UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington D.C., 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2019

Commission File No. 001-34600

TENAX THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**26-2593535**
(State or other jurisdiction of Incorporation or organization)	**(I.R.S. Employer Identification No.)**

ONE Copley Parkway, Suite 490, Morrisville, NC 27560
(Address of Principal Executive Offices) (Zip Code)

Registrant's Telephone Number and area code: (919) 855-2100

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, $0.0001 par value per share	TENX	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 Section 15(d) of the Act. Yes ☐ No ☒

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

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

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

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold as of June 30, 2019, the last business day of the registrant's most recently completed second fiscal quarter: $9,167,013.

The number of shares outstanding of the registrant's class of $0.0001 par value common stock as of March 25, 2020 was 7,608,243.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the registrant's proxy statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A in connection with the registrant's 2020 Annual Meeting of Stockholders, which will be filed subsequent to the date hereof, are incorporated by reference into Part III of this Form 10-K. Such proxy statement will be filed with the Securities and Exchange Commission not later than 120 days following the end of the registrant's fiscal year ended December 31, 2019.

TABLE OF CONTENTS

PART I

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safe harbor" created by those sections. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to them. In some cases, you can identify forward-looking statements by terminology such as "may", "will", "should", "expects", "plans", "anticipates", "believes", "estimates", "predicts", "potential" or "continue" or the negative of such terms or other comparable terminology. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including, but not limited to, progress in our product development activities, obtaining financing for operations, development of new technologies and other competitive pressures, legal and regulatory initiatives affecting our products, conditions in the capital markets, the risks discussed in Item 1A – "Risk Factors," and the risks discussed elsewhere in this report that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activities, performance or achievements expressed or implied by such forward-looking statements.

Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of such statements. We are under no duty to update any of the forward-looking statements after the date of filing of this report or to conform such statements to actual results, except as may be required by law.

All references in this Annual Report to "Tenax Therapeutics", "we", "our" and "us" means Tenax Therapeutics, Inc.

ITEM 1—BUSINESS

Tenax Therapeutics was originally formed as a New Jersey corporation in 1967 under the name Rudmer, David & Associates, Inc., and subsequently changed its name to Synthetic Blood International, Inc. Effective June 30, 2008, we changed the domiciliary state of the corporation to Delaware and changed the company name to Oxygen Biotherapeutics, Inc. On September 19, 2014, we changed the company name to Tenax Therapeutics, Inc.

We are a specialty pharmaceutical company focused on identifying, developing and commercializing products that address cardiovascular and pulmonary diseases of high unmet medical need. On November 13, 2013, through our wholly owned subsidiary, Life Newco, Inc., or Life Newco, we acquired a license granting Life Newco an exclusive, sublicenseable right to develop and commercialize pharmaceutical products containing levosimendan, 2.5 mg/ml concentrate for solution for infusion / 5ml vial in the United States and Canada.

Business Strategy

Our principal business objective is to identify, develop, and commercialize novel therapeutic products for disease indications that represent significant areas of clinical need and commercial opportunity. The key elements of our business strategy are outlined below.

Efficiently conduct clinical development to establish clinical proof of concept with our current product candidate. Levosimendan represents novel therapeutic modalities for the treatment of pulmonary hypertension and other cardiovascular and pulmonary diseases of high unmet medical need. We are conducting clinical development with the intent to establish proof of concept in several important disease areas where these therapeutics would be expected to have benefit. Our focus is on conducting well-designed studies to establish a robust foundation for subsequent development, partnership and expansion into complementary areas.

Efficiently explore new high potential therapeutic applications, leveraging third-party research collaborations and our results from related areas. Our product candidate has shown promise in multiple disease areas. We are committed to exploring potential clinical indications where our therapies may achieve best-in-class profile, and where we can address significant unmet medical needs. In order to achieve this goal, we have established collaborative research relationships with investigators from research and clinical institutions and our strategic partners. These collaborative relationships have enabled us to cost effectively explore where our product candidates may have therapeutic relevance, and how it may be utilized to advance treatment over current clinical care. Additionally, we believe we will be able to leverage clinical safety data and preclinical results from some programs to support accelerated clinical development efforts in other areas, saving substantial development time and resources compared to traditional drug development.

Continue to expand our intellectual property portfolio. Our intellectual property is important to our business and we take significant steps to protect its value. We have ongoing research and development efforts, both through internal activities and through collaborative research activities with others, which aim to develop new intellectual property and enable us to file patent applications that cover new applications of our existing technologies or product candidates.

Enter into licensing or product co-development arrangements. In addition to our internal development efforts, an important part of our product development strategy is to work with collaborators and partners to accelerate product development, reduce our development costs, and broaden our commercialization capabilities. We believe this strategy will help us to develop a portfolio of high-quality product development opportunities, enhance our clinical development and commercialization capabilities, and increase our ability to generate value from our proprietary technologies.

Our Current Programs

Levosimendan Background

Levosimendan was discovered and developed by Orion Corporation, a Finnish company, or Orion. Levosimendan is a *calcium sensitizer/K-ATP activator* developed for intravenous use in hospitalized patients with acutely decompensated heart failure. It is currently approved in over 60 countries for this indication and not available in the United States or Canada. It is estimated that to date over 1.5 million patients have been treated worldwide with levosimendan**.**

Levosimendan is a novel, first in class *calcium sensitizer/K-ATP activator*. The therapeutic effects of levosimendan are mediated through:

- Increased cardiac contractility by calcium sensitization of troponin C, resulting in a positive inotropic effect which is not associated with substantial increases in oxygen demand.
- Opening of potassium channels in the vasculature smooth muscle, resulting in a vasodilatory effect on all vascular beds.
- Opening of mitochondrial potassium channels in cardiomyocytes, resulting in a cardioprotective effect.

This triple mechanism of action helps to preserve heart function during cardiac surgery. Several studies have demonstrated that levosimendan protects the heart and improves tissue perfusion while minimizing tissue damage during cardiac surgery.

In 2013, we acquired certain assets of Phyxius Pharma, Inc., or Phyxius, including its North American rights to develop and commercialize levosimendan for any indication in the United States and Canada. In the countries where levosimendan is marketed, levosimendan is indicated for the short-term treatment of acutely decompensated severe chronic heart failure in situations where conventional therapy is not sufficient, and in cases where inotropic support is considered appropriate. In acute decompensated heart failure patients, levosimendan has been shown to significantly improve patients' symptoms as well as acute hemodynamic measurements such as increased cardiac output, reduced preload and reduced afterload.

The European Society of Cardiology, or the ESC, recommends levosimendan as a preferable agent over dobutamine to reverse the effect of beta blockade if it is thought to be contributing to hypotension. The ESC guidelines also state that levosimendan is not appropriate for patients with systolic blood pressure less than 85mmHg or in patients in cardiogenic shock unless it is used in combination with other inotropes or vasopressors. Other unique properties of levosimendan include sustained efficacy through the formation of a long acting metabolite, lack of impairment of diastolic function, and evidence of better compatibility with beta blockers than dobutamine.

Levosimendan Development for Pulmonary Hypertension Patients

We are currently conducting a Phase 2 clinical trial of levosimendan in North America for the treatment of patients with pulmonary hypertension associated with heart failure with preserved ejection fraction, or PH-HFpEF. PH-HFpEF is defined hemodynamically by a pulmonary artery pressure, or mPAP, ≥25 mmHg, a pulmonary capillary wedge pressure, or PCWP, >15 mmHg, and a diastolic pressure gradient, or diastolic PAP – PCWP, >7mmHg. Pulmonary hypertension in these patients initially develops from a passive backward transmission of elevated filling pressures from left-sided heart failure. These mechanical components of pulmonary venous congestion may trigger pulmonary vasoconstriction, decreased nitric oxide availability, increased endothelin expression, desensitization to natriuretic peptide induced vasodilation, and vascular remodeling. Finally, these changes often lead to advanced pulmonary vascular disease, increased right ventricle, or RV, afterload, and RV failure.

PH-HFpEF is a common form of pulmonary hypertension with an estimated US prevalence exceeding 1.5 million patients. Currently, no pharmacologic therapies are approved for treatment of PH-HFpEF. Despite the fact that many therapies have been studied in PH-HFpEF patients, including therapies approved to treat pulmonary arterial hypertension patients, no therapies have been shown to be effective in treating PH-HFpEF patients.

Published pre-clinical and clinical studies indicate that levosimendan may provide important benefits to patients with pulmonary hypertension. Data from these published trials indicate that levosimendan may reduce pulmonary vascular resistance and improve important cardiovascular hemodynamics such as reduced pulmonary capillary wedge pressure in patients with pulmonary hypertension. In addition, several published studies provide evidence that levosimendan may improve right ventricular dysfunction which is a common comorbidity in patients with pulmonary hypertension. While none of these studies have focused specifically on PH-HFpEF patients, the general hemodynamic improvements in these published studies of various types of pulmonary hypertension provide an indication that levosimendan may be beneficial in PH-HFpEF patients.

In March 2018, we met with the United States Food and Drug Administration, or FDA, to discuss development of levosimendan in PH-HFpEF patients. The FDA agreed with our planned Phase 2 design, patient entry criteria, and endpoints. It was agreed the study could be conducted under the existing investigational new drug application with no additional nonclinical studies required to support full development. The FDA recognized there were no approved drug therapies to treat PH-HFpEF patients and acknowledged this provided an opportunity for a limited Phase 3 clinical program. This topic will be discussed further at the End-of-Phase 2 Meeting following completion of the Phase 2 study in PH-HFpEF patients, which is known as the HELP Study – **H**emodynamic **E**valuation of **L**evosimendan in **P**H-HFpEF. We initiated the first of our expected 10-12 HELP Study clinical sites in November 2018 and the first of 36 patients was enrolled in the HELP Study in March 2019. Enrollment in the HELP Study was completed in March 2020. The primary endpoint of the HELP Study is based on change in PCWP vs baseline compared to placebo. The HELP Study utilizes a double-blind randomized design following five weekly infusions of levosimendan. The primary endpoint data will be available once the HELP Study data is unblinded.

The HELP Study design is novel in several respects. To date, no other multi-center levosimendan study has evaluated levosimendan in heart failure patients with preserved ejection fraction (HFpEF) or pulmonary hypertension patients with heart failure and preserved ejection fraction (PH-HFpEF). Instead, all previous levosimendan heart failure studies have enrolled heart failure patients with reduced ejection fraction (HFrEF), which specifically excluded HFpEF patients. Also, the HELP Study utilizes a unique 24-hour weekly infusion regimen of 0.075- 0.1µm/kg/min. Finally, the HELP Study employs a unique home-based IV infusion administration via an ambulatory infusion pump. This home-based weekly IV administration is unlike all other chronic dosing studies of levosimendan that have typically employed a shorter duration and less frequent infusion regimen administered in a hospital setting. Despite the unique patient population, weekly dosing, and home-based administration, there have been no reported serious adverse events reported for the first 30 randomized patients.

Investigator reported open-label data from the HELP Study has provided encouraging preliminary signs of efficacy during the initial lead-in infusion phase of the trial. The open-label lead-in infusion phase is designed to identify responders prior to randomization. To date, 80-85% of patients have met the lead infusion responder criteria. Analysis of investigator reported data following the 24-hour open-label levosimendan lead-in infusion for the first 30 evaluable responders indicated the following mean changes in exercise hemodynamics: PCWP of –7.5mm Hg, exercise right atrial pressure of -5.0mm Hg, mean pulmonary arterial pressure (mPAP) of -5.1 mm Hg and an increase in cardiac output of 0.6 liter/min. All of these improvements in exercise hemodynamics were found to be statistically significant via paired t-test $P<0.01$.

We believe that the combination of the unique HELP Study patient population, innovative weekly 24-hour dosing, unique home-based site of administration, and novel findings of efficacy and safety in PH-HFpEF patients represent unique discoveries and significant intellectual property. These discoveries, among others from the HELP Study, form the basis for a U.S. patent application that we have filed.

Levosimendan Development for Cardiac Surgery Patients

Low cardiac output syndrome, or LCOS, is generally defined as a patient's inability to maintain a cardiac index >2.2 L/min/m2 and hence requiring use of inotropic agents and/or mechanical assist devices such as an intra-aortic balloon pump or a left ventricular assistance device. LCOS in the cardiac surgery setting is reported to occur in 5-10% of patients undergoing cardiac surgery and is associated with 10-15-fold higher mortality or severe sequelae as a result of poor organ perfusion.

Currently, no pharmacologic therapies are approved for management or prevention of post-cardiotomy LCOS. While conventional inotropes are used to manage cardiac hemodynamics in the peri-operative setting, none have been shown to improve outcomes.

Substantial published scientific research indicates that levosimendan may provide important benefits to cardiac surgery patients, including 35 published prospectively designed clinical trials and multiple published meta-analyses. Many of these publications indicate that levosimendan provides substantial mortality and or morbidity benefits to cardiac surgery patients, particularly those at risk of developing LCOS.

In 2014, we initiated a Phase 3 trial (LEVO-CTS) to investigate the safety and efficacy of pre-operative administration of levosimendan treatment to reduce the mortality and morbidity in cardiac surgery patients at risk for developing LCOS. The Phase 3 trial was conducted under an FDA approved Special Protocol Assessment, or SPA, and with FDA granted Fast Track status for the development of levosimendan to reduce mortality and morbidity in cardiac surgery patients at risk of LCOS. Pursuant to our license to levosimendan, we are required to use the "Simdax®" trademark to commercialize this product.

The LEVO-CTS trial design was guided by the published literature, including important dosing refinements and inclusion of patients with low preoperative ejection fraction. In addition, we relied heavily on the input of European clinicians who have significant personal clinical experience with the use of levosimendan in treating cardiac surgery patients.

Current data in cardiac surgery suggest that levosimendan is superior to traditional inotropes (dobutamine, phosphodiesterase [PDE]-inhibitors) as it achieves:

- sustained hemodynamic improvement;
- diminished myocardial injury;
- improved tissue perfusion;
- better outcomes and fewer hospital days;
- effects most favorable in patients with low left ventricular ejection fraction (LVEF) (< 40%); and
- opportunity to initiate therapy pre-operatively due to increased cardiac contractility without increasing intracellular calcium, without increasing oxygen consumption, or affecting cardiac rhythm and relaxation.

The Phase 3 trial was conducted in approximately 60 major cardiac surgery centers in North America. The trial enrolled patients undergoing coronary artery bypass grafts, or CABG, and/or mitral valve surgery, and CABG with aortic valve surgery who are at risk for developing LCOS. The trial was designed as a double blind, randomized, placebo-controlled study seeking to enroll 760 patients. During 2016, we made the decision to increase enrollment in the LEVO-CTS trial to 880 patients. These additional patients were necessary to ensure sufficient powering and were necessary due to:

- a small percentage of patients who were randomized but did not receive the study drug;
- a small percentage of patients who were missing one or more component measurements of the primary endpoint; and
- a slightly lower primary endpoint event rate than we originally projected.

Enrollment began in the third quarter of calendar year 2014 and was completed in December of 2016. On January 31, 2017, we announced top-line results from the Phase 3 LEVO-CTS trial. Levosimendan, given prophylactically prior to cardiac surgery to patients with reduced left ventricular function, had no effect on the co-primary outcomes. The study did not achieve statistically significant reductions in the dual endpoint of death or use of a mechanical assist device at 30 days, nor in the quad endpoint of death, myocardial infarction, need for dialysis, or use of a mechanical assist device at 30 days.

However, the study results demonstrated statistically significant reductions in two of three secondary endpoints including reduction in LCOS and a reduction in postoperative use of secondary inotropes. Additionally, levosimendan was found to be safe with no clinically significant increases in hypotension or cardiac arrhythmias and the clinical data showed a non-significant numerical reduction in 90-day mortality.

A post hoc analysis on patients in whom isolated CABG surgery was performed (66% of the patients) revealed that levosimendan improved 90-day survival significantly (p=0.0017). This was accompanied with a significant improvement in postoperative cardiac index, in the frequency of LCOS and in the need for further inotropic support. Accordingly, the reductions in the incidence of LCOS were associated with a substantial improvement in mortality. However, there was essentially no effect on any of these endpoints in those LEVO-CTS patients receiving valve surgeries.

In the second and third quarters of 2017 we explored the opportunity for submitting a new drug application, or NDA, for use of levosimendan in CABG surgery patients on the basis of the robust reduction in 90-day mortality observed in the LEVO-CTS trial. However, the FDA advised that another study in CABG surgery patients would be required that prospectively tests levosimendan's effectiveness in improving mortality.

Accordingly, we have suspended development of levosimendan for use in CABG patients due to the scope of the repeat study, as required by the FDA. The incidence of 90-day mortality in CABG surgery patients is low (~8%). The repeat study would need to randomize approximately 1200 CABG surgery patients with low LVEF (<35%) to demonstrate a >50% risk reduction in mortality. Based on this analysis, we determined the cost and timing of this study would outweigh the likely benefit.

Suppliers

Pursuant to the terms of our license for levosimendan, Orion is our sole manufacturing source for levosimendan.

Intellectual Property

We rely on a combination of patent applications, patents, trade secrets, proprietary know-how, trademarks, and contractual provisions to protect our proprietary rights. We believe that to have a competitive advantage, we must develop and maintain the proprietary aspects of our technologies. Currently, we require our officers, employees, consultants, contractors, manufacturers, outside scientific collaborators and sponsored researchers, and other advisors to execute confidentiality agreements in connection with their employment, consulting, or advisory relationships with us, where appropriate. We also require our employees, consultants, and advisors who we expect to work on our products to agree to disclose and assign to us all inventions conceived during the workday, developed using our property, or which relate to our business.

To date, we own or in-license the rights to six U.S. and foreign patents. In addition, we have one U.S. patent application pending related to a product candidate and proprietary process, method and technology. Our issued and in-licensed patents, as well as our pending patents, expire between 2023 and 2038.

We have:

- one U.S. patent (8,404,752), one Australian Patent (209,271,530) and one European patent (EPO9798325.8) held jointly with Virginia Commonwealth University Intellectual Property Foundation for the treatment of traumatic brain injury;
- one Israeli patent (215516) and numerous patent applications, including one U.S. patent application, for the formulation of perfluorocarbon emulsion with an average remaining life of approximately 13 years; and
- two U.S. patents (6,730,673 and 6,943,164) for the intravenous formulation of levosimendan as in-licensed patent rights for our development and commercialization of levosimendan in the United States and Canada.

Our patent and patent applications include claims covering all various uses of levosimendan, our lead product candidate currently under development, as well as the manufacturing and use of our perfluorocarbon emulsion formulation. We have filed a patent application for a subcutaneous formulation of levosimendan that we have developed in collaboration with a formulation development partner. In addition, we have filed a provisional patent application for the use of levosimendan in the treatment of PH-HFpEF patients based on several discoveries that have emerged from the HELP Study. The HELP Study is the first and only trial to evaluate the use of levosimendan to treat PH-HFpEF patients, a patient population where all previously tested therapies have failed to show effectiveness.

