

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2021

OR

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

For the transition period from ____ to ____

Commission File No. 001-34600

TENAX THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

26-2593535

(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, including area code: (919) 855-2100

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

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, \$0.0001 par value per share	TENX	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: NONE

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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

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

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

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, 2021, the last business day of the registrant's most recently completed second fiscal quarter, was \$30,558,921.

The number of shares outstanding of the registrant's class of \$0.0001 par value common stock as of March 28, 2022 was 25,206,914.

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 2022 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, 2021.

TABLE OF CONTENTS

<u>PART I</u>	1
<u>ITEM 1—BUSINESS</u>	4
<u>ITEM 1A—RISK FACTORS</u>	13
<u>ITEM 1B—UNRESOLVED STAFF COMMENTS</u>	32
<u>ITEM 2—PROPERTIES</u>	32
<u>ITEM 3—LEGAL PROCEEDINGS</u>	32
<u>ITEM 4— MINE SAFETY DISCLOSURES</u>	32
<u>PART II</u>	34
<u>ITEM 5—MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES</u>	34
<u>ITEM 6—RESERVED</u>	34
<u>ITEM 7—MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	34
<u>ITEM 7A—QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	42
<u>ITEM 8—FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA</u>	42
<u>ITEM 9—CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE</u>	42
<u>ITEM 9A—CONTROLS AND PROCEDURES</u>	42
<u>ITEM 9B—OTHER INFORMATION</u>	43
<u>ITEM 9C— DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.</u>	43
<u>PART III</u>	45
<u>ITEM 10—DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE</u>	45
<u>ITEM 11—EXECUTIVE COMPENSATION</u>	44
<u>ITEM 12—SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS</u>	44
<u>ITEM 13—CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE</u>	45
<u>ITEM 14—PRINCIPAL ACCOUNTANT FEES AND SERVICES</u>	45
<u>PART IV</u>	46
<u>ITEM 15—EXHIBIT AND FINANCIAL STATEMENT SCHEDULES</u>	46
<u>ITEM 16—FORM 10-K SUMMARY</u>	50

PART I

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the “safe harbor” created by those sections. Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to them. In some cases, you can identify forward-looking statements by terminology such as “may”, “will”, “should”, “expects”, “plans”, “anticipates”, “believes”, “estimates”, “predicts”, “potential” or “continue” or the negative of such terms or other comparable terminology. Actual results might differ materially from those explicit or implicit in the forward-looking statements. Important factors that could cause actual results to differ materially include: our ability to raise additional money to fund our operations for at least the next 12 months as a going concern; risks of our clinical trials, including, but not limited to, the timing, delays, costs, design, initiation, enrollment, and results of such trials; reliance on third parties, including Orion Corporation, our manufacturers and CROs; risks regarding the formulation, production, marketing and customer acceptance of our product candidates; intellectual property risks; our ability to maintain our culture and recruit, integrate and retain qualified personnel and advisors, including on our Board of Directors; volatility and uncertainty in the global economy and financial markets in light of the evolving COVID-19 pandemic and geopolitical uncertainties, including tensions in Ukraine; changes in legal, regulatory and legislative environments in the markets in which we operate and the impact of these changes on our ability to obtain regulatory approval for our products; and the risks discussed in “Risk Factors” included in Item 1A of Part I of this Annual Report on Form 10-K, and the risks discussed in our other filings with the U.S. Securities and Exchange Commission, or the SEC.

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. The forward-looking statements represent our views as of the date of this Annual Report on Form 10-K. We undertake no obligation 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.

NOTES

All references in this Annual Report on Form 10-K to the “Company,” “Tenax Therapeutics”, “we”, “our” and “us” means Tenax Therapeutics, Inc.

This Annual Report on Form 10-K contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report on Form 10-K, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies’ trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other company.

[Table of Contents](#)

RISK FACTOR SUMMARY

Our business is subject to significant risks and uncertainties that make an investment in us speculative and risky. Below we summarize what we believe are the principal risk factors but these risks are not the only ones we face, and you should carefully review and consider the full discussion of our risk factors in the section titled “Risk Factors”, together with the other information in this Annual Report on Form 10-K. If any of the following risks actually occurs (or if any of those listed elsewhere in this Annual Report on Form 10-K occur), our business, reputation, financial condition, results of operations, revenue, and future prospects could be seriously harmed. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that adversely affect our business.

Risks Related to Our Financial Position and Need for Additional Capital

- Our independent registered public accounting firm auditors’ report includes an explanatory paragraph stating that there is substantial doubt about our ability to continue as a going concern.
- We have incurred losses since our inception, expect to continue to incur losses in the foreseeable future, and may never become profitable.
- We will require substantial additional financing to further develop our product candidates.
- 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.

Risks Related to Our Business Strategy and Operations

- 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.
- A pandemic, epidemic, or outbreak of an infectious disease, such as COVID-19, or outbreak of a similar disrupting illness, may materially and adversely affect our business and our financial results.
- If we fail to attract and retain senior management and key scientific personnel, we may be unable to successfully develop and commercialize our product candidates.

Risks Related to Drug Development and Commercialization

- We currently have no approved drug products for sale, and we cannot guarantee that we will ever have marketable drug products.
- 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.
- The market may not accept our products.
- Interim and preliminary results from our clinical trials may change and could result in material changes in the final data.
- Any collaboration we enter with third parties to develop and commercialize any future product candidates may be on terms unfavorable to us.
- 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.

Risks Relating to Our Industry

- Intense competition might render our product candidates noncompetitive or obsolete.
- Our activities are and will continue to be subject to extensive government regulation and we will not be able to sell our products without regulatory approval.
- We may not receive all of the anticipated market exclusivity benefits of imatinib's orphan drug designation.
- 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.
- We are subject to uncertainty relating to healthcare reform measures and reimbursement policies that, if not favorable to our products, could hinder or prevent our products' commercial success, if any of our product candidates are approved.
- 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.
- 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 and operations would suffer in the event of computer system failures, cyber-attacks or deficiencies in our cyber-security

[Table of Contents](#)

Risks Related to Our Dependence on Third Parties

- We currently rely significantly on third parties to conduct our nonclinical testing and clinical studies and other aspects of our development programs.
- We depend on third parties to formulate and manufacture our products.
- We currently have no marketing capabilities and no sales organization.

Risks Related to Intellectual Property

- Our success will depend in part on obtaining and maintaining effective patent and other intellectual property protection for our product candidates and proprietary technology.
- 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.
- 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.
- 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 may infringe or be alleged to infringe intellectual property rights of third parties.

Risks Related to Owning Our Common Stock

- Future sales and issuances of shares of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.
- 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 failure to maintain compliance with Nasdaq's continued listing requirements could result in the delisting of our common stock.
- We have a significant security holder, which could exert substantial influence over our business.
- Anti-takeover provisions in our corporate charter documents and under Delaware law could make an acquisition of us more difficult, which could discourage takeover attempts and lead to management entrenchment, and the market price of our common stock may be lower as a result.
- Our bylaws contain an exclusive forum provision, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees, or agents.
- We have not paid cash dividends in the past and do not expect to pay dividends in the future.
- Our ability to use our net operating loss carryforwards and certain other tax attributes to offset future taxable income may be subject to certain limitations.

[Table of Contents](#)

ITEM 1—BUSINESS

Overview

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.

On November 13, 2013, we acquired a license granting Life Newco, our wholly-owned subsidiary, an exclusive, sublicensable 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. On October 9, 2020 and January 25, 2022, we entered into an amendment to the license to include two new oral products containing levosimendan, in capsule and solid dosage form, and a subcutaneously administered product containing levosimendan, subject to specified limitations.

On January 15, 2021, we acquired 100% of the equity of PHPrecisionMed Inc., a Delaware corporation, or PHPM, with PHPM surviving as our wholly-owned subsidiary. As a result of the merger, we are developing and plan to commercialize pharmaceutical products containing imatinib for the treatment of pulmonary arterial hypertension, or PAH.

Business Strategy

Our principal business objective is to identify, develop, and commercialize late-stage pharmaceutical therapeutic products for serious cardiovascular and pulmonary diseases with high unmet medical need. Following a transformation of the Company in 2021 at the director and executive level, completion of the integration of a biotechnology company focused on PAH, the publication of the results of our HELP study (as described below), our Phase II TNX-103 (oral levosimendan) study, and formulation progress on a novel oral imatinib mesylate tablet, Tenax Therapeutics is committed to remaining operationally-efficient, scientifically-directed, and patient-centered in our effort to bring to market two potentially life-changing therapies to patients with two devastating forms of pulmonary hypertension. The Company believes that through our proprietary formulation advances, advanced clinical trial design, and growing patent estate, it can bring these product candidates to an approved and commercial state.

The key elements of our business strategy are outlined below.

Efficiently conduct clinical development to establish clinical proof of principle in new indications, refine formulation, and commence Phase 3 testing of our current product candidates.

Levosimendan and imatinib have been approved and prescribed globally for more than 20 years, but we believe their mechanisms of action have not been fully exploited, despite promising evidence they may significantly improve the lives of patients with pulmonary hypertension. We are conducting clinical development with the intent to establish proof of beneficial activity in cardiopulmonary diseases in which these therapeutics would be expected to have benefit for patients with diseases for which either no pharmaceutical therapies are approved at all, or in the case of PAH, where numerous expensive therapies generally offer a modest reduction of symptoms. Our focus is primarily on designing and executing formulation improvements, protecting these innovations with patents and other forms of exclusivity, and employing innovative clinical trial science to establish a robust foundation for subsequent development, product approval, and commercialization. We intend to submit marketing authorization applications following a single Phase 3 trial for each product. Our trials are designed to incorporate and reflect advanced clinical trial design science and the regulatory and advisory experience of our team. We intend to continue partnering with innovative companies, renowned medical and regulatory experts, and premier clinical testing organizations to help expedite development, and continue expanding into complementary areas when opportunities arise through our development, research, and discoveries. We also intend to continue outsourcing to a limited number of premier clinical trial testing organizations, and seeking the advice of world-renowned biostatisticians, medical experts, and formulation and regulatory experts, in the design and execution of our research.

[Table of Contents](#)

Efficiently explore new high-potential therapeutic applications, in particular where expedited regulatory pathways are available, leveraging third-party research collaborations and our results from related areas.

Levosimendan has shown promise in multiple disease areas in its two decades of use following its approval. Our own Phase 2 extension protocol research has demonstrated that a formerly under-appreciated mechanism of action of levosimendan, its property of relaxing the venous circulation, brings about a durable improvement in exercise capacity and quality of life, as well as other clinical assessments, in patients with heart failure with preserved ejection fraction and associated pulmonary hypertension (PH-HFpEF). We believe this patient population today has no pharmaceutical therapies available and 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. We believe these factors will support approval by the United States Food and Drug Administration, or FDA, of these product candidates based on positive data from a single, rather than two, pivotal Phase 3 trials. Through our agreement with our licensor, Orion Corporation, or Orion, the originator of levosimendan for acute decompensated heart failure, we have access to a library of ongoing and completed trials and research projects, including certain documentation, which we believe, in combination with positive Phase 3 data that we hope to generate in at least one indication, will support FDA approval of TNX-103. Likewise, the regulatory pathway for approval of imatinib for the treatment of PAH, as formulated by Tenax Therapeutics at the dose shown to be effective in a prior Phase 3 trial conducted by Novartis, allows Tenax to build on the dossier of research results already reviewed by the FDA. In order to achieve our objectives of developing these medicines for new groups of patients, we have established collaborative research relationships with investigators from leading 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, gain the advice and support of key opinion leaders in medicine and clinical trial science, and invest in development efforts to exploit opportunities to advance beyond 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, and the confidentiality of all our company information, 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, including an extension protocol to the Phase 2 TNX-103 trial referenced above, which aim to develop new intellectual property and enable us to file patent applications that cover new applications of our existing technologies, alone or in combination with existing therapies, as well as other product candidates. We received in 2022 a patent covering the subcutaneous administration of levosimendan (TNX-102) in humans for any medical condition, through 2039. At present, we have three patents pending, with some decisions expected as early as late 2022.

Enter into licensing or product co-development arrangements.

In addition to our internal development efforts, an important part of our product development strategy is to work with collaborators and partners to accelerate product development, maintain our low development and business operations costs, and broaden our commercialization capabilities globally. 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

TNX-103 and TNX-102 (levosimendan) Background

Levosimendan was discovered and developed by 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 but is not available in the United States or Canada. It is estimated that to date over 1.5 million patients have been treated worldwide with levosimendan.

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

- Opening of potassium channels in the vasculature smooth muscle, resulting in a vasodilatory effect on all vascular beds.
- 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 mitochondrial potassium channels in cardiomyocytes, resulting in a cardioprotective effect.

[Table of Contents](#)

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 Phylisus Pharma, Inc., or Phylisus, including its North American rights to develop and commercialize intravenous levosimendan for any indication in the United States and Canada. The license was subsequently amended in 2020 to include the rights to develop and commercialize oral and subcutaneous formulations of levosimendan. In the countries where it is marketed, intravenous levosimendan is indicated for the short-term treatment of acutely decompensated 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.

TNX-103 and TNX-102 (levosimendan) Development for Pulmonary Hypertension Patients

In 2020, we completed a Phase 2 clinical trial of intravenous levosimendan in North America for the treatment of patients with pulmonary hypertension associated with heart failure with PH-HFpEF, a disease defined hemodynamically by a mean pulmonary artery pressure, or mPAP, ≥ 25 mmHg, and a pulmonary capillary wedge pressure, or PCWP, >15 mmHg. Pulmonary hypertension in these patients is believed to arise from a passive backward transmission of elevated filling pressures from left-sided heart failure. These mechanical components of pulmonary venous congestion can trigger pulmonary vasoconstriction, decreased nitric oxide availability, increased endothelin expression, desensitization to natriuretic peptide induced vasodilation, and vascular remodeling. Over time, these changes often lead to advanced pulmonary arterial and venous disease, increased right ventricle afterload, and right ventricle failure.

PH-HFpEF is the most common of five forms of pulmonary hypertension, with an estimated U.S. 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 PAH patients, no therapies have been shown to be effective in treating PH-HFpEF patients.

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 a basis for further research into the potential beneficial impact of levosimendan in PH-HFpEF patients.

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 a basis for further research into the potential beneficial impact of levosimendan in PH-HFpEF patients.

In March 2018, we met with the FDA to discuss development of levosimendan in these patients. The FDA agreed with our planned Phase 2 design, patient entry criteria, and endpoints. It was agreed the study could be conducted under the existing investigational new drug application with no additional nonclinical studies required to support full development. The FDA recognized there were no approved drug therapies to treat PH-HFpEF patients and acknowledged this provided an opportunity for a limited Phase 3 clinical program. This topic was discussed further at the End-of-Phase 2 Meeting following completion of the Phase 2 study in PH-HFpEF patients, which is known as the HELP Study – Hemodynamic Evaluation of Levosimendan in PH-HFpEF.

We initiated the first of our expected 10-12 HELP Study clinical sites in November 2018 and the first of 37 patients was enrolled in the HELP Study in March 2019. Enrollment in the HELP Study was completed about one year later, in March 2020. The primary endpoint of the HELP Study was based on the change in PCWP during exercise versus baseline compared to placebo. The HELP Study utilized a double-blind randomized design following five weekly outpatient infusions of levosimendan.

On June 2, 2020, we announced preliminary, top-line data from the study. The primary efficacy analysis, pulmonary capillary wedge pressure (PCWP) during exercise did not demonstrate a statistically significant reduction from baseline. Levosimendan did demonstrate a statistically significant reduction in PCWP compared to baseline ($p < 0.0017$) and placebo ($p < 0.0475$) when the measurements at rest, with legs up and on exercise were combined. Levosimendan also demonstrated a statistically significant improvement in 6-minute walk distance as compared to placebo ($p = 0.0329$). These findings from the HELP Study represent important discoveries related to the use of levosimendan in PH-HFpEF patients since this is the first study to evaluate levosimendan in PH-HFpEF patients and this is the first study ever conducted of any therapy in PH-HFpEF patients to show such positive improvements in hemodynamics and 6-minute walk distance.

[Table of Contents](#)

Hemodynamic Results

Hemodynamic measurements were made at rest (supine), after leg raise on a supine bicycle (a test of rapid increase in ventricular filling) and during exercise (25 watts for 3 minutes or until the patient tired). In the initial open-label phase, 84% of the patients had a significant reduction in right atrial pressure, or RAP, pulmonary artery pressure, or PAP, and PCWP at rest and during exercise. In the randomized double-blinded 6-week trial, levosimendan demonstrated a statistically significant reduction in PCWP compared to baseline ($p < 0.0017$) and placebo ($p < 0.0475$) when these three measurements were combined: at rest, with legs up, and on exercise. While there was no significant change in PCWP during exercise, patients receiving levosimendan had reductions from baseline at Week 6 in PCWP and PAP that were statistically significant when patients were “at rest” and/or with their “legs raised” ($p < 0.05$).

Clinical Results (6-Minute Walk Distance)

The clinical efficacy was confirmed by a statistically significant improvement in 6-minute walk distance of 29 meters ($p = 0.0329$). The 6-minute walk distance was a secondary endpoint in the trial and is a validated and accepted endpoint used in many pulmonary hypertension registration trials.

Safety

The incidence of adverse events or serious adverse events between the control and treated groups was similar. In addition, there were no arrhythmias observed, atrial or ventricular, when comparing baseline electrocardiographic monitoring with 72-hour monitoring after five weeks of treatment.

