authorized shares due to the fact that we anticipate the need to issue additional shares of common stock in the future in connection with one or more of the following:

- financing transactions, such as public or private offerings of common stock or derivative securities;
- our equity incentive plans and employee stock purchase plan;
- debt, warrant or other equity restructuring or refinancing transactions, such as debt or warrant exchanges or offerings of new convertible debt or modifications to existing securities, or as payments of interest on debt securities;
- acquisitions, strategic partnerships, collaborations, joint ventures, restructurings, divestitures, business combinations and strategic investments;
- corporate transactions, such as stock splits or stock dividends; and
- other corporate purposes that have not yet been identified.

At our 2019 annual meeting of stockholders, our stockholders approved an amendment to our certificate of incorporation to increase the total number of authorized shares and the total number of authorized shares of common stock by 30 million and we may seek approval to increase the number of authorized shares again in the future. Without such increases in the number of authorized shares, we may be constrained in our ability to raise capital when needed, and may lose important business opportunities, including to competitors, which could adversely affect our financial performance, growth and ability to continue our operations. As opportunities or circumstances that require prompt action frequently arise, we believe that the delay necessitated for stockholder approval of a specific issuance could result in a material and adverse impact on our business.

Even if we obtain approval to further increase the number of authorized shares, we are required under the Nasdaq Marketplace Rules to obtain stockholder 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 a minimum price as set forth in the Nasdaq Marketplace Rules 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 stockholder approval for any future issuance that requires stockholder approval pursuant to applicable rules and regulations. If we are unable to obtain financing or our financing options are limited due to stockholder approval difficulties, such failure may harm our ability to continue operations.

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

Provisions of our certificate of incorporation and bylaws may have the effect of deterring or delaying attempts by our stockholders 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 stockholder nominations and proposals;

- the ability of our Board of Directors to amend our bylaws without stockholder approval; and

- the ability of our Board of Directors to issue shares of preferred stock without stockholder approval upon the terms and conditions and with the rights, privileges and preferences as our Board of Directors may determine.

In addition, as a Delaware corporation, we are subject to Delaware's anti-takeover statute, which imposes restrictions on some transactions between a corporation and certain interested stockholders. 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. Our shareholder rights plan expired pursuant to its terms on December 2, 2018, and was not replaced; however, the Board may, subject to its fiduciary duties under applicable law, choose to implement a similar plan in the future. Likewise, because our principal executive offices are located in Washington, the anti-takeover provisions of the Washington Business Corporation Act may apply to us under certain circumstances now or in the future. These provisions prohibit a "target corporation" from engaging in any of a broad range of business combinations with any stockholder constituting an "acquiring person" for a period of five years following the date on which the stockholder became an "acquiring person."

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

If we fail to maintain effective internal controls over financial reporting, we may not be able to accurately report our financial results, which could adversely affect our investors' confidence, our business and the trading prices of our securities.

If we fail to maintain the adequacy of our internal controls, we may be unable to provide financial information in a timely and reliable manner within the time periods required for our financial reporting under SEC rules and regulations. Internal controls over financial reporting may not prevent or detect misstatements or omissions in our financial statements because of their inherent limitations, including the possibility of human error, the circumvention or overriding of controls or fraud. We have recently implemented a reduction in force, which may result in changes to our internal controls over financial reporting. The changes could relate to different employees performing internal control activities than those who have previously performed those activities or revisions to our actual control activities as we evaluate the appropriate internal control structure after our workforce reduction. A changing internal control environment increases the risk that our system of internal controls is not designed effectively or that internal control activities will not occur as designed. The occurrence of or failure to remediate a significant deficiency material weakness may adversely affect our reputation and business and the market price of shares of our common stock.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could cause you to incur dilution and could cause the market price of our common stock to fall.

As of December 31, 2019, options to purchase 10,953,805 shares of our common stock with a weighted-average exercise price of $2.56 per share were outstanding. The exercise of any of these options would result in dilution to current stockholders. Further, because we will need to raise additional capital to fund our operations and clinical development programs, we may in the future sell substantial amounts of common stock or securities convertible into or exchangeable for common stock. Pursuant to our equity incentive plans, our compensation committee is authorized to grant equity-based incentive awards to our employees, directors and consultants. Future option grants and issuances of common stock under our share-based compensation plans may have an adverse effect on the market price of our common stock.

These future issuances of common stock or common stock-related securities, together with the exercise of outstanding options and any additional shares of common stock issued in connection with acquisitions, if any, may result in further dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to those of holders of our common stock.

If securities or industry analysts do not publish research reports about our business, or if they issue an adverse opinion about our business, the market price of our common stock and the trading volume of our common stock could decline.

The trading market for our common stock is influenced by the research and reports that securities or industry analysts publish about us or our business. If too few securities or industry analysts cover our company, the market price of our common stock would likely be negatively impacted. If securities and industry analysts who cover us downgrade our common stock or

publish inaccurate or unfavorable research about our business, the market price of our common stock would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause the market price of our common stock and the trading volume of our common stock to decline.

Our management team has broad discretion as to the use of the net proceeds from public or private equity or debt financings and the investment of these proceeds may not yield a favorable return. We may invest the proceeds in ways with which our stockholders disagree.

We have broad discretion in the application of the net proceeds to us from our "at the market" equity offering program and 2020 rights offering. You may not agree with our decisions, and our use of the proceeds and our existing cash and cash equivalents and marketable securities may not improve our results of operation or enhance the value of our common stock. The results and effectiveness of the use of proceeds are uncertain, and we could spend the proceeds in ways that you do not agree with or that do not improve our results of operations or enhance the value of our common stock. Our failure to apply these funds effectively could have a material adverse effect on our business, delay the development of our product candidates and cause the market price of our common stock to decline. In addition, until the net proceeds are used, they may be placed in investments that do not produce significant income or that may lose value.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We currently lease approximately 66,000 square feet of space at 3101 Western Avenue in Seattle, Washington. The lease commenced in May 2012 and expires in April 2022. Approximately 44,000 square feet of space at this address has been subleased commencing December 2017 and ending April 2022. 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

Except as set forth below, we are not engaged in any material legal proceedings. From time to time, we may become involved in litigation relating to claims arising from the ordinary course of business. Except as set forth below, we believe that there are no claims or actions pending against us currently, the ultimate disposition of which would have a material adverse effect on our consolidated results of operation, financial condition or cash flows.

In April 2009, December 2009 and June 2010, the Italian Tax Authority, or the ITA, issued notices of assessment to CTI - Sede Secondaria, or CTI (Europe), based on the ITA's audit of CTI (Europe)'s value added tax, or 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). The assessments, including interest and penalties, for the years 2003, 2006 and 2007 are €0.6 million, €2.8 million and €0.9 million, respectively. We believe that the services invoiced were non-VAT taxable consultancy services and that the VAT returns are correct as originally filed. We have appealed all the assessments and are defending ourselves against the assessments both on procedural grounds and on the merits of the cases, 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 VAT Assessment**. In June 2013, the Regional Tax Court issued decision no. 119/50/13 in regards to the 2003 VAT Assessment, which accepted the October 2012 appeal of the ITA and reversed a 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 VAT Assessment**. In January 2018, the Italian Supreme Court issued decision No. 02250/2018 which (i) rejected the April 2013 appeal of the ITA, (ii) confirmed the October 2012 decision of the Regional Tax Court (127/31/2012), which fully accepted the merits of our earlier appeal and confirmed that no penalties could be imposed against us, and (iii) due to the novelty of the arguments at stake, compensated the legal expenses incurred by the parties. The ITA may

not use any ordinary means of appeal against the Italian Supreme Court decision, and we have applied for a refund based on the guidance from the ITA.

• **2006 and 2007 VAT Assessments**. In November 2013, the ITA appealed to the Italian Supreme Court an April 2013 decision of the Regional Tax Court (57/35/13), that fully rejected the merits of an earlier ITA appeal, declared that no penalties could be imposed against us and found the ITA liable to pay us approximately €12,000, as a partial refund of legal expenses we incurred.

No hearing has been fixed yet for either the 2003 VAT Assessment or consolidated 2006 and 2007 VAT Assessment cases.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock is currently traded under the symbol "CTIC" on the Nasdaq Capital Market.
As of March 5, 2020, there were 112 stockholders of record of our common stock.

Dividend Policy

We have never declared or paid 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.

Item 6. Selected Financial Data

As a smaller reporting company, we are not required to provide the information requested by this item pursuant to Item 301(c) of Regulation S-K.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes appearing elsewhere in this Annual Report on Form 10-K. In addition to historical information, some of the information contained in this discussion and analysis or set forth elsewhere in this report, including information with respect to our plans and strategy for our business, future financial performance, expense levels and liquidity sources, includes forward-looking statements that involve risks and uncertainties. You should read the "Risk Factors" section of this report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a biopharmaceutical company focused on the acquisition, development and commercialization of novel targeted therapies for blood-related cancers that offer a unique benefit to patients and their healthcare providers. Our goal is to build a profitable company by generating income from products we develop and commercialize, either alone or with partners. We concentrate our efforts on treatments that target blood-related cancers where there is an unmet medical need. In particular, we are focused on evaluating pacritinib, our sole product candidate currently in active development, for the treatment of adult patients with myelofibrosis.

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.

We have funded our operations through the sale of equity securities, funding received from our licensees and collaborators and debt financing. For 2019 and 2018, we recognized revenues of approximately $3.3 million and $26.3 million, respectively, consisting of license and contract revenues. We do not expect to have sustained profitability for the foreseeable future. We had a net loss of $40.0 million for the year ended December 31, 2019 and an accumulated deficit of $2.3 billion as of December 31, 2019, primarily from expenses incurred in connection with our research programs and from general and administrative costs associated with our operations.

We expect to continue to incur significant expenses and operating losses for at least the next 12 to 24 months. We anticipate that our expenses will increase as we:

- continue our research and clinical development of pacritinib;
- seek regulatory and marketing approvals for pacritinib if we successfully complete the remainder of its anticipated clinical development; and
- maintain, protect and expand our intellectual property portfolio.

Factors Affecting Our Performance

Research and Development Activities

We will need to commit significant time and resources to develop our current and any future product candidates. Our sole product candidate currently in active development, pacritinib, is currently in clinical development. 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 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.

Regulatory agencies, including the FDA and EMA, regulate many aspects of a product candidate's life cycle, including research and development and preclinical and clinical testing. We or regulatory authorities may suspend clinical trials at any time on the basis that the participants are being exposed to unacceptable health risks. In addition, based on our interactions with regulatory authorities we have, and may in the future, seek changes to the protocol of clinical trials if we believe such changes may enhance the probability of approval or are necessary to protect patient safety. Such changes, if any, would impact the size, timing and cost of clinical development. Even if a product candidate progresses successfully through initial human testing in clinical trials, it may fail in later stages of development, including as a result of a failure to adequately demonstrate safety or efficacy to the satisfaction of applicable regulatory authorities. 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 any product candidate will be completed, if ever, or when we will be able to begin commercializing pacritinib to generate material net cash inflows. In order to generate revenue from any of these compounds, any product candidate needs to be developed to a stage that will enable us to commercialize, sell or license related marketing rights to third parties.

We may 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 any of our product candidates or the ultimate product development costs.

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" of this Annual Report on Form 10-K.

Financial Summary

Our revenues are generated from license and development services agreements. Our license and contract revenues primarily reflect milestone and royalty payments under such agreements. We had PIXUVRI sales prior to April 2017 when we entered into the Amended and Restated Exclusive License and Collaboration Agreement, or the Restated Agreement, with Servier, which was terminated in February 2019. All of our rights and responsibilities for PIXUVRI were transferred and assigned globally to Servier in September 2019. Total revenues were $3.3 million and $26.3 million for the years ended December 31, 2019 and 2018, respectively. Loss from operations was $40.7 million and $32.9 million for the years ended December 31, 2019 and 2018, respectively. Results of operations may vary substantially from year to year and from quarter to quarter and, as a result, you should not rely on them as being indicative of our future performance.

As of December 31, 2019, we had cash, cash equivalents and short-term investments of $33.7 million.

Results of Operations

Years ended December 31, 2019 and 2018

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

		Years ended December 31,	
		2019	2018
Servier	Milestone revenue	$ -	$ 3,397
	Development services revenue	99	1,759
	Royalty revenue	446	765
	Other revenue	2,800	369
	Total Servier revenue	3,345	6,290
Teva	Milestone revenue	-	20,000
	Total Teva revenue	-	20,000
Total		$ 3,345	$ 26,290

Servier. License and contract revenues for the year ended December 31, 2019 included $0.1 million of development services revenue relating to the reimbursement of certain regulatory agency costs. Other revenue for the year ended December 31, 2019 included a one-time revenue in the amount of $2.2 million recognized in connection with the Asset Purchase Agreement with Servier. In addition, other revenue for the year ended December 31, 2019 included $0.6 million of revenue related to transition period activities pursuant to the terms of the Termination Agreement with Servier. See Part II, Item 8, Financial Statements and Supplementary Data - Notes to Consolidated Financial Statements - Note 10. Collaboration, Licensing and Milestone Agreements - *Servier* for further details.