The U.S. trademark registration for Simdax® is owned by Orion and is licensed to us for sales and marketing purposes for any pharmaceutical products containing levosimendan that are commercialized in the United States and Canada.

Competition

The pharmaceutical and biotechnology industries are intensely competitive. Many companies, including biotechnology, chemical and pharmaceutical companies, are actively engaged in activities similar to ours, including research and development of drugs for the treatment of rare medical conditions. Many of these companies have substantially greater financial and other resources, larger research and development staffs, and more extensive marketing and manufacturing organizations than we do. In addition, some of them have considerable experience in preclinical testing, clinical trials and other regulatory approval procedures. There are also academic institutions, governmental agencies and other research organizations that are conducting research in areas in which we are working. We expect to encounter significant competition for any of the pharmaceutical products we plan to develop.

We believe the concept of using levosimendan to treat patients with PH-HFpEF is novel. Because no therapies are approved to treat PH-HFpEF, our ability to succeed in the market is dependent on our ability to change the established practice paradigm, which is never an easy task. Key factors on which we will compete with regards to the development and marketing of levosimendan for the treatment of pulmonary hypertension include, among others, the ability to obtain adequate efficacy data, safety data, cost effectiveness data and hospital formulary approval, as well as sufficient distribution and handling. Furthermore, while we believe the mechanism of action of levosimendan is novel, other low-priced, generically available products possess some similar qualities, which could present competition in the form of therapeutic substitution.

In order to compete successfully in this and other therapeutic areas, we must develop proprietary positions in patented drugs for therapeutic markets that have not been satisfactorily addressed by conventional research strategies. Our product candidates, even if successfully tested and developed, may not be adopted by physicians over other products and may not offer economically feasible alternatives to other therapies.

Government Regulation

The manufacture and distribution of levosimendan will require the approval of United States government authorities as well as those of foreign countries. In the United States, the FDA regulates medical products. The Federal Food, Drug and Cosmetic Act and the Public Health Service Act govern the testing, manufacture, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of our medical products. In addition to FDA regulations, we are also subject to other federal and state regulations, such as the Occupational Safety and Health Act and the Environmental Protection Act. Product development and approval within this regulatory framework requires a number of years and involves the expenditure of substantial funds.

Preclinical tests include evaluation of product chemistry and studies to assess the safety and effectiveness of the product and its formulation. The results of the preclinical tests are submitted to the FDA as part of the application. The goal of clinical testing is the demonstration in adequate and well-controlled studies of substantial evidence of the safety and effectiveness of the product in the setting of its intended use. The results of preclinical and clinical testing are submitted to the FDA from time to time throughout the trial process. In addition, before approval for the commercial sale of a product can be obtained, results of the preclinical and clinical studies must be submitted to the FDA. The testing and approval process requires substantial time and effort and there can be no assurance that any approval will be granted on a timely basis, if at all. The approval process is affected by a number of factors, including the severity of the condition being treated, the availability of alternative treatments and the risks and benefits demonstrated in clinical trials. Additional preclinical studies or clinical trials may be requested during the FDA review process and may delay product approval. After FDA approval for its initial indications, further clinical trials may be necessary to gain approval for the use of a product for additional indications. The FDA may also require post-marketing testing, which can involve significant expense, to monitor for adverse effects.

The HELP Study in PH-HFpEF patients incorporates FDA advice. An End of Phase 2 Meeting with the FDA is planned in 2020 to review results of the HELP Study and Phase 3 study design in development of levosimendan for treatment of PH-HFpEF patients.

Employees

We believe that our success will be based on, among other things, the quality of our clinical programs, our ability to invent and develop superior and innovative technologies and products, and our ability to attract and retain capable management and other personnel. We have assembled a high-quality team of clinical development managers and executives with significant experience in the biotechnology and pharmaceutical industries.

As of December 31, 2019, we had nine full-time employees and one part-time employee. In addition to our employees, we also use the service and support of outside consultants and advisors. None of our employees are represented by a union, and we believe relationships with our employees are good.

Available Information

Our website address is www.tenaxthera.com, and our investor relations website is located at http://investors.tenaxthera.com. Information on our website is not incorporated by reference herein. Copies of our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and our Proxy Statements for our annual meetings of stockholders, and any amendments to those reports, as well as Section 16 reports filed by our insiders, are available free of charge on our website as soon as reasonably practicable after we file the reports with, or furnish the reports to, the Securities and Exchange Commission, or the SEC. Our SEC filings are also publicly available on the SEC's website located at www.sec.gov, which contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

ITEM 1A—RISK FACTORS

Risks Related to Our Financial Position and Need for Additional Capital

We have a limited operating history, and we expect a number of factors to cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance.

Our operations, to date, have been primarily limited to organizing and staffing our company, licensing our technology from Orion and undertaking preclinical studies and clinical trials of our product candidates. We have not yet obtained regulatory approvals for any of our clinical product candidates. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

Specifically, our financial condition and operating results have varied significantly in the past and will continue to fluctuate from quarter-to-quarter and year-to-year in the future due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following factors, among others:

- our ability to obtain additional funding to develop our product candidates, and any further product candidate which we may develop or in license in the future;
- the need to obtain regulatory approval of our product candidates;
- potential risks related to any collaborations we may enter into for our product candidates;
- delays in the commencement, enrollment and completion of clinical testing, as well as the analysis and reporting of results from such clinical testing;
- the success of clinical trials of our product candidates;
- any delays in regulatory review and approval of product candidates in development;
- our ability to establish an effective sales and marketing infrastructure;
- competition from existing products or new products that may emerge;
- the ability to receive regulatory approval or commercialize our products;
- potential side effects of our product candidates that could delay or prevent commercialization;
- potential product liability claims and adverse events;
- potential liabilities associated with hazardous materials;
- our ability to maintain adequate insurance policies;
- our dependency on third-party manufacturers to supply or manufacture our products;
- our ability to establish or maintain collaborations, licensing or other arrangements;
- our ability, our partners' abilities, and third parties' abilities to protect and assert intellectual property rights;
- costs related to and outcomes of potential litigation;
- compliance with obligations under intellectual property licenses with third parties;
- our ability to adequately support future growth; and
- our ability to attract and retain key personnel to manage our business effectively.

Due to the various factors mentioned above, and others, the results of any prior quarterly or annual periods should not be relied upon as indications of our future operating performance.

We may need additional funding and if we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate our product development programs.

Developing biopharmaceutical products, including conducting preclinical studies and clinical trials and establishing manufacturing capabilities, is expensive. We expect our research and development expenses to increase in connection with our ongoing activities. In addition, our expenses could increase beyond expectations if applicable regulatory authorities, including the FDA, require that we perform additional studies to those that we currently anticipate, in which case the timing of any potential product approval may be delayed. As of December 31, 2019, we had $4.9 million of cash and cash equivalents, including the fair value of our marketable securities on hand. On March 13, 2020, we received $2.75 million in gross proceeds in exchange for the issuance of common stock, pre-funded warrants, and common stock warrants, or the March 2020 offering, as described further in Item 7 – "Management's Discussion and Analysis of Financial Condition and Results of Operations". Based on our current operating plans, we believe that our existing cash and cash equivalents, including the proceeds from our March 2020 offering, will be sufficient to fund our projected operating requirements through the third quarter of calendar year 2020. We will need substantial additional capital in the future in order to complete the regulatory approval and commercialization of levosimendan and to fund the development and commercialization of future product candidates. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Such funding, if needed, may not be available on favorable terms, if at all. In the event we are unable to obtain additional capital, we may delay or reduce the scope of our current research and development programs and other expenses. As a result of our historical operating losses and expected future negative cash flows from operations, we have concluded that there is substantial doubt about our ability to continue as a going concern. Similarly, the report of our independent registered public accounting firm on our December 31, 2019 Consolidated Financial Statements includes an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern. Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock and make it more difficult to obtain financing.

If adequate funds are not available, we may also be required to eliminate one or more of our clinical trials, delaying approval of levosimendan or our commercialization efforts. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional significant dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates or to grant licenses on terms that may not be favorable to us. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. We may also consider strategic alternatives, including a sale of our company, merger, other business combination or recapitalization.

Our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- the costs and timing of regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the effect of competing technological and market developments;
- the terms and timing of any collaboration, licensing or other arrangements that we may establish;
- the cost and timing of completion of clinical and commercial-scale manufacturing activities; and
- the costs of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval.

Risks Related to Commercialization and Product Development

A pandemic, epidemic, or outbreak of an infectious disease, such as COVID-19, or coronavirus, may materially and adversely affect our business and our financial results.

The spread of COVID-19 has affected segments of the global economy and may affect our operations, including the potential interruption of our clinical trial activities and our supply chain. The recent outbreak of COVID-19 originated in Wuhan, China, in December 2019 and has since spread to multiple countries. The continued spread of COVID-19 may result in a period of business disruption, including delays in our clinical trials or delays or disruptions in our supply chain. In addition, there could be a potential effect of COVID-19 to the business at FDA or other health authorities, which could result in delays of reviews and approvals, including with respect to our product candidates.

The continued spread of COVID-19 globally could adversely affect our clinical trial operations in the United States and elsewhere, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. Further, some patients may be unable to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services, or if the patients become infected with COVID-19 themselves, which would delay our ability to conduct clinical trials or release clinical trial results. COVID-19 may also affect our employees or employees of third-party contract research organizations, or CROs, located in affected geographies that we rely upon to carry out our clinical trials, which could result in inefficiencies due to reductions in staff and disruptions to work environments.

The spread of COVID-19, or another infectious disease, could also negatively affect the operations at our third-party manufacturers, which could result in delays or disruptions in the supply of our product candidates. In addition, we may take temporary precautionary measures intended to help minimize the risk of the virus to our employees, including temporarily requiring all employees to work remotely, suspending all non-essential travel worldwide for our employees, and discouraging employee attendance at industry events and in-person work-related meetings, which could negatively affect our business.

We cannot presently predict the scope and severity of any potential business shutdowns or disruptions. If we or any of the third parties with whom we engage, however, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business and our results of operation and financial condition.

We are limited in the number of products we can simultaneously pursue and therefore our survival depends on our success with a small number of product opportunities.

We have limited financial resources, so at present we are primarily focusing these resources on developing levosimendan for the treatment of pulmonary hypertension, in addition to exploring strategic alternatives in order to maximize stockholder value. On January 31, 2017, we announced top-line results from the Phase 3 LEVO-CTS trial for the treatment of LCOS. The study did not achieve statistically significant reductions in the dual endpoint of death or use of a mechanical assist device at 30 days, nor in the quad endpoint of death, myocardial infarction, need for dialysis, or use of a mechanical assist device at 30 days. Nevertheless, the study demonstrated statistically significant reductions in two of three secondary endpoints including reduction in LCOS and a reduction in postoperative use of secondary inotropes. Additionally, we observed a non-significant numerical reduction in 90-day mortality. At present, we intend to commit most of our resources to advancing levosimendan to the point it receives regulatory approval for the treatment of pulmonary hypertension. If as a consequence of the results of our Phase 3 LEVO-CTS trial or our current Phase 2 trial in PH-HFpEF, we are unable to receive regulatory approval of levosimendan, then we may not have resources to pursue development of any other products and our business could terminate.

We currently have no approved drug products for sale, and we cannot guarantee that we will ever have marketable drug products.

We currently have no approved drug products for sale. The research, testing, manufacturing, labeling, approval, selling, marketing, and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, with regulations differing from country to country. We are not permitted to market our product candidates in the United States until we receive approval of an NDA from the FDA for each product candidate. We have not submitted an NDA or received marketing approval for any of our product candidates, and obtaining approval of an NDA is a lengthy, expensive and uncertain process. In addition, markets outside of the United States also have requirements for approval of drug candidates which we must comply with prior to marketing. Accordingly, we cannot guarantee that we will ever have marketable drug products.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we or our collaborators must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA, that such product candidates are safe and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Additionally, the FDA may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or post-approval, or it may object to elements of our clinical development program.

The development of levosimendan is subject to a high level of technological risk.

We have devoted a substantial portion of our financial and managerial resources to pursue Phase 3 clinical trials for levosimendan. The biomedical field has undergone rapid and significant technological changes. Technological developments may result in our products becoming obsolete or non-competitive before we are able to recover any portion of the research and development and other expenses we have incurred to develop and clinically test levosimendan. As our opportunity to generate substantial product revenues within the next three to four years is most likely dependent on successful testing and commercialization of levosimendan for pulmonary hypertension, any such occurrence would have a material adverse effect on our operations and could result in the cessation of our business.

We are required to conduct additional clinical trials in the future, which are expensive and time consuming, and the outcome of the trials is uncertain.

We expect to commit a substantial portion of our financial and business resources over the next three years to clinical testing of levosimendan and advancing this product to regulatory approval for use in one or more medical applications. All of these clinical trials and testing will be expensive and time consuming and the timing of the regulatory review process is uncertain. The applicable regulatory agencies may suspend clinical trials at any time if they believe that the subjects participating in such trials are being exposed to unacceptable health risks. We cannot ensure that we will be able to complete our clinical trials successfully or obtain FDA or other governmental or regulatory approval of levosimendan, or that such approval, if obtained, will not include limitations on the indicated uses for which levosimendan may be marketed. Our business, financial condition and results of operations are critically dependent on obtaining capital to advance our testing program and receiving FDA and other governmental and regulatory approvals of our products. A significant delay in or failure of our planned clinical trials or a failure to achieve these approvals would have a material adverse effect on us and could result in major setbacks or jeopardize our ability to continue as a going concern.

The market may not accept our products.

Even if regulatory approval is obtained, there is a risk that the efficacy and pricing of our products, considered in relation to our products' expected benefits, will not be perceived by health care providers and third-party payers as cost-effective, and that the price of our products will not be competitive with other new technologies or products. Our results of operations may be adversely affected if the price of our products is not considered cost-effective or if our products do not otherwise achieve market acceptance.

Any collaboration we enter with third parties to develop and commercialize any future product candidates may place the development of our product candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

We may enter into collaborations with third parties to develop and commercialize future product candidates. Our dependence on future partners for development and commercialization of our product candidates would subject us to a number of risks, including:

- we may not be able to control the amount and timing of resources that our partners may devote to the development or commercialization of our product candidates or to their marketing and distribution;
- partners may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

- disputes may arise between us and our partners that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and resources;
- partners may experience financial difficulties;
- partners may not properly maintain or defend our intellectual property rights, or may use our proprietary information, in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or proprietary information or expose us to potential litigation;
- business combinations or significant changes in a partner's business strategy may adversely affect a partner's willingness or ability to meet its obligations under any arrangement;
- a partner could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- the collaborations with our partners may be terminated or allowed to expire, which would delay the development and may increase the cost of developing our product candidates.

Delays in the enrollment and completion of clinical testing could result in increased costs to us and delay or limit our ability to obtain regulatory approval for our product candidates.

Delays in the enrollment and completion of clinical testing could significantly affect our ability to gain FDA approval of levosimendan and any other future product development costs. The completion of clinical trials requires us to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs for the same indication as our product candidates or may be required to withdraw from our clinical trial as a result of changing standards of care or may become ineligible to participate in clinical studies. The enrollment and completion of clinical trials can be delayed for a variety of other reasons, including delays related to:

- reaching agreements on acceptable terms with prospective trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among trial sites;
- obtaining institutional review board, or IRB, approval to conduct a clinical trial at numerous prospective sites;
- recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including meeting the enrollment criteria for our study and competition from other clinical trial programs for the same indication as our product candidates;
- maintaining and supplying clinical trial material on a timely basis; and
- collecting, analyzing and reporting final data from the clinical trials.

In addition, a clinical trial may be suspended or terminated by us, the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues or any determination that a trial presents unacceptable health risks; and
- lack of adequate funding to continue the clinical trial, including unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties.

Changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. Amendments may require us to resubmit our clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial. If we experience delays in the completion of, or if we terminate, our clinical trials, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Even if we are able to ultimately commercialize our product candidates, other therapies for the same or similar indications may have been introduced to the market and established a competitive advantage.

Risks Relating to Regulatory Matters

Our activities are and will continue to be subject to extensive government regulation, which is expensive and time consuming, and we will not be able to sell our products without regulatory approval.

Our development, marketing and distribution of levosimendan is, and will continue to be, subject to extensive regulation, monitoring and approval by the FDA and other regulatory agencies. There are significant risks at each stage of the regulatory scheme.

Product approval stage

During the product approval stage, we attempt to prove the safety and efficacy of our product for its indicated uses. There are numerous problems that could arise during this stage, including:

- the data obtained from laboratory testing and clinical trials are susceptible to varying interpretations, which could delay, limit or prevent FDA and other regulatory approvals;
- adverse events could cause the FDA and other regulatory authorities to halt trials;
- at any time, the FDA and other regulatory agencies could change policies and regulations that could result in delay and perhaps rejection of our products;
- if a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions; and
- even after extensive testing and clinical trials, there is no assurance that regulatory approval will ever be obtained for any of our products.

Post-commercialization stage

Discovery of previously unknown problems with our products, or unanticipated problems with our manufacturing arrangements, even after FDA and other regulatory approvals of our products for commercial sale may result in the imposition of significant restrictions, including withdrawal of the product from the market.

Additional laws and regulations may also be enacted that could prevent or delay regulatory approval of our products, including laws or regulations relating to the price or cost-effectiveness of medical products. Any delay or failure to achieve regulatory approval of commercial sales of our products is likely to have a material adverse effect on our financial condition, results of operations and cash flows.

The FDA and other regulatory agencies continue to review products even after they receive agency approval. If and when the FDA or another regulatory agency outside the United States approves one of our products, its manufacture and marketing will be subject to ongoing regulation, which could include compliance with current good manufacturing practices, adverse event reporting requirements and general prohibitions against promoting products for unapproved or “off-label” uses. We are also subject to inspection and market surveillance by the FDA for compliance with these and other requirements. Any enforcement action resulting from failure, even by inadvertence, to comply with these requirements could affect the manufacture and marketing of levosimendan or our other products. In addition, the FDA or other regulatory agencies could withdraw a previously approved product from the market upon receipt of newly discovered information. The FDA or another regulatory agency could also require us to conduct additional, and potentially expensive, studies in areas outside our approved indicated uses.

We must continually monitor the safety of our products once approved and marketed for signs that their use may elicit serious and unexpected side effects and adverse events, which could jeopardize our ability to continue marketing the products. We may also be required to conduct post-approval clinical studies as a condition to licensing a product.

As with all pharmaceutical products, the use of our products could sometimes produce undesirable side effects or adverse reactions or events (referred to cumulatively as adverse events). For the most part, we would expect these adverse events to be known and occur at some predicted frequency. When adverse events are reported to us, we will be required to investigate each event and circumstances surrounding it to determine whether it was caused by our product and whether it implies that a previously unrecognized safety issue exists. We will also be required to periodically report summaries of these events to the applicable regulatory authorities.