The detailed results from the Phase 2 HELP Study of levosimendan in PH-HFpEF were presented at the Heart Failure Society of America Virtual Annual Scientific Meeting on October 3, 2020 and at the American Heart Association Scientific Sessions 2020 on November 13, 2020. Additionally, the full manuscript was published in the peer-reviewed journal JACC: Heart Failure. Burkhoff D, Borlaug BA, Shah SJ, ...Rich S. Levosimendan Improves Hemodynamics and Exercise Tolerance in PH-HFpEF: Results of the Randomized Placebo-Controlled HELP Trial. JACC Heart Fail. 2021 May;9(5):360-370.

Next Steps

On October 9, 2020, we entered into an Amendment to the License Agreement between the Company and Orion to include two new product formulations containing levosimendan, in a capsule solid oral dosage form (TNX-103) and a subcutaneously administered dosage form (TNX-102), to the scope of the license, subject to specified limitations. On January 4, 2022, Tenax Therapeutics was issued US Pat. No. 11,213,524, entitled PHARMACEUTICAL COMPOSITIONS FOR SUBCUTANEOUS ADMINISTRATION OF LEVOSIMENDAN.

We are currently studying the safety and efficacy of TNX-103 in all patients participating in the open-label extension of the HELP Study, all of whom previously received weekly infusions of intravenous levosimendan. These patients were safely transitioned from the intravenous to the oral formulation in late 2021, with positive signs of efficacy observed across all measured parameters during the transition study phase of the open-label extension study, or OLE.

In October 2020, we met with the FDA for an End-of-Phase 2 Meeting to discuss the Phase 2 clinical data and further development of levosimendan in PH-HFpEF patients. The FDA agreed that one or two Phase 3 clinical studies (depending on the size) with a primary endpoint of change in 6-minute walk distance over 12 weeks or a single Phase 3 trial with clinical worsening (e.g., death, hospitalization for heart failure, or decline in exercise capacity) over 24 weeks would be sufficient to demonstrate the effectiveness of levosimendan in PH-HFpEF. The FDA also agreed to a plan to replace weekly intravenous levosimendan dosing with daily TNX-103 doses in a Phase 3 clinical study. The FDA expressed that a safety database could be necessary and indicated that the need for a larger safety database could be dependent on the final design of the Phase 3 study. A proposed Phase 3 study design was provided in late 2021 for FDA review and comment on the safety database requirements at filing. In February 2022, the FDA advised in a written response that the safety database at NDA filing should meet the minimum International Clinical Harmonization (ICH) standards for a chronic medication.

[Table of Contents](#)

The HELP Study design was novel in several respects. To date, no other multi-center study has evaluated levosimendan in heart failure patients with preserved ejection fraction, or HFpEF, patients or PH-HFpEF patients. Instead, all previous levosimendan heart failure studies have enrolled heart failure patients with reduced ejection fraction, or HFrEF, which specifically excluded HFpEF patients. Also, the HELP Study utilized a unique 24-hour weekly infusion regimen of 0.075- 0.1µm/kg/min. Finally, the HELP Study employed a unique home-based intravenous infusion administration via an ambulatory infusion pump. This home-based weekly intravenous administration is unlike all other chronic dosing studies of levosimendan that have typically employed a shorter duration and less frequent infusion regimen administered in a hospital setting. The transition of patients in the OLE from intravenous to oral therapy was encouraging. PH-HFpEF has an approximate 50% rate of survival of 5 years. The patients who enrolled in the HELP study had very advanced disease, with 87% Functional Class III at enrollment. At the time of the transition these patients had already been on levosimendan for 2 years or longer. The fact that there was an improvement in all measures of efficacy on oral therapy beyond what had been achieved on intravenous therapy speaks to the remarkable durability of the treatment effect.

We believe that the combination of the unique HELP Study patient population, innovative weekly 24-hour dosing, unique home-based site of administration, the transition from intravenous to oral therapy in a subset of these patients who continued in the OLE until the commencement of this transition sub study, and the novel findings of efficacy and safety in PH-HFpEF patients represent important discoveries and significant intellectual property. These discoveries, among others from the HELP Study, form the basis for U.S. patent applications we have filed.

TNX-201(imatinib) Background

Imatinib (marketed in the U.S. as Gleevec®) is a tyrosine kinase inhibitor, which changed the treatment of chronic myeloid leukemia, or CML, following its approval over 20 years ago, as the first curative treatment of chronic leukemia. The first clinical trial of imatinib took place in 1998 and the drug received FDA approval in May 2001. Encouraged by the success of imatinib in treating CML patients, scientists explored its effect in other cancers, and it was found to produce a similar positive effect in malignancies where tyrosine kinases were overexpressed.

Tyrosine kinases are important mediators of the signaling cascade, determining key roles in diverse biological processes like growth, differentiation, metabolism, and apoptosis in response to external and internal stimuli. Deregulation of protein kinase activity has been shown to play a central role in the pathogenesis of human cancers. Imatinib, a 2-phenyl amino pyrimidine derivative, is a tyrosine kinase inhibitor with activity against ABL, BCR-ABL, PDGFRA and PDGFRB, and c-KIT. Imatinib works by binding close to the ATP binding site therefore inhibiting the enzyme activity of the protein. Imatinib also inhibits the ABL protein of noncancer cells. Imatinib is well absorbed after oral administration with a bioavailability exceeding 90%. It is extensively metabolized, principally by cytochrome P450 (CYP)3A4 and CYP3A5 and can competitively inhibit the metabolism of drugs that are CYP3A4 or CYP3A5 substrates. Imatinib is generally well tolerated in cancer patients. Common side effects include fluid retention, headache, diarrhea, loss of appetite, weakness, nausea and vomiting, abdominal distention, edema, rash, dizziness, and muscle cramps. Serious side effects may include myelosuppression, heart failure, and liver function abnormalities. Novartis manufactures of Gleevec.

Previous Imatinib Development for Pulmonary Arterial Hypertension Patients

In PAH, a rare disease, patients who remain symptomatic despite available therapies have a high morbidity and mortality. Though several therapies are now available, there is no cure for the disease, and there is no data supporting that the existing therapies, all of which are pulmonary vasodilators, halt progression or induce regression of the disease. Imatinib has been shown in animal models of pulmonary hypertension to induce disease reversal by an effect on platelet derived growth factor, or PDGF, which appears to be causal in the disease. After that discovery was made, several case reports and small case series of patients with advanced PAH failing combination pulmonary vasodilator therapy were published showing a dramatic effect of imatinib on stabilizing and improving these patients. This led Novartis to develop imatinib as a treatment of PAH.

Novartis sponsored a Phase 2 proof-of-concept trial to evaluate the safety, tolerability, and efficacy of imatinib as an adjunct to PAH-specific therapy in patients with PAH. This was a 24-week randomized, double-blind, placebo-controlled study of PAH subjects who remained symptomatic on one or more PAH therapies in WHO Functional Class (FC) II-IV. The Phase 2 trial of imatinib in PAH caused significant hemodynamic improvement in some patients but failed to meet the primary endpoint of an increase in 6-minute walk distance (22 meters, $p=NS$). Novartis then sponsored a Phase 3 trial (IMPRES) which met its primary endpoint of significant increase in 6-minute walk (32 meters, $p=0.002$), an effect maintained in the extension study in patients remaining on imatinib. However, the data were confounded by a high rate of dropouts in the patients randomized to imatinib attributed largely to gastric intolerance during the first eight weeks. The sponsor proposed consideration of a surrogate endpoint under the subpart H provision as a basis for approval but was denied. Consequently, Novartis chose to withdraw the Investigational New Drug application as the drug went off patent.

[Table of Contents](#)

Current TNX-201 Development for Pulmonary Arterial Hypertension Patients

On May 30, 2019, PHPM, which was acquired by Tenax Therapeutics in January 2021, met with the FDA to discuss a proposal for a Phase 3 trial of imatinib for PAH. At that meeting, PHPM discussed a single Phase 3 trial using change in 6-minute walk distance as the primary endpoint ($p<0.05$). PHPM received agreement for submission under the 505(b)(2) regulatory pathway, and thereafter received orphan designation. In July 2020, PHPM received agreement from the FDA for the development of a modified release formulation that would require only a small comparative PK/bioavailability study. We recruited 16 volunteers, who received a single dose of the modified release formulation and a single dose of the existing immediate release formulation. The formulation has been optimized in preparation for a second Phase 1 study to be completed in the second quarter of 2022. A Phase 3 study is planned with TNX-201, the modified release formulation of imatinib, and is expected to be initiated in the second half of 2022.

Manufacturing and Supply

We contract with third parties for the manufacturing of all of our product candidates, and for pre-clinical and clinical studies, and intend to continue to do so in the future. We do not own or operate any manufacturing facilities and we have no plans to build any owned clinical or commercial scale manufacturing capabilities. We believe that the use of third-party manufacturers and contract manufacturing organizations (CMOs) eliminates the need to directly invest in manufacturing facilities, equipment and additional staff.

Pursuant to the terms of our license for levosimendan, Orion is contractually our sole manufacturing source for TNX-103. We may engage other third-party suppliers and CMOs for the supply and manufacture of TNX-102, or other formulations we may develop.

We have engaged various third-party suppliers and CMOs for the supply and manufacture of imatinib for planned, upcoming clinical trials, and relied on such contractors for material contributing to TNX-201, for testing in our completed Phase 1 trial, a second Phase 1 trial scheduled for the first half of 2022, and our planned Phase 3 trial, planned to start in the second half of 2022.

As we further develop our product pipeline, we expect to consider secondary or back-up manufacturers for both active pharmaceutical ingredient and drug product manufacturing. To date, our third-party manufacturers have met the manufacturing requirements for our product candidates. We expect third-party manufacturers to be capable of providing sufficient quantities of our product candidates to meet anticipated full-scale commercial demands, but we have not assessed these capabilities beyond the supply of clinical materials to date.

We believe alternate sources of manufacturing will be available to satisfy our clinical and future commercial requirements; however, we cannot guarantee that identifying and establishing alternative relationships with such sources will be successful, cost effective, or completed on a timely basis without significant delay in the development or commercialization of our product candidates. All of the vendors we use are required to conduct their operations under current Good Manufacturing Practices, or cGMP, a regulatory standard for the manufacture of pharmaceuticals.

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 whom we expect to work on our products to agree to disclose and assign to us all inventions conceived during the workday, developed using our property, or which relate to our business.

We have one granted patent, and three U.S. patent applications pending, related to product candidates and proprietary process, method and technology. Our issued patent expires in 2039.

On January 4, 2022, we filed and received a patent application for the subcutaneous administration of levosimendan, whether through the formulation we have developed in collaboration with a formulation development partner, or other subcutaneous formulations meeting certain broad characteristics defined in the patent. In addition, we have filed a patent application for the use of levosimendan in the treatment of PH-HFpEF patients, based on several discoveries that have emerged from the HELP Study and the OLE.

[Table of Contents](#)

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

Our success will in part depend on the ability to obtain and maintain patent and other proprietary rights in commercially important technology, inventions and know-how related to our business, the validity and enforceability of our patents, the continued confidentiality of our trade secrets and our ability to operate without infringing the valid and enforceable patents and proprietary rights of third parties. We also rely on continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications we may own or license in the future, nor can we be sure that any of our existing patents or any patents we may own or license in the future will be useful in protecting our technology and products. For this and more comprehensive risks related to our intellectual property, please see “Risk Factors - Risks Related to Our Intellectual Property”.

Licensing Agreement

Simdax License Agreement

On November 13, 2013, we acquired, through our wholly-owned subsidiary, a license agreement between Phyxius and Orion, which was later amended on October 9, 2020 and January 25, 2022 (as amended, the “License”). The License grants us an exclusive, sublicenseable right to develop and commercialize pharmaceutical products containing levosimendan in the United States and Canada and, pursuant to the October 9, 2020 amendment to the License, also includes two product dose forms containing levosimendan, in capsule and solid dosage form, and a subcutaneously administered product containing levosimendan, subject to specified limitations. Pursuant to the License, Tenax and Orion will agree to a new trademark when commercializing levosimendan in either of these forms.

Pursuant to the License, we have a right of first refusal to commercialize new developments of levosimendan, including developments as to the formulation, presentation, means of delivery, route of administration, dosage or indication (i.e., line extension products).

Orion’s ongoing role under the License includes sublicense approval, serving as the sole source of manufacture of oral formulations of levosimendan, holding a first right to enforce intellectual property rights in the United States and Canada, and certain regulatory participation rights. Orion must notify the Company before the end of 2024 if it chooses not to exercise its right to supply oral formulations of levosimendan to the Company for commercialization in the territory. Additionally, the Company must grant back to Orion a broad non-exclusive license to any patents or clinical trial data related to levosimendan developed by the Company under the License. The term of the License extends until 10 years after the launch of a levosimendan product in the United States and Canada, provided that the License will continue after the end of the term in each country in the territory until the expiration of Orion’s patent rights in levosimendan in such country. In the event that no regulatory approval for levosimendan has been granted in the United States on or before September 20, 2030, however, either party will have the right to terminate the License with immediate effect.

As consideration for the License, we agreed to pay Orion (i) a one-time up-front payment in the amount of \$1.0 million, (ii) development milestones consisting of (a) \$2.0 million upon the grant of FDA approval and (b) \$1.0 million upon the grant of regulatory approval for the Product in Canada, (iii) commercialization milestones aggregating to up to \$13.0 million, upon achievement of certain cumulative net sales amounts in the United States and Canada, and (iv) royalties based on net sales of the Product in the United States and Canada. After the end of the License term, the Company must pay Orion a royalty based on net sales of the Product in the Territory for as long as the Company sells the Product in the Territory.

[Table of Contents](#)

Competition

The pharmaceutical and biotechnology industries are intensely competitive. Many companies, including biotechnology, chemical, and pharmaceutical companies, are actively engaged in activities similar to ours, including research and development of drugs for the treatment of rare medical conditions. Many of these companies have substantially greater financial and other resources, larger research and development staffs, and more extensive marketing and manufacturing organizations than we do. In addition, some of them have considerable experience in preclinical testing, clinical trials and other regulatory approval procedures. There are also academic institutions, governmental agencies and other research organizations that are conducting research in areas in which we are working. Our success will be based in part on our ability to identify, develop and manage a portfolio of product candidates that are safer and more effective than any competing products.

We believe the concept of using TNX-102/103 (levosimendan) to treat patients with PH-HFpEF is novel. Because no therapies are approved to treat PH-HFpEF, we believe our ability to succeed in the market is primarily dependent on our ability to change the established practice paradigm, which could be difficult. Key factors on which we will compete with regards to the development and marketing of levosimendan for the treatment of pulmonary hypertension in these patients include, among others, the ability to obtain adequate efficacy data, safety data, cost effectiveness data and hospital formulary approval, marketing exclusivity, 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.

TNX-201 has the potential to be the first disease-modifying treatment of PAH, a fatal orphan disease. Pulmonary vasodilators, the only approved medications for PAH, do not have disease modifying properties. We do not expect these products, other than one which is not widely used today, to be contraindicated in patients taking TNX-201, and our intended protocol design tests TNX-201 as an additional therapy to one or more of these vasodilators.

Several other companies are developing new therapies to treat PAH, including some that may also be disease-modifying. Novartis developed imatinib for PAH and conducted a Phase 3 trial that in 2013 succeeded in meeting its primary endpoint. However, the high number of dropouts of patients randomized to imatinib led the FDA and EMA to request another trial before they would approve the product in PAH. To address this, we are developing a modified release oral formulation designed to reduce the stomach's exposure to imatinib, and the nausea and vomiting commonly observed in patients receiving imatinib. Other companies are developing an inhaled route of administration as their strategy to mitigate gastric intolerance. We believe that our development plan has advantages in that we already know the effective dose of imatinib administered orally, and the systemic exposure from an inhaled route remains uncertain, and costly to determine. Since only the first FDA approved formulation of imatinib to treat PAH will qualify for the 7 years of Orphan Drug exclusivity in the U.S., these alternative formulations of imatinib represent potential competitive threats.

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.

[Table of Contents](#)

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

The effects of government regulations on our business are discussed in "*Item 1A — Risk Factors — Risks Relating to Regulatory Matters*".

Employees and Human Capital

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, 2021, we had eight 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.

In response to the COVID-19 pandemic, we put in place several safety measures for our employees. These measures included, but were not limited to, substantially restricting travel, limiting access to our corporate office, including allowing employees to work remotely, providing personal protective equipment to employees, investigator sites and third-party vendors, implementing social distancing protocols, and coordinating safety protocols with our investigator sites.

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 meetings of stockholders, and any amendments to those reports, as well as Section 13 and 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 SEC. Our SEC filings are also publicly available on the SEC's website located at www.sec.gov, which contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

ITEM 1A—RISK FACTORS

Our business, financial condition and operating results may be affected by a number of factors, including but not limited to those described below. Any one or more of such factors could directly or indirectly cause our actual results of operations and financial condition to vary materially from our past or anticipated future results of operations and financial condition. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, results of operations and stock price. The following information should be read in conjunction with Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the accompanying financial statements and related notes in Part II, Item 8, “Financial Statements and Supplementary Data” of this Annual Report on Form 10-K.

Risks Related to Our Financial Position and Need for Additional Capital

Our independent registered public accounting firm auditors’ report includes an explanatory paragraph stating that there is substantial doubt about our ability to continue as a going concern.

