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, 2017

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	**Name of Each Exchange on Which Registered**
Common Stock, $0.0001 par value per share	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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

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. (Check one):

Large accelerated filer	☐		Accelerated filer ☐
Non-accelerated filer	☐	(Do not check if a smaller reporting company)	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, 2017, the last business day of the registrant's most recently completed second fiscal quarter: $20,740,682

The number of shares outstanding of the registrant's class of $0.0001 par value common stock as of March 28, 2018 was 1,428,037.

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 2018 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, 2017.

TABLE OF CONTENTS

PART I

FORWARD-LOOKING STATEMENTS

All statements contained in this report, other than statements of historical fact, which address activities, actions, goals, prospects, or new developments, that we expect or anticipate will or may occur in the future, including plans for clinical tests and other such matters pertaining to testing and development products, are forward-looking statements. 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 and testing 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 for the critical care market. 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.

In April 2017, we announced that we would be exploring strategic alternatives in order to maximize stockholder value and that we had formed a strategic committee of three independent board members to supervise management in this review. We engaged Ladenburg Thalmann & Co. Inc., a subsidiary of Ladenburg Thalmann Financial Services Inc., as our financial advisor to assist in the strategic review process.

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 lead product candidates. Levosimendan represents novel therapeutic modalities for the treatment of pulmonary hypertension and other critical care conditions. 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 candidates have 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 certain areas, while out-licensing opportunities in non-core areas. 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 1,000,000 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. 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.

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.

Levosimendan Development for Pulmonary Hypertension Patients

Levosimendan is under development 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.

We plan to meet with the United States Food and Drug Administration, or FDA, to discuss the design of a proposed Phase 2 trial in PH-HFpEF patients during the first half of 2018. Following feedback from that meeting, we plan to complete the design of the Phase 2 trial and begin enrollment of the trial in the second half of 2018.

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 work day, developed using our property, or which relate to our business.

To date, we own or in-license the rights to seven U.S. and foreign patents. In addition, we have one U.S. patent application pending that is complemented by the appropriate foreign patent applications 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 2018 and 2031.

We have:

- one Australian patent (759,557) pertaining to the use and application of perfluorocarbons as gas transport agents in blood substitutes and liquid ventilation which expires in 2018;
- 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.

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. In addition, 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 a medication to treat pulmonary hypertension is novel. Because therapies are commonly used to treat pulmonary hypertension, 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.

As noted above, following the announcement of the Phase 3 LEVO-CTS top-line results, we held a meeting with the FDA to review the preliminary trial data and discuss a path forward to file a NDA for levosimendan. We explored the opportunity to submit an NDA for use in CABG patients on the basis of the robust reduction in 90-day mortality observed in the LEVO-CTS trial. The FDA advised that another study in CABG surgery patients would be required that prospectively tests levosimendan’s effectiveness in improving mortality.

Research and Development

Our research and development efforts are focused on the development and commercialization of levosimendan for its use in clinical indications, primarily pulmonary hypertension. Previously, we were also focused on furthering the development of levosimendan for its use in clinical indications, primarily for the treatment of LCOS. However, we have suspended the development of levosimendan for the treatment of LCOS while we evaluate strategic alternatives.

We spent approximately $3.5 million and $13.1 million on research and development during the fiscal years ended December 31, 2017 and 2016, respectively.

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, 2017, we had seven 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.

Financial Information by Geographic Area

As of December 31, 2017 and 2016, all long-lived assets with a net book value were located in the United States.

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 available for reading and copying at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains an Internet site (http://www.sec.gov) containing 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, developing our technology 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;
- the need to obtain regulatory approval of our most advanced 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, 2017, we had $9.5 million of cash, including the fair value of our marketable securities on hand. Based on our current operating plans, we believe that our existing cash and cash equivalents will be sufficient to fund our projected operating requirements through the first quarter of calendar year 2019. We will need substantial additional capital in the future in order to complete the 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, 2017 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 research or development programs 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 the 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 our cosmetic products and any product candidates for which we may receive regulatory approval.

Risks Related to Commercialization and Product Development

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 Phase 2 trial in PH-HFpEF that we plan to conduct, 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. For example, we held a meeting with the FDA to review the preliminary trial data for our Phase 3 LEVO-CTS trial and discuss a path forward to file an NDA for levosimendan. We explored the opportunity for submitting an NDA for use 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 use in CABG due to the scope of the repeat study, as required by the FDA.

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 our products, or that such approval, if obtained, will not include limitations on the indicated uses for which our products may be marketed. For example, the top-line results of our Phase 3 LEVO-CTS trial for levosimendan did not achieve statistically significant reductions in dual or quad primary endpoints but did meet two secondary endpoints with statistically significant reduction in incidence of LCOS and use of postoperative secondary inotropes. 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. For instance, based on the results of our LEVO-CTS clinical trial and subsequent FDA feedback, we do not anticipate undertaking further development with levosimendan in the LCOS indication.

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 our 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 our 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 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 contract research organizations, or 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 research, development, testing, manufacturing, 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; 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 of $5,500 to $11,000 per 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 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. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017, repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code, commonly referred to as the individual mandate, beginning in 2019, and on October 13, 2017, President Trump signed an executive order terminating the cost-sharing subsidies that reimburse the insurers under the ACA. 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.

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. Instead, we rely on third party manufacturers. For example, 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.

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, in particular, Michael Jebsen, our Interim Chief Executive Officer and Chief Financial Officer, 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 limited experience in the sale and marketing of medical products.

We have limited 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 global 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 product candidates 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 third parties that covers our product candidates. We rely on certain of these third parties 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 does 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 eighteen 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.

On December 31, 2017 the last closing price of our common stock was $9.80, as compared to $39.00 as of December 31, 2016. During the year ended December 31, 2017, the lowest closing price for our common stock was $6.40 and the highest closing price was $50.00. All stock prices are as adjusted for the 1-for-20 reverse stock split effective on February 23, 2018 at 5:00 p.m.

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. However, Nasdaq subsequently notified us that we had regained compliance with the minimum bid price requirement. 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, 2017, we had $9.5 million of cash and cash equivalents on hand. Based on our current operating plans, we believe our existing cash and cash equivalents are sufficient to continue to fund operations through the first quarter of calendar year 2019. 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.

We have issued in the past, and may issue in the future, substantial amounts of instruments that are convertible into or exercisable for common stock, and our existing stockholders may face substantial dilution if such instruments are converted or exercised.

As of March 26, 2018, we had outstanding warrants and options, securities purchase agreements, and other instruments that are exercisable into an aggregate of 309,517 shares of our common stock, which, if exercised, would represent approximately 18% of our current outstanding common stock. These instruments carry a wide variety of different terms and prices, and there can be no assurance as to when or whether exercises of these instruments may occur. If all or any substantial portion of these instruments are exercised, our existing stockholders may face substantial dilution of their ownership interests.

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 $9,400 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 Price and Number of Stockholders

Our common stock is listed on the Nasdaq Capital Market under the symbol "TENX." The following table sets forth, for the periods indicated, the range of high and low sales prices in each fiscal quarter for our common stock, all as adjusted for the 1-for-20 reverse stock split effective February 23, 2018 at 5:00 p.m.

Year-Ended December 31, 2016	**High**	**Low**
First Quarter	$ 67.40	$ 38.80
Second Quarter	$ 58.80	$ 40.00
Third Quarter	$ 55.40	$ 43.20
Fourth Quarter	$ 48.58	$ 24.20

Year-Ended December 31, 2017	**High**	**Low**
First Quarter	$ 53.00	$ 8.30
Second Quarter	$ 15.80	$ 8.28
Third Quarter	$ 15.50	$ 6.20
Fourth Quarter	$ 11.96	$ 7.02

As of March 26, 2018, there were 1,357 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. On March 26, 2018, the last sale price reported on the Nasdaq Capital Market for our common stock was $6.03 per share.

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

The following table lists all repurchases during the three months ended December 31, 2017 of any of our securities registered under Section 12 of the Exchange Act by or on behalf of us or any affiliated purchaser**.**

Issuer Purchases of Equity Securities	Total Number of Shares Purchased (1)	Average Price Paid per Share (2)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs
Period				
October 1, 2017 - October 31, 2017	-	$ -	-	$ -
November 1, 2017 - November 30, 2017	-	$ -	-	$ -
December 1, 2017 - December 31, 2017	11	$ 8.60	-	$ -
Total	11	$ 8.60	-	$ -

(1) Represents shares repurchased in connection with tax withholding obligations under the 1999 Amended Stock Plan.
(2) Represents the average price paid per share for the shares repurchased in connection with tax withholding obligations under the 1999 Amended Stock Plan.

Unregistered Sales of Equity Securities

None.

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, 2017 and 2016

Overview

Strategy

Levosimendan is under development 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.

We plan to meet with the FDA to discuss the design of a proposed Phase 2 trial in PH-HFpEF patients during the first half of 2018. Following feedback from that meeting, we plan to complete the design of the Phase 2 trial and begin enrollment of the trial in the second half of 2018.

Additionally, our Board of Directors is conducting a comprehensive review of strategic alternatives focused on maximizing stockholder value and has formed a strategic committee of three independent board members to supervise management in this review. We have engaged Ladenburg Thalmann & Co. Inc. as our financial advisor to assist in the strategic review process; including, but not limited to a merger, a business combination, or a purchase, license or other acquisition of assets. 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

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 2018, 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, 2017 and 2016, respectively, are as follows:

	Year ended December 31,		Increase/ (Decrease)	% Increase/ (Decrease)
	2017	2016		
Personnel costs	$ 3,315,303	$ 3,390,457	$ (75,154)	(2)%
Legal and professional fees	1,737,574	1,878,032	(140,458)	(7)%
Other costs	472,518	824,307	(351,789)	(43)%
Facilities	142,769	140,575	2,194	2%
Depreciation and amortization	10,417	12,587	(2,170)	(17)%

Personnel costs:

Personnel costs decreased approximately $75,000 for the year ended December 31, 2017 compared to the prior year. The decrease was due primarily to a decrease of approximately $658,000 in the salaries and bonuses paid, partially offset by an increase of approximately $71,000 in the recognized expense for the vesting of outstanding stock option awards as compared to the prior year, and an increase of approximately $512,000 in severance costs in the current year.