License and contract revenues for the year ended December 31, 2018 included €3.0 million of milestone revenue (or $3.4 million using the currency exchange rate as of the date the milestone was achieved) relating to the attainment of a regulatory milestone in November 2018 under the Restated Agreement. Development services revenue for the year ended December 31, 2018 included $1.4 million of revenue recognized from the upfront payments we received in connection with the Restated Agreement and the Exclusive License and Collaboration Agreement, or the Original Agreement, with Servier. In addition, we recorded revenue of $0.3 million during the year ended December 31, 2018 for the reimbursement of pharmacovigilance expenses under the Restated Agreement. Other revenue for the year ended December 31, 2018 relates to the sale of PIXUVRI drug product to Servier, which had previously been written off.

Teva. There were no milestone revenues from Teva for the year ended December 31, 2019. For the year ended December 31, 2018, we recognized $10.0 million in revenue upon the achievement of a milestone in January 2018 for FDA approval of TRISENOX for first line treatment of acute promyelocytic leukemia. In addition, we recognized $10.0 million in revenue upon the achievement of a worldwide net sales milestone of TRISENOX in December 2018, which was included in *Receivables from license and development services arrangements* in our consolidated balance sheet as of December 31, 2018.

Operating costs and expenses

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,	
	2019	2018
Compounds under development:		
Pacritinib	$ 16,706	$ 17,991
PIXUVRI	1,290	5,998
Unallocated operating expenses	6,107	12,447
Research and preclinical development	4	31
Total research and development expenses	$ 24,107	$ 36,467

Costs for our compounds include external direct expenses such as principal investigator fees, charges from contract research organizations, or 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 United States and Europe, as well as upfront license fees for acquired

technology. Subsequent to receiving a positive opinion for conditional approval of PIXUVRI in the European Union 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 costs and an allocation of occupancy, depreciation and amortization expenses associated with developing these compounds. We are not able to capture the total cost of each compound because we do not allocate operating expenses to all of our compounds. External direct costs incurred by us through December 31, 2019 were $163.0 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) and $135.1 million for PIXUVRI (excluding costs prior to our 2004 merger with Novuspharma S.p.A, formerly a public pharmaceutical company located in Italy). We do not anticipate incurring additional material expenses related to PIXUVRI as the Restated Agreement with Servier was terminated in February 2019.

Research and development expenses decreased to $24.1 million for the year ended December 31, 2019 compared to $36.5 million for the year ended December 31, 2018. The decrease of $12.4 million between periods was primarily attributable to a $6.0 million decrease in personnel costs, which includes a $5.0 million decrease attributable to the reduction of our workforce in the fourth quarter of 2018, a $4.7 million decrease in PIX306 clinical trial close-out costs as well as decreased PIXUVRI activities associated with our entry into the Asset Purchase Agreement with Servier in September 2019, a $0.4 million decrease in other operating expenses and a $1.3 million net decrease in pacritinib development costs, which was primarily related to the PAC203 Phase 2 dosing clinical trial, partially offset by an increase due to the commencement of the PACIFICA Phase 3 trial.

Selling, general and administrative expenses. Selling, general and administrative expenses were $19.2 million for the year ended December 31, 2019 compared to $22.1 million for the year ended December 31, 2018. The decrease of $2.9 million between periods was primarily due to a $1.2 million decrease in professional and consulting services, a $1.3 million decrease in personnel costs due to the reduction of our workforce in the fourth quarter of 2018, a $0.5 million provision for excess, obsolete or unsalable inventory in 2018 and a $0.3 million net decrease in travel and other expenses, offset by a $0.4 million increase in tax expenses.

Restructuring expenses. In December 2018, we announced a plan to reduce our workforce in order to improve efficiencies, reduce costs within the organization and preserve capital for pacritinib development. As a result, we recorded $0.8 million and $0.7 million of employee separation costs for the year ended December 31, 2019 and 2018, respectively. The restructuring activities were substantially completed as of March 31, 2019 and as such, we do not anticipate additional employee separation costs. See Part II, Item 8, "Financial Statements and Supplementary Data - Notes to Consolidated Financial Statements - Note 11. Restructuring Activities" for further details.

Non-operating income and expenses

Interest income. Interest income was $1.2 million for each of the years ended December 31, 2019 and 2018, primarily related to our short-term investments and cash equivalent securities.

Interest expense. Interest expense was $1.0 million and $1.2 million for the year ended December 31, 2019 and 2018, respectively. Interest expense was primarily related to our secured term loan. The decrease between periods primarily relates to a lower loan principal balance outstanding in 2019 compared to 2018. See Part II, Item 8, "Financial Statements and Supplementary Data - Notes to Consolidated Financial Statements - Note 7. 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, 2019 and 2018 was primarily related to our senior secured term loan.

Foreign exchange loss. We had a foreign exchange loss of $0.3 million and $0.2 million for the years ended December 31, 2019 and 2018, respectively. The variances were due to fluctuations in foreign currency exchange rates, primarily related to operations in our European subsidiary as well as assets and liabilities denominated in foreign currencies.

Other non-operating income. Other non-operating income for the year ended December 31, 2019 and 2018 included gains of $1.3 million and $4.3 million, respectively, on the dissolution of our foreign entities, primarily relating to the release of cumulative translation adjustment.

Deemed dividends on preferred stock. There were no deemed dividends on preferred stock for the year ended December 31, 2019. Deemed dividends on preferred stock of approximately $0.1 million for the year ended December 31, 2018 were

related to the issuance of Series O Preferred Stock in February 2018. See Part II, Item 8, “Financial Statements and Supplementary Data - Notes to Consolidated Financial Statements - Note 8. Equity Transactions” for further details.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our operations from proceeds from sales and issuance of equity securities, payments pursuant to license and collaboration agreements and the incurrence of debt. As of December 31, 2019, we had $33.7 million in cash, cash equivalents and short-term investments.

Rights offering. In March 2020, we completed our rights offering through the distribution of subscription rights to holders of our common stock and Series O Preferred Stock, or the Rights Offering. The proceeds from the Rights Offering, net of offering costs, were approximately $59.3 million.

Common stock offering. In February 2018, we offered and sold 23.0 million shares of common stock at a $3.00 per share price. The net proceeds from the offering, after deducting underwriting commissions and discounts and other offering costs were approximately $64.2 million.

Loan agreement. In November 2017, we entered into a Loan and Security Agreement with Silicon Valley Bank, or SVB, which agreement was amended in May 2018, the proceeds of which were partially used to repay in full all outstanding indebtedness under a prior loan and security agreement. As of December 31, 2019, we had an outstanding principal balance under our secured term loan agreement of $10.2 million. We are required to pay interest plus principal payments in the approximate amount of $0.5 million per month until November 1, 2021, with the final principal plus interest payment totaling approximately $0.4 million as well as a back-end fee of $1.4 million. 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 secured term loan agreement requires us to comply with restrictive covenants, including those that limit our operating flexibility and ability to borrow additional funds. Among other events, a failure to make a required loan payment, an uncured covenant breach or a material adverse change in our business, operations or condition (financial or otherwise) could lead to an event of default, and in such case, all amounts then outstanding may become due and payable immediately.

Historical Cash Flows

Net cash used in operating activities. Net cash used in operating activities was $27.8 million during the year ended December 31, 2019 compared to $39.8 million for the same period in 2018. During the year ended December 31, 2019, we received €2.0 million pursuant to the Asset Purchase Agreement with Servier (or $2.2 million using the currency exchange rate as of the date of cash receipt). During this period, we also collected €3.0 million (or $3.3 million using the currency exchange rate as of the date of cash receipt) relating to the attainment of a regulatory milestone in November 2018 under the Restated Agreement with Servier and $10.0 million from Teva relating to the December 2018 achievement of a worldwide net sales milestone of TRISENOX. During the year ended December 31, 2018, we collected $10.0 million from Teva for the achievement of the milestone related to FDA approval of TRISENOX for first line treatment of acute promyelocytic leukemia. After taking these cash receipts into account, the remaining decrease in net cash used in operating activities was primarily due to a decrease in research and development activities between the two periods.

Net cash provided by (used in) investing activities. Net cash provided by investing activities was $28.1 million during the year ended December 31, 2019, and net cash used in investing activities was $30.5 million during the same period in 2018. The change was primarily attributable to a decrease in purchases of short-term investments as well as an increase in proceeds from maturities of short-term investments during the year ended December 31, 2019.

Net cash (used in) provided by financing activities. Net cash used in financing activities was $5.6 million for the year ended December 31, 2019, and net cash provided by financing activities was $63.5 million during the same period in 2018. The change was primarily due to the net proceeds from our February 2018 offering of common stock as well as repayment of debt in 2019.

In October 2016, we resumed primary responsibility for the development and commercialization of pacritinib as a result of the termination of the Pacritinib License Agreement. We currently have no commitments for additional financing to fund the development and commercial launch of pacritinib, and we may need to seek additional funding. The development and commercialization of a major product candidate like pacritinib without a collaborative partner will require a substantial amount of our time and financial resources, and as a result, we could experience a decrease in our liquidity and a new demand on our

capital resources. For additional information relating to the Pacritinib License Agreement, see Part I, Item 1, "Business - License Agreements - Baxalta" of this Annual Report on Form 10-K.

Capital Resources

We have prepared our consolidated 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, as of the date of the filing of this Annual Report on Form 10-K, our present financial resources, together with the net proceeds we received from the completion of our rights offering in March 2020, will be sufficient to fund our operations into the first quarter of 2022. However, we have incurred net losses since inception and expect to generate losses for the foreseeable future, primarily due to research and development costs for pacritinib. Because of our reacquisition of worldwide rights for pacritinib, we are no longer eligible to receive cost sharing or milestone payments for pacritinib's development from Baxalta, and losses related to research and development for pacritinib have increased. 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, 2019, our available cash, cash equivalents and short-term investment totaled $33.7 million. We had an outstanding principal balance under our secured term loan agreement of $10.2 million as of December 31, 2019.

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, following our and Servier's mutual termination of our collaborative agreement, we are no longer eligible to receive additional revenues or payments from Servier relating to PIXUVRI. Although we received a $10.0 million milestone payment from Teva in February 2019, which was recognized as revenue in 2018, relating to the achievement of a worldwide net sales milestone of TRISENOX, the achievement of the remaining milestones is uncertain at this time. Due to these and other factors, the foregoing forecast for the period for which we will have sufficient resources to fund our operations may be inaccurate.

Capital Requirements

We will need to acquire additional funds in order to develop our business and continue the development of pacritinib. 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 stockholders 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 and/or reduce our selling, general and administrative expenses, be unable to attract and retain highly qualified personnel, be unable to obtain and maintain contracts necessary to continue our operations and at affordable rates with competitive terms, 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. Our future capital requirements will depend on many factors, including:

- developments in and expenses associated with our research and development activities;
- changes in manufacturing;
- our clinical development plans and any changes that we may initiate or that may be requested by the FDA or other regulators;
- regulatory approval developments;
- our ability to generate sales of any approved product;
- our ability to execute appropriate collaborations for development and commercialization activities;
- our ability to reach milestones triggering payments under certain of our contractual arrangements;
- acquisitions of compounds or other assets;
- litigation and other disputes;

- competitive market developments; and
- other unplanned business developments.

Off-Balance Sheet Arrangements

We do not presently have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or for another contractually narrow or limited purpose.

Impact of Inflation

In the opinion of management, inflation has not had a material effect on our operations.

Critical Accounting Estimates

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

Revenue Recognition

We recognize license and contract revenue under license and development services arrangements that are within the scope of Accounting Standards Codification 606 - *Revenue From Contracts With Customers,* or ASC 606, which was adopted on January 1, 2018. The terms of these agreements may contain multiple, distinct performance obligations, which may include licenses and research and development activities. We apply the five-step model to arrangements that meet the definition of a contract under ASC 606 including when it is probable that we will collect the consideration we are entitled to in exchange for goods or services we transfer to the customer. At contract inception, we identify goods or services promised within each contract and determine those that are performance obligations and assess whether each promised good or service is distinct. Prior to recognizing revenue, we make estimates of the transaction price, including any variable consideration that is subject to a constraint. Amounts of variable consideration are included in the transaction price to the extent that it is probable that there will not be a significant reversal in the amount of cumulative revenue recognized and when the uncertainty associated with the variable consideration is subsequently resolved. Variable consideration may include nonrefundable upfront license fees, payments for research and development activities, reimbursement of certain third-party costs, payments based upon the achievement of specified milestones and royalty payments based on product sales derived from the contract. These assessments as well as the determination of variable consideration required under ASC 606 involve significant judgment and estimates made by us, which impacts the amount and timing of revenue we recognize in our consolidated results of operations.

Leases

Our operating lease liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As our leases do not provide a readily determinable implicit rate of return, we use our incremental borrowing rate to derive the present value of lease payments, which is the rate of interest that we would have to pay to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. The other areas that would involve our significant judgment and estimates include the determination of whether an arrangement is a lease or contains a lease, identification of lease modifications and reassessment events, and impairment of right-of-use assets.

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 United States Treasury securities at maturity with an equivalent term. We have not declared or paid 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.

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.

Contingencies

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.

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

As a smaller reporting company, we are not required to provide the information requested by this item pursuant to Item 305(e) of Regulation S-K.