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 consolidated financial statements included in this Annual Report on Form 10-K includes an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to raise additional capital and to achieve sustainable revenues and profitable operations. 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. Our consolidated financial statements included in this Annual Report on Form 10-K have been prepared assuming we will continue as a going concern and do not include any adjustments that might result from uncertainty about our ability to continue as a going concern.

We have incurred losses since our inception, expect to continue to incur losses in the foreseeable future, and may never become profitable.

We have incurred losses since inception. For the years ended December 31, 2021 and 2020, we incurred net operating losses of \$32.7 million and \$9.9 million, respectively. As of December 31, 2021, we had an accumulated deficit of \$278.5 million. We have funded our operations since September 1990 principally through the issuance of debt and equity securities and loans from stockholders. 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, imatinib for PAH, 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.

We will require substantial additional funding for further development of our product candidates. Failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development efforts and other operations.

Developing biopharmaceutical products, including conducting preclinical studies and clinical trials and establishing manufacturing and sales and marketing 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, 2021, we had \$5.6 million of cash and cash equivalents on hand. We will need substantial additional capital in the future in order to complete the regulatory approval and commercialization of levosimendan and imatinib 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.

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

Our 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 number of investigator sites and patients who participate, the rate of enrollment and the potential impact the COVID-19 pandemic could have on the expected timelines for each of our clinical programs;
- the costs and timing of regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the effect of competing technological and market developments;
- the terms and timing of any collaboration, licensing or other arrangements that we may establish;
- the cost and timing of completion of clinical and commercial-scale manufacturing activities; and
- the costs of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval.

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

- our ability to obtain additional funding to develop our product candidates, and any further product candidate which we may develop or in-license in the future;
- delays in the commencement, enrollment and completion of clinical testing, as well as the analysis and reporting of results from such clinical testing;
- the need to obtain regulatory approval of our product candidates;
- potential risks related to any collaborations we may enter into for our product candidates;
- 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 and clinical research organizations, or CROs;
- 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;
- our ability to attract and retain key personnel, including advisors and members of our Board of Directors; and
- volatility and uncertainty in the global economy and financial markets in light of the evolving COVID-19 pandemic and geopolitical uncertainties, including tensions in Ukraine.

[Table of Contents](#)

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.

Risks Related to Our Business Strategy and Operations

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 PH-HFpEF and imatinib for the treatment of PAH, in addition to exploring strategic alternatives in order to maximize stockholder value. At present, we intend to commit most of our resources to advancing our existing product candidates to the point they receive regulatory approval for the treatment of various pulmonary hypertension indications. If as a consequence of the results of our planned Phase 3 trials, or the results of prior clinical trials performed using levosimendan or imatinib, we are unable to receive regulatory approval of one or both of our existing product candidates, then we may not have resources to pursue development of any other products and our business could terminate.

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

The spread of COVID-19, including variant strains, has affected segments of the global economy and may affect our operations, including the potential interruption of our clinical trial activities and our supply chain. The continued spread of COVID-19 may result in a period of continued or recurring business disruption in these and other areas impacting our business, including the establishment of contractual relationships with investigators enrolling subjects in our clinical trials, the continuity of care provided by these institutions to the patients we seek to enroll and their ability to support industry-funded research as a means of caring for their patients, supply of these sites with study materials, and the enrolment of subjects and their adherence with study requirements. In addition, there could be a potential effect of COVID-19 to the business at FDA or other health authorities, which could result in delays of reviews and approvals, including with respect to our product candidates.

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

The spread of COVID-19, or another infectious disease, could also negatively affect the operations at our third-party manufacturers, which could result in delays or disruptions in the supply of our product candidates. In addition, we have taken temporary precautionary measures intended to help minimize the risk of the virus to our employees, including reducing non-essential travel worldwide for our employees and discouraging employee attendance at healthcare and investment industry events, which could negatively affect our business.

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

If we fail to attract and retain senior management and key scientific personnel, we may be unable to successfully develop and commercialize our product candidates.

We have historically operated with a limited number of employees. As of the date of this report, we have eight full-time employees and one part-time employee. Therefore, institutional knowledge is concentrated within a small number of employees. Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel to continue the development, regulatory approval and commercialization of our product candidates. We will need to hire or contract with additional qualified personnel with expertise in preclinical testing, clinical research and testing, government regulation, formulation and manufacturing, and sales and marketing. Additionally, our future success is highly dependent upon the contributions of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, completion of our planned clinical trials or the commercialization of our product candidates.

[Table of Contents](#)

We face intense competition from other companies and organizations for qualified personnel. Other companies and organizations with which we compete for personnel may have greater financial and other resources and different risk profiles than we do, and a history of successful development and commercialization of their product candidates. Replacing key employees and attracting sufficiently skilled new employees may be difficult and costly, and we may not have other personnel with the capacity to assume all the responsibilities of a key employee upon his or her departure or to take on the duties necessary to continue growing our company and pursuing our business strategy. If we cannot attract and retain skilled personnel, as needed, we may not achieve our development and other goals.

In addition, the success of our business will depend on our ability to develop and maintain relationships with respected service providers and industry-leading consultants and advisors. If we cannot develop and maintain such relationships, as needed, the rate and success at which we can develop and commercialize product candidates may be limited. In addition, our outsourcing strategy, which has included engaging consultants to manage core administrative and operational functions, may subject us to scrutiny under labor laws and regulations, which may divert management time and attention and have an adverse effect on our business and financial condition.

Risks Related to Drug Development and Commercialization

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 a New Drug Application, or 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.

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 four years to clinical testing of our product candidates and advancing these products 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 assure you that we will be able to complete our clinical trials successfully or obtain FDA or other governmental or regulatory approval of our product candidates, or that such approval, if obtained, will not include limitations on the indicated uses for which our product candidates may be marketed. Our business, financial condition and results of operations are critically dependent on obtaining capital to advance our testing program and receiving FDA and other governmental and regulatory approvals of our products. A significant delay in or failure of our planned clinical trials or a failure to achieve these approvals would have a material adverse effect on us and could result in major business and financial setbacks.

[Table of Contents](#)

The market may not accept our products.

If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant revenue and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy, safety and potential advantages of our product candidates;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments, if any;
- product labeling or product insert requirements of the FDA or foreign regulatory authorities, including any limitations or warnings contained in a product's approved labeling, including any black box warning;
- the willingness of the target patient population to try new treatments and of physicians to prescribe these treatments;
- our ability to hire and retain a sales force in the United States;
- the strength of manufacturing, marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement for of levosimendan, imatinib and any other product candidates, once approved;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

Interim “top-line” and preliminary results from our clinical trials that we announce or publish from time to time may change as more patient data become available, and these results are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim top-line or preliminary results from our clinical trials. Interim results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment and treatment extends, and more patient experience is observed. Preliminary or top-line results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

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

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

- 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.

[Table of Contents](#)

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

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

- the evolving COVID-19 pandemic, which might cause site closures because of infected staff or cause patients to avoid or be unable to travel to healthcare facilities and physicians' offices unless due to a health emergency;
- 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

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.

[Table of Contents](#)

Risks Relating to Our Industry

Intense competition might render our cardiovascular and pulmonary product candidates noncompetitive or obsolete.

Competition in the pharmaceutical industry in general and in our therapeutic sectors in particular is intense and characterized by extensive research efforts and rapid technological progress. Technological developments by competitors, regulatory approval for marketing competitive products, including potential generic or over-the-counter products, or superior marketing resources possessed by competitors could adversely affect the commercial potential of our cardiovascular and pulmonary disease product candidates and could have a material adverse effect on our future revenue and results of operations. We believe that there are numerous pharmaceutical and biotechnology companies, as well as academic research groups throughout the world, engaged in research and development efforts with respect to pharmaceutical products targeted at cardiovascular and pulmonary diseases and conditions addressed by our product pipeline. Developments by others might render our product pipeline obsolete or noncompetitive. Competitors might be able to complete the development and regulatory approval process sooner and, therefore, market their cardiovascular and pulmonary disease products earlier than we can.

Many of our current competitors have significant financial, marketing and personnel resources and development capabilities. For example, many large, well-capitalized companies already offer cardiovascular and pulmonary products and services in the United States and Europe that target the indications for which our product candidates are being developed. Currently, as an example, twelve vasodilators are marketed in the U.S. for use in patients with PAH, and sales teams from Janssen, Pfizer, Bayer, United Therapeutics, and other large companies with marketing and sales capabilities represent these products in the specialized care centers where the disease is treated.

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

Our development, marketing and distribution of levosimendan and imatinib are, 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 candidate for its indicated uses. There are numerous problems that could arise during this stage, including:

- the data obtained from laboratory testing and clinical trials are susceptible to varying interpretations, which could delay, limit or prevent FDA and other regulatory approvals;
- adverse events could cause the FDA and other regulatory authorities to halt trials;
- at any time, the FDA and other regulatory agencies could change policies and regulations that could result in delay and perhaps rejection of our products;
- if a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions; and
- even after extensive testing and clinical trials, and receiving agreements and reassurances from FDA, EMA, and others, as to their future position on a dataset or result to be generated from a trial the design of which they have weighed in on, 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.

[Table of Contents](#)

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

Ivosimendan, imatinib 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 may not receive all of the anticipated market exclusivity benefits of imatinib's orphan drug designation.

TNX-201, Tenax's proprietary formulation of imatinib mesylate, a kinase inhibitor, received Orphan Drug Designation from the FDA in the second quarter of 2020. Orphan Drug Designation may provide market exclusivity in the United States for seven years if (i) imatinib receives market approval before a competitor using a similar mechanism for the same indication, (ii) we are able to produce sufficient supply to meet demand in the marketplace, and (iii) another product with the same active ingredient is not subsequently deemed clinically superior.

Obtaining an Orphan Drug Designation from the FDA may not effectively protect our product candidates from competition because different drugs can be approved for the same condition, and orphan drug exclusivity does not prevent the FDA from approving the same or a different drug in another indication. Even after an orphan drug is approved, the FDA can subsequently approve a later application for the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer in a substantial portion of the target populations, more effective, or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

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

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

- the federal anti-kickback statute is a criminal statute that makes it a felony for individuals or entities knowingly and willfully to offer or pay, or to solicit or receive, direct or indirect remuneration, in order to induce the purchase, order, lease, or recommending of items or services, or the referral of patients for services, that are reimbursed under a federal health care program, including Medicare and Medicaid;
- the federal False Claims Act imposes liability on any person who knowingly submits, or causes another person or entity to submit, a false claim for payment of government funds, with penalties that include three times the government's damages plus civil penalties for each false claim; in addition, the False Claims Act permits a person with knowledge of fraud, referred to as a qui tam plaintiff, to file a lawsuit on behalf of the government against the person or business that committed the fraud, and, if the action is successful, the qui tam plaintiff is rewarded with a percentage of the recovery;
- the 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 monetary 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, impose more strict requirements than the federal laws and may require pharmaceutical companies to comply with certain price reporting and other compliance requirements.

[Table of Contents](#)

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.

We are subject to uncertainty relating to healthcare reform measures and reimbursement policies that, if not favorable to our products, could hinder or prevent our products' commercial success, if any of our product candidates are approved.

Our ability to successfully commercialize our products will depend in part on the extent to which governmental authorities, such as Medicare, private health insurers and other organizations establish what we believe to be appropriate coverage and reimbursement for our approved products. The unavailability or inadequacy of third-party payer coverage and reimbursement could negatively affect the market acceptance of our product candidates and the future revenues we may expect to receive from any approved products. The commercial success of our product candidates, if approved, will depend in part on the extent to which the costs of such products will be covered by third-party payers, such as government health programs, commercial insurance and other organizations. Third-party payers are increasingly challenging the prices and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. If these third-party payers do not consider our products to be cost-effective compared to other therapies, we may not obtain coverage for our products after approval as a benefit under the third-party payers' plans or, even if we do, the level of coverage or payment may not be sufficient to allow us to sell our products on a profitable basis.

Significant uncertainty exists as to the reimbursement status for newly approved drug products, including coding, coverage and payment. There is no uniform policy requirement for coverage and reimbursement for drug products among third-party payers in the United States; therefore, coverage and reimbursement for drug products can differ significantly from payer to payer. The coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payer separately, with no assurance that coverage and adequate payment will be applied consistently or obtained. The process for determining whether a payer will cover and how much it will reimburse a product may be separate from the process of seeking approval of the product or for setting the price of the product. Even if reimbursement is provided, market acceptance of our products may be adversely affected if the amount of payment for our products proves to be unprofitable for healthcare providers or less profitable than alternative treatments or if administrative burdens make our products less desirable to use. Third-party payer reimbursement to providers of our products, if approved, may be subject to a bundled payment that also includes the procedure of administering our products or third-party

payers may require providers to perform additional patient testing to justify the use of our products. To the extent there is no separate payment for our products, there may be further uncertainty as to the adequacy of reimbursement amounts.

The containment of healthcare costs is a priority of federal, state and foreign governments and the prices of drug products have been a focus in this effort. The continuing efforts of government, private insurance companies and other organizations to contain or reduce costs of healthcare may adversely affect our ability to set as high a price for our products as we might otherwise and the rate and scope of adoption of our products by healthcare providers. We expect that federal, state and local governments in the United States, as well as governments in other countries, will continue to consider legislation directed at lowering the total cost of healthcare. In addition, in certain foreign markets, the pricing of drug products is subject to government control and reimbursement may in some cases be unavailable or insufficient. It is uncertain whether and how future legislation, whether domestic or abroad, could affect prospects for our product candidates or what actions governmental or private payers for healthcare treatment and services may take in response to any such healthcare reform proposals or legislation. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, may prevent or limit our ability to generate revenue, attain profitability or commercialize our product candidates.

These potential courses of action are unpredictable and the potential impact of new legislation on our operations and financial position is uncertain, but may result in more rigorous coverage criteria, lower reimbursement and additional downward pressure on the price we may receive for an approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products, if approved.

[Table of Contents](#)

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.

We have distribution rights in the United States and Canada for levosimendan and worldwide distribution rights to imatinib, and 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.

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 Our Dependence on Third Parties

We currently rely significantly on third parties to conduct our nonclinical testing and clinical studies and other aspects of our development programs. If those third parties do not satisfactorily perform their contractual obligations or meet anticipated deadlines, the development of our product candidates could be adversely affected.

We do not currently employ personnel or possess the facilities necessary to conduct many of the activities associated with our development programs. We engage consultants, advisors, CROs and others to assist in the design and conduct of nonclinical and clinical studies of our product candidates, with interpretation of the results of those studies and with regulatory activities and expect to continue to outsource all or a significant amount of such activities. As a result, many important aspects of our development programs are and will continue to be outside our direct control and our third-party service providers may not perform their activities as required or expected, including the maintenance of Good Laboratory Practices (“GLP”) or Good Clinical Practices (“GCP”) compliance, which are ultimately our responsibility to ensure. Further, such third parties may not be as committed to the success of our programs as our own employees and, therefore, may not devote the same time, thoughtfulness, or creativity to completing projects or problem-solving as our own employees would. To the extent we are unable to successfully manage the performance of third-party service providers, our business may be adversely affected.

The CROs we engage or may engage to execute our clinical studies play a significant role in the conduct of the studies, including the collection and analysis of study data, and we likely will depend on CROs and clinical investigators to conduct future clinical studies and to assist in analyzing data from completed studies and developing regulatory strategies for our product candidates. Individuals working at the CROs with which we contract, as well as investigators at the sites at which our studies are conducted, are not our employees, and we have limited control over the amount or timing of resources that they devote to their programs. If our CROs, study investigators, and/or third-party sponsors fail to devote sufficient time and resources to studies of our product candidates, if we and/or our CROs do not comply with all GLP and GCP regulatory and contractual requirements, or if their performance is substandard, it could adversely affect the development of our product candidates.

In addition, the third parties we engage may have relationships with other commercial entities, some of which may compete with us. Through intentional or unintentional means, our competitors may benefit from lessons learned on the project that could ultimately harm our competitive position. Moreover, if a CRO fails to properly, or at all, perform our activities during a clinical study, we may not be able to enter into arrangements with alternative CROs on acceptable terms or in a timely manner, or at all. Switching CROs may increase costs and divert management time and attention. In addition, there likely would be a transition period before a new CRO commences work. These challenges could result in delays in the commencement or completion of our clinical studies, which could materially impact our ability to meet our desired and/or announced development timelines and have a material adverse impact on our business and financial condition.

We depend on third parties to formulate and manufacture our products.

We do not own or operate any manufacturing facilities for the clinical- or commercial-scale production of our products. To manufacture imatinib, we have contracted with various third-party suppliers and clinical manufacturing organizations, or CMOs, making us highly dependent on these CMOs. Currently, we do not have alternative CMOs to back up our primary vendors of clinical trial material or, if approved, commercial supply material. Identification of and discussions with other CMOs may be protracted and/or unsuccessful, or these new CMOs may be unsuccessful in producing the same results as the current primary CMOs producing the material. Therefore, if our primary CMOs become unable or unwilling to perform their required activities, we could experience protracted delays or interruptions in the supply of clinical trial material and, ultimately, product for commercial sale, which would materially and adversely affect our development programs, commercial activities, operating results and financial condition. In addition, the FDA or regulatory authorities outside of the United States may require us to have an alternate manufacturer of a drug product before approving any product candidate for marketing and sale in the United States or abroad. Securing such alternate manufacturer, if possible, could result in considerable additional time and cost prior to approval.

