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, 2020

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 Washington	
(Address of principal executive offices)	**98121 (Zip Code)**

Registrant's telephone number, including area code: (206) 282-7100
Securities registered pursuant to Section 12(b) of the Act:

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

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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, 2020, the aggregate market value of the registrant's common equity held by non-affiliates was approximately $77.3 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 10, 2021 was 76,687,332.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2021 annual meeting of stockholders, or the 2021 Proxy Statement, are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. We expect to file the 2021 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.

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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 business disruptions and related risks resulting from the ongoing worldwide coronavirus pandemic known as COVID-19;
- our expectations regarding sufficiency of cash resources, cash expenditures, sources of cash flows and other projections, product manufacturing and sales, research and development expenses, 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, including priority review and potential accelerated approval of pacritinib as a treatment for myelofibrosis patients with severe thrombocytopenia, 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 the successful completion of, 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. In addition, we have recently started developing pacritinib for use in hospitalized patients with severe COVID-19, in response to the COVID-19 pandemic.

Pacritinib is an investigational oral kinase inhibitor with specificity for JAK2, 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, prevention of graft versus host disease, or GvHD, and chronic lymphocytic leukemia, or CLL, due to its inhibition of JAK2, IRAK1, FLT3 and CSF1R. 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:

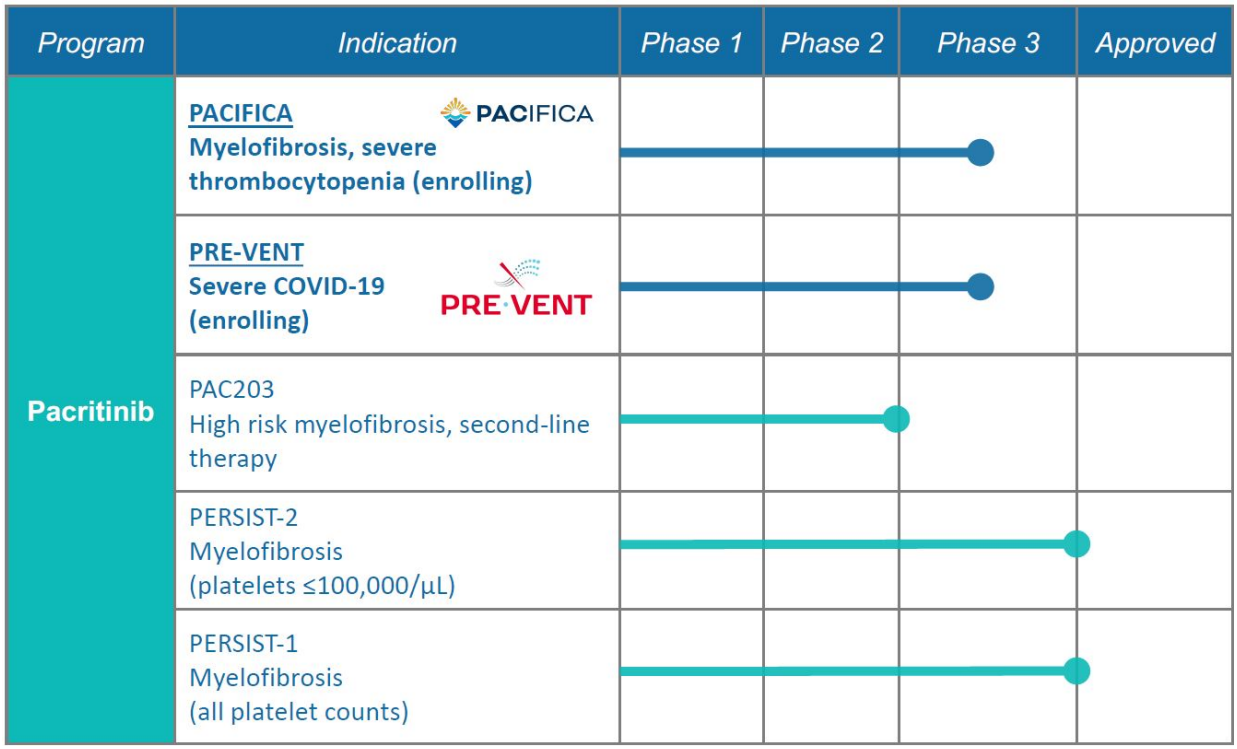
- **Develop Pacritinib in Myelofibrosis.** We intend to develop and commercialize pacritinib for adult patients with myelofibrosis.

- **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 1.9 million new cases of cancer are expected to be diagnosed in 2021 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 17,000 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

Pacritinib is an investigational oral kinase inhibitor with specificity for JAK2, 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, prevention of graft versus host disease, or GvHD, and chronic lymphocytic leukemia, or CLL, due to its inhibition

of JAK2, IRAK1, FLT3 and CSF1R. We believe pacritinib has the potential to be delivered as a single agent or in combination therapy regimens.

In September 2020, we reached an agreement with the U.S. Food and Drug Administration, or FDA, to submit a New Drug Application, or NDA, for the potential accelerated approval of pacritinib as a treatment for myelofibrosis patients with severe thrombocytopenia, and in October 2020 we commenced our rolling NDA submission. The NDA is based on the available data from our completed Phase 3 PERSIST-1 and PERSIST-2 trials and the Phase 2 PAC203 dose-ranging trial. Completion of the NDA submission is anticipated in the first quarter of 2021. The ongoing Phase 3 PACIFICA trial is expected to be completed as a post-marketing commitment.

PERSIST-1 and PERSIST-2 Trials

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.

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. 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 ($p<0.05$). 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.

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). 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. The most common treatment-emergent adverse events, 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 adverse events (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 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. On February 8, 2016, the FDA notified us that a full clinical hold had been placed on pacritinib clinical studies.

PAC203 Trial

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 adverse events 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 adverse events 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) adverse events: 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.

PACIFICA Phase 3 Trial

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 received the FDA's preliminary comments from a Type A meeting request and reached an agreement on the final design changes to our PACIFICA pivotal Phase 3 clinical trial, including changes to the statistical analysis plan that would allow for an accelerated approval pathway for pacritinib. We have amended our PACIFICA Phase 3 trial protocol, to allow for the primary analysis of Spleen Volume Reduction, or SVR, rate on the first 168 patients, with an end-of-study analysis of Total Symptom Score, or TSS, and Overall Survival, or OS, following the full enrollment of 348 patients. We previously anticipated reporting primary SVR data by the end of 2021 with final study efficacy data expected in 2023; however, as a result of the worldwide coronavirus pandemic known as COVID-19, we currently anticipate a lower enrollment rate than planned and at least a nine-month delay in the PACIFICA Phase 3 trial timeline.

PRE-VENT Phase 3 Trial

In April 2020, in response to the public health crisis due to the global COVID-19 pandemic, we initiated PRE-VENT, a Phase 3 trial evaluating pacritinib in hospitalized patients with severe COVID-19. PRE-VENT, a randomized, double-blind, placebo-controlled multicenter study will compare pacritinib plus Standard of Care, or SOC, versus placebo plus SOC in hospitalized patients with severe COVID-19, including those with a current or prior diagnosis of cancer. The primary endpoint of the trial will assess the proportion of patients who progress to invasive mechanical ventilation and/or extracorporeal membrane oxygenation or die by Day 28. We commenced enrollment of PRE-VENT in the second quarter of 2020 in the United States and currently anticipate the reporting of interim analysis from the PRE-VENT trial in mid-2021.

Patients enrolled in PRE-VENT will be randomized 1:1 to receive pacritinib (400 mg once on Day 1, then 200 mg twice daily from Day 2 to Day 14) plus SOC or placebo plus SOC. Assigned treatment will continue up to Day 14 or until the patient experiences intolerable adverse events, withdraws consent, initiates another investigational therapy or until the study is terminated. Assigned therapy may be given for an additional seven days (for a total of 21 days) at the discretion of the investigator and with medical monitor approval. In the event of hospital discharge, patients will complete treatment with the assigned therapy as an outpatient.

As a JAK2, IRAK1 and CSF1R inhibitor, pacritinib may ameliorate the effects of cytokine storm, a pathological immune reaction that can be triggered by viral infection and can lead to serious complications, including acute respiratory distress syndrome, or ARDS. Multiple inflammatory cytokines are upregulated in patients with severe COVID-19, including IL-1 and IL-6, and some patients have evidence of over-active macrophage activation. As a JAK2/IRAK1 inhibitor, pacritinib may ameliorate the effects of cytokine storm via inhibition of IL-6 and IL-1 signaling. Furthermore, as a CSF1R inhibitor, pacritinib may mitigate effects of macrophage activation syndrome.

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, GvHD, autoimmune diseases and breast cancer, some of which are currently being evaluated in investigator sponsored trials, or ISTs.

In December 2020, results from an IST evaluating pacritinib's ability to prevent GvHD were presented in an oral presentation at the American Society for Hematology conference. In this study, pacritinib was administered in combination with sirolimus and tacrolimus to patients who had undergone allogeneic stem cell transplantation for hematologic malignancies, which resulted in a significant reduction in the expected acute GvHD rates in patients within the first 100 days of therapy as compared to historical data. The Phase I portion of the study identified a biologically active and safe dose of pacritinib (100 mg twice daily) for use in this indication and showed preliminary evidence of efficacy in prevention of GvHD without compromising transplant outcomes and without any new safety concerns. Enrollment in Phase II of the study is ongoing.

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.

Pursuant to the Baxalta Termination Agreement, we are required to make a milestone payment to Takeda Pharmaceutical Company Limited, or Takeda, in the amount of approximately $10.3 million upon the first regulatory approval or any pricing and reimbursement approvals of a product containing pacritinib. Baxalta was acquired by Shire plc in 2016, and Shire plc was subsequently acquired by Takeda in 2019.

*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 clinical 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 face competition from the currently approved JAK1/JAK2 inhibitors, Jakafi® / Jakavi® (ruxolitinib) and Inrebic® (fedratinib). In August 2019, Celgene (which was subsequently acquired by Bristol Myers Squibb) 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, and in February 2021 Bristol Myers Squibb announced the European Commission approval of Inrebic®. 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, if we are successful in bringing pacritinib to market as a treatment to prevent progression to acute respiratory distress syndrome, or ARDS, and medical ventilation, we expect to face competition from numerous other companies that are currently pursuing clinical development programs for COVID-19 and related conditions.

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 calendar 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 Special Protocol Assessment, or 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 took 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 in December 2021.

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, 2020, we employed 23 individuals, 22 of whom were full-time. Our employees do not have a collective bargaining agreement. We believe our relations with our employees are good.

Corporate Information

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 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, 2020, 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 is our sole product candidate in active development and has not yet received regulatory approval.

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 significant 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. 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 regulatory authorities for one or more indications, 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.

Our business could be adversely affected by the effects of health epidemics, including the recent COVID-19 global pandemic, in regions where third parties for which we rely, as in Clinical Research Organizations, or CROs, have clinical trial sites or other business operations and may result in significant disruptions to our clinical trials, which could have a material adverse effect on our business.

Our business has been adversely affected and may continue to be adversely affected by the effects of health epidemics, including the ongoing worldwide COVID-19 pandemic, in regions where we have clinical trial sites or other business operations and has resulted in and may continue to result in significant disruptions to our clinical trials. On January 30, 2020, the World Health Organization (WHO) announced a global health emergency because of a new strain of novel coronavirus originating in Wuhan, China and the risks to the international community as the virus spreads globally beyond its point of origin. In March 2020, the WHO declared the coronavirus outbreak a pandemic, which virus has spread throughout the world, including to geographies where we are conducting the PACIFICA Phase 3 trial and the PRE-VENT Phase 3 trial. Further, the President of the United States declared the COVID-19 pandemic a national emergency. Similarly, numerous states have declared a state of emergency related to the spread of COVID-19 and/or issued executive orders directing all individuals living in their respective states to stay at their place of residence for an indefinite period of time (subject to certain exceptions to facilitate authorized necessary activities) to mitigate the impact of the COVID-19 pandemic. These states and others have repeated and may continue to repeat these mitigation steps in the future. The spread of this pandemic has caused significant volatility and uncertainty in U.S. and international markets. This has resulted in an economic downturn and may disrupt our business and delay our clinical trials and timelines.

Quarantines, shelter-in-place and similar government orders have been enacted in each of the geographies in which we are conducting our clinical trials and such orders, shutdowns or other restrictions on the conduct of business operations could

continue to remain in place for extended periods of time or subsequently reinstated, thereby further affecting 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 COVID-19. As COVID-19 affects the parts of the world where we are conducting our clinical trials, and the patients involved with these clinical trials become infected with COVID-19, we may have more adverse events and deaths in our clinical trials as a result.