Item 8. Financial Statements and Supplementary Data

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of CTI BioPharma Corp.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of CTI BioPharma Corp. (the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2019, and the related notes (collectively referred to as the consolidated) financial statements. In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with U.S. generally accepted accounting principles.

Adoption of New Accounting Standard

As discussed in Note 1 to the consolidated financial statements, the Company has changed its method for accounting for leases in 2019 due to the adoption of ASU No. 2016-02, Leases (Topic 842).

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. 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, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2018.

Seattle, Washington
March 12, 2020

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

	December 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	$ 31,144	$ 36,439
Short-term investments	2,522	30,599
Receivables from license and development services arrangements	-	13,679
Prepaid expenses and other current assets	1,914	1,775
Total current assets	35,580	82,492
Property and equipment, net	1,235	1,793
Other assets	9,465	5,547
Total assets	$ 46,280	$ 89,832
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ -	$ 4,498
Accrued expenses	11,606	12,852
Current portion of long-term debt	4,812	4,812
Other current liabilities	2,070	893
Total current liabilities	18,488	23,055
Long-term debt, less current portion	4,455	9,267
Other liabilities	5,407	4,571
Total liabilities	28,350	36,893
Commitments and contingencies (Note 18)		
Stockholders' equity:		
Preferred stock, $0.001 par value per share:		
Authorized shares - 33,333		
Series O Preferred Stock, 12,575 shares issued and outstanding as of December 31, 2019 and 2018 (Aggregate liquidation preference of $25,150 as of December 31, 2019 and 2018)	-	-
Common stock, $0.001 par value per share:		
Authorized shares - 131,500,000 and 101,500,000 as of December 31, 2019 and 2018, respectively		
Issued and outstanding shares - 57,979,725 and 57,986,075 as of December 31, 2019 and 2018, respectively	58	58
Additional paid-in capital	2,299,186	2,294,025
Accumulated other comprehensive loss	(11,993)	(10,643)
Accumulated deficit	(2,263,563)	(2,224,746)
Total CTI stockholders' equity	23,688	58,694
Noncontrolling interest	(5,758)	(5,755)
Total stockholders' equity	17,930	52,939
Total liabilities and stockholders' equity	$ 46,280	$ 89,832

See accompanying notes.

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

	Year Ended December 31,	
	2019	2018
License and contract revenues	$ 3,345	$ 26,290
Operating costs and expenses:		
Research and development	24,107	36,467
Selling, general and administrative	19,155	22,062
Restructuring expenses	794	660
Total operating costs and expenses	44,056	59,189
Loss from operations	(40,711)	(32,899)
Non-operating income (expense):		
Interest income	1,172	1,219
Interest expense	(1,002)	(1,209)
Amortization of debt discount and issuance costs	(521)	(525)
Foreign exchange loss	(281)	(233)
Other non-operating income	1,320	4,295
Total non-operating income, net	688	3,547
Net loss before noncontrolling interest	(40,023)	(29,352)
Noncontrolling interest	3	32
Net loss	(40,020)	(29,320)
Deemed dividends on preferred stock	-	(80)
Net loss attributable to common stockholders	$ (40,020)	$ (29,400)
Basic and diluted net loss per common share	$ (0.69)	$ (0.52)
Shares used in calculation of basic and diluted net loss per common share	57,974	56,073

See accompanying notes.

CTI BIOPHARMA CORP.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)

	Year Ended December 31,	
	2019	2018
Net loss before noncontrolling interest	$ (40,023)	$ (29,352)
Other comprehensive (loss) income:		
Foreign currency translation adjustments	(2,323)	(2,843)
Unrealized foreign exchange gain (loss) on intercompany balance	957	(1,513)
Net unrealized gain (loss) on securities available-for-sale	16	(15)
Other comprehensive loss	(1,350)	(4,371)
Comprehensive loss	(41,373)	(33,723)
Comprehensive loss attributable to noncontrolling interest	3	32
Comprehensive loss attributable to CTI	$ (41,370)	$ (33,691)

See accompanying notes.

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

	Preferred Stock		Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Noncontrolling	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Loss	Deficit	Interest	Equity
Balance at January 1, 2018	1	$ -	42,969	$ 43	$ 2,223,388	$ (6,272)	$ (2,195,346)	$ (5,723)	$ 16,090
Issuance of common stock, net of issuance costs	-	-	23,000	23	64,147	-	-	-	64,170
Exchange of common stock for preferred stock	12	-	(8,000)	(8)	8	-	-	-	-
Value of beneficial conversion features related to preferred stock	-	-	-	-	80	-	(80)	-	-
Equity-based compensation	-	-	-	-	6,369	-	-	-	6,369
Noncontrolling interest	-	-	-	-	-	-	-	(32)	(32)
Other	-	-	17	-	33	-	-	-	33
Net loss for the year ended December 31, 2018	-	-	-	-	-	-	(29,320)	-	(29,320)
Other comprehensive loss	-	-	-	-	-	(4,371)	-	-	(4,371)
Balance at December 31, 2018	13	$ -	57,986	$ 58	$ 2,294,025	$ (10,643)	$ (2,224,746)	$ (5,755)	$ 52,939
Cumulative effect adjustments related to adoption of accounting standards	-	-	-	-	(7)	-	1,203	-	1,196
Equity-based compensation	-	-	-	-	5,166	-	-	-	5,166
Other	-	-	(6)	-	2	-	-	-	2
Noncontrolling interest	-	-	-	-	-	-	-	(3)	(3)
Net loss for the year ended December 31, 2019	-	-	-	-	-	-	(40,020)	-	(40,020)
Other comprehensive loss	-	-	-	-	-	(1,350)	-	-	(1,350)
Balance at December 31, 2019	13	$ -	57,980	$ 58	$ 2,299,186	$ (11,993)	$ (2,263,563)	$ (5,758)	$ 17,930

See accompanying notes.

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

	Year Ended December 31,	
	2019	**2018**
Operating activities		
Net loss before noncontrolling interest	$ (40,023)	$ (29,352)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share-based compensation expense	5,166	6,369
Depreciation and amortization	546	593
Gain on dissolution of foreign entities	(1,332)	(4,288)
Noncash interest expense	521	525
Noncash rent benefit	(653)	(1,424)
Other	191	794
Changes in operating assets and liabilities:		
Receivables from license and development services arrangements	13,674	(12,389)
Prepaid expenses and other assets	1,120	(163)
Accounts payable and accrued expenses	(5,463)	923
Deferred revenue and other	(1,569)	(1,412)
Net cash used in operating activities	(27,822)	(39,824)
Investing activities		
Purchases of property and equipment	-	(33)
Purchases of short-term investments	(11,018)	(42,067)
Proceeds from maturities of short-term investments	39,150	11,610
Net cash provided by (used in) investing activities	28,132	(30,490)
Financing activities		
Proceeds from common stock offering, net of issuance costs	-	64,170
Cash paid for offering costs	(275)	(268)
Repayment of debt	(5,333)	(444)
Payment of tax withholding obligations related to restricted stock awards	-	(21)
Proceeds from stock option exercises and ESPP stock issuance	1	54
Net cash (used in) provided by financing activities	(5,607)	63,491
Effect of exchange rate changes on cash and cash equivalents	2	44
Net decrease in cash and cash equivalents	(5,295)	(6,779)
Cash and cash equivalents at beginning of year	36,439	43,218
Cash and cash equivalents at end of year	$ 31,144	$ 36,439

See accompanying notes.

CONSOLIDATED STATEMENTS OF CASH FLOWS-(Continued)
(In thousands)

	Year Ended December 31,	
	2019	**2018**
Supplemental disclosure of cash flow information		
Cash paid during the period for interest	$ 1,044	$ 1,197
Supplemental disclosure of noncash financing and investing activities		
Exchange of common stock and preferred stock for preferred stock	$ -	$ 24,080

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 subsidiary, 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 for blood-related cancers that offer a unique benefit to patients and their healthcare providers. Our goal is to build a profitable company by generating income from products we develop and commercialize, either alone or with partners. We concentrate our efforts on treatments that target blood-related cancers where there is an unmet medical need. In particular, we are focused on evaluating pacritinib, our sole product candidate currently in active development, for the treatment of adult patients with myelofibrosis.

We operate in a highly regulated and competitive environment. The manufacturing and marketing of pharmaceutical products requires approval from, and is subject to, ongoing oversight by the Food and Drug Administration, or the FDA, in the United States, the European Medicines Agency, or the EMA, in the European Union, or the EU, 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 subsidiary, CTI Life Sciences Limited, or CTILS, until its dissolution in November 2019. As of December 31, 2019, we also had an approximately 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.

Reincorporation Merger

In January 2018, we effected a reincorporation merger, or the Reincorporation, following approval by our Board and our shareholders at our Special Meeting of Shareholders held on January 24, 2018, for the sole purpose of changing the state of incorporation from the State of Washington to the State of Delaware. Prior to the Reincorporation, our preferred stock and common stock had no par value. Subsequent to the Reincorporation, our preferred stock and common stock each have a par value of $0.001 per share. There was no impact on our assets and liabilities as a result of the Reincorporation.

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 within one year after the date the consolidated financial statements are issued. Our management evaluates whether there are conditions or events, considered in aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements are issued.

In March 2020, as discussed in Note 18. Subsequent Events, we completed the closing of our rights offering and received approximately $59.3 million in net proceeds. Based on our evaluation completed pursuant to Accounting Standards Update No. 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern,* we expect that, as of the date of the filing of this Annual Report on Form 10-K, our present financial resources, together with the net proceeds we received from our rights offering, will be sufficient to meet our obligations as they come due and to fund our operations into the first quarter of 2022. Accordingly, the conditions that previously raised substantial doubt about our ability to continue as a going concern as of the date of the filing of our Quarterly Report on Form 10-Q as of and for the three and nine months ended September 30, 2019, have been alleviated.

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. In October 2016, we resumed primary responsibility for the development and commercialization of pacritinib as a result of the termination of a Development, Commercialization and License Agreement, or the Pacritinib License Agreement, with Baxalta and are no longer eligible to receive cost sharing or milestone payments for pacritinib's development. We have incurred a net operating loss every year since our formation. As of December 31, 2019, we had an accumulated deficit of $2.3 billion, and we expect to

incur net losses for the foreseeable future. Our available cash, cash equivalents and short-term investments were $33.7 million as of December 31, 2019.

We will need to acquire additional funds in order to develop our business and continue the development of pacritinib. 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 obtained through the sale of such shares or otherwise may not be sufficient, available on favorable terms or at all. If additional funds are raised by issuing equity securities, substantial dilution to existing stockholders 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, be unable to obtain and maintain contracts necessary to continue our operations and at affordable rates with competitive terms, refrain from making our contractually required payments when due (including debt payments) and/or may be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection. The amount of financing we require is dependent on many factors, such as the number of clinical trial sites, the number of patients in the trial, the pace of patient enrollment and other matters that may impact clinical development, including changes to the trial that we may initiate or that may be requested by the FDA or other regulators, and there can be no assurance as to the amount of funding necessary to fund the development of pacritinib to completion. In addition, our ability to comply with covenants under the loan and security agreement with Silicon Valley Bank, or SVB, may be affected by events beyond our control, and we may not be able to meet those covenants. A breach of any of these covenants, including a material adverse change in our business, operations or condition (financial or otherwise) could result in an event of default under the loan and security agreement, which could cause all of the outstanding indebtedness under the facility to become immediately due and payable. The accompanying consolidated financial statements do not include adjustments, if any, that may result from the outcome of this uncertainty.

Use of Estimates

The preparation of financial statements in conformity with U.S. Generally Accepted Accounting Principles, or GAAP, requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. For example, estimates include assumptions used in calculating share-based compensation expense, accruals, the allocation of operating expenses, provision for loss contingencies, the fair value of financial instruments, our tax provision and related valuation allowance, determining the useful lives of fixed assets and potential impairment of long-lived assets. Actual results could differ from those estimates.

Certain Risks, Uncertainties and Concentrations

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 values of the assets and liabilities, as well as the reported amounts of revenues and expenses are affected by fluctuations in the value of the U.S. dollar as compared to the euro. Certain of our transactions 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. We review our foreign currency risk periodically along with hedging options to mitigate such risk.

We source our drug products for 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 obtain the materials or services from other suppliers, manufacturers or distributors, certain research and development and sales activities may be delayed.

Fair Value of Financial Instruments

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at 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-Valuations based on unadjusted quoted prices for identical assets and liabilities in active markets.
- Level 2-Valuations based on observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data.

- Level 3-Valuations based on unobservable inputs that are supported by little or no market activity, reflecting our own assumptions. These valuations require significant judgment or estimation.

Our cash equivalents and short-term investments are recorded at fair value. As of December 31, 2019 and 2018, our cash, cash equivalents and short-term investments consisted of cash, money market funds, U.S. government and agency securities and corporate debt securities.