Pursuant to the terms of our license for levosimendan, Orion is at present our sole manufacturing source for TNX-103; should they opt not to provide us the product, our license agreement provides for 24 months’ notice to Tenax of same, to allow an alternative manufacturer to be brought onboard. We might engage other third-party suppliers and CMOs for the supply and manufacture of TNX-102, or other formulations we might develop. 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 avoid disruption of 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 currently have no marketing capabilities and no sales organization. If we are unable to establish sales and marketing capabilities on our own or through third parties, we will be unable to successfully commercialize our products, if approved, or generate product revenue.

To commercialize our products, if approved, in the United States and other jurisdictions in which we may seek approvals, we must build our marketing, sales, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. We have not decided upon a commercialization strategy in these areas. We have no experience in the sale and marketing of approved medical products and marketing the licensing of such products before FDA or other regulatory approval. We 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.

Further, 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.

[Table of Contents](#)

If we are unable to implement our own sales and marketing capability or are unable to contract with one or more third parties for such services on acceptable terms or at all, we may not be able to successfully commercialize our products in certain markets. Any failure or delay in the development of our internal or external sales, marketing and distribution capabilities would adversely impact the commercialization of our products. If we are not successful in commercializing our products, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we would incur significant additional losses.

Risks Related to Intellectual Property

Our success will depend in part on obtaining and maintaining effective patent and other intellectual property protection for our product candidates and proprietary technology.

Our commercial success will depend in part on obtaining and maintaining effective patent protection and other intellectual property 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, if any, will be dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

We are pursuing a multi-faceted IP strategy for levosimendan that includes filing patent applications in the U.S. and Canada that, if granted, could protect the use of levosimendan for subcutaneous administration, levosimendan use in the treatment of PH-HFpEF patients, as well as levosimendan use in combination with various approved drugs to treat cardiovascular conditions. In January 2022, the USPTO granted Tenax Therapeutics a patent protecting the subcutaneous administration of various cyclodextrin based formulations of levosimendan. Our other patent applications are in various stages of review.

Our strategy to maximize market exclusivity for imatinib relies on two forms of exclusivity. First, we have been granted Orphan Drug Designation for the treatment of PAH by the FDA which would provide seven years of regulatory exclusivity in the U.S. if our imatinib formulation is the first to receive FDA approval for PAH. In addition, we expect to file one or more applications for patent to cover our imatinib development. If granted, a patent would provide protection for 20 years from its filing date.

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 less certain still. 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. 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.

[Table of Contents](#)

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

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

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

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

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

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

[Table of Contents](#)

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

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

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.

[Table of Contents](#)

Some 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.

Risks Related to Owning Our Common Stock

Future sales and issuances of shares of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

Additional capital will be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating as a public company. As of December 31, 2021, we had \$5.6 million of cash and cash equivalents. Our ability to continue as a going concern is dependent upon our ability to raise additional capital and to achieve sustainable revenues and profitable operations. To raise capital, we may, among other things, sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner, we determine from time to time.

Additionally, as of December 31, 2021, we had exercisable outstanding options and warrants (excluding out-of-the-money stock options and warrants) that if exercised would result in the issuance of 20.2 million shares of our common stock. Further, we are authorized to grant equity awards, including stock grants and stock options, to our employees, directors and consultants. As of December 31, 2021, there were 819,750 shares available for future issuance under the 2016 Stock Incentive Plan, as amended.

Future sales or issuances of common stock, convertible securities or other equity securities, may cause investors to be materially diluted, and new investors could gain rights, preferences and privileges senior to our existing stockholders.

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

- actual or anticipated fluctuations in our financial condition and operating results;
- status and/or results of our clinical trials;
- status of ongoing litigation;
- results of clinical trials of our competitors' products;
- regulatory actions with respect to our products or our competitors' products;
- actions and decisions by our collaborators or partners;
- actual or anticipated changes in our growth rate relative to our competitors;

- actual or anticipated fluctuations in our competitors' operating results or changes in their growth rate;
- competition from existing products or new products that may emerge;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- market conditions for biopharmaceutical stocks in general;
- status of our search and selection of future management and leadership; and
- general economic and market conditions, including as a result of pandemics, epidemics, or outbreaks of an infectious disease, such as COVID-19, or other similar disrupting illnesses, and as a result of geopolitical uncertainties, including tensions in Ukraine.

[Table of Contents](#)

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. On February 17, 2022, we received a notification letter from Nasdaq's Listing Qualifications Department indicating that we were not in compliance with Nasdaq Listing Rule 5550(a)(2) because the minimum bid price of our common stock on the Nasdaq Capital Market closed below \$1.00 per share for 30 consecutive business days. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have 180 calendar days to regain compliance with the minimum bid requirement, or until August 16, 2022, to achieve compliance with the minimum bid price requirement. To regain compliance, the closing bid price of our common stock must meet or exceed \$1.00 per share for at least ten consecutive business days before August 16, 2022.

In addition, on September 9, 2021, we notified Nasdaq that as a result of James Mitchum's resignation from the Company's Board of Directors and the Audit and Compliance Committee of the Board, the Company was no longer in compliance with Nasdaq Listing Rule 5605(c)(2)(A), which requires the company's Audit Committee to be composed of at least three independent directors. The resignation of Mr. Mitchum left the Audit Committee with two independent directors. On September 10, 2021, the Company received a response from Nasdaq acknowledging the Company's non-compliance with Nasdaq Listing Rule 5605(c)(2)(A). Such letter further provided that pursuant to Nasdaq Listing Rule 5605(c)(4)(B), the Company was entitled to a cure period to regain compliance with Nasdaq Listing Rule 5605(c)(2)(A) through the earlier of the Company's next annual stockholders' meeting or September 8, 2022. Effective January 28, 2022, the Board appointed Robyn M. Hunter as a member of the Board and as a member and Chair of the Audit and Compliance Committee. As a result of her appointment, on February 17, 2022, we received a letter from Nasdaq notifying us that Nasdaq determined that we had regained compliance with Nasdaq Listing Rule 5605(c)(2)(A).

While we intend to engage in efforts to maintain compliance, and thus maintain our listing, there can be no assurance that we will continue to meet all applicable Nasdaq Capital Market requirements in the future. If our common stock were removed from listing with The Nasdaq Capital Market, it may be subject to the so-called "penny stock" rules. The SEC has adopted regulations that define a "penny stock" to be any equity security that has a market price per share of less than \$5.00, subject to certain exceptions, such as any securities listed on a national securities exchange, which is the exception on which we currently rely. For any transaction involving a "penny stock," unless exempt, the rules impose additional sales practice requirements on broker-dealers, subject to certain exceptions. If our common stock were delisted and determined to be a "penny stock," a broker-dealer may find it more difficult to trade our common stock and an investor may find it more difficult to acquire or dispose of our common stock on the secondary market.

If our common stock is delisted and there is no longer an active trading market for our shares, it may, among other things:

- cause stockholders difficulty in selling our shares without depressing the market price for the shares or selling our shares at all;
- substantially impair our ability to raise additional funds;
- result in a loss of institutional investor interest and fewer financing opportunities for us; and/or
- result in potential breaches of representations or covenants of agreements pursuant to which we made representations or covenants relating to our compliance with applicable listing requirements. Claims related to any such breaches, with or without merit, could result in costly litigation, significant liabilities and diversion of our management's time and attention and could have a material adverse effect on our financial condition, business and results of operations.

[Table of Contents](#)

A delisting would also reduce the value of our equity compensation plans, which could negatively impact our ability to retain key employees.

We have a significant security holder, which could exert substantial influence over our business.

As of March 28, 2022, to our knowledge, Armistice Capital, LLC, or Armistice, held 2,019,995 shares of our common stock, warrants to purchase up to 4,773,269 shares of our common stock at an exercise price of \$1.97 per share, warrants to purchase up to 2,072,538 shares of our common stock at an exercise price of \$1.93 per share, warrants to purchase up to 2,360,313 shares of our common stock at an exercise price of \$1.04 per share, warrants to purchase up to 7,783,616 shares of our common stock at an exercise price of \$0.903 per share, and pre-funded warrants to purchase up to 10,033,274 shares of our common stock at an exercise price of \$0.0001 per share. In addition, two members of our Board of Directors are affiliates of Armistice. Under the terms of the warrants and pre-funded warrants issued to Armistice, Armistice is not permitted to exercise such warrants to the extent that such exercise would result in Armistice (and its affiliates) beneficially owning more than 9.99% (or 4.99% in the case of the warrants with the \$1.04 and \$1.93 exercise prices per share) of the number of shares of our common stock outstanding immediately after giving effect to the issuance of shares of common stock issuable upon exercise of such warrants. After giving effect to the beneficial ownership limitations currently in effect with respect to the warrants and pre-funded warrants held by Armistice to our knowledge, as of March 28, 2022, Armistice beneficially owned 9.99% of our outstanding common stock. If the

warrants and pre-funded warrants held by Armistice could be exercised without the beneficial ownership limitations, then as of March 28, 2022, Armistice would have beneficially owned 53.5% of our common stock.

Additionally in connection with a sale of the Company, Armistice would be entitled to receive, with respect to each share of common stock issuable upon exercise of the warrants then held by it and without regard to the beneficial ownership limitations imposed on the conversion or exercise of such securities, the same amount and kind of securities, cash or property as it would have been entitled to receive if such securities had been converted into or exercised for shares of our common stock immediately prior to such sale of our company. Because Armistice would receive this sale consideration with respect to warrants not included in its reported beneficial ownership of our common stock, in the event of a sale of our Company, it would be entitled to receive a significantly larger portion of the total proceeds distributable to the holders of our securities than is represented by its reported beneficial ownership of our common stock.

Although there are contractual limitations on the beneficial ownership of Armistice, if Armistice were to exercise its warrants for common stock, it could be able to exert substantial influence over our business, including, for example, the ability to delay, defer or prevent a change of control, entrench our management and our Board of Directors or delay or prevent a merger, consolidation or other business combination.

Anti-takeover provisions in our corporate charter documents and under Delaware law could make an acquisition of us more difficult, which could discourage takeover attempts and lead to management entrenchment, and the market price of our common stock may be lower as a result.

Certain provisions in our certificate of incorporation and bylaws may make it difficult for a third party to acquire, or attempt to acquire, control of the Company, even if a change in control was considered favorable by the stockholders. For example, our Board of Directors has the authority to issue up to 10,000,000 shares of preferred stock. The Board can fix the price, rights, preferences, privileges and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change in control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our organizational documents also contain other provisions that could have an anti-takeover effect, including provisions that:

- provide that vacancies on the Board of Directors may be filled only by a majority of directors then in office, even though less than a quorum;
- eliminate cumulative voting in the election of directors;
- grant the Board of directors the authority to increase or decrease the size of the Board;
- prohibit stockholders from calling a special meeting of stockholders;
- require that stockholders give advance notice to nominate directors or submit proposals for consideration at stockholder meetings; and
- authorize the Board of Directors, by a majority vote, to amend the bylaws.

[Table of Contents](#)

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which limit the ability of stockholders owning in excess of 15% of our outstanding voting stock to merge or combine with us. These provisions could discourage potential acquisition proposals and could delay or prevent a change in control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in stockholder best interests. These provisions may also prevent changes in our management or limit the price that certain investors are willing to pay for our stock.

Our bylaws contain an exclusive forum provision, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees, or agents.

Our bylaws provide that, unless we consent in writing to the selection of an alternative forum, any North Carolina state court that has jurisdiction, or the Delaware Court of Chancery shall, to the fullest extent permitted by law, be the sole and exclusive forum for any internal corporate claims, including without limitation (i) any derivative action or proceeding brought on behalf of us, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of us to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the General Corporation Law of the State of Delaware, and (iv) any action asserting a claim governed by the internal affairs doctrine, in each case subject to said court having personal jurisdiction over the indispensable parties named as defendants in such action. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or the Securities Act, or any other claim for which federal courts have exclusive jurisdiction.

This exclusive forum provision may limit a stockholder's ability to bring a claim in a judicial forum of its choosing for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find the exclusive forum provision in our bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could harm our results of operations. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management and other employees.

We have not paid cash dividends in the past and do not expect to pay dividends in the future. Any return on investment may be limited to the value of our common stock.

We have never paid cash dividends on our common stock and do not anticipate paying cash dividends in the near future. The payment of dividends on our common stock will depend on our earnings and financial condition and other business and economic factors affecting us at such time as the Board of Directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on investment will only occur if our stock price appreciates.

Our ability to use our net operating loss carryforwards and certain other tax attributes to offset future taxable income may be subject to certain limitations.

We have U.S. federal net operating loss carryforwards, or NOLs, which expire in various years if not utilized. In addition, we have federal research and development credit carryforwards. The federal research and development credit carryforwards expire in various years if not utilized. Under Sections 382 and 383 of Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change," the corporation's ability to use its

pre-change NOLs and other pre-change tax attributes, such as research tax credits, to offset its future post-change income and taxes may be limited. In general, an “ownership change” occurs if there is a cumulative change in our ownership by “5% shareholders” that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. We have not performed a formal study to determine whether any of our NOLs are subject to these limitations. We have recorded deferred tax assets for our NOLs and research and development credits and have recorded a full valuation allowance against these deferred tax assets. In the event that it is determined that we have in the past experienced additional ownership changes, or if we experience one or more ownership changes as a result of future transactions in our stock, then we may be further limited in our ability to use our NOLs and other tax assets to reduce taxes owed on the net taxable income that we earn in the event that we attain profitability. Any such limitations on the ability to use our NOLs and other tax assets could adversely impact our business, financial condition and operating results in the event that we attain profitability.

[Table of Contents](#)

ITEM 1B—UNRESOLVED STAFF COMMENTS

Smaller reporting companies are not required to provide the information required by this Item.

ITEM 2—PROPERTIES

We own no real property. We lease approximately 6,000 square feet of office space at our principal executive office located at ONE Copley Parkway, Suite 490, Morrisville, North Carolina 27560. The current rent is approximately \$10,400 per month.

We believe that our existing facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

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.

EXECUTIVE OFFICERS

The following table sets forth information concerning our executive officers as of March 28, 2022:

Name	Age	Position
Christopher T. Giordano	48	President and Chief Executive Officer
Eliot M. Lurier, CPA	63	Interim Chief Financial Officer
Stuart Rich, MD	72	Chief Medical Officer

Christopher T. Giordano joined the Company as our Chief Executive Officer and a member of our Board of Directors in July 2021 and became President and Chief Executive Officer in October 2021. From March 2018 to July 2021, he served as President of IQVIA Biotech LLC and IQVIA MedTech Inc., a provider of integrated clinical and commercial solutions to smaller biotech companies, where he led an executive team that executed a clinical trial portfolio that grew from 250 to 400 active projects during his three years of leadership. Prior to that role, from August 2008 to March 2018 Mr. Giordano held roles of increasing responsibility at Quintiles Transnational Holdings Inc., a provider of pharmaceutical outsourcing services (acquired by IMS Health Holdings, Inc. in October 2016 to become IQVIA Holdings Inc.), and was most recently Global Vice President of the cardiovascular, renal, and metabolic group. From January 2001 to July 2008, Mr. Giordano served in various sales and management roles at PPD, Inc., a global clinical research organization. Mr. Giordano holds a B.A. in English from University of San Diego and a M.A. in English from the University of North Carolina at Chapel Hill.

Eliot M. Lurier joined the Company as our Interim Chief Financial Officer in October 2021. Since July 2021, Mr. Lurier has served as a consultant to several companies through Danforth Advisors, LLC, an advisory firm that provides operational and strategic support services to life science companies. Prior to joining Danforth, from September 2014 to December 2020, Mr. Lurier was Chief Financial Officer of the Joslin Diabetes Center, Inc., a preeminent diabetes research, clinical care, and education organization. Prior to that, from April 2008 to September 2014, Mr. Lurier was Chief Financial Officer of Interleukin Genetics, Inc., during which time it was a public company. From April 2005 to April 2008, Mr. Lurier was Vice President, Finance and Administration and Chief Financial Officer of NUCRYST Pharmaceuticals, where he assisted in its initial public offering and where he was responsible for the company’s SEC reporting and the implementation of Sarbanes-Oxley requirements. From April 2004 to March 2005, Mr. Lurier served as Chief Financial Officer and Chief Operating Officer for Bridge Pharmaceuticals, Inc., where he established policies for managing business operations. From 1983 to 2004, Mr. Lurier held a number of senior-level financial positions, including Chief Financial Officer of Admetric Biochem, Inc., and Chief Financial Officer, Treasurer and Vice President of Finance of Ascent Pediatrics, Inc. From 1981 to 1983, Mr. Lurier was an auditor at Coopers and Lybrand in Boston, Massachusetts. Mr. Lurier holds a B.S. in Accounting from Syracuse University and is a Certified Public Accountant in Massachusetts.

[Table of Contents](#)

Stuart Rich has served as our Chief Medical Officer since January 2021 and a director since February 2021. Dr. Rich joined the Company from PHPM, where he was a co-founder and held the positions of Chief Executive Officer and Director from October 2018 until PHPM’s merger with the Company in January 2021. Since July 2015, Dr. Rich has served as Professor of Medicine at Northwestern University Feinberg School of Medicine and as Director of the Pulmonary Vascular Disease Program at the Bluhm Cardiovascular Institute, a U.K. based charity, and since January 2011, he has also served as Director of the Cardiovascular Medical and Research Foundation, a U.S. based charity. Prior to Northwestern University, Dr. Rich was Professor of Medicine at the Section of Cardiology of the University of Chicago Pritzker School of Medicine from September 2004 to July 2015. Dr. Rich also served as

the Chief Medical Officer (part-time) of United Therapeutics from October 2003 until December 2004. He was Professor of Medicine at the Rush Heart Institute of the Rush University School of Medicine from July 1996 to September 2004 and Professor of Medicine and Chief of the Section of Cardiology at the University of Illinois College of Medicine in Chicago from July 1980 to July 1996. Dr. Rich received his B.S. in Biology at the University of Illinois and his M.D. at Loyola University Stritch School of Medicine, and he completed his residency in medicine at the Washington University of St. Louis and his fellowship in cardiology at the University of Chicago.