We have faced and may continue to face difficulties enrolling patients in our clinical trials as the patient populations that are eligible for our clinical trials are impacted by COVID-19. Patient enrollment may be further delayed due to the diversion of healthcare resources, such as hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials, away from the conduct of clinical trials, toward the COVID-19 pandemic.

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 COVID-19, we may experience higher drop-out rates or delays in our clinical trials. Similarly, we may struggle to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19. Any such delays in enrollment hinder our ability to obtain clinical data on the schedule we currently predict.

Travel restrictions continue to be implemented throughout the world in an effort to contain COVID-19, and several countries have expanded screenings of travelers.

We may experience additional disruptions due to the COVID-19 pandemic that could severely impact our business and clinical trials, including:

- evidence from the PRE-VENT Phase 3 trial showing increased adverse events in trial participants, which could affect the safety profile and/or acceptability of our application to the FDA;

- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials;

- changes in local regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;

- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;

- delays in necessary interactions with local regulators, ethics committees, and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;

- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;

- refusal of the FDA to accept data from clinical trials in affected geographies; and

- interruption or delays to our sourced discovery and clinical activities.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The global pandemic of COVID-19 continues to rapidly evolve. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. However, 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.

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 for indications such as MF, AML, MDS, CMML, or CLL, pacritinib may face competition from the currently approved JAK1/JAK2 inhibitors, Jakafi® / Jakavi® (ruxolitinib) and Inrebic® (fedratinib). In August 2019, Celgene (which was subsequently acquired by Bristol Myers Squibb) 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, and in February 2021 Bristol Myers Squibb announced the European Commission approval of Inrebic®. 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, if we are successful in bringing pacritinib to market as a treatment to prevent progression to acute respiratory distress syndrome, or ARDS, and medical ventilation, we expect to face competition from numerous other companies that are currently pursuing clinical development programs for COVID-19 and related conditions.

In addition to the specific competitive factors discussed above, new anti-cancer drugs or drugs for the treatment of COVID-19 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 ineffectiveness, harmful side effects, difficulty in scaling manufacturing, political and legislative changes, or competition from other existing or future alternatives. In addition, 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 or PRE-VENT will support regulatory approval. 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.

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 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.

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. In addition, we believe that our present financial resources will only be sufficient to fund our operations into the second quarter of 2021. This raises substantial doubt about our ability to continue as a going concern and we will need to raise substantial additional capital in the near term in order to fund our operations through and beyond the second quarter of 2021 and to continue as a going concern thereafter. See Note 1 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information on our assessment. Uncertainty regarding our ability to continue as a going concern could also have a material and adverse impact on the price of our common stock, which could negatively impact our ability to raise sufficient funds for the development and commercialization of pacritinib and continue as a going concern. In addition, 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 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 disclose, may fail.

We will need to acquire additional funds in order to develop our business, continue the development and prepare for the potential commercialization 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.

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 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 are dependent on third-party service providers for a number of critical operational 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 Good Laboratory Practices, or GLP, and current Good Manufacturing Practices, or 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. 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 Good Distribution Practices, or 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 Good Clinical Practices, or GCP, and in accordance with our timelines, expectations and requirements. To the extent any such third parties are delayed in achieving or fail to meet our clinical trial enrollment expectations, fail to conduct our trials in accordance with GCP or study protocol or otherwise take actions outside of our control or without our consent, our business may be harmed. Furthermore, we conduct clinical trials in foreign countries, subjecting us to additional risks and challenges, including 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 the event pacritinib is approved, we will initially have only one commercial supplier for pacritinib. 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.

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 to take various actions, and we are required under our loan agreement and security agreement to comply with various affirmative covenants, which may restrict our ability to finance our operations, engage in business activities or expand or fully pursue our business strategies. A breach of any of these restrictions or covenants 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 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.

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 Value Added Tax, or 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.

Further information pertaining to these cases can be found in Part II, Item 8, "Notes to Consolidated Financial Statements, Note 14. 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 $5.3 million converted using the currency exchange rate as of December 31, 2020, 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, "Notes to Consolidated Financial Statements - Note 14. Commitments and Contingencies " regarding the regulatory matters and legal claims in which we are currently involved. 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.

In addition, our insurance is subject to high deductibles and there is no guarantee that the insurance will cover any specific claim that we currently face or may face in the future, or that it will be adequate to cover all potential liabilities and damages. In the event of negative publicity resulting from allegations of wrong-doing and/or an adverse outcome under any currently pending or future lawsuit, our business could be materially harmed.

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

We have substantial tax loss carryforwards for U.S. federal income tax purposes, but our ability to use such carryforwards to offset future income or tax liability is limited under section 382 of the Internal Revenue Code of 1986, as amended, as a result of prior changes in the stock ownership of 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.

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. 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 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. 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.

If we or the third parties upon whom we depend are 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, tsunami, 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.

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. While the dose-exploration trial for pacritinib has been completed, further registration of 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.

Although the independent data monitoring committee, or 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. 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. Patients who receive access to unapproved drugs through compassionate use or EAPs have life-threatening illnesses and generally have exhausted all other available therapies. In April 2020 we announced the initiation of PRE-VENT, a Phase 3 trial evaluating pacritinib in hospitalized patients with severe COVID-19.The risk for serious adverse events, including those which may be unrelated to pacritinib, in these patient populations 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.

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.

We may amend the clinical protocols for our product candidates. The protocol amendment process requires review and approval by several review bodies, who may not accept the amendments 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. In March 2020, we submitted an amended 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 is time-consuming and expensive and may delay or prevent our ability to continue to study pacritinib. If our changes to the trial design do not 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.

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, which could have a material adverse effect on our business.

Compounds that appear promising in research and development may fail to reach later stages of development.

In addition, from time to time, we report top-line data for clinical trials. 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.

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. 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. Additionally, our clinical trials compete with other clinical trials for similar product candidates. This competition reduces the number and types of patients and qualified clinical investigators available to us. 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 rather than enroll patients in any one of our clinical trials.

Delays in patient enrollment may result in increased costs or 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.

We may be required to suspend, repeat or terminate 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 GCPs or other applicable foreign regulatory authority guidelines. In addition, clinical trials must be conducted with product candidates produced in accordance with applicable 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.

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 in our clinical trials, 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. 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. Moreover, the FDA may withdraw approval of a product candidate or indication approved under the accelerated approval pathway for a variety of reasons.

In January 2020, we reached agreement on an accelerated approval pathway for pacritinib and in September 2020, we reached an agreement with the U.S. Food and Drug Administration, or FDA, to submit a New Drug Application, or NDA, for the potential accelerated approval of pacritinib as a treatment for myelofibrosis patients with severe thrombocytopenia. In October 2020, we commenced our rolling NDA submission. The NDA is based on the available data from our completed Phase 3 PERSIST-1 and PERSIST-2 trials and the Phase 2 PAC203 dose-ranging trial. Completion of the NDA submission is anticipated in the first quarter of 2021.

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. 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. 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.

Disruptions at government agencies could negatively affect the review of our regulatory submissions.

The ability of the FDA to review and clear or approve regulatory submissions can be affected by a variety of factors. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs, medical devices, and biologics or modifications to cleared or approved drugs, medical devices, and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, the FDA postponed certain of its manufacturing facility inspections. If a prolonged government shutdown occurs, or if global health concerns continue to impact the FDA or other regulatory authorities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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.

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.

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. 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.

Any other failure to comply with applicable regulations could result in warning or untitled letters from the FDA, 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. We may also be subject to various federal and state physician payment transparency laws, including the federal Physician Payments Sunshine Act. 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.

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 the FCPA, 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 the 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. 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. 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 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.

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, 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.

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.

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. 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. 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.

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.

The U.S. Patent and Trademark Office, or PTO, has not established a consistent policy regarding the breadth of claims that it will allow in pharmaceutical and biotechnology patents. 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.

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. 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. 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.

Furthermore, our employees may be subject to claims that we or these employees have used or disclosed trade secrets or other proprietary information of the former employers. 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 such 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 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.

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 10, 2021, our stock price ranged from a low of $0.62 to a high of $4.03. Fluctuations in the market price or liquidity of our common stock may harm the value of your investment in our common stock. *The Nasdaq Stock Market*, or *the Nasdaq,* and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. In addition, broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

We may not be able to maintain our listing on the Nasdaq, or trading on the Nasdaq may otherwise be halted or suspended, which may negatively impact the price of our common stock.

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 any reason, it may harm our stock price, increase the volatility of our stock price, decrease the level of trading activity and make it more difficult for investors to buy or sell shares of our common stock. Our failure to maintain a listing on the Nasdaq 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.

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 2020 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 and we may seek approval to increase the number of authorized shares again in the future. Without future additional 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, which could adversely affect our financial performance, growth and ability to continue our operations. 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 certain issuances of additional equity securities. 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. 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. 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 could also have the effect of delaying or preventing a change in control of our company.

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 implemented a reduction in force in 2018, 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.

Raising additional capital could cause you to incur dilution and could cause the market price of our common stock to fall.

As of December 31, 2020, options to purchase 15,595,933 shares of our common stock with a weighted-average exercise price of $2.09 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.

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 in Part II, Item 8, “Financial Statements and Supplementary Data - Notes to Consolidated Financial Statements - Note 14. Commitments and Contingencies,” which is incorporated herein by reference, 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.

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 10, 2021, there were 109 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. In addition, we have recently started developing pacritinib for use in hospitalized patients with severe COVID-19, in response to the COVID-19 pandemic.

Pacritinib is an investigational oral kinase inhibitor with specificity for JAK2, 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 JAK2, IRAK1, FLT3 and CSF1R. We believe pacritinib has the potential to be delivered as a single agent or in combination therapy regimens.

We have historically funded our operations through the sale of equity securities, funding received from our licensees and collaborators and debt financing. We do not expect to achieve or sustain profitability for the foreseeable future. We had a net loss of $52.5 million for the year ended December 31, 2020 and an accumulated deficit of $2.3 billion as of December 31, 2020, primarily from expenses incurred in connection with our research programs and from general and administrative costs associated with our operations.

We have incurred significant operating losses to date and 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 paths;
- maintain, protect and expand our intellectual property portfolio; and
- prepare for and execute the commercialization of pacritinib.

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 in two clinical trial pathways. 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.

Additionally, we continue to evaluate and manage the impact of the COVID-19 global pandemic on our operations and the conduct of our clinical trials, including considerations of the vulnerable nature of the patient population participating in our trials, reduced or halted activities at our clinical trial sites, and an increase in fatalities or other adverse events due to medical problems related to the COVID-19 global pandemic and the benefits of continued patient access to pacritinib. 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 sought, 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 license and contract revenues reflect the earned amount of upfront payments and milestone payments under our product collaborations. We did not have any revenue for the year ended December 31, 2020. Total revenues were $3.3 million for the year ended December 31, 2019. Loss from operations was $47.8 million and $40.7 million for the years ended December 31, 2020 and 2019, 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, 2020, we had cash, cash equivalents and short-term investments of $52.5 million.

Results of Operations

Years ended December 31, 2020 and 2019

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

		Years ended December 31,	
		2020	2019
Servier	Development services revenue	$ —	$ 99
	Royalty revenue	—	446
	Other revenue	—	2,800
Total		$ —	$ 3,345

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 Les Laboratoires Servier and Institut de Recherches Internationales Servier, or collectively 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.

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,	
	2020	2019
Compounds under development:		
Pacritinib	$ 20,463	$ 16,706
PIXUVRI	—	1,290
Unallocated operating expenses	5,480	6,111
Total research and development expenses	$ 25,943	$ 24,107

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. Operating expenses include our personnel costs and an allocation of occupancy, depreciation and amortization expenses associated with developing our 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. Cumulative to date external direct costs incurred by us through December 31, 2020 were $183.4 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). We do not anticipate incurring additional expenses related to PIXUVRI, as the Amended and Restated Exclusive License and Collaboration Agreement, or the Restated Agreement, with Servier was terminated in February 2019, and all of our rights and responsibilities for PIXUVRI were transferred and assigned globally to Servier pursuant to the Asset Purchase Agreement with Servier during the year ended December 31, 2019.