Legal and professional fees:

Legal and professional fees consist of the costs incurred for legal fees, accounting fees, consulting fees, recruiting costs and investor relations services, as well as fees paid to our Board of Directors. Legal and professional fees decreased approximately $140,000 for the year ended December 31, 2017 compared to the prior year. This decrease was due primarily to decreases in costs incurred for auditing, investor relations services and consulting fees, and the vested value of stock option grants to our Board of Directors, partially offset by an increase in costs incurred for legal fees.

- Audit and accounting fees decreased approximately $53,000 in the current year. This decrease was due primarily to the costs incurred for the change in our fiscal year, which necessitated the filing of our audited transitional financial statements in the prior year which were not incurred in the current period.
- Costs associated with investor relations and communication decreased approximately $47,000 in the current period. This decrease was due primarily to fees paid to a third-party investor relations firm providing marketing and corporate communications services to us in the prior year, which were not incurred in the current year.
- Consulting fees decreased approximately $129,000 in the current period. This decrease was due primarily to the fees paid to third-party firms for pre-launch commercialization preparations for LCOS, nationwide registrations for drug distribution and market analysis and research for septic shock in the prior year which were not incurred in the current period, partially offset by an increase in fees paid for medical consulting services in the current period.
- Board of Directors fees decreased in the current period by approximately $77,000. This decrease was due primarily to a reduction in the recognized expense for the vesting of stock options awarded in the current year as compared to the recognized expense for stock options awarded in the prior year.
- Legal fees increased in the current year by approximately $156,000. This increase was due primarily to additional costs incurred in the current year related to our evaluation of strategic alternatives as directed by our Board of Directors which were not incurred in the prior year.

Other costs:

Other costs include costs incurred for travel, supplies, insurance and other miscellaneous charges. The approximately $352,000 decrease in other costs for the year ended December 31, 2017 was due primarily to a reduction of approximately $184,000 in franchise taxes paid, a reduction of approximately $38,000 in travel related costs, a reduction of approximately $25,000 in costs incurred for online database research subscriptions, a reduction of approximately $51,000 in bank fees associated with the management of our investments in marketable securities and an overall decrease in supplies expenses, insurance and other miscellaneous charges in the current period 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, 2017 and 2016.

Depreciation and Amortization:

Depreciation and amortization costs remained relatively consistent for the years ended December 31, 2017 and 2016.

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 manufacturing and 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, laboratory 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, 2017 and 2016, respectively, are as follows:

	Year ended December 31,		Increase/ (Decrease)	% Increase/ (Decrease)
	2017	2016		
Clinical and preclinical development	$ 3,227,523	$ 11,681,352	$ (8,453,829)	(72)%
Personnel costs	177,614	785,550	(607,936)	(77)%
Consulting	113,386	640,088	(526,702)	(82)%
Other costs	5,590	26,326	(20,736)	(79)%
Depreciation	3,204	6,365	(3,161)	(50)%

Clinical and preclinical development:

Clinical and preclinical development costs include the costs associated with our Phase 3 clinical trial for levosimendan. The decrease of approximately $8.5 million in clinical and preclinical development costs for the year ended December 31, 2017, compared to the prior year, was primarily due to decreased expenditures for CRO costs to manage the Phase 3 LEVO-CTS clinical trial in the current year. For the year ended December 31, 2017, we recorded CRO costs of approximately $3.2 million for the management of the Phase 3 trial, compared to CRO costs of approximately $11.7 million, which includes approximately $4.7 million in pass-through site activation and enrolled patient costs, during the prior year.

Personnel costs:

Personnel costs decreased approximately $608,000 for the year ended December 31, 2017 compared to the prior year. This decrease was primarily due to severance payments of approximately $156,000 incurred in the prior year upon resignation of our prior Chief Medical Officer and a decrease of approximately $452,000 in overall salaries, including payroll taxes and benefits, paid due to a decrease in headcount during the year.

Consulting fees:

Consulting fees decreased approximately $527,000 for the year ended December 31, 2017 compared to the prior year, primarily due to a decrease in fees paid to a third-party consulting firm for services provided to improve training and communication with active sites in support of our Phase 3 LEVO-CTS clinical trial and contract labor for additional clinical trial support services in the prior year which were not incurred in the current year.

Other costs:

Other costs decreased approximately $21,000 for the year ended December 31, 2017 as compared to the prior year due primarily to a reduction in travel related costs in the current period.

Depreciation:

Depreciation costs remained relatively consistent for the years ended December 31, 2017 and 2016.

Loss on impairment of long lived assets

Impairment losses and percentage changes for the years ended December 31, 2017 and 2016, respectively, are as follows:

	Year ended December 31,		Increase/ (Decrease)	% Increase/ (Decrease)
	2017	2016		
Loss on impairment of long-lived assets	$ -	$ 33,265,100	$ (33,265,100)	(100)%

During the year ended December 31, 2016, we recognized an impairment of $33.3 million related to our levosimendan product in Phase 3 clinical trial, which represents approximately $22 million for in-process research and development, or IPR&D, assets and approximately $11.3 million for Goodwill.

The LEVO-CTS trial was completed in December of 2016. Based on the data from the 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. Based on the results of the LEVO-CTS trial and subsequent FDA feedback we do not anticipate additional development of levosimendan for the treatment of LCOS in patients undergoing cardiac surgery. As of December 31, 2016, management determined the IPR&D asset, and corresponding Goodwill, was more than temporarily impaired.

Other income, net

Other income includes non-operating income and expense items not otherwise recorded in our consolidated statement of operations and comprehensive loss. These items include, but are not limited to, revenue earned under sublease agreements for our California facility, changes in the fair value of financial assets and liabilities, interest income earned and fixed asset disposals. Other income for the years ended December 31, 2017 and 2016, respectively, is as follows:

	Year ended December 31,		(Increase)/ Decrease
	2017	2016	
Other income, net	$ (366,216)	$ (764,735)	$ 398,519

Other income decreased approximately $399,000 for the year ended December 31, 2017 compared to the prior year. This decrease is due primarily to the change in fair value of our Series C warrant derivative liability in the current year and a reduction in the interest earned on our investment in marketable securities as compared to the prior year.

During the year ended December 31, 2017, we recorded a derivative gain of approximately $192,000 which compared to a derivative gain of approximately $298,000 in the prior year. These charges to income are derived from the free-standing Series C warrants which are measured at their fair market value each period using the Monte Carlo simulation model.

During the year ended December 31, 2017, we recorded interest income of approximately $174,000 from our investments in marketable securities. This income is derived from approximately $353,000 in bond interest paid, partially offset by approximately $188,000 in charges for amortization of premiums paid and fair-value adjustments measured each period, which compares to approximately $992,000 in bond interest paid, partially offset by approximately $603,000 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, 2017, we had an accumulated deficit of approximately $213 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. As noted above, in April 2017, we announced that we would be exploring strategic alternatives in order to maximize stockholder value and that we had formed a strategic committee of three independent board members to supervise management in this review. We engaged Ladenburg Thalmann & Co. Inc., a subsidiary of Ladenburg Thalmann Financial Services Inc., as our financial advisor to assist in the strategic review process.

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 $8,062,893 and $13,628,175 and working capital of $7,054,053 and $7,428,938 as of December 31, 2017 and December 31, 2016, 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 in the clinical trial stage in the development of our product candidates. We recently completed a Phase 3 clinical trial for levosimendan. We expect our primary focus will be on initiating additional clinical and preclinical studies for levosimendan for pulmonary hypertension or other potential indications. Our ability to continue to pursue testing and development of our products beyond the first quarter of calendar year 2019 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.

Financings

We did not complete any financings during the year ended December 31, 2017 or 2016.

Cash Flows

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

	Year ended December 31,	
	2017	2016
Net cash used in operating activities	$ (12,140,517)	$ (15,871,300)
Net cash provided by investing activities	3,749,372	22,206,802

Net cash used in operating activities. Net cash used in operating activities was $12.1 million for the year ended December 31, 2017 compared to net cash used in operating activities of $15.9 million for the year ended December 31, 2016. The decrease in cash used for operating activities of $3.8 million was due primarily to a reduction in the costs incurred for the Phase 3 clinic trials for LCOS, which were completed in the current year.

Net cash provided by investing activities. Net cash provided by investing activities was $3.7 million for the year ended December 31, 2017 compared to net cash provided by investing activities of $22.2 million for the year ended December 31, 2016. The decrease in cash provided by investing activities was due primarily to a reduction in the sale of marketable securities 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 candidates and potential product candidates;
- the outcome, timing and cost of regulatory approvals and the regulatory approval process;
- 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, 2017 we believe we have sufficient capital on hand to continue to fund operations through the first quarter of calendar year 2019.

We will need substantial additional capital in the future in order to continue the development 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.

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.

Contractual Obligations

Contractual obligations represent future cash commitments and liabilities under agreements with third parties and exclude contingent contractual liabilities for which we cannot reasonably predict future payment, including contingencies related to potential future development, financing, contingent royalty payments and/or scientific, regulatory or commercial milestone payments under development agreements. The following table summarizes our contractual obligations as of December 31, 2017:

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Operating Lease Obligations	$ 416,224	$ 115,220	$ 301,004	$ -	$ -

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.