In addition, the use of our products could be associated with serious and unexpected adverse events, or with less serious reactions at a greater than expected frequency. This may be especially true when our products are used in critically ill or otherwise compromised patient populations. When these unexpected events are reported to us, we will be required to make a thorough investigation to determine causality and implications for product safety. These events must also be specifically reported to the applicable regulatory authorities. If our evaluation concludes, or regulatory authorities perceive, that there is an unreasonable risk associated with the product, we would be obligated to withdraw the impacted lot(s) of that product. Furthermore, an unexpected adverse event of a new product could be recognized only after extensive use of the product, which could expose us to product liability risks, enforcement action by regulatory authorities and damage to our reputation and public image.

A serious adverse finding concerning the risk of our products by any regulatory authority could adversely affect our reputation, business and financial results.

When a new product is approved, the FDA or other regulatory authorities may require post-approval clinical trials, sometimes called Phase 4 clinical trials. If the results of such trials are unfavorable, this could result in the loss of the license to market the product, with a resulting loss of sales.

After our products are commercialized, we expect to spend considerable time and money complying with federal and state laws and regulations governing their sale, and, if we are unable to fully comply with such laws and regulations, we could face substantial penalties.

Health care providers, physicians and others will play a primary role in the recommendation and prescription of our clinical products. Our arrangements with third-party payers and customers may expose us to broadly applicable fraud and abuse and other health care laws and regulations that may constrain the business or financial arrangements and relationships through which we will market, sell and distribute our products. Applicable federal and state health care laws and regulations are expected to include, but not be limited to, the following:

- the federal anti-kickback statute is a criminal statute that makes it a felony for individuals or entities knowingly and willfully to offer or pay, or to solicit or receive, direct or indirect remuneration, in order to induce the purchase, order, lease, or recommending of items or services, or the referral of patients for services, that are reimbursed under a federal health care program, including Medicare and Medicaid;
- the federal False Claims Act imposes liability on any person who knowingly submits, or causes another person or entity to submit, a false claim for payment of government funds, with penalties that include three times the government's damages plus civil penalties for each false claim; in addition, the False Claims Act permits a person with knowledge of fraud, referred to as a qui tam plaintiff, to file a lawsuit on behalf of the government against the person or business that committed the fraud, and, if the action is successful, the qui tam plaintiff is rewarded with a percentage of the recovery;
- Health Insurance Portability and Accountability Act imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the Social Security Act contains numerous provisions allowing the imposition of a civil money penalty, a monetary assessment, exclusion from the Medicare and Medicaid programs, or some combination of these penalties; and
- many states have analogous state laws and regulations, such as state anti-kickback and false claims laws, which, in some cases, these state laws impose more strict requirements than the federal laws and may require pharmaceutical companies to comply with certain price reporting and other compliance requirements.

Our failure to comply with any of these federal and state health care laws and regulations, or health care laws in foreign jurisdictions, could have a material adverse effect on our business, financial condition, result of operations and cash flows.

Health care reform and controls on health care spending may limit the price we can charge for our products and the amount we can sell.

As a result of the Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010, collectively, the ACA, enacted in March 2010, substantial changes have occurred and are expected to continue to occur in the system for paying for health care in the United States, including changes made in order to extend medical benefits to those who currently lack insurance coverage. This comprehensive health care reform legislation also included provisions to control health care costs and improve health care quality. Together with ongoing statutory and budgetary policy developments at a federal level, this health care reform legislation could include changes in Medicare and Medicaid payment policies and other health care delivery administrative reforms that could potentially negatively impact our business. Because not all the administrative rules implementing health care reform under the legislation have been finalized, and because of ongoing federal fiscal budgetary pressures not yet resolved for federal health programs, the full impact of the ACA and of further statutory actions to reform healthcare payment on our business is unknown, but there can be no assurances that health care reform legislation will not adversely impact either our operational results or the manner in which we operate our business. There have been judicial and Congressional challenges to the ACA and there may be additional challenges and amendments to the ACA in the future, particularly in light of the current presidential administration and U.S. Congress. We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Cost of care could be reduced by reducing the level of reimbursement for medical services or products (including those biopharmaceuticals that we intend to produce and market), or by restricting coverage (and, thereby, utilization) of medical services or products. In either case, a reduction in the utilization of, or reimbursement for, our products could have a materially adverse impact on our financial performance. Moreover, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products. We cannot predict what healthcare reform initiatives may be adopted in the future.

Uncertainty of third-party reimbursement could affect our future results of operations.

Sales of medical products largely depend on the reimbursement of patients' medical expenses by governmental health care programs and private health insurers. We will be required to report detailed pricing information, net of included discounts, rebates and other concessions, to the Centers for Medicare and Medicaid Services, or CMS, for the purpose of calculating national reimbursement levels, certain federal prices, and certain federal rebate obligations. If we report pricing information that is not accurate to the federal government, we could be subject to fines and other sanctions that could adversely affect our business. In addition, the government could change its calculation of reimbursement, federal prices, or federal rebate obligations which could negatively impact us. There is no guarantee that government health care programs or private health insurers will reimburse for the sales of our products or permit us to sell our products at high enough prices to generate a profit.

Governments outside the United States tend to impose strict price controls and reimbursement approval policies, which may adversely affect our prospects for generating revenue outside the United States.

Although we only have distribution rights in the United States and Canada for levosimendan, in some countries, particularly European Union countries and Canada, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. To obtain or maintain reimbursement or pricing approval in some countries with respect to any product candidate that achieves regulatory approval, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products upon approval, if at all, is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our prospects for generating revenue, if any, could be adversely affected which would have a material adverse effect on our business and results of operations. Further, if we achieve regulatory approval of any product, we must successfully negotiate product pricing for such product in individual countries. As a result, the pricing of our products, if approved, in different countries may vary widely, thus creating the potential for third-party trade in our products in an attempt to exploit price differences between countries. This third-party trade of our products could undermine our sales in markets with higher prices.

Risks Relating to Our Dependence on Third Parties

We depend on third parties to manufacture our products.

We do not own or operate any manufacturing facilities for the commercial-scale production of our products. Pursuant to the terms of our license for levosimendan, Orion is our sole manufacturing source for levosimendan. Accordingly, our business is susceptible to disruption, and our results of operations can be adversely affected, by any disruption in supply or other adverse developments in our relationship with Orion. If supply from Orion is delayed or terminated, or if its facilities suffer any damage or disruption, we may need to successfully qualify an alternative supplier in a timely manner in order to not disrupt our business. If we cannot obtain an alternate manufacturer in a timely manner, we would experience a significant interruption in supply of levosimendan, which could negatively affect our financial condition, results of operations and cash flows.

In June 2019, Orion filed a request for arbitration against us seeking a declaration regarding the correct interpretation of the line extension provisions of the license and whether or not such provisions apply to the oral form of levosimendan recently developed by Orion. Additionally, Orion requested we reimburse Orion for all legal fees associated with the arbitration. We submitted our response to the request for arbitration and rejected Orion's position that the oral formation was not a line extension product under the license.

While the operations under the license have generally continued in their ordinary course during the dispute and filing for arbitration, the disagreement leading to the arbitration may result in a strain to our relationship with Orion. We cannot assure you that these tensions and disagreements will be resolved when the arbitration is concluded. Orion may also have economic or business interests or goals that are inconsistent with ours. If our relationship with Orion were to deteriorate, it could have a material adverse effect on our results of operations and financial condition.

We depend on the services of a limited number of key personnel.

Our success is highly dependent on the continued services of a limited number of scientists and support personnel. The loss of any of these individuals could have a material adverse effect on us. In addition, our success will depend, among other factors, on the recruitment and retention of additional highly skilled and experienced management and technical personnel. There is a risk that we will not be able to retain existing employees or to attract and retain additional skilled personnel on acceptable terms given the competition for such personnel among numerous large and well-funded pharmaceutical and health care companies, universities, and non-profit research institutions, which could negatively affect our financial condition, results of operations and cash flows.

We have no experience in the sale and marketing of medical products.

We have no experience in the sale and marketing of approved medical products and marketing the licensing of such products before FDA or other regulatory approval. We have not decided upon a commercialization strategy in these areas. We do not know of any third party that is prepared to distribute our products should they be approved. If we decide to establish our own commercialization capability, we will need to recruit, train and retain a marketing staff and sales force with sufficient technical expertise. We do not know whether we can establish a commercialization program at a cost that is acceptable in relation to revenue or whether we can be successful in commercializing our product. Factors that may inhibit our efforts to commercialize our products directly and without strategic partners include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating and sustaining an independent sales and marketing organization.

Failure to successfully commercialize our products or to do so on a cost-effective basis would likely result in failure of our business.

We may enter into distribution arrangements and marketing alliances for certain products and any failure to successfully identify and implement these arrangements on favorable terms, if at all, may impair our ability to commercialize our product candidates.

We do not anticipate having the resources in the foreseeable future to develop sales and marketing capabilities for all of the products we develop, if any. We may pursue arrangements regarding the sales and marketing and distribution of one or more of our product candidates and our future revenues may depend, in part, on our ability to enter into and maintain arrangements with other companies having sales, marketing and distribution capabilities and the ability of such companies to successfully market and sell any such products. Any failure to enter into such arrangements and marketing alliances on favorable terms, if at all, could delay or impair our ability to commercialize our product candidates and could increase our costs of commercialization. Any use of distribution arrangements and marketing alliances to commercialize our product candidates will subject us to a number of risks, including the following:

- we may be required to relinquish important rights to our products or product candidates;
- we may not be able to control the amount and timing of resources that our distributors or collaborators may devote to the commercialization of our product candidates;
- our distributors or collaborators may experience financial difficulties;
- our distributors or collaborators may not devote sufficient time to the marketing and sales of our products; and
- business combinations or significant changes in a collaborator’s business strategy may adversely affect a collaborator’s willingness or ability to complete its obligations under any arrangement.

We may need to enter into additional co-promotion arrangements with third parties where our own sales force is neither well situated nor large enough to achieve maximum penetration in the market. We may not be successful in entering into any co-promotion arrangements, and the terms of any co-promotion arrangements we enter into may not be favorable to us.

Risks Relating to Intellectual Property

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our future product candidates, if any, and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our products is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

We license certain intellectual property from Orion that covers our product candidate levosimendan. The principal United States patents that we license from Orion expire in September 2020. We rely on Orion to file, prosecute and maintain patent applications and otherwise protect the intellectual property to which we have a license, and we have not had and do not have primary control over these activities for certain of these patents or patent applications and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. Our enforcement of certain of these licensed patents or defense of any claims asserting the invalidity of these patents would also be subject to the cooperation of the third parties.

The patent positions of pharmaceutical and biopharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biopharmaceutical patents has emerged to date in the United States. The biopharmaceutical patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in the patents we own or to which we have a license from a third-party. Further, if any of our patents are deemed invalid and unenforceable, it could impact our ability to commercialize or license our technology.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make compositions or formulations that are similar to our product candidates but that are not covered by the claims of our patents;
- we might not have been the first to make the inventions covered by our issued patents or pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications will not result in issued patents;
- our issued patents may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties;
- we may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business.

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

We rely on confidentiality agreements that, if breached, may be difficult to enforce and could have a material adverse effect on our business and competitive position.

Our policy is to enter agreements relating to the non-disclosure and non-use of confidential information with third parties, including our contractors, consultants, advisors and research collaborators, as well as agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees and consultants while we employ them. However, these agreements can be difficult and costly to enforce. Moreover, to the extent that our contractors, consultants, advisors and research collaborators apply or independently develop intellectual property in connection with any of our projects, disputes may arise as to the proprietary rights to the intellectual property. If a dispute arises, a court may determine that the right belongs to a third party, and enforcement of our rights can be costly and unpredictable. In addition, we rely on trade secrets and proprietary know-how that we seek to protect in part by confidentiality agreements with our employees, contractors, consultants, advisors or others. Despite the protective measures we employ, we still face the risk that:

- these agreements may be breached;
- these agreements may not provide adequate remedies for the applicable type of breach; or
- our trade secrets or proprietary know-how will otherwise become known.

Any breach of our confidentiality agreements or our failure to effectively enforce such agreements would have a material adverse effect on our business and competitive position.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use, our technology.

If we or our partners choose to go to court to stop someone else from using the inventions claimed in our patents, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to these patents.

Furthermore, a third party may claim that we or our manufacturing or commercialization partners are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we or our commercialization partners are infringing the third party's patents and would order us or our partners to stop the activities covered by the patents. In addition, there is a risk that a court will order us or our partners to pay the other party damages for having violated the other party's patents. We have agreed to indemnify certain of our commercial partners against certain patent infringement claims brought by third parties. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use either do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents by others covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the U.S. Patent and Trademark Office, or USPTO, to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

Our collaborations with outside scientists and consultants may be subject to restriction and change.

We work with chemists, biologists and other scientists at academic and other institutions, and consultants who assist us in our research, development, regulatory and commercial efforts, including the members of our scientific advisory board. These scientists and consultants have provided, and we expect that they will continue to provide, valuable advice on our programs. These scientists and consultants are not our employees, may have other commitments that would limit their future availability to us and typically will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, we will be unable to prevent them from establishing competing businesses or developing competing products. For example, if a key scientist acting as a principal investigator in any of our clinical trials identifies a potential product or compound that is more scientifically interesting to his or her professional interests, his or her availability to remain involved in our clinical trials could be restricted or eliminated.

Under current law, we may not be able to enforce all employees' covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former employees.

We have entered into non-competition agreements with certain of our employees. These agreements prohibit our employees, if they cease working for us, from competing directly with us or working for our competitors for a limited period. Under current law, we may be unable to enforce these agreements against certain of our employees and it may be difficult for us to restrict our competitors from gaining the expertise our former employees gained while working for us. If we cannot enforce our employees' non-compete agreements, we may be unable to prevent our competitors from benefiting from the expertise of our former employees.

We may infringe or be alleged to infringe intellectual property rights of third parties.

Our products or product candidates may infringe on, or be accused of infringing on, one or more claims of an issued patent or may fall within the scope of one or more claims in a published patent application that may be subsequently issued and to which we do not hold a license or other rights. Third parties may own or control these patents or patent applications in the United States and abroad. These third parties could bring claims against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit.

If we are found to infringe the patent rights of a third party, or in order to avoid potential claims, we or our collaborators may choose or be required to seek a license from a third party and be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms.

There have been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference proceedings declared by the USPTO and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to our products. Our products, after commercial launch, may become subject to Paragraph IV certification under the Hatch-Waxman Act, thus forcing us to initiate infringement proceedings against such third-party filers. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Patent litigation and other proceedings may also absorb significant management time.

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We try to ensure that our employees do not use the proprietary information or know-how of others in their work for us. We may, however, be subject to claims that we or these employees have inadvertently or otherwise used or disclosed intellectual property, trade secrets or other proprietary information of any such employee's former employer. Litigation may be necessary to defend against these claims and, even if we are successful in defending ourselves, could result in substantial costs to us or be distracting to our management. If we fail to defend any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel.

Product liability lawsuits against us could cause us to incur substantial liabilities, limit sales of our existing products and limit commercialization of any products that we may develop.

Our business exposes us to the risk of product liability claims that are inherent in the manufacturing, distribution, and sale of biotechnology products. We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and an even greater risk when we commercially sell any products. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our products and any product candidates that we may develop;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We currently maintain limited product liability insurance coverage for our clinical trials in the total amount of $3 million. However, our profitability will be adversely affected by a successful product liability claim in excess of our insurance coverage. There can be no assurance that product liability insurance will be available in the future or be available on reasonable terms.

Our business and operations would suffer in the event of computer system failures, cyber-attacks or deficiencies in our cyber-security.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials 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 was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability, and damage to our reputation, and the further development of our product candidates could be delayed.

Our disclosure controls and procedures address cybersecurity and include elements intended to ensure that there is an analysis of potential disclosure obligations arising from security breaches. We also maintain compliance programs to address the potential applicability of restrictions against trading while in possession of material, nonpublic information generally and in connection with a cyber-security breach. However, a breakdown in existing controls and procedures around our cyber-security environment may prevent us from detecting, reporting or responding to cyber incidents in a timely manner and could have a material adverse effect on our financial position and value of our stock.

Risks Related to Owning Our Common Stock

Our share price has been volatile and may continue to be volatile which may subject us to securities class action litigation in the future.

Our stock price has in the past been, and is likely to be in the future, volatile. The stock market in general has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, our existing stockholders may not be able to sell their stock at a favorable price. The market price for our common stock may be influenced by many factors, including:

- actual or anticipated fluctuations in our financial condition and operating results;
- status and/or results of our clinical trials;
- status of ongoing litigation;
- results of clinical trials of our competitors' products;
- regulatory actions with respect to our products or our competitors' products;
- actions and decisions by our collaborators or partners;
- actual or anticipated changes in our growth rate relative to our competitors;
- actual or anticipated fluctuations in our competitors' operating results or changes in their growth rate;
- competition from existing products or new products that may emerge;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- market conditions for biopharmaceutical stocks in general;
- status of our search and selection of future management and leadership; and
- general economic and market conditions, including as a result of pandemics, epidemics, or outbreaks of an infectious disease, such as COVID-19, or coronavirus.

Some companies that have had volatile market prices for their securities have had securities class action lawsuits filed against them. Such lawsuits, should they be filed against us in the future, could result in substantial costs and a diversion of management's attention and resources. This could have a material adverse effect on our business, results of operations and financial condition.

Our failure to maintain compliance with Nasdaq's continued listing requirements could result in the delisting of our common stock.

Our common stock is currently listed on The Nasdaq Capital Market. In order to maintain this listing, we must satisfy minimum financial and other requirements. In the past, we have received a notification letter from Nasdaq indicating that we were not in compliance with listing requirements because the minimum bid price of our common stock closed below $1.00 per share for 30 consecutive business days. As part of our plan to regain compliance with the minimum bid price requirement, we effected a 1-for-20 reverse stock split on February 23, 2018. If we fail to satisfy Nasdaq's listing requirements in the future, we expect to take actions to regain compliance, but we can provide no assurance that any such action would prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements. If our common stock is delisted from Nasdaq, the delisting could substantially decrease trading in our common stock and adversely affect the market liquidity of our common stock; adversely affect our ability to obtain financing on acceptable terms, if at all; and may result in the potential loss of confidence by investors, suppliers, customers, and employees and fewer business development opportunities. Additionally, the market price of our common stock may decline further, and stockholders may lose some or all of their investment.

We are likely to attempt to raise additional capital through issuances of debt or equity securities, which may cause our stock price to decline, dilute the ownership interests of our existing stockholders, and/or limit our financial flexibility.