We measure the fair value of money market funds based on the closing price reported by a fund sponsor from an actively traded exchange. We value all other securities using broker quotes that utilize observable market inputs. We did not hold cash, cash equivalents and short-term investments categorized as Level 3 assets as of December 31, 2019 and 2018. The following table summarizes, by major security type, our cash, cash equivalents and short-term investments that are measured at fair value on a recurring basis and are categorized using the fair value hierarchy (in thousands):

	December 31, 2019				December 31, 2018
	Cost or Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Estimated Fair Value	Total Estimated Fair Value
Cash	$ 188	$ -	$ -	$ 188	$ 919
Level 1 securities:					
Money market funds	28,957	-	-	28,957	20,525
Level 2 securities:					
U.S. government and agency securities	2,522	-	-	2,522	15,213
Corporate debt securities	1,999	-	-	1,999	30,381
Total cash, cash equivalents and short-term investments	$ 33,666	$ -	$ -	$ 33,666	$ 67,038

There were no other financial instruments requiring fair value measurement as of December 31, 2019 and 2018.

At December 31, 2019 and 2018, the carrying value of our 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, 2019 and 2018 based on borrowing rates for similar loans and maturities.

Cash and Cash Equivalents

We consider all highly liquid instruments with original maturities of three months or less at the time acquired to be cash equivalents.

Receivables from License and Development Services Arrangements

Our receivables relate to amounts payable or reimbursable to us under the terms of license and development services arrangements with our partners. The receivable balance as of December 31, 2018 related primarily to a milestone receivable from Servier for the attainment of a regulatory milestone in November 2018 as well as a milestone receivable from Teva for the attainment of a worldwide net sales milestone of TRISENOX in December 2018. There were no such receivables as of December 31, 2019. Receivables are reviewed for collectability whenever circumstances indicate that the carrying amount of the receivable may not be recoverable. We had no allowance for doubtful accounts from license and development services arrangements as of December 31, 2019 and 2018.

Italian Value Added Tax Receivable

We historically carried out research and development activities in Italy and incurred value added tax, or VAT, from Italian suppliers on the acquisition of goods and services in Italy. This VAT should be considered as an Input VAT credit. We treated the majority of our sales made in Italy without output VAT (on the basis that the supplies should be considered outside the scope of Italian VAT). This resulted in the value of input VAT exceeding the value of output VAT, and accordingly we submitted a refund claim for the VAT. The Italian Tax Authority, or the ITA, has challenged the treatment of the sales transactions and claimed that the sales transactions made by us should have been subject to output VAT. Our Italian VAT receivable was approximately $4.4 million and $4.5 million as of December 31, 2019 and 2018, respectively. Substantially all of our VAT receivable is included in *Other assets*. As disclosed in Note 16. Commitments and Contingencies, the ITA assessed

us for additional VAT payments for services we provided in Italy, which we do not believe we owe. We have not recorded an amount in the financial statements for this contingent liability as we do not believe the potential payment of up to €4.3 million (or approximately $4.8 million converted using the currency exchange rate as of December 31, 2019), to the ITA is probable at this time.

Leases

As discussed in *Recently Adopted Accounting Standards* below, we adopted Accounting Standards Codification, or ASC, Topic 842 - *Leases,* on January 1, 2019. Under ASC 842, we determine if an arrangement is a lease at inception. We recognize a right-of-use asset and lease liability on the balance sheet for all leases with a term longer than 12 months. Leases are classified as operating or finance at lease commencement, which will affect the pattern and classification of expense recognition in our consolidated statements of operations.

Right-of-use assets represent the right to use an underlying asset for the lease term and lease liabilities represent the obligation to make lease payments arising from the lease. Operating lease liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As our leases do not provide a readily determinable implicit rate of return, we use our incremental borrowing rate to derive the present value of lease payments, which is the rate of interest that we would have to pay to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment.

An operating lease right-of-use asset is measured at the amount of the lease liability, adjusted for prepaid or accrued lease payments, lease incentives received, unamortized initial direct costs and the impairment of the right-of-use asset. A lease may include options to extend or terminate the lease. When it is reasonably certain that we will exercise such an option, it is considered in the lease term. Right-of-use assets are tested for impairment in the same manner as long-lived assets used in operations. Leasehold improvements are capitalized at cost and amortized over the lesser of their expected useful life or the lease term.

Lease expense for operating leases is recognized on a straight-line basis over the lease term as part of *Research and development* expenses and *Selling, general and administrative* expenses in our consolidated statements of operations. Right-of-use assets are included in *Other assets.* The current portion of lease liabilities and the non-current portion of lease liabilities are included in *Other current liabilities* and *Other liabilities*, respectively, in our consolidated balance sheets.

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 lives 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. If an impairment is indicated, the asset is written down to its estimated fair value.

Contingencies

We record liabilities associated with loss contingencies to the extent that we conclude that 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 10. Collaboration, Licensing and Milestone Agreements and Note 16. Commitments and Contingencies for further information regarding our current contingencies.

Revenue Recognition

ASC 606 - *Revenue from Contracts with Customers* applies to all contracts with customers, except for contracts that are within the scope of other authoritative literature. Under ASC 606, we recognize revenue when a customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to be entitled in exchange for those goods or services.

To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize revenue when (or as) we satisfy a performance obligation. We apply the five-step model to arrangements that meet the definition of a contract under ASC 606 including when it is probable that we will collect the consideration we are entitled to in exchange for goods or services we transfer to the customer. At contract inception, we assess the goods or services promised within each contract and determine those that are performance obligations, and assesses whether each promised good or service is distinct. We recognize revenue for the amount of the transaction price that is allocated to the respective performance obligation as the performance obligation is satisfied.

License and Development Services Arrangements

We recognize license and contract revenue under license and development services arrangements that are within the scope of ASC 606. The terms of these agreements may contain multiple performance obligations, which may include licenses and research and development activities. We evaluate these agreements under ASC 606 to determine distinct performance obligations. Prior to recognizing revenue, we make estimates of the transaction price, including any variable consideration that is subject to a constraint. Amounts of variable consideration are included in the transaction price to the extent that it is probable that there will not be a significant reversal in the amount of cumulative revenue recognized and when the uncertainty associated with the variable consideration is subsequently resolved. Variable consideration may include nonrefundable upfront license fees, payments for research and development activities, reimbursement of certain third-party costs, payments based upon the achievement of specified milestones, and royalty payments based on product sales derived from the collaboration. If there are multiple, distinct performance obligations, we allocate the transaction price to each distinct performance obligation based on its relative standalone selling price. Revenue is recognized by measuring the progress toward complete satisfaction of the performance obligations using an input measure in accordance with ASC-340-40, *Other Assets and Deferred Costs: Contracts with Customers*.

Research and Development Expenses

Research and development costs are expensed as incurred in accordance with ASC 730, *Research and Development*. Research and development expenses include related salaries and benefits, clinical trial and related manufacturing costs, contract and other outside service fees, and facilities and overhead costs related to our research and development efforts. Research and development expenses also consist of costs incurred for proprietary and collaboration research and development and include activities such as product registries and investigator-sponsored trials. In instances where we enter into agreements with third parties for research and development activities, we may prepay fees for services at the initiation of the contract. We record the prepayment as a prepaid asset and amortize the asset into research and development expense over the period of time the contracted research and development services are performed. Other types of arrangements with third parties may be fixed fee or fee for service, and may include monthly payments or payments upon completion of milestones or receipt of deliverables. 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 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 stockholders' equity, 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 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 year ended December 31, 2019, in connection with the dissolution of CTILS, a gain in the amount of $1.3 million was released from the cumulative foreign currency translation adjustment account and recorded in *Other non-operating income* in the consolidated statement of operations in accordance with ASC 830, *Foreign Currency Matters.* See Note 9. Other Comprehensive Loss for additional details. During the year ended December 31, 2018, the intercompany balance due from CTILS was considered to be of a long-term nature, and as such, an unrealized foreign exchange loss of $1.5 million was recorded in the cumulative foreign currency translation adjustment account. As of December 31, 2018, such intercompany balance due from CTILS was €28.7 million (or $32.8 million upon conversion from euros as of December 31, 2018).

Income Taxes

We record a tax provision for the anticipated tax consequences of our 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 basis 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 in effect for the years in which those tax assets and liabilities are expected to be realized or settled. We provide a valuation allowance to reduce deferred tax assets to the amount that is more likely than not to be realized.

Net Loss per Share

Basic net loss per common share is calculated based on the net loss attributable to common stockholders divided by the weighted average number of shares outstanding for the period. The calculation of diluted net loss per common share excludes the potential conversion of all dilutive convertible securities, such as convertible preferred stock, using the if-converted method, and the potential exercise or vesting of other dilutive securities, such as options, warrants and restricted stock, using the treasury stock method, as their inclusion would have an anti-dilutive effect.

Recently Adopted Accounting Standards

In February 2016, the FASB issued ASC 842 - *Leases*, which requires lessees to recognize virtually all of their leases (other than leases that meet the definition of a short-term lease) on the balance sheet. On January 1, 2019, we adopted ASC 842 using the modified retrospective approach with a cumulative-effect adjustment as of January 1, 2019 in accordance with ASU No. 2018-11, *Leases* (Topic 842) - *Targeted Improvements*. Prior period amounts are not adjusted and continue to be reported under previous lease guidance, ASC 840 - *Leases*.

We have performed an evaluation of our contracts with customers and suppliers in accordance with ASC 842 and have determined that the agreements for our office space, parking and office equipment contained a lease. All identified leases are classified as operating leases. We had no finance or capital leases as of and for the years ended December 31, 2019 and 2018. We also elected a package of practical expedients permitted under the transition guidance within the new standard.

The impact of the adoption of ASC 842 on our consolidated balance sheet as of January 1, 2019 was as follows (in thousands):

	December 31, 2018	Adjustments due to adoption of ASC 842	January 1, 2019
Right-of-use assets	$ -	$ 4,208	$ 4,208
Lease liabilities, current	$ -	$ 1,687	$ 1,687
Lease liabilities, non-current	$ -	$ 4,946	$ 4,946
Deferred rent, current	$ 893	$ (893)	$ -
Deferred rent, non-current	$ 2,157	$ (2,157)	$ -
Accumulated deficit	$ (2,224,746)	$ 1,196	$ (2,223,550)

The adoption of the standard did not materially impact our consolidated statements of operations or consolidated statements of cash flows. See Note 5. Leases for further details about our leases.

In June 2018, the FASB issued new accounting guidance which simplifies the accounting for share-based payments granted to nonemployees for goods and services by aligning it with the accounting for share-based payments to employees, with certain exceptions. The guidance is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. We adopted this guidance on January 1, 2019. The adoption of this accounting guidance did not have a material impact on our consolidated financial statements.

In December 2019, the FASB issued new accounting guidance which modifies ASC 740 - *Income Taxes* to simplify the accounting for income taxes. These modifications include, among other things, elimination of certain exceptions to the guidance in ASC 740 related to the approach for intra-period tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The guidance is effective for fiscal years beginning after December 15, 2020, including interim periods therein. Early adoption is permitted. We early adopted this guidance on January 1, 2019. The adoption of this accounting guidance did not have a material impact on our consolidated financial statements. See Note 17. Income Taxes for further details.

Recently Issued Accounting Standards

In June 2016, the FASB issued new accounting guidance which amends the impairment model for most financial assets and certain other instruments. For trade and other receivables, held-to-maturity debt securities, loans and other financial instruments, the standard requires the use of a new forward-looking "expected credit loss" model that generally will result in the earlier recognition of allowances for losses. For available-for-sale debt securities with unrealized losses, the standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. The guidance is effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. Early adoption is permitted. We do not expect the adoption of this accounting guidance to have a material impact on our consolidated financial statements.

In August 2018, the FASB issued new accounting guidance which eliminates certain disclosure requirements for fair value measurements for all entities, requires public entities to disclose certain new information and modifies some disclosure requirements. The guidance is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. We do not expect the adoption of this accounting guidance to have a material impact on our consolidated financial statements.

Although there were several other new accounting pronouncements issued or proposed by the FASB, we do not believe any of these have had or will have material impact on our consolidated financial statements.

Reclassifications

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

2. Property and Equipment

Property and equipment are composed of the following as of December 31, 2019 and 2018 (in thousands):

	2019	2018
Furniture and office equipment	$ 2,872	$ 4,445
Leasehold improvements	5,140	5,168
Lab equipment	-	63
	8,012	9,676
Less: accumulated depreciation and amortization	(6,777)	(7,883)
Property and equipment, net	$ 1,235	$ 1,793

Depreciation expense for the years ended December 31, 2019 and 2018 was $0.5 million and $0.6 million, respectively.

3. Other Assets

Other assets consisted of the following as of December 31, 2019 and 2018 (in thousands):

	2019	2018
Right-of-use assets	$ 3,379	$ -
Italian VAT receivables	4,390	4,480
Italian VAT deposit	483	493
Clinical trial deposits	720	-
Refundable security deposit	194	194
Other	299	380
Other assets	$ 9,465	$ 5,547

On January 1, 2019, we adopted ASC 842 - *Leases* and recorded right-of-use assets for our operating leases. See Note 1. Description of Business and Summary of Significant Accounting Policies - *Recently Adopted Accounting Standards* and Note 5. Leases for further details.

For details regarding our Italian VAT receivables and Italian VAT deposit, see Note 1. Description of Business and Summary of Significant Accounting Policies - *Italian Value Added Tax Receivable* and Note 16. Commitments and Contingencies.

