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, 2022

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	**CTIC**	**The Nasdaq 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, 2022, the aggregate market value of the registrant's common equity held by non-affiliates was approximately $625.7 million. Shares of common stock held by each executive officer and director and by each other person who may be deemed to be an affiliate of the registrant have been excluded from this computation. This determination of affiliate status for this purpose is not necessarily a conclusive determination for other purposes.

The number of outstanding shares of the registrant's common stock as of February 21, 2023 was 131,835,892.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2023 annual meeting of stockholders, or the 2023 Proxy Statement, are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. We expect to file the 2023 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" that involve risks and uncertainties. We make such-forward looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. All statements other than statements of historical fact are forward-looking statements. In some cases, forward-looking statements can be identified by terms such as "anticipates," "assume," "believes," "continue," "could," "estimates," "expects," "forecast," "goal," "intends," "may," "plans," "potential," "predicts," "projects," "should," "target," or "will" or the negative thereof, variations thereof and similar expressions. These forward-looking statements include, but are not limited to, statements about:

- our expectations regarding sufficiency of cash resources, cash expenditures, sources of cash flows and other projections, product manufacturing and sales, research and development expenses, selling, general and administrative expenses and additional losses;
- our ability to obtain funding for our operations;
- the continued commercialization of VONJO® (pacritinib) as a treatment for adult myelofibrosis patients with severe thrombocytopenia;
- our ability to develop, commercialize and obtain regulatory approval of pacritinib for other development programs we may pursue in the future;
- the design of our clinical trials and their anticipated enrollment;
- the safety, effectiveness and potential benefits and indications of VONJO and any other product candidates we may develop in the future;
- the rate and degree of market acceptance and clinical utility of VONJO or 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 VONJO and any other product candidates we may develop in the future;
- our ability to advance product candidates, including VONJO 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;
- our and our collaborators' ability to obtain and maintain regulatory approvals, and the timing of such approvals, for VONJO or any other product candidates we may develop in the future;
- 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, including the Inflation Reduction Act of 2022;
- 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;

- our expectations regarding business disruptions and related risks resulting from the ongoing worldwide coronavirus pandemic known as COVID-19; and

- other risks and uncertainties, including those listed under the heading Risk Factors in this Annual Report on Form 10-K and in other filings we periodically make with the U.S. Securities and Exchange Commission, or the SEC.

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 and cause them to differ materially from our current expectations, 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 our 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., except where it is otherwise made clear.

PART I

Item 1. Business

Overview

We are a commercial biopharmaceutical company focused on the acquisition, development and commercialization of novel targeted therapies for blood-related cancers where there is a significant unmet medical need. Our goal is to build a profitable company by generating income from products we develop and commercialize, either alone or with partners. We have one commercially approved product, VONJO® (pacritinib), which has received Accelerated Approval in the United States from the U.S. Food and Drug Administration, or the FDA, for the treatment of adult patients with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 x 10^9/L.

Our Strategy

Our objective is to become a leader in the development and commercialization of novel targeted therapeutics for the treatment of blood-related cancers. The key elements of our strategy to achieve these objectives are to:

- **Successfully Commercialize VONJO.** Since VONJO's approval by the FDA in February 2022, our commercial and supply infrastructure has enabled a successful commercial launch of VONJO. We continue to focus our efforts on the strategic and operational capabilities that support the ongoing commercialization of VONJO in the United States through the coordinated efforts of our sales, marketing and market access teams.

- **Evaluate Strategic Product Collaborations to Accelerate Development and Commercialization.** Where we believe it may be beneficial, we intend to evaluate collaborations to broaden and accelerate the clinical trial development and commercialization of VONJO. 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:

TRIAL/STATUS	INDICATION	OVERVIEW
PACIFICA Phase 3 Ongoing	Myelofibrosis with severe thrombocytopenia	The PACIFICA trial is a randomized, controlled Phase 3 study of pacritinib versus Physician's Choice in patients with primary myelofibrosis, post polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis with severe thrombocytopenia (platelet count <50,000/µL).

Oncology Market Overview and Opportunity

According to the American Cancer Society, 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 2.0 million new cases of cancer are expected to be diagnosed in 2023 in the United States. While the exact prevalence of myelofibrosis is uncertain, it is estimated that there are approximately 21,000 myelofibrosis patients in the United States, 7,000 of whom have severe thrombocytopenia (defined as a platelet count of less than 50 x10^9/L). 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 oral kinase inhibitor with activity against wild type Janus Associated Kinase 2 (JAK2), mutant $JAK2^{V617F}$ form, IRAK1, ACVR1 (ALK2) and FLT3, which contribute to signaling of a number of cytokines and growth factors that are important for hematopoiesis and immune function. At clinically relevant concentrations, pacritinib does not inhibit JAK1. 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. Myelofibrosis is often associated with dysregulated JAK2 signaling. 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, graft versus host disease, or GvHD, and chronic lymphocytic leukemia, or CLL, due to its inhibition of JAK2, IRAK1, FLT3, ACVR1 (ALK2) and CSF1R. We believe pacritinib has the potential to be delivered as a single agent or in combination therapy regimens.

U.S. FDA Approval of VONJO

In September 2020, we reached an agreement with the FDA to submit a New Drug Application, or NDA, for the potential Accelerated Approval of VONJO as a treatment for myelofibrosis patients with severe thrombocytopenia, and in March 2021 we completed our rolling NDA submission. The NDA was based on the available data from our completed Phase 3 PERSIST-1 and PERSIST-2 trials and the Phase 2 PAC203 trial. In May 2021, the FDA accepted our NDA and granted pacritinib Priority Review, with the Prescription Drug User Fee Act, or PDUFA, target action date set for November 30, 2021, which was subsequently extended by three months to February 28, 2022. On February 28, 2022, the FDA granted Accelerated Approval of VONJO for the treatment of adult patients with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 x 10^9/L. This indication is approved under FDA Accelerated Approval based on the surrogate end point of spleen volume reduction. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. As agreed with the FDA, the PACIFICA Phase 3 trial will be completed as a post-marketing requirement. On February 7, 2023, VONJO was granted seven years of orphan-drug exclusive approval by the FDA for treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 x10^9/L, pursuant to section 527 of the Federal Food, Drug, and Cosmetic Act, or FDCA (21 U.S.C. 360cc). The seven-year exclusive approval began on February 28, 2022.

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, 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

As part of the Accelerated Approval of VONJO, we agreed with the FDA to amend the design of PACIFICA to have co-primary endpoints of Spleen Volume Reduction, or SVR, and modified Total Symptom Score, or TSS, with both endpoints being analyzed after the complete enrollment of the study. As a result of this amendment, we increased the study size to 399 patients to maintain appropriate powering for the endpoints. This change was implemented in a study amendment that was submitted on June 30, 2022. In addition to co-primary endpoints SVR and TSS, overall survival is a secondary endpoint. Enrollment in this trial is progressing despite the challenges of conducting clinical trials during the COVID-19 pandemic. Additionally, enrollment at sites in Russia, Ukraine and Belarus has been indefinitely paused in response to the conflict in the region. As agreed with the FDA, following the Accelerated Approval of VONJO, we plan to complete the PACIFICA Phase 3 trial as a post-marketing requirement, with the expected completion of enrollment by the end of 2026. Meeting this timeline is dependent upon the addition of new clinical sites.

License Agreements

*S*BIO*

We acquired the compounds SB1518 (which is referred to as “pacritinib”) and SB1578, which inhibit JAK2 and FLT3, from S*BIO Pte Ltd., or S*BIO, in May 2012. Under our agreement with S*BIO, we are required to make milestone payments to S*BIO up to an aggregate amount of $132.5 million if certain U.S., 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. In addition, S*BIO is 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. Following FDA approval of VONJO in February 2022, a $25.0 million milestone payment was made to S*BIO during the second quarter of 2022. 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 automatically convertible into our common stock.

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 Teva having achieved certain sales milestones. The achievement of the remaining milestones is uncertain at this time.

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. Patent coverage for our individual products extends for varying periods according to the date of the patent filing or grant and the legal term of patents in the various countries where we have obtained patent protection.

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 that any patents issued from our U.S. and foreign patent applications for use of pacritinib for treating transplant rejection will expire in 2036.

In April 2022, we filed patent term extension applications for U.S. Patent No. 8,153,632, which includes claims covering pacritinib and pharmaceutically acceptable salts thereof, and for U.S. Patent No. 9,573,964, which includes claims covering methods of treating certain proliferative diseases, such as myelofibrosis. For U.S. Patent No. 8,153,632, we requested five years of extension, which, if granted, would extend the expiration date of that patent from January 2029 to January 2034. For U.S. Patent No. 9,573,964, we requested 1,085 days of extension, which, if granted, would extend the expiration date of that patent from May 2028 to April 2031. The U.S. Patent and Trademark Office, or USPTO, can often take several years to respond to patent term extension applications. If the USPTO determines that both applications are eligible for extension of patent term, we will be required to elect which of these two patents will receive the requested extension of term. We will be required to make this election after we receive notice that the applications are eligible. If we fail to make an election, the USPTO will apply the extension to U.S. Patent No. 8,153,632, the longer of the two extension requests.

Each patent in our portfolio may be eligible for 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, which period is extended to seven years for an orphan drug indication. Pacritinib has orphan drug designation for myelofibrosis in the United States and the European Union, or EU.

Under the Orphan Drug Act, the FDA grants drug exclusivity to a drug intended to treat a rare disease or condition, generally meaning a disease or condition affecting fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States, but for which there is no reasonable expectation that the cost of developing and manufacturing the drug in the United States will be recovered from sales in the United States. Orphan drug designation entitles an applicant to grant funding applied towards clinical studies, tax incentives, and waivers of FDA user fees.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other application to market the same drug for the same indication, except in very limited circumstances, for seven years. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. On February 7, 2023, VONJO was granted seven years of orphan-drug exclusive approval by the FDA for the treatment of adults with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF) with a platelet count below 50 $x10^9$/L, pursuant to section 527 of the FDCA. The seven-year exclusive approval began on February 28, 2022.

The FDA's interpretation of the scope of orphan drug exclusivity may change. The FDA's longstanding interpretation of the Orphan Drug Act is that exclusivity is specific to the orphan indication for which the drug was actually approved. As a result, the scope of exclusivity has been narrow and protected only against competition from the same "use or indication" rather than the broader "disease or condition." In the September 2021 case *Catalyst Pharmaceuticals, Inc. v. FDA,* a federal circuit court suggested orphan drug exclusivity covers the full scope of the orphan-designated disease or condition regardless of whether a drug obtains approval only for a narrower use. Depending on how this decision is applied beyond this case, it may be used to limit the drugs that can receive exclusivity. In January 2023, the FDA published a notice that it intends to continue to interpret orphan drug exclusivity based on its longstanding practice, rather than the federal court interpretation.

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 a result of the February 2022 FDA approval of VONJO and the continued expansion of our clinical development activities, we expect that our manufacturing, distribution and related operational requirements will continue to increase correspondingly. 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.

VONJO faces competition from the currently-approved JAK1/JAK2 inhibitors, Jakafi® / Jakavi® (ruxolitinib) and Inrebic® (fedratinib) as well as BESREMi® (ropeginterferon alfa-2b-njft). 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, or EC, approval of Inrebic®. In November 2021, PharmaEssentia announced FDA approval of BESREMi® for the treatment of adults with polycythemia vera. VONJO 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 June 2021, Sierra Oncology announced that the Phase 3 trial enrollment was completed and in January 2022, announced top-line data from the Phase 3 trial. In June 2022, Sierra Oncology announced that an NDA was submitted to the FDA for momelotinib. Sierra Oncology was acquired by GSK plc, or GSK, in July 2022. In August 2022, GSK announced that the NDA was accepted by the FDA and that the FDA assigned a PDUFA action date of June 16, 2023.

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 EC approval. However, cancer drugs with distinctly different mechanisms of action are often used together in combination for treating cancer, allowing several different products to target the same cancer indication or disease type. Such combination therapy is typically supported by clinical trials that demonstrate the advantage of combination therapy over that of a single-agent treatment.

We believe that our ability to compete successfully will be based on our ability to create and maintain scientifically advanced technology, develop proprietary products, attract and retain scientific personnel, obtain patent or other protection for our products, obtain required regulatory approvals and manufacture and successfully market our products, either alone or through outside parties. We will continue to seek licenses with respect to technology related to our field of interest and may face competition with respect to such efforts. See the risk factor, "*We face direct and intense competition from our competitors in the biotechnology and pharmaceutical industries, and we may not compete successfully against them.*" in Part I, Item 1A, "Risk Factors" of this Annual Report on Form 10-K for additional information regarding the risks and uncertainties we face due to competition in our industry.

Government Regulation

We are subject to extensive regulation by the FDA and other federal, state, and local regulatory agencies. The FDCA and its implementing regulations set forth, among other things, requirements for the testing, development, manufacture, quality control, safety, effectiveness, approval, labeling, storage, record keeping, reporting, distribution, import, export, advertising and promotion of our products. 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 EU are addressed in a centralized way through the EMA and the EC, 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, or GLP, 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 Good Clinical Practice, or GCP, requirements, which establish standards for conducting, recording data from and reporting the results of, clinical trials, and are intended to assure that the data and reported results are credible and accurate, and that the rights, safety, and well-being of study participants are protected.

Clinical trials must be conducted under protocols that detail the study objectives, parameters for monitoring safety, and the efficacy criteria, if any, to be evaluated. Each protocol is reviewed by the FDA as part of the IND application. In addition, each clinical trial must be reviewed, approved, and conducted under the auspices of an institutional review board, or IRB, at the institution conducting the clinical trial. Companies sponsoring the clinical trials, investigators, and IRBs also must comply with regulations and guidelines for obtaining informed consent from the study subjects, complying with the protocol and investigational plan, adequately monitoring the clinical trial and timely reporting adverse events. Foreign studies conducted under an IND application must meet the same requirements that apply to studies being conducted in the 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. Companies are not permitted to market drugs in the United States until receiving approval of an NDA or BLA 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.

Before approving an 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

As a result of approval for VONJO in the United States, our operations and business arrangements, including with third-parties (including but not limited to researchers, healthcare professionals, consultants, payors, and customers), are 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. The U.S. federal Physician Payments Sunshine Act requires certain manufacturers of drugs and biologics covered by Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, such reporting obligations were expanded to include payments and other transfers of value provided in 2021 to certain other healthcare professionals.

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 Anti-Kickback Statute and 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. 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 VONJO is subject to significant uncertainty. Sales of and revenue from VONJO 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 VONJO can be subject to challenge, reduction, or denial by payors. Government health programs and 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 VONJO. 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 HIPAA 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., including new and recently enacted laws, that may apply to us now or in the future and that require that we take measures to be transparent regarding, honor rights with respect to, and protect the privacy and security of certain information we gather and use in our business, including personal information, particularly personal information that is not otherwise subject to HIPAA. For example, the California Consumer Privacy Act, or CCPA, took effect on January 1, 2020, and is now amended by the California Privacy Rights Act (CPRA), which took effect on January 1, 2023. Other states, including Virginia, Colorado, Connecticut and Utah, also have enacted similar laws, which take effect in 2023. These laws require businesses collecting information about residents in those states to disclose what personal information is collected about the

consumer, the purposes for which that personal information is used, what personal information is sold or shared for a business purpose, and to whom, and other privacy practices of the business. They also require offering and adhering to certain privacy rights, including relating to providing access to information, allowing individuals to delete information, or allowing consumers to stop selling or sharing for targeted advertising purposes such information upon request (subject to exceptions). While we do not sell or share personal information in the traditional context, depending on how we decide to use information in the future, we may need to comply with such rights. Failure to comply with the requirements of U.S. privacy laws may result in monetary fines for noncompliance, other administrative penalties, and potential private rights of action, including relating to certain data breaches. Enforcement authorities may still implement certain variations, and introduce additional national regulations and guidelines; because certain of the laws are new, it is unclear how they will be enforced. 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, we must obtain requisite approval from regulatory authorities in foreign countries 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, which would make launch of such products commercially unfeasible in such countries.

Conduct of clinical trials in the European Union

The conduct of clinical trials in the EU is governed by the EU Clinical Trials Regulation (EU) No. 536/2014, or CTR, which entered into force on January 31, 2022. The CTR replaced the Clinical Trials Directive 2001/20/EC (Clinical Trials Directive), and introduced a complete overhaul of the existing regulation of clinical trials for medicinal products in the EU.

Under the former regime, which will expire after a transition period of one or three years before a clinical trial can be initiated, it must be approved in each EU Member State where there is a site at which the clinical trial is to be conducted.

A more unified procedure will apply under the new CTR. A sponsor will be able to submit a single application for approval of a clinical trial through a centralized EU clinical trials portal. One national regulatory authority (the reporting EU Member State proposed by the applicant) will take the lead in validating and evaluating the application and consult and coordinate with the other concerned EU Member States. If an application is rejected, it may be amended and resubmitted through the EU clinical trials portal. If an approval is issued, the sponsor may start the clinical trial in all concerned EU Member States. However, a concerned EU Member State may in limited circumstances declare an "opt-out" from an approval and prevent the clinical trial from being conducted in such EU Member State. From January 31, 2023, submission of initial clinical trial applications via the Clinical Trials Information System, or CTIS, has become mandatory, and by January 31, 2025, all ongoing trials approved under the former Clinical Trials Directive will be governed by the new Regulation and have to be transitioned to CTIS.