Research and development expenses increased to $25.9 million for the year ended December 31, 2020 compared to $24.1 million for the year ended December 31, 2019. The increase of $1.8 million between periods was primarily attributable to a $7.8 million increase and a $5.9 million increase in development costs related to the PACIFICA Phase 3 trial and the PRE-VENT Phase 3 trial, respectively, offset by a $8.8 million decrease in development costs from the completion of the PAC203 dosing clinical trial in 2019, a $1.3 million decrease in the PIX306 clinical trial close-out in 2019, a $1.2 million decrease in regulatory and consulting costs as well as a $0.6 million decrease in unallocated operating expenses.

General and administrative expenses. General and administrative expenses were $17.6 million for the year ended December 31, 2020 compared to $19.2 million for the year ended December 31, 2019. The decrease of $1.6 million between periods was primarily attributable to a $0.8 million decrease in travel and other expenses, a $0.4 million decrease in tax expenses and a $0.4 million decrease in personnel costs.

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. For the year ended December

31, 2019, we recorded $0.8 million of restructuring expenses related to employee separation costs. There were no such expenses for the year ended December 31, 2020 as we fully recognized the restructuring expenses during the first quarter of 2019.

Other operating expenses. Other operating expense of $4.2 million for the year ended December 31, 2020 relates to a full provision for uncollectability of our Italian VAT receivables and deposit. See Part II, Item 8, Notes to Consolidated Financial Statements, Note 1. Description of Business and Summary of Significant Accounting Policies - *Italian Value Added Tax Receivable* for further details. There was no such expense for the year ended December 31, 2019.

Non-operating income and expenses

Interest income. Interest income was $0.2 million and $1.2 million for the years ended December 31, 2020 and 2019, respectively. Interest income was primarily related to our short-term investments and cash equivalent securities. The change was primarily due to decreases in short-term investments and interest rates for the year ended December 31, 2020 as compared to 2019.

Interest expense. Interest expense was $0.5 million and $1.0 million for the year ended December 31, 2020 and 2019, respectively. Interest expense was related to our secured term loan. The change between periods primarily relates to a lower average loan principal balance outstanding as well as a lower average interest rate during the year ended December 31, 2020 as compared to 2019.

Amortization of debt discount and issuance costs. Amortization of debt discount and issuance costs of $0.5 million for each of the years ended December 31, 2020 and 2019, were primarily related to our senior secured term loan.

(Loss) gain on dissolution of subsidiary. A loss of $3.8 million for the year ended December 31, 2020 was related to a loss recognized upon dissolution of our majority-owned subsidiary, Aequus Biopharma, Inc. in June 2020. See Part II, Item 8, Notes to Consolidated Financial Statements, Note 13. Related Party Transactions for further details. A gain of $1.3 million for the year ended December 31, 2019 was related to a gain released from the cumulative foreign currency translation adjustment account upon dissolution of our foreign entity in accordance with ASC 830, *Foreign Currency Matters*.

Liquidity and Capital Resources

Sources of Liquidity

We have funded our operations with proceeds from the sales and the issuance of equity securities, payments pursuant to license and collaboration agreements and the incurrence of debt. As of December 31, 2020, we had $52.5 million in cash, cash equivalents and short-term investments.

Rights offering. In March 2020, we issued 15.7 million shares of our common stock at a $1.00 per share price and 4,429 shares of our Series X Preferred Stock at a $10,000 per share price, collecting net proceeds of $59.1 million upon completion of our rights offering.

At-The-Market Equity Offering. In November 2019, we entered into an Open Market Sale Agreement℠ with Jefferies LLC 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 acted as sales agent. In November and December 2020, we sold 2.1 million shares of our common stock for net proceeds of approximately $7.2 million after compensation to Jefferies. As discussed in Note 16. Subsequent Events to our consolidated financial statements, in January 2021 we entered into a new Open Market Sale Agreement℠ with Jefferies LLC to sell shares of our common stock having aggregate sales proceeds of up to $50.0 million, and received approximately $3.0 million in net proceeds as of the date of filing of this Annual Report on Form 10-K.

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 our Loan and Security Agreement, dated March 26, 2013, as amended, with Hercules Technology Growth Capital, Inc., or Hercules (and certain of its affiliates). As of December 31, 2020, we had an outstanding principal balance under our secured term loan agreement of $4.9 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. A failure to make a required loan payment or a covenant breach 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 $42.2 million during the year ended December 31, 2020 compared to $27.8 million for the same period in 2019. The increase was primarily due to revenue generated in 2019, the timing of payments and accruals and the 2019 collection of 2018 receivables from license and development services arrangements. During the year ended December 31, 2019, we received €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 also collected $10.0 million from Teva relating to the December 2018 achievement of a worldwide net sales milestone of TRISENOX.

Net cash (used in) provided by investing activities. Net cash used in investing activities was $9.6 million during the year ended December 31, 2020, and net cash provided by investing activities was $28.1 million during the same period in 2019. The change was primarily due to the amounts of short-term investments matured between periods.

Net cash provided by (used in) financing activities. Net cash provided by financing activities was $61.1 million for the year ended December 31, 2020, and net cash used in financing activities was $5.6 million during the same period in 2019. The change was primarily attributable to the net proceeds from the completion of our rights offering in March 2020 and the net proceeds from our at-the-market equity offering.

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. However, we believe that, as of the date of the filing of this Annual Report on Form 10-K, our present financial resources will only be sufficient to fund our operations into the second quarter of 2021. This raises substantial doubt about our ability to continue as a going concern and we will need to raise substantial additional capital in the near term in order to fund our operations through and beyond the second quarter of 2021 and to continue as a going concern thereafter. See Note 1 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for additional information on our assessment. Further, 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, 2020, our available cash, cash equivalents and short-term investment totaled $52.5 million. We had an outstanding principal balance under our secured term loan agreement of $4.9 million as of December 31, 2020.

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 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:

- disruptions or other delays to our business and clinical trials resulting from the ongoing worldwide COVID-19 pandemic;
- 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.

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. Given the global economic climate and additional or unforeseen effects from the COVID-19 pandemic, these estimates are becoming more challenging. 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:

Research and Development Expenses

We accrue expenses for clinical trial activities performed by CROs based upon the estimated amount of work completed on each trial. The significant factors used in estimating accruals include the number of patients enrolled, the number of active clinical sites, clinical milestones achieved, the duration for which the patients have been enrolled in the trial, and other criteria

related to the efforts of our vendors. We monitor patient enrollment levels and related activities to the extent possible through internal reviews, review of contractual terms and correspondence with CROs. We base our estimates on the best information available at the time. However, these estimates will be subject to change as additional information becomes available, which will allow us to make a more accurate estimate in future periods. In that event, we may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes more certain. Amounts ultimately incurred in relation to amounts accrued for these services may be substantially higher or lower than our estimates. Depending on the timing of payments to vendors and estimated services provided, we record net prepaid or accrued expenses related to these costs.

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.

Equity-based Compensation Expense

Equity-based compensation expense for all equity-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 equity-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 equity-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 equity-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, 2020 and 2019, 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, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered losses from operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Accrued Clinical Trial Expenses

Description of the Matter	As of December 31, 2020, the Company recorded $3.5 million for accrued clinical trial expenses. As described in Note 4 to the consolidated financial statements, the Company's expense accruals for clinical trials are based on estimates of contracted services provided by third-party vendors not yet billed. Management is required to make estimates of outstanding obligations to those third-party vendors as of period end regardless of how timely invoices are sent to the Company and whether or not billing terms under vendor contracts coincide with the timing of when services are provided. Accrual estimates are based on a number of factors, including management's knowledge of the research and development programs and clinical activities, invoicing to date, and the provisions in vendor contracts. If possible, the Company obtains information regarding unbilled services directly from its service providers and performs procedures to challenge these estimates based on its internal understanding of the services provided to date. However, the Company may also be required to estimate these services based on information available to its internal clinical or administrative staff if such information is not able to be obtained timely from its service providers. Auditing accrued clinical trial expenses is complex because of the judgments applied by management to determine the commencement and completion date of vendor tasks and the extent of work performed during the reporting period for services not yet billed by contracted third-party vendors.
How We Addressed the Matter in Our Audit	We obtained an understanding of the Company's process for estimating the accrued clinical trial expenses. To test the estimate of accrued clinical trial expenses, we performed audit procedures that included, among others, direct confirmation of billed and unbilled amounts with a sample of the Company's third-party vendors. We confirmed progress of contracted clinical activities with third-party vendors and compared such data to the Company's estimates of progress as reflected in their accrual models. We further tested the accuracy of the calculations; the reliability, completeness and relevance of management's data utilized; and the reasonableness of the assumptions used in management's accrual models by testing actual invoices paid to date, agreeing inputs back to contractual terms and holding discussions with clinical or administrative staff outside of the finance function to corroborate progress and estimated level of expended effort incurred by the Company's third-party vendors.

/s/ Ernst & Young LLP

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

Seattle, Washington
March 17, 2021

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

	December 31, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 40,394	$ 31,144
Short-term investments	12,057	2,522
Prepaid expenses and other current assets	1,874	1,914
Total current assets	54,325	35,580
Property and equipment, net	719	1,235
Other assets	3,197	9,465
Total assets	$ 58,241	$ 46,280
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,637	$ —
Accrued expenses	7,191	11,606
Current portion of long-term debt	4,455	4,812
Other current liabilities	3,755	2,070
Total current liabilities	17,038	18,488
Long-term debt, less current portion	—	4,455
Other liabilities	1,174	5,407
Total liabilities	18,212	28,350
Commitments and contingencies (Note 14)		
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, 2020 and 2019 (Aggregate liquidation preference of $25,150 as of December 31, 2020 and 2019)	—	—
Series X Preferred Stock, 4,429 shares and 0 shares issued and outstanding as of December 31, 2020 and 2019, respectively (Aggregate liquidation preference of $44,290 and $0 as of December 31, 2020 and 2019, respectively)	—	—
Common stock, $0.001 par value per share:		
Authorized shares - 166,500,000 and 131,500,000 as of December 31, 2020 and 2019, respectively		
Issued and outstanding shares - 75,896,884 and 57,979,725 as of December 31, 2020 and 2019, respectively	76	58
Additional paid-in capital	2,367,958	2,299,186
Accumulated other comprehensive income	2	—
Accumulated deficit	(2,328,007)	(2,275,556)
Total CTI stockholders' equity	40,029	23,688
Noncontrolling interest	—	(5,758)
Total stockholders' equity	40,029	17,930
Total liabilities and stockholders' equity	$ 58,241	$ 46,280

See accompanying notes.

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

	Year Ended December 31,	
	2020	**2019**
License and contract revenues	$ —	$ 3,345
Operating costs and expenses:		
Research and development	25,943	24,107
General and administrative	17,626	19,155
Restructuring expenses	—	794
Other operating expenses	4,200	—
Total operating costs and expenses	47,769	44,056
Loss from operations	(47,769)	(40,711)
Non-operating income (expense):		
Interest income	204	1,172
Interest expense	(511)	(1,002)
Amortization of debt discount and issuance costs	(521)	(521)
Foreign exchange loss	(80)	(281)
(Loss) gain on dissolution of subsidiary	(3,774)	1,320
Total non-operating (income) expense, net	(4,682)	688
Net loss before noncontrolling interest	(52,451)	(40,023)
Noncontrolling interest	—	3
Net loss	$ (52,451)	$ (40,020)
Basic and diluted net loss per common share	$ (0.74)	$ (0.69)
Shares used in calculation of basic and diluted net loss per common share	71,141	57,974

See accompanying notes.

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

	Year Ended December 31,	
	2020	2019
Net loss before noncontrolling interest	$ (52,451)	$ (40,023)
Other comprehensive income (loss):		
Foreign currency translation adjustments	—	(2,323)
Unrealized foreign exchange gain on intercompany balance	—	957
Net unrealized gain on securities available-for-sale	2	16
Other comprehensive income (loss)	2	(1,350)
Comprehensive loss	(52,449)	(41,373)
Comprehensive loss attributable to noncontrolling interest	—	3
Comprehensive loss attributable to CTI	$ (52,449)	$ (41,370)

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) Income	Deficit	Interest	Equity
Balance at January 1, 2019	13	$ —	57,986	$ 58	$ 2,294,025	$ 1,350	$ (2,236,739)	$ (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	$ —	$ (2,275,556)	$ (5,758)	$ 17,930
Issuance of common stock, net of issuance costs	—	—	17,770	18	22,607	—	—	—	22,625
Conversion of Series X preferred stock to common stock	—	—	3	—	3	—	—	—	3
Reclassification of Series X preferred stock from mezzanine equity	4	—	—	—	43,637	—	—	—	43,637
Dissolution of majority-owned subsidiary	—	—	—	—	(1,949)	—	—	5,758	3,809
Equity-based compensation	—	—	—	—	4,317	—	—	—	4,317
Other	—	—	144	—	157	—	—	—	157
Net loss for the year ended December 31, 2020	—	—	—	—	—	—	(52,451)	—	(52,451)
Other comprehensive income	—	—	—	—	—	2	—	—	2
Balance at December 31, 2020	17	$ —	75,897	$ 76	$ 2,367,958	$ 2	$ (2,328,007)	$ —	$ 40,029

See accompanying notes.