4. Accrued Expenses

Accrued expenses consisted of the following as of December 31, 2019 and 2018 (in thousands):

	2019	2018
Clinical trial expenses	$ 7,920	$ 6,573
Employee compensation and related expenses	2,851	4,216
Restructuring expenses	-	660
Manufacturing expenses	228	458
Other	607	945
Total accrued expenses	$ 11,606	$ 12,852

5. Leases

In January 2012, we entered into an agreement with Selig Holdings Company LLC, or Selig, to lease approximately 66,000 square feet of office space in Seattle, Washington for a term of 10 years, commencing May 2012. We have two five-year options to extend the term of the lease at a market rate determined according to the lease. We also had an option to early terminate the lease after the fifth anniversary from the commencement date. We were provided with a total of $3.9 million for certain tenant improvements and other lease incentives. The options to extend or terminate the lease were not considered in the determination of the right-of-use asset and the lease liability as we did not consider it reasonably certain that we would exercise such options. We also lease parking space and certain office equipment. We have elected not to separate a non-lease component from a lease component for these leases.

In December 2017, we entered into an agreement to sublease approximately 44,000 square feet of our office space. No payments were due through May 2018, after which monthly rent is due through the sublease termination date in April 2022.

The operating lease for our office space includes common area maintenance services provided by Selig, which are considered a non-lease component. Since the payments for these services are based on the actual costs incurred by Selig in providing the services, we consider these payments as variable lease expenses.

The components of lease expense, which were included in our consolidated statements of operations, were as follows (in thousands):

	Year Ended December 31,	
	2019	2018
Operating lease expense	$ 1,696	$ 1,384
Variable lease expense	178	195
Sublease income	(1,247)	(1,247)
Total lease expense, net	$ 627	$ 332

The balance sheet classification of operating lease right-of-use assets and operating lease liabilities were as follows (in thousands):

	December 31, 2019
Right-of-use assets (included in *Other assets*)	$ 3,379
Lease liabilities, current (included in *Other current liabilities*)	$ 1,953
Lease liabilities, non-current (included in *Other liabilities*)	2,993
Total lease liabilities	$ 4,946

As of December 31, 2019, the maturities of operating lease liabilities were as follows (in thousands):

	Operating Lease Payments	Sublease Rental Receipts	Net
2020	$ 2,443	$ (1,410)	$ 1,033
2021	2,438	(1,454)	984
2022	820	(499)	321
Thereafter	-	-	-
Total payments	5,701	$ (3,363)	$ 2,338
Less imputed interest	(755)		
Total lease liabilities	$ 4,946		

Supplemental information relating to our operating leases is as follows (in thousands):

	December 31, 2019
Supplemental cash flow information	
Cash paid for amounts included in the measurement of lease liabilities	$ 2,391
Weighted-average remaining lease term of operating leases (years)	2.31
Weighted-average discount rate of operating leases	12.4%

6. Other Liabilities

Other liabilities consisted of the following as of December 31, 2019 and 2018 (in thousands):

	2019	2018
Lease liabilities, non-current	$ 2,993	$ -
Deferred rent, non-current	-	2,157
Other long-term obligations	2,414	2,414
Total other liabilities	$ 5,407	$ 4,571

On January 1, 2019, we adopted ASC 842 - *Leases* and recorded lease liabilities and corresponding right-of-use assets for our operating leases. Deferred rent, less current portion as of December 31, 2018 included amounts related to lease incentives associated with our operating lease for office space. Under ASC 842, such lease incentives are accounted for as a reduction to the right-of-use asset balance. See Note 1. Description of Business and Summary of Significant Accounting Policies - *Recently Adopted Accounting Standards* and Note 5. Leases for further details.

Other long-term obligations as of December 31, 2019 and 2018 included a fee in the amount of $1.4 million payable to Silicon Valley Bank. See Note 7. Long-term Debt for additional information.

7. Long-term Debt

In November 2017, we entered into a Loan and Security Agreement with Silicon Valley Bank, or SVB, for a secured term loan of up to $18.0 million. The first $16.0 million of the term loan was funded in November 2017. We had an option to

borrow an additional $2.0 million, which option expired unexercised on July 31, 2018. The loan proceeds were used to repay in full all outstanding indebtedness under a prior loan and security agreement and to fund our general business requirements. The term loan is repayable over 36 months after an initial interest-only period of 12 months after closing. The interest rate on the term loan floats at a rate per annum equal to the greater of 2.5 percent above the prime rate and 6.75 percent. We may elect to prepay some or all of the loan balance at any time subject to a prepayment fee. A back-end fee in the amount of 9 percent of the total principal amount funded to us is payable to SVB on the date on which the term loan is paid or becomes due and payable in full. The loan obligations are secured by a first priority security interest on substantially all of our personal property except our intellectual property and subject to certain other exceptions.

We also issued warrants to SVB and Life Science Loans II, LLC in November 2017, pursuant to a participation arrangement among SVB, Loan Manager II, LLC and Life Science Loans II, LLC, to purchase up to 190,140 shares of our common stock. Warrants have an initial exercise price of $2.84 per share of our common stock and will expire on November 28, 2027.

The back-end fee in the amount of $1.4 million and the warrants, which had a fair value of $0.5 million on the date of grant, were together recorded as a $1.9 million debt discount. In connection with the Loan and Security Agreement, we also recorded debt issuance costs of $0.1 million. As of December 31, 2019, $0.9 million of the original debt discount and $0.1 million of the debt issuance costs remained unamortized. The outstanding principal balance on the term loan was $10.2 million as of December 31, 2019.

As of December 31, 2019, the scheduled principal and interest payments (based on the interest rate of 7.25 percent as of December 31, 2019) as well as the back-end fee described above are as follows:

	Principal	Interest	Back-end fee	Total
2020	$ 5,333	$ 573	$ -	$ 5,906
2021	4,889	180	1,440	6,509
Thereafter	-	-	-	-
Total scheduled payments	**$ 10,222**	**$ 753**	**$ 1,440**	**$ 12,415**
Less: debt discount and issuance costs	$ (955)			
Less: current portion of long-term debt	$ (4,812)			
Long-term debt	$ 4,455			

8. Equity Transactions

Preferred Stock

In February 2018, 575 shares of our Series N Preferred Stock owned by BVF Partners L.P., or BVF, along with 8.0 million shares of our common stock owned by BVF were exchanged for 12,575 shares of our Series O Preferred Stock. For the year ended December 31, 2018, we recognized $0.1 million in *deemed dividends on preferred stock* related to the beneficial conversion feature on the Series O Preferred Stock. There were 12,575 shares of Series O Preferred Stock outstanding as of December 31, 2019 and 2018. BVF is an existing stockholder of the Company, and was one of our investors in the Common Stock offering in February 2018 discussed below. See Note 15. Related Party Transactions for further details.

Each share of Series O Preferred Stock is convertible at the option of the holder (subject to certain limitations) into shares of common stock at a conversion price of $3.00 per share of common stock. Each share of Series O Preferred Stock is entitled to a liquidation preference equal to the initial stated value of $2,000 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 O Preferred Stock. The Series O Preferred Stock is not entitled to dividends except to share in any dividends actually paid on common stock or any *pari passu* or junior securities. The Series O Preferred Stock has no voting rights, except as otherwise expressly provided in the certificate of incorporation of CTI or as otherwise required by law.

Common Stock

In February 2018, we offered and sold 23.0 million shares of our common stock, referred to as the Offering. The price to the public in this Offering was $3.00 per share of common stock. The gross proceeds from the Offering were $69.0 million before deducting underwriting commissions and discounts and other offering costs of approximately $4.8 million.

In November 2019, we entered into an Open Sale Agreement with Jefferies LLC, referred to as the Jefferies Sale Agreement, to sell shares of our common stock, having aggregate sales proceeds of up to $15.0 million, from time to time, through an "at the market" equity offering program under which Jefferies will act as sales agent. Under the terms of the Jefferies Sale Agreement, we will set the parameters for the sale of shares, including the number of shares to be issued, the time period during which sales are requested to be made, limitation on the number of shares that may be sold in any one trading day and any minimum price below which sales may not be made. Subject to the terms and conditions of the Jefferies Sale Agreement, Jefferies may sell the shares by methods deemed to be an "at-the-market" offering as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, including sales made directly on The Nasdaq Capital Market or on any other existing trading market for the common stock. Jefferies will use commercially reasonable efforts in conducting such sales activities consistent with its normal trading and sales practices, applicable state and federal laws, rules and regulations and the rules of The Nasdaq Stock Market LLC. We and Jefferies may each terminate the Jefferies Sale Agreement at any time upon one trading day's prior notice. We may also sell shares to Jefferies acting as principal for Jefferies' own account. The compensation to Jefferies for sales of our common stock will be an amount equal to 3% of the gross proceeds of any shares of common stock sold under the Jefferies Sale Agreement. We have no obligation to sell any shares under the Jefferies Sale Agreement, and may at any time suspend solicitation and offers under the Jefferies Sale Agreement. We recorded financing costs of $0.2 million in *Selling, general and administrative* expenses in connection with the Jefferies Sale Agreement for the year ended December 31, 2019. No shares of common stock were sold under the Jefferies Sale Agreement during the year ended December 31, 2019.

Rights Offering

In March 2020, we completed our rights offering. See Note 18. Subsequent Events for further details.

Common Stock Authorized

In May 2018, the Company's certificate of incorporation was amended to increase the total number of authorized shares of common stock from 81.5 million to 101.5 million.

In May 2019, the Company's certificate of incorporation was amended to increase the total number of authorized shares of common stock from 101.5 million to 131.5 million.

Common Stock Reserved

As of December 31, 2019, we had 131.5 million authorized shares of common stock, of which 58.0 million shares were issued and outstanding, and 21.4 million shares were reserved for future issuances as follows (in thousands):

Equity incentive plans	11,211
Option agreement with Adam R. Craig	1,120
Common stock purchase warrants	514
Series O convertible preferred stock	8,383
Employee stock purchase plan	176
Total common stock reserved	21,404

Warrants

Warrants to purchase up to 29,239 shares of our common stock with an exercise price of $17.10 per share, issued in connection with the Third Amendment to the Loan Agreement with Hercules Technology Growth Capital, Inc. in 2015, were outstanding and exercisable as of December 31, 2019.

Warrants to purchase up to 190,140 shares of our common stock with an exercise price of $2.84 per share, issued in connection with the Loan and Security Agreement with SVB in 2017, were outstanding as of December 31, 2019. Of this amount, warrants to purchase up to 169,014 shares of our common stock were exercisable as of December 31, 2019.

Warrants to purchase up to 294,117 shares of our common stock with an exercise price of $1.70 per share, which were issued to a vendor in 2018 as part of compensation for services, were outstanding but remained unexercisable as of December 31, 2019.

9. Other Comprehensive Loss

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

	Net Unrealized (Loss) Gain on Available-For-Sale Securities	Foreign Currency Translation Adjustments (1)	Unrealized Foreign Exchange Loss on Intercompany Balance (1)	Accumulated Other Comprehensive Loss
December 31, 2018	$ (14)	$ (9,672)	$ (957)	$ (10,643)
Current period other comprehensive income (loss)	16	(2,323)	957	(1,350)
December 31, 2019	$ 2	$ (11,995)	$ -	$ (11,993)

(1) In accordance with ASC 830, *Foreign Currency Matters*, the current period change includes a release of cumulative translation adjustment in the amount of $1.3 million upon dissolution of CTILS, our foreign subsidiary, which was recognized in *Other non-operating income* in the consolidated statement of operations for the year ended December 31, 2019.

10. Collaboration, Licensing and Milestone Agreements

Servier

In September 2014, we entered into an Exclusive License and Collaboration Agreement, or the Original Agreement, with Les Laboratoires Servier and Institut de Recherches Internationales Servier, or collectively, Servier. In April 2017, we entered into an Amended and Restated Exclusive License and Collaboration Agreement, or the Restated Agreement, with Servier, pursuant to which the Original Agreement was amended and restated in its entirety. Under the Restated 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, or Licensed Products, outside of the United States (and its territories and possessions).

In February 2019, we entered into a Termination and Transfer Agreement, or the Servier Termination Agreement, among, on the one hand, the Company and its subsidiary, CTILS, and, on the other hand, Servier, which terminated the Restated Agreement. Under the Servier Termination Agreement, we were responsible for non-U.S. pharmacovigilance for PIXUVRI (pixantrone), the submission of a marketing authorization application for PIXUVRI and wind down of the PIX306 clinical trial during a transition period. Servier reimbursed us €620,000 (of which, €65,000 was reimbursed and recognized as license and contract revenue in 2018) for costs incurred in connection with transition period activities, and as such we recognized $0.6 million of license and contract revenue related to the transition period activities during the year ended December 31, 2019.

In April 2019, Servier announced that the EMA's Committee for Medicinal Products for Human Use, or CHMP, issued a positive opinion for PIXUVRI to convert its conditional approval into a standard marketing authorization as a single agent for the treatment of adult patients with multiply relapsed or refractory aggressive non-Hodgkin B-cell lymphoma, and in June 2019, the European Commission adopted the decision to grant non-conditional marketing authorization for PIXUVRI. Pursuant to the Servier Termination Agreement, we agreed to transfer and assign all of our rights and responsibilities for PIXUVRI globally to Servier pursuant to an asset purchase agreement.