During the development of a medicinal product, the European Medical Agency, or EMA, and national regulators within the EU provide the opportunity for dialogue and guidance on the development program. At the EMA level, this is usually done in the form of scientific advice, which is given by the Committee for Medicinal Products for Human Use, or CHMP, on the recommendation of the Scientific Advice Working Party. A fee is incurred with each scientific advice procedure, but is significantly reduced for designated orphan medicines. Advice from the EMA is not legally binding with regard to any future Marketing Authorization Application, or MAA, of the product concerned.

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

In the EU and in Iceland, Norway and Liechtenstein (together, the European Economic Area, or EEA), after completion of all required clinical testing, pharmaceutical products may only be placed on the market after obtaining a MA. To obtain an MA of a drug under EU regulatory systems, an applicant can submit an MAA through, amongst others, a centralized or decentralized procedure.

The centralized procedure provides for the grant of a single MA by the EC that is valid for all EU Member States in the three additional EEA Member States. The centralized procedure is mandatory for certain medicinal products, including for medicines developed by means of certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products, or ATMP, and medicinal products with a new active substance indicated for the treatment of certain diseases (AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases). For medicinal products containing a new active substance that is not yet authorized in the EEA before May 20, 2004 and indicated for the treatment of other diseases, medicinal products that constitute significant therapeutic, scientific or technical innovations, or for which the grant of a MA through the centralized procedure would be in the interest of public health at EU level, an applicant may voluntarily submit an application for a MA through the centralized procedure. Under the centralized procedure, the CHMP, established at the EMA, is responsible for conducting the initial assessment of a drug and for several post-authorization and maintenance activities, such as the assessment of modifications or extensions to an existing marketing authorization.

MAs have an initial duration of five years, after which the authorization may subsequently be renewed on the basis of a reevaluation of the risk-benefit balance. Once renewed, the MA is valid for an unlimited period unless the EC or the national competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with only one additional five-year renewal. Applications for renewal must be made to the EMA at least nine months before the five-year period expires.

Similar to Accelerated Approval regulations in the United States, conditional MAs can be granted in the EU by the EC in exceptional circumstances.

Orphan Designation and Exclusivity

As in the United States, it may be possible to obtain a period of market and/or data exclusivity in the EU that would have the effect of postponing the entry into the marketplace of a competitor's generic, hybrid or biosimilar product (even if the medicinal product has already received a MA) and prohibiting another applicant from relying on the MA holder's pharmacological, toxicological and clinical data in support of another MA for the purposes of submitting an application, obtaining MA or placing the product on the market. New chemical entities, or NCEs, approved in the EU qualify for eight years of data exclusivity and 10 years of marketing exclusivity.

An additional non-cumulative one-year period of marketing exclusivity is possible if, during the data exclusivity period (the first eight years of the 10-year marketing exclusivity period), the MA holder obtains an authorization for one or more new therapeutic indications that are deemed to bring a significant clinical benefit compared to existing therapies.

Even if a compound is considered to be a NCE and the MA applicant is able to gain the prescribed period of data exclusivity, another company nevertheless could also market another version of the medicinal product if such company can complete a full MA application with their own complete database of pharmaceutical tests, preclinical studies and clinical trials and obtain MA of its product.

Additionally, the EMA may grant orphan drug designation similar in principle to that in the United States. Upon the grant of a marketing authorization, orphan drug designation provides up to ten years of market exclusivity in the orphan indication.

The 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation. When the period of orphan market exclusivity for an indication ends, the orphan drug designation for that indication expires as well. Orphan exclusivity runs in parallel with normal rules on data exclusivity and market protection. Additionally, a marketing authorization may be granted to a similar medicinal product (orphan or not) for the same or overlapping indication subject to certain requirements.

PRIME Designation

In March 2016, the EMA launched an initiative to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The Priority Medicines, or PRIME, scheme is intended to encourage drug development in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation reviewed under the centralized procedure. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MA application assessment once a dossier has been submitted. PRIME eligibility does not change the standards for product approval, and there is no assurance that any such designation or eligibility will result in expedited review or approval.

Pricing and reimbursement in the European Union

Even if a medicinal product obtains a MA in the EU, there can be no assurance that reimbursement for such product will be secured on a timely basis or at all. The EU Member States are free to restrict the range of medicinal products for which their national health insurance systems provide reimbursement, and to control the prices and reimbursement levels of medicinal products for human use. An EU Member State may approve a specific price or level of reimbursement for the medicinal product, or alternatively, may adopt a system of direct or indirect controls on the profitability of the company responsible for placing the medicinal product on the market, including volume-based arrangements, caps and reference pricing mechanisms.

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.

In the EU, 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 both at the 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 EU. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of the EU Member States. 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 regulatory professional organization, and/or the competent authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct, applicable in 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

The collection and use of personal health data and other personal data in the EU is governed by the provisions of the European General Data Protection Regulation (EU) 2016/679, or GDPR, which came into force in May 2018, and related ilaws in individual EU Member States.

The GDPR imposes a number of strict obligations and restrictions on the ability to process (processing includes collection, analysis and transfer of) personal data of individuals, in particular with respect to health data from clinical trials and adverse event reporting. The GDPR includes requirements relating to the legal basis of the processing (such as consent of the individuals to whom the personal data relates), the information provided to the individuals prior to processing their personal data, the notification obligations to the national data protection authorities, and the security and confidentiality of the personal data. EU Member States may also impose additional requirements in relation to health, genetic and biometric data through their national legislation.

The GDPR also imposes on us, as a controller, the obligation to notify without undue delay and, where feasible, not later than 72 hours after having become aware of it, the supervisory authority and/or the data subject, in the event of a personal data breach, regardless of whether the processing is carried out on our or our vendors' systems, unless the personal data breach is unlikely to result in a risk to the rights and freedoms of natural persons. In addition to the disruptions to our business and impact to our reputation that any such breach of security could cause, we may be subject to regulatory fines, class actions, or other costly measures if there is a personal data breach on our or our vendors' systems. We maintain cyber-liability insurance, however, that insurance may be insufficient to fully cover the losses associated with such a breach, including any resulting regulatory fines. Furthermore, under the GDPR, when we act as a processor, we must notify the relevant controller without undue delay after become aware of a personal data breach.

Failure to comply with the requirements of the GDPR and the related national data protection laws of the EU Member States may result in significant monetary fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater, other administrative penalties and a number of criminal offenses (punishable by uncapped fines) for organizations and, in certain cases, their directors and officers, as well as civil liability claims from individuals whose personal data was processed. Data protection authorities from the different EU Member States may still implement certain variations, enforce the GDPR and national data protection laws differently, and introduce additional national regulations and guidelines, which adds to the complexity of processing personal data in the EU. Guidance developed at both the

EU level and at the national level in individual EU Member States concerning implementation and compliance practices are often updated or otherwise revised.

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, 2022, we employed 128 individuals, 127 of whom were full-time. Of these employees, 25 were in research and development, 80 were in sales and marketing, and 23 were in business and administrative positions. Our employees do not have a collective bargaining agreement. We believe our relations with our employees are good.

Corporate Information

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 or incorporated by reference into this Annual Report on Form 10-K, and any references to our website are intended to be inactive textual references only provided for convenience. 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 amendments to those reports, 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, liquidity, operating results and prospects and the trading price of our securities.

Risk Factor Summary

Risks Related to Our Business

- We are currently a single product company and have limited experience in generating revenue from product sales, and our ability to generate future revenue and achieve profitability will depend on several factors, including the successful commercialization of VONJO. We expect to continue to incur net losses, and we may never achieve profitability.

- We depend on a limited number of customers for a significant amount of our revenue, and if we lose any of our significant customers, our business could be harmed. Further, we are dependent on third-party service providers for a number of critical operational activities. Any failure or delay in these actions by third parties could harm our business.

- We face direct and intense competition from our competitors in the biotechnology and pharmaceutical industries, and we may not compete successfully against them. Our competitive position and the success of our business also depends on our ability to recruit, retain, integrate and motivate senior management, other key personnel and directors, and on such persons' ability to perform effectively.

- Failure to comply with regulatory requirements or unanticipated problems with VONJO may result in adverse actions such as the suspension or withdrawal of VONJO, closure of a facility or enforcement of substantial penalties or fines.

- 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 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.

- If we are unable to in-license or acquire additional product candidates, our future product portfolio and potential profitability could be harmed. Further, we may incur a variety of costs for, and may never realize the anticipated benefits of, acquisitions, collaborations or other strategic transactions. We may encounter other difficulties in managing our expected growth and in expanding our operations successfully.

- We may in the future have significant inventory levels of drug products, and write-downs related to the impairment of those inventories may adversely impact our profitability.

- We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents or data breaches, could harm us. We are also subject to stringent and evolving obligations related to data privacy and security. Any actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions, litigation, fines and penalties, a disruption of our business operations, reputational harm and other adverse business consequences.

Risks Related to the Development and Commercialization of Our Product Candidates

- If the market opportunities for VONJO are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer. The commercial success of any current or future product will depend upon the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community. Further, the insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for VONJO or any future products could limit our ability to market those products and decrease our ability to generate revenue.

- If we fail to develop our current and any future product candidates for additional indications, our commercial opportunity will be limited. Further, 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.

- Drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies may not be predictive of future study results. 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. In addition, we are subject to extensive post-approval or authorization regulatory requirements, including labeling and promoting requirements and post-marketing confirmatory trials as a condition of receiving Accelerated Approval for VONJO, and any failure to satisfy such ongoing obligations or unanticipated problems with any of our drugs that receive regulatory authorization could negatively affect our business.

- The commercial use of VONJO and any future products may cause unintended side effects or adverse reactions, or incidents of misuse may occur, which could adversely affect our business. We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for a product candidate and may have to limit its commercialization.

- 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.

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 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. Further, patent litigation is widespread in the pharmaceutical and biotechnology industry. If we fail to adequately protect our intellectual property, our competitive position and the potential for long-term success could be harmed.

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.

- 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. Further, raising additional capital could cause you to incur dilution and could cause the market price of our common stock to fall.

General Risk Factors

- Unfavorable global economic conditions, whether brought about by global crises, health epidemics, military conflicts and war, geopolitical and trade disputes or other factors, may have a material adverse effect on our business and financial results.

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, 2022, we had an accumulated deficit of $2.5 billion, and we expect to continue to incur net losses. As part of our business plan, we must continue to successfully commercialize our one product approved for commercialization, VONJO, continue to conduct research, development, testing and regulatory compliance activities with respect to pacritinib for additional indications and ensure the procurement of manufacturing and drug supply services for our commercial and drug development efforts, 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.

We are currently a single product company and have limited experience in generating revenue from product sales, and our ability to generate future revenue and achieve profitability will depend on several factors, including the successful commercialization of VONJO.

We have one product approved for commercial sale, VONJO, which received Accelerated Approval on February 28, 2022 from the FDA in the United States for the treatment of adult patients with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 x 10^9/L. VONJO is the only product for which we currently receive product revenue, and we expect VONJO to constitute the vast majority of our product revenue for the foreseeable future. Given that we are dependent on a single product, we do not have the ability to spread out risk of commercial fluctuations across a portfolio of products, and VONJO may not 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 existing or future alternatives. Further, we currently have limited commercialization expertise, including sales, marketing, distribution, or market access and reimbursement capabilities. As a result, our ability to generate significant revenue from product sales and achieve profitability depends heavily on our success in many areas, including, but not limited to:

- continuing to develop sustainable manufacturing processes for VONJO and maintaining raw material supplies, product supply and manufacturing relationships with third parties that can conduct the processes and provide adequate (in amount and quality) product supply to support market demand for VONJO;
- continuing to successfully commercialize VONJO;
- developing and obtaining regulatory and marketing approvals necessary to commercialize pacritinib for other indications;
- obtaining adequate market share, reimbursement and pricing for VONJO;
- generating and disseminating new data analyses and the consistency of any new data with prior results, whether they support a favorable safety, efficacy and effectiveness profile of our products and any potential impact on our FDA Accelerated Approval status;
- our ability to timely comply with FDA post-marketing requirements and commitments, including through successfully conducting additional studies that confirm clinical efficacy, effectiveness and safety of our products and acceptance of the same by the FDA and medical community, as continued approval may be contingent upon verification of a clinical benefit in confirmatory trials;
- our ability to find patients so they can be diagnosed and begin receiving treatment;
- addressing any competing technological and market developments;
- negotiating favorable terms, including commercial rights, in any collaboration, licensing, or other arrangements into which we may enter, any amendments thereto or extensions thereof;
- maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how; and
- attracting, hiring, and retaining qualified personnel.

Further, obtaining regulatory approval requires substantial time, effort and financial resources, and without additional financing, we lack sufficient resources to pursue the development of pacritinib. Other than our Credit Agreement with Drug Royalty III LP 2, or DRI, we currently have no commitments or arrangements for any significant additional financing to fund the development of pacritinib for additional indications, 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 additional development and commercialization of pacritinib, which may not be available on reasonable terms or at all. If we further 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.

Our costs and expenses associated with commercializing VONJO could increase beyond expectations if we are required by the FDA or other regulatory agencies, domestic or foreign, to change our manufacturing processes or assays, or to perform clinical, nonclinical, or other types of post-approval studies in addition to those that we currently anticipate. Our revenue from sales of VONJO will be dependent, in part, upon market size, the accepted price for the product, the approved indication(s), and the ability to obtain reimbursement at any price. If the number of our addressable patients is not as significant as we estimate or

the reasonably accepted population for treatment is narrowed by competition, physician choice, or treatment guidelines, we may not generate significant revenue from sales of VONJO. VONJO is the first product that we have launched and commercialized, and there is no guarantee that we will be able to do so successfully. There are numerous examples of unsuccessful product launches and failures to meet high expectations of market potential, including by pharmaceutical companies with more experience and resources than we have.

We depend on a limited number of customers for a significant amount of our revenue, and if we lose any of our significant customers, our business could be harmed.

The majority of our revenue comes from a limited number of specialty distributor and specialty pharmacy companies. We expect that revenue from a limited number of customers will continue to account for a large portion of our revenue in the future. See Part II, Item 8, "Notes to Financial Statements - Note 1. Description of Business and Summary of Significant Accounting Policies - *Concentrations of Credit Risk and Uncertainties*" for additional details. The loss by us of any of these customers, or a material reduction in their purchases or their marketing pricing, could harm our business, results of operations, financial condition and prospects. In addition, if any of these customers were to fail to pay us in a timely manner, it could harm our cash flow.

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. See "Part I, Item 1, "Competition" in this Annual Report on Form 10-K for information on our specific competitors. 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.

Failure to comply with regulatory requirements or unanticipated problems with VONJO may result in various adverse actions such as the suspension or withdrawal of VONJO, closure of a facility or enforcement of substantial penalties or fines.

Regulatory agencies will subject VONJO and any other marketed product(s), as well as the manufacturing facilities, to continual review and periodic inspection. For example, the Accelerated Approval for VONJO was based on efficacy results from our pivotal Phase 3 PERSIST-2 study of VONJO in patients with myelofibrosis (platelet counts less than or equal to 100 x 10^9/L). VONJO, and any other marketed product(s), will be subject to ongoing FDA requirements governing labeling, packaging, storage, advertising, promotion and recordkeeping, and we are required to submit additional safety, efficacy and other post-marketing information to the FDA.

Under the Accelerated Approval pathway, continued approval may be contingent upon verification of a clinical benefit in confirmatory trials. To fulfill this post-approval requirement for VONJO, we plan to complete the PACIFICA confirmatory trial. These trials are expensive and time-consuming and may not confirm such benefit. If a confirmatory trial does not verify clinical benefit for an indication, we may have to withdraw our Accelerated Approval for that indication. If any of these outcomes occur, either to VONJO or to any future product candidates for which we may seek marketing approval, we may be forced to abandon our development efforts for VONJO or such future product candidates, which could significantly harm our business. These and other post-approval requirements and commitments may not be feasible and/or could impose significant burdens and costs on us; could negatively impact our development, manufacturing and supply of our products; and could negatively impact our financial results. Failure to meet post-approval commitments and requirements, including completion of enrollment and, in particular, any failure to obtain positive safety and efficacy data from our ongoing and planned studies of VONJO and any other marketed product(s), would lead to negative regulatory action from the FDA and/or withdrawal of regulatory approval of VONJO.

Moreover, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. Drug product manufacturers are required to

continuously monitor and report adverse events from clinical trials and commercial use of the product. Further, sponsors of drugs approved under FDA Accelerated Approval provisions also are required to submit to the FDA, at least 30 days before initial use, all promotional materials intended for use after the first 120 days following marketing approval. If we fail to comply with these or any other applicable regulatory approval requirements, such as the requirement to demonstrate a clinical benefit for VONJO in a confirmatory trial, or if previously unknown problems with a product or with regulatory requirements are discovered, such as adverse events of unanticipated severity or frequency, serious or unexpected side effects or other safety risks, or problems with a manufacturing process or laboratory facility, a regulatory agency may impose restrictions or penalties on that product or on us. Such restrictions or penalties may include, among other things:

- restrictions on the marketing or manufacturing of the product, the withdrawal of the product from the market or product recalls;
- warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- closure of the facility, enforcement of substantial fines, injunctions, or the imposition of civil or criminal penalties.