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

	Year Ended December 31,	
	2020	**2019**
Operating activities		
Net loss before noncontrolling interest	$ (52,451)	$ (40,023)
Adjustments to reconcile net loss to net cash used in operating activities:		
Equity-based compensation expense	4,317	5,166
Depreciation and amortization	532	546
Provision for Italian VAT receivables and deposit	4,200	—
Loss (gain) on dissolution of subsidiary	3,774	(1,320)
Other	(155)	47
Changes in operating assets and liabilities:		
Receivables from license and development services arrangements	—	13,674
Prepaid expenses and other assets	2,274	1,120
Accounts payable, accrued expenses and other liabilities	(4,696)	(7,032)
Net cash used in operating activities	(42,205)	(27,822)
Investing activities		
Purchases of property and equipment	(17)	—
Purchases of short-term investments	(12,100)	(11,018)
Proceeds from maturities of short-term investments	2,500	39,150
Net cash (used in) provided by investing activities	(9,617)	28,132
Financing activities		
Proceeds from rights offering, net of issuance costs	59,108	—
Proceeds from at-the-market equity offering, net of issuance costs	7,157	—
Cash paid for at-the-market equity offering costs	—	(275)
Repayment of debt	(5,333)	(5,333)
Proceeds from stock option exercises and ESPP stock issuance	140	1
Net cash provided by (used in) financing activities	61,072	(5,607)
Effect of exchange rate changes on cash and cash equivalents	—	2
Net increase (decrease) in cash and cash equivalents	9,250	(5,295)
Cash and cash equivalents at beginning of year	31,144	36,439
Cash and cash equivalents at end of year	$ 40,394	$ 31,144
Supplemental disclosure of cash flow information		
Cash paid during the period for interest	$ 547	$ 1,044

See accompanying notes.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Description of Business and Summary of Significant Accounting Policies

CTI BioPharma Corp., together with its 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. In addition, we have recently started developing pacritinib for use in hospitalized patients with severe COVID-19, in response to the COVID-19 pandemic.

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 the expenditure of substantial resources.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of CTI, its wholly-owned subsidiary CTI Life Sciences Limited, or CTILS, until its dissolution in November 2019, and our majority-owned subsidiary, Aequus Biopharma, Inc., or Aequus, until its dissolution in June 2020, as discussed in Note 13. Related Party Transactions. We had an approximately 60% interest in Aequus; the remaining interest not held by CTI was reported as *noncontrolling interest* in the consolidated financial statements until its dissolution. All intercompany transactions and balances were eliminated in consolidation.

Liquidity

The accompanying consolidated financial statements have been prepared assuming that we will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business 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.

Over the next year and in the normal course of business, we will need to continue to conduct research, development, testing and regulatory compliance activities with respect to pacritinib and prepare for potential commercialization, and in the course of such activities, we will incur general and administrative expenses. Additional business activities will include procuring manufacturing and drug supply services, the costs of which, together with our projected general and administrative expenses, are expected to result in operating losses for the foreseeable future. We have incurred a net operating loss every year since our formation. As of December 31, 2020, 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 $52.5 million as of December 31, 2020, and we expect that our present financial resources will only be sufficient to meet our obligations as they come due and to fund our operations into the second quarter of 2021. 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, these factors raise substantial doubt about our ability to continue as a going concern.

Accordingly, we will need to acquire additional funds in order to develop our business and continue the development and prepare for the potential commercialization of pacritinib. The amount of funds that we will ultimately require will depend, in part, upon: regulatory approval developments and the extent to which we are required to conduct additional clinical trials; competitive market developments which require us to alter our business practices; and other unplanned expenses or business developments. 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 available 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, be required to reduce our 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 at affordable rates with competitive terms, have to 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 upon many factors relating to drug approval status and our commercialization plans, as well as our clinical trials. These factors include the number of clinical trial sites in a given clinical trial, the number of patients treated in a given clinical trial, the pace of patient enrollment and other matters that may impact clinical development, including changes to a clinical trial that we may initiate or that may be requested by the FDA or other regulators. There can be no assurance as to the amount of funding necessary to fund the development of pacritinib to completion or that we will be able to obtain this funding. 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 estimates and assumptions that affect the reported amounts of assets and liabilities, revenues and expenses, and related disclosures of loss contingencies in the consolidated financial statements and accompanying notes. Estimates are used for, but not limited to, clinical accruals, income taxes, useful lives of property and equipment, commitments and contingencies, equity-based compensation forfeiture rates, collectability of receivables, and impairment of investments. Given the global economic climate and additional or unforeseen effects from the COVID-19 pandemic, these estimates are becoming more challenging, and actual results could differ materially from those estimates.

Certain Risks, Uncertainties and Concentrations

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, 2020 and 2019, 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, 2020 and 2019. 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, 2020				December 31, 2019
	Cost or Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Total Estimated Fair Value	Total Estimated Fair Value
Cash	$ 385	$ —	$ —	$ 385	$ 188
Level 1 securities:					
Money market funds	40,009	—	—	40,009	28,957
Level 2 securities:					
U.S. government and agency securities	—	—	—	—	2,522
Corporate debt securities	12,055	2	—	12,057	1,999
Total cash, cash equivalents and short-term investments	$ 52,449	$ 2	$ —	$ 52,451	$ 33,666

There were no other financial instruments requiring fair value measurement as of December 31, 2020 and 2019.

At December 31, 2020 and 2019, 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, 2020 and 2019 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.

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 €3.9 million as of December 31, 2020 and 2019. While we believe that our refund claim is valid, we concluded that the ongoing COVID-19 global pandemic negatively impacted the collectability of our Italian VAT receivables and deposit. Accordingly, we recorded a full provision against our Italian VAT receivables and deposit in the amount of $4.2 million, which is included in *Other operating expenses* for the year ended December 31, 2020.

In addition, as disclosed in Note 14. 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 $5.3 million converted using the currency exchange rate as of December 31, 2020), to the ITA is probable at this time.

Leases

Under ASC 842 - *Leases*, 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 derive the present value of lease payments using our incremental borrowing rate, 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 *General and administrative* expenses in our consolidated statements of operations. Right-of-use assets are included in *Other assets*, and 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 9. Collaboration, Licensing and Milestone Agreements and Note 14. 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 assess 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.

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 net loss 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.

Immaterial Correction of an Error in Prior Periods

During the quarter ended June 30, 2020, we identified errors related to an overstatement of accumulated other comprehensive loss that arose from foreign currency losses recorded in 2007 to accumulated other comprehensive loss instead of net loss. In accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification 250, *Accounting Changes and Error Corrections*, we evaluated the materiality of the errors from quantitative and qualitative perspectives and concluded that the errors were immaterial to our financial statements. No amendments to previously filed interim or annual periodic reports were required. Consequently, we have adjusted for these errors by revising the historical financial statements presented herein. We recognized the cumulative effect of the error on periods prior to those that are presented herein by reducing unrealized loss of $12.0 million from accumulated other comprehensive loss and increasing accumulated deficit as of December 31, 2018. The correction did not have an impact on total assets, total stockholders' equity, the consolidated statements of operations, comprehensive loss, or cash flows.

Recently Adopted Accounting Standards

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 adopted this guidance on January 1, 2020. The adoption of this accounting guidance did not have a material impact on our consolidated financial statements.

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. For smaller reporting companies, the guidance is effective for fiscal years beginning after December 15, 2022, including interim periods therein. 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 October 2020, the FASB issued a new accounting guidance to provide incremental improvements to its Accounting Standards Codification on various topics. Such improvements include conforming amendments, clarifications to guidance, simplifications to wording or structure of guidance, and other minor changes. For smaller reporting companies, the guidance is effective for fiscal years beginning after December 15, 2021, and interim periods within annual periods beginning after December 15, 2022. Early adoption is permitted for any annual or interim period for which financial statements have not been issued. The codification amendments do not change GAAP, therefore 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 a material impact on our consolidated financial statements.

Reclassifications

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

2. Property and Equipment

Property and equipment consisted of the following as of December 31, 2020 and 2019 (in thousands):

	2020	2019
Furniture and office equipment	$ 663	$ 2,872
Leasehold improvements	5,140	5,140
	5,803	8,012
Less: accumulated depreciation and amortization	(5,084)	(6,777)
Property and equipment, net	$ 719	$ 1,235

Depreciation expense was $0.5 million for each of the years ended December 31, 2020 and 2019.

3. Other Assets

Other assets consisted of the following as of December 31, 2020 and 2019 (in thousands):

	2020	2019
Right-of-use assets	$ 2,149	$ 3,379
Italian VAT receivables, net (1)	—	4,390
Italian VAT deposit, net (1)	—	483
Refundable security deposit	194	194
Clinical trial deposits	770	720
Other	84	299
Other assets	$ 3,197	$ 9,465

(1) During the year ended December 31, 2020, we recorded full allowances against our Italian VAT receivables and deposit. See Note 1. Description of Business and Summary of Significant Accounting Policies for further details.

4. Accrued Expenses

Accrued expenses consisted of the following as of December 31, 2020 and 2019 (in thousands):

	2020	2019
Clinical trial expenses	$ 3,512	$ 7,920
Employee compensation and related expenses	2,792	2,851
Manufacturing expenses	238	228
Other	649	607
Total accrued expenses	$ 7,191	$ 11,606

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 had certain office equipment leases until October 2020. 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,	
	2020	2019
Operating lease expense	$ 1,653	$ 1,696
Variable lease expense	230	178
Sublease income	(1,247)	(1,247)
Total lease expense, net	$ 636	$ 627

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

	December 31, 2020
Right-of-use assets (included in *Other Assets*)	$ 2,149
Lease liabilities, current (included in *Other current liabilities*)	$ 2,193
Lease liabilities, non-current (included in *Other liabilities*)	800
Total lease liabilities	$ 2,993

As of December 31, 2020, the maturities of operating lease liabilities were as follows (in thousands):

	Operating Lease Payments	Sublease Rental Receipts	Net
2021	$ 2,437	$ (1,454)	$ 983
2022	820	(499)	321
Thereafter	—	—	—
Total payments	3,257	$ (1,953)	$ 1,304
Less imputed interest	(264)		
Total lease liabilities	$ 2,993		

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

	December 31, 2020
Supplemental cash flow information	
Cash paid for amounts included in the measurement of lease liabilities	$ 2,443
Weighted-average remaining lease term of operating leases (years)	1.33
Weighted-average discount rate of operating leases	12.4 %

6. Other Liabilities

Other liabilities consisted of the following as of December 31, 2020 and 2019 (in thousands):

	2020	2019
Lease liabilities, non-current	$ 800	$ 2,993
End-of-facility lender fee (1)	—	1,440
Other long-term obligations	374	974
Total other liabilities	$ 1,174	$ 5,407

(1) End-of-facility lender fee as of December 31, 2019 represents an amount payable to SVB upon repayment of our secured term loan. This fee is classified in *Other current liabilities* as of December 31, 2020 due to the November 2021 loan maturity date. 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 under which $16.0 million was funded in November 2017. 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, 2020, $0.4 million of the original debt discount and $27,000

of the debt issuance costs remained unamortized. The outstanding principal balance on the term loan was $4.9 million as of December 31, 2020.

As of December 31, 2020, the scheduled principal and interest payments (based on the interest rate of 6.75 percent as of December 31, 2020) as well as the back-end fee described above are as follows:

	Principal	Interest	Back-end fee	Total
2021	$ 4,889	$ 167	$ 1,440	$ 6,496
Thereafter	—	—	—	—
Total scheduled payments	$ 4,889	$ 167	$ 1,440	$ 6,496
Less: debt discount and issuance costs	$ (434)			
Current portion of long-term debt	$ 4,455			

8. Equity Transactions

At-The-Market Equity Offering

In November 2019, we entered into an Open Market Sale Agreement℠ with Jefferies LLC, or 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 acted as sales agent.