Historically we have financed our operations through the issuance of equity securities and debt financings, and we expect to continue to do so for the foreseeable future. As of December 31, 2019, we had $4.9 million of cash and cash equivalents on hand. Based on our current operating plans, we believe our existing cash and cash equivalents, including the $2.75 million in gross proceeds from our March 2020 offering, are sufficient to continue to fund operations through the third quarter of calendar year 2020. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution of their ownership interests. Debt financing, if available, may involve restrictive covenants that limit our financial flexibility or otherwise restrict our ability to pursue our business strategies. Additionally, if we issue shares of common stock, or securities convertible or exchangeable for common stock, the market price of our existing common stock may decline. There can be no assurance that we will be successful in obtaining any additional capital resources in a timely manner, on favorable terms, or at all.

ITEM 1B—UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2—PROPERTIES

We own no real property. We lease our principal executive office at ONE Copley Parkway, Suite 490, Morrisville, North Carolina 27560. The current rent is approximately $9,900 per month for the facility.

ITEM 3—LEGAL PROCEEDINGS

We are subject to litigation in the normal course of business, none of which management believes will have a material adverse effect on our Consolidated Financial Statements.

ITEM 4— MINE SAFETY DISCLOSURES

Not applicable

PART II

ITEM 5—MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information and Number of Stockholders

Our common stock is listed on the Nasdaq Capital Market under the symbol "TENX."

As of March 25, 2020, there were 1,343 holders of record of our common stock. In addition, we believe that a significant number of beneficial owners of our common stock hold their shares in nominee or in "street name" accounts through brokers, and any such beneficial owners are not included in this number of holders of record.

Dividend Policy

Since our inception, we have not paid dividends on our common stock. We intend to retain any earnings for use in our business activities, so it is not expected that any dividends on our common stock will be declared and paid in the foreseeable future.

Repurchases of Common Stock

None.

Unregistered Sales of Equity Securities

During the year ended December 31, 2019, we did not issue or sell any unregistered securities not previously disclosed in a Quarterly Report on Form 10-Q or in a Current Report on Form 8-K.

ITEM 6—SELECTED FINANCIAL DATA

Not applicable.

ITEM 7—MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis together with the Consolidated Financial Statements and the related notes to those statements included in Item 8 – "Consolidated Financial Statements and Supplementary Data". This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under "Risk Factors" and elsewhere in this Annual Report on Form 10-K, our actual results may differ materially from those anticipated in these forward-looking statements.

Results of operations- Comparison of the years ended December 31, 2019 and 2018

Overview

Strategy

We are currently conducting a Phase 2 clinical trial of levosimendan in North America for the treatment of patients with pulmonary hypertension associated with heart failure with preserved ejection fraction, or PH-HFpEF. PH-HFpEF is defined hemodynamically by a pulmonary artery pressure, or mPAP, ≥25 mmHg, a pulmonary capillary wedge pressure, or PCWP, >15 mmHg, and a diastolic pressure gradient, or diastolic PAP – PCWP, >7mmHg. Pulmonary hypertension in these patients initially develops from a passive backward transmission of elevated filling pressures from left-sided heart failure. These mechanical components of pulmonary venous congestion may trigger pulmonary vasoconstriction, decreased nitric oxide availability, increased endothelin expression, desensitization to natriuretic peptide induced vasodilation, and vascular remodeling. Finally, these changes often lead to advanced pulmonary vascular disease, increased right ventricle, or RV, afterload, and RV failure.

PH-HFpEF is a common form of pulmonary hypertension with an estimated US prevalence exceeding 1.5 million patients. Currently, no pharmacologic therapies are approved for treatment of PH-HFpEF. Despite the fact that many therapies have been studied in PH-HFpEF patients, including therapies approved to treat pulmonary arterial hypertension patients, no therapies have been shown to be effective in treating PH-HFpEF patients.

Published pre-clinical and clinical studies indicate that levosimendan may provide important benefits to patients with pulmonary hypertension. Data from these published trials indicate that levosimendan may reduce pulmonary vascular resistance and improve important cardiovascular hemodynamics such as reduced pulmonary capillary wedge pressure in patients with pulmonary hypertension. While none of these studies have focused specifically on PH-HFpEF patients, the general hemodynamic improvements in these published studies of various types of pulmonary hypertension provide an indication that levosimendan may be beneficial in PH-HFpEF patients.

In March 2018, we met with the United States Food and Drug Administration, or FDA, to discuss development of levosimendan in PH-HFpEF patients. The FDA agreed with our planned Phase 2 design, patient entry criteria, and endpoints. It was agreed the study could be conducted under the existing investigational new drug application with no additional nonclinical studies required to support full development. The FDA recognized there were no approved drug therapies to treat PH-HFpEF patients and acknowledged this provided an opportunity for a limited Phase 3 clinical program. This topic will be discussed further at the End-of-Phase 2 Meeting following completion of the Phase 2 study in PH-HFpEF patients, which is known as the HELP Study – **H**emodynamic **E**valuation of **L**evosimendan in **P**H-HFpEF. We initiated the first of our expected 10-12 HELP Study clinical sites in November 2018 and the first of 36 patients was enrolled in the HELP Study in March 2019. Enrollment in the HELP Study was completed in March 2020. The primary endpoint of the HELP Study is based on change in PCWP vs baseline compared to placebo. The HELP Study utilizes a double-blind randomized design following five weekly infusions of levosimendan. The primary endpoint data will be available once the HELP Study data is unblinded.

The HELP Study design is novel in several respects. To date, no other multi-center levosimendan study has evaluated levosimendan in heart failure patients with preserved ejection fraction (HFpEF) or pulmonary hypertension patients with heart failure and preserved ejection fraction (PH-HFpEF). Instead, all previous levosimendan heart failure studies have enrolled heart failure patients with reduced ejection fraction (HFrEF), which specifically excluded HFpEF patients. Also, the HELP Study utilizes a unique 24-hour weekly infusion regimen of 0.075- 0.1µm/kg/min. Finally, the HELP Study employs a unique home-based IV infusion administration via an ambulatory infusion pump. This home-based weekly IV administration is unlike all other chronic dosing studies of levosimendan that have typically employed a shorter duration and less frequent infusion regimen administered in a hospital setting. Despite the unique patient population, weekly dosing, and home-based administration, there have been no reported serious adverse events reported for the first 30 randomized patients.

Investigator reported open-label data from the HELP Study has provided encouraging preliminary signs of efficacy during the initial lead-in infusion phase of the trial. The open-label lead-in infusion phase is designed to identify responders prior to randomization. To date, 80-85% of patients have met the lead infusion responder criteria. Analysis of investigator reported data following the 24-hour open-label levosimendan lead-in infusion for the first 30 evaluable responders indicated the following mean changes in exercise hemodynamics: PCWP of –7.5mm Hg, exercise right atrial pressure of -5.0mm Hg, mean pulmonary arterial pressure (mPAP) of -5.1 mm Hg and an increase in cardiac output of 0.6 liter/min. All of these improvements in exercise hemodynamics were found to be statistically significant via paired t-test $P<0.01$.

We believe that the combination of the unique HELP Study patient population, innovative weekly 24-hour dosing, unique home-based site of administration, and novel findings of efficacy and safety in PH-HFpEF patients represent unique discoveries and significant intellectual property. These discoveries, among others from the HELP Study, form the basis for a US patent application that we have filed.

Additionally, our Board of Directors continues to review strategic alternatives focused on maximizing stockholder value. This process may not result in any transaction and we do not intend to disclose additional details unless and until we determine further disclosure is appropriate or required.

Opportunities and Trends

The continued spread of COVID-19 globally could adversely affect our ability to recruit and retain patients, principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. Further, some patients may be unable to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services, or if the patients become infected with COVID-19 themselves, which would delay our ability to complete our phase 2 clinical trial or release clinical trial results.

As we focus on the development of our existing product candidate, we also continue to position ourselves to execute upon licensing and other partnering opportunities. To do so, we will need to continue to maintain our strategic direction, manage and deploy our available cash efficiently and strengthen our collaborative research development and partner relationships.

During 2020, we are focused on the following initiatives:

- Working with collaborators and partners to accelerate product development, reduce our development costs, and broaden our commercialization capabilities; and
- Identifying strategic alternatives, including, but not limited to, the potential acquisition of additional products or product candidates.

Financial Overview

General and Administrative Expenses

General and administrative expenses consist primarily of compensation for executive, finance, legal and administrative personnel, including stock-based compensation. Other general and administrative expenses include facility costs not otherwise included in research and development expenses, legal and accounting services, other professional services, and consulting fees. General and administrative expenses and percentage changes for the years ended December 31, 2019 and 2018, respectively, are as follows:

	For the year ended December 31,		Increase/	% Increase/
	2019	2018	(Decrease)	(Decrease)
Personnel costs	$ 2,782,798	$ 3,473,068	$ (690,270)	(20)%
Legal and professional fees	1,545,890	1,386,299	159,591	12%
Other costs	602,611	650,513	(47,902)	(7)%
Facilities	152,812	144,100	8,712	6%

Personnel costs:

Personnel costs decreased approximately $690,000 for the year ended December 31, 2019 compared to the prior year. This decrease was due primarily to a reduction of approximately $473,000 in bonuses paid in the prior year that were not incurred in the current year as well as a reduction of approximately $386,000 for the vested value of stock-based compensation in the current year as compared to the prior year, partially offset by an increase of approximately $169,000 in salaries and benefits paid due primarily to the salary of the CEO not incurred in the prior year.

Legal and professional fees:

Legal and professional fees consist of the costs incurred for legal fees, accounting fees, recruiting costs, consulting fees and investor relations services, as well as fees paid to our Board of Directors. Legal and professional fees increased approximately $160,000 for the year ended December 31, 2019 compared to the prior year. This increase was due primarily to increases in costs incurred for legal fees and investor relations services, partially offset by a reduction in consulting costs, accounting fees, and Board of Directors costs.

- Legal fees increased approximately $227,000 in the current year as compared to the prior year. This increase was due primarily to approximately $273,000 in costs incurred for arbitration in the current year that were not incurred in the prior year, partially offset by a reduction in fees paid for filings associated with our Special Meeting of Stockholders and registration statements in the prior year that were not incurred in the current year.
- Investor relations costs increased approximately $146,000 in the current year as compared to the prior year. This increase was primarily due to fees paid to a third-party investor relations firm in the current year that was not engaged during the prior year as well as fees paid for communication and shareholder outreach efforts in the current year that were not incurred in the prior year.
- Accounting fees decreased approximately $24,000 in the current year as compared to the prior year. This decrease was due primarily to the costs incurred for the filings associated with our registration statements in the prior year that were not incurred in the current year.
- Consulting costs decreased approximately $85,000 in the current year as compared to the prior year. This decrease was due primarily to recruiting costs of approximately $28,000, approximately $39,000 in costs associated with market research and approximately $18,000 in payments to our scientific advisory board members in the prior year which were not incurred in the current year.
- Capital market expenses decreased approximately $71,000 in the current year as compared to the prior year. This decrease was due primarily to the Special Meeting of Shareholders and the costs associated with the proxy solicitation services in the prior year that were not incurred in the current year.
- Board of Directors fees decreased approximately $34,000 in the current year as compared to the prior year. This decrease was due primarily the transition of a director to CEO and a reduction in the recognized expense for the vesting of outstanding stock options in the current year as compared to the prior year.

Other costs:

Other costs include costs incurred for franchise and other taxes, travel, supplies, insurance, depreciation and other miscellaneous charges. The approximately $48,000 decrease in other costs for the current year as compared to the prior year was due primarily to decreases of approximately $34,000 in travel costs, approximately $30,000 in relocation costs and approximately $20,000 for bank fees in the current year as compared to the prior year, partially offset by an increase of approximately $19,000 in franchise taxes paid and general increases in costs incurred for information technology and other miscellaneous expenses in the current year as compared to the prior year.

Facilities:

Facilities expenses include costs paid for rent and utilities at our corporate headquarters in North Carolina. Facilities costs remained relatively consistent for the years ended December 31, 2019 and 2018.

Research and Development Expenses

Research and development expenses include, but are not limited to, (i) expenses incurred under agreements with CROs and investigative sites, which conduct our clinical trials and a substantial portion of our pre-clinical studies; (ii) the cost of supplying clinical trial materials; (iii) payments to contract service organizations, as well as consultants; (iv) employee-related expenses, which include salaries and benefits; and (v) facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, depreciation of leasehold improvements, equipment, and other supplies. All research and development expenses are expensed as incurred. Research and development expenses and percentage changes for the years ended December 31, 2019 and 2018, respectively, are as follows:

	For the year ended December 31,		Increase/	% Increase/
	2019	2018	(Decrease)	(Decrease)
Clinical and preclinical development	$ 3,217,596	$ 1,022,035	$ 2,195,561	215%
Personnel costs	215,907	193,036	22,871	12%
Other costs	21,050	17,295	3,755	22%
Consulting	16,600	6,934	9,666	139%

Clinical and preclinical development:

Clinical and preclinical development costs include, primarily, the costs associated with our Phase 2 HELP Study for levosimendan, which was initiated during fiscal year 2018. The increase of approximately $2.2 million in clinical and preclinical development costs for the year ended December 31, 2019 compared to the prior year was primarily due to an increase of approximately $875,000 in expenditures for CRO costs and clinical research associates to manage the Phase 2 HELP Study, as well as an increase of approximately $1.4 million in the direct costs associated with clinical site activations and enrolled patient costs, partially offset by a decrease of approximately $82,000 in formulation development incurred in the prior year that was not incurred in the current year.

Personnel costs:

Personnel costs increased approximately $23,000 for the year ended December 31, 2019 primarily due to an increase in headcount in the current year as compared to the prior year.

Other costs:

Other costs remained relatively consistent for the years ended December 31, 2019 and 2018.

Consulting fees:

Consulting fees remained relatively consistent for the years ended December 31, 2019 and 2018.

Other income, net

Other income and expense include non-operating income and expense items not otherwise recorded in our consolidated statement of comprehensive loss. These items include, but are not limited to, changes in the fair value of financial assets and derivative liabilities, interest income earned and fixed asset disposals. Other income for the years ended December 31, 2019 and 2018, respectively, is as follows:

	For the year ended December 31,		(Increase)/
	2019	2018	Decrease
Other income, net	$ (160,901)	$ (79,835)	$ (81,066)

Other income increased approximately $81,000 for the year ended December 31, 2019 compared to the prior year. This increase is due primarily to an increase in the interest earned on our investment in marketable securities.

During the year ended December 31, 2019, we recorded interest income of approximately $146,000 from our investments in marketable securities. This income is derived from approximately $144,000 in bond interest paid and approximately $2,000 in fair-value adjustments for the year, which compares to approximately $171,000 in bond interest paid, partially offset by approximately $91,000 in charges for amortization of premiums paid and fair-value adjustments during the prior year.

Liquidity, capital resources and plan of operation

We have incurred losses since our inception and as of December 31, 2019, we had an accumulated deficit of approximately $236 million. We will continue to incur losses until we generate sufficient revenue to offset our expenses, and we anticipate that we will continue to incur net losses for at least the next several years. We expect to incur additional expenses related to our development and potential commercialization of levosimendan for pulmonary hypertension and other potential indications, as well as identifying and developing other potential product candidates, and as a result, we will need to generate significant net product sales, royalty and other revenues to achieve profitability.

Liquidity

We have financed our operations since September 1990 through the issuance of debt and equity securities and loans from stockholders. We had total current assets of $6,180,829 and $13,320,240 and working capital of $3,648,434 and $11,754,571 as of December 31, 2019 and December 31, 2018, respectively. Our practice is to invest excess cash, where available, in short-term money market investment instruments and high quality corporate and government bonds.

Clinical and Preclinical Product Development

We are currently conducting a Phase 2 clinical trial of levosimendan in North America for the treatment of pulmonary hypertension. Our ability to continue to pursue development of our product beyond the third quarter of calendar year 2020 will depend on obtaining license income or outside financial resources. There is no assurance that we will obtain any license agreement or outside financing or that we will otherwise succeed in obtaining any necessary resources.

The continued spread of COVID-19 globally could adversely affect our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. Further, some patients may be unable to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services, or if the patients become infected with COVID-19 themselves, which would delay our ability to complete our clinical trials or release clinical trial results. See ITEM 1A – RISK FACTORS above for additional discussion.

Financings

On March 11, 2020, we entered into a definitive agreement with a single healthcare-focused institutional investor for the issuance and sale of 750,000 shares of our common stock at a purchase price of $1.1651 per share and pre-funded warrants to purchase up to 1,610,313 shares of common stock, at a purchase price of $1.1650 per pre-funded warrant (which represents the per share offering price for the common stock less $0.0001, the exercise price of each pre-funded warrant), for gross proceeds of approximately $2.75 million, in a registered direct offering priced at-the-market under Nasdaq rules. Additionally, in a concurrent private placement, we also agreed to issue to the investor unregistered warrants to purchase up to 2,360,313 shares of common stock. The unregistered warrants have an exercise price of $1.04 per share and exercise period commencing immediately upon the issuance date and a term of five and one-half years. The offering closed on March 13, 2020.

We agreed to pay H.C. Wainwright & Co., LLC, or the Placement Agent, a cash fee equal to 7.5% of the gross proceeds of the March 2020 offering, totaling approximately $206,250. We also agreed to pay the Placement Agent $75,000 for non-accountable expenses, a management fee equal to 1.0% of the gross proceeds and up to $12,900 for clearing fees. In addition, we issued designees of the Placement Agent warrants to purchase 177,023 shares of common stock (representing 7.5% of the aggregate number of shares of common stock (or common stock equivalents) sold in the March 2020 offering). The Placement Agent warrants have substantially the same terms as the unregistered warrants, except that the Placement Agent warrants have an exercise price equal to $1.4564, or 125% of the offering price per share of common stock, and will be exercisable for five years from the effective date of the March 2020 offering.

The shares of common stock and pre-funded warrants offered in the registered direct offering (including the shares of common stock underlying the pre-funded warrants) were offered and sold pursuant to a "shelf" registration statement on Form S-3, which was declared effective by the Securities and Exchange Commission (SEC) on May 23, 2018. The unregistered warrants described above were offered in a private placement under Section 4(a)(2) of the Securities Act, and Regulation D promulgated thereunder and, along with the shares of common stock underlying the warrants, have not been registered under the Securities Act, or applicable state securities laws. The net proceeds from the March 2020 offering, after deducting placement agent fees and other direct offering expenses, were approximately $2.125 million. We intend to use the net proceeds to further our clinical trials of levosimendan, for research and development and general corporate purposes, including working capital and potential acquisitions.

On December 7, 2018, we entered into an underwriting agreement with Ladenburg Thalmann & Co. Inc., or the Underwriter, pursuant to which we agreed to issue and sell 5,181,346 units, or the Units, with each Unit consisting of (a) one share of Series A convertible preferred stock, par value $0.0001 per share, or the Series A Preferred Stock, (b) a two-year warrant to purchase one share of common stock, exercisable at a price of $1.93, or the Series 1 Warrants, and (c) a five-year warrant to purchase one share of common stock, exercisable at a price of $1.93, or the Series 2 Warrants, with each Unit to be offered at an offering price of $1.93 per Unit. The initial conversion price of the Series A Preferred Stock is $1.93 per share. We agreed to pay the Underwriter an aggregate fee equal to 8.0% of the gross proceeds received in the offering and to reimburse the Underwriter for up to $95,000 of expenses incurred by the Underwriter in connection with the offering. The offering closed on December 11, 2018.