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 commercialization of VONJO and the development of pacritinib in other indications, and we have significant contractual payment obligations under our debt arrangements. In addition, we believe that our present financial resources will be sufficient to fund our operations at least through the fourth quarter of 2023. This raises substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements are issued, and we will need to raise additional capital in the near term in order to fund our operations through and beyond the first quarter of 2024 and to continue as a going concern thereafter. See Part II, Item 8, Notes to Financial Statements, Note 1 of this Annual Report on Form 10-K for additional information on our assessment of our ability to continue as a going concern. 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 our operations 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 commercialization activities and with our clinical trials and other research and development activities may consume capital resources earlier than planned. Due to these and other factors, forecasts for any periods in which we indicate that we expect to have sufficient resources to fund our operations, as well as any other operational or business projection we have disclosed, or may disclose, may not be achieved.

We will need to acquire additional funds in order to develop our business, continue the commercialization of VONJO and conduct research and development for pacritinib in other indications. 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 selling, general and administrative expenses, be unable to attract and retain highly qualified personnel, refrain from making our contractually required payments when due (including debt payments) and/or be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection. Any of these consequences could harm our business, financial condition, operating results and prospects.

We are dependent on third-party service providers for a number of critical operational activities. Any failure or delay in these actions 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 for the testing or production of our compounds in compliance with GLP and cGMP. As a result, we rely on third parties to supply us in a timely manner with manufactured products or product candidates in a manner that is compliant with these standards. 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, raw material supply concerns or other challenges that may adversely affect supply. Furthermore, in order to 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. There are no guarantees we will be able to supply the quantities necessary to effect a successful commercial launch of VONJO or 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 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. We only have one commercial supplier of VONJO. 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.

Many of our vendors process personal data on our behalf which is subject to the GDPR, or governed by U.S. State privacy, cybersecurity or data breach laws (e.g., the New York Shield Act or the CCPA). Failure of our vendors to adequately secure that data or comply with their and our legal obligations may result in exposure to us, as controller for that data, under the GDPR or any of the U.S. State laws in the form of legal costs associated with investigation, notification, and reporting of such a breach, and any resulting fines or penalties. Any breach of the security or other significant disruptions to our information technology systems or those of our vendors could have significant implications for our ability to continually operate our business, and may cause reputational harm. While we maintain cybersecurity insurance, such insurance may not cover the full extent of any financial, legal, reputational or business losses associated with any breach or disruption including any vendor systems processing our data.

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 August 2021, we entered into a Credit Agreement with DRI, or the Credit Agreement, the proceeds of which were partially used to repay in full all outstanding indebtedness under our prior loan and security agreement with Silicon Valley Bank.

Borrowings under the Credit Agreement are secured by a first-priority security interest in, subject to certain exceptions, substantially all of our assets. The Credit Agreement subjects us to customary affirmative and negative covenants that limit our

ability to, among other things, grant liens, make investments, incur additional indebtedness, dispose of assets, license certain property, distribute dividends, make certain restricted payments, change the nature of our business, engage in transactions with affiliates and insiders, prepay other indebtedness, or engage in sale and leaseback transactions, subject to certain exceptions. In addition, the Credit Agreement contains a minimum liquidity covenant requiring us to maintain at all times at least $10 million of unrestricted cash and cash equivalents, subject to certain exceptions. As a result of all of these restrictions, we may be limited in how we conduct our business, unable to raise additional debt or equity financing to operate during general economic or business downturns, unable to compete effectively or to take advantage of new business opportunities or unable to execute our business strategy.

A breach of the covenants under the Credit Agreement could result in an event of default under the Credit Agreement. If any other event of default occurs and is not cured or waived, DRI would be permitted to accelerate repayment of the loans under the Credit Agreement. If we were unable to repay the amounts due and payable under the Credit Agreement upon acceleration, DRI could proceed against the collateral securing the Credit Agreement which could adversely impact our ability to conduct our business.

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 VONJO through the commercialization process has required, and will continue to 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. 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 the continued successful commercialization of VONJO.

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 in the future be subject to proceedings and/or allegations of wrong-doing, which could harm our financial condition and operating results.

We 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. 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.

We may 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.

We may in the future have significant inventory levels of drug products, and write-downs related to the impairment of those inventories may adversely impact or delay our profitability.

We may in the future have significant inventory levels of drug products, and we may increase those inventory levels as we continue to commercialize VONJO. We determine inventory levels of drug products based on a variety of estimates, including timing of regulatory approval of our drug products, market demand for our drug products and those of our competitors, entrance of competing drug products, introduction of new, or changes in interpretations of, pharmaceutical regulations and changes in healthcare provider and insurer reimbursement policies. These estimates are inherently difficult to make and may be inaccurate. We analyze our inventory levels and will write down excess or obsolete inventory. If our

initial estimate of the appropriate inventory levels of drug products is or becomes inaccurate, write-downs of inventory may be required, which would be recorded as cost of product sales and thereby adversely impact or delay our profitability.

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.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents or data breaches, could harm us.

Our internal computer systems and those of third parties with which we contract may be vulnerable to damage from cyber-attacks, “phishing” attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures despite the implementation of security measures. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period. System failures, accidents or security breaches could cause interruptions in our operations and could result in a material disruption of our clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our research and development programs and the development of our drug candidates could be delayed.

We are subject to stringent and evolving obligations related to data privacy and security. Any actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions, litigation, fines and penalties, a disruption of our business operations, reputational harm and other adverse business consequences.

We process personal data and other sensitive information (including patient health data, and proprietary and confidential business data), including in connection with our clinical trials. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and by others on our behalf. Data protection has become a significant issue in the United States, China, countries in the EEA and in many other countries in which we may operate.

In the United States, federal, state and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, and consumer protection laws. These privacy laws include, without limitation, the following laws and regulations: Section 5 of the Federal Trade Commission Act, HIPAA (which imposes specific requirements relating to the privacy, security and transmission of individually identifiable health information), the CCPA and CPRA (which imposes specific requirements on covered businesses relating to personal data practices). To the extent we are or become subject to these laws and/or new or amended data privacy laws, the risk of enforcement actions against us could increase because we may be subject to obligations under applicable regulatory frameworks and the number of individuals or entities that could initiate actions against us may increase (including individuals via a private right of action).

These regulatory frameworks may impact our ability to utilize individuals' personal data, may impose significant penalties for the misuse of personal data and reflect our vulnerability to the evolving regulatory environment related to such data.

Internationally, any operations that we may engage in may become subject to increased scrutiny or attention from foreign data protection authorities. For example, any clinical trial programs and research collaborations that we may conduct outside the United States may implicate foreign data protection laws, including in China and Europe. Many jurisdictions have established, or are in the process of establishing, privacy and data security regulatory frameworks that may require compliance by us or third parties upon whom we rely. For example, European data protection laws, including, without limitation, the EU's GDPR and the UK's equivalent impose stringent data protection requirements for processing personal data of individuals located in the EEA and UK. Under the GDPR, government regulators may impose monetary fines for noncompliance of up to €20 million or 4% of a company's worldwide annual revenues, whichever is greater, and authorizes government regulators to impose penalties for non-compliance (such as bans on personal data processing). Further, individuals may initiate litigation related to our processing of their personal data.

In addition, many jurisdictions, including China, have enacted data localization and cross-border personal data transfer laws. These laws may make it more difficult for us to transfer personal data across jurisdictions, which could impede our business. For example, EU data protection laws, including the GDPR, generally restrict the transfer of personal data from the EU to the United States and most other countries unless the parties to the transfer have implemented specific safeguards designed to protect the relevant personal data. Uncertainties exist with respect to the legality under EU law of such safeguards. As a result, there is a risk that any personal data transfers by us or parties upon which we rely from the EU may not comply with EU data protection laws. Any such noncompliance may increase our exposure to the GDPR's heightened sanctions, restrict our ability to conduct clinical trials in the EU, require us to increase our personal data processing capabilities in the EU and limit our ability to collaborate with parties that are subject to EU data protection laws. Further, the UK's decision to leave the EU, often referred to as Brexit, created uncertainty regarding data protection regulation in the UK, leading to further uncertainty and risk of liability.

Our obligations related to data privacy and security are evolving and may result in increasing regulatory and public scrutiny and escalating levels of enforcement and sanctions, including potentially substantial monetary penalties and personal data processing penalties that could require us to change our business practices. Interpretation of these frameworks is likely to remain uncertain and potentially inconsistent for the foreseeable future. This evolution may create uncertainty in our business and that of parties upon whom we rely. Furthermore, this evolution may impact our ability to operate in certain jurisdictions and our ability to collect, store, transfer, use, share or otherwise process personal data; necessitate our accepting more onerous obligations in contracts; as well as result in liability or impose additional costs (including financial and time-related resources) on us. These obligations may necessitate changes to our information technology systems and practices and to those of any third parties that process personal data on our behalf. Despite our efforts to bring our business practices into compliance with these obligations, we may not be successful in our efforts to achieve compliance (for example, due to lack of clarity in the obligations or to internal or external factors such as resource allocation limitations or a lack of cooperation from third parties upon which we rely). Alleged noncompliance could result in proceedings (e.g., investigations, fines, penalties, audits, inspections and similar); litigation (including class-related claims); additional reporting and/or oversight; bans on personal data processing; and orders not to use personal data. Any of these events could have a material adverse effect on our reputation, business and financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including any future commercial launches and clinical trials); inability to process personal data or to operate in certain jurisdictions; limitations in our ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; and revision or restructuring of our operations.

Risks Related to the Development and Commercialization of Our Product Candidates

If the market opportunities for VONJO are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer.

Our projections of both the number of patients with myelofibrosis, including patients with myelofibrosis with a platelet count below 50 x 10^9/L who have the potential to benefit from treatment with VONJO are based on our beliefs and estimates. These estimates have been derived from a variety of sources and may prove to be incorrect or new studies may change the estimated incidence or prevalence, and the number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for VONJO may be limited or may not be amenable to treatment with VONJO, and new patients may become increasingly difficult to identify or access, which would adversely affect our results of operations and our business. Even if we obtain significant market share for VONJO, because the potential target populations are small, we may never become or remain profitable nor generate sufficient revenue growth to sustain our business. If we fail to maintain orphan

drug exclusivity, competitors may develop and sell products that compete with VONJO, decreasing projected market opportunities.

If we fail to develop our current and any future product candidates for additional indications, our commercial opportunity will be limited.

Developing, obtaining regulatory approval and commercializing pacritinib for additional indications will require substantial additional funding and is prone to the risks of failure inherent in drug development. We may not be able to successfully advance any of these indications through the development process. Even if we receive regulatory approval to market pacritinib for the treatment of additional indications, if any, any such additional indications may not be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize pacritinib for additional indications, our commercial opportunity will be limited.

The commercial success of any current or future product will depend upon the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community.

Even with the requisite approvals from the FDA and comparable foreign regulatory authorities, the commercial success of VONJO and any future products will depend in part on the medical community's, patients', and payors' acceptance of VONJO and any future products as medically useful, cost-effective, and safe. Any product that we bring to the market may not gain market acceptance by physicians, patients, payors, and others in the medical community. The degree of market acceptance of VONJO and any future products will depend on a number of factors, including:

- the efficacy of the product as demonstrated in clinical studies and potential advantages over competing treatments;
- the prevalence and severity of any side effects, including any limitations or warnings contained in a product's approved labeling;
- the clinical indications for which Accelerated Approval is granted;
- relative convenience and ease of administration;
- the cost of treatment, particularly in relation to competing treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the effectiveness of our field forces and marketing efforts;
- the strength of marketing and distribution support and timing of market introduction of competitive products;
- publicity concerning our products or competing products and treatments; and
- sufficient third-party insurance coverage and reimbursement.

Even if a potential product displays a favorable efficacy and safety profile in nonclinical and clinical studies, market acceptance of the product will not be fully known until after it is launched. Our efforts to educate the medical community and payors on the benefits of VONJO require significant resources and may never be successful. If VONJO fails to maintain, and any future products fail to achieve an adequate level of acceptance by physicians, patients, payors, and others in the medical community, we will not be able to generate sufficient revenue to become or remain profitable.

The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for VONJO or any future products could limit our ability to market those products and decrease our ability to generate revenue.

Our target patient populations are small, and accordingly the pricing, coverage, and reimbursement of VONJO and other product candidates, if approved, must be adequate to support our commercial infrastructure. Our per-patient prices must be sufficient to recover our development and manufacturing costs and potentially achieve profitability. The cost of a single administration of VONJO is deemed substantial. Accordingly, the availability and adequacy of coverage and reimbursement by governmental and private payors are essential for most patients to afford expensive treatments such as ours. Sales of VONJO

depend substantially, both domestically and abroad, on the extent to which their costs will be paid for by health maintenance, managed care, pharmacy benefit, and similar healthcare management organizations, or reimbursed by government authorities, private health insurers, and other payors. If coverage and reimbursement are not available, are available only to limited levels, or are not available on a timely basis, we may not be able to continue to successfully commercialize VONJO. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to sustain our overall enterprise.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, decides whether and to what extent a new drug will be covered and reimbursed under Medicare. Private payors tend to follow the coverage reimbursement policies established by CMS to a substantial degree. It is difficult to predict what CMS or private payors will decide with respect to reimbursement for a product such as ours.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, and other countries will put pressure on the pricing and usage of VONJO and other product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medicinal products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for VONJO. Accordingly, in markets outside the United States, the reimbursement for VONJO may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for new products and, as a result, they may not cover or provide adequate payment for VONJO. Further federal and state proposals and healthcare reforms are likely, which could limit the prices that can be charged for the product candidates that we develop and may further limit our commercial opportunity. Most recently, the Inflation Reduction Act of 2022, or IRA, includes several measures intended to lower the cost of prescription drugs and related healthcare reforms, including limits on price increases and subjecting an escalating number of drugs to annual price negotiations with CMS. For example, the IRA includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, amongst other changes. We cannot be sure whether additional legislation or rulemaking related to the IRA will be issued or enacted, or what impact, if any, such changes will have on the profitability of VONJO or any other drug candidates if approved for commercial use in the future. There also may be future changes unrelated to the IRA that result in reductions in potential coverage and reimbursement levels for our product candidates, if approved and commercialized, and we cannot predict the scope of any future changes or the impact that those changes would have on our operations.

We expect to experience pricing pressures in connection with the sale of VONJO due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, additional legislative changes, and statements by elected officials. The downward pressure on healthcare costs in general, and with respect to prescription drugs, surgical procedures, and other treatments in particular, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

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 GCP 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.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for a product candidate and may have to limit its commercialization.

The sale of VONJO and the use of pacritinib in clinical trials expose us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling VONJO, or clinical trial participants. If we cannot successfully defend ourselves against these claims, we may incur substantial liabilities. Regardless of merit or eventual outcomes of such claims, product liability claims may result in:

- decreased demand for VONJO;
- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs of litigation;
- substantial monetary awards to patients or other claimants; and
- loss of revenues.

Our insurance coverage may not be sufficient to reimburse us for all expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses.

The commercial use of VONJO and any future products may cause unintended side effects or adverse reactions, or incidents of misuse may occur, which could adversely affect our business.

We cannot predict whether any commercial use of VONJO or other product candidates, if any, once approved, will produce undesirable or unintended side effects that have not been evident in clinical trials conducted for such product candidates to date. Additionally, incidents of product misuse may occur. These events, including the reporting of adverse safety events, among others, could result in product recalls, product liability actions related to our products or withdrawals or additional regulatory controls (including additional regulatory scrutiny and requirements for additional labeling), all of which could have a material adverse effect on our business, financial condition, cash flows and results of operations.

We are subject to extensive post-approval or authorization regulatory requirements, including post-marketing confirmatory trials as a condition of receiving Accelerated Approval for VONJO, and any failure to satisfy such ongoing obligations or unanticipated problems with any of our drugs that receive regulatory authorization could negatively affect our business.

We are and will continue to be subject to numerous regulatory requirements, including with respect to development, testing, manufacturing, labeling, marketing, reporting, sales, and reimbursement for VONJO. For example, as a condition of receiving Accelerated Approval from the FDA for VONJO for the treatment of adult patients with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 x 10^9/L, continued approval for this indication is contingent upon verification and description of clinical benefit in post-marketing confirmatory trials. To fulfill this post-marketing requirement, we plan to complete the PACIFICA confirmatory trial. However, if confirmatory trials are unsuccessful for a given indication, VONJO may be subject to withdrawal procedures. If we fail to comply with other regulatory requirements or if we experience unanticipated problems with any of our drugs that receive regulatory authorization, it may result in, among other things:

- 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;

- Clinical holds on clinical trials;
- Warning or untitled letters from the FDA;
- Refusal by the FDA, EMA or comparable regulatory authority to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of drug license approvals;
- Drug seizure or detention, or refusal to permit the import or export of drugs; and
- Injunctions or the imposition of civil or criminal penalties.

Any of these events could negatively affect our business, financial condition, operating results or prospects, generate negative publicity, and require us to expend significant time and resources.

Even if we obtain FDA approval for products in the United States, we may never obtain approval to or successfully commercialize any product candidates outside of the United States, which would limit our ability to realize their full market potential.

In order to develop and market any products outside of the United States, including VONJO, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and effectiveness. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional or different administrative review periods from those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Seeking foreign regulatory approval could result in difficulties and costs and require additional nonclinical studies or clinical trials which would be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates in those countries. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. While we have one product approved for sale in the United States, we do not have any product candidates approved for sale in international markets. If we fail to obtain or maintain required regulatory approvals from foreign regulatory authorities or to comply with regulatory requirements in international markets, or if regulatory approval in international markets is delayed, our target market will be reduced and our ability to realize the full market potential of our products will be inhibited.