Under the terms of the Jefferies Sale Agreement, we 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 used 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 could each terminate the Jefferies Sale Agreement at any time upon one trading day's prior notice. We could also sell shares to Jefferies acting as principal for Jefferies' own account. The compensation to Jefferies for sales of our common stock was an amount equal to 3% of the gross proceeds of any shares of our common stock sold under the Jefferies Sale Agreement. We had no obligation to sell any shares under the Jefferies Sale Agreement, and could at any time suspend solicitation and offers under the Jefferies Sale Agreement. In connection with the Jefferies Sales Agreement, we recorded financing costs of $0.2 million in *General and administrative* expenses for the year ended December 31, 2019. No shares of our common stock were sold under the Jefferies Sale Agreement during the year ended December 31, 2019. In November and December 2020, we sold 2.1 million shares of our common stock for net proceeds of approximately $7.2 million after compensation to Jefferies. Subsequent to the expiry of the Form S-3 Registration Statement (File No. 333-221382) in December 2020 pursuant to which shares of our common stock under the Jefferies Sale Agreement could be issued, no shares were sold under the Jefferies Sale Agreement.

In January 2021, we entered into a new Open Market Sale Agreement℠ with Jefferies LLC. See Note 16. Subsequent Events for additional information.

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, we issued a total of 15.7 million shares of our common stock and 4,429 shares of our Series X Preferred Stock, which shares of Series X Preferred Stock are convertible into 44.3 million shares of our common stock, for aggregate gross proceeds of approximately $60.0 million. Total offering costs were approximately $0.9 million. There was no beneficial conversion feature on our Series X Preferred Stock. Due to the revocable nature of the Rights Offering prior to closing, there was no separate accounting for the subscription rights and purchase guarantees made by certain of our stockholders prior to the closing date.

At the time of issuance of our Series X Preferred Stock, the carrying amount of our Series X Preferred Stock was initially classified as mezzanine equity in the consolidated balance sheet since we did not have an adequate number of authorized shares of our common stock to satisfy the number of required shares under the conversion option of our Series X Preferred Stock. In

June 2020, our stockholders approved an increase in the number of authorized shares of our common stock, and as such, the settlement of the conversion option's exercise can now be controlled. Accordingly, the carrying amount of our Series X Preferred Stock was reclassified to permanent equity in June 2020.

During the first quarter of 2020, 0.2873 of a share of our Series X Preferred Stock was converted into 2,873 shares of our common stock. There were 4,429 shares of our Series X Preferred Stock outstanding as of December 31, 2020.

Each share of our 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 except as described above. The Series X Preferred Stock is 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 our common stock and holders of our Series O Preferred Stock. Holders of our Series X Preferred Stock are also 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 our 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.

Common Stock Authorized

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.

In June 2020, the Company's certificate of incorporation was amended to increase the total number of authorized shares of common stock from 131.5 million to 166.5 million.

Common Stock Reserved

As of December 31, 2020, we had 166.5 million authorized shares of common stock, of which 75.9 million shares were issued and outstanding, and 70.0 million shares were reserved for future issuances as follows (in thousands):

Equity incentive plans	15,878
Option agreement with Adam R. Craig per Nasdaq Listing Rule 5635(c)(4)	1,120
Employee stock purchase plan	138
Convertible preferred stock	52,673
Common stock purchase warrants	190
Total common stock reserved	69,999

Warrants

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, 2020. Of this amount, warrants to purchase up to 169,014 shares of our common stock were exercisable as of December 31, 2020.

9. Collaboration, Licensing and Milestone Agreements

Baxalta

In November 2013, we entered into the Pacritinib License Agreement with Baxter for the development and commercialization of pacritinib for use in oncology and potentially additional therapeutic areas. 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 which 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. Pursuant to the Baxalta Termination Agreement, we are required to make a milestone payment to Takeda in the amount of approximately $10.3 million upon the first regulatory approval or any pricing and reimbursement approvals of a product containing pacritinib. Baxalta was acquired by Shire plc in 2016, and Shire plc was subsequently acquired by Takeda in 2019.

*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.

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, 2020, we had earned $60.0 million of such potential milestone payments as a result of having achieved certain milestones. We did not earn any milestone revenues during the years ended December 31, 2020 and 2019. The achievement of the remaining milestones is uncertain at this time.

Other Agreements

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

10. Equity-Based Compensation

Equity-Based Compensation Expense

Equity-based compensation expense for all equity-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 equity-based compensation using the straight-line, single-award method based on the value of the portion of equity-based payment awards that is ultimately expected to vest during the period. Equity-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 equity-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.

All of equity-based compensation expense recognized during the years ended December 31, 2020 and 2019 was related to stock options. The following table summarizes equity-based compensation expense for the years ended December 31, 2020 and 2019, which was allocated as follows (in thousands):

	2020	2019
Research and development	$ 522	$ 506
General and administrative	3,795	4,660
Total equity-based compensation expense	$ 4,317	$ 5,166

Equity-based compensation had a $4.3 million and $5.2 million effect on net loss for the years ended December 31, 2020 and 2019, respectively. It had no effect on cash flows from operating activities for the periods presented.

As of December 31, 2020, unrecognized compensation cost related to unvested stock options amounted to $4.0 million, which will be recognized over the remaining weighted-average requisite service period of 1.59 years.

For the years ended December 31, 2020 and 2019, no tax benefits were attributed to equity-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 the 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, 2020, 18.3 million shares were authorized for issuance under equity incentive plans, of which 1.4 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,	
	2020	2019
Risk-free interest rate	0.5 %	2.3 %
Expected dividend yield	None	None
Expected life (in years)	4.6	4.4
Volatility	88 %	89 %

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 both historical and implied volatilities of CTI BioPharma Corp. and our selected peer group of comparable companies within the 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, 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, 2019 (4,047,000 exercisable)	10,954,000	$ 2.56		
Granted	5,264,000	$ 1.04		
Exercised	(107,000)	$ 1.13		$ 170
Forfeited	(459,000)	$ 1.08		
Cancelled and expired	(56,000)	$ 6.30		
Outstanding at December 31, 2020 (8,099,000 exercisable)	15,596,000	$ 2.09	7.8	$ 23,423
Vested or expected to vest at December 31, 2020	15,223,000	$ 2.11	7.8	$ 22,635
Exercisable at December 31, 2020	8,099,000	$ 3.01	7.0	$ 7,276

The weighted average exercise price of options exercisable at December 31, 2020 and 2019 was $3.01 and $4.39, respectively. The weighted average grant-date fair value of options granted during 2020 and 2019 was $0.76 and $0.60 per option, respectively.

In March 2017, Dr. Adam R. Craig, our President and CEO, was granted stock options to purchase 1.2 million shares of our 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).

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 39,000 shares of our common stock to employees during the year ended December 31, 2020. There are 0.2 million shares of common stock authorized under the Purchase Plan and approximately 0.1 million shares are reserved for future purchases as of December 31, 2020.

11. Employee Benefit Plans

Our 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 related to discretionary matching contributions for each of the years ended December 31, 2020 and 2019.

12. Net Loss Per Share

Basic net loss per share is calculated based on net loss 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,	
	2020	2019
Net loss	$ (52,451)	$ (40,020)
Basic and diluted:		
Weighted average shares outstanding	71,146	57,980
Less: weighted average restricted shares outstanding	(5)	(6)
Shares used in calculation of basic and diluted net loss per common share	71,141	57,974
Net loss per common share: Basic and diluted	$ (0.74)	$ (0.69)

Common shares underlying equity awards, warrants and convertible preferred stock aggregating 56.9 million shares and 18.9 million shares prior to the application of the treasury stock method for the years ended December 31, 2020 and 2019, respectively, have been excluded from the calculation of diluted net loss per share because they were anti-dilutive.

13. Related Party Transactions

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, pursuant to which we funded Aequus until 2017. In March 2017, we and Aequus entered into a License and Promissory Note Termination Agreement. We had 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 did not file an Investigational New Drug Application, or IND, for an ACTH Product with the FDA by September 6, 2019. Aequus did not file an IND by September 6, 2019. In June 2020, we terminated the License and Promissory Note Termination Agreement; however, we did not request Aequus to assign all ACTH Product related assets to us. In connection with such termination, we were also deemed to have relinquished all of our ownership interest in Aequus as it had been administratively dissolved at the time of termination.

As discussed in Note 1. Description of Business and Summary of Significant Accounting Policies - *Principles of Consolidation,* Aequus was our majority-owned subsidiary until its dissolution in June 2020. Upon deconsolidation of Aequus, we recognized a loss of $3.8 million, which was recorded in *(Loss) gain on dissolution of subsidiary* during the year ended December 31, 2020.

BVF Partners L.P.

In March 2020, in connection with our rights offering as discussed in Note 8. Equity Transactions, 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. During the year ended December 31, 2020, no shares of Series X Preferred Stock owned by BVF were converted into our common stock. As of December 31, 2020 and 2019, BVF beneficially owned approximately 9.1% and 12.0% of our outstanding common stock, respectively. Matthew D. Perry, a member of our Board, is the President of BVF and portfolio manager for the underlying funds managed by the firm.

14. 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 9. 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.

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 $5.3 million converted using the currency exchange rate as of December 31, 2020, 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.

15. 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,	
	2020	2019
United States	$ (52,451)	$ (40,242)
Foreign	—	219
Net loss before noncontrolling interest and income taxes	$ (52,451)	$ (40,023)

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

	2020	2019
Federal income tax rate	21 %	21 %
Research and development tax credits	4	14
Non-deductible compensation	(2)	(2)
Valuation allowance	20	(31)
Receivable impairment	(2)	—
Expired tax attribute carryforwards / Section 382 limitation	(29)	—
(Loss) gain on subsidiary liquidations	(14)	1
Foreign currency gains and losses	—	1
Unrecognized tax benefits	2	(3)
Other	—	(1)
Net effective tax rate	— %	— %

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

	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 22,756	$ 27,151
Capitalized research and development	33,280	32,907
Research and development tax credit carryforwards	1,779	7,317
Equity-based compensation	3,176	3,109
Intangible assets	7,251	7,519
Depreciation and amortization	699	618
Lease liability	629	1,039
Other deferred tax assets	312	918
Total deferred tax assets	69,882	80,578
Less: valuation allowance	(69,085)	(79,506)
	797	1,072
Deferred tax liabilities:		
Right-of-use asset	(451)	(667)
Deductions for tax in excess of financial statements	(346)	(405)
Total deferred tax liabilities	(797)	(1,072)
Net deferred tax assets	$ —	$ —

As of December 31, 2020 and 2019, we had U.S. federal net operating loss carryforwards, or the NOL, of approximately $99.9 million and $92.0 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 $87.9 million with an indefinite life as of December 31, 2020. In June 2020, as discussed in Note 13. Related Party Transactions, we were deemed to have relinquished all of our ownership interest in Aequus. The associated net operating loss carryforward of $10.3 million was written off due to the termination of this investment in Aequus. We have accumulated state tax losses of approximately $12.3 million and $12.7 million as of December 31, 2020 and 2019, respectively. We also had U.S. federal tax credits of $1.8 million and $7.3 million as of December 31, 2020 and 2019, respectively, which may be used to offset future tax liabilities. The NOL and tax credit carryforwards, some of which expire in 2021, are 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 limits 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.

In November 2019, CTILS, our wholly-owned subsidiary in the United Kingdom, was deemed dissolved. In June 2020, the liquidation of CTILS was complete. Accordingly, during the year ended December 31, 2020, the NOL carryforwards of approximately $40.9 million was written off as a result of the liquidation.

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 decreased by $10.4 million during the year ended December 31, 2020 primarily due to the reductions in net operating loss carryforwards and tax credit carryforwards as a result of the 2020 Section 382 analysis. Additionally, the valuation allowance decreased due to the write-off of Aequus and CTILS 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 2001 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):

	2020	2019
Balance at beginning of period	$ 1,268	$ —
Gross increases to tax positions in prior periods	—	633
Gross decreases to tax positions in current periods	(1,268)	—
Gross increases to tax positions in current periods	390	635
Balance at end of period	$ 390	$ 1,268

As of December 31, 2020, the total amount of unrecognized tax benefits was $0.4 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, 2020.

16. Subsequent Events

At-The-Market Equity Offering

In January 2021, we entered into an Open Market Sale Agreement℠ with Jefferies LLC, or the Sale Agreement, to sell shares of our common stock, having aggregate sales proceeds of up to $50.0 million, from time to time, through an "at the market" equity offering program under which Jefferies will act as sales agent.

Under the 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 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 Sale Agreement at any time upon ten trading days' 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 our common stock sold under the Sale Agreement.