Impairment Testing—In accordance with GAAP, goodwill impairment testing is performed annually, or more frequently if indicated by events or conditions. In the course of the evaluation of the potential impairment of goodwill, either a qualitative or a quantitative assessment may be performed. If a qualitative evaluation determines that no impairment exists, then no further analysis is performed. If a qualitative evaluation is unable to determine whether impairment has occurred, a quantitative evaluation is performed. The quantitative impairment test first identifies potential impairments by comparing the fair value of the reporting unit with its carrying value. If the fair value exceeds the carrying amount, goodwill is not impaired. If the carrying value exceeds the fair value, the implied fair value of goodwill is calculated, and an impairment is recorded if the implied fair value is less than the carrying amount. The determination of goodwill impairment is highly subjective. It considers many factors both internal and external and is subject to significant changes from period to period.

During the year ended December 31, 2016, we recognized an impairment charge of $33.3 million related to our levosimendan product in Phase 3 clinical trial, which represents approximately $22 million for IPR&D assets and approximately $11.3 million for goodwill.

The LEVO-CTS trial was completed in December of 2016. Based on the data from the 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. Based on the results of the LEVO-CTS trial and subsequent FDA feedback we do not anticipate additional development of levosimendan for the treatment of LCOS in patients undergoing cardiac surgery. As of December 31, 2016, management determined the IPR&D asset, and corresponding Goodwill, was more than temporarily impaired.

Fair market value accounting (derivative warrant liability)—A significant estimate that could have a material effect on net (loss) gain is the fair market value accounting for our derivative liability. Our derivative liability consists of free standing warrants that are recorded as liabilities due to the price protection anti-dilution provisions in the event of a subsequent equity sale. As a result, the warrants must be recorded as a liability at fair value. The changes in fair value are posted in other (income) expense. We utilize the Monte Carlo method to estimate the fair value of our warrants. The three most significant factors in the Monte Carlo method are (i) our stock price, (ii) the volatility of our stock price and (iii) the remaining term of the warrants. During the year ending December 31, 2017, a $0.80 decrease in the value of our stock was the primary cause of the $192,419 derivative gain.

Recent Accounting Pronouncements

In July 2017, the Financial Accounting Standards Board, or the FASB, issued an accounting standard that changes the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. The amendments also clarify existing disclosure requirements for equity-classified instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. The standard will be effective on January 1, 2019. Early adoption is permitted, including adoption in an interim period. We do not believe adoption of this standard will have a material impact on our consolidated financial statements and related disclosures.

In January 2017, the FASB issued an accounting standard that provides guidance for evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The guidance provides a screen to determine when an integrated set of assets and activities, or a set, does not qualify to be a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in an identifiable asset or a group of similar identifiable assets, the set is not a business. If the screen is not met, the guidance requires a set to be considered a business to include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create outputs and removes the evaluation as to whether a market participant could replace the missing elements. The standard became effective on January 1, 2018 and was adopted on a prospective basis. We do not believe adoption of this standard will have a material impact on our consolidated financial statements and related disclosures.

In August 2016, the FASB issued an accounting standard that clarifies how companies present and classify certain cash receipts and cash payments in the statement of cash flows where diversity in practice exists. The standard is effective in our first quarter of fiscal 2018. We do not believe that adopting this updated standard will have a material impact on our consolidated financial statements and related disclosures.

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 will require 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, 2020, with early adoption permitted, but not earlier than annual reporting periods beginning January 1, 2019. 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 adoption of this standard will have a material impact on our consolidated financial statements and related disclosures.

In May 2014, the FASB issued an accounting standard that supersedes nearly all existing revenue recognition guidance under GAAP. The standard is principles-based and provides a five-step model to determine when and how revenue is recognized. The core principle of the standard is that revenue should be recognized when a company transfers promised goods or services to customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services. In March 2016, the FASB issued a standard to clarify the implementation guidance on principal versus agent considerations, and in April 2016, the FASB issued a standard to clarify the implementation guidance on identifying performance obligations and licensing. The standard also requires disclosure of qualitative and quantitative information surrounding the amount, nature, timing and uncertainty of revenues and cash flows arising from contracts with customers. In July 2015, the FASB agreed to defer the effective date of the standard from annual periods beginning after December 15, 2016, to annual periods beginning after December 15, 2017. Early application prior to the original effective date was not permitted. The standard permits the use of either the retrospective or cumulative effect transition method.

We reviewed our current accounting policies and practices to assess the impact of the guidance on our business processes. Based on this evaluation, the adoption of this standard will not have a material impact on our 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 will require us to recognize on the balance sheet the assets and liabilities for the rights and obligations created by all leased assets. The standard will also require 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 is effective for financial statements beginning after December 15, 2018, and interim periods within those annual periods. Early adoption is permitted. We are currently evaluating the impact that this standard will have on our consolidated financial statements and related disclosures.

In January 2016, the FASB issued an accounting standard that will enhance our reporting for financial instruments. The standard is effective for financial statements issued for annual periods beginning after December 15, 2017, and interim periods within those annual periods. Earlier adoption is permitted for interim and annual reporting periods as of the beginning of the fiscal year of adoption. We do not believe 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 of Tenax Therapeutics, Inc.

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, 2017 and 2016, 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, 2017, 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, 2017 and 2016, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2017, 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 to the financial statements, the Company has an accumulated deficit and has experienced negative operating cash flows for the year ended December 31, 2017. 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 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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ CHERRY BEKAERT LLP

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

Raleigh, North Carolina
April 2, 2018

TENAX THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2017	December 31, 2016
ASSETS		
Current assets		
Cash and cash equivalents	$ 1,604,810	$ 9,995,955
Marketable securities	6,122,400	3,284,616
Accounts receivable	50,171	72,599
Prepaid expenses	285,512	275,005
Total current assets	8,062,893	13,628,175
Marketable securities	1,809,428	8,586,110
Property and equipment, net	9,945	19,105
Other assets	8,435	1,106,785
Total assets	$ 9,890,701	$ 23,340,175
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 611,861	$ 727,599
Accrued liabilities	363,306	5,245,546
Warrant liabilities	33,673	226,092
Total current liabilities	1,008,840	6,199,237
Total liabilities	1,008,840	6,199,237
Commitments and contingencies; see Note F		
Stockholders' equity		
Common stock, par value $.0001 per share; authorized 400,000,000 shares; issued and outstanding 1,411,840 and 1,406,002, respectively	141	2,812
Additional paid-in capital	222,397,198	221,816,447
Accumulated other comprehensive loss	(16,193)	(18,718)
Accumulated deficit	(213,499,285)	(204,659,603)
Total stockholders' equity	8,881,861	17,140,938
Total liabilities and stockholders' equity	$ 9,890,701	$ 23,340,175

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,	
	2017	**2016**
Operating expenses		
General and administrative	5,678,581	6,245,958
Research and development	3,527,317	13,139,681
Loss on impairment of long-lived assets	-	33,265,100
Total operating expenses	9,205,898	52,650,739
Net operating loss	9,205,898	52,650,739
Other income	(366,216)	(764,735)
Income tax benefit	-	(7,962,100)
Net loss	$ 8,839,682	$ 43,923,904
Unrealized gain on marketable securities	(2,525)	(110,724)
Total comprehensive loss	$ 8,837,157	$ 43,813,180
Net loss per share, basic and diluted	$ (6.27)	$ (31.24)
Weighted average number of common shares outstanding, basic and diluted	1,410,630	1,405,992

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

TENAX THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock					
	Number of Shares	Amount	Additional paid-in capital	Accumulated other comprehensive gain (loss)	Accumulated deficit	Total stockholders' equity
Balance at December 31, 2015	**1,405,985**	**$ 2,812**	**$ 221,285,677**	**$ (129,442)**	**$ (160,735,699)**	**$ 60,423,348**
Compensation on options and restricted stock issued	17	-	530,770			530,770
Unrealized gain on marketable securities				110,724		110,724
Net loss					(43,923,904)	(43,923,904)
Balance at December 31, 2016	**1,406,002**	**$ 2,812**	**$ 221,816,447**	**$ (18,718)**	**$ (204,659,603)**	**$ 17,140,938**
Compensation on options and restricted stock issued	5,838	12	578,068			578,080
Unrealized gain on marketable securities				2,525		2,525
Par value adjustment due to reverse stock split		(2,683)	2,683			-
Net loss					(8,839,682)	(8,839,682)
Balance at December 31, 2017	**1,411,840**	**$ 141**	**$ 222,397,198**	**$ (16,193)**	**$ (213,499,285)**	**$ 8,881,861**

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

TENAX THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,	
	2017	**2016**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (8,839,682)	$ (43,923,904)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	13,621	18,952
Loss on impairment, disposal and write down of long-lived assets	-	33,265,100
Loss (Gain) on disposal of property and equipment	76	(74,388)
Issuance and vesting of compensatory stock options and warrants	498,491	529,708
Issuance of common stock as compensation	79,589	1,062
Change in the fair value of warrants	(192,419)	(298,248)
Amortization of premium on marketable securities	187,513	652,861
Deferred income taxes	-	(7,962,100)
Changes in operating assets and liabilities		
Accounts receivable, prepaid expenses and other assets	1,110,272	23,801
Accounts payable and accrued liabilities	(4,997,978)	1,895,856
Net cash used in operating activities	(12,140,517)	(15,871,300)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of marketable securities	(299,172)	(7,255,578)
Sale of marketable securities	4,053,081	29,390,264
Purchase of property and equipment	(4,537)	(2,884)
Proceeds from the sale of property and equipment	-	75,000
Net cash provided by investing activities	3,749,372	22,206,802
Net change in cash and cash equivalents	(8,391,145)	6,335,502
Cash and cash equivalents, beginning of period	9,995,955	3,660,453
Cash and cash equivalents, end of period	$ 1,604,810	$ 9,995,955

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

NOTE A—DESCRIPTION OF BUSINESS

Description of Business—Tenax Therapeutics (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 $213,499,285 and $204,659,603 at December 31, 2017 and 2016, respectively, and used cash in operations of $12,140,517 and $15,871,300 during the years ended December 31, 2017 and 2016, 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, 2017 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 accounting principles generally accepted in the United States of America ("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.