We may be subject to fines, penalties, injunctions and other sanctions if we are deemed to be promoting the use of our products for non-FDA-approved, or off-label, uses.

Our business and future growth depend on the development, ultimate sale and use of products that are subject to FDA, EMA and or other regulatory agencies regulation, clearance and approval. Under the FDCA and other laws, we are prohibited from promoting our products for off-label uses, or uses not approved by the FDA. This means that in the United States, we may not make claims about the safety or effectiveness of our products and may not proactively discuss or provide information on the uses of our products that are not approved by the FDA, unless otherwise allowed by the FDA by policy or other guidance.

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, the Physician Payments Sunshine Act and the FCPA, and 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 Physician Payments Sunshine Act, 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, litigation, significant diversion of resources, exclusion from government health care reimbursement programs and the curtailment or restructuring of our operations, or 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.

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.

Drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies may not be predictive of future study results.

We are a commercial-stage biopharmaceutical company with additional indications in various stages of clinical development. Clinical testing is expensive and generally takes many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the clinical study process. The results of preclinical studies and early clinical studies of our product candidates may not be predictive of the results of larger, later-stage controlled clinical studies. Product candidates that have shown promising results in early-stage clinical studies may still suffer significant setbacks in subsequent clinical studies. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical studies due to lack of efficacy or adverse safety profiles despite promising results in earlier, smaller clinical studies. Moreover, clinical data are often susceptible to varying interpretations and analyses. We do not know whether any Phase 2, Phase 3, or other clinical studies we have conducted or may conduct will demonstrate consistent or adequate efficacy and safety with respect to the proposed indication for use sufficient to obtain regulatory approval to receive regulatory approval or market our drug candidates.

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 VONJO. 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 VONJO and other product candidates. Patent coverage for our individual products extends for varying periods according to the date of the patent filing or grant and the legal term of patents in the various countries where we have obtained patent protection.

In addition to our patent rights, we rely, to the extent possible, on 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 February 21, 2023, our stock price ranged from a low of $1.82 to a high of $7.80. 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.

We have in the past 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.

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, 2022, options to purchase 21,517,244 shares of our common stock with a weighted-average exercise price of $2.94 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.

If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, our ability to operate our business and investors' views of us.

We are subject to the rules and regulations of the SEC, including those rules and regulations mandated by the Sarbanes-Oxley Act. Section 404 of the Sarbanes-Oxley Act requires public companies to include in their annual report a statement of management's responsibilities for establishing and maintaining adequate internal control over financial reporting, together with

an assessment of the effectiveness of those internal controls. Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that will need to be evaluated frequently. Our failure to maintain the effectiveness of our internal controls in accordance with the requirements of the Sarbanes-Oxley Act could have a material adverse effect on our business. We could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on the price of our common stock. In addition, if our efforts to comply with new or changed laws, regulations, and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

General Risk Factors

Unfavorable global economic conditions, whether brought about by global crises, health epidemics, military conflicts and war, geopolitical and trade disputes or other factors, may have a material adverse effect on our business and financial results.

Our business is sensitive to global economic conditions, which can be adversely affected by public health crises (including the COVID-19 pandemic) and epidemics, political and military conflict, trade and other international disputes, significant natural disasters (including as a result of climate change) or other events that disrupt macroeconomic conditions. Adverse macroeconomic conditions, including inflation, slower growth or recession, new or increased tariffs and other barriers to trade, changes to fiscal and monetary policy or government budget dynamics (particularly in the pharmaceutical and biotech areas), tighter credit, higher interest rates, volatility in financial markets, high unemployment, labor availability constraints, currency fluctuations and other challenges in the global economy have in the past adversely affected, and may in the future adversely affect, us and our business partners and suppliers.

For example, military conflicts or wars (such as the ongoing conflict between Russia and Ukraine) can cause exacerbated volatility and disruptions to various aspects of the global economy. The uncertain nature, magnitude, and duration of hostilities stemming from such conflicts, including the potential effects of sanctions and counter-sanctions, or retaliatory cyber-attacks on the world economy and markets, have contributed to increased market volatility and uncertainty, which could have an adverse impact on macroeconomic factors that affect our business and operations, such as worldwide supply chain issues. Additionally, enrollment sites in Russia, Ukraine and Belarus have been indefinitely paused in response to the conflict in the region. We cannot be certain of the overall impact of the conflict between Russia and Ukraine on our ability to conduct and complete our clinical trials as planned, and any interruptions of our clinical trials can result in significant delays or termination of the research, development or commercialization of our drug candidates, which could impair our ability to generate revenues and harm our business and financial condition. It is not possible to predict the short and long-term implications of military conflicts or wars or geopolitical tensions which could include further sanctions, uncertainty about economic and political stability, increases in inflation rate and energy prices, cyber-attacks, supply chain challenges and adverse effects on currency exchange rates and financial markets.

Further, trade policies and geopolitical disputes (including as a result of China-Taiwan relations) and other international conflicts can result in tariffs, sanctions and other measures that restrict international trade, and can materially adversely affect our business. For example, tensions between the United States and China have led to a series of tariffs being imposed by the United States on imports from China mainland, as well as other business restrictions. Countries may also adopt other measures, such as controls on imports or exports of goods, technology or data, that could adversely impact our operations and supply chain.

Additionally, our operations and facilities, as well as operations of our service providers and manufacturers, may be located in areas that are prone to earthquakes and other natural disasters. Such operations and facilities are also subject to the risk of interruption by fire, drought, power shortages, nuclear power plant accidents and other industrial accidents, terrorist attacks and other hostile acts, ransomware and other cybersecurity attacks, telecommunication failure, labor disputes, public health crises (including the COVID-19 pandemic) and other events beyond our control. Global climate change is resulting in certain types of natural disasters occurring more frequently or with more intense effects. 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. Because we rely on a single or limited sources for the supply and manufacture of many critical components, a business interruption affecting such sources would exacerbate any negative consequences on our business. 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.

Any public health crises, including the COVID-19 pandemic, may affect our operations and those of third parties on which we rely, including our business partners and suppliers. In the past three years, the COVID-19 pandemic has caused, and likely will continue to cause, significant volatility and uncertainty in U.S. and international markets, disruptions to our business

and delays in our clinical trials and timelines, including as a result of impacts associated with protective health measures that we, other businesses and governments are taking or might have to take again in the future to manage the pandemic. The extent to which the COVID-19 pandemic and measures taken in response thereto impact our business, results of operations and financial condition will depend on future developments which are highly uncertain and difficult to predict. These developments include, but are not limited to, future resurgences of the virus and its variants, actions taken to contain the virus or address its impact, and the timing, distribution and efficacy of vaccines and other treatments.

Without limiting the foregoing, we have experienced and/or may in the future experience:

- difficulties enrolling patients in our clinical trials as the patient populations that are eligible for our clinical trials are impacted by COVID-19;
- delays or difficulties in conducting clinical trials, whether due to changing local regulations, supply chain constraints, travel restrictions or other related factors;
- delays in necessary interactions with local regulators, ethics committees, and other important agencies and contractors due to limitations in employee resources;
- refusal of the FDA to accept data from clinical trials in affected geographies; and
- adverse impacts on our workforce and/or key employees.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We currently lease approximately 23,000 square feet of space at 3101 Western Avenue in Seattle, Washington. The lease expires in April 2025. 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

We are not currently 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. 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 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 February 21, 2023, there were 106 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.

Recent Sales of Unregistered Securities

None.

Repurchases of Equity Securities

None.

Item 6. Reserved

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 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 commercial biopharmaceutical company focused on the acquisition, development and commercialization of novel targeted therapies for blood-related cancers where there is a significant unmet medical need. Our goal is to build a profitable company by generating income from products we develop and commercialize, either alone or with partners. We have one commercially approved product, VONJO® (pacritinib), which has received Accelerated Approval in the United States from the U.S. Food and Drug Administration, or the FDA, for the treatment of adult patients with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 x 10^9/L.

Pacritinib is an oral kinase inhibitor with activity against wild type Janus Associated Kinase 2 (JAK2), mutant $JAK2^{V617F}$ form, IRAK1, ACVR1 (ALK2) and FLT3, which contribute to signaling of a number of cytokines and growth factors that are important for hematopoiesis and immune function. At clinically-relevant concentrations, pacritinib does not inhibit JAK1. 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. Myelofibrosis is often associated with dysregulated JAK2 signaling. 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, graft versus host disease, or GvHD, and chronic lymphocytic leukemia, or CLL, due to its inhibition of JAK2, IRAK1, FLT3, ACVR1 (ALK2) 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 product sales, the sale of equity securities, debt financing, sale of certain future royalties and funding received from our licensees and collaborators. We do not expect to achieve or sustain profitability for the foreseeable future. We had a net loss of $93.0 million for the year ended December 31, 2022 and an accumulated deficit of $2.5 billion as of December 31, 2022, primarily from expenses incurred in connection with our research programs and from selling, general and administrative costs associated with our operations, partially offset by the commencement of product sales in March 2022.

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 commercialization efforts for VONJO;
- 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; and
- maintain, protect and expand our intellectual property portfolio.

Factors Affecting Performance

Product Sales

Following FDA approval of VONJO on February 28, 2022, we commenced shipping of VONJO to a limited number of specialty distributor customers and specialty pharmacy customers in March 2022. Product sales are recognized upon delivery of

our product to our customers and are recorded net of applicable deductions, including trade discounts, distribution service fees, product returns, chargebacks and discounts, rebates and other incentives such as co-pay assistance. Our realization of product sales will be dependent, in part, upon our continued commercialization efforts and the market acceptance of VONJO among physicians, patients, healthcare payers and the medical community.

Cost of Sales

Cost of sales for the year ended December 31, 2022 primarily consisted of shipping and distribution costs of VONJO, amortization expense for intangible assets and third-party royalty costs. Cost of sales includes only a portion of the costs related to the manufacture of VONJO and related materials, since, prior to FDA approval, these costs were expensed as research and development expenses. We expect to utilize zero cost inventory with respect to VONJO for an extended period of time.

Research and Development

We expect to commit significant time and resources to research and development activities relating to our current and any future product candidates. Pacritinib has received Accelerated Approval for the treatment of adult patients with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 x 10^9/L and is being marketed as VONJO. However, a confirmatory study, PACIFICA, is ongoing and we expect to continue to devote resources to the completion of this study.

Selling, General and Administrative

Selling, general and administrative expenses consist primarily of personnel costs, including related equity-based compensation, expenses for outside consulting and professional services, allocated facilities costs and costs required to support the marketing and sales operations of our commercialized product. We anticipate that selling, general and administrative expenses associated with the commercialization of VONJO, primarily related to our sales force, our marketing, market access and commercial capabilities, will approximate 2022 levels during 2023.

Impact of COVID-19

We continue to evaluate and manage the impact of the global COVID-19 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, an increase in fatalities or other adverse events due to medical problems related to the COVID-19 pandemic and the benefits of continued patient access to VONJO.

Financial Summary

Our net product sales reflect sales of VONJO, which was commercially launched in the United States in March 2022 following FDA approval on February 28, 2022. Net product sales were $53.9 million for the year ended December 31, 2022. We did not have any product sales for the year ended December 31, 2021. Loss from operations was $79.8 million and $95.3 million for the years ended December 31, 2022 and 2021, 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, 2022, our cash, cash equivalents and short-term investments were $79.9 million.

Results of Operations

Years ended December 31, 2022 and 2021

Net product sales. We began recognizing product sales in March 2022 following FDA approval of VONJO on February 28, 2022 and its subsequent commercial launch in the United States. Net product sales were as follows for the years ended December 31, 2022 and 2021 and for each of the quarterly periods therein (in thousands):

	December 31, 2022	December 31, 2021
First quarter	$ 2,295	$ —
Second quarter	12,329	—
Third quarter	18,241	—
Fourth quarter	21,083	—
Total	$ 53,948	$ —

The activities and ending reserve balances for significant categories of allowances for VONJO (which constitute variable consideration that is deducted from gross product sales) during the year ended December 31, 2022 were as follows (in thousands):

	Chargebacks and rebates	Service fees, returns, co-pay assistance and other	Total
Balance, January 1, 2022	$ —	$ —	$ —
Provision related to current year sales	6,862	2,797	9,659
Payments / credits for current year sales	(5,017)	(2,299)	(7,316)
Balance, December 31, 2022	$ 1,845	$ 498	$ 2,343

Chargebacks and rebates are expected to be the most significant component of our total gross-to-net deductions. Future gross-to-net deductions will fluctuate based on the volume of purchases eligible for government-mandated discounts and rebates as well as changes in the discount percentage which is impacted by external factors. We anticipate that the overall gross-to-net deduction percentage will begin to stabilize during 2023.

Operating costs and expenses

Cost of sales. During the year ended December 31, 2022, we recorded $3.5 million of cost of sales, which primarily consisted of amortization expense for intangible assets, shipping and distribution costs and third-party royalty costs. We did not have any cost of sales for the year ended December 31, 2021. The manufacturing costs for VONJO incurred prior to FDA approval on February 28, 2022 were not capitalized as inventory but were expensed as research and development costs since product manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. As such, cost of sales currently reflects only a portion of the costs related to the manufacture of VONJO and related materials.

The time period over which reduced-cost VONJO inventory is consumed will depend on a number of factors, including the amount of future sales, the ultimate use of this inventory in either commercial sales, clinical development or other research activities, and the ability to utilize inventory prior to its expiration date. At this time, we expect that cost of sales in relation to net product sales will progressively increase towards 2025 as VONJO product manufactured and expensed prior to capitalization is sold.

Research and development expenses. Research and development expenses decreased to $36.9 million for the year ended December 31, 2022 compared to $39.1 million for the year ended December 31, 2021. All of our research and development expenses for the years ended December 31, 2022 and 2021 were related to our pacritinib program. The decrease between periods was attributable to a $3.1 million decrease in the PRE-VENT Phase 3 trial and a $1.8 million decrease in the PACIFICA Phase 3 trial, partially offset by a $2.7 million increase that primarily resulted from additional staffing and personnel costs.

Research and development expenses include external direct costs 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. Indirect costs include personnel costs, an allocation of overhead costs and other costs not directly charged to development programs. Cumulative to date external direct costs incurred by us through December 31, 2022 were $240.4 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).

Selling, general and administrative expenses. Selling, general and administrative expenses were $84.8 million for the year ended December 31, 2022 compared to $56.2 million for the year ended December 31, 2021. Substantially all of the increase between periods was attributable to activities associated with the commercialization of VONJO, which consisted of the following: a $23.0 million increase in additional staffing and personnel costs, a $2.4 million increase in professional services, a $2.4 million increase in travel expenses, and a $0.8 million increase in infrastructure and other expenses, including sales-related service agreements.

Other operating expenses. Other operating expenses of $8.5 million for the year ended December 31, 2022 were attributable to a $10.3 million milestone expense relating to resolution of a contingency in the Asset Return and Termination Agreement with Baxalta, which became payable to Takeda Pharmaceutical Company Limited upon FDA approval of VONJO,

as well as a $0.3 million expense relating to the 2003 Italian VAT assessment, partially offset by a $2.1 million income related to the collection of 2011 Italian VAT receivable, which had been previously written off from the balance sheet.

Non-operating expense

Interest expense, net. Interest expense, net was as follows (in thousands):

	Years ended December 31,	
	2022	2021
Interest income	$ 1,684	$ 38
Interest expense	(6,134)	(1,921)
Imputed interest expense (royalty financing obligation)	(8,001)	—
Amortization of debt discount and issuance costs	(688)	(532)
Interest expense, net	$ (13,139)	$ (2,415)

Interest income was $1.7 million and less than $0.1 million for the years ended December 31, 2022 and 2021, respectively. Interest income primarily relates to our cash equivalent securities and short-term investments. The increase between periods was primarily due to higher interest rates on cash equivalent securities and increases in short-term investments.

Interest expense was $6.1 million and $1.9 million for the years ended December 31, 2022 and 2021, respectively, and was primarily related to the $50.0 million Credit Agreement that we entered into with DRI in August 2021. In addition, interest expense for the year ended December 31, 2022 included a $0.5 million interest expense on the milestone payable to Takeda. The increase between periods primarily resulted from the higher average loan principal balance outstanding and the higher average interest rates during the year ended December 31, 2022 compared to the same period in the prior year.

Imputed interest expense (royalty financing obligation) for the year ended December 31, 2022 was related to non-cash interest expense recognized on the royalty financing obligation for the sale of the right to receive certain royalty payments from us under the Purchase and Sale Agreement entered into in August 2021 with DRI, or the Royalty Financing Agreement. The amount of non-cash interest expense that we recognize in future periods will primarily depend on our net sales of VONJO. See Part II, Item 8, “Notes to Financial Statements, Note 8. Debt Financing Arrangements” for additional information. There was no such expense for the year ended December 31, 2021.

Amortization of debt discount and issuance costs for the year ended December 31, 2022 was related to the Credit Agreement and Royalty Financing Agreement with DRI. Amortization of debt discount and issuance costs for the year ended December 31, 2021 was related to the Credit Agreement with DRI and our term loan with Silicon Valley Bank, which was repaid in full in August 2021.

Other non-operating expenses. Other non-operating expenses of $0.1 million for the year ended December 31, 2022 was related to a foreign exchange loss. Other non-operating expenses of $0.2 million for the year ended December 31, 2021 was primarily related to a loss on extinguishment of debt upon repayment of our secured term loan with Silicon Valley Bank in August 2021.