In August 2019, we entered into an asset purchase agreement, which was amended and restated in September 2019, or the Asset Purchase Agreement. The Asset Purchase Agreement required, among other things, Servier to pay us €2.0 million and assume responsibility for all of the obligations related to PIXUVRI, including the Company’s remaining royalty payments to Novartis International Pharmaceutical Ltd. and the University of Vermont. For the year ended December 31, 2019, we recognized $2.2 million of license and contract revenue related to the Asset Purchase Agreement, and all of our rights and responsibilities for PIXUVRI were transferred and assigned globally to Servier pursuant to the Asset Purchase Agreement.

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. As of December 31, 2019, we had earned $60.0 million of such potential milestone payments as a result of having achieved certain milestones. For the year ended December 31, 2018, we received $10.0 million from Teva upon the achievement of a milestone for FDA approval of TRISENOX for first line treatment of acute promyelocytic leukemia. We also earned $10.0 million upon the achievement of

worldwide net sales milestones of TRISENOX during the year ended December 31, 2018. The achievement of the remaining milestones is uncertain at this time.

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. Baxter assigned its rights and obligations under the Pacritinib License Agreement to Baxalta. Under the Pacritinib License Agreement, we granted to Baxter an exclusive, worldwide (subject to our certain co-promotion rights in the United States), royalty-bearing, non-transferable, and (under certain circumstances outside of the United States) sub-licensable license to our know-how and patents relating to pacritinib.

In October 2016, we entered into the Asset Return and Termination Agreement, or the Baxalta Termination Agreement, with Baxalta. Pursuant to the Baxalta Termination Agreement, the Pacritinib License Agreement was terminated in its entirety (other than with respect to certain customary provisions that survive termination, including those pertaining to confidentiality and indemnification), the Pacritinib License Agreement has no further force or effect, and all rights and obligations of the Company and Baxalta under the Pacritinib License Agreement were terminated.

In October 2016, we resumed primary responsibility for the development and commercialization of pacritinib as a result of the Baxalta Termination Agreement and are no longer eligible to receive cost sharing or milestone payments for pacritinib's development from Baxalta. In addition, under the Baxalta Termination Agreement, we are required to make a milestone payment to Baxalta in the amount of approximately $10.3 million upon the first regulatory approval or any pricing and reimbursement approvals of a product containing pacritinib.

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, as amended, or the Original Novartis Agreement. Pursuant to the Novartis Termination Agreement, the Original Novartis Agreement was terminated in its entirety, other than with respect to 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, provided that such payments would 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 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. Notwithstanding the foregoing, royalty payments for the Compounds are subject to certain minimum floor percentages in the low single-digits.

During the year ended December 31, 2019, pursuant to the Asset Purchase Agreement discussed in *Servier* above, all of our responsibilities and obligations related to PIXUVRI under the Novartis Termination Agreement were fully transferred and assigned to Servier.

University of Vermont

In March 1995, the University of Vermont, or UVM, entered into an agreement, or the UVM Agreement, which, as amended in March 2000, 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. We were obligated to make royalty payments to UVM that ranged 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.

During the year ended December 31, 2019, pursuant to the Asset Purchase Agreement discussed in *Servier* above, all of our responsibilities and obligations related to PIXUVRI under the UVM Agreement were fully transferred and assigned to Servier.

*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 United States, EU 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. 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: (1) 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, (2) Vernalis has the right to terminate in the event of our uncured failure to pay sums due, and (3) either party has the right to terminate in the event of the other party's uncured material breach or insolvency. We have ceased development of tosedostat and do not anticipate incurring additional material expenses related to this terminated program.

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.

11. Restructuring Activities

In December 2018, we announced a restructuring plan to improve efficiencies and reduce costs within the Company, which impacted a total of 21 positions. The restructuring activities were substantially completed as of March 31, 2019, and we incurred total restructuring expenses of approximately $1.5 million, of which $0.8 million had been incurred during the year ended December 31, 2019.

The following table summarizes the accrual balance and utilization for the year ended December 31, 2019 (in thousands):

	Employee separation costs
Restructuring accruals - December 31, 2018	$ 660
Restructuring expenses	794
Cash payments	(1,454)
Restructuring accruals - December 31, 2019	$ -

12. 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 U.S. GAAP. 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.

During the years ended December 31, 2019 and 2018, we recognized share-based compensation expense which consisted of the following types of awards (in thousands):

	2019	2018
Restricted stock	-	102
Options	5,166	6,267
Total share-based compensation expense	$ 5,166	$ 6,369

The following table summarizes share-based compensation expense for the years ended December 31, 2019 and 2018, which was allocated as follows (in thousands):

	2019	2018
Research and development	$ 506	$ 1,950
Selling, general and administrative	4,660	4,419
Total share-based compensation expense	$ 5,166	$ 6,369

Share-based compensation had a $5.2 million and $6.4 million effect on our net loss attributable to common stockholders for the years ended December 31, 2019 and 2018, respectively. It had no effect on cash flows from operating activities for the periods presented; however, during the year ended December 31, 2018, we made a payment of $21,000 relating to 5,800 shares of our common stock withheld upon vesting of employee restricted stock awards based on taxes owed by employees upon vesting, which impacted cash flows used in financing activities. We made no such payments during the year ended December 31, 2019 as no shares of restricted stock awards vested during the year ended December 31, 2019 .

As of December 31, 2019, unrecognized compensation cost related to unvested stock options amounted to $4.7 million, which will be recognized over the remaining weighted-average requisite service period of 1.73 years. There was no unrecognized compensation cost related to unvested restricted stock awards (other than performance-based awards) as of December 31, 2019. The unrecognized compensation cost related to unvested options and unvested restricted stock does not include the value of performance-based awards since we do not believe vesting of such awards is probable at this time.

For the years ended December 31, 2019 and 2018, no tax benefits were attributed to share-based compensation expense because a valuation allowance was maintained for all net deferred tax assets.

Stock Plans

In May 2017, the Company's 2017 Equity Incentive Plan, or the 2017 Plan, was approved by the Company's shareholders, and no additional awards will be granted under the 2015 Equity Incentive Plan, or the 2015 Plan.

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 0.2 million shares. Refer to *Employee Stock Purchase Plan* below for further details.

Pursuant to our 2017 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 2017 Plan is administered by the Compensation Committee of our Board, which has the discretion to

determine the employees and consultants who shall be granted incentive awards. The Board retained sole authority under the 2017 Plan with respect to non-employee directors' awards, although the Compensation Committee has authority 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, 2019, 13.6 million shares were authorized for issuance under equity incentive plans, of which 1.0 million shares of common stock were available for future grants under the 2017 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,	
	2019	2018
Risk-free interest rate	2.3%	2.9%
Expected dividend yield	None	None
Expected life (in years)	4.4	5.4
Volatility	89%	82%

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 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, 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, involve management's best estimates. As we 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, 2018 (2,597,000 exercisable)	7,219,000	$ 4.08		
Granted	5,307,000	$ 0.91		
Exercised	-	$ -		
Forfeited	(1,115,000)	$ 2.16		
Cancelled and expired	(457,000)	$ 8.35		
Outstanding at December 31, 2019 (4,047,000 exercisable)	10,954,000	$ 2.56	8.3	$ 3,504
Vested or expected to vest at December 31, 2019	10,510,000	$ 2.61	8.3	$ 3,252
Exercisable at December 31, 2019	4,047,000	$ 4.39	7.2	$ 6

The weighted average exercise price of options exercisable at December 31, 2019 and 2018 was $4.39 and $5.49, respectively. The weighted average grant-date fair value of options granted during 2019 and 2018 was $0.60 and $2.09 per option, respectively. The number of options vested or expected to vest at December 31, 2019 does not include 4,000 performance-based options with the weighted average exercise price of $22.35 since the achievement of such performance-based milestone was not deemed probable as of December 31, 2019.

In March 2017, Dr. Adam R. Craig, our President and CEO, was granted stock options to purchase 1.2 million shares of common stock at an exercise price of $4.24 per share. The stock options have a maximum term of ten years and vest in six equal semi-annual installments over the three-year period beginning March 20, 2017, subject to his continued employment through the applicable vesting dates and acceleration under certain circumstances. The stock options were granted in connection with his entering into employment with the Company as President and CEO. A portion of the stock options covering 80,000 shares were granted under the 2015 Plan. The balance of such stock options was granted in accordance with Nasdaq Listing Rule 5635(c)(4).

Restricted Stock

No shares of restricted stock awards were issued in 2019 or 2018. Additionally, 8,000 and 15,000 shares of restricted stock awards were cancelled during 2019 and 2018, respectively.

The total fair value of restricted stock awards vested during the year ended December 31, 2018 was $0.1 million. No shares of restricted stock awards vested during the year ended December 31, 2019.

A summary of the status of nonvested restricted stock awards as of December 31, 2019 and 2018 and changes during the periods then ended, is presented below:

	Nonvested Shares		Weighted Average Grant-Date Fair Value Per Share
Nonvested at December 31, 2017	63,000	$	15.93
Issued	-	$	-
Vested	(35,000)	$	12.00
Forfeited	(15,000)	$	16.12
Nonvested at December 31, 2018	13,000	$	26.23
Issued	-	$	-
Vested	-	$	-
Forfeited	(8,000)	$	19.12
Nonvested at December 31, 2019	5,000	$	38.90

All nonvested restricted stock outstanding as of December 31, 2019 was performance-based awards. We do not believe vesting of such awards is probable at this time.

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 2,000 and 5,000 shares of our common stock to employees during the years ended December 31, 2019 and 2018, respectively. There are 0.2 million shares of common stock authorized under the Purchase Plan and approximately 0.2 million shares are reserved for future purchases as of December 31, 2019.

13. Employee Benefit Plans

Our 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 $0.1 million and $0.2 million related to discretionary matching contributions during the year ended December 31, 2019 and 2018, respectively.

14. Net Loss Per Share

Basic net loss per share is calculated based on the net loss attributable to common stockholders divided by the weighted average number of shares outstanding for the period. The calculation of diluted net loss per share excludes the potential conversion of all dilutive convertible securities, such as convertible debt and convertible preferred stock, and the potential exercise or vesting of other dilutive securities, such as options, warrants and restricted stock, as their inclusion would have an anti-dilutive effect. Accordingly, diluted net loss per share is the same as basic net loss per share**.**

The computation of net loss per share is as follows (in thousands, except per share amounts):

	Year Ended December 31,	
	2019	2018
Net loss attributable to common stockholders	$ (40,020)	$ (29,400)
Basic and diluted:		
Weighted average shares outstanding	57,980	56,106
Less: weighted average restricted shares outstanding	(6)	(33)
Shares used in calculation of basic and diluted net loss per common share	57,974	56,073
Net loss per common share: Basic and diluted	$ (0.69)	$ (0.52)

Common shares underlying equity awards, warrants and convertible preferred stock aggregating 18.9 million shares and 15.3 million shares for the years ended December 31, 2019 and 2018, respectively, prior to the application of the treasury stock method, have been excluded from the calculation of diluted net loss per share because they were anti-dilutive.

15. Related Party Transactions

Aequus

We have a majority ownership interest in Aequus. In May 2007, we entered into a license agreement with Aequus whereby Aequus gained rights to our Genetic Polymer™ technology. We also entered into an agreement to fund Aequus in exchange for a convertible promissory note.

In March 2017, we and Aequus entered into a License and Promissory Note Termination Agreement and a Note Cancellation Agreement, pursuant to which (1) all of the then-outstanding principal, plus all accrued and unpaid interest, approximately $13.7 million in total, was cancelled and terminated, (2) our license agreement with Aequus was terminated, (3) all obligations to Aequus were terminated with the exception of providing additional funding of up to $347,500 to Aequus, and (4) Aequus agreed to pay us a) 20% of milestone and similar payments, up to a maximum amount of $20.0 million, and b) royalties, on a product-by-product and county-by country basis, of 5% of net sales of certain ACTH Products being developed by Aequus. The additional funding of $347,500 had been provided in full as of September 30, 2017. Payments from Aequus are due the later of (1) expiration of the last to expire valid patent claim that claims the ACTH Product, or (2) ten years from the first commercial sale of the applicable ACTH Product. We have the right to terminate the License and Promissory Note Termination Agreement and require Aequus to assign all ACTH Product related assets to us without further compensation to Aequus if Aequus does not file an Investigational New Drug Application for an ACTH Product with the FDA by September 6, 2019. Aequus did not file an Investigational New Drug Application by September 6, 2019; however, we have not exercised such right and have not requested Aequus to assign all ACTH Product related assets to us.

BVF Partners L.P.

In February 2018, in connection with the public offering of common stock (also discussed in Note 8. Equity Transactions), BVF purchased 6.3 million shares of our common stock. In addition, BVF exchanged 8.0 million shares of our common stock owned by BVF and 575 shares of our Series N Preferred Stock owned by BVF for 12,575 shares of our Series O Preferred Stock. As of December 31, 2019 and 2018, BVF beneficially owned approximately 12.0% of our outstanding common stock. Matthew D. Perry, a member of our Board, is the President of BVF and portfolio manager for the underlying funds managed by the firm.