Goodwill

Acquired businesses are accounted for using the acquisition method of accounting, which requires that assets acquired, including identifiable intangible assets, and liabilities assumed be recorded at fair value, with limited exceptions. Any excess of the purchase price over the fair value of the net assets acquired is recorded as goodwill. If the acquired net assets do not constitute a business, the transaction is accounted for as an asset acquisition and no goodwill is recognized.

Goodwill is reviewed for impairment on an annual basis or more frequently if events or circumstances indicate potential impairment. The Company's goodwill evaluation is based on both qualitative and quantitative assessments regarding the fair value of goodwill relative to its carrying value. The Company assesses qualitative factors to determine if its sole reporting unit's fair value is more likely than not to exceed its carrying value, including goodwill. In the event the Company determines that it is more likely than not that its reporting unit's fair value is less than its carrying amount, quantitative testing is performed comparing recorded values to estimated fair values. If the fair value exceeds the carrying value, goodwill is not impaired. If the carrying value exceeds the fair value, an impairment charge is recognized through a charge to operations based upon the excess of the carrying value of goodwill over the implied fair value.

During the year ended December 31, 2016, the Company recognized an impairment charge of $33.3 million related to our levosimendan product in Phase 3 clinical trial, which represents approximately $22 million for in-process research and development ("IPR&D") assets and approximately $11.3 million for goodwill.

The LEVO-CTS trial was completed in December of 2016. Based on the data from the 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. Based on the results of the LEVO-CTS trial and subsequent U.S. Food and Drug Administration ("FDA") feedback, the Company does not anticipate additional development of levosimendan for the treatment of low cardiac output syndrome ("LCOS") in patients undergoing cardiac surgery. As of December 31, 2016, management determined the IPR&D asset, and corresponding goodwill, was more than temporarily impaired.

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

On July 21, 2010, the Wall Street Reform and Consumer Protection Act permanently increased the Federal Deposit Insurance Corporation (the "FDIC") insurance limits to $250,000 per depositor per insured bank. The Company had cash balances of $849,851 and $9,362,812 uninsured by the FDIC as of December 31, 2017 and 2016, 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 $8,062,893 and $13,628,175 and working capital of $7,054,053 and $7,428,937 as of December 31, 2017 and 2016, respectively.

Cash resources, including the fair value of the Company's available for sale marketable securities as of December 31, 2017 were approximately $9.5 million, compared to approximately $21.9 million as of December 31, 2016.

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, 2017, the Company believes that it has sufficient capital to fund its planned operations through the first quarter of calendar year 2019. 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.

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 FASB 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, 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 and a substantial portion of our preclinical studies; (ii) the cost of manufacturing and 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, 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 compensation in accordance with ASC 718 Compensation — Stock Compensation, which requires the measurement and recognition of compensation expense for all stock-based payment awards granted, modified and settled to our employees and directors. The Company chose the "straight-line" attribution method for allocating compensation costs of each stock option on a straight-line basis over the requisite service period using the Black-Scholes Option Pricing Model to calculate the grant date fair value.

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 note 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,	
	2017	**2016**
Options to purchase common stock	188,744	236,706
Warrants to purchase common stock	120,773	120,794
Restricted stock grants	-	12

Operating Leases

The Company maintains operating leases for its office and laboratory facilities. The lease agreements may include rent escalation clauses and tenant improvement allowances. The Company recognizes scheduled rent increases on a straight-line basis over the lease term beginning with the date the company takes possession of the leased space. Differences between rental expense and actual rental payments are recorded as deferred rent liabilities and are included in "Other liabilities" on the consolidated balance sheets.

Recent Accounting Pronouncements

In July 2017, the Financial Accounting Standards Board (the "FASB"), issued an accounting standard that changes the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. The amendments also clarify existing disclosure requirements for equity-classified instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. The standard will be effective on January 1, 2019. Early adoption is permitted, including adoption in an interim period. The Company does not believe adoption of this standard will have a material impact on its consolidated financial statements and related disclosures.

In January 2017, the FASB issued an accounting standard that provides guidance for evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The guidance provides a screen to determine when an integrated set of assets and activities, or a set, does not qualify to be a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in an identifiable asset or a group of similar identifiable assets, the set is not a business. If the screen is not met, the guidance requires a set to be considered a business to include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create outputs and removes the evaluation as to whether a market participant could replace the missing elements. The standard became effective on January 1, 2018 and was adopted on a prospective basis. The Company does not believe adoption of this standard will have a material impact on its consolidated financial statements and related disclosures.

In August 2016, the FASB issued an accounting standard that clarifies how companies present and classify certain cash receipts and cash payments in the statement of cash flows where diversity in practice exists. The standard is effective in the Company's first quarter of fiscal 2018. The Company does not believe adoption of this standard will have a material impact on its consolidated financial statements and related disclosures.

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 will require 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, 2020, with early adoption permitted, but not earlier than annual reporting periods beginning January 1, 2019. 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 adoption of this standard will have a material impact on its consolidated financial statements and related disclosures.

In May 2014, the FASB issued an accounting standard that supersedes nearly all existing revenue recognition guidance under GAAP. The standard is principles-based and provides a five-step model to determine when and how revenue is recognized. The core principle of the standard is that revenue should be recognized when a company transfers promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. In March 2016, the FASB issued a standard to clarify the implementation guidance on principal versus agent considerations, and in April 2016, the FASB issued a standard to clarify the implementation guidance on identifying performance obligations and licensing. The standard also requires disclosure of qualitative and quantitative information surrounding the amount, nature, timing and uncertainty of revenues and cash flows arising from contracts with customers. In July 2015, the FASB agreed to defer the effective date of the standard from annual periods beginning after December 15, 2016, to annual periods beginning after December 15, 2017. Early application prior to the original effective date was not permitted. The standard permits the use of either the retrospective or cumulative effect transition method.

The Company reviewed its current accounting policies and practices to assess the impact of the guidance on its business processes. Based on this evaluation, the adoption of this standard will not 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 will require the Company to recognize on the balance sheet the assets and liabilities for the rights and obligations created by all leased assets. The standard will also require 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 is effective for financial statements beginning after December 15, 2018, and interim periods within those annual periods. Early adoption is permitted. The Company is currently evaluating the impact that this standard will have on its consolidated financial statements and related disclosures.

In January 2016, the FASB issued an accounting standard that will enhance the Company's reporting for financial instruments. The standard is effective for financial statements issued for annual periods beginning after December 15, 2017, and interim periods within those annual periods. Earlier adoption is permitted for interim and annual reporting periods as of the beginning of the fiscal year of adoption. The Company does not believe adoption of this standard will have a material impact on its consolidated financial statements and related disclosures.

Fair Value

The Company determines the fair value of its financial assets and liabilities in accordance with the FASB Accounting Standards Codification ("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 $422 and a loss $41,955 for the years ended December 31, 2017 and 2016, 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, 2017, 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 are classified as Level 2 in the fair value hierarchy as defined in U.S. GAAP. These fair values are obtained from independent pricing services which utilize Level 2 inputs:

	December 31, 2017				
	Amortized Cost	Accrued Interest	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities	$ 7,878,955	$ 69,066	$ 2,322	$ (18,515)	$ 7,931,828

The following table summarizes the scheduled maturity for the Company's investments at December 31, 2017 and 2016, respectively:

	December 31, 2017	December 31, 2016
Maturing in one year or less	$ 6,122,400	$ 3,284,616
Maturing after one year through three years	1,809,428	8,586,110
Total investments	$ 7,931,828	$ 11,870,726

Warrant liability

On July 23, 2013, the Company issued common stock warrants in connection with the issuance of Series C 8% Preferred Stock (the "Series C Warrants"). As part of the offering, the Company issued 137,668 warrants at an exercise price of $52.00 per share and contractual term of 6 years. On November 11, 2013, the Company satisfied certain contractual obligations pursuant to the Series C offering which caused certain "down-round" price protection clauses in the outstanding warrants to become effective on that date. In accordance with ASC 815-40-35-9, the Company reclassified these warrants as a current liability and recorded a warrant liability of $1,380,883, which represents the fair market value of the warrants at that date. The initial fair value recorded as warrants within stockholders' equity of $233,036 was reversed and the subsequent changes in fair value are recorded as a component of other expense.

Financial assets or liabilities are considered Level 3 when their fair values are determined using pricing models, discounted cash flow methodologies or similar techniques and at least one significant model assumption or input is unobservable. The Series C Warrants are measured using the Monte Carlo valuation model which is based, in part, upon inputs for which there is little or no observable market data, requiring the Company to develop its own assumptions. The assumptions used in calculating the estimated fair value of the warrants represent the Company's best estimates; however, these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and different assumptions are used, the warrant liabilities and the change in estimated fair value of the warrants could be materially different.

Inherent in the Monte Carlo valuation model are assumptions related to expected stock-price volatility, expected life, risk-free interest rate and dividend yield. The Company estimates the volatility of its common stock based on historical volatility that matches the expected remaining life of the warrants. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected remaining life of the warrants. The expected life of the warrants is assumed to be equivalent to their remaining contractual term. The dividend rate is based on the historical rate, which the Company anticipates to remain at zero.