Liquidity and Capital Resources

Sources of Liquidity

We have historically funded our operations from product sales, proceeds from the sales and the issuance of equity securities, the incurrence of debt, the sale of certain future royalties and payments received pursuant to license and collaboration agreements. As of December 31, 2022, we had $79.9 million in cash, cash equivalents and short-term investments.

Product Sales. We commercially launched VONJO in March 2022 following the Accelerated Approval of VONJO by the FDA on February 28, 2022. We intend to rely on cash flows from product sales as our source of liquidity in the near future as we expand our commercialization efforts with respect to VONJO.

Public Offering of Common Stock and Series X[1] Preferred Stock. In April 2021, we issued 16.4 million shares of our common stock at a $2.50 per share price and 600 shares of our Series X[1] Preferred Stock at a $25,000 per share price, collecting net proceeds of approximately $53.6 million.

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.

At-The-Market Equity Offering. In January 2021, we entered into an Open Market Sale Agreement℠ with Jefferies LLC, or the 2021 Sale Agreement, to sell shares of our common stock having aggregate sales proceeds of up to $50.0 million. We sold 0.9 million shares of our common stock under the 2021 Sale Agreement for net proceeds of approximately $2.7 million during the year ended December 31, 2021. For the year ended December 31, 2022, we sold 9.4 million shares of our common stock for net proceeds of approximately $45.5 million under the 2021 Sale Agreement. As of the second quarter of 2022, all $50.0 million of the aggregate sales capacity under the 2021 Sale Agreement was fully utilized. In August 2022, we entered into a new Open Market Sale Agreement℠ with Jefferies, or the 2022 Sale Agreement, to sell shares of our common stock having aggregate sales proceeds of up to $100.0 million. The 2021 Sale Agreement was terminated upon entry into the 2022 Sale Agreement. For the year ended December 31, 2022, we sold 1.7 million shares of our common stock for approximately $9.7 million, net of sales agent commission of $0.3 million, under the 2022 Sale Agreement. As of December 31, 2022, the remaining facility under the 2022 Sale Agreement was $90.0 million.

Credit Agreement. In August 2021, we entered into the Credit Agreement with DRI as lender and administrative agent, which provided for a loan in the principal amount of $50 million funded by DRI at closing. As of December 31, 2022, we had an outstanding principal balance under the Credit Agreement of $50.0 million. We are required to pay quarterly interest-only payments until August 25, 2026, or the maturity date, with the unpaid principal amount of the outstanding loan due and payable on the maturity date. The loan bears interest at a rate equal to 8.25% per annum, plus the greater of (i) 1.75% and (ii) the three-month LIBOR rate and requires a back-end fee of $1.0 million. These borrowings are secured by a first priority security interest on substantially all of our assets, subject to certain exceptions. In addition, the Credit Agreement contains a minimum liquidity covenant requiring us to maintain at least $10.0 million of unrestricted cash and cash equivalents, subject to certain exceptions. The Credit Agreement also requires us to comply with restrictive covenants, including those that limit our operating flexibility and ability to borrow additional funds. A failure to make a required payment or an uncured covenant breach could lead to an event of default, and in such case, all amounts then outstanding may become due and payable immediately.

Royalty Financing Agreement. In connection with the Credit Agreement discussed above, we and DRI entered into the Royalty Financing Agreement, pursuant to which we sold to DRI the right to receive certain royalty payments from us for a purchase price of up to $85.0 million in cash. In March 2022, DRI funded the upfront purchase price of $60.0 million following FDA approval of VONJO in February 2022. In January 2023, we received $6.5 million in additional funding in connection with the achievement of a certain minimum VONJO sales threshold. DRI will be required to provide up to $18.5 million of remaining contractual funding if certain minimum VONJO sales thresholds are met by the end of the third quarter of 2023. Under the Royalty Financing Agreement, DRI is entitled to receive tiered, sales-based royalties on net product sales of VONJO in the United States.

Historical Cash Flows

Net cash used in operating activities. Net cash used in operating activities was $81.2 million during the year ended December 31, 2022 compared to $84.9 million for the same period in 2021. The decrease was primarily due to cash receipts from VONJO product sales, partially offset by increases in payments for selling, general and administrative expenses associated with the commercialization of VONJO.

Net cash (used in) provided by investing activities. Net cash used in investing activities was $73.9 million during the year ended December 31, 2022 and was attributable to a $25.0 million milestone payment to S*BIO and purchases and maturities of short-term investments. Net cash provided by investing activities was $12.0 million during the same period in 2021 and was attributable to the maturities of short-term investments.

Net cash provided by financing activities. Net cash provided by financing activities was $120.0 million and $97.9 million during the years ended December 31, 2022 and 2021, respectively. Net cash provided during the year ended December 31, 2022 was primarily attributable to net proceeds from the Royalty Financing Agreement with DRI and the utilization of the at-the-market equity facility. Net cash provided during the year ended December 31, 2021 was primarily attributable to net proceeds from the public offering of common stock and Series X^1 preferred stock in April 2021 and the loan proceeds from DRI.

Capital Resources

We have prepared our financial statements assuming that we will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business. However, we believe that, as of the date of the filing of this Annual Report on Form 10-K, our present financial resources, together with expected cash receipts from net product sales of VONJO and the $6.5 million in additional contractual funding received from DRI in January 2023 in connection with the achievement of minimum net product sales of VONJO, will be sufficient to meet our obligations as they come due and to fund our operations at least through the fourth quarter of 2023. 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 first quarter of 2024 and to continue as a going concern thereafter. See "Part II, Item 8, Notes to Financial Statements, Note 1. Description of Business and Summary of Significant Accounting Policies - *Liquidity*" of 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. We have historically funded our operations through product sales, equity financings, borrowings, sale of certain future royalties and funds obtained under product collaborations, any or all of which may not be available to us in the future. As of December 31, 2022, our available cash, cash equivalents and short-term investments totaled $79.9 million and we had an outstanding principal balance of $50.0 million under our Credit Agreement with DRI.

Financial resource forecasts are subject to change as a result of a variety of risks and uncertainties. Changes in our commercialization efforts, 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. 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 require additional capital in order to pursue our longer-term strategic objectives. We expect to satisfy our capital needs through existing capital balances, revenues from VONJO and a combination of 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 commercialization efforts and/or reduce our selling, general and administrative expenses, be unable to attract and retain highly-qualified personnel, be unable to obtain and maintain contracts necessary to continue our operations at affordable rates with competitive terms, be unable to or elect to 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: our ability to generate sales of VONJO; the cost of ongoing organization and maintenance of our commercial infrastructure and distribution capabilities; our ability to reach milestones triggering payments to be made or received under certain of our contractual arrangements; the cost of manufacturing VONJO; the cost of manufacturing clinical supplies of our product candidates or of establishing commercial supplies of any products that we may develop in the future; developments in and expenses associated with our research and development activities; our clinical development plans and any changes that we may initiate or that may be requested by the FDA or other regulators as we seek approval for products we may develop in the future; acquisitions or collaborations with respect to compounds or other assets; competitive market developments; disruptions or other delays to our business and clinical trials resulting from ongoing worldwide current events; and other unplanned business developments.

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 financial statements. We evaluate our estimates and judgments on an ongoing 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, 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 financial statements and require our subjective or complex judgment in the preparation of our financial statements:

Revenue Recognition

Under Accounting Standards Codification 606, *Revenue from Contracts with Customers*, or ASC 606, we recognize revenue when our customer obtains control of promised goods or services in an amount that reflects the consideration which we expect to receive 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. As part of accounting for these arrangements, we make significant judgments in estimating the amount of variable consideration to include in the transaction price as discussed below.

Reserves for Variable Consideration

Revenues from product sales are recorded at the net sales price (i.e., the transaction price discussed in *Revenue Recognition* above), which includes estimates of variable consideration. We establish reserves for such variable consideration which results from customer credits, service fees, returns, chargebacks, discounts, rebates and co-pay assistance that are offered within contracts between us and our customers and other indirect healthcare entities relating to our product sales. These reserves are based on the amounts earned or to be claimed on the related sales. Where appropriate, our estimates take into consideration a range of possible outcomes that are probability-weighted for relevant factors such as our historical data, current contractual and statutory requirements, specific known market trends and industry data, and forecasted customer purchase and payment patterns. These reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. The amount of variable consideration that is included in the transaction price may be constrained and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized will not occur in a future period. Actual amounts of consideration ultimately received may differ from our estimates. If actual results in the future vary from our estimates, we will adjust these estimates, which would affect net product sales and earnings in the period such variances become known.

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.

Royalty Financing Obligation

The royalty financing obligation is eligible to be repaid based on royalties from net sales of VONJO. Interest expense is accrued using the effective interest rate method over the estimated repayment period of the obligation. This requires us to estimate the total amount of future royalty payments to be generated from VONJO product sales over the life of the agreement. We impute interest on the carrying value of the royalty financing obligation and record interest expense using an imputed

effective interest rate. We will reassess the expected royalty payments at each reporting period and account for any changes through an adjustment to the effective interest rate on a prospective basis. The assumptions used in determining the expected repayment term of the royalty financing obligation require that we make estimates which could impact the carrying value of the liability. A significant increase or decrease in forecasted product sales could materially impact the liability balance, the amount of interest expense and the timing of repayment.

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.

Recently Issued and Adopted Accounting Pronouncements

For a description of recently issued and adopted accounting pronouncements, refer to Part II, Item 8, "Financial Statements and Supplementary Data - Notes to Financial Statements - Note 1. Description of Business and Summary of Significant Accounting Policies," which is incorporated herein by reference. We do not anticipate any material impact on our results of operations and financial conditions upon adoption of recent accounting pronouncements.

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 FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying balance sheets of CTI BioPharma Corp. (the Company) as of December 31, 2022 and 2021, the related statements of operations, comprehensive loss, stockholders' equity (deficit) and cash flows for each of the two years in the period ended December 31, 2022, and the related notes (collectively referred to as the financial statements.) In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying 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 recurring 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 financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 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 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 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 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 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 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 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.

Royalty Financing Obligation

Description of the Matter	As more fully described in Note 8 of the financial statements, the Company carries a liability related to a Royalty Financing Agreement ("RFA"). Pursuant to the RFA, the Company must make certain royalty payments based on future net sales of the Company's drug, VONJO. The Company recorded a $61.1 million royalty financing obligation on the balance sheet as of December 31, 2022. Interest expense associated with the RFA liability is imputed using the effective interest rate method. The effective interest rate is determined based on the rate that would enable the liability to be repaid in full over the anticipated life of the arrangement. The interest rate on this liability may vary during the term of the agreement depending on the level and timing of forecasted net revenues which affects the repayment timing and ultimate amount of repayment. In order to amortize the royalty financing obligation, the Company utilizes the prospective method to estimate the future royalties to be paid by the Company to the third party over the life of the arrangement. Under the prospective method, a new effective interest rate is determined each reporting period based on the revised estimate of future net revenue. Auditing the royalty financing obligation involves complex judgments due to the estimation uncertainty in determining the effective interest rate. The Company's effective interest rate model includes revenue projections for which future royalties will be paid, which are sensitive to significant assumptions that are affected by expectations about future market conditions, including product supply, penetration, and sales price, among others.
How We Addressed the Matter in Our Audit	We obtained an understanding of the royalty financing obligation through review of the royalty financing agreement and management's accounting treatment memorandum. To evaluate the royalty financing obligation and related interest expenses, our audit procedures included, among others, assessing the underlying data and assumptions used by the Company in its effective interest rate model. We compared the significant assumptions in the revenue projections to current industry, market and economic trends. We recalculated the current year interest expense based on the amortization schedules and estimates of royalties using the effective interest method, and performed sensitivity analyses over the Company's forecasted revenues to evaluate the changes in the effective interest rates, and associated interest expense, that would result from changes in the assumptions.

/s/ Ernst & Young LLP

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

Seattle, Washington
March 6, 2023

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

	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 30,420	$ 65,446
Short-term investments	49,519	—
Accounts receivable, net	15,387	—
Inventories	733	—
Prepaid expenses and other current assets	3,337	2,933
Total current assets	99,396	68,379
Property and equipment, net	—	176
Intangible assets, net	23,226	—
Other assets	3,303	3,879
Total assets	$ 125,925	$ 72,434
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	$ 2,008	$ 3,891
Accrued expenses	29,402	12,720
Current portion of long-term debt	47,943	47,380
Other current liabilities	1,781	2,660
Total current liabilities	81,134	66,651
Royalty financing obligation	61,134	—
Other liabilities	1,234	2,016
Total liabilities	143,502	68,667
Commitments and contingencies (Note 14)		
Stockholders' (deficit) equity:		
Preferred stock, $0.001 par value per share:		
Authorized shares - 33,333		
Series O Preferred Stock, 0 shares and 12,575 shares issued and outstanding as of December 31, 2022 and 2021, respectively (Aggregate liquidation preference of $0 and $25,150 as of December 31, 2022 and 2021, respectively)	—	—
Series X Preferred Stock, 3,047 shares and 3,794 shares issued and outstanding as of December 31, 2022 and 2021, respectively (Aggregate liquidation preference of $30,470 and $37,940 as of December 31, 2022 and 2021, respectively)	—	—
Series X[1] Preferred Stock, 600 shares issued and outstanding as of December 31, 2022 and 2021 (Aggregate liquidation preference of $15,000 as of December 31, 2022 and 2021)	—	—
Common stock, $0.001 par value per share:		
Authorized shares - 266,500,000 shares as of December 31, 2022 and 2021		
Issued and outstanding shares - 130,747,161 and 99,763,922 as of December 31, 2022 and 2021, respectively	131	100
Additional paid-in capital	2,501,234	2,429,582
Accumulated other comprehensive loss	(35)	—
Accumulated deficit	(2,518,907)	(2,425,915)
Total stockholders' (deficit) equity	(17,577)	3,767
Total liabilities and stockholders' (deficit) equity	$ 125,925	$ 72,434

See accompanying notes.

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

	Year Ended December 31,	
	2022	2021
Net product sales	$ 53,948	$ —
Operating costs and expenses:		
Cost of sales	3,514	—
Research and development	36,895	39,136
Selling, general and administrative	84,826	56,196
Other operating expenses	8,510	—
Total operating costs and expenses	133,745	95,332
Loss from operations	(79,797)	(95,332)
Non-operating expenses:		
Interest expense, net	(13,139)	(2,415)
Other non-operating expenses	(56)	(161)
Total non-operating expenses	(13,195)	(2,576)
Net loss	$ (92,992)	$ (97,908)
Basic and diluted net loss per common share	$ (0.81)	$ (1.09)
Shares used in calculation of basic and diluted net loss per common share	114,694	90,117

See accompanying notes.

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

	Year Ended December 31,	
	2022	2021
Net loss	$ (92,992)	$ (97,908)
Other comprehensive loss:		
Change in unrealized loss on marketable securities	(35)	(2)
Other comprehensive loss	(35)	(2)
Comprehensive loss	$ (93,027)	$ (97,910)

See accompanying notes.

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

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance at January 1, 2021	17	$ —	75,897	$ 76	$ 2,367,958	$ 2	$ (2,328,007)	$ 40,029
Issuance of common stock, net (at-the-market equity offering)	—	—	858	1	2,961	—	—	2,962
Issuance of common stock and Series X[1] Preferred Stock, net	1	—	16,400	16	53,537	—	—	53,553
Conversion of Series X preferred stock to common stock	(1)	—	6,350	7	(7)	—	—	—
Equity-based compensation	—	—	—	—	4,743	—	—	4,743
Exercise of stock options and shares issued under employee stock purchase plan	—	—	263	—	390	—	—	390
Cancellation of restricted stock	—	—	(4)	—	—	—	—	—
Net loss for the year ended December 31, 2021	—	—	—	—	—	—	(97,908)	(97,908)
Other comprehensive loss	—	—	—	—	—	(2)	—	(2)
Balance at December 31, 2021	17	$ —	99,764	$ 100	$ 2,429,582	$ —	$ (2,425,915)	$ 3,767
Issuance of common stock, net (at-the-market equity offering)	—	—	11,042	11	54,884	—	—	54,895
Conversion of Series O preferred stock to common stock	(13)	—	8,383	8	(8)	—	—	—
Conversion of Series X preferred stock to common stock	—	—	7,470	8	(8)	—	—	—
Equity-based compensation	—	—	—	—	10,030	—	—	10,030
Exercise of stock options and shares issued under employee stock purchase plan	—	—	4,088	4	6,754	—	—	6,758
Net loss for the year ended December 31, 2022	—	—	—	—	—	—	(92,992)	(92,992)
Other comprehensive loss	—	—	—	—	—	(35)	—	(35)
Balance at December 31, 2022	4	$ —	130,747	$ 131	$ 2,501,234	$ (35)	$ (2,518,907)	$ (17,577)

See accompanying notes.