[Table of Contents](#)

PART II

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

Market Information and Number of Stockholders

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

Based upon information furnished by our transfer agent, as of March 28, 2022, there were approximately 1,338 holders of record of our common stock.

Dividend Policy

We have never declared dividends on our equity securities, and currently do not plan to declare dividends on shares of our common stock in the foreseeable future. We expect to retain our future earnings, if any, for use in the operation and expansion of our business. Subject to the foregoing, the payment of cash dividends in the future, if any, will be at the discretion of our Board of Directors and will depend upon such factors as earnings levels, capital requirements, our overall financial condition and any other factors deemed relevant by our Board.

Repurchases of Common Stock

None.

Unregistered Sales of Equity Securities

During the year ended December 31, 2021, we did not issue or sell any unregistered securities not previously disclosed in a Quarterly Report on Form 10-Q or in a Current Report on Form 8-K.

ITEM 6—RESERVED

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 – “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.

Overview

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.

On November 13, 2013, we acquired a license granting Life Newco, our wholly-owned subsidiary, an exclusive, sublicensable 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. On October 9, 2020 and January 25, 2022, we entered into amendments to the license to include two product dose forms containing levosimendan, in capsule and solid dosage form, and a subcutaneously administered product containing levosimendan, subject to specified limitations.

On January 15, 2021, we acquired 100% of the equity of PHPrecisionMed Inc., a Delaware corporation, or PHPM, with PHPM surviving as our wholly-owned subsidiary. As a result of the merger, we plan to develop and commercialize pharmaceutical products containing imatinib for the treatment of pulmonary arterial hypertension, or PAH.

[Table of Contents](#)

Strategy

Our principal business objective is to identify, develop, and commercialize late-stage pharmaceutical therapeutic products for serious cardiovascular and pulmonary diseases with high unmet medical need. The key elements of our business strategy are outlined below.

- *Efficiently conduct clinical development to establish clinical proof of principle in new indications, refine formulation, and commence Phase 3 testing of our current product candidates.*

Levosimendan and imatinib have been approved and prescribed globally for more than 20 years, but we believe their mechanisms of action

have not been fully exploited, despite promising evidence they may significantly improve the lives of patients with pulmonary hypertension. We are conducting clinical development with the intent to establish proof of beneficial activity in cardiopulmonary diseases in which these therapeutics would be expected to have benefit for patients with diseases for which either no pharmaceutical therapies are approved at all, or in the case of PAH, where numerous expensive therapies generally offer a modest reduction of symptoms. Our focus is primarily on designing and executing formulation improvements, protecting these innovations with patents and other forms of exclusivity, and employing innovative clinical trial science to establish a robust foundation for subsequent development, product approval, and commercialization.

- *Efficiently explore new high-potential therapeutic applications, in particular where expedited regulatory pathways are available, leveraging third-party research collaborations and our results from related areas.*

Levosimendan has shown promise in multiple disease areas in its two decades of use following its approval. In order to achieve our objectives of developing these medicines for new groups of patients, we have established collaborative research relationships with investigators from leading research and clinical institutions, and our strategic partners. 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, and the confidentiality of all our company information, 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, alone or in combination with existing therapies, as well as other product candidates.

- *Enter into licensing or product co-development arrangements.*

In addition to our internal development efforts, an important part of our product development strategy is to work with collaborators and partners to accelerate product development, maintain our low development and business operations costs, and broaden our commercialization capabilities globally.

As we focus on the development of our existing product candidates, 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.

Historically, we have financed our operations principally through equity and debt offerings, including private placements and loans from our stockholders. Based on our current operating plan, there is substantial doubt about our ability to continue as going concern. Our ability to continue as a going concern depends on our ability to raise additional capital, through the sale of equity or debt securities and through collaboration and licensing agreements, to support our future operations. If we are unable to secure additional capital, we may be required to curtail our research and development initiatives and take additional measures to reduce costs.

[Table of Contents](#)

COVID-19

The continued spread of COVID-19, including variant strains, globally, may affect our operations, including the potential interruption of our clinical trial activities and our supply chain. The continued spread of COVID-19 may result in a period of continued or recurring business disruption in these and other areas impacting our business, including the establishment of contractual relationships with investigators enrolling subjects in our clinical trials, the continuity of care provided by these institutions to the patients we seek to enroll and their ability to support industry-funded research as a means of caring for their patients, supply of these sites with study materials, and the enrolment of subjects and their adherence with study requirements. In addition, there could be a potential effect of COVID-19 to the business at FDA or other health authorities, which could result in delays of reviews and approvals, including with respect to our product candidates.

Financial Overview

General and Administrative Expenses

General and administrative expenses were \$7.6 million for the year ended December 31, 2021, compared to \$5.3 million for the same period in 2020. 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, and other professional and consulting services. General and administrative expenses and percentage changes for the years ended December 31, 2021 and 2020, respectively, are as follows:

	For the year ended December 31,		Increase/ (Decrease)	% Increase/ (Decrease)
	2021	2020		
Personnel costs	\$ 4,952,334	\$ 3,478,186	\$ 1,474,148	42%
Legal and professional fees	1,770,483	1,043,139	727,344	70%
Other costs	698,473	630,959	67,514	11%
Facilities	159,557	154,922	4,635	3%

Personnel costs increased approximately \$1.5 million for the year ended December 31, 2021, compared to the same period in the prior year. The increase was primarily due to approximately \$1.2 million in severance costs associated with the departure from the Company of the former CEO and other employees, as well as approximately \$266,000 in noncash compensation expense resulting from the modification of the former CEO's outstanding stock options and the grant of an additional stock option on his separation date.

Legal and professional fees increased approximately \$727,000 for the year ended December 31, 2021, compared to the same period in the prior year. Professional fees consist of the costs incurred for accounting fees, capital market expenses, consulting fees and investor relations services, as well as fees paid to the members of our Board of Directors.

Legal fees increased approximately \$566,000 for the year ended December 31, 2021, as compared to the same period in the prior year. The increase was primarily due to the reimbursement of approximately \$358,000 in legal fees associated with arbitration proceedings in the prior year, as well as an increase in fees paid associated with the PHPM acquisition and costs associated with the CEO transition that were not incurred during the same period in the prior year.

Professional fees increased approximately \$161,000 for the year ended December 31, 2021, compared to the same period in the prior year. The increase was primarily attributable to increased accounting, director, consulting and capital market fees offset by a decrease in investor relations costs.

Other costs increased approximately \$68,000 for the year ended December 31, 2021, compared to the same period in the prior year. Other costs include expenses incurred for franchise and other taxes, travel, supplies, insurance, depreciation and other miscellaneous charges. The increase was primarily attributable to increased costs for insurance offset by decreases in franchise and other taxes.

Facilities costs include costs paid for rent and utilities at our corporate headquarters in North Carolina. Facilities costs remained relatively unchanged for the years ended December 31, 2021 and 2020.

[Table of Contents](#)

Research and Development Expenses

Research and development expenses were \$25.1 million for the year ended December 31, 2021 as compared to \$4.6 million for the same period in the prior year. Research and development expenses include, but are not limited to, (i) expenses incurred under agreements with CROs and investigative sites, which conduct our clinical trials and a substantial portion of our pre-clinical studies; (ii) the cost of supplying clinical trial materials; (iii) payments to contract service organizations, as well as consultants; (iv) employee-related expenses, which include salaries and benefits; and (v) facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, depreciation of leasehold improvements, equipment, and other supplies. All research and development expenses are expensed as incurred. Research and development expenses and percentage changes for the years ended December 31, 2021 and 2020, respectively, are as follows:

	For the year ended December 31,		Increase/ (Decrease)	% Increase/ (Decrease)
	2021	2020		
Clinical and preclinical development	\$ 2,653,571	\$ 4,281,884	\$ (1,628,313)	(38)%
Personnel costs	689,183	250,228	438,955	175%
Other costs	21,804,640	28,612	21,776,028	76108%

Clinical and preclinical development costs decreased approximately \$1.6 million for the year ended December 31, 2021 as compared to the same period in the prior year. Clinical and preclinical development costs consist of expenses associated with our Phase 2 HELP Study for levosimendan, which was completed during fiscal year 2020, costs associated with our intravenous to oral levosimendan transition study and development costs associated with the formulation for imatinib. The decrease is primarily attributable to a decrease of approximately \$2.0 million in expenditures for CRO costs, a reduction of approximately \$1.1 million in enrolled patient and direct site costs and a decrease of approximately \$86,000 in fees paid for clinical research associates and other direct costs to manage the Phase 2 HELP Study in the current period as compared to the same period in the prior year. These cost reductions were partially offset by an increase of approximately \$1.5 million in costs associated with formulation development of imatinib in the current period that were not incurred in the same period in the prior year.

Personnel costs increased approximately \$439,000 for the year ended December 31, 2021, as compared to the same period in the prior year, primarily attributable to the addition of our Chief Medical Officer in the current period.

Other costs increased approximately \$21.8 million for the year ended December 31, 2021, as compared to the same period in the prior year, primarily attributable to the recognition of in-process research and development acquired as part of the merger with PHPM in the current period. There were no such expenses incurred in the same period in the prior year.

Other Income and Expense

Other income and expense include non-operating income and expense items not otherwise recorded in our consolidated statement of comprehensive loss. These items include, but are not limited to, changes in the fair value of financial assets and derivative liabilities, interest income earned and fixed asset disposals. Other income increased approximately \$237,000 for the year ended December 31, 2021, compared to the same period in the prior year. This increase is due primarily to the forgiveness of our PPP Loan in the current period.

Liquidity, Capital Resources and Plan of Operation

We have incurred losses since our inception and, as of December 31, 2021, we had an accumulated deficit of approximately \$278 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 and imatinib 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.

The process of conducting preclinical studies and clinical trials necessary to obtain approval from the FDA is costly and time consuming. The probability of success for each product candidate and clinical trial may be affected by a variety of factors, including, among other things, the quality of the product candidate's early clinical data, investment in the program, competition, manufacturing capabilities and commercial viability. As a result of the uncertainties discussed above, uncertainty associated with clinical trial enrollment and risks inherent in the development process, we are unable to determine the duration and completion costs of current or future clinical stages of our product candidates or when, or to what extent, we will generate revenues from the commercialization and sale of any of our product candidates. Development timelines, probability of success and development costs vary widely. We are currently focused on developing our two product candidates, levosimendan and imatinib; however, we will need substantial additional capital in the future in order to complete the development and potential commercialization of levosimendan and imatinib, and to continue with the development of other potential product candidates.

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 \$5,689,000 and \$6,795,506 and working capital of \$4,125,022 and \$4,676,543 as of December 31, 2021 and December 31, 2020, respectively. Our practice is to invest excess cash, where available, in short-term money market investment instruments and high quality corporate and government bonds.

Clinical and Preclinical Product Development

We are currently developing a new formulation for imatinib and conducting a clinical trial to transition from an intravenous to oral formulation of levosimendan in North America for the treatment of pulmonary hypertension. Our ability to continue to pursue development of our products beyond the second quarter of calendar year 2022 will depend on obtaining license income or outside financial resources. There is no assurance that we will obtain any license agreement or outside financing or that we will otherwise succeed in obtaining any necessary resources.

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

Financings

On July 6, 2021, we sold 4,773,269 units in a private placement at a purchase price of \$2.095 per unit for net proceeds of approximately \$10 million. Each unit consisted of one unregistered pre-funded warrant to purchase one share of our common stock and one unregistered warrant to purchase one share of common stock.

On July 6, 2020, we sold 2,523,611 shares of our common stock at a purchase price of \$1.0278 per share and pre-funded warrants to purchase up to 652,313 shares of common stock, at a purchase price of \$1.0277 per pre-funded warrant, in a registered direct offering. Additionally, in a concurrent private placement, sold pre-funded warrants to purchase up to 4,607,692 shares of common stock, at the same purchase price as the registered pre-funded warrants, as well as unregistered warrants to purchase up to an aggregate of 7,783,616 shares of common stock. The unregistered warrants have an exercise price of \$0.903 per share, were immediately exercisable upon issuance, and expire five and one-half years from the date of issuance. We also issued to the placement agent five-year warrants to purchase 583,771 shares of common stock with an exercise price of \$1.2848. The aggregate net proceeds for offerings were approximately \$6.5 million after deducting placement agent discounts and commissions and offering expenses. We are using the net proceeds to further our clinical trials of levosimendan, for research and development and general corporate purposes, including working capital and potential acquisitions.

On March 11, 2020, we sold 750,000 shares of our common stock at a purchase price of \$1.1651 per share and pre-funded warrants to purchase up to 1,610,313 shares of common stock, at a purchase price of \$1.1650 per pre-funded warrant, in a registered direct offering. Additionally, in a concurrent private placement, we sold unregistered warrants to purchase up to 2,360,313 shares of common stock. The unregistered warrants have an exercise price of \$1.04 per share and exercise period commencing immediately upon the issuance date and a term of five and one-half years. We also issued to the placement agent five-year warrants to purchase 177,023 shares of common stock with an exercise price of \$1.4564. The net proceeds from the March 2020 offering, after deducting placement agent fees and other direct offering expenses, were approximately \$2.125 million.

Paycheck Protection Program Loan

On April 30, 2020, we received a loan in the principal amount of \$244,657 pursuant to the Paycheck Protection Program (the "PPP Loan") under the Coronavirus Aid, Relief, and Economic Security Act, as administered by the U.S. Small Business Administration ("SBA").

On May 28, 2021, we received notice from the SBA that the SBA had remitted \$244,657 in principal and \$2,576 in interest to the lender in full forgiveness of our PPP Loan pursuant to our application to the SBA for forgiveness of the PPP Loan. The total amount was recorded as other income in our consolidated statement of comprehensive loss for the year ended December 31, 2021.

Cash Flows

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

For the year ended December	
31,	
2021	2020

Net cash used in operating activities	\$ (10,856,203)	\$ (9,272,856)
Net cash provided by investing activities	452,609	20,109
Net cash provided by financing activities	9,737,275	10,596,995

Net cash used in operating activities. Net cash used in operating activities was approximately \$10.9 million for the year ended December 31, 2021 compared to approximately \$9.3 million for the year ended December 31, 2020. The increase in cash used for operating activities was primarily due to an increase in our annual insurance premiums, employee severance and accrued bonuses paid in the current period as compared to the prior year.

Net cash provided by investing activities. Net cash provided by investing activities was approximately \$453,000 for the year ended December 31, 2021, compared to approximately \$20,000 in the year ended December 31, 2020. The increase in cash provided by investing activities was primarily due to the sale of marketable securities in the current period.

Net cash provided by financing activities.

Net cash provided by financing activities was approximately \$9.7 million, for the year ended December 31, 2021, primarily attributable to net proceeds from the sale of stock units in our July 2021 private placement of \$9.2 million and the exercise of stock warrants of \$0.5 million.

Net cash provided by financing activities in the prior year totaled \$10.6 million, primarily attributable to aggregate net proceeds from the sale of common stock, warrants and pre-funded warrants in our July 2020 registered direct offering and concurrent private placement of \$6.5 million, aggregate net proceeds from the sale of common stock and pre-funded warrants in our March 2020 registered direct offering and concurrent private placement of \$2.1 million, \$0.2 million in proceeds from the PPP Loan under the Cares Act and \$1.7 million of proceeds from the exercise of stock warrants.

Operating Capital and Capital Expenditure Requirements

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

[Table of Contents](#)

- 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 the global coronavirus pandemic;
- 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 on December 31, 2021, we believe we have sufficient capital on hand to continue to fund operations through the second quarter of calendar year 2022.

We will need substantial additional capital beyond the second quarter of calendar year 2022 and in the future in order to complete the regulatory approval and commercialization of imatinib and levosimendan as well as to fund the development and commercialization of other future product candidates. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Such funding, if needed, may not be available on favorable terms, if at all. In the event we are unable to obtain additional capital, we may delay or reduce the scope of our current research and development programs and other expenses. As a result of our historical operating losses and expected future negative cash flows from operations, we have concluded that there is substantial doubt about our ability to continue as a going concern. Similarly, the report of our independent registered public accounting firm on our December 31, 2021 consolidated financial statements include an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern. Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock and make it more difficult to obtain financing.

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

Off-Balance Sheet Arrangements

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

Summary of Critical Accounting Policies

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

40

[Table of Contents](#)

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

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

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

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

Recent Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board, or FASB, issued an accounting standard intended to simplify accounting for income taxes. It removes certain exceptions to the general principles in Topic 740, Income Taxes, and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020 and early adoption is permitted. We adopted this standard on January 1, 2021. Our adoption of the new guidance did not have a material impact on our consolidated financial statements.

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

41

[Table of Contents](#)

ITEM 7A—QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Smaller reporting companies are not required to provide the information required by this item.

ITEM 8—FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

See the financial statements included at the end of this report beginning on page F-1.

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

None.