The Monte Carlo model is used for the Series C Warrants to appropriately value the potential future exercise price adjustments triggered by the anti-dilution provisions. This requires Level 3 inputs which are based on the Company's estimates of the probability and timing of potential future financings and fundamental transactions. The other assumptions used by the Company are summarized in the following table for the Series C Warrants that were outstanding as of December 31, 2017 and December 31, 2016:

Series C Warrants	December 31, 2017	December 31, 2016
Closing stock price	$ 9.80	$ 39.00
Expected dividend rate	0%	0%
Expected stock price volatility	81.26%	79.60%
Risk-free interest rate	1.83%	1.35%
Expected life (years)	1.56	2.56

As of December 31, 2017, the fair value of the warrant liability was $33,673. The Company recorded a gain of $192,419 for the change in fair value as a component of other expense on the consolidated statement of comprehensive loss for the year ended December 31, 2017.

The Company recorded a gain of $298,248 for the change in fair value as a component of other expense on the consolidated statement of comprehensive loss for the year ended December 31, 2016.

As of December 31, 2017, 12,035 Series C Warrants are outstanding.

The following tables summarize information regarding assets and liabilities measured at fair value on a recurring basis as of December 31, 2017 and December 31, 2016:

	Balance as of December 31, 2017	Fair Value Measurements at Reporting Date Using: 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	$ 1,604,810	$ 1,604,810	$ -	$ -
Marketable securities	$ 6,122,400	$ -	$ 6,122,400	$ -
Long-term Assets				
Marketable securities	$ 1,809,428	$ -	$ 1,809,428	$ -
Current Liabilities				
Warrant liabilities	$ 33,673	$ -	$ -	$ 33,673

	Balance as of December 31, 2016	Fair Value Measurements at Reporting Date Using: 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	$ 9,995,955	$ 9,995,955	$ -	$ -
Marketable securities	$ 3,284,616	$ -	$ 3,284,616	$ -
Long-term Assets				
Marketable securities	$ 8,586,110	$ -	$ 8,586,110	$ -
Current Liabilities				
Warrant liabilities	$ 226,092	$ -	$ -	$ 226,092

There were no significant transfers between levels during the year ended December 31, 2017.

NOTE C—BALANCE SHEET COMPONENTS

Property and equipment, net

Property and equipment consist of the following:

	December 31, 2017	December 31, 2016
Laboratory equipment	$ 354,861	$ 354,861
Computer equipment and software	88,998	101,677
Office furniture and fixtures	130,192	130,192
	574,051	586,730
Less: Accumulated depreciation	(564,106)	(567,625)
	$ 9,945	$ 19,105

Depreciation and amortization expense was $13,621 and $18,952 for the years ended December 31, 2017 and 2016, respectively.

Accrued liabilities

Accrued liabilities consist of the following:

	December 31, 2017	December 31, 2016
Operating costs	$ 39,252	$ 4,361,538
Employee related	324,054	884,008
	$ 363,306	$ 5,245,546

NOTE D—INTANGIBLE ASSETS

In Process Research and Development—The levosimendan product in Phase 3 clinical trial represents an IPR&D asset. The IPR&D asset is a research and development project rather than a product or processes already in service or being sold. Research and development intangible assets are considered indefinite-lived until the abandonment or completion of the associated research and development efforts. If abandoned, the assets would be impaired. Research and development expenditures that are incurred after the acquisition, including those for completing the research and development activities related to the acquired intangible research and development assets, are generally expensed as incurred.

During the year ended December 31, 2016, the Company recognized an impairment charge of $33.3 million related to our levosimendan product in Phase 3 clinical trial, which represents approximately $22 million for IPR&D assets and approximately $11.3 million for goodwill.

The LEVO-CTS trial was completed in December of 2016. Based on the data from the 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. Based on the results of the LEVO-CTS trial and subsequent FDA feedback, the Company does not anticipate additional development of levosimendan for the treatment of LCOS in patients undergoing cardiac surgery. As of December 31, 2016, the Company determined the IPR&D asset, and corresponding Goodwill, was more than temporarily impaired.

NOTE E—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.

As of December 31, 2017, 10,000,000 shares of preferred stock are undesignated.

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, 2017, and December 31, 2016 there were 1,411,840 and 1,406,002 shares of common stock issued and outstanding.

Warrants

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 5 years. The warrant is initially exercisable for 1,250 shares of common stock, and the number of shares of common stock exercisable under this warrant 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 eighteen 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 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, 2017, 1,250 of these warrants are outstanding.

Series D Warrants

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 6 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 is exercisable beginning on the date of issuance and expires on August 22, 2019. The exercise price and the number of shares issuable upon exercise of Series D Warrant is 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 is obtained, the Series D Warrant will 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 exceeds $130.00 and the daily dollar trading volume exceeds $350,000 per trading day.

On January 30, 2014, the Company entered into an agreement with the OXBT Fund to amend the terms of the outstanding Series D Warrants. The amendment replaced the price protection anti-dilution provision of each warrant with a covenant that the Company will not issue common stock or common stock equivalents at an effective price per share below the exercise price of such warrant without prior written consent, subject to certain exceptions.

The Series D Stock and the Series D Warrant were 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 may exercise the 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.

On June 17, 2014, the Company received proceeds of $544,000 and issued 10,461 shares of common stock upon the exercise of the Series D warrants. As of December 31, 2017, 107,488 Series D Warrants are outstanding.

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 6 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.

In connection with the Series C Offering described above, the Company entered into a Placement Agency Agreement (the "Placement Agency Agreement") with Ladenburg Thalmann & Co. Inc. (the "Placement Agent") pursuant to which the Placement Agent agreed to act as the Company's exclusive placement agent for the Series C Offering. In accordance with the Placement Agency Agreement, on July 23, 2013 the Company issued to the Placement Agent warrants to purchase 2,677 shares of common stock at an exercise price of $48.75 per share and a contractual term of 3 years. In accordance with ASC 815, these warrants are classified as equity and their relative fair-value of $51,231 was recognized as additional paid in capital 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.

Between October 2013 and April 2014, the Company received cash of approximately $6.5 million and issued 125,633 shares of common stock upon the exercise of outstanding Series C Warrants. As of December 31, 2017, 12,035 Series C Warrants are outstanding.

In accordance with ASC 815-40-35-8, the Company reassessed the classification of the remaining Series C Warrants. On November 11, 2013, the Company satisfied certain contractual obligations pursuant to the Series C offering which caused certain "down-round" price protection clauses in the outstanding warrants to become effective on that date. In accordance with ASC 815-40-35-9, on November 11, 2013, the Company reclassified these warrants as a current liability and recorded a warrant liability of $1,082,941 which represents the fair market value of the warrants at that date. The initial fair value recorded as warrants within stockholders' equity of $233,036 was reversed and the change in fair value was recorded as a component of other expense.

The estimated fair value is determined using the Monte Carlo 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, expected volatility of the price of the underlying common stock as well as other estimates and assumptions.

As of December 31, 2017, the fair value of the warrant liability was $33,673. The Company recorded a gain of $192,419 for the change in fair value as a component of other expense on the consolidated statement of operations and comprehensive loss for the year ended December 31, 2017.

As of December 31, 2017, the Company has 120,773 warrants outstanding. During the years ended December 31, 2017 and 2016, no warrants were issued or exercised.

The following table summarizes the Company's warrant activity for the year ended December 31, 2017 and December 31, 2016:

	Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2015	**136,423**	**$ 87.76**
Issued	-	-
Exercised	-	-
Forfeited	(15,629)	358.71
Outstanding at December 31, 2016	**120,794**	**$ 52.71**
Issued	-	-
Exercised	-	-
Forfeited	(21)	2,460.00
Outstanding at December 31, 2017	**120,773**	**$ 52.29**

1999 Amended Stock Plan

In October 2000, the Company adopted the 1999 Stock Plan, as amended and restated on June 17, 2008 (the "Plan"). Under the Plan, with the approval of the Compensation Committee of the Board of Directors, the Company may grant stock options, restricted stock, stock appreciation rights and new shares of common stock upon exercise of stock options. On September 30, 2011, the Company's stockholders approved an amendment to the Plan which increased the number of shares authorized for issuance under the Plan to 15,000, up from 2,000 previously authorized.

On March 13, 2014, the Company's stockholders approved an amendment to the Plan which increased the number of shares of common stock authorized for issuance to a total of 200,000 shares, up from 15,000 previously authorized.

In accordance with the terms of the acquisition of certain rights to levosimendan from Phyxius, the Company issued an aggregate of 178,644 stock options with a grant date fair value of $15,818,512, to the Chief Executive Officer, the Chief Financial Officer, the Executive Vice President, Business and Commercial Operations and the Executive Vice President, Regulatory Affairs. These options were issued with a six-year term and subject to multiple performance-based vesting conditions. During the year ended April 30, 2014, the Company recorded approximately $7.9 million of compensation expense for the vested options in its consolidated statements of operations. An additional $5.9 million of compensation expense related to these grants will be recognized as performance vesting conditions are achieved.

On September 15, 2015, the Company's stockholders approved an additional amendment to the Plan which increased the number of shares of common stock authorized for issuance to a total of 250,000 shares, up from 200,000 previously authorized.

As of December 31, 2017 the Company had 55,561 shares of common stock available for grant under the Plan.