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

	Year Ended December 31,	
	2022	**2021**
Operating activities		
Net loss	$ (92,992)	$ (97,908)
Adjustments to reconcile net loss to net cash used in operating activities:		
Equity-based compensation expense	10,030	4,743
Imputed interest expense on royalty financing obligation	8,001	—
Depreciation and amortization	1,951	526
Other	(265)	(113)
Changes in operating assets and liabilities:		
Accounts receivable, net	(15,387)	—
Inventories	(733)	—
Prepaid expenses and other assets	464	2,278
Accounts payable, accrued expenses and other liabilities	7,737	5,585
Net cash used in operating activities	(81,194)	(84,889)
Investing activities		
Milestone payment to S*BIO Pte Ltd.	(25,000)	—
Purchases of short-term investments	(88,853)	—
Proceeds from maturities of short-term investments	40,000	12,000
Net cash (used in) provided by investing activities	(73,853)	12,000
Financing activities		
Gross proceeds from public offering of common stock and Series X[1] preferred stock	—	56,000
Cash paid for offering costs - public offering of common stock and Series X[1] preferred stock	—	(2,447)
Gross proceeds from at-the-market equity offering	56,943	3,064
Cash paid for offering costs - at the-market equity offering	(2,004)	(411)
Gross proceeds from DRI Credit Agreement	—	50,000
Cash paid for issuance costs - DRI Credit Agreement	—	(1,813)
Gross proceeds from DRI Royalty Financing Agreement	60,000	—
Cash paid for issuance costs - DRI Royalty Financing Agreement	(1,284)	(531)
Repayment of Silicon Valley Bank debt	—	(6,329)
Proceeds from stock option exercises	4,934	156
Proceeds from ESPP stock issuance	1,432	252
Net cash provided by financing activities	120,021	97,941
Net (decrease) increase in cash and cash equivalents	(35,026)	25,052
Cash and cash equivalents at beginning of year	65,446	40,394
Cash and cash equivalents at end of year	$ 30,420	$ 65,446
Supplemental disclosure of cash flow information		
Cash paid during the period for interest	$ 6,134	$ 1,950
Supplemental disclosure of noncash financing and investing activities		
Conversion of preferred stock to common stock	$ 32,530	$ 6,350

See accompanying notes.

NOTES TO FINANCIAL STATEMENTS

1. Description of Business and Summary of Significant Accounting Policies

CTI BioPharma Corp., also referred to in these financial statements as “we,” “us,” “our,” the “Company” and “CTI,” is a commercial biopharmaceutical company focused on the acquisition, development and commercialization of novel targeted therapies for blood-related cancers where there is a significant unmet medical need. Our goal is to build a profitable company by generating income from products we develop and commercialize, either alone or with partners. We have one commercially approved product, VONJO® (pacritinib), which received Accelerated Approval on February 28, 2022 from the U.S. Food and Drug Administration, or FDA, in the United States, for the treatment of adult patients with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 x 10^9/L. We commercially launched VONJO in March 2022. We are conducting the Phase 3 PACIFICA study of VONJO in patients with myelofibrosis and severe thrombocytopenia as a post-marketing requirement.

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 FDA, the European Medicines Agency, or the EMA, in 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.

Liquidity

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

While we have seen strong refill demand and expect revenues from VONJO to be one of our primary sources of liquidity, we may not be able to accurately predict the market acceptance or growth trajectory of VONJO’s revenues. We project operating expenses, when offset against our projected revenues, will result in operating losses for the foreseeable future as we expect to conduct research, development, testing and regulatory compliance activities with respect to other development pathways for pacritinib. We have incurred a net operating loss every year since our formation and expect to continue to incur net losses for the foreseeable future. As of December 31, 2022, we had an accumulated deficit of $2.5 billion. Our available cash, cash equivalents and short-term investments were $79.9 million as of December 31, 2022. We expect that our present financial resources, together with expected cash receipts from net product sales of VONJO and the $6.5 million in additional contractual funding received from DRI in January 2023 in connection with the achievement of minimum net product sales of VONJO, will be sufficient to meet our obligations as they come due and to fund our operations at least through the fourth quarter of 2023. Based on our evaluation completed pursuant to ASC 205-40 *Presentation of Financial Statements-Going Concern*, these factors raise substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements are issued.

We will require additional capital in order to pursue our longer-term strategic objectives. We expect to satisfy our capital needs through existing capital balances, revenues from VONJO, and a combination of 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 commercialization efforts and/or reduce our selling, general and administrative expenses, be unable to attract and retain highly-qualified personnel, be unable to obtain and maintain contracts necessary to continue our operations at affordable rates with competitive terms, be unable to or elect to 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: our ability to generate sales of VONJO; the cost of ongoing organization and maintenance of our commercial infrastructure and distribution capabilities; our ability to reach milestones triggering payments to be made or received under certain of our contractual arrangements; the cost of manufacturing VONJO; the cost of manufacturing clinical supplies of our product candidates or of establishing commercial supplies of any products that we may develop in the future; developments in and expenses associated with our research and development activities; our clinical development plans and any changes that we may initiate or that may be requested by the FDA or other regulators as we seek approval for products that we may develop in the future; acquisitions or collaborations with respect to

compounds or other assets; competitive market developments; disruptions or other delays to our business and clinical trials resulting from ongoing worldwide current events; and other unplanned business developments.

In addition, our ability to comply with covenants under our Credit Agreement, or the Credit Agreement, with Drug Royalty III LP 2, or DRI, 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 Credit Agreement, which could cause all of the outstanding indebtedness under the facility to become immediately due and payable. The Credit Agreement also contains a minimum liquidity covenant requiring us to maintain at least $10.0 million of unrestricted cash and cash equivalents, subject to certain exceptions. The accompanying financial statements do not include adjustments, if any, that may result from the outcome of this uncertainty. See 8. Debt Financing Arrangements for additional information regarding the Credit Agreement with DRI.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires estimates and assumptions that affect the reported amounts of assets and liabilities, revenues and expenses, and related disclosures in the financial statements and accompanying notes. Estimates are used for, but not limited to, evaluation of going concern and classification of liabilities, net product sales, clinical accruals, intangible assets, interest expense on royalty financing obligation, income taxes, commitments and contingencies, equity-based compensation and the collectability of receivables. Given the global economic climate, these estimates are becoming more challenging, and actual results could differ materially from those estimates.

Segment Information

Operating segments are defined as components of an enterprise engaging in business activities for which discrete financial information is available and regularly reviewed by the chief operating decision maker in deciding how to allocate resources and in assessing performance. We view our operations and manage our business in a single operating segment focused on the business of acquiring, developing and commercializing novel targeted therapies for blood-related cancers. All of our revenues and assets are related to our operations in the United States.

Concentrations of Credit Risk and Uncertainties

Our VONJO product sales are concentrated in a number of specialty distributor customers and specialty pharmacy customers. The following table presents each customer that accounted for more than 10% of total net product sales for the year ended December 31, 2022:

	December 31, 2022
Customer A	30 %
Customer B	23 %
Customer C	21 %
Customer D	17 %

Cash, cash equivalents, short-term investments and accounts receivable are financial instruments that potentially subject us to concentrations of credit risk. All of our accounts receivable relate to VONJO product sales. We have no off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts or other hedging arrangements.

We have not experienced any significant credit losses on cash, cash equivalents, short-term investments or accounts receivable to date and do not require collateral on accounts receivable. To estimate credit losses for accounts receivable, we consider our historical experience and other currently available information, including customer financial condition, as well as current and forecasted economic conditions affecting our customers. We consider the risk of potential credit losses to be low based on our evaluation of the creditworthiness of our customers who are specialty distributors and specialty pharmacies.

We source our drug products for commercial operations and clinical trials from a concentrated group of third-party contractors. If we are unable to obtain sufficient quantities of source materials, manufacture or distribute our products to customers from existing suppliers and service providers, or obtain the materials or services from other suppliers or manufacturers, certain sales and research and development 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, 2022 and 2021, our cash, cash equivalents and short-term investments consisted of cash, money market funds and corporate debt securities.

We measure the fair value of money market funds based on the closing price reported by the 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, 2022 and 2021. 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, 2022			December 31, 2021
	Cost or Amortized Cost	Gross Unrealized Losses	Fair Value	Fair Value
Cash	$ 337	$ —	$ 337	$
Level 1 securities:				
Money market funds	30,083	—	30,083	65,
Level 2 securities:				
Corporate debt securities	49,554	(35)	49,519	
Total cash, cash equivalents and short-term investments	$ 79,974	$ (35)	$ 79,939	$ 65,

We review investments for other-than-temporary impairment whenever the fair value of an investment is less than the amortized cost and evidence indicates that an investment's carrying amount is not recoverable within a reasonable period of time. Other-than-temporary impairments of investments are recognized in the statements of operations if we have experienced a credit loss and have the intent to sell the investment or if it is more likely than not that we will be required to sell the investment before recovery of the amortized cost basis.

As of December 31, 2022 and 2021, the carrying value of our receivables, payables and accruals approximated their fair values due to the short-term nature of these items. As of December 31, 2022 and 2021, the carrying value of our term loan under the Credit Agreement (See Note 8. Debt Financing Arrangements) approximated its fair value based on borrowing rates for similar loans and maturities, which are considered Level 2 measurements. As of December 31, 2022, the carrying value of royalty financing obligation under the Royalty Financing Agreement (See Note 8. Debt Financing Arrangements) approximated its fair value and was measured using the estimates of future net product sales (and resulting royalty payments) based on key assumptions such as population, market penetration and forecasts from market data sources, which are considered Level 3 measurements.

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. The carrying value of cash and cash equivalents approximates fair value due to the short-term nature of these items.

Accounts Receivable

Accounts receivable, net consist of amounts due from customers, net of customer allowances for prompt-pay discounts, chargebacks, rebates and product returns, as well as distribution service fees. Accounts receivable are stated at amortized cost

less allowance for credit losses. Our standard credit terms range from 30 days to 66 days, and all arrangements are payable within one year of the transfer of control of the product; as such, we do not adjust our revenues for the effects of a significant financing component. We analyze past due accounts for collectability and periodically evaluate the creditworthiness of our customers. As of December 31, 2022, we determined that an allowance for credit losses was not required based on our review of customer accounts and individual circumstances.

Inventories

Prior to regulatory approval, we expense costs related to the production of inventories as research and development expenses in the period in which they are incurred because product manufactured prior to regulatory approval may not be sold unless regulatory approval is obtained. Subsequent to regulatory approval, we capitalize costs incurred to manufacture our products as inventories when the related costs are expected to be recoverable through the commercialization of the product. VONJO inventory that is deployed for clinical, research or development purposes is charged to research and development expense.

As of December 31, 2022, inventories consisted of active pharmaceutical ingredients and capitalized shipping, packaging and labeling costs incurred subsequent to FDA approval of VONJO. Inventories are recorded at the lower of cost and net realizable value with the cost of inventories determined on a specific identification basis in a manner that approximates the first-in, first-out method. We perform an assessment of the recoverability of capitalized inventory during each reporting period and write down excess and obsolete inventories to their net realizable value in the period in which the impairment is first identified.

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 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.

Lease expense for operating leases is recognized on a straight-line basis over the lease term as part of *Research and development* expenses and *Selling, general and administrative* expenses in our 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 balance sheets.

Intangible Assets

Intangible assets as of December 31, 2022 consisted of a capitalized milestone payment incurred upon FDA approval and commercialization of VONJO during the first quarter of 2022. See “Note 10. Collaboration, Licensing and Milestone Agreements - *S*BIO Pte Ltd.*” for additional details. Intangible assets are amortized on a straight-line basis over the patent life of the VONJO product compound, which was 11.9 years upon FDA approval, with a remaining amortization period of 11.0 years as of December 31, 2022. For the year ended December 31, 2022, we recognized $1.8 million of amortization expense, which was included in *Cost of sales*. We expect the amount of amortization expense to be $2.1 million annually prior to the year of patent expiry. The gross carrying amount and accumulated amortization were $25.0 million and $1.8 million as of December 31, 2022, respectively.

We review for impairment when events or circumstances indicate that the carrying value of intangible assets may not be recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset and its eventual disposition are less than its carrying amount. Such estimated undiscounted future cash flows

are derived from projected sales of VONJO and other competitive factors. The amount of impairment is measured as the difference between the carrying amount and the fair value of the impaired asset.

Net Product Sales

On February 28, 2022, the FDA granted Accelerated Approval of VONJO for the treatment of adult patients with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a platelet count below 50 x 10^9/L. We commercially launched VONJO in March 2022. We entered into a limited number of distribution arrangements with specialty distributors and specialty pharmacies in the United States to distribute VONJO. Our specialty pharmacy customers resell VONJO directly to patients while our specialty distributor customers resell VONJO to healthcare entities, who then resell to patients. Such specialty distributors and specialty pharmacies are referred to as our customers in the context of ASC 606.

We recognize revenue for product sales when our customers obtain control of the product, which generally occurs upon delivery. Upon receipt of the product by our customers, we recognize revenues net of variable consideration, which relates to allowances for customer credits, distribution service fees, product returns, chargebacks, rebates and co-payment assistance programs as discussed below. The reserves for these allowances are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if the amount is payable to the customer) or a current liability (if the amount is payable to a party other than the customer). Taxes collected from the customer relating to product sales and remitted to governmental authorities are excluded from product sales.

Customer Credits and Distribution Service Fees: Our customers are offered prompt payment discounts. We expect our customers will pay timely enough to utilize prompt payment discounts and therefore we deduct the full amount of these discounts from total product sales when revenues are recognized. In addition, we pay a fee to our customers for their sales order management, data, and distribution services to us. Distribution service fees are also deducted from total product sales as they are incurred.

Returns: We offer our customers and other indirect purchasers a limited right of return for purchased units of VONJO for damaged, defective, in-dated or expired product beginning six months prior to the product's expiration date and ending 12 months after the product's expiration date. As we do not have sufficient historical experience with VONJO sales, we estimate the amount of product returns initially based on data from similar products and other qualitative considerations, such as visibility into the inventory remaining in the distribution channel.

Chargebacks: Chargebacks result from our contractual commitments to provide our product to discount-eligible healthcare entities, group purchasing organizations, 340B eligible covered entities and federal government entities purchasing via the Federal Supply Schedule, at prices lower than the list prices charged to our customers. Our customers charge us back for the discount provided to the contracted entities. Our reserves for chargebacks consist of credits that we expect to issue for units that remain in the distribution channel inventory, which we expect will be sold to the contracted entities, as well as chargebacks that customers have claimed, but for which we have not yet issued a credit. We record reserves for chargebacks based on contractual terms in the same period that the related revenue is recognized.

Rebates: We are subject to discount and rebate obligations under government programs such as the Medicaid Drug Rebate Program, the Medicare Part D Coverage Gap Discounts Program and the 340B Drug Pricing Program, as well as under commercial contracts. Rebate amounts owed after the final dispensing of the product to a benefit plan participant are based upon contractual agreements or legal requirements with public sector benefit providers, such as Medicaid. The allowance for rebates is based on statutory or contractual discount rates and expected utilization. Our estimates for the expected utilization of rebates are based on data received from our customers and historical utilization rates observed subsequent to product launch.

Our accrual for these rebates consists of invoices received for claims from prior and current quarters that have not been paid or for which an invoice has not yet been received as well as estimates of claims for the current period's shipment to our customers, which include estimated future claims that will be made for product that has been recognized as revenue but which remains in distribution channel inventories at the end of the reporting period.

Co-payment Assistance: We offer co-payment assistance to patients who have commercial insurance and meet certain eligibility requirements. We accrue a liability for co-payment assistance based on actual program participation and estimates of program redemption based on data provided by the third-party administrator.

Cost of Sales

Cost of sales includes the cost of manufacturing inventories that are related to product sales, including overhead costs, amortization expense for intangible assets, and third-party royalties payable on net product sales. In addition, shipping and handling costs for product shipments are recorded in cost of sales as incurred. Cost of sales may also include costs related to

excess or obsolete inventory adjustment charges, abnormal costs, unabsorbed manufacturing and overhead costs and manufacturing variances. For the year ended December 31, 2022, cost of sales primarily consisted of amortization expense for intangible assets, shipping and handling costs, and third-party royalty costs. Substantially all of the manufacturing costs of VONJO product sold during the current period were previously expensed as research and development expenses.

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.

Advertising

Advertising costs are expensed as incurred. Advertising expenses, recorded in *Selling, general and administrative* expenses, were $14.8 million for the year ended December 31, 2022. We had no comparable advertising expenses for the year ended December 31, 2021.

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. We apply estimated forfeiture rates at the time of grant and make revisions, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Income Taxes

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. Future realization of deferred tax assets is dependent upon a number of factors, including the existence of sufficient taxable income based on future earnings, the timing and amount of which is uncertain. The assessment regarding whether a valuation allowance is required considers the evaluation of both positive and negative evidence when concluding whether it is more likely than not that deferred tax assets are realizable. Based upon a review of all available evidence, we determined that it is not more likely than not that the U.S. deferred tax assets will be realized, and therefore the deferred tax assets have been fully offset by a valuation allowance.

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 stock options, warrants and restricted stock, using the treasury stock method, as their inclusion would have an anti-dilutive effect.

Recently Issued Accounting Standards

In March 2020, the Financial Accounting Standards Board, or the FASB, issued accounting guidance to provide temporary optional expedients to ease the potential burden in accounting for reference rate reform. The guidance includes an optional expedient that simplifies accounting for contract modifications to loans receivable and debt, by prospectively adjusting the effective interest rate. The accounting guidance is effective as of January 7, 2021 through December 31, 2022. As discussed

in “Note 8. Debt Financing Arrangements”, in August 2021, we entered into the Credit Agreement, which has an interest rate referenced to the London Interbank Offered Rate, or LIBOR. We plan to elect the optional expedient for our credit facility by prospectively adjusting the effective interest rate if the cessation of the LIBOR reference rate occurs. We do not expect the adoption of this guidance to have a material impact on our 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 financial statements.