We offered the Units pursuant to a registration statement on Form S-1, which was declared effective by the SEC on December 7, 2018.

The net proceeds from the offering, after deducting Underwriter fees and other direct offering expenses was approximately $9 million. We have been using the net proceeds to further our clinical trials and efforts to obtain regulatory approval of levosimendan, for research and development and for general corporate purposes, including working capital and potential acquisitions.

We have an effective shelf registration statement on Form S-3 on file with the SEC that allows us to periodically offer and sell, individually or in any combination, shares of common stock, shares of preferred stock, debt securities, warrants to purchase shares of common stock or preferred stock or debt securities, and units consisting of any combination of the foregoing types of securities, up to a total of $75.0 million (of which approximately $72.3 million remains available), but not to exceed one-third of our public float in any 12-month period. As of March 25, 2020, our public float (which is the aggregate market value of our outstanding common stock held by non-affiliates) is $4.1 million. Our ability to issue securities under the shelf registration statement is also subject to market conditions.

Cash Flows

The following table shows a summary of our cash flows for the periods indicated:

	For the year ended December 31,	
	2019	2018
Net cash used in operating activities	$ (7,556,177)	$ (5,499,461)
Net cash (used in) provided by investing activities	(1,651)	7,354,798
Net cash provided by financing activities	96,500	8,907,174

Net cash used in operating activities. Net cash used in operating activities was approximately $7.6 million for the year ended December 31, 2019 compared to net cash used in operating activities of approximately $5.5 million for the year ended December 31, 2018. The increase in cash used for operating activities was due primarily to an increase in our accrued costs related to the Phase 2 clinical trial for levosimendan in the current period.

Net cash (used in) provided by investing activities. Net cash used in investing activities was approximately $2,000 for the year ended December 31, 2019 compared to approximately $7.4 million provided for the year ended December 31, 2018. The decrease in cash provided by investing activities was primarily due to a decrease in the sale of marketable securities in the current period.

Net cash provided by financing activities. Net cash provided by financing activities was approximately $97,000 for the year ended December 31, 2019 compared to approximately $9 million for the year ended December 31, 2018. The decrease in cash provided by financing activities resulted from the closing of the offering of Series A Preferred Stock, the Series 1 Warrants and the Series 2 Warrants in the prior year compared to an exercise of warrants in the current year.

Operating Capital and Capital Expenditure Requirements

Our future capital requirements will depend on many factors that include, but are not limited to the following:

- the initiation, progress, timing and completion of clinical trials for our product candidate and potential product candidates;
- the outcome, timing and cost of regulatory approvals and the regulatory approval process;
- delays that may be caused by the global coronavirus pandemic. The continued spread of COVID-19 globally could adversely affect our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. Further, some patients may be unable to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services, or if the patients become infected with COVID-19 themselves, which would delay our ability to complete our phase 2 clinical trial or release clinical trial results;
- delays that may be caused by changing regulatory requirements;
- the number of product candidates that we pursue;
- the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims;
- the timing and terms of future collaboration, licensing, consulting or other arrangements that we may enter into;
- the cost and timing of establishing sales, marketing, manufacturing and distribution capabilities;
- the cost of procuring clinical and commercial supplies of our product candidates;
- the extent to which we acquire or invest in businesses, products or technologies; and
- the possible costs of litigation.

Based on our working capital at December 31, 2019 and the net proceeds from our March 2020 offering, we believe we have sufficient capital on hand to continue to fund operations through the third quarter of calendar year 2020.

We will need substantial additional capital in the future in order to complete the regulatory approval and commercialization of levosimendan and to fund the development and commercialization of other future product candidates. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Such funding, if needed, may not be available on favorable terms, if at all. In the event we are unable to obtain additional capital, we may delay or reduce the scope of our current research and development programs and other expenses. As a result of our historical operating losses and expected future negative cash flows from operations, we have concluded that there is substantial doubt about our ability to continue as a going concern. Similarly, the report of our independent registered public accounting firm on our December 31, 2019 Consolidated Financial Statements includes an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern. Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock and make it more difficult to obtain financing.

If adequate funds are not available, we may also be required to eliminate one or more of our clinical trials, delaying approval of levosimendan or our commercialization efforts. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional significant dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates or grant licenses on terms that may not be favorable to us. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. We may also consider strategic alternatives, including a sale of our company, merger, other business combination or recapitalization.

Off-Balance Sheet Arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities.

Summary of Critical Accounting Policies

Use of Estimates—The preparation of the accompanying Consolidated Financial Statements in conformity with accounting principles generally accepted in the United States of America, or GAAP, requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the Consolidated Financial Statements and reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Preclinical Study and Clinical Accruals—We estimate our preclinical study and clinical trial expenses based on the services received pursuant to contracts with several research institutions and CROs that conduct and manage preclinical and clinical trials on our behalf. The financial terms of the agreements vary from contract to contract and may result in uneven expenses and payment flows. Preclinical study and clinical trial expenses include the following:

- fees paid to CROs in connection with clinical trials;
- fees paid to research institutions in conjunction with preclinical research studies; and
- fees paid to contract manufacturers and service providers in connection with the production and testing of active pharmaceutical ingredients and drug materials for use in preclinical studies and clinical trials.

Stock-Based Compensation—We account for stock-based awards to employees in accordance with Accounting Standards Codification, or ASC, 718, Compensation — Stock Compensation, which provides for the use of the fair value-based method to determine compensation for all arrangements where shares of stock or equity instruments are issued for compensation. Fair values of equity securities are determined by management based predominantly on the trading price of our common stock. The values of these awards are based upon their grant-date fair value. That cost is recognized over the period during which the employee is required to provide service in exchange for the reward.

We account for equity instruments issued to non-employees in accordance with ASC 505-50, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services. Equity instruments issued to non-employees are recorded at their fair value on the measurement date and are subject to periodic adjustment as the underlying equity instruments vest.

Recent Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board (“FASB”) issued an accounting standard intended to simplify accounting for income taxes. It removes certain exceptions to the general principles in Topic 740, Income Taxes and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020 and early adoption is permitted. We are currently evaluating this standard, but we do not believe the adoption of the new guidance will have a material impact on our consolidated financial statements.

In February 2016, the FASB issued an accounting standard intended to improve financial reporting regarding leasing transactions. The standard requires us to recognize on our balance sheet the assets and liabilities for the rights and obligations created by all leased assets. The standard also requires us to provide enhanced disclosures designed to enable users of financial statements to understand the amount, timing, and uncertainty of cash flows arising from all leases, operating and capital, with lease terms greater than 12 months. The standard was effective for financial statements beginning after December 15, 2018, and interim periods within those annual periods. Early adoption was permitted.

We adopted this standard on January 1, 2019, using the required modified-retrospective approach as of the effective date. We elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allows us to carryforward the historical lease classification. We made an accounting policy election to account for leases with an initial term of 12 months or less similar to previous guidance for operating leases, under which we recognize those lease payments in the consolidated statements of operations and comprehensive loss on a straight-line basis over the lease term. Results for the year ended December 31, 2018 continue to be reported in accordance with historical accounting under previous lease guidance, the ASC Topic 840, Leases.

In June 2016, the FASB issued an accounting standard that amends how credit losses are measured and reported for certain financial instruments that are not accounted for at fair value through net income. This standard requires that credit losses be presented as an allowance rather than as a write-down for available-for-sale debt securities and will be effective for interim and annual reporting periods beginning January 1, 2023, with early adoption permitted. A modified retrospective approach is to be used for certain parts of this guidance, while other parts of the guidance are to be applied using a prospective approach. We do not believe the adoption of this standard will have a material impact on our consolidated financial statements and related disclosures.

ITEM 7A—QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8—CONSOLIDATED FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

TENAX THERAPEUTICS, INC.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders
Tenax Therapeutics, Inc.
Raleigh, North Carolina

Opinion on the Financial Statements
We have audited the accompanying consolidated balance sheets of Tenax Therapeutics, Inc. and Subsidiary (the "Company") as of December 31, 2019 and 2018, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2019, 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 as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty
The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note A and Note B to the financial statements, the Company has suffered recurring losses from operations and negative cash flows from operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans concerning these matters are described in Note A and Note B to the financial statements. 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 audits 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.

/s/ Cherry Bekaert LLP

We have served as the Company's auditor since 2009.

Raleigh, North Carolina
March 30, 2020

TENAX THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2019	December 31, 2018
ASSETS		
Current assets		
Cash and cash equivalents	$ 4,905,993	$ 12,367,321
Marketable securities	493,884	494,633
Prepaid expenses	780,952	458,286
Total current assets	6,180,829	13,320,240
Right of use asset	169,448	-
Property and equipment, net	6,559	8,525
Other assets	8,435	8,435
Total assets	$ 6,365,271	$ 13,337,200
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,661,054	$ 749,814
Accrued liabilities	871,341	815,855
Total current liabilities	2,532,395	1,565,669
Lease liability	60,379	-
Total liabilities	2,592,774	1,565,669
Commitments and contingencies; see Note E		
Stockholders' equity		
Preferred stock, undesignated, authorized 4,818,654 shares; See Note D		
Series A Preferred stock, par value $.0001, issued 5,181,346 shares; outstanding 38,606 and 2,854,593, respectively	4	285
Common stock, par value $.0001 per share; authorized 400,000,000 shares; issued and outstanding 6,741,860 and 3,792,249, respectively	674	379
Additional paid-in capital	239,939,797	239,572,094
Accumulated other comprehensive gain	458	516
Accumulated deficit	(236,168,436)	(227,801,743)
Total stockholders' equity	3,772,497	11,771,531
Total liabilities and stockholders' equity	$ 6,365,271	$ 13,337,200

The accompanying notes are an integral part of these Consolidated Financial Statements

TENAX THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Year ended December 31,	
	2019	**2018**
Operating expenses		
General and administrative	$ 5,084,111	$ 5,653,980
Research and development	3,471,153	1,239,300
Total operating expenses	8,555,264	6,893,280
Net operating loss	8,555,264	6,893,280
Other income, net	(160,901)	(79,835)
Deemed dividend on preferred stock	-	7,330,604
Net loss	$ 8,394,363	$ 14,144,049
Unrealized loss (gain) on marketable securities	58	(16,709)
Total comprehensive loss	$ 8,394,421	$ 14,127,340
Net loss per share, basic and diluted	$ (1.35)	$ (9.04)
Weighted average number of common shares outstanding, basic and diluted	6,195,444	1,564,773

The accompanying notes are an integral part of these Consolidated Financial Statements

TENAX THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Preferred Stock		Common Stock		Additional	Accumulated other comprehensive		Total
	Number of Shares	Amount	Number of Shares	Amount	paid-in capital	gain (loss)	Accumulated deficit	stockholders' equity
Balance at December 31, 2017	**-**	**$ -**	**1,411,840**	**$ 141**	**$ 222,397,198**	**$ (16,193)**	**$ (213,499,285)**	**$ 8,881,861**
Preferred stock sold, net of offering costs	5,181,346	518			8,906,656			8,907,174
Common stock issued for convertible preferred stock	(2,326,753)	(233)	2,326,753	233				-
Compensation on options and restricted stock issued			37,420	4	645,193			645,197
Common stock issued for services rendered			10,241	1	100,361			100,362
Deemed dividend on preferred stock					7,330,604			7,330,604
Unrealized gain on marketable securities						16,709		16,709
Fractional shares of common stock due to reverse stock split			5,995					-
Adoption of ASU 2017-11: Reclassification of equity related financial instruments					192,082		(158,409)	33,673
Net loss							(14,144,049)	(14,144,049)
Balance at December 31, 2018	**2,854,593**	**$ 285**	**3,792,249**	**$ 379**	**$ 239,572,094**	**$ 516**	**$ (227,801,743)**	**$ 11,771,531**
Compensation on options and restricted stock issued			12,195	1	171,215			171,216
Common stock issued for services rendered			71,429	7	99,993			100,000
Common stock issued for convertible preferred stock	(2,815,987)	(281)	2,815,987	282				1
Exercise of warrants			50,000	5	96,495			96,500
Adoption of ASC Topic 842: Leases							27,670	27,670
Unrealized loss on marketable securities						(58)		(58)
Net loss							(8,394,363)	(8,394,363)
Balance at December 31, 2019	**38,606**	**$ 4**	**6,741,860**	**$ 674**	**$ 239,939,797**	**$ 458**	**$ (236,168,436)**	**$ 3,772,497**

The accompanying notes are an integral part of these Consolidated Financial Statements

TENAX THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,	
	2019	**2018**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (8,394,363)	$ (14,144,049)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	5,017	9,016
Amortization of right of use asset	102,262	-
Loss (gain) on disposal of property and equipment	522	-
Issuance and vesting of compensatory stock options and warrants	171,216	316,260
Issuance of common stock as compensation	-	190,083
Issuance of common stock for services rendered	100,000	100,362
Deemed dividend on preferred stock	-	7,330,604
Amortization of premium on marketable securities	(1,230)	91,511
Changes in operating assets and liabilities		
Accounts receivable, prepaid expenses and other assets	(322,666)	(122,605)
Accounts payable and accrued liabilities	883,042	729,357
Long term portion of lease liability	(99,977)	-
Net cash used in operating activities	(7,556,177)	(5,499,461)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of marketable securities	(618,100)	(493,822)
Sale of marketable securities	620,023	7,856,215
Purchase of property and equipment	(3,574)	(7,595)
Net cash (used in) provided by investing activities	(1,651)	7,354,798
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from the exercise of warrants	96,500	-
Proceeds for issuance of convertible preferred stock, net of issuance costs	-	8,907,174
Net cash provided by financing activities	96,500	8,907,174
Net change in cash and cash equivalents	(7,461,328)	10,762,511
Cash and cash equivalents, beginning of period	12,367,321	1,604,810
Cash and cash equivalents, end of period	$ 4,905,993	$ 12,367,321
Non-cash financing activity		
Adoption of ASU 2017-11: Reclassification of equity related financial instruments	$ -	$ 33,673

The accompanying notes are an integral part of these Consolidated Financial Statements

NOTE A—DESCRIPTION OF BUSINESS

Description of Business—Tenax Therapeutics, Inc. (the "Company") was originally formed as a New Jersey corporation in 1967 under the name Rudmer, David & Associates, Inc., and subsequently changed its name to Synthetic Blood International, Inc. On June 17, 2008, the stockholders of Synthetic Blood International approved the Agreement and Plan of Merger dated April 28, 2008, between Synthetic Blood International and Oxygen Biotherapeutics, Inc., a Delaware corporation. Oxygen Biotherapeutics was formed on April 17, 2008, by Synthetic Blood International to participate in the merger for the purpose of changing the state of domicile of Synthetic Blood International from New Jersey to Delaware. Certificates of Merger were filed with the states of New Jersey and Delaware, and the merger was effective June 30, 2008. Under the Plan of Merger, Oxygen Biotherapeutics was the surviving corporation and each share of Synthetic Blood International common stock outstanding on June 30, 2008 was converted to one share of Oxygen Biotherapeutics common stock. On September 19, 2014, the Company changed its name to Tenax Therapeutics, Inc.

On October 18, 2013, the Company created a wholly owned subsidiary, Life Newco, Inc., a Delaware corporation ("Life Newco"), to acquire certain assets of Phyxius Pharma, Inc., a Delaware corporation ("Phyxius"), pursuant to an Asset Purchase Agreement, dated October 21, 2013 (the "Asset Purchase Agreement"), by and among the Company, Life Newco, Phyxius and the stockholders of Phyxius (the "Phyxius Stockholders"). On November 13, 2013, under the terms and subject to the conditions of the Asset Purchase Agreement, Life Newco acquired certain assets, including a license granting Life Newco an exclusive, sublicenseable right to develop and commercialize pharmaceutical products containing levosimendan, 2.5 mg/ml concentrate for solution for infusion / 5ml vial in the United States and Canada.

Reverse Stock Split

The Company initiated a 1-for-20 reverse stock split effective February 23, 2018 at 5:00 p.m. All shares and per share amounts in these Consolidated Financial Statements and notes thereto have been retroactively adjusted to give effect to the reverse stock split.

Going Concern

Management believes the accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"), which contemplate continuation of the Company as a going concern. The Company has an accumulated deficit of $236,168,436 and $227,801,743 at December 31, 2019 and 2018, respectively, and used cash in operations of $7,556,177 and $5,499,461 during the years ended December 31, 2019 and 2018, respectively. The Company requires substantial additional funds to complete clinical trials and pursue regulatory approvals. Management is actively seeking additional sources of equity and/or debt financing; however, there is no assurance that any additional funding will be available.

In view of the matters described above, recoverability of a major portion of the recorded asset amounts shown in the accompanying December 31, 2019 balance sheet is dependent upon continued operations of the Company, which in turn is dependent upon the Company's ability to meet its financing requirements on a continuing basis, to maintain present financing, and to generate cash from future operations. These factors, among others, raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence.

NOTE B—SUMMARY OF CRITICAL ACCOUNTING POLICIES

Use of Estimates

The preparation of the accompanying consolidated financial statements in conformity with GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

On an ongoing basis, management reviews its estimates to ensure that these estimates appropriately reflect changes in the Company's business and new information as it becomes available. If historical experience and other factors used by management to make these estimates do not reasonably reflect future activity, the Company's results of operations and financial position could be materially impacted.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts and transactions of Tenax Therapeutics, Inc. and Life Newco, Inc. All material intercompany transactions and balances have been eliminated in consolidation.

Cash and Cash Equivalents

The Company considers all highly liquid instruments with a maturity date of three months or less, when acquired, to be cash equivalents.

Cash Concentration Risk

The Federal Deposit Insurance Corporation (the "FDIC") insurance limits are $250,000 per depositor per insured bank. The Company had cash balances of $4,533,976 and $11,876,765 uninsured by the FDIC as of December 31, 2019 and 2018, respectively.

Liquidity and Capital Resources

The Company has financed its operations since September 1990 through the issuance of debt and equity securities and loans from stockholders. The Company had total current assets of $6,180,829 and $13,320,240 and working capital of $3,648,434 and $11,754,571 as of December 31, 2019 and 2018, respectively.

Cash resources, including the fair value of the Company's available for sale marketable securities as of December 31, 2019 were approximately $5.4 million, compared to approximately $12.9 million as of December 31, 2018.