The following table summarizes the shares available for grant under the Plan for the years ended December 31, 2017 and 2016:

	Shares Available for Grant
Balances, at December 31, 2015	49,736
Options granted	(36,300)
Restricted stock granted	(22)
Restricted stock cancelled/forfeited	11
Balances, at December 31, 2016	13,425
Options granted	(13,000)
Options cancelled/forfeited	60,962
Restricted stock granted	(10,691)
Restricted stock cancelled/forfeited	4,865
Balances, at December 31, 2017	55,561

Plan Stock Options

Stock options granted under the 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 Plan may 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 Plan for the years ended December 31, 2017 and 2016:

	Outstanding Options		
	Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value
Balances at December 31, 2015	200,406	$ 110.00	
Options granted	36,300	$ 42.40	
Options cancelled	-	$ -	
Balances at December 31, 2016	236,706	$ 99.74	
Options granted	13,000	$ 11.06	
Options cancelled	(60,962)	$ 94.75	
Balances at December 31, 2017	188,744	$ 95.24	$ - (1)

(1)Amount represents the difference between the exercise price and $9.80, the closing price of Tenax Therapeutics' stock on December 31, 2017, as reported on the Nasdaq Capital Market, for all in-the-money options outstanding.

The following table summarizes all options outstanding as of December 31, 2017:

	Options Outstanding at December 31, 2017			Options Exercisable and Vested at December 31, 2017	
Exercise Price	Number of Options	Weighted Average Remaining Contractual Life (Years)	Number of Options	Weighted Average Exercise Price
$ 10.60 to $63.20	44,500	8.8	13,881	$ 53.64
$ 67.00 to $95.20	6,251	6.8	6,249	$ 77.14
$ 96.40 to $113.00	137,733	2.4	70,743	$ 112.41
$ 296.00 to $2,760.00	260	3.3	260	$ 1,105.85
	188,744	4.0	91,133	$ 103.88

The following table summarizes options outstanding that have vested and are expected to vest based on options outstanding as of December 31, 2017:

	Number of Option Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value (1)	Weighted Average Remaining Contractual Life (Years)
Vested	91,133	$ 103.88	$ -	3.7
Vested and expected to vest	118,389	$ 87.02	$ -	4.9

(1)Amount represents the difference between the exercise price and $9.80, the closing price of Tenax Therapeutics' stock on December 31, 2017, 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 its stock option plans for the years ended December 31, 2017 and 2016:

	For the year ended December 31,	
	2017	2016
Risk-free interest rate (weighted average)	2.19%	2.28%
Expected volatility (weighted average)	99.59%	83.38%
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 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, 2017 and 2016 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, 2017 was $11.00.

The weighted-average grant-date fair value of options granted during the year ended December 31, 2016 was $42.40.

The Company recorded compensation expense for these stock options grants of $498,491 and $529,708 for the years ended December 31, 2017 and 2016, respectively.

As of December 31, 2017, there were unrecognized compensation costs of approximately $384,000 related to non-vested stock option awards that will be recognized on a straight-line basis over the weighted average remaining vesting period of 1.6 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 2.3 years. As of December 31, 2017, none of these milestones have been achieved.

Inducement Stock Options

The table below summarizes the employment inducement stock option award for 1,250 shares of common stock made to our Chief Medical Officer on February 15, 2015. This employment inducement stock option was awarded in accordance with the employment inducement award exemption provided by Nasdaq Rule 5635(c)(4) and was therefore not awarded under the Company's stockholder approved equity plan. The option award will vest over a three year period, with one-third vesting per year, beginning one year from the grant date. The options have a 10-year term and an exercise price of $64.40 per share, the February 13, 2015 closing price of the Company's common stock.

A summary of the activity and related information for our stock options follows:

	Number of Shares	Weighted Average Exercise Price
Inducement Stock Options outstanding at December 31, 2015	1,250	$ 64.40
Options granted	-	-
Options exercised	-	-
Options forfeited or expired	(833)	64.40
Inducement Stock Options outstanding at December 31, 2016	417	$ 64.40
Options granted	-	-
Options exercised	-	-
Options forfeited or expired	(417)	64.40
Inducement Stock Options outstanding at December 31, 2017	-	$ -
Options exercisable at December 31, 2017	-	$ -

Inducement stock option compensation expense was approximately $8,000 for the year ended December 31, 2017.

Inducement stock option compensation expense was approximately $20,000 for the year ended December 31, 2016.

There were no inducement stock options outstanding as of December 31, 2017.

The estimated weighted average fair value per inducement option share granted was $64,343 in 2015 using a Black-Scholes option pricing model based on market prices and the following assumptions at the date of inducement option grant: weighted average risk-free interest rate of 1.84%, dividend yield of 0%, volatility factor for our common stock of 93.90% and a weighted average expected life of 7 years for inducement options not forfeited.

Restricted Stock Grants

The following table summarizes the outstanding restricted stock under the Plan for the years ended December 31, 2017 and 2016:

	Outstanding Restricted Stock Grants	
	Number of Shares	Weighted Average Grant Date Fair Value
Balances, at December 31, 2015	20	$ 66.80
Restricted stock granted	22	$ 54.40
Restricted stock vested	(16)	$ 62.20
Restricted stock cancelled	(14)	$ 62.60
Balances, at December 31, 2016	12	$ 54.40
Restricted stock granted	10,691	$ 13.60
Restricted stock vested	(5,838)	$ 13.60
Restricted stock cancelled	(4,865)	$ 13.60
Balances, at December 31, 2017	-	$ -

The Company recorded compensation expense for these restricted stock grants of $560 and $1,758 for the years ended December 31, 2017 and 2016, respectively.

As of December 31, 2017, there were no unrecognized compensation costs related to the non-vested restricted stock grants that will be recognized on a straight-line basis over the remaining vesting period.

2016 Stock Incentive Plan

On June 16, 2016, the Company's stockholders approved the 2016 Stock Incentive Plan (the "2016 Plan"), which provides for the issuance of up to 150,000 shares of common stock. 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.

As of December 31, 2017 the Company had not issued any awards under the 2016 Plan and there were 150,000 shares of common stock available for grant under the 2016 Plan.

NOTE F—COMMITMENTS AND CONTINGENCIES

Operating Leases

The Company leases its office space under an operating lease that includes fixed annual increases and expires in June 2021. Total rent expense was $112,431 and $91,208 for the years ended December 31, 2017 and 2016, respectively.

The future minimum payments for the long-term, non-cancelable lease are as follows:

Year ending December 31,	
2018	115,220
2019	118,117
2020	121,084
2021	61,803
	$ 416,224

Simdax license agreement

On November 13, 2013 the Company acquired 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"), which granted it an exclusive, sublicenseable right to develop and commercialize pharmaceutical products containing levosimendan in the United States and Canada. Pursuant to the License, the Company must use the "Simdax®" trademark owned by Orion to commercialize pharmaceutical products containing levosimendan, 2.5 mg/ml concentrate for solution for infusion / 5ml vial (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.

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 United States and Canada (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 (15) year term, provided, however, that the License will continue after the end of the fifteen year term in each country in the Territory until the expiration of Orion's patent rights in the Product in such country. Orion had the right to terminate the License if the human clinical trial using the Product and studying reduction in morbidity and mortality of cardiac surgery patients at risk of LCOS was not started by July 31, 2014. While the Company did not commence the trial by that date, on September 9, 2014, Orion notified the Company in writing that it did not intend to terminate the License so long as the trial was commenced on or before October 31, 2014. The Company subsequently commenced the human clinical trial for levosimendan on September 18, 2014 when the first patient was enrolled.

The License includes the following development milestones for which the Company shall make non-refundable payments to Orion no later than twenty-eight (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, the Company must pay Orion a royalty based on net sales of the Product in the Territory for as long as Life Newco sells the Product in the Territory.

As of December 31, 2017, the Company has not met any of the developmental milestones and, accordingly, has not recorded any liability for the contingent payments due to Orion.

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 G—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, 2017 and 2016, the Company recorded $74,990 and $83,589 for matching contributions expense, respectively.

NOTE H—INCOME TAXES

The Company has not recorded any income tax expense (benefit) for the period ended December 31, 2017 due to its history of net operating losses.

The Company's provision for income taxes is summarized as follows:

	December 31,	
	2017	2016
Current federal income tax expense	$ -	$ -
Deferred federal income tax benefit	-	(7,139,565)
Provision for federal income taxes:	-	(7,139,565)
Current state income tax expense	-	-
Deferred state income tax benefit	-	(822,535)
Provision for state income taxes:	-	(822,535)
Total	$ -	$ (7,962,100)

The reconciliation of income tax expenses (benefit) at the statutory federal income tax rate of 34% for the periods ended December 31, 2017 and December 31, 2016 is as follows:

	December 31,	
	2017	2016
U.S. federal taxes (benefit) at statutory rate	$ (3,005,491)	$ (17,641,231)
State income tax benefit, net of federal benefit	(346,057)	(2,031,238)
Stock compensation	169,312	141,807
Other nondeductible, including goodwill impairment	(71,044)	4,160,717
Change in state tax rate	(426,159)	241,518
Change in the federal tax rate	17,474,188	-
Federal and state net operating loss adjustments	774,875	-
Other, including effect of tax rate brackets	(265,181)	(57,490)
Change in valuation allowance	(14,304,443)	7,223,817
	$ -	$ (7,962,100)

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	2017	2016
Net operating loss carryforwards	$ 32,239,768	$ 46,227,681
Accruals and other	567,090	902,546
Capital loss carryforwards	16,466	12,395
Valuation allowance	(32,781,999)	(47,086,442)
Net deferred tax assets	41,325	56,180
Deferred Tax Liabilities		
Other liabilities	(41,325)	(56,180)
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 decrease in the valuation allowance during 2017 was approximately $14.3 million.

On December 22, 2017, the Tax Cuts and Jobs Act (the "Tax Act") was enacted into law, which reduced the federal corporate income tax rate to 21% for tax years beginning after December 31, 2017. As a result of the newly enacted tax rate, the Company adjusted its deferred tax assets as of December 31, 2017, by applying the new 21% rate, which resulted in a decrease to the net deferred tax asset of approximately $17.5 million.