2. Inventories

Inventories consisted of the following as of December 31, 2022 and 2021 (in thousands):

	2022	2021
Raw materials	$ 156	$ —
Work-in-process	496	—
Finished goods	81	—
Total inventories	$ 733	$ —

3. Property and Equipment

Property and equipment consisted of the following as of December 31, 2022 and 2021 (in thousands):

	2022	2021
Furniture and office equipment	$ 597	$ 597
Leasehold improvements	1,755	5,140
	2,352	5,737
Less: accumulated depreciation and amortization	(2,352)	(5,561)
Property and equipment, net	$ —	$ 176

Depreciation expense was $0.2 million and $0.5 million for the years ended December 31, 2022 and 2021, respectively.

4. Other Assets

Other assets consisted of the following as of December 31, 2022 and 2021 (in thousands):

	2022	2021
Right-of-use assets	$ 2,078	$ 3,109
Prepaid manufacturing	855	—
Clinical trial deposits	370	770
Total other assets	$ 3,303	$ 3,879

5. Accrued Expenses

Accrued expenses consisted of the following as of December 31, 2022 and 2021 (in thousands):

	2022	2021
Milestone payment due to Takeda Pharmaceutical Company Limited (1)	$ 10,291	$ —
Employee compensation and related expenses	7,207	4,783
Clinical trial expenses	5,256	4,053
Royalty expenses	2,446	—
Commercial expenses	2,424	3,075
Accrued rebates	1,289	—
Other	489	809
Total accrued expenses	$ 29,402	$ 12,720

(1) See “Note 10. Collaboration, Licensing and Milestone Agreements - *Baxalta*” for details.

6. Other Current Liabilities

Other current liabilities consisted of the following as of December 31, 2022 and 2021 (in thousands):

	2022	2021
Operating lease liabilities - current	$ 781	$ 1,160
End-of-facility lender fee (1)	1,000	1,000
Other current obligations	—	500
Total other current liabilities	$ 1,781	$ 2,660

(1) The end-of-facility lender fee as of December 31, 2022 and 2021 represents an amount payable to DRI, upon repayment of our secured term loan under the Credit Agreement with DRI. See “Note 8. Debt Financing Arrangements” for additional information.

7. 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 and expiring April 2022. In December 2021, we entered into an amendment to extend the term of the existing lease by 3 years to April 2025 and to reduce the leased office space, beginning May 2022, to approximately 23,000 square feet. We were also provided with certain tenant improvement costs of up to $50,000. The amendment provides for one five-year option to extend the term of the lease at a market rate at the time of such extension. The option to extend the lease was not considered in the remeasurement of lease liability and the adjustment of the right-of-use asset as we did not consider it reasonably certain that we would exercise such option. The amended lease is classified as an operating lease. As a result of this amendment, the lease liability balance as well as the right-of-use asset balance increased by $2.4 million as of the effective date. We also lease parking space under the agreement. We elected not to separate a non-lease component from a lease component for the parking lease. In addition, the agreement to sublease approximately 44,000 square feet of our office space was terminated 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 statements of operations, were as follows (in thousands):

	Year Ended December 31,	
	2022	2021
Operating lease expense	$ 1,208	$ 1,586
Variable lease expense	50	183
Sublease income	(415)	(1,254)
Total lease expense, net	$ 843	$ 515

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

	December 31, 2022
Right-of-use assets (included in *Other Assets*)	$ 2,078
Operating lease liabilities, current (included in *Other current liabilities*)	$ 781
Operating lease liabilities, non-current (included in *Other liabilities, less current portion*)	1,234
Total lease liabilities	$ 2,015

As of December 31, 2022, the maturities of operating lease liabilities were as follows (in thousands):

	Operating Lease Payments
2023	$ 975
2024	1,002
2025	337
Thereafter	—
Total payments	2,314
Less imputed interest	(299)
Total lease liabilities	$ 2,015

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

	December 31, 2022
Supplemental cash flow information	
Cash paid for amounts included in the measurement of lease liabilities	$ 1,450
Weighted-average remaining lease term of operating leases (years)	2.33
Weighted-average discount rate of operating leases	11.6 %

8. Debt Financing Arrangements

Drug Royalty III LP 2

Credit Agreement

In August 2021, we entered into a Credit Agreement with DRI, as lender and as administrative agent for the lenders, and received a term loan in the principal amount of $50.0 million under the Credit Agreement, or the Term Loan, with a maturity date of August 25, 2026. The Credit Agreement provides for quarterly interest-only payments until the maturity date, with the unpaid principal amount of the Term Loan due and payable on the maturity date. The Term Loan bears interest at a rate equal to the greater of (i) 1.75% per annum and (ii) the three-month LIBOR rate, plus 8.25% (or, upon the occurrence of and during the continuance of any event of default, plus 10.25% per annum). Our obligations under the Credit Agreement are secured by a first

priority security interest in substantially all of our assets, subject to certain exceptions. Upon prepayment or repayment, including at maturity, of all or any portion of the Term Loan, we are obligated to pay an exit fee in an amount equal to 2.00% of the principal amount of the Term Loan prepaid or repaid, which is recorded in *Other current liabilities*. See "Note 6. Other Current Liabilities" for additional information.

The Credit Agreement contains representations and warranties and affirmative and negative covenants customary for financings of this nature, as well as customary events of default. The Credit Agreement also contains a minimum liquidity covenant requiring us to maintain at least $10.0 million of unrestricted cash and cash equivalents, subject to certain exceptions. A failure to comply with the covenants in the Credit Agreement could permit the lenders under the Credit Agreement to declare the outstanding principal as well as accrued interest and fees to be immediately due and payable.

In addition, the Credit Agreement contains an affirmative covenant requiring us to deliver to DRI, within 120 days after the end of each fiscal year, audited financial statements of the Company accompanied by an unqualified report and opinion of an independent certified public accountant, which report and opinion shall not be subject to any "going concern" or like qualification or exception. We have obtained a permanent waiver of breach of such covenant from DRI.

As of December 31, 2022, we had an outstanding Term Loan principal balance of $50.0 million under the Credit Agreement. In connection with the Credit Agreement, we recorded debt discount and debt issuance costs of $1.5 million and $1.3 million, respectively, at issuance, of which $1.1 million and $1.0 million were unamortized as of December 31, 2022, respectively. The Credit Agreement contains certain settlement provisions which, if deemed probable, would result in the recognition of an embedded feature. However, we do not believe such provisions are probable at this time.

All amounts due under the Credit Agreement have been recorded in current liabilities on the balance sheet as of December 31, 2022 due to the considerations discussed in "Note 1. Description of Business and Summary of Significant Accounting Policies - Liquidity" and the assessment that the events of default clause, which includes a material adverse effect provision under the Credit Agreement, that is not within our control. We have not been notified by DRI that an event of default has been triggered as of the date of the filing of this Annual Report on Form 10-K.

As of December 31, 2022, the scheduled principal and interest payments (based on the interest rate of 13.06% as of December 31, 2022) as well as the back-end fee described above are as follows (in thousands):

	Principal	Interest	Back-end fee	Total
2023	$ —	$ 6,622	$ —	$ 6,
2024	—	6,640	—	6,
2025	—	6,622	—	6,
2026 and thereafter	50,000	4,282	1,000	55,
Total scheduled payments	$ 50,000	$ 24,166	$ 1,000	$ 75,
Less: debt discount and issuance costs	(2,057)			
Current portion of long-term debt	$ 47,943			

Royalty Financing Agreement

In August 2021, we entered into a Purchase and Sale Agreement with DRI, or the Royalty Financing Agreement, pursuant to which we sold to DRI the right to receive certain royalty payments from us for a purchase price of up to $85.0 million in cash. Under the Royalty Financing Agreement, DRI is entitled to receive tiered royalties based on net product sales of VONJO in the United States in an amount equal to: (i) 9.60% of annual net sales of VONJO in the United States for annual net sales up to $125 million, (ii) 4.50% of annual net sales of VONJO in the United States for annual net sales between $125 million and $175 million, and (iii) 0.50% of annual net sales of VONJO in the United States for annual net sales between $175 million and $400 million. No royalty payments are payable on annual net sales of VONJO in the United States over $400 million.

In March 2022, DRI funded the upfront purchase price of $60.0 million following FDA approval of VONJO in February 2022. In January 2023, we received $6.5 million in additional funding in connection with the achievement of a certain minimum VONJO sales threshold. DRI will be required to provide up to $18.5 million of remaining contractual funding if certain minimum VONJO sales thresholds are met by the end of the third quarter of 2023, or sooner.

We are required to make payments of amounts owed to DRI each calendar quarter from and after the first commercial sale of the applicable product in the United States until the patent expiry of the VONJO product compound.

Under the Royalty Financing Agreement, we agreed to specified affirmative and negative covenants, including without limitation covenants regarding periodic reporting of information by us to DRI, obligations to use commercially reasonable efforts to commercialize VONJO in the United States and restrictions on our ability to incur certain indebtedness, which restrictions are eliminated after the earliest of: (a) the date on which the trailing twelve months' of VONJO sales equals at least $200 million, (b) the date on which the Company's market capitalization (determined on an as-converted basis) is at least $1.0 billion for 20 consecutive trading days or (c) DRI receiving royalty payments in an amount equal to 100% of their purchase price. The Royalty Financing Agreement also contains representations and warranties, other covenants, indemnification obligations, settlement clauses and other provisions customary for transactions of this nature. Certain of these provisions would, if deemed probable, result in the recognition of an embedded feature. However, we do not believe such provisions are probable at this time. The Royalty Financing Agreement does not contain subjective acceleration clauses or provisions that would require repayment of funding.

We evaluated the terms of the Royalty Financing Agreement and concluded that the features of the funding from DRI are similar to those of a debt instrument. Accordingly, the funding from DRI is recorded as *Royalty financing obligation* on our balance sheet. The Royalty Financing Agreement does not contain subjective acceleration clauses or provisions that would require repayment of funding; as such, the funding received under the Royalty Financing Agreement is classified in long-term liabilities. In connection with the Royalty Financing Agreement, we recorded debt issuance costs of $1.8 million, of which $1.7 million remained unamortized as of December 31, 2022. The royalty financing obligation is amortized over the expected repayment term using an effective interest rate method that is calculated based on the rate that would enable the debt to be repaid in full over the patent life of the VONJO product compound, which was 11.8 years upon funding, with a remaining amortization period of 11.0 years as of December 31, 2022. The effective interest rate may vary during the term of the agreement depending on a number of factors, including the amount and timing of forecasted net product sales which affects the repayment timing and ultimate amount of repayment. As of December 31, 2022, the effective interest rate was 18.8%. We recognized non-cash interest expense of $8.0 million related to the royalty financing obligation for the year ended December 31, 2022. We will evaluate the effective interest rate quarterly based on our current revenue forecasts utilizing the prospective method.

The activities related to the royalty financing obligation for the year ended December 31, 2022 were as follows (in thousands):

Royalty financing obligation - initial funding	$	60,000
Less: debt issuance costs		(1,814)
Royalty financing obligation - beginning balance	$	58,186
Accretion of imputed interest on the royalty financing obligation balance		8,001
Amortization of debt issuance costs		126
Less: Royalty payments made to DRI		(3,155)
Less: Royalty payable to DRI (classified in accrued expenses)		(2,024)
Royalty financing obligation - ending balance	$	61,134

9. Equity Transactions

At-The-Market Equity Offering

In January 2021, we entered into an Open Market Sale Agreement℠ with Jefferies LLC, or the 2021 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. For the year ended December 31, 2022, we sold 9.4 million shares of our common stock for approximately $45.5 million, net of sales agent commission of $1.4 million, under the 2021 Sale Agreement. As of the second quarter of 2022, all $50.0 million of the aggregate sales capacity under the 2021 Sale Agreement was fully utilized.

In August 2022, we entered into a new Open Market Sale Agreement℠ with Jefferies, or the 2022 Sale Agreement, to sell shares of our common stock having aggregate sales proceeds of up to $100.0 million, from time to time, through an "at the market" equity offering program under which Jefferies acts as sales agent. The 2021 Sale Agreement was terminated when the sales agent placed the Maximum Program Amount (as defined therein). Under the 2022 Sale Agreement, we have the ability to 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 2022 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 2022 Sale Agreement at any time upon one trading day’s prior notice. We may also sell shares to Jefferies acting as principal for Jefferies’ own account. The compensation to Jefferies for sales of our common stock will be an amount equal to 3% of the gross proceeds of any shares of our common stock sold under the 2022 Sale Agreement. We have no obligation to sell any shares under the 2022 Sale Agreement, and may at any time suspend solicitation and offers under the 2022 Sale Agreement. For the year ended December 31, 2022, we sold 1.7 million shares of our common stock for approximately $9.7 million, net of sales agent commission of $0.3 million, under the 2022 Sale Agreement. As of December 31, 2022, the remaining facility under the 2022 Sale Agreement was $90.0 million.

Series O Preferred Stock

In February 2018, we issued 12,575 shares of our Series O Preferred Stock to BVF Partners L.P., or BVF, an existing stockholder of the Company, pursuant to the stock exchange agreement between BVF and the Company. Matthew D. Perry, a member of our Board, is the President of BVF and portfolio manager for the underlying funds managed by the firm. See Part II, Item 8, “Notes to Consolidated Financial Statements, Note 8. Equity Transactions” of our Annual Report on Form 10-K for the year ended December 31, 2018 for additional information. During the year ended December 31, 2022, all of the 12,575 shares of our Series O Preferred Stock were converted into 8.4 million shares of our common stock. As of December 31, 2022, BVF beneficially owned a total of 27.1% of our common stock and as-converted preferred stock outstanding, which includes 5.3% common stock and 21.8% as-converted preferred stock, respectively.

Series X Preferred Stock

In March 2020, we completed a rights offering whereby 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. See Part II, Item 8, “Notes to Consolidated Financial Statements, Note 8. Equity Transactions” of our Annual Report on Form 10-K for the year ended December 31, 2020 for additional information. During the year ended December 31, 2022, 747 shares of our Series X Preferred Stock were converted into 7.5 million shares of our common stock. There were 3,047 shares of our Series X Preferred Stock outstanding as of December 31, 2022.

Common Stock Authorized

In June 2021, the Company's certificate of incorporation was amended to increase the total number of authorized shares of common stock from 166.5 million to 266.5 million. There was no increase to the total number of authorized shares during 2022.

Common Stock Reserved

As of December 31, 2022, we had 266.5 million authorized shares of common stock, of which 130.7 million shares were issued and outstanding, and 53.2 million shares were available for future issuances. The remaining authorized shares were reserved as follows (in thousands):

Equity incentive plans	26,278
Option agreement with Adam R. Craig per Nasdaq Listing Rule 5635(c)(4)	1,120
New hire stock options granted per Nasdaq Listing Rule 5635(c)(4)	2,676
Employee stock purchase plan	831
At-the-market equity program	15,006
Convertible preferred stock	36,470
Common stock purchase warrants	169
Total common stock reserved	82,550

Warrants

A warrant to purchase up to 169,014 shares of our common stock with an exercise price of $2.84 per share, issued in connection with the Loan and Security Agreement with Silicon Valley Bank in 2017, was outstanding as of December 31, 2022. The warrant will expire in November 2027.

10. Collaboration, Licensing and Milestone Agreements

Baxalta

In November 2013, we entered into a Development, Commercialization and License Agreement, or the Pacritinib License Agreement, with Baxter International Inc., or Baxter, for the development and commercialization of pacritinib for use in oncology and potentially additional therapeutic areas. 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.

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. Upon FDA approval of VONJO on February 28, 2022, the $10.3 million milestone payment became payable to Takeda and is included within *Accrued expenses* as of December 31, 2022. The payment was originally due 60 days following FDA approval; however, the due date was subsequently amended such that the payment is now required to be made in full on or prior to March 15, 2023, subject to our timely payment of monthly interest on the outstanding amount due at an applicable interest rate specified in the amendment. Interest payments made on the amount owed were $0.5 million in aggregate as of December 31, 2022. Since the $10.3 million payment does not relate to our intellectual property and arose from a contingency in the Baxalta Termination Agreement that was resolved in the first quarter of 2022, it was recorded in *Other operating expenses* for the year ended December 31, 2022. Under the terms of the Baxalta Termination Agreement, we will have no further obligations to Takeda after settlement of this payment.

*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. S*BIO is also 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. Upon FDA approval of VONJO on February 28, 2022, a $25.0 million milestone payment became payable to S*BIO, which was recorded in *Intangible assets, net* due to the fact that this payment represents contingent consideration for the acquired pacritinib compound that became marketable and capable of generating cash flows from sales during the first quarter of 2022. The milestone payment was made to S*BIO during the second quarter of 2022. 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.

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. To date, we have earned $60.0 million in such potential milestone payments as a result of Teva having achieved certain milestones. We did not earn any milestone revenues during the years ended December 31, 2022 and 2021. The achievement of the remaining milestones is uncertain at this time.

11. Equity-Based Compensation

Substantially all of equity-based compensation expense recognized during the years ended December 31, 2022 and 2021 was related to stock options. The following table summarizes equity-based compensation expense for the years ended December 31, 2022 and 2021, which was allocated as follows (in thousands):

	2022	2021
Research and development	$ 1,291	$ 758
Selling, general and administrative	8,739	3,985
Total equity-based compensation expense	$ 10,030	$ 4,743

Equity-based compensation expense had an effect on net loss for the years ended December 31, 2022 and 2021, respectively, but had no effect on cash flows from operating activities for the periods presented.