The Company expects to continue to incur expenses related to development of levosimendan for pulmonary hypertension and other potential indications, as well as identifying and developing other potential product candidates. Based on its resources at December 31, 2019, and including the net proceeds from its March 2020 offering, the Company believes that it has sufficient capital to fund its planned operations through the third quarter of calendar year 2020. However, the Company will need substantial additional financing in order to fund its operations beyond such period and thereafter until it can achieve profitability, if ever. The Company depends on its ability to raise additional funds through various potential sources, such as equity and debt financing, or to license its product candidates to another pharmaceutical company. The Company will continue to fund operations from cash on hand and through sources of capital similar to those previously described. The Company cannot assure that it will be able to secure such additional financing, or if available, that it will be sufficient to meet its needs.

The continued spread of COVID-19 globally could adversely affect the Company's clinical trial operations, including its ability to recruit and retain patients, principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. Further, some patients may be unable to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services, or if the patients become infected with COVID-19 themselves, which would delay the Company's ability to complete its phase 2 clinical trial or release its clinical trial results.

To the extent that the Company raises additional funds by issuing shares of its common stock or other securities convertible or exchangeable for shares of common stock, stockholders will experience dilution, which may be significant. In the event the Company raises additional capital through debt financings, the Company may incur significant interest expense and become subject to covenants in the related transaction documentation that may affect the manner in which the Company conducts its business. To the extent that the Company raises additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to its technologies or product candidates or grant licenses on terms that may not be favorable to the Company.

Any or all of the foregoing may have a material adverse effect on the Company's business and financial performance.

Deferred financing costs

Deferred financing costs represent legal, due diligence and other direct costs incurred to raise capital or obtain debt. Direct costs include only "out-of-pocket" or incremental costs directly related to the effort, such as a finder's fee and accounting and legal fees. These costs will be capitalized if the efforts are successful or expensed when unsuccessful. Indirect costs are expensed as incurred. Deferred financing costs related to debt are amortized over the life of the debt. Deferred financing costs related to issuing equity are charged to Additional Paid-in Capital.

Derivative financial instruments

The Company does not use derivative instruments to hedge exposures to cash flow, market or foreign currency risk. Terms of convertible promissory note instruments and other convertible equity instruments are reviewed to determine whether or not they contain embedded derivative instruments that are required under Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 815, Derivatives and Hedging ("ASC 815") to be accounted for separately from the host contract and recorded on the balance sheet at fair value. The fair value of derivative liabilities, if any, is required to be revalued at each reporting date, with corresponding changes in fair value recorded in current period operating results.

Freestanding warrants issued by the Company in connection with the issuance or sale of debt and equity instruments are considered to be derivative instruments and are evaluated and accounted for in accordance with the provisions of ASC 815.

Preclinical Study and Clinical Accruals

The Company estimates its preclinical study and clinical trial expenses based on the services received pursuant to contracts with several research institutions and contract research organizations ("CROs") that conduct and manage preclinical and clinical trials on its behalf. The financial terms of the agreements vary from contract to contract and may result in uneven expenses and payment flows. Preclinical study and clinical trial expenses include the following:

- fees paid to CROs in connection with clinical trials,
- fees paid to research institutions in conjunction with preclinical research studies, and
- fees paid to contract manufacturers and service providers in connection with the production and testing of active pharmaceutical ingredients and drug materials for use in preclinical studies and clinical trials.

Property and Equipment, Net

Property and equipment are stated at cost, subject to adjustments for impairment, less accumulated depreciation and amortization. Depreciation and amortization are computed using the straight-line method over the following estimated useful lives:

Laboratory equipment	3 – 5 years
Office equipment	5 years
Office furniture and fixtures	7 years
Computer equipment and software	3 years
Leasehold improvements	Shorter of useful life or remaining lease term

Maintenance and repairs are charged to expense as incurred, and improvements to leased facilities and equipment are capitalized.

Research and Development Costs

Research and development costs include, but are not limited to, (i) expenses incurred under agreements with CROs and investigative sites, which conduct our clinical trials; (ii) the cost of supplying clinical trial materials; (iii) payments to contract service organizations, as well as consultants; (iv) employee-related expenses, which include salaries and benefits; and (v) depreciation and other allocated expenses, which include direct and allocated expenses for equipment, laboratory and other supplies. All research and development expenses are expensed as incurred.

Income Taxes

Deferred tax assets and liabilities are recorded for differences between the financial statement and tax bases of the assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized. Income tax expense is recorded for the amount of income tax payable or refundable for the period increased or decreased by the change in deferred tax assets and liabilities during the period.

Stock-Based Compensation

The Company accounts for stock-based awards to employees in accordance with ASC 718, Compensation — Stock Compensation, which provides for the use of the fair value-based method to determine compensation for all arrangements where shares of stock or equity instruments are issued for compensation. Fair values of equity securities are determined by management based predominantly on the trading price of the Company's common stock. The values of these awards are based upon their grant-date fair value. That cost is recognized over the period during which the employee is required to provide service in exchange for the reward.

The Company accounts for equity instruments issued to non-employees in accordance with ASC 505-50, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services. Equity instruments issued to non-employees are recorded at their fair value on the measurement date and are subject to periodic adjustment as the underlying equity instruments vest.

Loss Per Share

Basic loss per share, which excludes antidilutive securities, is computed by dividing net loss by the weighted-average number of common shares outstanding for that particular period. In contrast, diluted loss per share considers the potential dilution that could occur from other equity instruments that would increase the total number of outstanding shares of common stock. Such amounts include shares potentially issuable under outstanding options, restricted stock and warrants.

The following outstanding options, restricted stock grants, convertible preferred shares and warrants were excluded from the computation of basic and diluted net loss per share for the periods presented because including them would have had an anti-dilutive effect.

	Year ended December 31,	
	2019	**2018**
Warrants to purchase common stock	10,519,945	10,690,718
Options to purchase common stock	244,206	241,735
Convertible preferred shares outstanding	38,606	2,854,593
Restricted stock grants	-	19,914

Operating Leases

The Company determines if an arrangement includes a lease at inception. Operating leases are included in operating lease right-of-use assets, other current liabilities, and long-term lease liabilities in the Company's consolidated balance sheet as of December 31, 2019. Right-of-use assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the net present value of lease payments, the Company uses the incremental borrowing rate based on the information available at the lease commencement date. The operating lease right-of-use assets also include any lease payments made and exclude lease incentives. The Company's leases may include options to extend or terminate the lease which are included in the lease term when it is reasonably certain that the Company will exercise any such option. Lease expense is recognized on a straight-line basis over the expected lease term. The Company has elected to account for leases with an initial term of 12 months or less similar to previous guidance for operating leases, under which the Company will recognize those lease payments in the consolidated statements of operations and comprehensive loss on a straight-line basis over the lease term.

Prior period amounts continue to be reported in accordance with the Company's historic accounting under previous lease guidance, see "Recent Accounting Pronouncements" below, for more information about the impact of the adoption of the new lease standard.

Recent Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board ("FASB") issued an accounting standard intended to simplify accounting for income taxes. It removes certain exceptions to the general principles in Topic 740, Income Taxes and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020 and early adoption is permitted. The Company is currently evaluating this standard, but it does not believe the adoption of the new guidance will have a material impact on its consolidated financial statements.

In June 2016, the FASB issued an accounting standard that amends how credit losses are measured and reported for certain financial instruments that are not accounted for at fair value through net income. This standard requires that credit losses be presented as an allowance rather than as a write-down for available-for-sale debt securities and will be effective for interim and annual reporting periods beginning January 1, 2023, with early adoption permitted. A modified retrospective approach is to be used for certain parts of this guidance, while other parts of the guidance are to be applied using a prospective approach. The Company does not believe the adoption of this standard will have a material impact on its consolidated financial statements and related disclosures.

In February 2016, the FASB issued an accounting standard intended to improve financial reporting regarding leasing transactions. The standard requires the Company to recognize on its balance sheet the assets and liabilities for the rights and obligations created by all leased assets. The standard also requires it to provide enhanced disclosures designed to enable users of financial statements to understand the amount, timing, and uncertainty of cash flows arising from all leases, operating and capital, with lease terms greater than 12 months. The standard was effective for financial statements beginning after December 15, 2018, and interim periods within those annual periods. Early adoption was permitted.

The Company adopted this standard on January 1, 2019, using the required modified-retrospective approach as of the effective date. The Company elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allows it to carryforward the historical lease classification. The Company made an accounting policy election to account for leases with an initial term of 12 months or less similar to previous guidance for operating leases, under which the Company recognizes those lease payments in the consolidated statements of operations and comprehensive loss on a straight-line basis over the lease term. Results for the year ended December 31, 2018 continue to be reported in accordance with historical accounting under previous lease guidance, ASC Topic 840, Leases.

The Company recorded a net reduction of $27,670 to opening accumulated deficit as of January 1, 2019, due to the cumulative impact of adopting the new leasing standard, with the impact relating to a change in the classification of the Company's office space. The adoption of the lease standard did not have a material impact on the Company's condensed consolidated balance sheets. The table below summarizes the impact of adopting the new standard on its condensed consolidated balance sheet as of January 1, 2019.

	As Previously Reported	New Lease Standard Adjustment	As Adjusted
Operating lease right-of-use asset	$ -	$ 271,710	$ 271,710
Operating lease liabilites	$ -	$ 271,710	$ 271,710
Deferred lease liabilities	$ 27,670	$ (27,670)	$ -

Fair Value

The Company determines the fair value of its financial assets and liabilities in accordance with the ASC 820, Fair Value Measurements. The Company's balance sheet includes the following financial instruments: cash and cash equivalents, investments in marketable securities and warrant liabilities. The Company considers the carrying amount of its cash and cash equivalents and short-term notes payable to approximate fair value due to the short-term nature of these instruments.

Accounting for fair value measurements involves a single definition of fair value, along with a conceptual framework to measure fair value, with a fair value 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." The fair value measurement hierarchy consists of three levels:

Level one	Quoted market prices in active markets for identical assets or liabilities;
Level two	Inputs other than level one inputs that are either directly or indirectly observable; and
Level three	Unobservable inputs developed using estimates and assumptions; which are developed by the reporting entity and reflect those assumptions that a market participant would use.

The Company applies valuation techniques that (1) place greater reliance on observable inputs and less reliance on unobservable inputs and (2) are consistent with the market approach, the income approach and/or the cost approach, and include enhanced disclosures of fair value measurements in the Company's consolidated financial statements.

Investments in Marketable Securities

The Company classifies all of its investments as available-for-sale. Unrealized gains and losses on investments are recognized in comprehensive income/(loss), unless an unrealized loss is considered to be other than temporary, in which case the unrealized loss is charged to operations. The Company periodically reviews its investments for other than temporary declines in fair value below cost basis and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company believes the individual unrealized losses represent temporary declines primarily resulting from interest rate changes. Realized gains and losses are reflected in other income (expense) in the Consolidated Statements of Operations and Comprehensive Loss and are determined using the specific identification method with transactions recorded on a settlement date basis.

The Company recognized a gain of $66 and a loss of $10,439 for the years ended December 31, 2019 and 2018, respectively.

Investments with original maturities at date of purchase beyond three months and which mature at or less than 12 months from the balance sheet date are classified as current. Investments with a maturity beyond 12 months from the balance sheet date are classified as long-term. At December 31, 2019, the Company believes that the costs of its investments are recoverable in all material respects.

The following tables summarize the fair value of the Company's investments by type. The estimated fair value of the Company's fixed income investments is classified as Level 2 in the fair value hierarchy as defined in GAAP. These fair values are obtained from independent pricing services which utilize Level 2 inputs:

	December 31, 2019				
	Amortized Cost	Accrued Interest	Gross Unrealized Gains	Gross Unrealized losses	Estimated Fair Value
Corporate debt securities	$ 490,741	$ 2,687	$ 555	$ (99)	$ 493,884
Total investments	$ 490,741	$ 2,687	$ 555	$ (99)	$ 493,884

The following table summarizes the scheduled maturity for the Company's investments at December 31, 2019 and 2018, respectively:

	December 31, 2019	December 31, 2018
Maturing in one year or less	$ 493,884	$ 494,633
Maturing after one year through three years	-	-
Total investments	$ 493,884	$ 494,633

The following tables summarize information regarding assets and liabilities measured at fair value on a recurring basis as of December 31, 2019 and December 31, 2018:

		Fair Value Measurements at Reporting Date Using		
	Balance as of December 31, 2019	Quoted prices in Active Markets for Identical Securities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Current Assets				
Cash and cash equivalents	$ 4,905,993	$ 4,905,993	$ -	$ -
Marketable securities	$ 493,884	$ -	$ 493,884	$ -

		Fair Value Measurements at Reporting Date Using		
	Balance as of December 31, 2018	Quoted prices in Active Markets for Identical Securities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Current Assets				
Cash and cash equivalents	$ 12,367,321	$ 12,367,321	$ -	$ -
Marketable securities	$ 494,633	$ -	$ 494,633	$ -

There were no significant transfers between levels during the year ended December 31, 2019.

NOTE C—BALANCE SHEET COMPONENTS

Property and equipment, net

Property and equipment consist of the following:

	December 31, 2019	December 31, 2018
Office furniture and fixtures	$ 130,192	$ 130,192
Computer equipment and software	80,669	96,593
Laboratory equipment	-	354,861
	210,861	581,646
Less: Accumulated depreciation	(204,302)	(573,121)
	$ 6,559	$ 8,525

Depreciation and amortization expense were $5,017 and $9,015 for the years ended December 31, 2019 and 2018, respectively.

Accrued liabilities

Accrued liabilities consist of the following:

	December 31, 2019	December 31, 2018
Operating costs	$ 426,115	$ 244,456
Lease liability	111,353	-
Employee related	333,873	571,399
	$ 871,341	$ 815,855

NOTE D—STOCKHOLDERS' EQUITY

Preferred Stock

Under the Company's Certificate of Incorporation, the Board of Directors is authorized, without further stockholder action, to provide for the issuance of up to 10,000,000 shares of preferred stock, par value $0.0001 per share, in one or more series, to establish from time to time the number of shares to be included in each such series, and to fix the designation, powers, preferences and rights of the shares of each such series and the qualifications, limitations and restrictions thereof.

Series A Stock

On December 11, 2018, the Company closed its underwritten offering of 5,181,346 units for net proceeds of approximately $9 million. Each unit consists of (a) one share of the Company's Series A convertible preferred stock, par value $0.0001 per share (the "Series A Stock"), (b) a two-year warrant to purchase one share of common stock at an exercise price of $1.93 (the "Series 1 Warrants"), and (c) a five-year warrant to purchase one share of common stock at an exercise price of $1.93 (the "Series 2 Warrants"). In accordance with ASC 480, the estimated fair-value of $1,800,016 for the beneficial conversion feature was recognized as a deemed dividend on the Series A Stock during the year ended December 31, 2018.

The table below sets forth a summary of the designation, powers, preferences and rights of the Series A Stock.

Conversion	Subject to the ownership limitations described below, the Series A Stock is convertible at any time at the option of the holder into shares of the Company's common stock at a conversion ratio determined by dividing the stated value of the Series A Stock by a conversion price of $1.93 per share. The conversion price is subject to adjustment in the case of stock splits, stock dividends, combinations of shares and similar recapitalization transactions. The Company will not affect any conversion of the Series A Stock, nor shall a holder convert its shares of Series A Stock, to the extent that such conversion would cause the holder to have acquired, through conversion of the Series A Stock or otherwise, beneficial ownership of a number shares of common stock in excess of 4.99% (or, at the election of the holder prior to the issuance of any shares of Series A Stock, 9.99%) of the common stock outstanding after giving effect to such exercise.
Dividends	In the event the Company pays dividends on its shares of common stock, the holders of the Series A Stock will be entitled to receive dividends on shares of Series A Stock equal, on an as-if-converted basis, to and in the same form as paid on the common stock. No other dividends will be paid on the shares of Series A Stock.
Liquidation	Upon any liquidation, dissolution or winding up of the Company after payment or provision for payment of debts and other liabilities of the Company, the holders of Series A Stock shall be entitled to be paid out of the assets of the Company available for distribution to its stockholders an amount equal to the amount that a holder of common stock would receive if the Series A Stock were fully converted to common stock, which amounts will be paid pari passu with all holders of common stock.
Voting rights	Shares of Series A Stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the then outstanding Series A Stock will be required to amend the terms of the Series A Stock or to take other action that adversely affects the rights of the holders of Series A Stock.

During the years ended December 31, 2019 and 2018, 2,815,987 and 2,326,753 shares of Series A Stock were converted into 2,815,987 and 2,326,753 shares of common stock, respectively.

As of December 31, 2019, there were 38,606 shares of Series A Stock outstanding.

Common Stock

The Company's Certificate of Incorporation authorizes it to issue 400,000,000 shares of $0.0001 par value common stock. As of December 31, 2019, and December 31, 2018 there were 6,741,860 and 3,792,249 shares of common stock issued and outstanding, respectively.

Warrants

Series 1 Warrants

As part of the offering of Series A Stock, the Company issued 5,181,346 Series 1 Warrants at an exercise price of $1.93 per share and contractual term of two years. In accordance with ASC 480, these warrants are classified as equity and their relative fair-value of $2,621,809 was recognized as a deemed dividend on the Series A Stock during the year ended December 31, 2018. The estimated fair value is determined using the Black-Scholes Option Pricing Model which is based on the value of the underlying common stock at the valuation measurement date, the remaining contractual term of the warrants, risk-free interest rates, expected dividends and expected volatility of the price of the underlying common stock.

During the year ended December 31, 2019, the Company received $96,500 and issued 50,000 shares upon the exercise of outstanding Series 1 Warrants.

As of December 31, 2019, there were 5,131,346 Series 1 Warrants outstanding .

Series 2 Warrants

As part of the offering of Series A Stock, the Company issued 5,181,346 Series 2 Warrants at an exercise price of $1.93 per share and contractual term of five years. In accordance with ASC 480, these warrants are classified as equity and their relative fair-value of $2,908,778 was recognized as a deemed dividend on the Series A Stock during the year ended December 31, 2018. The estimated fair value is determined using the Black-Scholes Option Pricing Model which is based on the value of the underlying common stock at the valuation measurement date, the remaining contractual term of the warrants, risk-free interest rates, expected dividends and expected volatility of the price of the underlying common stock.

As of December 31, 2019, all 5,181,349 Series 2 Warrants remain outstanding.

Warrants Issued for Services

In connection with the offering of Series A Stock described above, the Company entered into an Underwriting Agreement (the "Underwriting Agreement") with Ladenburg Thalmann & Co. Inc. (the "Underwriter") pursuant to which, on December 7, 2018, the Company issued to the Underwriter a warrant to purchase 207,253 shares of common stock at an exercise price of $2.4125 per share and contractual term of five years. In accordance with ASC 815, this warrant is classified as equity and its relative fair-value of $183,433 was recognized as additional paid in capital during the year ended December 31, 2018. The estimated fair value is determined using the Black-Scholes Option Pricing Model which is based on the value of the underlying common stock at the valuation measurement date, the remaining contractual term of the warrant, risk-free interest rates, expected dividends and expected volatility of the price of the underlying common stock.

As of December 31, 2019, all 207,253 of these Underwriter warrants remain outstanding.