The SEC staff issued SAB 118 which will allow the Company to record provisional amounts related to accounting for the Tax Act during a measurement period which is similar to the measurement period used when accounting for business combinations. The Company is following the guidance set forth by SAB 118 and any amounts calculated are provisional estimates and will be reevaluated as more information or guidance becomes available. The Company will continue to assess the impact of the recently enacted Tax Act on its business and consolidated financial statements.

As of December 31, 2017, the Company had federal and state net operating loss carryforwards of approximately $132.2 million and $105.6 million available to offset future federal and state taxable income, respectively. The federal and state net operating loss carryforwards begin to expire in 2018 and valuation allowances have been provided.

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, 2017.

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 I—SUBSEQUENT EVENTS

On February 22, 2018, the Company filed a Certificate of Amendment to the Company's Certificate of Incorporation with the Secretary of State of the State of Delaware (the "Amendment") to effect a reverse stock split of the Company's common stock at a ratio of one-for-twenty, effective as of February 23, 2018 at 5:00 p.m. The Amendment did not change the number of authorized shares or the par value of the Company's common stock. The Amendment provides that every twenty shares of the Company's issued and outstanding common stock were automatically combined into one issued and outstanding share of the Company's common stock.

The Amendment was approved by the stockholders of the Company at a special meeting of stockholders held on February 15, 2018, with the ratio of the reverse stock split to be not less than one-for-five and not more than one-for-fifty, as determined by the Company's Board of Directors. The Company's Board of Directors approved the Amendment with the one-for-twenty ratio on the same date.

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, 2017, 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, 2017, 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, 2017. 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, 2017.

ITEM 9B—OTHER INFORMATION

There is no information to report under this item for the quarter ended December 31, 2017.

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 2018 Annual Meeting of Stockholders, which will be filed with the SEC within 120 days after the end of fiscal 2017.

ITEM 11— EXECUTIVE COMPENSATION

The information required by this item is incorporated by reference to our Proxy Statement for our 2018 Annual Meeting of Stockholders, which will be filed with the SEC within 120 days after the end of fiscal 2017.

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 2018 Annual Meeting of Stockholders, which will be filed with the SEC within 120 days after the end of fiscal 2017.

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 2018 Annual Meeting of Stockholders, which will be filed with the SEC within 120 days after the end of fiscal 2017.

ITEM 14— PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference to our Proxy Statement for our 2018 Annual Meeting of Stockholders, which will be filed with the SEC within 120 days after the end of fiscal 2017.

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, 2017 and December 31, 2016.
- Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2017 and 2016.
- Consolidated Statements of Stockholders' Equity for the years ended December 31, 2017 and 2016.
- Consolidated Statements of Cash Flows for the years ended December 31, 2017 and 2016.
- 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 dated April 28, 2008 (1)
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 (31)
3.1	Certificate of Incorporation (1)
3.2	Certificate of Amendment of the Certificate of Incorporation (12)
3.3	Certificate of Amendment of the Certificate of Incorporation (28)
3.4	Certificate of Amendment of the Certificate of Incorporation (35)
3.5	Certificate of Amendment of the Certificate of Incorporation (41)
3.6	Third Amended and Restated Bylaws (37)
4.1	Specimen Stock Certificate (17)
10.1	Agreement with Leland C. Clark, Jr., Ph.D. dated November 20, 1992 with amendments, Assignment of Intellectual Property/ Employment (2)
10.2	Agreement between the Registrant and Keith R. Watson, Ph.D. Assignment of Invention (2)
10.3	Children's Hospital Research Foundation License Agreement dated February 28, 2001 (2)
10.4	Form of Option issued to Executive Officers and Directors (2) +

10.5	Form of Option issued to Employees (2) +
10.6	Form of Option Agreement with Form of Notice of Grant (43) +
10.7	Form of Inducement Stock Option Award (38) +
10.8	Restricted Stock Award Agreement (20) +
10.9	Form of Warrant issued to Unsecured Note Holders 2006-2007 (3)
10.10	Form of Convertible Note – 2008 (4)
10.11	Form of Warrant issued to Convertible Note Holders (4)
10.12	Form of Purchase Agreement – US Purchase (without exhibits, which are included as exhibits 10.16 and 10.17, above) (4)
10.13	Form of Purchase Agreement – Non-US Purchase (without exhibits, which are included as exhibits 10.16 and 10.17, above) (4)
10.14	Form of Purchase Agreement – US Note Exchange (without exhibits, which are included as exhibits 10.16 and 10.17, above) (4)
10.15	Form of Purchase Agreement – Non-US Note Exchange (without exhibits, which are included as exhibits 10.16 and 10.17, above) (4)
10.16	Form of Warrant issued to Financing Consultants (5)
10.17	1999 Amended Stock Plan (amended 2008) (5) +
10.18	Amendment No. 1 to Oxygen Biotherapeutics, Inc. 1999 Amended Stock Plan (36) +
10.19	Amendment No. 2 to Oxygen Biotherapeutics, Inc. 1999 Amended Stock Plan (36) +
10.20	2016 Stock Incentive Plan (39) +
10.21	Employment Agreement with John Kelley dated November 13, 2013 (32) +
10.22	First Amendment to Employment Agreement with John Kelley dated June 18, 2015 (34) +
10.23	Amended and Restated Employment Agreement with Michael B. Jebsen dated May 19, 2011 (18) +
10.24	Second Amended and Restated Employment Agreement with Michael Jebsen dated November 13, 2013 (32) +
10.25	First Amendment to Second Amended and Restated Employment Agreement with Michael Jebsen dated June 18, 2015 (34) +
10.26	Separation and General Release Agreement dated April 7, 2017 between Tenax Therapeutics, Inc. and John Kelley (42) +

10.27	Form of Indemnification Agreement (18) +
10.28	Description of Non-Employee Director Compensation (23) +
10.29	Description of Non-Employee Director Compensation, effective June 15, 2015 (37) +
10.30	Securities Purchase Agreement (including exhibits) between Oxygen Biotherapeutics and Vatea Fund, Segregated Portfolio dated June 8, 2009 (6)
10.31	Amendment no. 1 to the Securities Purchase Agreement between Oxygen Biotherapeutics and Vatea Fund, Segregated Portfolio (9)
10.32	Amendment no. 2 to the Securities Purchase Agreement between Oxygen Biotherapeutics and Vatea Fund, Segregated Portfolio (10)
10.33	Amendment no. 3 to the Securities Purchase Agreement between Oxygen Biotherapeutics and Vatea Fund, Segregated Portfolio (21)
10.34	Form of Exchange Agreement dated July 20, 2009 (7)
10.35	Waiver—Convertible Note (8)
10.36	Amendment—Common Stock Purchase Warrant (8)
10.37	Form of Warrant for May 2010 offering (11)
10.38	Form of Subscription Agreement for May 2010 offering (11)
10.39	Warrant issued to Blaise Group International, Inc. (12)
10.40	Note Purchase Agreement between Oxygen Biotherapeutics and JP SPC 1 Vatea, Segregated Portfolio (13)
10.41	Form of Promissory Note under Note Purchase Agreement between Oxygen Biotherapeutics and JP SPC 1 Vatea, Segregated Portfolio (13)
10.42	First Amendment to Note Purchase Agreement between Oxygen Biotherapeutics and JP SPC 1 Vatea, Segregated Portfolio (15)
10.43	Lease Agreement for North Carolina corporate office (16)
10.44	Task Order between the Company and NextPharma, dated November 15, 2011 (21)
10.45	Form of Convertible Note for July 2011 offering (included in exhibit 10.47)
10.46	Form of Warrant for July 2011 offering (included in exhibit 10.47)
10.47	Form of Convertible Note and Warrant Purchase Agreement for July 2011 offering (19)
10.48	Placement Agency Agreement, dated December 8, 2011, between Oxygen Biotherapeutics, Inc. and William Blair & Company, L.L.C., as placement agent (22)

10.49	Form of Warrant for December 2011 offering (22)
10.50	Form of Securities Purchase Agreement for December 2011 offering (22)
10.51	Form of Amendment Agreement for December 2011 offering (24)
10.52	Form of Lock-up Agreement for December 2011 offering (22)
10.53	Form of Amendment Agreement for December 2011 offering (25)
10.54	Fluoromed Supply Agreement (26)
10.55	Form of Warrant for February 2013 offering (27)
10.56	Placement Agency Agreement, dated February 22, 2013, between Oxygen Biotherapeutics, Inc. and Ladenburg Thalmann & Co. Inc., as placement agent (27)
10.57	Form of Securities Purchase Agreement for February 2013 offering (27)
10.58	Form of Registration Rights Agreement for February 2013 offering (27)
10.59	Form of Warrant Exchange Agreement, dated February 21, 2013, between Oxygen Biotherapeutics, Inc. and certain institutional investors party to the Securities Purchase Agreement for December 2011 Offering (27)
10.60	License and Supply Agreement dated February 5, 2013, between Oxygen Biotherapeutics, Inc. and Valor SA (36)
10.61	Settlement Agreement, dated March 14, 2013, among Oxygen Biotherapeutics, Inc., Tenor Opportunity Master Fund Ltd., Aria Opportunity Fund, Ltd., and Parsoon Opportunity Fund, Ltd. (36)
10.62	Form of Warrant for Series C 8% Convertible Preferred Stock Offering (29)
10.63	Placement Agency Agreement, dated July 21, 2013, between Oxygen Biotherapeutics, Inc. and Ladenburg Thalmann & Co. Inc., as placement agent (29)
10.64	Form of Securities Purchase Agreement for Series C 8% Convertible Preferred Stock Offering (29)
10.65	Lock-Up Agreement, dated August 16, 2013, between Oxygen Biotherapeutics, Inc. and JPS SPC 3 obo OXBT Fund, SP (30)
10.66	Warrant for Series D 8% Convertible Preferred Stock Offering (30)
10.67	Form of February Warrant Amendment (30)
10.68	Form of July Warrant Amendment (30)
10.69	Form of Securities Purchase Agreement for Series D 8% Convertible Preferred Stock Offering (31)

10.70	License Agreement dated September 20, 2013 by and between Phyxius Pharma, Inc. and Orion Corporation (33)
10.71	Amendment to Common Stock Purchase Agreement (33)
10.72	Sales Agreement dated as of February 23, 2015, between Tenax Therapeutics, Inc. and Cowen and Company, LLC(38)
10.73	First Amendment to Lease Agreement for North Carolina corporate office (40)
21.1	Subsidiaries of Tenax Therapeutics, Inc.(38)
23.1	Consent of Independent Registered Public Accounting Firm*
31.1	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*
32.1	Certification of Chief Executive Officer and Chief 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

(1) These documents were filed as exhibits to the current report on Form 8-K filed by Tenax Therapeutics with the SEC on June 30, 2008, and are incorporated herein by this reference.