In March 2020, in connection with our rights offering as discussed in Note 18. Subsequent Events, BVF purchased a total of 3,047 shares of our Series X Preferred Stock, which are convertible into 30.5 million shares of our common stock. As of the date of the filing of this Annual Report on Form 10-K, no shares of Series X Preferred Stock owned by BVF have been converted into our common stock.

16. Commitments and Contingencies

Commitments

See Note 5. Leases and Note 7. Long-term Debt for scheduled lease and debt payments. In addition, certain of our licensing agreements obligate us to make payments upon achievement of milestones and pay a royalty on net sales of products utilizing licensed compounds. See Note 10. Collaboration, Licensing and Milestone Agreements for further details. Purchase commitments relating to clinical trial contracts, manufacturing supply, insurance and other obligations also arise in the ordinary course of business. We anticipate the timing of payments under these contracts to range from less than one year to more than three years.

Contingencies

In April 2009, December 2009 and June 2010, the Italian Tax Authority, or the ITA, issued notices of assessment to CTI - Sede Secondaria, or CTI (Europe), based on the ITA's audit of CTI (Europe)'s value added tax, or 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). The assessments, including interest and penalties, for the years 2003, 2006 and 2007 are €0.6 million, €2.8 million and €0.9 million, respectively. We believe that the services invoiced were non-VAT taxable consultancy services and that the VAT returns are correct as originally filed. We have appealed all the assessments and are defending ourselves against the assessments both on procedural grounds and on the merits of the cases, 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 VAT Assessment. In June 2013, the Regional Tax Court issued decision no. 119/50/13 in regards to the 2003 VAT Assessment, which accepted the October 2012 appeal of the ITA and reversed a 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, which is included in *Other assets* in our consolidated balance sheets.

2005 VAT Assessment. In January 2018, the Italian Supreme Court issued decision No. 02250/2018 which (i) rejected the April 2013 appeal of the ITA, (ii) confirmed the October 2012 decision of the Regional Tax Court (127/31/2012), which fully accepted the merits of our earlier appeal and confirmed that no penalties could be imposed against us, and (iii) due to the novelty of the arguments at stake, compensated the legal expenses incurred by the parties. The ITA may not use any ordinary means of appeal against the Italian Supreme Court decision, and we have applied for a refund based on the guidance from the ITA.

2006 and 2007 VAT Assessments. In November 2013, the ITA appealed to the Italian Supreme Court an April 2013 decision of the Regional Tax Court (57/35/13), that fully rejected the merits of an earlier ITA appeal, declared that no penalties could be imposed against us and found the ITA liable to pay us approximately €12,000, as a partial refund of legal expenses we incurred.

No hearing dates have been fixed yet for either the 2003 VAT Assessment or consolidated 2006 and 2007 VAT Assessment 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 €4.3 million, or approximately $4.8 million converted using the currency exchange rate as of December 31, 2019, including interest and penalties for the period lapsed between the date in which the assessments were issued and the date of effective payment. We have not recorded this contingent liability in the financial statements as we do not believe the potential payment to the ITA is probable at this time.

17. Income Taxes

We file income tax returns in the United States and the United Kingdom. A substantial part of our operations takes place in the State of Washington, which does not impose an income tax as that term is defined in ASC 740, *Accounting for 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.

Loss before income taxes is attributable to the following tax jurisdictions (in thousands):

	Year ended December 31,	
	2019	2018
United States	$ (40,242)	$ (29,162)
Foreign	219	(190)
Net loss before noncontrolling interest and income taxes	$ (40,023)	$ (29,352)

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

	2019	2018
Federal income tax rate	21%	21%
Research and development tax credits	14	6
Non-deductible executive compensation	(2)	(1)
Valuation allowance	(31)	(12)
Expired tax attribute carryforwards	-	(17)
Gain on foreign entity liquidation	1	3
Foreign currency gains and losses	1	2
Unrecognized tax benefits	(3)	-
Other	(1)	(2)
Net effective tax rate	-%	-%

The principal components of our deferred tax assets and liabilities as of December 31 were as follows (in thousands):

	2019	2018
Deferred tax assets:		
Net operating loss carryforwards	$ 27,151	$ 18,792
Capitalized research and development	32,907	32,029
Research and development tax credit carryforwards	7,317	3,061
Stock-based compensation	3,109	2,940
Intangible assets	7,519	7,802
Depreciation and amortization	618	549
Lease liability	1,039	-
Other deferred tax assets	918	1,806
Total deferred tax assets	80,578	66,979
Less: valuation allowance	(79,506)	(66,698)
	1,072	281
Deferred tax liabilities:		
Right-of-use asset	(667)	-
Deductions for tax in excess of financial statements	(405)	(281)
Total deferred tax liabilities	(1,072)	(281)
Net deferred tax assets	$ -	$ -

As of December 31, 2019 and 2018, we had U.S. federal net operating loss carryforwards, or the NOL, of approximately $92.0 million and $56.6 million respectively, which are available to reduce future taxable income. The Tax Cuts and Jobs Act enacted in December 2017 altered the carryforward period for federal net operating losses and as a result, all net operating losses generated in 2018 and forward have an indefinite life. Of the net operating losses reported, we have accumulated $48.7 million with an indefinite life as of December 31, 2019. We have accumulated state tax losses of approximately $12.7 million and $18.0 million as of December 31, 2019 and 2018, respectively. We also had U.S. federal tax credits of $7.3 million and $3.1 million as of December 31, 2019 and 2018, respectively, which may be used to offset future tax liabilities. The NOL and tax credit carryforwards began to expire in 2018 and may become subject to annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined under

Sections 382 and 383 of the Internal Revenue Code, or the IRC, of 1986, as amended. This could limit the amount of tax attributes that can be utilized annually to offset future taxable income or future tax liabilities. We have undertaken a formal IRC Section 382 study and the attributes disclosed in this footnote reflect the conclusion of that study. However, subsequent ownership changes may further affect the limitation in future years.

At December 31, 2019, the NOL carryforwards in the United Kingdom, which have an indefinite carryforward period, were approximately $40.9 million.

Certain of the net operating loss deferred tax assets in the table above, totaling $10.3 million at December 31, 2019 are consolidated in our U.S. GAAP income tax provision due to our 60% ownership in Aequus; however, Aequus is not consolidated for income tax purposes and therefore these net operating losses will not be available to us in our future tax filings.

We maintain a full valuation allowance on our net deferred tax assets. The assessment regarding whether a valuation allowance is required considers both positive and negative evidence when determining whether it is more likely than not that deferred tax assets are recoverable. In making this assessment, significant weight is given to evidence that can be objectively verified. In our valuation, we considered our cumulative loss in recent years and forecasted losses in the near term as significant negative evidence. Based upon a review of the four sources of income identified within ASC 740, we determined that the negative evidence outweighed the positive evidence and that a full valuation allowance on our net deferred tax assets will be maintained. We will continue to assess the realizability of our deferred tax assets going forward and will adjust the valuation allowance as needed. Our valuation allowance increased by $12.8 million during the year ended December 31, 2019 primarily due to increases in capitalized research and development, increases in our tax credit carryforwards and increases in our net operating loss carryforwards.

We follow the provisions in ASC 740 and the guidance related to accounting for uncertainty in income taxes. We determine our uncertain tax positions based on a determination of whether and how much of a tax benefit taken by us in our tax filings or positions is more likely than not to be sustained upon examination by the relevant income tax authorities. We are subject to U.S. federal and state and U.K. income taxes with varying statutes of limitations. Tax years from 2000 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.

The total balance of unrecognized tax benefits as of December 31 is as follows (in thousands):

	2019	2018
Balance at beginning of period	$ -	$ -
Gross increases to tax positions in prior periods	633	-
Gross increases to tax positions in current periods	635	-
Balance at end of period	$ 1,268	$ -

As of December 31, 2019, the total amount of unrecognized tax benefits was $1.3 million, which was recorded as a reduction to the deferred tax asset. We do not anticipate that the amount of existing unrecognized tax benefits will significantly increase or decrease within the next 12 months. We had no accrued interest or penalties as of December 31, 2019.

As discussed in Note 1. Description of Business and Summary of Significant Accounting Policies - *Recently Adopted Accounting Standards,* the FASB issued new accounting guidance which modifies ASC 740 - *Income Taxes* to simplify the accounting for income taxes. We have early adopted this standard on January 1, 2019. Since we have incurred net losses since our inception and maintain a full valuation allowance on our net deferred tax assets, the adoption of this guidance did not have a material impact on our consolidated balance sheets, statements of operations and cash flows or financial statement disclosures.

18. Subsequent Events

Rights Offering

In March 2020, we completed a rights offering through the distribution of subscription rights to holders of our common stock and Series O Preferred Stock, or the Rights Offering. Under the Rights Offering and separate purchase commitments by certain of our investors, we sold a total of 15.7 million shares of our common stock and approximately 4,429 shares of Series X Preferred Stock, which are convertible into 44.3 million shares of our common stock, for aggregate gross proceeds of approximately

$60.0 million. Total offering costs are estimated to be $0.7 million. As of the date of the filing of this Annual Report on Form 10-K, no shares of Series X Preferred Stock have been converted into common stock.

Each share of Series X Preferred Stock has a stated value of $10,000 per share and is convertible into 10,000 shares of our common stock at the option of the holder at any time; subject to certain limitations, including, that the holder will be prohibited from converting Series X Preferred Stock into common stock, if, as a result of such conversion, the holder, together with its affiliates, would beneficially own a number of shares of common stock above a conversion blocker, which is initially set at 9.99% of the total common stock then issued and outstanding immediately following the conversion of such shares of Series X Preferred Stock. In the event of our liquidation, dissolution or winding up, holders of Series X Preferred Stock will participate pari passu with any distribution of proceeds to holders of common stock and Series O Preferred Stock holders of Series X Preferred Stock are entitled to receive dividends on shares of Series X Preferred Stock equal (on an as-if-converted-to-common stock basis) to and in the same form as dividends actually paid on the common stock or other junior securities of the Company. Shares of Series X Preferred Stock will generally have no voting rights, except as required by law and except that the consent of a majority of the holders of the outstanding Series X Preferred Stock will be required to amend the terms of the Series X Preferred Stock.

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

As previously disclosed, on July 13, 2018, the Audit Committee approved the dismissal of Marcum LLP, as our independent registered public accounting firm effective on August 2, 2018, which was the date of filing of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2018. Ernst & Young LLP's engagement as our independent auditor and independent registered public accounting firm was effective August 2, 2018.

The reports of Marcum LLP on our financial statements for the two fiscal years ended December 31, 2017 and 2016 did not contain an adverse opinion or a disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope, or accounting principles, except that the report of Marcum LLP dated March 2, 2017, relating to our consolidated balance sheets as of December 31, 2016 and 2015 and the related consolidated statements of operations, comprehensive loss, shareholders' equity, and cash flows and the related financial statement schedule for each of the three years in the period ended December 31, 2016, included an explanatory paragraph as to the uncertainty of our ability to continue as a going concern. The audit reports of Marcum LLP on our effectiveness of internal control over financial reporting for the two fiscal years ended December 31, 2017 and 2016 did not contain any adverse opinion or disclaimer of opinion.

In connection with the audits of our financial statements for each of the two fiscal years ended December 31, 2017 and 2016, and in the subsequent interim period through August 2, 2018, there were no disagreements with Marcum LLP on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedures, which, if not resolved to the satisfaction of Marcum LLP, would have caused Marcum LLP to make reference to the matter in its reports for such years. There were no "reportable events" as that term is described in Item 304(a)(1)(v) of Regulation S-K.

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 President and Chief Executive Officer, or CEO, and Chief Financial Officer, or CFO, 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 CEO and CFO 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 2019 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, 2019 was effective.

(c) Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm due to an exemption for "non-accelerated filers."

(d) 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

The information required by Item 10 of Form 10-K is incorporated herein by reference to information in our Proxy Statement for the 2020 Annual Meeting of Stockholders, which we expect to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2019.

Item 11. Executive Compensation

The information required by Item 11 of Form 10-K is incorporated herein by reference to information in our Proxy Statement for the 2020 Annual Meeting of Stockholders, which we expect to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2019.

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

The information required by Item 12 of Form 10-K is incorporated herein by reference to information in our Proxy Statement for the 2020 Annual Meeting of Stockholders, which we expect to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2019.

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

The information required by Item 13 of Form 10-K is incorporated herein by reference to information in our Proxy Statement for the 2020 Annual Meeting of Stockholders, which we expect to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2019.

Item 14. Principal Accounting Fees and Services

The information required by Item 14 of Form 10-K is incorporated herein by reference to information in our Proxy Statement for the 2020 Annual Meeting of Stockholders, which we expect to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2019.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) The following documents are filed as part of this report:

(1) Financial Statements - The financial statements filed as part of this Annual Report on Form 10-K are listed on the Index to Consolidated Financial Statements in Item 8.

(2) Financial Statement Schedules - The financial statement schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or the notes thereto.

(3) Exhibits - The exhibits required by Item 601 of Regulation S-K are listed in paragraph (b) below.