On November 11, 2014, the Company issued common stock warrants in connection with the execution of a service agreement for investor relations and corporate communications. As part of the compensation under the agreement, the Company issued up to 8,750 warrants at an exercise price of $80.00 per share and contractual term of five years. The warrants were initially exercisable for 1,250 shares of common stock, and the number of shares of common stock exercisable under these warrants would be automatically increased by 2,500 upon the first occurrence of market price goals of $120.00, $160.00 and $200.00, respectively, during the 18-month period beginning on the effective date. Effective May 11, 2016, the additional 7,500 warrants were no longer exercisable as none of the market price goals were achieved. In accordance with ASC 815, these warrants are classified as equity and their estimated fair-value of $478,115 was recorded as an operating expense in the consolidated statement of operations and as additional paid in capital during the fiscal year ended April 30, 2015. The estimated fair value was determined using the Black-Scholes Option Pricing Model which is based on the value of the underlying common stock at the valuation measurement date, the remaining contractual term of the warrants, risk-free interest rates, expected dividends and expected volatility of the price of the underlying common stock.

During the year ended December 31, 2019, all of the 1,250 previously outstanding service agreement warrants expired unexercised.

Series D Warrant

On August 22, 2013, the Company closed its private placement of an aggregate of $4.6 million shares of the Company's Series D Stock to OXBT Fund. In connection with the purchase of shares of Series D Stock, OXBT Fund received the Series D Warrant to purchase 117,949 shares of common stock at an exercise price equal to $52.00 and contractual term of six years. In accordance with ASC 815, these warrants are classified as equity and their relative fair-value of $1,531,167 was recognized as a deemed dividend on the Series D Stock during the prior fiscal year ended April 30, 2014. The estimated fair value is determined using the Black-Scholes Option Pricing Model which is based on the value of the underlying common stock at the valuation measurement date, the remaining contractual term of the warrants, risk-free interest rates, expected dividends and expected volatility of the price of the underlying common stock.

The Series D Warrant was exercisable beginning on the date of issuance and expired on August 22, 2019. The exercise price and the number of shares issuable upon exercise of Series D Warrant was subject to appropriate adjustment in the event of recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting the Company's common stock, and also upon any distributions of assets, including cash, stock or other property to the Company's stockholders. In addition, if stockholder approval for the transaction was obtained, the Series D Warrant would be subject to anti-dilution provisions until such time that for 25 trading days during any 30 consecutive trading day period, the volume weighted average price of the Company's common stock exceeded $130.00 and the daily dollar trading volume exceeds $350,000 per trading day.

The Series D Warrant was issued and sold without registration under the Securities Act in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act and/or Regulation D promulgated thereunder and in reliance on similar exemptions under applicable state laws. Accordingly, OXBT Fund could exercise the Series D Warrant and sell the Series D Stock and underlying shares only pursuant to an effective registration statement under the Securities Act covering the resale of those securities, an exemption under Rule 144 under the Securities Act or another applicable exemption under the Securities Act.

During the year ended December 31, 2019, all of the 107,488 previously outstanding Series D Warrants expired unexercised.

Series C Warrants

On July 23, 2013, as part of the offering of Series C Stock, the Company issued 137,668 Series C Warrants at an exercise price of $52.00 per share and contractual term of six years. In accordance with ASC 815, these warrants are classified as equity and their relative fair-value of $1,867,991 was recognized as a deemed dividend on the Series C Stock during the prior fiscal year ended April 30, 2014. The estimated fair value is determined using the Black-Scholes Option Pricing Model which is based on the value of the underlying common stock at the valuation measurement date, the remaining contractual term of the warrants, risk-free interest rates, expected dividends and expected volatility of the price of the underlying common stock.

During the year ended December 31, 2019, all of the 12,035 previously outstanding Series C Warrants expired unexercised

The following table summarizes the Company's warrant activity for the years ended December 31, 2019 and December 31, 2018:

	Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2017	**120,773**	**$ 52.29**
Issued	10,569,945	1.94
Outstanding at December 31, 2018	**10,690,718**	**$ 2.45**
Exercised	(50,000)	1.93
Expired	(120,773)	47.30
Outstanding at December 31, 2019	**10,519,945**	**$ 1.94**

Stock Options

The following table summarizes all options outstanding as of December 31, 2019:

	Options Outstanding at December 31, 2019		Options Exercisable and Vested at December 31, 2019	
Exercise Price	Number of Options	Weighted Average Remaining Contractual Life (Years)	Number of Options	Weighted Average Exercise Price
$1.72 to $11.20	68,500	8.2	23,500	$ 7.78
$41.40 to $96.40	40,251	5.4	35,377	$ 58.25
$113.00 to $860.00	135,413	0.3	68,423	$ 114.68
$1,012.00 to $2,580.00	42	0.5	42	$ 1,580.00
	244,206	3.4	127,342	$ 79.76

The following table summarizes options outstanding that have vested and are expected to vest based on options outstanding as of December 31, 2019:

	Number of Option Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value (1)	Weighted Average Remaining Contractual Life (Years)
Vested	127,342	$ 79.76	$ -	3.4
Vested and expected to vest	231,355	$ 74.91	$ -	3.5

(1) Amount represents the difference between the exercise price and $1.41, the closing price of Tenax Therapeutics' stock on December 31, 2019, as reported on the Nasdaq Capital Market, for all in-the-money options outstanding.

2016 Stock Incentive Plan

In June 2016, the Company adopted the 2016 Stock Incentive Plan (the "2016 Plan"). Under the 2016 Plan, with the approval of the Compensation Committee of the Board of Directors, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares, performance units, cash-based awards or other stock-based awards. On June 16, 2016, the Company's stockholders approved the 2016 Plan and authorized for issuance under the 2016 Plan a total of 150,000 shares of common stock. On June 13, 2019, the Company's stockholders approved an amendment to the 2016 Plan which increased the number of shares of common stock authorized for issuance under the 2016 Plan to a total of 750,000 shares, up from 150,000 previously authorized.

The following table summarizes the shares available for grant under the Plan for the years ended December 31, 2019 and 2018:

	Shares Available for Grant
Balances, at December 31, 2017	150,000
Options granted	(50,000)
Balances, at December 31, 2018	100,000
Additional shares reserved	600,000
Options granted	(2,500)
Balances, at December 31, 2019	697,500

2016 Plan Stock Options

Stock options granted under the 2016 Plan may be either incentive stock options ("ISOs"), or nonqualified stock options ("NSOs"). ISOs may be granted only to employees. NSOs may be granted to employees, consultants and directors. Stock options under the 2016 Plan may be granted with a term of up to ten years and at prices no less than fair market value at the time of grant. Stock options granted generally vest over three to four years.

The following table summarizes the outstanding stock options under the 2016 Plan for the years ended December 31, 2019 and 2018:

	Outstanding Options		
	Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value
Balances at December 31, 2017	-	$ -	
Options granted	50,000	$ 6.10	
Balances at December 31, 2018	50,000	$ 6.10	
Options granted	2,500	$ 1.72	
Balances at December 31, 2019	52,500	$ 5.89	$ -(1)

(1) Amount represents the difference between the exercise price and $1.41, the closing price of Tenax Therapeutics' stock on December 31, 2019, as reported on the Nasdaq Capital Market, for all in-the-money options outstanding.

The Company chose the "straight-line" attribution method for allocating compensation costs of each stock option over the requisite service period using the Black-Scholes Option Pricing Model to calculate the grant date fair value.

The Company used the following assumptions to estimate the fair value of options granted under the 2016 Plan for the years ended December 31, 2019 and 2018:

	For the year ended December 31,	
	2019	2018
Risk-free interest rate (weighted average)	2.39%	2.85%
Expected volatility (weighted average)	106.74%	102.37%
Expected term (in years)	7	7
Expected dividend yield	0.00%	0.00%

Risk-Free Interest Rate — The risk-free interest rate assumption was based on U.S. Treasury instruments with a term that is consistent with the expected term of the Company's stock options.

Expected Volatility — The expected stock price volatility for the Company's common stock was determined by examining the historical volatility and trading history for its common stock over a term consistent with the expected term of its options.

Expected Term — The expected term of stock options represents the weighted average period the stock options are expected to remain outstanding. It was calculated based on the Company's historical experience with its stock option grants.

Expected Dividend Yield — The expected dividend yield of 0% is based on the Company's history and expectation of dividend payouts. The Company has not paid and does not anticipate paying any dividends in the near future.

Forfeitures — As stock-based compensation expense recognized in the statement of operations for the years ended December 31, 2019 and 2018 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on the Company's historical experience.

The weighted-average grant-date fair value of options granted during the years ended December 31, 2019 and 2018 was $1.47 and $5.20, respectively.

The Company recorded compensation expense for these stock options grants of $92,919 and $89,194 for the years ended December 31, 2019 and 2018, respectively.

As of December 31, 2019, there were unrecognized compensation costs of approximately $72,000 related to non-vested stock option awards under the 2016 Plan that will be recognized on a straight-line basis over the weighted average remaining vesting period of 1.35 years.

1999 Amended Stock Plan

In October 2000, the Company adopted the 1999 Stock Plan, as amended and restated on June 17, 2008 (the "1999 Plan"). Under the 1999 Plan, with the approval of the Compensation Committee of the Board of Directors, the Company could grant stock options, restricted stock, stock appreciation rights and new shares of common stock upon exercise of stock options. On March 13, 2014, the Company's stockholders approved an amendment to the 1999 Plan which increased the number of shares of common stock authorized for issuance under the 1999 Plan to a total of 200,000 shares, up from 15,000 previously authorized. On September 15, 2015, the Company's stockholders approved an additional amendment to the 1999 Plan which increased the number of shares of common stock authorized for issuance under the 1999 Plan to a total of 250,000 shares, up from 200,000 previously authorized. The 1999 Plan expired on June 17, 2018 and no new grants may be made under that plan after that date. However, unexpired awards granted under the 1999 Plan remain outstanding and subject to the terms of the 1999 Plan.

1999 Plan Stock Options

Stock options granted under the 1999 Plan may be ISOs or NSOs. ISOs could be granted only to employees. NSOs could be granted to employees, consultants and directors. Stock options under the 1999 Plan could be granted with a term of up to ten years and at prices no less than fair market value for ISOs and no less than 85% of the fair market value for NSOs. Stock options granted generally vest over one to three years.

The following table summarizes the outstanding stock options under the 1999 Plan for the years ended December 31, 2019 and 2018:

	Outstanding Options		
	Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value
Balances at December 31, 2017	188,744	$ 95.24	
Options granted	3,000	$ 6.23	
Options cancelled	(9)	$ 2,760.00	
Balances at December 31, 2018	191,735	$ 93.72	
Options cancelled	(29)	$ 2,203.00	
Balances at December 31, 2019	191,706	$ 93.40	$ -(1)

(1) Amount represents the difference between the exercise price and $1.41, the closing price of Tenax Therapeutics' stock on December 31, 2019, as reported on the Nasdaq Capital Market, for all in-the-money options outstanding.

The Company chose the "straight-line" attribution method for allocating compensation costs of each stock option over the requisite service period using the Black-Scholes Option Pricing Model to calculate the grant date fair value.

The Company used the following assumptions to estimate the fair value of options granted under the 1999 Plan for the year ended December 31, 2018:

	For the year ended December 31, 2018
Risk-free interest rate (weighted average)	2.91%
Expected volatility (weighted average)	102.63%
Expected term (in years)	7
Expected dividend yield	0.00%

Risk-Free Interest Rate The risk-free interest rate assumption was based on U.S. Treasury instruments with a term that is consistent with the expected term of the Company's stock options.

Expected Volatility The expected stock price volatility for the Company's common stock was determined by examining the historical volatility and trading history for its common stock over a term consistent with the expected term of its options.

Expected Term The expected term of stock options represents the weighted average period the stock options are expected to remain outstanding. It was calculated based on the historical experience that the Company has had with its stock option grants.

Expected Dividend Yield The expected dividend yield of 0% is based on the Company's history and expectation of dividend payouts. The Company has not paid and do not anticipate paying any dividends in the near future.

Forfeitures As stock-based compensation expense recognized in the statement of operations for the years ended December 31, 2019 and 2018 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on the Company's historical experience.

The weighted-average grant-date fair value of options granted during the year ended December 31, 2018 was $5.19.

The Company recorded compensation expense for these stock options grants of $78,297 and $227,066 for the years ended December 31, 2019 and 2018, respectively.

As of December 31, 2019, there were unrecognized compensation costs of approximately $40,000 related to non-vested stock option awards that will be recognized on a straight-line basis over the weighted average remaining vesting period of 0.9 years. Additionally, there were unrecognized compensation costs of approximately $5.9 million related to non-vested stock option awards subject to performance-based vesting milestones with a weighted average remaining life of four months. As of December 31, 2019, none of these milestones have been achieved.

Restricted Stock Grants

The following table summarizes the outstanding restricted stock under the 1999 Plan for the years ended December 31, 2019 and 2018:

	Outstanding Restricted Stock Grants	
	Number of Shares	Weighted Average Grant Date Fair Value
Balances, at December 31, 2017	-	$ -
Restricted stock granted	85,900	$ 5.82
Restricted stock vested	(37,420)	$ 5.69
Restricted stock cancelled	(28,566)	$ 5.66
Balances, at December 31, 2018	19,914	$ 6.29
Restricted stock vested	(12,195)	$ 6.28
Restricted stock cancelled	(7,719)	$ 6.27
Balances at December 31, 2019	-	$ -

The Company recorded no compensation expense for these restricted stock grants for the year ended December 31, 2019, and $250,009 for the year ended December 31, 2018.

As of December 31, 2019, there were no unrecognized compensation costs related to the non-vested restricted stock grants.

NOTE E—COMMITMENTS AND CONTINGENCIES

Operating Leases

As described above in “NOTE B- SUMMARY OF CRITICAL ACCOUNTING POLICIES”, the Company adopted ASC 842 as of January 1, 2019. Prior period amounts have not been adjusted and continue to be reported in accordance with the Company’s historic accounting under ASC 840.

In January 2011, the Company entered into the Lease with Concourse Associates, LLC for office facilities located at the premises in Morrisville, North Carolina (the “Lease”). The Lease was amended in August 2015 to extend the term for the 5,954 square foot rental. The current term began on March 1, 2016 and continues for 64 months to September 30, 2021. Rent payments began on July 1, 2016, following the conclusion of a four-month rent abatement period. The Company has two five-year options to extend the Lease and a one-time option to terminate the Lease 36 months after the commencement of the initial term if no additional space (“Expansion Space”) became available; none of these optional periods have been considered in the determination of the right-of-use asset or the lease liability for the Lease as the Company did not consider it reasonably certain that it would exercise any such options. The Lease further provides that the Company is obligated to pay to the landlord certain variable costs, including taxes and operating expenses. The Company also has a right of first offer to lease the Expansion Space, of no less than 1,000 square feet, as that additional space becomes available adjacent to the premises over the remainder of the initial term of the Lease, at the same rate per square foot as the current premises, with an extension of the term of 60 additional months starting at the commencement date of acquiring the Expansion Space.

The Company performed an evaluation of its other contracts with customers and suppliers in accordance with ASC 842 and determined that, except for the Lease described above, none of the Company's contracts contain a lease.

The balance sheet classification of our lease liabilities was as follows:

	December 31, 2019	December 31, 2018
Current portion included in accrued liabilities	$ 111,353	$ -
Long term lease liability	60,379	-
	$ 171,732	$ -

As of December 31, 2019, the maturities of our operating lease liabilities were as follows:

Year ending December 31,	
2020	$ 121,084
2021	61,803
Total lease payments	$ 182,887
Less: Imputed interest	(11,155)
Operating lease liability	$ 171,732

Simdax license agreement

On November 13, 2013, the Company acquired, through its wholly owned subsidiary, Life Newco, that certain License Agreement (the "License"), dated September 20, 2013 by and between Phyxius and Orion Corporation, a global healthcare company incorporated under the laws of Finland ("Orion"), and that certain Side Letter, dated October 15, 2013 by and between Phyxius and Orion. The License grants the Company an exclusive, sublicenseable right to develop and commercialize pharmaceutical products containing levosimendan (the "Product") in the United States and Canada (the "Territory") from Orion. Pursuant to the License, the Company must use Orion's "Simdax®" trademark to commercialize the Product. The License also grants to the Company a right of first refusal to commercialize new developments of the Product, including developments as to the formulation, presentation, means of delivery, route of administration, dosage or indication, i.e. line extension products. Orion's ongoing role under the License includes sublicense approval, serving as the sole source of manufacture, holding a first right to enforce intellectual property rights in the Territory, and certain regulatory participation rights. Additionally, the Company must grant back to Orion a broad non-exclusive license to any patents or clinical trial data related to the Product developed by the Company under the License. The License has a fifteen-year term, provided, however, that the License will continue after the end of the 15-year term in each country in the Territory until the expiration of Orion's patent rights in the Product in such country.

Pursuant to the terms of the License, the Company paid to Orion a non-refundable up-front payment in the amount of $1.0 million. The License also includes the following development milestones for which the Company shall make non-refundable payments to Orion no later than 28 days after the occurrence of the applicable milestone event: (i) $2.0 million upon the grant of FDA approval, including all registrations, licenses, authorizations and necessary approvals, to develop and/or commercialize the Product in the United States; and (ii) $1.0 million upon the grant of regulatory approval for the Product in Canada. Once commercialized, the Company is obligated to make certain non-refundable commercialization milestone payments to Orion, aggregating up to $13.0 million, contingent upon achievement of certain cumulative net sales amounts in the Territory. The Company must also pay Orion tiered royalties based on net sales of the Product in the Territory made by the Company and its sublicensees. After the end of the term of the License, the Company must pay Orion a royalty based on net sales of the Product in the Territory for as long as the Company sells the Product in the Territory.

As of December 31, 2019, the Company has not met any of the developmental milestones and, accordingly, has not recorded any liability for the contingent payments due to Orion.

In June 2019, Orion filed a request for arbitration against the Company seeking a declaration regarding the correct interpretation of the line extension provisions of the License and whether or not such provisions apply to the oral form of levosimendan recently developed by Orion. Additionally, Orion requested the Company reimburse Orion for all legal fees associated with the arbitration. The Company submitted its response to the request for arbitration and rejected Orion's position that the oral formation was not a line extension product under the License and requested Orion reimburse the Company for all legal fees associated with the arbitration.

Litigation

The Company is subject to litigation in the normal course of business, none of which management believes will have a material adverse effect on the Company's consolidated financial statements.

NOTE F—401(k) BENEFIT PLAN

The Company sponsors a 401(k) Retirement Savings Plan (the "401(k) Plan") for all eligible employees. Full-time employees over the age of 18 are eligible to participate in the 401(k) Plan after 90 days of continuous employment. Participants may elect to defer earnings into the 401(k) Plan up to the annual IRS limits and the Company provides a matching contribution up to 5% of the participants' annual salary in accordance with the 401(k) Plan documents. The 401(k) Plan is managed by a third-party trustee.