(2) These documents were filed as exhibits to the annual report on Form 10-K filed by Tenax Therapeutics with the SEC on August 13, 2004, and are incorporated herein by this reference.

(3) These documents were filed as exhibits to the current report on Form 8-K filed by Tenax Therapeutics with the SEC on September 6, 2006, and are incorporated herein by this reference.

(4) These documents were filed as exhibits to the quarterly report on Form 10-Q filed by Tenax Therapeutics with the SEC on March 21, 2008, and are incorporated herein by this reference.

(5) These documents were filed as exhibits to the annual report on Form 10-K filed by Tenax Therapeutics with the SEC on August 13, 2008, and are incorporated herein by this reference.

(6) This document was filed as an exhibit to the current report on Form 8-K filed by Tenax Therapeutics with the SEC on June 8, 2009, and is incorporated herein by this reference.

(7) This document was filed as an exhibit to the current report on Form 8-K filed by Tenax Therapeutics with the SEC on July 21, 2009, and is incorporated herein by this reference.

(8) These documents were filed as exhibits to the quarterly report on Form 10-Q filed by Tenax Therapeutics with the SEC on March 19, 2010, and are incorporated herein by this reference.

(9) This document was filed as an exhibit to the current report on Form 8-K filed by Tenax Therapeutics with the SEC on September 2, 2009, and is incorporated herein by this reference.

(10) These documents were filed as exhibits to the current report on Form 8-K filed by Tenax Therapeutics with the SEC on April 28, 2010, and are incorporated herein by this reference.

(11) These documents were filed as exhibits to the current report on Form 8-K filed by Tenax Therapeutics with the SEC on May 4, 2010, and are incorporated herein by this reference.

(12) These documents were filed as exhibits to the current report on Form 8-K filed by Tenax Therapeutics with the SEC on November 13, 2009, and are incorporated herein by reference.

(13) These documents were filed as exhibits to the current report on Form 8-K filed by Tenax Therapeutics with the SEC on October 13, 2010, and are incorporated herein by this reference.

(14) These documents were filed as exhibits to the quarterly report on Form 10-Q filed by Tenax Therapeutics with the SEC on December 9, 2010, and are incorporated herein by this reference.

(15) This document was filed as an exhibit to the current report on Form 8-K filed by Tenax Therapeutics with the SEC on December 30, 2010, and is incorporated herein by this reference.

(16) These documents were filed as exhibits to the quarterly report on Form 10-Q filed by Tenax Therapeutics with the SEC on March 21, 2011, and are incorporated herein by this reference.

(17) These documents were filed as exhibits to the annual report on Form 10-K filed by Tenax Therapeutics with the SEC on July 23, 2010, and are incorporated herein by this reference.

(18) This document was filed as an exhibit to the annual report on Form 10-K filed by Tenax Therapeutics with the SEC on July 15, 2011, and is incorporated herein by this reference.

(19) This document was filed as an exhibit to the current report on Form 8-K/A filed by Tenax Therapeutics with the SEC on July 1, 2011, and is incorporated herein by this reference.

(20) This document was filed as an exhibit to the quarterly report on Form 10-Q filed by Tenax Therapeutics with the SEC on December 15, 2011, and is incorporated herein by this reference.

(21) These documents were filed as exhibits to the current report on Form 8-K filed by Tenax Therapeutics with the SEC on November 16, 2011, and are incorporated herein by this reference.

(22) These documents were filed as exhibits to the current report on Form 8-K filed by Tenax Therapeutics with the SEC on December 9, 2011, and are incorporated herein by this reference.

(23) This document was filed as an exhibit to the quarterly report on Form 10-Q filed by Tenax Therapeutics with the SEC on March 15, 2012, and is incorporated herein by this reference.

(24) This document was filed as an exhibit to the current report on Form 8-K filed by Tenax Therapeutics with the SEC on June 15, 2012, and is incorporated herein by this reference.

(25) This document was filed as an exhibit to the current report on Form 8-K filed by Tenax Therapeutics with the SEC on June 15, 2012, and is incorporated herein by reference.

(26) These documents were filed as exhibits to the annual report on Form 10-K filed by Tenax Therapeutics with the SEC on July 25, 2012, and are incorporated herein by this reference.

(27) These documents were filed as exhibits to the current report on Form 8-K filed by Tenax Therapeutics with the SEC on February 25, 2013, and are incorporated herein by this reference.

(28) This document was filed as an exhibit to the current report on Form 8-K filed by Tenax Therapeutics with the SEC on May 15, 2013, and is incorporated herein by this reference.

(29) These documents were filed as exhibits to the current report on Form 8-K filed by Tenax Therapeutics with the SEC on July 25, 2013, and are incorporated herein by reference.

(30) These documents were filed as exhibits to the current report on Form 8-K filed by Tenax Therapeutics with the SEC on August 26, 2013, and are incorporated herein by reference.

(31) This document was filed as an exhibit to the current report on Form 8-K filed by Tenax Therapeutics with the SEC on October 25, 2013, and is incorporated herein by reference.

(32) These documents were filed as exhibits to the current report on Form 8-K filed by Tenax Therapeutics with the SEC on November 19, 2013, and are incorporated herein by reference

(33) These documents were filed as exhibits to the quarterly report on Form 10-Q filed by Tenax Therapeutics with the SEC on March 17, 2014, and are incorporated herein by this reference.

(34) These documents were filed as exhibits to the current report on Form 8-K filed by Tenax Therapeutics with the SEC on June 19, 2015, and are incorporated herein by reference.

(35) This document was filed as an exhibit to the quarterly report on Form 10-Q filed by Tenax Therapeutics with the SEC on December 15, 2014, and is incorporated herein by this reference.

(36) These documents were filed as exhibits to the annual report on Form 10-K filed by Tenax Therapeutics with the SEC on July 29, 2014, and are incorporated herein by this reference.

(37) These documents were filed as exhibits to the quarterly report on Form 10-Q filed by Tenax Therapeutics with the SEC on September 9, 2015, and are incorporated herein by this reference.

(38) These documents were filed as exhibits to the annual report on Form 10-K filed by Tenax Therapeutics with the SEC on July 14, 2015, and are incorporated herein by this reference.

(39) This document was filed as an exhibit to the quarterly report on Form 10-Q filed by Tenax Therapeutics with the SEC on August 9, 2016, and is incorporated herein by this reference.

(40) This document was filed as an exhibit to the transition report on Form 10-KT filed by Tenax Therapeutics with the SEC on March 14, 2016, and is incorporated herein by this reference.

(41) This document was filed as an exhibit to the current report on Form 8-K filed by Tenax Therapeutics with the SEC on February 23, 2018, and is incorporated herein by this reference.

(42) This document was filed as an exhibit to the quarterly report on Form 10-Q filed by Tenax Therapeutics with the SEC on August 9, 2017, and is incorporated herein by this reference.

(43) This document was filed as an exhibit to the annual report on Form 10-K filed by Tenax Therapeutics with the SEC on March 16, 2017, and is incorporated herein by this reference.

* Filed herewith.

\+ 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.

Date: April 2, 2018

TENAX THERAPEUTICS, INC.

By: /s/ Michael B. Jebsen

Michael B. Jebsen
Interim Chief Executive Officer and Chief Financial Officer
(Principal Executive Officer and 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.

uirements 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/ Michael B. Jebsen Michael B. Jebsen	Interim Chief Executive Officer, President and Chief Financial Officer (Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)	April 2, 2018
/s/ Ronald R. Blanck, DO Ronald R. Blanck, DO	Director	April 2, 2018
/s/ Gregory Pepin Gregory Pepin	Director	April 2, 2018
/s/ James Mitchum James Mitchum	Director	April 2, 2018
/s/ Chris A. Rallis Chris A. Rallis	Director	April 2, 2018
/s/ Anthony DiTonno Anthony DiTonno	Director	April 2, 2018
/s/ Gerald Proehl Gerald Proehl	Director	April 2, 2018

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 (No. 333-167175, 333-196464, and 333-210182) and on Form S-3 (No. 333-202244, 333-187466, and 333-196468) of our report dated April 2, 2018 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, 2017 and 2016, 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, 2017.

/s/ CHERRY BEKAERT LLP

Raleigh, North Carolina
April 2, 2018

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND 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. I am 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. I have disclosed, based on my 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: April 2, 2018

TENAX THERAPEUTICS, INC.

By: /s/ Michael B. Jebsen

Michael B. Jebsen
Interim Chief Executive Officer and Chief Financial Officer
(Principal Executive Officer and 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, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael B. Jebsen, Interim Chief Executive Officer and Chief Financial Officer (Principal Executive Officer and 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: April 2, 2018

/s/ Michael B. Jebsen
Michael B. Jebsen
Interim Chief Executive Officer and Chief Financial Officer
(Principal Executive Officer and 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.