(b) Exhibits

Exhibit Number	Exhibit Description	Incorporated by Reference			
		Form	File No.	Exhibit Number	Filing Date
2.1	Agreement and Plan of Merger, dated January 24, 2018, by and between CTI BioPharma Corp., a Washington corporation, and CTI BioPharma Corp., a Delaware corporation.	8-K	000-28386	2.1	January 24, 2018
3.1	Certificate of Incorporation of CTI BioPharma Corp., a Delaware corporation, dated January 24, 2018.	8-K	000-28386	3.1	January 24, 2018
3.2	Certificate of Amendment to the Certificate of Incorporation of CTI BioPharma Corp., dated May 17, 2018.	10-Q	000-28386	3.1	August 3, 2018
3.3	Certificate of Amendment to the Certificate of Incorporation of CTI BioPharma Corp., dated May 17, 2019.	10-Q	000-28386	3.1	August 1, 2019
3.4	Certificate of Designation for Series O Convertible Preferred Stock.	8-K	000-28386	3.1	February 12, 2018
3.5	Amended and Restated Bylaws of CTI BioPharma Corp., a Delaware corporation.	8-K	000-28386	3.1	March 23, 2018
4.1	Specimen Common Stock Certificate.	8-K	000-28386	4.1	February 12, 2018
4.2	Warrant Agreement, dated June 9, 2015, by and between Registrant and Hercules Technology Growth Capital, Inc.	8-K	001-12465	4.1	June 10, 2015
4.3	Warrant to Purchase Stock, dated November 28, 2017, by and between CTI BioPharma Corp. and Silicon Valley Bank.	8-K	000-28386	4.1	November 28, 2017
4.4	Warrant to Purchase Stock, dated November 28, 2017, by and between CTI BioPharma Corp. and Life Science Loans II, LLC.	8-K	000-28386	4.2	November 28, 2017
4.5	Form of Warrant to Purchase Common Stock, dated November 6, 2018, issued to consultant to CTI BioPharma Corp.	10-K	000-28386	4.5	March 13, 2019
4.6	Description of Securities.				Filed herewith
10.1	Office Lease, dated January 27, 2012, by and between CTI BioPharma Corp. and Selig Holdings Company LLC.	10-K	001-12465	10.4	March 8, 2012
10.2†	Sublease agreement by and between CTI BioPharma Corp. and Cascadian Therapeutics, Inc.	8-K	000-28386	10.1	December 5, 2017
10.3*	Offer Letter, dated July 2, 2015, by and between CTI BioPharma Corp. and Bruce J. Seeley.	10-Q	001-12465	10.3	August 6, 2015
10.4*	Employment Agreement, dated February 24, 2017, by and between CTI BioPharma Corp. and Adam Craig.	8-K	000-28386	10.1	February 27, 2017
10.5*	Amendment to Employment Agreement, dated October 31, 2018, by and between CTI BioPharma Corp. and Adam R. Craig.	10-Q	000-28386	10.2	November 1, 2018

10.6*	Form of Severance Agreement for CTI BioPharma Corp.'s Executive Officers (as in effect as of January 6, 2015).	10-K	001-12465	10.6	March 12, 2015
10.7*	Severance Agreement, dated July 27, 2015, by and between CTI BioPharma Corp. and Bruce J. Seeley.	10-K	001-12465	10.11	February 17, 2016
10.8*	Offer Letter, dated August 1, 2017, by and between CTI BioPharma Corp. and David Kirske.	10-Q	000-28386	10.3	August 4, 2017
10.9*	Severance Agreement, dated September 25, 2017, by and between CTI BioPharma Corp. and David Kirske.	8-K	000-28386	10.1	September 26, 2017
10.10*	Form of Indemnity Agreement for CTI BioPharma Corp.'s Executive Officers and Directors.	8-K	000-28386	10.1	January 24, 2018
10.11*	2007 Employee Stock Purchase Plan, as amended and restated.	DEF 14A	001-12465	Appendix B	July 29, 2015
10.12*	CTI BioPharma Corp. 2015 Equity Incentive Plan, as amended.	8-K	001-12465	10.1	April 29, 2016
10.13*	Global Form of 2015 Equity Incentive Plan Restricted Stock Unit Award Agreement.	10-Q	001-12465	10.3	November 5, 2015
10.14*	Global Form of 2015 Equity Incentive Plan Stock Option Agreement.	10-Q	001-12465	10.4	November 5, 2015
10.15*	Global Form of 2015 Equity Incentive Plan Stock Bonus Award Agreement.	10-Q	001-12465	10.5	November 5, 2015
10.16*	2007 Equity Incentive Plan, as amended and restated.	10-Q	001-12465	10.1	October 31, 2014
10.17*	Form of 2007 Equity Incentive Plan Restricted Stock Award Agreement.	10-K	001-12465	10.14	March 12, 2015
10.18*	Global Form of 2007 Equity Incentive Plan Restricted Stock Unit Award Agreement.	10-K	001-12465	10.15	March 12, 2015
10.19*	Global Form of 2007 Equity Incentive Plan Stock Option Agreement.	10-K	001-12465	10.16	March 12, 2015
10.20*	Form of 2007 Equity Incentive Plan Restricted Stock Award Agreement for Directors (relating to applicable awards granted prior to December 17, 2014).	10-Q	001-12465	10.7	April 26, 2011
10.21*	Form of 2007 Equity Incentive Plan Restricted Stock Award Agreement (relating to applicable awards granted prior to December 17, 2014).	10-Q	001-12465	10.3	October 30, 2013
10.22*	Form of 2007 Equity Incentive Plan Restricted Stock Award Agreement for employees (relating to applicable awards granted prior to December 17, 2014).	10-Q	001-12465	10.6	April 26, 2011
10.23*	Form of 2007 Equity Incentive Plan Stock Option Agreement for Directors and Officers (relating to applicable awards granted prior to December 17, 2014).	10-Q	001-12465	10.1	October 30, 2013
10.24*	Form of Stock Award Agreement for grants of fully vested shares under CTI BioPharma Corp's 2007 Equity Incentive Plan, as amended.	10-Q	001-12465	10.2	October 30, 2013
10.25*	Form of Equity/Long-Term Incentive Award Agreement for Bruce J. Seeley.	10-K	001-12465	10.35	February 17, 2016

10.26*	Form of Amendment to Form of Equity/Long-Term Incentive Award Agreement, dated December 23, 2015, for Bruce J. Seeley.	10-K	001-12465	10.37	February 17, 2016
10.27*	Amended and Restated 2017 Equity Incentive Plan of the Registrant.	8-K	000-28386	10.1	May 21, 2018
10.28*	Form of Stock Option Agreement under the CTI BioPharma Corp. Amended and Restated 2017 Equity Incentive Plan.	8-K	000-28386	10.2	May 21, 2018
10.29	Acquisition Agreement, dated June 10, 2005, by and among CTI BioPharma Corp., CTI Technologies, Inc. and Cephalon, Inc.	8-K	001-12465	10.1	June 14, 2005
10.30†	Termination Agreement, effective January 3, 2014, by and between CTI BioPharma Corp. and Novartis International Pharmaceutical Ltd.	10-Q	001-12465	10.2	April 29, 2014
10.31†	Asset Purchase Agreement, dated April 18, 2012, by and between CTI BioPharma Corp. and S*BIO Pte Ltd.	8-K	001-12465	10.1	April 24, 2012
10.32†	Amended and Restated Exclusive License and Collaboration Agreement, dated April 21, 2017, by and among CTI BioPharma Corp., CTI Life Sciences Limited, Laboratoires Servier and Institut de Recherches Internationales Servier.	10-Q	000-28386	10.4	May 3, 2017
10.33	Asset Return and Termination Agreement, dated October 21, 2016, by and between CTI BioPharma Corp. and Baxalta.	8-K	001-12465	10.2	October 24, 2016
10.34	Letter Agreement, dated June 9, 2017, by and between CTI BioPharma Corp. and BVF Partners L.P.	8-K	000-28386	10.1	June 9, 2017
10.35†	Amended and Restated Exclusive License Agreement, dated October 24, 2014, by and between CTI BioPharma Corp. and Vernalis (R&D) Ltd.	8-K/A	001-12465	10.3	November 6, 2014
10.36†	Manufacturing and Supply Agreement, dated April 15, 2014, by and between CTI BioPharma Corp. and DSM Fine Chemicals Austria Nfg GmbH & Co KG.	10-Q	001-12465	10.1	August 4, 2014
10.37	Loan and Security Agreement, dated November 28, 2017, by and between CTI BioPharma Corp. and Silicon Valley Bank.	8-K	000-28386	10.1	November 28, 2017
10.38	First Amendment to Loan and Security Agreement, dated May 17, 2018, by and between CTI BioPharma Corp. and Silicon Valley Bank.	10-Q	000-28386	10.3	August 3, 2018
10.39	Waiver Agreement, dated January 19, 2018, by and between CTI BioPharma Corp. and Silicon Valley Bank.	10-K	000-28386	10.58	March 7, 2018
10.40	Stipulation of Settlement.	8-K	000-28386	99.2	December 15, 2017
10.41	Letter Agreement, dated December 9, 2015, by and between CTI BioPharma Corp. and BVF Partners L.P.	8-K	001-12465	10.1	December 9, 2015

10.42	Exchange Agreement, dated February 8, 2018, by and between CTI BioPharma Corp. and BVF Partners L.P.	8-K	000-28386	10.1	February 12, 2018
10.43	Separation Agreement and Release dated September 4, 2018, by and between CTI BioPharma Corp. and Jack W. Singer.	8-K	000-28386	1	September 6, 2018
10.44	Termination and Transfer Agreement, dated February 25, 2019, by and among on the one hand, CTI BioPharma Corp. and CTI Life Sciences Limited, and, on the other hand, Les Laboratoires Servier and Institut de Recherches Internationales Servier.	8-K	000-28386	10.1	February 27, 2019
10.45*	CTI BioPharma Corp. Executive Incentive Compensation Plan.	10-K	000-28386	10.45	March 13, 2019
10.46*	Director Compensation Policy.				Filed herewith
10.47	Open Market Sale AgreementSM, dated November 15, 2019, between CTI BioPharma Corp. and Jefferies LLC.	8-K	000-28386	1.1	November 15, 2019
21.1	Subsidiaries of the Registrant.				Filed herewith.
23.1	Consent of Ernst & Young 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.				
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.

Item 16. Form 10-K Summary

None.

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.

Dated: March 12, 2020

CTI BioPharma Corp.

By: /s/ Adam R. Craig

Adam R. Craig, M.D., Ph.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 Adam R. Craig and David H. Kirske, and each of them, with full power of substitution and resubstitution and full power to act without the other, as his true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file, any and all documents in connection therewith, with the Securities and Exchange commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorneys-in-fact and agents or any of them or their and his or her substitute or substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K 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/ Laurent Fischer **Laurent Fischer, M.D.**	Chairman of the Board and Director	March 12, 2020
/s/ Adam R. Craig **Adam R. Craig, M.D., Ph.D.**	President and Chief Executive Officer and Director (Principal Executive Officer)	March 12, 2020
/s/ David H. Kirske **David H. Kirske**	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 12, 2020
/s/ Michael A. Metzger **Michael A. Metzger**	Director	March 12, 2020
/s/ David Parkinson **David Parkinson, M.D.**	Director	March 12, 2020
/s/ Matthew D. Perry **Matthew D. Perry**	Director	March 12, 2020
/s/ Reed V. Tuckson **Reed V. Tuckson, M.D.**	Director	March 12, 2020

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO
SECURITIES EXCHANGE ACT OF 1934 RULES 13a-14(a) AND 15d-14(a)
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Adam R. Craig, certify that:

1. I have reviewed this Annual Report on Form 10-K of CTI BioPharma Corp.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions) of internal control over financial reporting:

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 12, 2020

By: /s/ Adam R. Craig

Adam R. Craig

President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO
SECURITIES EXCHANGE ACT OF 1934 RULES 13a-14(a) AND 15d-14(a)
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, David H. Kirske, certify that:

1. I have reviewed this Annual Report on Form 10-K of CTI BioPharma Corp.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: March 12, 2020

By: /s/ David H. Kirske
David H. Kirske
Chief Financial Officer

Exhibit 32

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Adam R. Craig, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of CTI BioPharma Corp. on Form 10-K for the fiscal year ended December 31, 2019 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report on Form 10-K fairly presents in all material respects the financial condition and results of operations of CTI BioPharma Corp.

A signed original of this written statement required by Section 906 has been provided to CTI BioPharma Corp. and will be retained by CTI BioPharma Corp. and furnished to the Securities and Exchange Commission or its staff upon request.

Dated: March 12, 2020

By: /s/ Adam R. Craig
Adam R. Craig
President and Chief Executive Officer

I, David H. Kirske, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Annual Report of CTI BioPharma Corp. on Form 10-K for the fiscal year ended December 31, 2019 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and that information contained in such Annual Report on Form 10-K fairly presents in all material respects the financial condition and results of operations of CTI BioPharma Corp.

A signed original of this written statement required by Section 906 has been provided to CTI BioPharma Corp. and will be retained by CTI BioPharma Corp. and furnished to the Securities and Exchange Commission or its staff upon request.

Dated: March 12, 2020

By: /s/ David H. Kirske
David H. Kirske
Chief Financial Officer

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