For the years ended December 31, 2019 and 2018, the Company recorded $68,587 and $63,647 for matching contributions expense, respectively.

NOTE G—INCOME TAXES

The Company has not recorded any income tax expense (benefit) for the period ended December 31, 2019 due to its history of net operating losses.

The reconciliation of income tax expense (benefit) at the statutory federal income tax rate of 21% for the periods ended December 31, 2019 and December 31, 2018 is as follows:

	December 31,	
	2019	2018
U.S. federal tax benefit at statutory rate	$ (1,762,816)	$ (2,970,250)
State income tax benefit, net of federal benefit	(165,789)	(246,376)
Stock compensation	37,761	68,249
Interest	-	1,667,118
Other nondeductible, including goodwill impairment	1,373	1,257
Change in state tax rate	27,945	45,864
Change in the federal tax rate	-	-
Federal and state net operating loss adjustments	234,659	451,652
Other, including effect of tax rate brackets	(17,043)	(31,810)
Change in valuation allowance	1,643,910	1,014,296
	$ -	$ -

The tax effects of temporary differences and carry forwards that give rise to significant portions of the deferred tax assets are as follows:

	December 31,	
Deferred Tax Assets	2019	2018
Net operating loss carryforwards	$ 34,933,500	$ 33,283,250
Accruals and other	498,572	509,069
Capital loss carryforwards	16,908	16,708
Valuation allowance	(35,440,205)	(33,796,295)
Net deferred tax assets	8,775	12,732
Deferred Tax Liabilities		
Other liabilities	(8,775)	(12,732)
Net Deferred Tax Liabilities	$ -	$ -

The Company has established a valuation allowance against net deferred tax assets due to the uncertainty that such assets will be realized. The Company periodically evaluates the recoverability of the deferred tax assets. At such time that it is determined that it is more likely than not that deferred tax assets will be realizable, the valuation allowance will be reduced. The net increase in the valuation allowance during 2019 was approximately $1.6 million.

As of December 31, 2019, the Company had federal and state net operating loss carryforwards of approximately $145.1 million and $117.5 million available to offset future federal and state taxable income, respectively. Federal net operating losses of $130.4 million begin to expire in 2021, while the remaining $14.7 million carryforward indefinitely. State net operating losses begin to expire in 2024.

Utilization of the net operating loss carryforwards may be subject to an annual limitation due to the ownership percentage change limitations provided by the Internal Revenue Code of 1986 and similar state provisions. The annual limitations may result in the expiration of the net operating losses before utilization.

Management has evaluated all other tax positions that could have a significant effect on the financial statements and determined the Company had no uncertain income tax positions at December 31, 2019.

The Company files U.S. and state income tax returns with varying statutes of limitations. The tax years 2001 and forward remain open to examination due to the carryover of unused net operating losses or tax credits.

NOTE H—SUBSEQUENT EVENTS

On March 11, 2020, the Company entered into a definitive agreement with a single healthcare-focused institutional investor for the issuance and sale of 750,000 shares of its common stock at a purchase price of $1.1651 per share and pre-funded warrants to purchase up to 1,610,313 shares of its common stock, at a purchase price of $1.1650 per pre-funded warrant (which represents the per share offering price for the common stock less the $0.0001, the exercise price of each pre-funded warrant), for gross proceeds of approximately $2.75 million, in a registered direct offering priced at-the-market under Nasdaq rules. Additionally, in a concurrent private placement, the Company also agreed to issue to the investor unregistered warrants to purchase up to 2,360,313 shares of its common stock. The unregistered warrants have an exercise price of $1.04 per share and exercise period commencing immediately upon the issuance date and a term of five and one-half years. The offering closed on March 13, 2020.

The Company agreed to pay H.C. Wainwright & Co., LLC (the “Placement Agent”), a cash fee equal to 7.5% of the gross proceeds of the offerings, totaling approximately $206,250. The Company also agreed to pay the Placement Agent $75,000 for non-accountable expenses, a management fee equal to 1.0% of the gross proceeds and up to $12,900 for clearing fees. In addition, the Company issued designees of the Placement Agent warrants to purchase 177,023 shares of common stock (representing 7.5% of the aggregate number of shares of common stock (or common stock equivalents) sold in the offerings). The Placement Agent warrants have substantially the same terms as the unregistered warrants, except that the Placement Agent warrants have an exercise price equal to $1.4564, or 125% of the offering price per share of common stock, and will be exercisable for five years from the effective date of the offerings.

The shares of common stock and pre-funded warrants offered in the registered direct offering (including the shares of common stock underlying the pre-funded warrants) were offered and sold by the Company pursuant to a "shelf" registration statement on Form S-3, which was declared effective by the Securities and Exchange Commission (the "SEC") on May 23, 2018. The unregistered warrants described above were offered in a private placement under Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"), and Regulation D promulgated thereunder and, along with the shares of common stock underlying the warrants, have not been registered under the Securities Act, or applicable state securities laws.

The net proceeds from the offerings, after deducting placement agent fees and other direct offering expenses were approximately $2.125 million. The Company intends to use the net proceeds to further its clinical trials of levosimendan, for research and development and general corporate purposes, including working capital and potential acquisitions.

ITEM 9—CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A—CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our disclosure controls and procedures, as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, are designed to ensure that information required to be disclosed in reports filed or submitted under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in rules and forms adopted by the SEC, and that such information is accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosures.

Management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Form 10-K. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2019, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Controls over Financial Reporting

From time to time, we may review and make changes to our internal control over financial reporting that are intended to enhance the effectiveness of our internal control over financial reporting and which do not have a material effect on our overall internal control over financial reporting. During the three months ended December 31, 2019, we made no changes to our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act, that we believe materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting, as defined in rules promulgated under the Exchange Act, is a process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer and affected by our Board of Directors, management and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of Consolidated Financial Statements for external purposes in accordance with GAAP. Internal control over financial reporting includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of Consolidated Financial Statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and our Board of Directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our Consolidated Financial Statements.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting can also be circumvented by collusion or improper override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process, and it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2019. In making its assessment, management used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in its 2013 *Internal Control — Integrated Framework*. Based on its assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2019.

ITEM 9B—OTHER INFORMATION

There is no information to report under this item for the quarter ended December 31, 2019.

PART III

ITEM 10— DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

The information required by this item is incorporated by reference to our Proxy Statement for our 2020 Annual Meeting of Stockholders, which will be filed with the SEC within 120 days after the end of fiscal 2019.

ITEM 11— EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to our Proxy Statement for our 2020 Annual Meeting of Stockholders, which will be filed with the SEC within 120 days after the end of fiscal 2019.

ITEM 12— SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this item is incorporated by reference to our Proxy Statement for our 2020 Annual Meeting of Stockholders, which will be filed with the SEC within 120 days after the end of fiscal 2019.

ITEM 13— CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by this item is incorporated by reference to our Proxy Statement for our 2020 Annual Meeting of Stockholders, which will be filed with the SEC within 120 days after the end of fiscal 2019.

ITEM 14— PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference to our Proxy Statement for our 2020 Annual Meeting of Stockholders, which will be filed with the SEC within 120 days after the end of fiscal 2019.

PART IV

ITEM 15—EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(A)(1) The Consolidated Financial Statements and information listed below are included in this report in Part II, Item 8.

- Report of Independent Registered Public Accounting Firm.
- Consolidated Balance Sheets as of December 31, 2019 and December 31, 2018.
- Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2019 and 2018.
- Consolidated Statements of Stockholders' Equity for the years ended December 31, 2019 and 2018.
- Consolidated Statements of Cash Flows for the years ended December 31, 2019 and 2018.
- Notes to the Consolidated Financial Statements.

(A)(2) No schedules have been included because they are not applicable, or the required information is shown in our Consolidated Financial Statements or our notes thereto.

(A)(3) The following exhibits have been or are being filed herewith and are numbered in accordance with Item 601 of Regulation S-K:

Exhibit No.	Exhibits Required by Item 601 of Regulation S-K
2.1	Agreement and Plan of Merger between Synthetic Blood International, Inc. and Oxygen Biotherapeutics, Inc. dated April 28, 2008 (incorporated herein by reference to Exhibit 2.01 to our current report on Form 8-K filed with the SEC on June 30, 2008)
2.2	Asset Purchase Agreement by and between Oxygen Biotherapeutics, Inc., Life Newco, Inc., Phyxius Pharma, Inc., and the stockholders of Phyxius Pharma, Inc. dated October 21, 2013 (incorporated herein by reference to Exhibit 2.1 to our current report on Form 8-K filed with the SEC on October 25, 2013)
3.1	Certificate of Incorporation (incorporated herein by reference to Exhibit 3.01 to our current report on Form 8-K filed with the SEC on June 30, 2008)
3.2	Certificate of Amendment of the Certificate of Incorporation (incorporated herein by reference to Exhibit 3.1 to our current report on Form 8-K filed with the SEC on November 13, 2009)
3.3	Certificate of Amendment of the Certificate of Incorporation (incorporated herein by reference to Exhibit 3.1 to our current report on Form 8-K filed with the SEC on May 15, 2013)
3.4	Certificate of Amendment of the Certificate of Incorporation (incorporated herein by reference to Exhibit 3.4 to our quarterly report on Form 10-Q filed with the SEC on December 15, 2014)
3.5	Certificate of Amendment of the Certificate of Incorporation (incorporated herein by reference to Exhibit 3.1 to our current report on Form 8-K filed with the SEC on February 23, 2018)
3.6	Certificate of Designation of Series A Convertible Preferred Stock (incorporated herein by reference to Exhibit 4.1 to our current report on Form 8-K filed with the SEC on December 11, 2018)

3.7	Third Amended and Restated Bylaws (incorporated herein by reference to Exhibit 3.1 to our quarterly report on Form 10-Q filed with the SEC on September 9, 2015)
4.1	Specimen Stock Certificate (incorporated herein by reference to Exhibit 4.1 to our annual report on Form 10-K filed with the SEC on July 23, 2010)
10.1	Agreement with Leland C. Clark, Jr., Ph.D. dated November 20, 1992 with amendments, Assignment of Intellectual Property/ Employment (incorporated herein by reference to Exhibit 10.1 to our annual report on Form 10-K filed with the SEC on August 13, 2004)
10.2	Agreement between the Registrant and Keith R. Watson, Ph.D. Assignment of Invention (incorporated herein by reference to Exhibit 10.2 to our annual report on Form 10-K filed with the SEC on August 13, 2004)
10.3	Children's Hospital Research Foundation License Agreement dated February 28, 2001 (incorporated herein by reference to Exhibit 10.3 to our annual report on Form 10-K filed with the SEC on August 13, 2004)
10.4	1999 Amended Stock Plan (as amended and restated in 2008) (incorporated herein by reference to Exhibit 10.15 to our annual report on Form 10-K with the SEC on August 13, 2008) +
10.5	Amendment No. 1 to Oxygen Biotherapeutics, Inc. 1999 Amended Stock Plan (incorporated herein by reference to Exhibit 10.19 to our annual report on Form 10-K filed with the SEC on July 29, 2014) +
10.6	Amendment No. 2 to Oxygen Biotherapeutics, Inc. 1999 Amended Stock Plan (incorporated herein by reference to Exhibit 10.20 to our annual report on Form 10-K filed with the SEC on July 29, 2014) +
10.7	Form of Option issued to Executive Officers and Directors (incorporated herein by reference to Exhibit 10.5 to our annual report on Form 10-K filed with the SEC on August 13, 2004) +
10.8	Form of Option issued to Employees (incorporated herein by reference to Exhibit 10.6 to our annual report on Form 10-K filed with the SEC on August 13, 2004) +
10.9	Form of Option Agreement with Form of Notice of Grant (incorporated herein by reference to Exhibit 10.9 to our annual report on Form 10-K filed with the SEC on March 16, 2017) +
10.10	2016 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.1 to our quarterly report on Form 10-Q filed with the SEC on August 9, 2016) +
10.11	Amendment No. 1 to 2016 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.1 to our quarterly report on Form 10-Q filed with the SEC on August 14, 2019) +
10.12	Form of Option issued to Non-Employee Directors under 2016 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.2 to our quarterly report on Form 10-Q filed with the SEC on August 14, 2018) +

10.13	Form of Option issued to Employees and Contractors under 2016 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.3 to our quarterly report on Form 10-Q filed with the SEC on August 14, 2018) +
10.14	Form of Incentive Stock Option Agreement under 2016 Stock Incentive Plan (incorporated herein by reference to Exhibit 10.4 to our quarterly report on Form 10-Q filed with the SEC on August 14, 2018) +
10.15	Second Amended and Restated Employment Agreement with Michael Jebsen dated November 13, 2013 (incorporated herein by reference to Exhibit 10.2 to our current report on Form 8-K filed with the SEC on November 19, 2013) +
10.16	First Amendment to Second Amended and Restated Employment Agreement with Michael Jebsen dated June 18, 2015 (incorporated herein by reference to Exhibit 10.2 to our current report on Form 8-K filed with the SEC on June 19, 2015) +
10.17	Employment Agreement with Anthony DiTonno dated June 1, 2018 (incorporated herein by reference to Exhibit 10.36 to our annual report on Form 10-K filed with the SEC on July 15, 2011) +
10.18	Form of Indemnification Agreement (incorporated herein by reference to Exhibit 10.36 to our annual report on Form 10-K filed with the SEC on July 15, 2011) +
10.19	Description of Non-Employee Director Compensation, effective June 15, 2015 (incorporated herein by reference to Exhibit 10.1 to our quarterly report on Form 10-Q filed with the SEC on September 9, 2015) +
10.20	Lease Agreement for North Carolina corporate office (incorporated herein by reference to Exhibit 10.6 to our quarterly report on Form 10-Q filed with the SEC on March 21, 2011)
10.21	First Amendment to Lease Agreement for North Carolina corporate office (incorporated herein by reference to Exhibit 10.74 to our transition report on Form 10-KT filed with the SEC on March 14, 2016)
10.22	Task Order between the Company and NextPharma, dated November 15, 2011 (incorporated herein by reference to Exhibit 10.2 to our current report on Form 8-K filed with the SEC on November 16, 2011)
10.23	Fluoromed Supply Agreement (incorporated herein by reference to Exhibit 10.62 to our annual report on Form 10-K filed with the SEC on July 25, 2012)
10.24	License and Supply Agreement dated February 5, 2013, between Oxygen Biotherapeutics, Inc. and Valor SA (incorporated herein by reference to Exhibit 10.60 to our annual report on Form 10-K filed with the SEC on July 29, 2014)
10.25	License Agreement dated September 20, 2013 by and between Phyxius Pharma, Inc. and Orion Corporation (incorporated herein by reference to Exhibit 10.3 to our quarterly report on Form 10-Q filed with the SEC on March 17, 2014)**
10.26	Sales Agreement dated as of February 23, 2015, between Tenax Therapeutics, Inc. and Cowen and Company, LLC (incorporated herein by reference to Exhibit 10.72 to our annual report on Form 10-K filed with the SEC on July 14, 2015)

10.27	Representative's Warrant to Purchase Shares of Common Stock (incorporated herein by reference to Exhibit 4.2 to our current report on Form 8-K filed with the SEC on December 11, 2018)
10.28	Form of Warrant to Purchase Shares of Common Stock (incorporated herein by reference to Exhibit 4.3 to our current report on Form 8-K filed with the SEC on December 11, 2018)
10.29	Warrant Agency Agreement (incorporated herein by reference to Exhibit 4.4 to our current report on Form 8-K filed with the SEC on December 11, 2018)
21.1	Subsidiaries of Tenax Therapeutics, Inc. (incorporated herein by reference to Exhibit 21.1 to our annual report on Form 10-K filed with the SEC on July 14, 2015)
23.1	Consent of Independent Registered Public Accounting Firm*
24.1	Power of Attorney (contained on signature page)*
31.1	Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*
31.2	Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350*
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350*
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

** Asterisks located within the exhibit denote information which has been redacted pursuant to a request for confidential treatment filed with the SEC.

\+ Management contract or compensatory plan or arrangement.

ITEM 16—FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TENAX THERAPEUTICS, INC.

Date: March 30, 2020

By: /s/ Michael B. Jebsen
Michael B. Jebsen
President and Chief Financial Officer
(On behalf of the Registrant and as Principal Financial Officer)

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS that each individual whose signature appears below constitutes and appoints Michael B. Jebsen his true and lawful attorney-in-fact and agent with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with all exhibits thereto, and all documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Title	Date
/s/ Anthony DiTonno Anthony DiTonno	Chief Executive Officer and Director (Principal Executive Officer)	March 30, 2020
/s/ Michael B. Jebsen Michael B. Jebsen	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 30, 2020
/s/ Ronald R. Blanck Ronald R. Blanck, DO	Director	March 30, 2020
/s/ Gregory Pepin Gregory Pepin	Director	March 30, 2020
/s/ James Mitchum James Mitchum	Director	March 30, 2020
/s/ Chris A. Rallis Chris A. Rallis	Director	March 30, 2020
/s/ Gerald Proehl Gerald Proehl	Director	March 30, 2020

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-167175, 333-196464, 333-210182, 333-224120, and 333-233571), Form S-3 (No. 333-224951), and Form S-1 (No. 333-228212) of our report dated March 30, 2020 included in this Annual Report on Form 10-K of Tenax Therapeutics, Inc. and Subsidiary (the "Company"), relating to the consolidated balance sheets of the Company as of December 31, 2019 and 2018, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows, and the related notes (which report expresses an unqualified opinion and contains an explanatory paragraph regarding substantial doubt about the Company's ability to continue as a going concern) for each of the years in the two-year period ended December 31, 2019.

/s/ CHERRY BEKAERT LLP

Raleigh, North Carolina
March 30, 2020

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Anthony DiTonno, certify that:

1. I have reviewed this Annual Report on Form 10-K of Tenax Therapeutics, Inc.;

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 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 the 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.

Date: March 30, 2020

TENAX THERAPEUTICS, INC.

By: /s/ Anthony DiTonno
Anthony DiTonno
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Michael B. Jebsen, certify that:

1. I have reviewed this Annual Report on Form 10-K of Tenax Therapeutics, Inc.;

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 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 the 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.

Date: March 30, 2020

TENAX THERAPEUTICS, INC.

By: /s/ Michael B. Jebsen
Michael B. Jebsen
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Annual Report of Tenax Therapeutics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Anthony DiTonno, Chief Executive Officer (Principal Executive Officer) of the Company, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 30, 2020

/s/ Anthony DiTonno
Anthony DiTonno
Chief Executive Officer
(Principal Executive Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350 and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

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

In connection with the Annual Report of Tenax Therapeutics, Inc. (the "Company") on Form 10-K for the period year December 31, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael B. Jebsen, Chief Financial Officer (Principal Financial Officer) of the Company, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 30, 2020

/s/ Michael B. Jebsen
Michael B. Jebsen
Chief Financial Officer
(Principal Financial Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350 and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.