ITEM 9A—CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

As required by paragraph (b) of Rules 13a-15 and 15d-15 promulgated under the Exchange Act, under the supervision and with the participation of our management, including our President and Chief Executive Officer and our Interim Chief Financial Officer, we conducted an evaluation as of the end of the period covered by this Annual Report on Form 10-K, of the effectiveness of our disclosure controls and procedures as defined in Exchange Act Rules 13a-15(e) and 15d-15(e).

In designing and evaluating our disclosure controls and procedures, management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Based on their evaluation, our President and Chief Executive Officer and Interim Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2021, the end of the period covered by this Annual Report on Form 10-K, in that they provide reasonable assurance that the information we are required to disclose in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods required by the SEC and is accumulated and communicated to our management, including our President and Chief Executive Officer and Interim Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Controls over Financial Reporting

There were no changes in our internal control over financial reporting during our most recently completed fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We routinely review our internal controls over financial reporting and from time to time make changes intended to enhance the effectiveness of our internal control over financial reporting. We will continue to evaluate the effectiveness of our disclosure controls and procedures and internal controls over financial reporting on an ongoing basis and will take action as appropriate.

During the most recently completed fiscal quarter, management reviewed all work generated in support of the financial statements and corresponding footnotes in order to determine areas which may be susceptible to human error. The review focused on limiting manual inputs into work papers wherever possible and tying inputs to external source documents. In addition, management also enhanced its work paper review to compare figures to prior year amounts or source documents and increased the number of calculations in the work papers that are reviewed and re-performed.

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 Rule 13a-15(f) and Rule 15(d)-15(f) under the Exchange Act, is a process designed by, or under the supervision of, our President and Chief Executive Officer and Interim 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 financial statements for external purposes in accordance with GAAP. Internal control over financial reporting includes those policies and procedures that:

42

[Table of Contents](#)

- 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 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 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, 2021. In making its assessment, management used the criteria established by the Committee of Sponsoring Organizations of the Treadway Commission 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, 2021.

Attestation Report of Registered Public Accounting Firm

Our independent registered public accounting firm has not assessed the effectiveness of our internal control over financial reporting and, under SEC rules, will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting so long as we qualify as a “non-accelerated filer”.

ITEM 9B—OTHER INFORMATION

None.

ITEM 9C—DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

43

[Table of Contents](#)

PART III

ITEM 10— DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

Information required by this Item concerning our directors is incorporated by reference from the sections captioned “Election of Directors” and “Corporate Governance Matters” contained in our proxy statement related to the 2022 Annual Meeting of Stockholders currently scheduled to be held on June 9, 2022, which we intend to file with the SEC within 120 days of the end of our fiscal year pursuant to General Instruction G(3) of Form 10-K.

The information required by this Item concerning our Audit and Compliance Committee is incorporated by reference from the section captioned “Corporate Governance Matters—Standing Committees—Audit and Compliance Committee” contained in our proxy statement related to the 2022 Annual Meeting of Stockholders.

We have adopted a Code of Ethics and Business Conduct (the “Code of Ethics”) applicable to all of our officers, directors and employees, including our principal executive officer, principal financial officer, principal accounting officer, controller, or persons performing similar functions. A copy of this Code of Ethics is posted on our website at http://investors.tenaxthera.com/corporate_governance. In the event the Code of Ethics is revised, or any waiver is granted under the Code of Ethics with respect to our principal executive officer, principal financial officer, principal accounting officer, controller, or persons performing similar functions, notice of such revision or waiver will be posted on our website or disclosed on a current report on Form 8-K as required.

The information required by this Item concerning our executive officers is set forth at the end of Part I of this Annual Report on Form 10-K.

The information required by this Item concerning compliance with Section 16(a) of the Exchange Act is incorporated by reference from the section of the proxy statement captioned “Delinquent Section 16(a) Reports”.

ITEM 11— EXECUTIVE COMPENSATION

The information required by this Item is incorporated by reference to the information under the sections captioned “Executive Compensation” and “Director Compensation” in our proxy statement.

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

Equity Compensation Plan Information

The following table provides information about the securities authorized for issuance under our equity compensation plans as of December 31, 2021.

<u>Plan category</u>	<u>Number of securities to be issued upon exercise of outstanding options, warrants and rights</u>	<u>Weighted-average exercise price of outstanding options, warrants and rights</u>	<u>Number of securities remaining available for future issuances under equity compensation plans (excluding securities reflected in column (a))</u>
Equity compensation plans approved by security holders:			
2016 Stock Incentive Plan, as amended	663,250	\$ 1.90	819,750
Amended and Restated 1999 Amended Stock Plan, as amended	36,317	\$ 42.26	-
Equity compensation plans not approved by security holders:			
Plan for Employee Inducement Stock Option Grants	600,000	\$ 1.89	-
Total	1,299,567	\$ 3.02	819,750

The other information required by this Item is incorporated by references to the information under the section captioned “Security Ownership of Certain Beneficial Owners and Management” contained in our proxy statement.

[Table of Contents](#)

ITEM 13— CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

The information required by this Item is incorporated by reference to the information under the section captioned “Certain Relationships and Related Transactions” and “Corporate Governance Matters” in our proxy statement.

ITEM 14— PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this Item is incorporated by reference to the information under the section captioned “Audit and Compliance Committee Report” in our proxy statement.

[Table of Contents](#)

ITEM 15—EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) List of documents filed as part of this report:

1. Financial Statements:

The financial statements of the Company and the related reports of the Company's independent registered public accounting firm thereon have been filed under Item 8 hereof.

2. Financial Statement Schedules:

None.

3. Exhibit Index

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

Exhibit Number	Exhibit Title	Incorporated by Reference (Unless Otherwise Indicated)			
		Form	File	Exhibit	Filing Date
2.1	Agreement and Plan of Merger between Synthetic Blood International, Inc. and Oxygen Biotherapeutics, Inc. dated April 28, 2008.	8-K	002-31909	2.01	June 30, 2008
2.2	Asset Purchase Agreement by and between Oxygen Biotherapeutics, Inc., Life Newco, Inc., Phyxius Pharma, Inc., and the stockholders of Phyxius Pharma, Inc. dated October 21, 2013.	8-K	001-34600	2.1	October 25, 2013
2.3	Agreement and Plan of Merger among PHPrecisionMed Inc., Tenax Therapeutics, Inc., Life Newco II, Inc., and Dr. Stuart Rich dated January 15, 2021.	8-K	001-34600	2.1	January 19, 2021
3.1.1	Certificate of Incorporation of Oxygen Biotherapeutics, Inc., dated April 17, 2008.	8-K	002-31909	3.01	June 30, 2008
3.1.2	Certificate of Amendment of the Certificate of Incorporation, effective November 9, 2009.	8-K	002-31909	3.1	November 13, 2009
3.1.3	Certificate of Amendment of the Certificate of Incorporation, effective May 10, 2013.	8-K	001-34600	3.1	May 15, 2013
3.1.4	Certificate of Amendment of the Certificate of Incorporation, effective September 19, 2014.	10-Q	001-34600	3.4	December 15, 2014
3.1.5	Certificate of Amendment of the Certificate of Incorporation, effective February 23, 2018.	8-K	001-34600	3.1	February 23, 2018
3.2	Certificate of Designation of Series A Convertible Preferred, dated December 10, 2018.	8-K	001-34600	4.1	December 11, 2018

Table of Contents

3.3	Certificate of Designation of Series B Convertible Preferred Stock, dated January 15, 2021.	8-K	001-34600	4.1	January 19, 2021
3.4	Third Amended and Restated Bylaws.	10-Q	001-34600	3.1	September 9, 2015
4.1	Specimen Stock Certificate.	10-K	001-34600	4.1	July 23, 2010
4.2	Representative's Warrant to Purchase Shares of Common Stock, dated December 11, 2018.	8-K	001-34600	4.2	December 11, 2018
4.3	Form of Warrant to Purchase Shares of Common Stock, dated December 11, 2018.	8-K	001-34600	4.3	December 11, 2018
4.4	Warrant Agency Agreement, dated December 11, 2018	8-K	001-34600	4.4	December 11, 2018
4.5	Form of Pre-Funded Warrant, dated March 13, 2020.	8-K	001-34600	4.1	March 13, 2020

4.6	Form of Unregistered Warrant, dated March 13, 2020.	8-K	001-34600	4.2	March 13, 2020
4.7	Form of Placement Agent Warrant, dated March 13, 2020.	8-K	001-34600	4.3	March 13, 2020
4.8	Form of Pre-Funded Warrant, dated July 6, 2020.	8-K	001-34600	4.1	July 8, 2020
4.9	Form of Unregistered Warrant, dated July 6, 2020.	8-K	001-34600	4.2	July 8, 2020
4.10	Form of Placement Agent Warrant, dated July 6, 2020.	8-K	001-34600	4.3	July 8, 2020
4.11	Form of Unregistered Pre-Funded Warrant, dated July 6, 2021.	8-K	001-34600	4.1	July 8, 2021
4.12	Form of Unregistered Warrant, dated July 6, 2021.	8-K	001-34600	4.2	July 8, 2021
4.13	Form of HCW Warrant, dated July 6, 2021.	8-K	001-34600	4.3	July 8, 2021
4.14	Description of Common Stock.	-	-	-	Filed herewith
10.1.1+	1999 Amended Stock Plan, as amended and restated June 17, 2008.	10-K	002-31909	10.15	August 13, 2008
10.1.2+	Amendment No. 1 to Oxygen Biotherapeutics, Inc. 1999 Amended Stock Plan.	10-K	001-34600	10.19	July 29, 2014
10.1.3+	Amendment No. 2 to Oxygen Biotherapeutics, Inc. 1999 Amended Stock Plan.	10-K	001-34600	10.20	July 29, 2014
10.1.4+	Form of Option issued to Executive Officers and Directors.	10-K	002-31909	10.5	August 13, 2004
10.1.5+	Form of Option issued to Employees.	10-K	002-31909	10.6	August 13, 2004
10.1.6+	Form of Option Agreement with Form of Notice of Grant.	10-K	001-34600	10.9	March 16, 2017
10.2.1	Lease Agreement for North Carolina Corporate Office.	10-Q	001-34600	10.6	March 21, 2011
10.2.2	First Amendment to Lease Agreement for North Carolina Corporate Office.	10-K	001-34600	10.74	March 14, 2016

Table of Contents

10.3+	Form of Indemnification Agreement.	10-K	001-34600	10.36	July 15, 2011
10.4.1*	License Agreement dated September 20, 2013 by and between Phyxius Pharma, Inc. and Orion Corporation.	10-Q	001-34600	10.3	March 17, 2014
10.4.2*	Amendment to License Agreement, dated as of October 9, 2020, by and between Tenax Therapeutics, Inc. and Orion Corporation.	8-K	001-34600	10.1	October 15, 2020
10.4.3*	Amendment to the License Agreement of September 20, 2013 by and between Tenax Therapeutics, Inc. and Orion Corporation, dated as of January 25, 2022.	8-K	001-34600	10.1	January 28, 2022
10.5.1+	Second Amended and Restated Employment Agreement with Michael Jebsen dated November 13, 2013.	8-K	001-34600	10.2	November 19, 2013
10.5.2+	First Amendment to Second Amended and Restated Employment Agreement with Michael Jebsen dated June 18, 2015.	8-K	001-34600	10.2	June 19, 2015
10.6+	Description of Non-Employee Director Compensation, effective June 15, 2015.	10-Q	001-34600	10.1	September 9, 2015
10.7.1+	2016 Stock Incentive Plan.	10-Q	001-34600	10.1	August 9, 2016
10.7.2+	Amendment No. 1 to 2016 Stock Incentive Plan.	10-Q	001-34600	10.1	August 14, 2019
10.7.3+	Amendment No. 2 to 2016 Stock Incentive Plan.	10-Q	001-34600	10.1	August 16,

					2021
10.7.4+	Form of Option issued to Non-Employee Directors under 2016 Stock Incentive Plan.	10-Q	001-34600	10.2	August 14, 2018
10.7.5+	Form of Option issued to Employees and Contractors under 2016 Stock Incentive Plan.	10-Q	001-34600	10.3	August 14, 2018
10.7.6+	Form of Incentive Stock Option Agreement under 2016 Stock Incentive Plan.	10-Q	001-34600	10.4	August 14, 2018
10.8+	Employment Agreement with Anthony DiTonno dated June 1, 2018.	8-K	001-34600	10.1	June 5, 2018
10.9	Form of Securities Purchase Agreement, dated as of March 11, 2020, by and between Tenax Therapeutics, Inc. and the investor identified on the signature page thereto.	8-K	001-34600	10.1	March 13, 2020
10.10	Note, dated April 30, 2020, between Tenax Therapeutics, Inc. and First Horizon Bank.	10-Q	001-34600	10.1	May 15, 2020
10.11	Form of Securities Purchase Agreement for Class C Units and Class D Units, dated as of July 6, 2020, by and between Tenax Therapeutics, Inc. and the Investor.	8-K	001-34600	10.1	July 8, 2020
10.12	Form of Securities Purchase Agreement for Class E Units and Class F Units, dated as of July 6, 2020, by and between Tenax Therapeutics, Inc. and the Investor.	8-K	001-34600	10.2	July 8, 2020

10.13	Form of Registration Rights Agreement, dated as of July 6, 2020, by and between Tenax Therapeutics, Inc. and the Investor.	8-K	001-34600	10.3	July 8, 2020
10.14+	Executive Employment Agreement with Dr. Stuart Rich dated January 15, 2021.	8-K	001-34600	10.1	January 19, 2021
10.15	Securities Purchase Agreement for Unregistered Pre-Funded Warrant, dated as of July 6, 2021 by and between Tenax Therapeutics, Inc. and the Investor.	8-K	001-34600	10.1	July 8, 2021
10.16	Registration Rights Agreement, dated July 6, 2021, by and between Tenax Therapeutics, Inc. and the Investor.	8-K	001-34600	10.2	July 8, 2021
10.17+	Separation and General Release Agreement dated July 6, 2021, by and between Tenax Therapeutics, Inc. and Anthony A. DiTonno.	8-K	001-34600	10.3	July 8, 2021
10.18+	Executive Employment Agreement dated July 6, 2021, by and between Tenax Therapeutics, Inc. and Christopher T. Giordano.	8-K	001-34600	10.4	July 8, 2021
10.19+	Plan for Employee Inducement Stock Options adopted July 6, 2021 with Form of Stock Option Agreement.	8-K	001-34600	10.5	July 8, 2021
10.20 +*	Consulting Agreement dated October 14, 2021, by and between Tenax Therapeutics, Inc. and Danforth Advisors, LLC.	-	-	-	Filed herewith
10.21+	Separation and Release Agreement dated October 14, 2021, by and between Tenax Therapeutics, Inc. and Michael B. Jebsen.	-	-	-	Filed herewith
10.22+	Consulting Agreement dated October 14, 2021, by and between Tenax Therapeutics, Inc. and Michael B. Jebsen.	-	-	-	Filed herewith
21.1	List of Subsidiaries of Registrant.	-	-	-	Filed herewith
23.1	Consent of Independent Registered Public Accounting Firm.	-	-	-	Filed herewith
31.1	Certification of President and Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	-	-	-	Filed herewith
31.2	Certification of Interim Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	-	-	-	Filed herewith
32.1	Certification of the President and Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	-	-	-	Furnished herewith
32.2	Certification of the Interim Chief Financial Officer pursuant to 18 U.S.C. Section	-	-	-	Furnished

Table of Contents

101.INS	XBRL Instance Document.	-	-	-	Filed herewith
101.SCH	XBRL Taxonomy Extension Schema Document.	-	-	-	Filed herewith
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.	-	-	-	Filed herewith
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.	-	-	-	Filed herewith
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.	-	-	-	Filed herewith
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.	-	-	-	Filed herewith
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).	-	-	-	Filed herewith

+ Management contract or compensatory plan.

* Certain confidential portions and/or the schedules and attachments to this exhibit have been omitted from this filing pursuant to a confidential treatment request filed with the SEC, or Item 601(a)(5) or 601(b)(10) of Regulation S-K, as applicable. The Company agrees to furnish supplementally an unredacted copy of the exhibit to the SEC upon request.

ITEM 16—FORM 10-K SUMMARY

None.

Table of Contents**SIGNATURES**

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

TENAX THERAPEUTICS, INC.

Date: March 29, 2022

By: /s/ Eliot M. Lurier

Eliot M. Lurier
Interim Chief Financial Officer
(On behalf of the Registrant and as Principal
Financial and Accounting Officer)

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.

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Christopher T. Giordano</u> Christopher T. Giordano	President and Chief Executive Officer and Director (Principal Executive Officer)	March 29, 2022
<u>/s/ Eliot M. Lurier</u> Eliot M. Lurier	Interim Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 29, 2022
<u>/s/ Gerald Proehl</u> Gerald Proehl	Chairman of the Board and Director	March 29, 2022
<u>/s/ June Almenoff, MD</u> June Almenoff, MD	Director	March 29, 2022
<u>/s/ Steven Boyd</u>	Director	March 29, 2022

Steven Boyd

<u>/s/ Michael Davidson, MD</u> Michael Davidson, MD	Director	March 29, 2022
<u>/s/ Declan Doogan, MD</u> Declan Doogan, MD	Director	March 29, 2022
<u>/s/ Robyn M. Hunter</u> Robyn M. Hunter	Director	March 29, 2022
<u>/s/ Keith Maher, MD</u> Keith Maher, MD	Director	March 29, 2022
<u>/s/ Stuart Rich, MD</u> Stuart Rich, MD	Director	March 29, 2022

51

[Table of Contents](#)

TENAX THERAPEUTICS, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM (PCAOB ID: 00677)	F-2
CONSOLIDATED BALANCE SHEETS	F-3
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS	F-4
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY	F-5
CONSOLIDATED STATEMENTS OF CASH FLOWS	F-6
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS	F-7

F-1

[Table of Contents](#)

TENAX THERAPEUTICS, INC.