We have no obligation to sell any shares under the Sale Agreement, and may at any time suspend solicitation and offers under the Sale Agreement.

As of the date of filing of this Annual Report on Form 10-K, we have sold 0.9 million shares of our common stock for net proceeds of approximately $3.0 million after compensation to Jefferies under the Sale Agreement.

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

None.

Item 9A. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in reports filed under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the 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 2020 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, 2020 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 2021 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, 2020.

Our Code of Ethics applies to all of our directors, officers and employees, including our principal executive, principal financial and principal accounting officers, or persons performing similar functions. Our Code of Ethics is posted on our website located at www.ctibiopharma.com. We intend to disclose future amendments to certain provisions of the Code of Ethics, and waivers of the Code of Ethics granted to executive officers and directors, on the website within four business days following the date of the amendment or waiver.

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 2021 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, 2020.

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 2021 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, 2020.

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 2021 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, 2020.

Item 14. Principal Accountant 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 2021 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, 2020.

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
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 Amendment to the Certificate of Incorporation of CTI BioPharma Corp., dated June 9, 2020	10-Q	000-28386	3.1	August 7, 2020
3.5	Certificate of Designation for Series O Convertible Preferred Stock.	8-K	000-28386	3.1	February 12, 2018
3.6	Certification of Designation of Preferences, Rights and Limitations of Series X Convertible Preferred Stock	8-K	000-28386	3.1	February 14, 2020
3.7	Amended and Restated Bylaws of CTI BioPharma Corp., a Delaware corporation.	8-K	000-28386	3.1	April 13, 2020
4.1	Specimen Common Stock Certificate.	8-K	000-28386	4.1	February 12, 2018
4.2	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
4.3	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
4.4	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
4.5	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	June 10, 2020
10.28*	Form of Stock Option Agreement under the CTI BioPharma Corp. Amended and Restated 2017 Equity Incentive Plan.	10-Q	000-28386	10.1	November 10, 2020
10.29*	CTI BioPharma Corp. Stock Option Agreement (Inducement Form)				Filed herewith.
10.30	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
10.31†	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	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
10.41	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
10.42	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

10.43*	CTI BioPharma Corp. Executive Incentive Compensation Plan.	10-K	000-28386	10.45	March 13, 2019
10.44*	Director Compensation Policy.	10-K	000-28386	10.46	March 13, 2020
10.45	Open Market Sale Agreement℠, dated November 15, 2019, between CTI BioPharma Corp. and Jefferies LLC.	8-K	000-28386	1.1	November 15, 2019
10.46	Open Market Sale Agreement℠, dated January 15, 2021, between CTI BioPharma Corp. and Jefferies LLC.	8-K	000-28386	1.1	January 15, 2021
10.47	Investment Agreement, dated as of January 31, 2020, by and among the Registrant, on the one hand, and the purchasers identified on the signature pages thereto, on the other hand.	8-K	000-28386	10.1	February 3, 2020
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	The following financial statements from the Company's Annual Report on Form 10-K for the year ended December 31, 2020, formatted in Inline XBRL: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Comprehensive Loss, (iv) Consolidated Statements of Stockholders' Equity, (v) Consolidated Statements of Cash Flows, and (vi) Notes to Consolidated Financial Statements, tagged as blocks of text and including detailed tags.				
104	Cover page interactive data file (formatted in Inline XBRL and contained in Exhibit 101).				

* 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 17, 2021

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 17, 2021
/s/ Adam R. Craig **Adam R. Craig, M.D., Ph.D.**	President and Chief Executive Officer and Director (Principal Executive Officer)	March 17, 2021
/s/ David H. Kirske **David H. Kirske**	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 17, 2021
/s/ Michael A. Metzger **Michael A. Metzger**	Director	March 17, 2021
/s/ David Parkinson **David Parkinson, M.D.**	Director	March 17, 2021
/s/ Matthew D. Perry **Matthew D. Perry**	Director	March 17, 2021
/s/ Reed V. Tuckson **Reed V. Tuckson, M.D.**	Director	March 17, 2021

Exhibit 4.5

DESCRIPTION OF REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following description of our capital stock is intended as a summary only and therefore is not a complete description of our capital stock. This description is based upon, and is qualified by reference to, our certificate of incorporation, as amended (certificate of incorporation), our amended and restated by-laws (bylaws) and applicable provisions of Delaware corporate law. You should read our certificate of incorporation and by-laws, which are filed as exhibits to our Annual Report on Form 10-K, to which this exhibit is also appended.

Our authorized capital stock consists of 166,500,000 shares of common stock, par value $0.001 per share, and 33,333 shares of preferred stock, par value $0.001 per share, of which 12,575 are designated as the Series O Preferred Stock and 4,500 are designated as the Series X Convertible Preferred Stock.

Common Stock

General

Each holder of common stock is generally entitled to one vote for each share held on all matters to be voted upon by the shareholders and there are no cumulative voting rights. All matters put to a shareholder vote generally require the approval of a majority of shares entitled to vote, except as otherwise provided by our certificate of incorporation or bylaws or required by law. Subject to preferences that may be applicable to any outstanding preferred stock, holders of common stock are entitled to receive ratably the dividends, if any, that are declared from time to time by the board of directors out of funds legally available for that purpose. In the event of our liquidation, dissolution or winding up, the holders of common stock are entitled to share in our assets remaining after the payment of liabilities and the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock. Holders of common stock have no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of common stock are validly issued, fully paid and non-assessable, and any issued shares of common stock will be validly issued, fully paid and non-assessable. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate in the future.

Bylaw Amendments

The Board is expressly authorized to make, alter or repeal any provision of our bylaws.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.

Listing

Our shares of common stock trade on The Nasdaq Capital Market under the symbol "CTIC".

Preferred Stock

Under our certificate of incorporation, our board of directors has the authority, without further action by stockholders, to designate up to 33,333 shares of preferred stock, par value $0.001 per share, in one or more series and to fix the rights, preferences, privileges, qualifications and restrictions granted to or imposed upon the preferred stock, including but not limited to dividend rights, conversion rights, voting rights, rights and terms of redemption, liquidation preference and sinking fund terms, any or all of which may be greater than the rights of our common stock.

Certain Anti-Takeover Matters

Delaware corporate law contains certain provisions that may have the effect of delaying, deterring or preventing a change in control of the company. Section 203 of the Delaware General Corporation Law (DGCL) prohibits us, with certain exceptions, from engaging in certain business combinations with an interested shareholder (defined generally as a person who owns 15% or more of our voting stock or is an affiliate of the Company and the owner of 15% of our voting stock within a 3

year period) for a period of three years following date that such shareholder becomes an interested shareholder. The prohibited transactions include, among others, a merger or consolidation with, disposition of assets to, or issuance or redemption of stock to or from, the interested shareholder, or any other receipt by the interested shareholder of a disproportionate benefit as a shareholder. Exceptions to this statutory prohibition include approval of the business combination or transaction which resulted in the shareholder becoming an interested shareholder by the board of directors, ownership of at least 85% of the voting stock of the company outstanding at the time of the transaction or approval of the business combination and approval by the board of directors and holders of not less than two-thirds of the outstanding shares entitled to vote on the business combination which is not owned by the interested shareholder on or subsequent to the date of the business combination. Our certificate of incorporation does not exclude us from the restrictions imposed under Section 203 of the DGCL. These statutory provisions may have the effect of delaying, deterring or preventing a change in control of the company.

Directors are elected annually, for terms of one year and until their successors are elected and qualified. Our bylaws provide that, in any election of directors, those candidates receiving the largest number of votes cast by the shares entitled to vote in the election, up to the number of directors to be elected by such shares, will be elected to our board of directors. Our bylaws also provide that any vacancy in our board of directors may be filled only by the affirmative vote of a majority of directors then in office, though less than a quorum. Further, our bylaws require a shareholder to provide notice to us of such shareholder's intention to nominate a person or persons for election as directors not later than 90 days prior to the first anniversary of the previous year's annual meeting or, in the case of an election to be held at a special meeting of the shareholders for the election of directors, the close of business on the tenth day following the date on which notice of such meeting is first given to shareholders. A shareholder must also provide us with notice of such shareholder's intent to make any proposal at an annual meeting of shareholders not later than 90 days prior to the first anniversary of the previous year's annual meeting of shareholders. These provisions may have the effect of deterring hostile takeovers or delaying a change in control of our management.

Exhibit 10.29

CTI BIOPHARMA CORP.
STOCK OPTION AGREEMENT
(INDUCEMENT FORM)

THIS STOCK OPTION AGREEMENT, including any country-specific appendices attached hereto, (collectively the "**Option Agreement**") is dated as of _____ (the "**Grant Date**") by and between CTI BioPharma Corp., a Delaware corporation (the "**Corporation**"), and _____ (the "**Participant**"). Capitalized terms used herein and not otherwise defined shall have the meaning assigned to such terms in the CTI BioPharma Corp. Amended and Restated 2017 Equity Incentive Plan, as amended and restated (the "**Plan**").

W I T N E S S E T H

WHEREAS, the Corporation desires to grant to the Participant, effective as of the date hereof, the Option (as defined below);

WHEREAS, the Option is not granted under the Plan but is instead being granted to Participant as an inducement material to Participant's entry into employment with the Corporation in accordance with Nasdaq Listing Rule 5635(c)(4);

WHEREAS, the Corporation and the Participant acknowledge and agree that the Option shall nonetheless be subject to terms and conditions consistent with the terms and conditions set forth in the Plan applicable to stock options granted under the Plan.

NOW THEREFORE, in consideration of the mutual promises made herein and the mutual benefits to be derived therefrom, the parties agree as follows:

1. Grant.

Subject to the terms and conditions of this Option Agreement, as well as in accordance with the terms and conditions set forth in the Plan applicable to stock options granted thereunder (which terms and conditions are incorporated herein by reference), the Corporation hereby grants to the Participant the option (the "**Option**") to purchase all or any part of an aggregate of _____ shares of Common Stock (the "**Shares**") at the exercise price of $____ per Share (the "**Exercise Price**"). The Option will be treated as a Nonqualified Stock Option (for U.S. employees). A copy of the Plan is publicly available and has been filed with the SEC and will be furnished to the Participant upon the Participant's request. The Exercise Price and the number of Shares covered by the Option are subject to adjustment in the manner set forth in Section 7.1 of the Plan.

2. Vesting; Limits on Exercise.

The Option may be exercised only to the extent it is vested. Subject to Section 5 below, the Option shall vest and become exercisable in percentage installments of the aggregate number of Shares subject to the Option in accordance with the following schedule[; provided, however, that if a Change in Control (as defined below) occurs, any portion of the Option that remains outstanding and unvested immediately prior to the Change in Control shall accelerate and become vested upon (or, to the extent necessary to give effect to the acceleration, immediately prior to) the Change in Control:

Date of Vesting	Portion of Shares with respect to which the Option is Vested/Exercisable

"**Change in Control**" shall be deemed to have occurred as of the first day after the Grant Date on which one or more of the following conditions shall have been satisfied:

a. The acquisition by any individual, entity or group (a "**Person**") (within the meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934 (the "**Exchange Act**")) of beneficial ownership (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of 50% or more of either (1) the then-outstanding Shares (the "**Outstanding Shares**") or (2) the combined voting power of the then-outstanding voting securities of the Corporation entitled to vote generally in the election of Directors (the "**Outstanding**

Company Voting Securities"); provided, however, that, for purposes of this clause (a), the following acquisitions shall not constitute a Change in Control; (A) any acquisition directly from the Corporation, (B) any acquisition by the Corporation, (C) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Corporation or any affiliate of the Corporation or a successor, or (D) any acquisition by any entity pursuant to a transaction that complies with Sections 2(c)(1), (2) and (3) below;

b. Individuals who, as of the Grant Date, constitute the Board (the "**Incumbent Board**") cease for any reason to constitute at least a majority of the Board; provided, however, that any individual becoming a member of the Board (a "**Director**") subsequent to the Grant Date whose election, or nomination for election by the Corporation's stockholders, was approved by a vote of at least two-thirds of the Directors then comprising the Incumbent Board (including for these purposes, the new members whose election or nomination was so approved, without counting the member and his predecessor twice) shall be considered as though such individual were a member of the Incumbent Board, but excluding, for this purpose, any such individual whose initial assumption of office occurs as a result of an actual or threatened election contest with respect to the election or removal of Directors or other actual or threatened solicitation of proxies or consents by or on behalf of a Person other than the Board;

c. Consummation of a reorganization, merger, statutory share exchange or consolidation or similar corporate transaction involving the Corporation or any of its Subsidiaries, a sale or other disposition of all or substantially all of the assets of the Corporation, or the acquisition of assets or stock of another entity by the Corporation or any of its Subsidiaries (each, a "**Business Combination**"), in each case unless, following such Business Combination, (1) all or substantially all of the individuals and entities that were the beneficial owners of the Outstanding Shares and the Outstanding Company Voting Securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than 50% of the then-outstanding Shares and the combined voting power of the then-outstanding voting securities entitled to vote generally in the election of Directors, as the case may be, of the entity resulting from such Business Combination (including, without limitation, an entity that, as a result of such transaction, owns the Corporation or all or substantially all of the Corporation's assets directly or through one or more subsidiaries (a "**Parent**")) in substantially the same proportions as their ownership immediately prior to such Business Combination of the Outstanding Shares and the Outstanding Company Voting Securities, as the case may be, (2) no Person (excluding any entity resulting from such Business Combination or a Parent or any employee benefit plan (or related trust) of the Corporation or such entity resulting from such Business Combination or Parent) beneficially owns, directly or indirectly, 50% or more of, respectively, the then-outstanding shares of common stock of the entity resulting from such Business Combination or the combined voting power of the then-outstanding voting securities of such entity, except to the extent that the ownership of 50% or more existed prior to the Business Combination, and (3) at least a majority of the of the Board or trustees of the entity resulting from such Business Combination or a Parent were members of the Incumbent Board at the time of the execution of the initial agreement or of the action of the Board providing for such Business Combination; or

d. Approval by the stockholders of the Corporation of a complete liquidation or dissolution of the Corporation other than in the context of a transaction that does not constitute a Change in Control under clause (c) above.