As of December 31, 2022, unrecognized compensation cost related to unvested stock options amounted to $13.0 million, which will be recognized over the remaining weighted-average requisite service period of 2.26 years.

For the years ended December 31, 2022 and 2021, 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 2017 Plan was amended and restated in June 2022 to increase the maximum number of shares of the Company’s common stock authorized for issuance by 8.0 million shares.

The Company's 2007 Employee Stock Purchase Plan, as amended and restated in August 2009, September 2015, June 2021 and June 2022, or the Purchase Plan, was amended in June 2022 to increase the maximum number of shares of the Company’s common stock authorized for issuance by 0.5 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, 2022, 32.5 million shares were authorized for issuance under equity incentive plans, of which 8.5 million shares of common stock were available for future grants under the 2017 Plan.

Inducement Grants Outside of Stock Plans

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 vested in six equal semi-annual installments over the three-year period beginning March 20, 2017. 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 outside of stock plans in accordance with Nasdaq Listing Rule 5635(c)(4). All the options were fully vested and remained outstanding as of December 31, 2022.

Inducement stock options are granted to our newly-hired employees as an inducement award to each employee entering into employment with the Company. Inducement stock options are granted outside of stock plans in accordance with Nasdaq Listing Rule 5635(c)(4). The stock options have a maximum term of ten years and vest in equal annual installments over a four-year period, subject to the employee's continued employment through the applicable vesting dates. As of December 31, 2022, 2.7 million inducement stock options with a weighted average exercise price of $3.25 were issued and outstanding.

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,	
	2022	2021
Risk-free interest rate	2.0 %	0.8 %
Expected dividend yield	None	None
Expected life (in years)	5.5	5.2
Volatility	84 %	101 %

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 during the year ended December 31, 2022:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (In Thousands)
Outstanding at December 31, 2021 (11,776,000 exercisable)	20,691,000	$ 2.31		
Granted	5,037,000	$ 4.52		
Exercised	(3,600,000)	$ 1.48		$ 15,900
Forfeited	(530,000)	$ 3.40		
Cancelled and expired	(81,000)	$ 2.66		
Outstanding at December 31, 2022 (13,417,000 exercisable)	21,517,000	$ 2.94	7.0	$ 67,705
Vested or expected to vest at December 31, 2022	20,558,000	$ 2.90	6.9	$ 65,584
Exercisable at December 31, 2022	13,417,000	$ 2.51	5.9	$ 48,549

The weighted average exercise price of options exercisable at December 31, 2022 and 2021 was $2.51 and $2.39, respectively. The weighted average grant-date fair value of options granted during 2022 and 2021 was $3.14 and $2.07 per option, respectively.

Employee Stock Purchase Plan

Under the Purchase Plan, eligible employees may purchase a limited number of shares of our common stock at 85% of the lower of the subscription date fair market value and the purchase date fair market value. There are two six-month offerings per year. During the year ended December 31, 2022, we issued 0.5 million shares of our common stock to employees under the Purchase Plan and recognized equity-based compensation expense of $0.7 million. The amount of equity-based compensation expense recognized during the year ended December 31, 2021 was nominal. There are 1.5 million shares of common stock authorized under the Purchase Plan and 0.8 million shares are reserved for future purchases as of December 31, 2022.

12. 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 $1.3 million and $0.3 million related to discretionary matching contributions for the years ended December 31, 2022 and 2021, respectively.

13. 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,	
	2022	2021
Net loss	$ (92,992)	$ (97,908)
Basic and diluted:		
Weighted average common shares outstanding used in calculation of basic and diluted net loss per common share	114,694	90,117
Net loss per common share: Basic and diluted	$ (0.81)	$ (1.09)

Common shares underlying equity awards, warrants and convertible preferred stock aggregating 68.8 million shares and 74.5 million shares prior to the application of the treasury stock method for the years ended December 31, 2022 and 2021, respectively, have been excluded from the calculation of diluted net loss per share because they were anti-dilutive.

14. Commitments and Contingencies

Commitments

See “Note 7. Leases” and “Note 8. Debt Financing Arrangements” for scheduled lease and debt payments. In addition, certain of our licensing agreements obligate us to make payments upon achievement of milestones and pay a royalty on net sales of products utilizing licensed compounds. See “Note 10. Collaboration, Licensing and Milestone Agreements” for further details. Purchase commitments relating to clinical trial contracts, manufacturing supply, insurance and other obligations also arise in the ordinary course of business. We anticipate the timing of payments under these contracts to range from less than one year to more than three years.

Legal Proceedings

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 were €0.7 million, €2.8 million and €0.9 million, respectively. We believed that the services invoiced were non-VAT taxable consultancy services and that the VAT returns were correct as originally filed. We appealed all the assessments and defended ourselves against the assessments both on procedural grounds and on the merits of the cases. The following is a summary of the outcomes of the legal proceedings surrounding each respective VAT year return at issue:

2003 VAT Assessment. In April 2022, the Italian Supreme Court rejected our arguments both on procedural grounds and on the merits of the case and ruled in favor of the ITA. Accordingly, we accrued a liability of €0.7 million for the 2003 VAT assessment, which was recorded in *Other operating expenses*. During the third quarter of 2022, the 2003 VAT liability was reduced to approximately €0.3 million or approximately $0.3 million converted using the currency exchange rate at the end of the third quarter of 2022, based on the application of a €0.4 million deposit made to the ITA in 2014, which was previously written off from the balance sheet. The 2003 VAT liability was settled in the fourth quarter of 2022.

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 March 2022, the Italian Supreme Court issued decision No. 10355/22 which (i) rejected the appeal of the ITA, (ii) confirmed the decision of the Regional Tax Court which ruled fully in our favor, and (iii) due to a change of law, compensated the legal expenses incurred by the parties for the appeals. We have applied for refunds based on the guidance from the ITA.

As of the filing date of this Annual Report on Form 10-K, there have been no changes to the status of our applications for refunds related to the 2005, 2006 and 2007 VAT returns for which the Italian Supreme Court ruled in our favor.

15. Income Taxes

We file income tax returns in the United States and Germany. We are not currently under examination by an income tax authority, nor have we been notified that an examination is contemplated.

The Inflation Reduction Act of 2022, or the Act, was signed into U.S. law on August 16, 2022. The Act includes various tax provisions, including an excise tax on stock repurchases, expanded tax credits for clean energy incentives, and a corporate alternative minimum tax that generally applies to U.S. corporations with average adjusted financial statement income over a three year period in excess of $1 billion. We do not expect the Act to materially impact our financial statements.

The following table presents U.S. and foreign components of loss before income taxes (in thousands):

	Year ended December 31,	
	2022	2021
United States	$ (92,992)	$ (97,908)
Foreign	—	—
Net loss before income taxes	$ (92,992)	$ (97,908)

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

	2022	2021
Federal income tax rate	21 %	21 %
State income tax rate	11	—
Research and development tax credits	1	5
Equity-based compensation	1	(1)
Valuation allowance	(47)	(24)
Adjustment of tax attributes	13	—
Unrecognized tax benefits	—	(1)
Net effective tax rate	— %	— %

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

	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 55,984	$ 40,061
Capitalized research and development	38,830	35,910
Royalty financing obligation	14,989	—
Research and development tax credit carryforwards	13,942	5,386
Intangible assets	6,421	7,026
Equity-based compensation	4,827	3,337
Accrued liabilities and allowances	1,206	—
Lease liability	494	670
Depreciation and amortization	316	785
Other deferred tax assets	3	231
Total deferred tax assets	137,012	93,406
Less: valuation allowance	(136,051)	(92,395)
	961	1,011
Deferred tax liabilities:		
Right-of-use asset	(509)	(656)
Other deferred tax liabilities	(452)	(355)
Total deferred tax liabilities	(961)	(1,011)
Net deferred tax assets	$ —	$ —

As of December 31, 2022 and 2021, we had U.S. federal net operating loss carryforwards, or the NOL, of approximately $242.8 million and $182.7 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 $209.8 million with an indefinite life as of December 31, 2022. We have state net operating loss carryforwards of approximately $43.2 million and $15.0 million as of December 31, 2022 and 2021, respectively. We also had U.S. federal tax credits of $16.8 million and $5.4 million as of December 31, 2022 and 2021, respectively, which may be used to offset future tax liabilities. The NOL and tax credit carryforwards 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.

The Tax Cuts and Jobs Act contained a provision which requires the capitalization of Section 174 costs incurred in years beginning on or after Jan. 1, 2022. Section 174 costs are expenditures which represent research and development costs that are incident to the development or improvement of a product, process, formula, invention, computer software, or technique. This provision changes the treatment of Section 174 costs such that the expenditures are no longer allowed as an immediate deduction but rather must be capitalized and amortized. We have included the impact of this provision, which results in a deferred tax asset of approximately $7.3 million as of December 31, 2022.

We maintain a full valuation allowance on our net deferred tax assets. The assessment regarding whether a valuation allowance is required considers both positive and negative evidence when determining whether it is more likely than not that deferred tax assets are recoverable. In making this assessment, significant weight is given to evidence that can be objectively verified. In our valuation, we considered our cumulative loss in recent years and forecasted losses in the near term as significant negative evidence. Based upon a review of the four sources of income identified within ASC 740, we determined that the negative evidence outweighed the positive evidence and that a full valuation allowance on our net deferred tax assets will be maintained. We will continue to assess the realizability of our deferred tax assets going forward and will adjust the valuation allowance as needed. Our valuation allowance increased by $43.7 million during the year ended December 31, 2022 primarily due to the increase in net operating loss carryforwards, tax credit carryforwards and debt basis difference on royalty financing obligation.

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 German income taxes with varying statutes of limitations. Tax years from 2003 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):

	2022	2021
Balance at beginning of period	$ 1,209	$ 390
Gross increases to tax positions in prior periods	1,353	—
Gross decreases to tax positions in current periods	—	—
Gross increases to tax positions in current periods	261	819
Balance at end of period	$ 2,823	$ 1,209

As of December 31, 2022, the total amount of unrecognized tax benefits was $2.8 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, 2022.

We have not recorded a liability for U.S. income taxes and foreign withholding taxes on the undistributed earnings of foreign subsidiaries as of December 31, 2022 as we intend to permanently reinvest future such earnings outside the United States. The amount of the unrecognized deferred tax liability, if incurred, is expected to be immaterial.

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 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 2022 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, 2022 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 Control

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.

Item 9C. Disclosure Regarding Foreign Jurisdictions That Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item 10 of Form 10-K will be included in our 2023 Proxy Statement to be filed with the SEC in connection with the solicitation of proxies for our 2023 Annual Meeting of Stockholders and is incorporated herein by reference. The 2023 Proxy Statement will be filed with the SEC within 120 days after the end of the fiscal year to which this report relates.

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, if any, 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 this Item 11 of Form 10-K will be included in our 2023 Proxy Statement and is incorporated herein by reference.

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

The information required by this Item 12 of Form 10-K will be included in our 2023 Proxy Statement and is incorporated herein by reference.

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

The information required by this Item 13 of Form 10-K will be included in our 2023 Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

The information required by this Item 14 of Form 10-K will be included in our 2023 Proxy Statement and is incorporated herein by reference.

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 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	Amended and Restated Certificate of Incorporation of CTI BioPharma Corp.	S-8	333-257174	4.1	June 17, 2021
3.2	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	Description of Securities.				Filed herewith.
10.1*	CTI BioPharma Corp. Amended and Restated 2007 Employee Stock Purchase Plan	8-K	000-28386	10.2	June 3, 2022
10.2*	2007 Equity Incentive Plan, as amended and restated.	10-Q	001-12465	10.1	October 31, 2014
10.3*	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
10.4*	Global Form of 2007 Equity Incentive Plan Stock Option Agreement.	10-K	001-12465	10.16	March 12, 2015
10.5*	CTI BioPharma Corp. 2015 Equity Incentive Plan, as amended.	8-K	001-12465	10.1	April 29, 2016
10.6*	Global Form of 2015 Equity Incentive Plan Stock Option Agreement.	10-Q	001-12465	10.4	November 5, 2015
10.7*	CTI BioPharma Corp. Amended and Restated 2017 Equity Incentive Plan.	8-K	000-28386	10.1	June 3, 2022
10.8*	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
10.9*	CTI BioPharma Corp. Stock Option Agreement (Inducement Form)	10-K	000-28386	10.29	March 17, 2021
10.10*	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
10.11*	Form of Indemnity Agreement for CTI BioPharma Corp.'s Executive Officers and Directors.	8-K	000-28386	10.1	January 24, 2018
10.12*	CTI BioPharma Corp. Executive Incentive Compensation Plan.	10-K	000-28386	10.45	March 13, 2019
10.13*	CTI BioPharma Corp. Director Compensation Policy.	10-Q	000-28386	10.46	May 6, 2021
10.14*	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

10.15*	Employment Agreement, dated February 24, 2017, by and between CTI BioPharma Corp. and Adam Craig.	8-K	000-28386	10.1	February 27, 2017
10.16*	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
10.17*	Offer Letter, dated August 1, 2017, by and between CTI BioPharma Corp. and David Kirske.	10-Q	000-28386	10.3	August 4, 2017
10.18*	Severance Agreement, dated September 25, 2017, by and between CTI BioPharma Corp. and David Kirske.	8-K	000-28386	10.1	September 26, 2017
10.19*	Offer Letter, by and between CTI BioPharma Corp. and James K. Fong, dated as of March 1, 2022	8-K	000-28386	10.1	March 4, 2022
10.20*	Severance Agreement, by and between CTI BioPharma Corp. and James K. Fong, dated as of January 6, 2015	8-K	000-28386	10.2	March 4, 2022
10.21*	Amendment to Severance Agreement, by and between CTI BioPharma Corp. and James K. Fong, dated as of March 1, 2022	8-K	000-28386	10.3	March 4, 2022
10.22	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
10.23	Investment Agreement, dated as of January 31, 2020, by and among CTI BioPharma Corp., 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
10.24	Open Market Sale Agreement℠, dated August 16, 2022, between CTI BioPharma Corp. and Jefferies LLC.	S-3	333-266926	1.2	August 17, 2022
10.25††	Purchase and Sale Agreement, dated August 25, 2021, by and between CTI BioPharma Corp. and Drug Royalty III LP 2.	10-Q	000-28386	10.1	November 12, 2021
10.26††	Credit Agreement, dated August 25, 2021, by and between CTI BioPharma Corp. and Drug Royalty III LP 2.	10-Q	000-28386	10.2	November 12, 2021
10.27	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
10.28†	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
10.29	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
10.30	Amendment No 1. to the Asset Return and Termination Agreement, by and between Baxalta Incorporated and CTI BioPharma Corp., dated as of May 31, 2022	10-Q	000-28386	10.3	August 8, 2022
10.31	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
10.32	Second Amendment to Office Lease, dated December 6, 2021, by and between CTI BioPharma Corp. and Selig Holdings Company, LLC.	10-K	000-28386	10.47	March 31, 2022
23.1	Consent of Independent Registered Public Accounting Firm.				Filed herewith.

31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	Filed herewith.
32	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	Furnished herewith.
101	The following financial statements from the Company's Annual Report on Form 10-K for the year ended December 31, 2022, formatted in Inline XBRL: (i) Balance Sheets, (ii) Statements of Operations, (iii) Statements of Comprehensive Loss, (iv) Statements of Stockholders' Equity (Deficit), (v) Statements of Cash Flows, and (vi) Notes to 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.

†† Portions of this Exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv).

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 6, 2023

CTI BioPharma Corp.

By: /s/ Adam R. Craig
Adam R. Craig, M.D., Ph.D.
President and Chief Executive Officer

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 6, 2023
/s/ Adam R. Craig **Adam R. Craig, M.D., Ph.D.**	President and Chief Executive Officer and Director (Principal Executive Officer)	March 6, 2023
/s/ David H. Kirske **David H. Kirske**	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 6, 2023
/s/ Michael A. Metzger **Michael A. Metzger**	Director	March 6, 2023
/s/ Diane Parks **Diane Parks**	Director	March 6, 2023
/s/ David Parkinson **David Parkinson, M.D.**	Director	March 6, 2023
/s/ Matthew D. Perry **Matthew D. Perry**	Director	March 6, 2023
/s/ Reed V. Tuckson **Reed V. Tuckson, M.D.**	Director	March 6, 2023

Exhibit 4.4

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 amended and restated certificate of incorporation ("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 266,500,000 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 4,500 are designated as the Series X Convertible Preferred Stock, and 600 are designated as the Series X^1 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 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. 333-266926, 333-251161, 333-200453, 333-192749, 333-182330, 333-163479, 333-152171, 333-149981, 333-149980, 333-134126, and 333-108926 of CTI BioPharma Corp., and

(2) Form S-8 Nos. 333-265655, 333-257174, 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, 333-146624 and 333-257174 pertaining to equity and option plans of CTI BioPharma Corp.

of our report dated March 6, 2023, with respect to the financial statements of CTI BioPharma Corp. included in this Annual Report (Form 10-K) of CTI BioPharma Corp. for the year ended December 31, 2022.

/s/ Ernst & Young LLP

Seattle, Washington
March 6, 2023

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 6, 2023

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 6, 2023

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, 2022 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 6, 2023

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, 2022 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 6, 2023

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