Report of Independent Registered Public Accounting Firm

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Tenax Therapeutics, Inc. and Subsidiaries (the "Company") as of December 31, 2021 and 2020, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows each of the years in the two-year period ended December 31, 2021, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2021, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note A and Note B to the consolidated financial statements, the Company has suffered recurring losses from operations and negative cash flows from operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans concerning these matters are described in Note A and Note B to the consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by

management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

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

<i>Description of Matter</i>	<p>Asset Acquisition</p> <p>As disclosed in Note E to the consolidated financial statements, the Company completed the acquisition PHPrecisionMed, Inc. (“PHPM”) in an all-stock transaction whereby PHPM merged into a wholly-owned subsidiary of the Company. The transaction involved a purchase of common stock, conversion of preferred stock to common stock, and a fair value calculation of the consideration. The accounting for the transaction was complex as it required judgement to determine whether the transaction constituted an asset acquisition and whether to capitalize or expense the acquired assets.</p>
<i>How We Addressed the Matter in Our Audit</i>	<p>Our audit procedures included the following:</p> <ul style="list-style-type: none"> · We obtained an understanding of the internal controls and processes in place over management’s process that related to the recording of the asset acquisition. · We obtained and read the underlying agreements. · We verified proper approval by the Board of Directors. · We tested management’s application of the relevant accounting guidance. · We evaluated the completeness and accuracy of the underlying data supporting the total consideration given in the acquisition. · We vouched inputs to agreements and recalculated where necessary to determine reasonableness of the purchase price allocation used by management.

<i>Description of Matter</i>	<p>Capital Raise Transaction Involving Equity Instruments</p> <p>As disclosed in Note F to the consolidated financial statements, the Company participated in a significant capital raise transaction during the year which involved the issuance of shares of the Company’s common stock, registered pre-funded warrants, unregistered pre-funded warrants, unregistered common stock warrants, and placement agent warrants to purchase shares of the Company’s common stock. The accounting for the transaction was complex and a valuation of the freestanding warrants was required, which involved estimation of the fair value, and evaluation of the appropriate classification of both the pre-funded warrants and common stock warrants in the consolidated financial statements.</p>
<i>How We Addressed the Matter in Our Audit</i>	<p>Our audit procedures included the following:</p> <ul style="list-style-type: none"> · We obtained an understanding of the internal controls and processes in place over management’s process for recording transactions involving equity instruments. · We obtained and read the underlying agreements. · We confirmed shares outstanding with the stock transfer agent as of December 31, 2021. · We verified proper approval of equity transactions by the Board of Directors. · We evaluated the Company’s selection of the valuation methodology and significant assumptions used by the Company and evaluated the completeness and accuracy of the underlying data supporting the significant assumptions. · Specifically, when assessing the key assumptions, we evaluated the appropriateness of the Company’s estimates of its credit risk, volatility, dividend yield, and the market risk free rate. · We tested management’s application of the relevant accounting guidance.

/s/ Cherry Bekaert LLP

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

Raleigh, North Carolina
March 29, 2022

[Table of Contents](#)

TENAX THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

	<u>December 31,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
ASSETS		
Current assets		
Cash and cash equivalents	\$ 5,583,922	\$ 6,250,241
Prepaid expenses	105,078	82,578
Marketable securities	-	462,687

Total current assets	5,689,000	6,795,506
Right of use asset	287,692	58,778
Property and equipment, net	7,108	5,972
Other assets	8,435	8,435
Total assets	<u>\$ 5,992,235</u>	<u>\$ 6,868,691</u>

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities		
Accounts payable	\$ 859,638	\$ 757,856
Accrued liabilities	704,340	1,240,616
Note payable	-	120,491
Total current liabilities	<u>1,563,978</u>	<u>2,118,963</u>
Long term liabilities		
Lease liability	183,589	-
Note payable	-	124,166
Total long term liabilities	<u>183,589</u>	<u>124,166</u>
Total liabilities	<u>1,747,567</u>	<u>2,243,129</u>
Commitments and contingencies; see Note G		
Stockholders' equity		
Preferred stock, undesignated, authorized 4,818,654 shares; See Note F		
Series A Preferred stock, par value \$.0001, issued 5,181,346 shares; outstanding 210, respectively	-	-
Common stock, par value \$.0001 per share; authorized 400,000,000 shares; issued and outstanding 25,206,914 and 12,619,369, respectively	2,521	1,262
Additional paid-in capital	282,736,332	250,644,197
Accumulated other comprehensive loss	-	(70)
Accumulated deficit	(278,494,185)	(246,019,827)
Total stockholders' equity	<u>4,244,668</u>	<u>4,625,562</u>
Total liabilities and stockholders' equity	<u>\$ 5,992,235</u>	<u>\$ 6,868,691</u>

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

F-3

[Table of Contents](#)

TENAX THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	<u>Year ended December 31,</u>	
	<u>2021</u>	<u>2020</u>
Operating expenses		
General and administrative	\$ 7,580,847	\$ 5,307,206
Research and development	25,147,394	4,560,724
Total operating expenses	<u>32,728,241</u>	<u>9,867,930</u>
Net operating loss	32,728,241	9,867,930
Interest expense	949	1,627
Other income, net	(254,832)	(18,166)
Net loss	<u>\$ 32,474,358</u>	<u>\$ 9,851,391</u>
Unrealized (gain)/loss on marketable securities	(70)	528
Total comprehensive loss	<u>\$ 32,474,288</u>	<u>\$ 9,851,919</u>
Net loss per share, basic and diluted	\$ (1.58)	\$ (0.95)
Weighted average number of common shares outstanding, basic and diluted	20,577,246	10,365,826

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

F-4

[Table of Contents](#)

TENAX THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

<u>Preferred Stock</u>	<u>Common Stock</u>	<u>Accumulated other</u>	<u>Total</u>
------------------------	---------------------	------------------------------	--------------

	Number of Shares	Amount	Number of Shares	Amount	Additional paid-in capital	comprehensive gain (loss)	Accumulated deficit	stockholders' equity
Balance at December 31, 2019	38,606	\$ 4	6,741,860	\$ 674	\$ 239,939,797	\$ 458	\$ (236,168,436)	\$ 3,772,497
Common stock and pre-funded warrants sold, net of offering costs			3,273,611	327	8,658,850			8,659,177
Common stock issued for services rendered			77,987	8	99,992			100,000
Common stock issued for convertible preferred stock	(38,396)	(4)	38,396	4				-
Exercise of pre-funded warrants			1,610,313	161				161
Exercise of warrants			877,202	88	1,692,912			1,693,000
Compensation on options issued					252,646			252,646
Unrealized loss on marketable securities						(528)		(528)
Net loss							(9,851,391)	(9,851,391)
Balance at December 31, 2020	210	\$ -	12,619,369	\$ 1,262	\$ 250,644,197	\$ (70)	\$ (246,019,827)	\$ 4,625,562
Common stock and preferred stock issued for asset acquisition	10,232	1	1,892,905	189	21,582,141			21,582,331
Common stock issued for convertible preferred stock	(10,232)	(1)	10,232,000	1,023	(1,022)			-
Pre-funded warrants sold, net of offering costs					9,192,624			9,192,624
Compensation on options issued					773,787			773,787
Exercise of warrants			457,038	46	544,605			544,651
Exercise of stock options			5,602	1				1
Unrealized loss on marketable securities						70		70
Net loss							(32,474,358)	(32,474,358)
Balance at December 31, 2021	210	\$ -	25,206,914	\$ 2,521	\$ 282,736,332	\$ -	\$ (278,494,185)	\$ 4,244,668

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

F-5

[Table of Contents](#)

TENAX THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,	
	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	\$ (32,474,358)	\$ (9,851,391)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	4,116	4,077
Interest on debt instrument	949	1,627
Amortization of right of use asset	104,866	110,671
Gain on debt settlement and extinguishment	(247,233)	-
Issuance and vesting of compensatory stock options and warrants	773,787	252,646
Issuance of common stock and preferred stock for asset acquisition	21,582,331	-
Issuance of common stock for services rendered	-	100,000
Amortization of premium on marketable securities	9,427	7,069
Changes in operating assets and liabilities		
Accounts receivable, prepaid expenses and other assets	(22,500)	698,374
Accounts payable and accrued liabilities	(544,589)	(535,550)
Long term portion of lease liability	(42,999)	(60,379)
Net cash used in operating activities	(10,856,203)	(9,272,856)
CASH FLOWS FROM INVESTING ACTIVITIES		
Sale of marketable securities	803,401	620,123

Purchase of marketable securities	(345,540)	(596,524)
Purchase of property and equipment	(5,252)	(3,490)
Net cash provided by investing activities	452,609	20,109
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common stock and pre-funded warrants, net of issuance costs	9,192,624	8,659,177
Proceeds from the exercise of warrants	544,651	1,693,161
Proceeds from the issuance of notes payable	-	244,657
Net cash provided by financing activities	9,737,275	10,596,995
Net change in cash and cash equivalents	(666,319)	1,344,248
Cash and cash equivalents, beginning of period	6,250,241	4,905,993
Cash and cash equivalents, end of period	\$ 5,583,922	\$ 6,250,241
Non-cash investing activity		
Addition to right of use asset obtained from new operating lease liability	\$ 333,779	\$ -

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

F-6

[Table of Contents](#)

TENAX THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE A—DESCRIPTION OF BUSINESS

Tenax Therapeutics, Inc. (the “Company”) was originally formed as a New Jersey corporation in 1967 under the name Rudmer, David & Associates, Inc., and subsequently changed its name to Synthetic Blood International, Inc. On June 17, 2008, the stockholders of Synthetic Blood International approved the Agreement and Plan of Merger dated April 28, 2008, between Synthetic Blood International and Oxygen Biotherapeutics, Inc., a Delaware corporation. Synthetic Blood International formed Oxygen Biotherapeutics on April 17, 2008 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 into one share of Oxygen Biotherapeutics common stock. On September 19, 2014, the Company changed its name to Tenax Therapeutics, Inc.

On November 13, 2013, the Company, through its wholly-owned subsidiary, Life Newco, Inc., a Delaware corporation, acquired 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. Among these assets was a license with Orion Corporation, a global healthcare company incorporated under the laws of Finland (“Orion”) for the 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. On October 9, 2020 and January 25, 2022, the Company amended the license (as amended, the “License”), to include two new oral product dose forms containing levosimendan, in capsule and solid dosage form, and a subcutaneously administered product containing levosimendan, subject to certain limitations. Pursuant to the License, the Company and Orion will agree to a new trademark when commercializing levosimendan in either of these forms. The term of the License has been extended until 10 years after the launch of the Product in the Territory, provided that the License will continue after the end of the term in each country in the Territory until the expiration of Orion’s patent rights in the Product in such country. In the event that no regulatory approval for the Product has been granted in the United States on or before September 20, 2030, however, either party will have the right to terminate the License with immediate effect. The Company intends to conduct an upcoming Phase 3 study in pulmonary hypertension patients utilizing one of these oral formulations. See “Note 8 - Commitments and Contingencies” below for a further discussion of the License.

On January 15, 2021, the Company, Life Newco II, Inc., a Delaware corporation and a wholly-owned, subsidiary of the Company (“Life Newco II”), PHPrecisionMed Inc., a Delaware corporation (“PHPM”) and Dr. Stuart Rich, solely in his capacity as holders’ representative (the “Representative”), entered into an Agreement and Plan of Merger (the “Merger Agreement”) pursuant to which the Company acquired all of the equity of PHPM, a company developing pharmaceutical products containing imatinib for the treatment of PAH (“PAH”) in the United States and the rest of the world. Under the terms of the Merger Agreement, Life Newco II merged with and into PHPM, with PHPM surviving as a wholly-owned subsidiary of the Company (the “Merger”). See “Note 7 - Merger” below for a further discussion of the Merger.

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 \$278,494,185 and \$246,019,827 on December 31, 2021 and 2020, respectively, and used cash in operations of \$10,856,203 and \$9,272,856 during the years ended December 31, 2021 and 2020, 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, 2021 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.

[Table of Contents](#)**NOTE B—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES*****Use of Estimates***

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

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

Principles of Consolidation

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

Cash and Cash Equivalents

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

Cash Concentration Risk

The Federal Deposit Insurance Corporation (the "FDIC") insurance limits are \$250,000 per depositor per insured bank. The Company had cash balances of \$5,127,956 and \$5,870,477 uninsured by the FDIC as of December 31, 2021 and 2020, 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 \$5,689,000 and \$6,795,506 and working capital of \$4,125,022 and \$4,676,543 as of December 31, 2021 and 2020, respectively.

The Company's cash resources were approximately \$5.6 million as of December 31, 2021, compared to cash resources, including the fair value of the Company's available for sale marketable securities of approximately \$6.7 million as of December 31, 2020.

The Company expects to continue to incur expenses related to development of imatinib for PAH and levosimendan for pulmonary hypertension and other potential indications, as well as identifying and developing other potential product candidates. Based on its resources on December 31, 2021, the Company believes that it has sufficient capital to fund its planned operations through the second quarter of calendar year 2022. 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 provide assurance 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.

[Table of Contents](#)

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

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

Deferred financing costs

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

Derivative financial instruments

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

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

Preclinical Study and Clinical Accruals

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

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

Property and Equipment, Net

Property and equipment are stated at cost, subject to adjustments for impairment, less accumulated depreciation and amortization. Depreciation and amortization are computed using the straight-line method with estimated useful lives of three to seven years.

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

[Table of Contents](#)

Research and Development Costs

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

Income Taxes

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

Stock-Based Compensation

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

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

Loss Per Share

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

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

	Year ended December 31,	
	2021	2020
Warrants to purchase common stock	20,928,767	16,599,079

Pre-funded warrants to purchase common stock	10,033,274	5,260,005
Options to purchase common stock	1,299,567	451,148
Convertible preferred shares outstanding	210	210

[Table of Contents](#)

Operating Leases

The Company determines if an arrangement includes a lease at inception. Operating leases are included in operating lease right-of-use assets, other current liabilities, and long-term lease liabilities in the Company's consolidated balance sheet as of December 31, 2021. Right-of-use assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the net present value of lease payments, the Company uses the incremental borrowing rate based on the information available at the lease commencement date. The operating lease right-of-use assets also include any lease payments made and exclude lease incentives. The Company's leases may include options to extend or terminate the lease which are included in the lease term when it is reasonably certain that the Company will exercise any such option. Lease expense is recognized on a straight-line basis over the expected lease term. The Company has elected to account for leases with an initial term of 12 months or less similar to previous guidance for operating leases, under which the Company will recognize those lease payments in the consolidated statements of operations and comprehensive loss on a straight-line basis over the lease term.

Recent Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board ("FASB") issued accounting standards update ("ASU"), ASU-2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes, intended to simplify accounting for income taxes. It removes certain exceptions to the general principles in Topic 740, Income Taxes and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020 and early adoption is permitted. The Company adopted this standard on January 1, 2021. The Company's adoption of the new guidance did not have a material impact on its consolidated financial statements.

In June 2016, the FASB issued an accounting standard, ASU-2016-13, Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, that amends how credit losses are measured and reported for certain financial instruments that are not accounted for at fair value through net income. This standard requires that credit losses be presented as an allowance rather than as a write-down for available-for-sale debt securities and will be effective for interim and annual reporting periods beginning January 1, 2023, with early adoption permitted. A modified retrospective approach is to be used for certain parts of this guidance, while other parts of the guidance are to be applied using a prospective approach. The Company does not believe the adoption of this standard will have a material impact on its consolidated financial statements and related disclosures.

Fair Value

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

[Table of Contents](#)

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 in the consolidated statements of comprehensive loss and are determined using the specific identification method with transactions recorded on a settlement date basis. 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. As of December 31, 2021, the Company held no investments in marketable securities.

The following tables summarize information regarding assets and liabilities measured at fair value on a recurring basis as of December 31, 2021 and December 31, 2020:

	Balance as of December 31, 2021	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)
Cash and cash equivalents	\$ 5,583,922	\$ 5,583,922	\$ -	\$ -

	Balance as of December 31, 2020	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)
Cash and cash equivalents	\$ 6,250,241	\$ 6,250,241	\$ -	\$ -
Marketable securities	\$ 462,687	\$ -	\$ 462,687	\$ -

There were no significant transfers between levels in the year ended December 31, 2021.

NOTE C—BALANCE SHEET COMPONENTS

Property and equipment, net

Property and equipment primarily consist of office furniture and fixtures.

Depreciation and amortization expense were \$4,116 and \$4,077 for the years ended December 31, 2021 and 2020, respectively.

Accrued liabilities

Accrued liabilities consist of the following:

	December 31, 2021	December 31, 2020
Employee related	\$ 597,148	\$ 860,629
Lease liability	107,192	60,379
Operating costs	-	319,608
	<u>\$ 704,340</u>	<u>\$ 1,240,616</u>

[Table of Contents](#)

NOTE D—NOTE PAYABLE

Payroll Protection Program Loan

On April 30, 2020, the Company received a loan pursuant to the Paycheck Protection Program (the “PPP Loan”) under the Coronavirus Aid, Relief, and Economic Security Act, as administered by the U.S. Small Business Administration (“SBA”). The PPP Loan in the principal amount of \$244,657 was disbursed by First Horizon Bank (the “Lender”) pursuant to a promissory note issued by the Company.