The Option may be exercised only to the extent the Option is vested and exercisable.

- Cumulative Exercisability. To the extent that the Option is vested and exercisable, the Participant has the right to exercise the Option (to the extent not previously exercised), and such right shall continue, until the expiration or earlier termination of the Option as provided in this Option Agreement and in accordance with the termination provisions of the Plan applicable to stock options granted thereunder.

- No Fractional Shares. Fractional share interests shall be disregarded, but may be cumulated.

3. Continuance of Employment/Service Required; No Employment/Service Commitment.

The Participant must not have had a Termination of Service on or before each applicable vesting date of the Option in order to vest in the applicable installment of the Option and the rights and benefits under this Option Agreement. Employment or service for only a portion of the vesting period, even if a substantial portion, will not entitle the Participant to any proportionate vesting or avoid or mitigate a termination of rights and benefits upon or following a Termination of Service (as defined below), as provided in Section 5 below.

The Option grant shall not create a right to continued employment or service with the Corporation or any Subsidiary nor shall it create a right to employment or be interpreted as forming an employment or services contract with the Corporation

or any Subsidiary and shall not interfere with the ability of the Corporation or any Subsidiary, as applicable, to terminate the Participant's employment or service relationship (if any) or affect the right of the Corporation or any Subsidiary to increase or decrease the Participant's other compensation. Nothing in this Option Agreement, however, is intended to adversely affect any contractual right(s) of the Participant, independent of the Option grant and this Option Agreement, between the Participant and Corporation or any Subsidiary without his or her consent thereto.

For purposes of the Option, "**Termination of Service**" means a cessation of the employee-employer relationship between the employee and the Corporation or one of its Subsidiaries for any reason, including, but not by way of limitation, a termination by resignation, discharge, death, Disability (as defined below) or the disaffiliation of a Subsidiary, but excluding any such termination where there is a simultaneous reemployment by the Corporation or one of its Subsidiaries. The determination of whether a Termination of Service has occurred shall be made by the Board or one or more committees appointed by the Board or another committee (the "**Administrator**"), in its sole discretion, in accordance with the terms of the Plan including, without limitation, Section 6 of the Plan.

4. Method of Exercise of Option.

Any vested portion of the Option may be exercised by the Participant's delivery of a written or electronic notice of exercise (in a form acceptable to the Corporation) to the Secretary of the Corporation (or its designee), setting forth the number of Shares with respect to which the Option is to be exercised, accompanied by full payment of the aggregate Exercise Price and any Tax-Related Items (as defined in Section 7 below).

The Exercise Price shall be payable to the Corporation by one or more following methods:

a. by check;

b. through irrevocable instructions from the Participant to the Corporation's designated broker or other broker permitted by the Corporation to remit funds required to satisfy all or a portion of the Exercise Price to the Corporation under a broker-assisted cashless exercise; provided, however, that the Participant shall be permitted to engage an individual broker in connection with the cashless exercise contemplated under this Section 4(b) to the extent the Participant has adopted an arrangement that is intended to comply with the requirements of Rule 10b5-1(c)(1)(i)(B) under the Exchange Act (a "**10b5-1 Trading Plan**") with respect to transactions involving the Option and/or Shares subject to the Option; or

c. through such other method of exercise permitted by the Administrator, in its sole discretion, in accordance with Section 5.5 of the Plan.

As soon as practicable after receipt of the Participant's written notice of exercise and full payment of the Exercise Price and any Tax-Related Items, the Corporation shall deliver to the Participant Share certificates (which may be in book entry form) representing the Shares underlying the exercised Option. No Shares shall be issued pursuant to the exercise of an Option unless such issuance and such exercise comply with applicable laws. Assuming such compliance, for income tax purposes the Shares shall be considered transferred to Participant on the date on which the Option is exercised with respect to such Shares.

5. Early Termination of Option.

1. **Expiration Date.** Subject to earlier termination as provided below in this Section 5, the Option will terminate on the tenth (10th) anniversary of the Grant Date (the "**Expiration Date**").

2. **Possible Termination of Option upon Certain Corporate Events**. The Option is subject to possible termination in connection with certain corporate events as described in Section 7.2 of the Plan.

3. **Termination of Option upon the Participant's Termination of Service**. The Option, to the extent not vested on the date of the Participant's Termination of Service (the "**Termination Date**"), shall terminate on such date and the Participant shall have no right to any unvested portion of the Option or any underlying Shares; provided, however, that if the Participant is a U.S. employee and is entitled to any accelerated vesting of the Option in connection with such Termination of Service pursuant to the express provisions of any employment agreement, service agreement, severance agreement or similar agreement between the Participant and the Corporation or any of its Subsidiaries then in effect (a "**Service Agreement**"), such accelerated vesting provisions shall apply. The Option, to the extent vested and outstanding on the Participant's Termination of Service, will terminate (a) on the expiration of twelve (12) months from the Termination Date if such Termination

of Service is the result of the Participant's death or Disability, or (b) three (3) months from the Termination Date for any other reason. For these purposes, "**Disability**" means a permanent and total disability within the meaning of Section 22(e)(3) of the Code, provided that if the Option is not an Incentive Stock Option, the Administrator in its discretion may determine whether a permanent and total disability exists in accordance with uniform and non-discriminatory standards adopted by the Administrator from time to time.

In all events the Option is subject to earlier termination on the Expiration Date of the Option or as contemplated by Section 5.1.

6. Non-Transferability.

The Option may not be subject to sale, transfer, alienation, assignment, pledge, encumbrance, charge, hypothecation, or disposition other than by will or by the laws of descent and distribution and the Option may only be exercised by the Participant during his or her lifetime.

7. Tax Withholding.

The Participant acknowledges that, regardless of any action taken by the Corporation or, if different, the Subsidiary employing the Participant, the ultimate liability for all income tax, social insurance, payroll tax, fringe benefits tax, payment on account or other tax-related items related to the Participant's receipt and ownership of the Option and legally applicable to the Participant ("**Tax-Related Items**"), is and remains the Participant's responsibility and may exceed the amount actually withheld by the Corporation or the Subsidiary employing the Participant. The Participant further acknowledges that the Corporation and/or the Subsidiary employing the Participant (1) make no representations or undertakings regarding the treatment of any Tax-Related Items in connection with any aspect of the Option, including, but not limited to, the grant, vesting or exercise of the Option, the subsequent sale of Shares acquired pursuant to such exercise and the receipt of any dividends; and (2) do not commit to and are under no obligation to structure the terms of the grant or any aspect of the Option to reduce or eliminate the Participant's liability for Tax-Related Items or achieve any particular tax result except as otherwise expressly provided in the Option Agreement or any other agreement with the Participant. Further, if the Participant is subject to Tax-Related Items in more than one jurisdiction between the Grant Date and the date of any relevant taxable or tax withholding event, as applicable, the Participant acknowledges that the Corporation and/or the Subsidiary employing the Participant (or former employer, as applicable) may be required to withhold or account for Tax-Related Items in more than one jurisdiction.

Prior to the relevant taxable or tax withholding event, as applicable, the Participant agrees to make adequate arrangements satisfactory to the Corporation and/or the Subsidiary employing the Participant to satisfy all Tax-Related Items. In this regard, the Participant authorizes the Corporation and/or the Subsidiary employing the Participant, or their respective agents, at their discretion, to satisfy the obligations with regard to all Tax-Related Items by withholding from proceeds of the sale of Shares acquired at exercise of the Option either through:

- a voluntary sale by the Participant by providing irrevocable instructions to the Corporation's designated broker to remit funds required to satisfy all or a portion of the Tax-Related Items to the Corporation and/or the Subsidiary employing the Participant under a broker-assisted cashless exercise program implemented by the Corporation in connection with the Plan; provided, however, that the Participant shall be permitted to engage an individual broker in connection with the cashless exercise to the extent the Participant has adopted a 10b5-1 Trading Plan with respect to transactions involving the Option and/or Shares subject to the Option; or

- through a mandatory sale arranged by the Corporation on the Participant's behalf pursuant to this authorization (without further consent).

The Corporation may withhold or account for Tax-Related Items by considering maximum applicable rates, in which case the Participant will receive a refund of any over-withheld amount in cash and will have no entitlement to the Share equivalent. Finally, the Participant agrees to pay to the Corporation or the Subsidiary employing the Participant, including through withholding from the Participant's wages or other cash compensation payable to the Participant by the Corporation and/or the Subsidiary employing the Participant any amount of Tax-Related Items that the Corporation or the Subsidiary employing the Participant may be required to withhold or account for as a result of the Participant's receipt and ownership of the Option that cannot be satisfied by the means previously described. The Corporation may refuse to issue or deliver the Shares or the proceeds of the sale of Shares, if the Participant fails to comply with his or her obligations in connection with the Tax-Related Items.

8. Nature of Grant.

In accepting the grant of the Option, the Participant acknowledges, understands and agrees that:

a. the grant of the Option is voluntary and occasional and does not create any contractual or other right to receive future grants of options, or benefits in lieu of options, even if options have been granted in the past;

b. all decisions with respect to future option or other grants of Awards, if any, will be at the sole discretion of the Corporation;

c. the Participant is voluntarily receiving this Option;

d. the Option and the Shares subject to the Option are not intended to replace any pension rights or compensation;

e. the Option and the Shares subject to the Option, and the income and value of same, are not part of normal or expected compensation for purposes of calculating any severance, resignation, termination, redundancy, dismissal, end-of-service payments, bonuses, long-service awards, pension or retirement or welfare benefits or similar payments;

f. the future value of the underlying Shares is unknown, indeterminable and cannot be predicted with certainty;

g. for purposes of the Option, unless otherwise expressly provided in this Option Agreement or determined by the Corporation, the Participant's right to vest in the Option, if any, will terminate as of the Termination Date and will not be extended by any notice period (*e.g.*, the Participant's period of service would not include any contractual notice period or any period of "garden leave" or similar period mandated under employment laws in the jurisdiction where the Participant is employed or providing services or the terms of the Service Agreement, if any), and the Administrator shall have the exclusive discretion to determine the Termination Date for purposes of the Option grant (including whether the Participant may still be considered to be providing services while on a leave of absence);

h. unless otherwise provided by the Corporation in its discretion, the Option and the benefits evidenced by this Option Agreement do not create any entitlement to have the Option or any such benefits transferred to, or assumed by, another company nor be exchanged, cashed out or substituted for, in connection with any corporate transaction affecting the Corporation's Shares; and

i. the following provisions apply if the Participant is providing services outside the United States:

    A. the Corporation (which may or may not be Participant's employer) is granting the Option, the Corporation will administer this Option Agreement from outside Participant's country of residence, and United States law will govern this Option;

    B. Participant has received of a copy of the Plan (including any applicable appendices or sub-plans thereunder) and is familiar with the terms and provisions thereof, and hereby accepts this Option subject to all of the terms and provisions herein and in accordance with the terms and conditions set forth in the Plan applicable to stock options granted thereunder; Participant has reviewed the Plan (including any applicable appendices or sub-plans thereunder) and this Option Agreement in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Option Agreement and fully understands all provisions of the Option; and Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan or this Option Agreement;

    C. the Option and the Shares subject to the Option are not part of normal or expected compensation or salary for any purpose;

    D. no claim or entitlement to compensation or damages shall arise from forfeiture of the Option resulting from the Participant's Termination of Service (for any reason whatsoever whether or not later found to be invalid or in breach of employment laws in the jurisdiction where the Participant is employed or providing services or the terms of the Service Agreement, if any), and in consideration of the grant of the Option to which the Participant is otherwise not entitled, the Participant irrevocably agrees never to institute any claim against the Corporation or any Subsidiary, waives his or her ability, if any, to bring any

such claim, and releases the Corporation and its Subsidiaries from any such claim; if, notwithstanding the foregoing, any such claim is allowed by a court of competent jurisdiction, then, by receiving and owning the Option, the Participant shall be deemed irrevocably to have agreed not to pursue such claim and agrees to execute any and all documents necessary to request dismissal or withdrawal of such claim; and

E. the Participant acknowledges and agrees that neither the Corporation nor any Subsidiary shall be liable for any foreign exchange rate fluctuation between the Participant's local currency and the United States Dollar that may affect the value of the Option or of any amounts due to the Participant pursuant to the exercise of the Option or the subsequent sale of any Shares acquired upon exercise.

9. No Advice Regarding Grant.

The Participant is hereby advised to consult with his or her own tax, legal and/or investment advisors with respect to any advice the Participant may determine is needed or appropriate with respect to the Option (including, without limitation, to determine the tax consequences with respect to the Option and any Shares that may be acquired upon exercise of the Option). Neither the Corporation nor any of its officers, Directors, affiliates or advisors makes any representation (except for the terms and conditions expressly set forth in this Option Agreement) or recommendation with respect to the Option.

10. Data Privacy.

The Participant hereby explicitly and unambiguously consents to the collection, use and transfer, in electronic or other form, of the Participant's personal data by and among, as applicable, the Corporation, the Participant's employer and any Subsidiaries ("Data") for the exclusive purpose of implementing, administering and managing the Participant's receipt and ownership of this Option. The Participant understands that the Corporation, the Participant's employer or any Subsidiary retaining the Participant may hold certain personal information about Participant, including, but not limited to, the Participant's name, home address and telephone number, date of birth, social insurance number or other identification number, salary, nationality, job title, any Shares or directorships held in the Corporation, details of all Options or any other entitlement to Shares awarded, canceled, exercised, vested, unvested or outstanding in the Participant's favor, for the exclusive purpose of implementing, administering and managing this Option Agreement. The Participant understands that Data may be transferred to [ ] or any other possible recipients which may be assisting the Corporation (presently or in the future) with the implementation, administration and management of this Option Agreement. The Participant understands that the recipients of the Data may be located in the United States or elsewhere, and that the recipients' country (e.g., the United States) may have different data privacy laws and protections than the Participant's country. The Participant understands that, if he or she resides outside the United States, the Participant may request a list with the names and addresses of any potential recipients of the Data by contacting the Participant's employer's human resources representative or the Subsidiary retaining the Participant. The Participant authorizes the Corporation, [ ] and any other possible recipients which may assist the Corporation (presently or in the future) with implementing, administering and managing this Option Agreement to receive, possess, use, retain and transfer the Data, in electronic or other form, for the sole purpose of implementing, administering and managing the Participant's receipt and ownership of the Option. The Participant understands that Data will be held only as long as is necessary to implement, administer and manage the Participant's receipt and ownership of the Option. The Participant understands that, if he or she resides outside the United States, the Participant may, at any time, view Data, request additional information about the storage and processing of Data, require any necessary amendments to Data or refuse or withdraw the consents herein, in any case without cost, by contacting in writing Participant's human resources representative or the Subsidiary retaining the Participant. Further, the Participant understands that the Participant is providing the consents herein on a purely voluntary basis. If the Participant does not consent, or if the Participant later seeks to revoke the Participant's consent, the Participant's employment status or service and career with the Participant's employer or the Subsidiary retaining the Participant will not be adversely affected; the only adverse consequence of refusing or withdrawing the Participant's consent is that the Corporation may not be able to grant Options to the Participant or administer or maintain such Options. Therefore, Participant understands that refusing or withdrawing the Participant's consent may affect the Participant's ability to receive or own Options. For more information on the consequences of the Participant's refusal to consent or withdrawal of consent, the Participant understands that the Participant may contact the Participant's employer's human resources representative or the Subsidiary retaining the Participant.

11. Insider Trading Restrictions/Market Abuse Laws.

The Participant acknowledges that the Participant may be subject to insider trading restrictions and/or market abuse laws in applicable jurisdictions, including the United States and the Participant's country of residence (if different), which may affect his or her ability to acquire or sell Shares or rights to Shares (*e.g.*, Options) during such times as the Participant is

considered to have "inside information" regarding the Corporation (as defined by the laws in the applicable jurisdictions, including the United States and the Participant's country of residence). Any restrictions under these laws or regulations are separate from and in addition to any restrictions that may be imposed under any applicable Corporation insider trading policy. The Participant is responsible for ensuring compliance with any applicable restrictions and is advised to consult his or her personal legal advisor on this matter.

12. Notices.

Any notice to be given under the terms of this Option Agreement shall be in writing and addressed to the Corporation at its principal office to the attention of the Secretary, and to the Participant at the address last reflected on the Corporation's payroll records, or at such other address as either party may hereafter designate in writing to the other. Any such notice shall be delivered in person or shall be enclosed in a properly sealed envelope addressed as aforesaid, registered or certified, and deposited (postage and registry or certification fee prepaid) in a post office or branch post office regularly maintained by the United States Government or any equivalent non-United States postal office. Any such notice shall be given only when received, but if the Participant is no longer employed by or providing services to the Corporation or a Subsidiary, shall be deemed to have been duly given five (5) business days after the date mailed in accordance with the foregoing provisions of this Section 12.

13. Plan.

The Option and all rights of the Participant under this Option Agreement shall be interpreted in accordance with the terms and conditions of the Plan applicable to stock options granted thereunder, which terms and conditions are incorporated herein by reference. For the avoidance of doubt, the Option has not been granted under the Plan meaning that the Participant is not a participant in the Plan by virtue of the Option. The Participant agrees to be bound by the terms of this Option Agreement. The Participant acknowledges having read and understanding the Plan, the prospectus for the Plan, and this Option Agreement. Unless otherwise expressly provided in other sections of this Option Agreement, provisions of the Plan that confer discretionary authority on the Administrator do not and shall not be deemed to create any rights in the Participant unless such rights are expressly set forth herein or are otherwise in the sole discretion of the Administrator so conferred by appropriate action of the Administrator consistent with the Plan after the date hereof.

14. Entire Agreement.

This Option Agreement (and, if the Participant is a U.S. employee, any Service Agreement as to any accelerated vesting right as contemplated by Section 5.3, but only as to such an accelerated vesting right) constitutes the entire agreement and supersedes all prior understandings and agreements, written or oral, of the parties hereto with respect to the subject matter hereof. In the event of any conflict between this Option Agreement, the Plan and Service Agreement (if any) in effect, the terms of this Option Agreement shall control. Notwithstanding the foregoing, the treatment of the Option upon a Termination of Service and/or a Change in Control shall be as set forth in the Service Agreement (if any) in effect between the Corporation or any Subsidiary in the event of any conflict with the Plan or this Option Agreement.

This Option Agreement may be amended by the Administrator from time to time, provided that any such amendment must be in writing and signed by the Corporation. Except as otherwise described in the Plan, any such amendment that materially and adversely affects the Participant's rights under this Option Agreement requires the consent of the Participant in order to be effective with respect to the Option, provided that such consent shall not be required if the Administrator determines, in its sole and absolute discretion, that the amendment is required or advisable in order for the Corporation or this Option to satisfy applicable law, to meet the requirements of any accounting standard or to avoid any adverse accounting treatment. The Corporation may, however, unilaterally waive any provision hereof in writing to the extent such waiver does not adversely affect the interests of the Participant hereunder, but no such waiver shall operate as or be construed to be a subsequent waiver of the same provision or a waiver of any other provision hereof.

15. Effect of this Agreement.

Subject to the Corporation's right to terminate the Option in a manner consistent with Section 8.6 of the Plan, this Option Agreement shall be assumed by, be binding upon and inure to the benefit of any successor or successors to the Corporation.

16. Counterparts.

This Option Agreement may be executed simultaneously in any number of counterparts, including through electronic transmission, each of which counterparts shall be deemed an original but all of which together shall constitute one and the same instrument.

17. Section Headings.

The section headings of this Option Agreement are for convenience of reference only and shall not be deemed to alter or affect any provision hereof.

18. Governing Law; Venue.

This Option Agreement shall be governed by and construed and enforced in accordance with the laws of the State of Washington without regard to conflict of law principles thereunder. For purposes of litigating any dispute that arises under this grant or the Option Agreement, the parties hereby submit to and consent to the jurisdiction of the State of Washington, and agree that such litigation shall be conducted in the courts of King County, Washington, or the federal courts for the United States for the Western District of Washington, where this grant is made and/or to be performed.

19. Clawback Policy.

The Option is subject to the terms of any recoupment, clawback or similar policy of the Corporation as may be in effect from time to time, as well as any similar provisions of applicable law (in each case, without regard to whether any such policy or application law was implemented or promulgated, as applicable, after the date the Option was granted), any of which could in certain circumstances require forfeiture of the Option and repayment or forfeiture of any Shares or other cash or property received with respect to the Option (including any value received from a disposition of the Shares acquired upon exercise of the Option).

20. Language.

If the Participant has received this Option Agreement or any other document related to the Plan translated into a language other than English and if the meaning of the translated version is different than the English version, the English version will control.

21. Electronic Delivery and Acceptance.

The Corporation may, in its sole discretion, decide to deliver any documents related to this Option by electronic means. The Participant hereby consents to receive such documents by electronic delivery and agrees to participate in his receipt and ownership of the Option through an on-line or electronic system established and maintained by the Corporation or a third party designated by the Corporation.

22. Severability.

The provisions of this Option Agreement are severable and if any one or more provisions are determined to be illegal or otherwise unenforceable, in whole or in part, the remaining provisions shall nevertheless be binding and enforceable.

23. Appendices.

Notwithstanding any provisions in this Option Agreement, the Option shall be subject to any special terms and conditions set forth in any Appendix to this Option Agreement for the Participant's country. Moreover, if the Participant relocates to any other country, special terms and conditions for such country will apply to the Participant (including, to the extent that an Appendix hereto pertains to the country to which the Participant relocates, those specified in such applicable Appendix), to the extent the Corporation determines that the application of such terms and conditions is necessary or advisable for legal or administrative reasons. The Appendices constitute part of this Option Agreement.

24. Imposition of Other Requirements.

Subject to Section 14 of this Option Agreement, the Corporation reserves the right to impose other requirements on the Participant's receipt and ownership of the Option and on any Shares acquired pursuant to the Option, to the extent the Corporation determines it is necessary or advisable for legal or administrative reasons and to require the Participant to sign any additional agreements or undertakings that may be necessary to accomplish the foregoing.

CTI BioPharma Corp.
a Delaware corporation

By: _____

PARTICIPANT

_____
Signature

_____
Print Name

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

(1) Form S-3 Nos. 333-251161, 333-221382 and 333-200453, 333-192749, 333-192748, 333-182330, 333-163479, 333-157376, 333-152171, 333-149981, 333-149980, 333-134126, and 333-108926 of CTI BioPharma Corp., and

(2) Form S-8 Nos. 333-239311, 333-231708, 333-225116, 333-218947, 333-218946, 333-211006, 333-207177, 333-207176, 333-196510, 333-189611, 333-184004, 333-178158, 333-170044, 333-162955, 333-158260, 333-152168, and 333-146624 pertaining to equity and option plans of CTI BioPharma Corp.

of our report dated March 17, 2020, with respect to the consolidated financial statements of CTI BioPharma Corp. included in this Annual Report (Form 10-K) of CTI BioPharma Corp. for the year ended December 31, 2020.

/s/ Ernst & Young LLP

Seattle, Washington
March 17, 2021

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 17, 2021

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 17, 2021

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, 2020 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 17, 2021

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, 2020 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 17, 2021

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