On May 28, 2021, the Company received notice from the SBA that the SBA had remitted \$244,657 in principal and \$2,576 in interest to the Lender in full forgiveness of the Company’s PPP Loan pursuant to the Company’s application to the SBA for forgiveness of the PPP Loan. The total amount was recorded as other income in our consolidated statement of comprehensive loss.

NOTE E—MERGER

On January 15, 2021, the Company, Life Newco II, PHPM, and Dr. Rich, as Representative, entered into the Merger Agreement, pursuant to which, the Company acquired all of the equity of PHPM. Under the terms of the Merger Agreement, Life Newco II merged with and into PHPM, with PHPM surviving as a wholly-owned subsidiary of the Company.

As consideration for the Merger, the stockholders of PHPM received (i) 1,892,905 shares of Company common stock, and (ii) 10,232 shares of the Company’s Series B convertible preferred stock (“Series B Stock”), which were convertible into up to an aggregate of 10,232,000 shares of common stock (collectively, the “Merger Consideration”). To satisfy the Company’s post-closing rights to closing adjustments and indemnification by PHPM and the

former stockholders of PHPM pursuant to the Merger Agreement, 1,212,492 shares of common stock issuable upon conversion of the Series B Stock, which represented approximately 10% of the Merger Consideration, are subject to holdback restrictions for 24 months following closing of the transaction (the “Holdback Shares”).

Pursuant to the Merger Agreement, the Company’s Board of Directors, at its annual meeting of stockholders held on June 10, 2021, recommended to the Company’s stockholders, and the stockholders approved, the conversion of the Series B Stock pursuant to the Certificate of Designation. As a result, each share of Series B Stock automatically converted into (i) 881.5 shares of common stock, and (ii) the right to receive up to 118.5 Holdback Shares, to be delivered 24 months after the date of issuance of the Series B Stock, subject to reduction for indemnification claims.

Pursuant to the terms of the Merger Agreement, on February 25, 2021, the Board appointed three directors designated by the PHPM representative to serve on the Board, Dr. Rich, the co-founder and Chief Executive Officer and a stockholder of PHPM, and Drs. Michael Davidson and Declan Doogan. In connection with the closing of the Merger, Dr. Rich also was appointed Chief Medical Officer of the Company.

The Company evaluated this acquisition in accordance with ASC 805, Business Combinations, to determine whether the assets and operations of PHPM met the definition of a business. Included in the in-process research and development project is the historical know-how, formula protocols, designs, and procedures expected to be needed to complete the related phase of testing. The Company concluded that the in-process research and development project is an identifiable intangible asset that would be accounted for as a single asset in a business combination. The Company also qualitatively concluded that there is no fair value associated with the clinical research organization contract and the clinical manufacturing organization contract because the services are being provided at market rates and could be provided by multiple vendors in the marketplace. Therefore, all of the consideration in the transaction was allocated to the in-process research and development project. As such, the Company concluded that substantially all of the fair value of the gross assets acquired was concentrated in the single in-process research and development asset and the set was not a business.

The Company is planning to use the acquired asset to further its clinical development in an upcoming phase 3 clinical trial for the treatment of patients with PAH. Although the acquired asset may have utility in other patient populations, future development decisions for the acquired asset will be contingent upon the results of the contemplated phase 3 program for PAH. As such, the acquired asset does not have an alternative future use at the acquisition date. In accordance with ASC 730, Research and Development, the Company concluded the entire Purchase Price for the asset acquisition was an expense on the acquisition date.

[Table of Contents](#)

The consideration transferred, assets acquired and liabilities assumed were recognized as follows:

Fair value of shares of Common Stock issued	\$ 3,369,371
Fair Value of Series B Convertible Preferred Stock issued at closing	18,212,960
Total fair value of consideration transferred	<u>\$ 21,582,331</u>
Tangible assets acquired	\$ -
Accounts payable assumed	(150,000)
Total identifiable net assets	(150,000)
IPR&D expense recognized	21,732,331
Total fair value of consideration	<u>\$ 21,582,331</u>

NOTE F—STOCKHOLDERS’ EQUITY

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

Series B Stock

As further discussed in “Note E—Merger” above, on January 15, 2021 the Company issued 10,232 shares of its Series B Stock, which were convertible into an aggregate of 10,232,000 shares of common stock, to the stockholders of PHPM as partial consideration for the Merger with PHPM pursuant to the Merger Agreement.

The rights, preferences and privileges of the Series B Stock are set forth in the Certificate of Designation. Following receipt of the approval of the stockholders of the Company on June 10, 2021 for the Conversion, each share of Series B Stock automatically converted into (i) 881.5 shares of common stock and (ii) the right to receive up to 118.5 Holdback Shares, to be delivered 24 months after the date of issuance of the Series B Stock, subject to reduction for indemnification claims.

As of December 31, 2021, there were no shares of Series B Stock outstanding.

Series A Stock

On December 11, 2018, the Company closed its underwritten offering of 5,181,346 units for net proceeds of approximately \$9.0 million (the “2018 Offering”). Each unit consisted of (i) one share of the Company’s Series A convertible preferred stock, par value \$0.0001 per share (the “Series A Stock”), (ii) a two-year warrant to purchase one share of common stock at an exercise price of \$1.93, and (iii) a five-year warrant to purchase one share of common stock at an exercise price of \$1.93. In accordance with ASC 480, Distinguishing Liabilities from Equity, the estimated fair value of \$1,800,016 for the beneficial conversion feature was recognized as a deemed dividend on the Series A Stock during the year ended December 31, 2020.

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

Conversion Subject to the ownership limitations described below, the Series A Stock is convertible at any time at the option of the holder into shares

of the Company's common stock at a conversion ratio determined by dividing the stated value of the Series A Stock by a conversion price of \$1.93 per share. The conversion price is subject to adjustment in the case of stock splits, stock dividends, combinations of shares and similar recapitalization transactions.

The Company will not affect any conversion of the Series A Stock, nor shall a holder convert its shares of Series A Stock, to the extent that such conversion would cause the holder to have acquired, through conversion of the Series A Stock or otherwise, beneficial ownership of a number shares of common stock in excess of 4.99% (or, at the election of the holder prior to the issuance of any shares of Series A Stock, 9.99%) of the common stock outstanding after giving effect to such exercise.

[Table of Contents](#)

Dividends	In the event the Company pays dividends on its shares of common stock, the holders of the Series A Stock will be entitled to receive dividends on shares of Series A Stock equal, on an as-if-converted basis, to and in the same form as paid on the common stock. No other dividends will be paid on the shares of Series A Stock.
Liquidation	Upon any liquidation, dissolution or winding up of the Company after payment or provision for payment of debts and other liabilities of the Company, the holders of Series A Stock shall be entitled to be paid out of the assets of the Company available for distribution to its stockholders an amount equal to the amount that a holder of common stock would receive if the Series A Stock were fully converted to common stock, which amounts will be paid pari passu with all holders of common stock.
Voting rights	Shares of Series A Stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the then outstanding Series A Stock will be required to amend the terms of the Series A Stock or to take other action that adversely affects the rights of the holders of Series A Stock.

As of December 31, 2021, there were 210 shares of Series A Stock outstanding.

Common Stock and Pre-Funded Warrants

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, 2021, and December 31, 2020, there were 25,206,914 and 12,619,369 shares of common stock issued and outstanding, respectively. As of December 31, 2021, there were 10,033,274 pre-funded warrants outstanding.

July 2021 Private Placement (the "July 2021 Offering")

On July 6, 2021, the Company entered into a securities purchase agreement with an institutional investor pursuant to which the Company agreed to sell and issue to the investor 4,773,269 Units in a private placement at a purchase price of \$2.095 per unit. Each Unit consisted of (i) one unregistered pre-funded warrant to purchase one share of common stock and (ii) one unregistered warrant to purchase one share of common stock (together with the pre-funded warrants, the "2021 Warrants"). In the aggregate, 9,546,538 shares of the Company's common stock are underlying the 2021 Warrants. The net proceeds from the private placement, after deducting placement agent fees and other direct offering expenses, were approximately \$9.2 million. The fair value allocated to the pre-funded warrants and warrants was \$5.5 million and \$4.5 million, respectively.

Also, on July 6, 2021 and in connection with the July 2021 Offering, the Company entered into a registration rights agreement (the "July 2021 Registration Rights Agreement") with the investor, pursuant to which the Company agreed to register for resale the shares of common stock issuable upon exercise of the 2021 Warrants within 120 days following the effective date of the July 2021 Registration Rights Agreement. Pursuant to the July 2021 Registration Rights Agreement, on August 20, 2021, the Company filed a resale registration statement on Form S-3, which went effective on September 1, 2021.

July 2020 Registered Direct Offering and Private Placement (the "July 2020 Offering")

On July 6, 2020, the Company completed a registered direct offering with an investor for the issuance and sale of 2,523,611 shares of its common stock at a purchase price of \$1.0278 per share and pre-funded warrants to purchase up to 652,313 shares of its common stock, at a purchase price of \$1.0277 per pre-funded warrant (which represents the per share offering price for the common stock less \$0.0001, the exercise price of each pre-funded warrant). The Company issued in a concurrent private placement unregistered pre-funded warrants to purchase up to 4,607,692 shares of common stock at the same purchase price as the registered pre-funded warrants, and unregistered common stock warrants to purchase up to 7,783,616 shares of common stock for aggregate gross proceeds of approximately \$8.0 million, priced at-the-market under Nasdaq rules. The unregistered warrants have an exercise price of \$0.903 per share and exercise period commencing immediately upon the issuance date and a term of five and one-half years. The net proceeds from the offerings, after deducting placement agent fees and other direct offering expenses were approximately \$6.5 million. The fair value allocated to the common stock, pre-funded warrants and warrants was \$1.5 million, \$3.0 million and \$3.5 million, respectively.

[Table of Contents](#)

Also, on July 6, 2020 and in connection with the concurrent private placement, the Company entered into a registration rights agreement (the "July 2020 Registration Rights Agreement") with the investor, pursuant to which the Company agreed to register for resale the shares of common stock issuable upon exercise of the unregistered pre-funded warrants and the unregistered warrants within 120 days following the date of the Registration Rights Agreement. Pursuant to the Registration Rights Agreement, on August 20, 2020, the Company filed a resale registration statement on Form S-3, which went effective on September 30, 2020.

March 2020 Registered Direct Offering and Private Placement (the "March 2020 Offering")

On March 13, 2020, the Company completed a registered direct offering to an investor for the issuance and sale of 750,000 shares of its common stock at a purchase price of \$1.1651 per share and pre-funded warrants to purchase up to 1,610,313 shares of its common stock, at a purchase price of \$1.1650 per pre-funded warrant (which represents the per share offering price for the common stock less \$0.0001, the exercise price of each pre-funded warrant), for gross proceeds of approximately \$2.75 million, priced at-the-market under Nasdaq rules. Additionally, in a concurrent private placement, the Company issued to the investor unregistered warrants to purchase up to 2,360,313 shares of its common stock. The unregistered warrants have an exercise price of \$1.04 per share and exercise period commencing immediately upon the issuance date and a term of five and one-half years. The net proceeds from the offerings, after deducting placement agent fees and other direct offering expenses were approximately \$2.1 million. The fair value allocated to the common stock, pre-funded warrants and warrants was \$0.5 million, \$1.1 million and \$1.1 million, respectively.

Warrants

During the year ended December 31, 2021, the Company received approximately \$545,000 and issued 282,202 shares of common stock upon the exercise of previously outstanding warrants issued in connection with the Company's December 2018 Offering.

During the year ended December 31, 2021, the Company issued 519,374 shares of common stock upon the cashless exercise of previously outstanding placement agent warrants issued in connection with the Company's July 2020 and March 2020 Offerings.

As of December 31, 2021, the Company has 20,928,767 warrants outstanding. The following table summarizes the Company's warrant activity for the year ended December 31, 2020 and 2021:

	Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2019	10,519,945	\$ 1.94
Issued	11,310,480	0.98
Exercised	(877,202)	1.93
Expired	(4,354,144)	1.93
Outstanding at December 31, 2020	16,599,079	\$ 1.29
Issued	5,131,264	2.00
Exercised	(801,576)	1.54
Outstanding at December 31, 2021	20,928,767	\$ 1.45

July 2021 Warrants

As described above, as a part of the July 2021 Offering, the Company issued unregistered warrants to purchase 4,773,269 shares of its common stock at an exercise price of \$1.97 per share and contractual term of five and one-half years. The unregistered warrants were offered in a private placement under Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act") and Regulation D promulgated thereunder. In accordance with ASC 480, these warrants are classified as equity and their relative fair value of approximately \$4.5 million was recognized as additional paid in capital. 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.

[Table of Contents](#)

July 2020 Warrants

As described above, as a part of the July 2020 offering, the Company issued unregistered warrants to purchase 7,783,616 shares of its common stock at an exercise price of \$0.903 per share and contractual term of five and one-half years. The unregistered warrants were offered in a private placement under Section 4(a)(2) of the Securities Act, and Regulation D promulgated thereunder. In accordance with ASC 815, Derivatives and Hedging, these warrants are classified as equity and their relative fair value of approximately \$3.5 million was recognized as additional paid in capital. 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.

March 2020 Warrants

As described above, as part of the March 2020 Offering, the Company issued unregistered warrants to purchase 2,360,313 shares of its common stock at an exercise price of \$1.04 per share and contractual term of five and one-half years. The unregistered warrants were offered in a private placement under Section 4(a)(2) of the Securities Act, and Regulation D promulgated thereunder. In accordance with ASC 815, Derivatives and Hedging, these warrants are classified as equity and their relative fair value of approximately \$1.1 million was recognized as additional paid in capital. 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.

Warrants Issued for Services

In connection with the July 2021 Offering described above, the Company issued designees of the placement agent warrants to purchase 357,995 shares of common stock at an exercise price of \$2.46 and a contractual term of five years. In accordance with ASC 815, Derivatives and Hedging, these warrants are classified as equity and its estimated fair value of \$558,472 was recognized as additional paid in capital. The estimated fair value is determined using the Black-Scholes Option Pricing Model which is based on the value of the underlying common stock at the valuation measurement date, the remaining contractual term of the warrant, risk-free interest rates, expected dividends and expected volatility of the price of the underlying common stock.

In connection with the July 2020 Offering described above, the Company issued designees of the placement agent warrants to purchase 583,771 shares of common stock at an exercise price of \$1.2848 and a contractual term of five years. In accordance with ASC 815, these warrants are classified as equity and its estimated fair value of \$399,445 was recognized as additional paid in capital. Additionally, the Company issued to its previous underwriter a warrant to purchase 311,345 shares of common stock at an exercise price of \$1.2848 per share and contractual term of five years. In accordance with ASC 815, this warrant is classified as equity and its estimated fair value of \$213,038 was recognized as additional paid in capital. The estimated fair value is determined using the Black-Scholes Option Pricing Model which is based on the value of the underlying common stock at the valuation measurement date, the remaining contractual term of the warrant, risk-free interest rates, expected dividends and expected volatility of the price of the underlying common stock.

In connection with the March 2020 Offering described above, the Company issued designees of the placement agent warrants to purchase 177,023 shares of common stock at an exercise price of \$1.4564 and a contractual term of five years. In accordance with ASC 815, these warrants are classified as equity and its estimated fair value of \$66,201 was recognized as additional paid in capital. Additionally, the Company issued to its previous underwriter a warrant to purchase 94,413 shares of common stock at an exercise price of \$1.4564 per share and contractual term of five years. In accordance with ASC 815, this warrant is classified as equity and its estimated fair value of \$35,308 was recognized as additional paid in capital. The estimated fair value is determined using the Black-Scholes Option Pricing Model which is based on the value of the underlying common stock at the valuation measurement date, the remaining contractual term of the warrant, risk-free interest rates, expected dividends and expected volatility of the price of the underlying common stock.

Stock Options

The following table summarizes all options outstanding as of December 31, 2021:

Exercise Price	Options Outstanding at December 31, 2021			Options Exercisable and Vested at December 31, 2021		
	Number of Options	Weighted Average Remaining Contractual Life (Years)		Number of Options	Weighted Average Exercise Price	
\$ 0.66 to \$1.85	539,500	8.1		237,171	\$ 1.43	
\$ 1.97 to \$11.20	135,750	4.7		37,000	\$ 7.60	
\$ 41.40 to \$63.20	19,500	4.7		19,500	\$ 46.54	
\$ 68.40 to \$748.00	4,817	2.4		4,817	\$ 103.99	
	<u>699,567</u>	<u>7.3</u>		<u>298,488</u>	<u>\$ 6.80</u>	

The following table summarizes options outstanding that have vested and are expected to vest based on options outstanding as of December 31, 2021:

	Number of Option Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value ⁽¹⁾	Weighted Average Remaining Contractual Life (Years)
Vested	296,488	\$ 6.80	\$ 190	7.4
Vested and expected to vest	655,451	\$ 4.13	\$ 190	7.3

(1) Amount represents the difference between the exercise price and \$1.04, the closing price of Tenax Therapeutics' stock on December 31, 2021, as reported on the Nasdaq Capital Market, for all in-the-money options outstanding.

2016 Stock Incentive Plan

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

On June 10, 2021, the Company's stockholders approved an amendment to the 2016 Plan which increased the number of shares of common stock authorized for issuance under the 2016 Plan to a total of 1.5 million shares, up from 750,000 previously authorized.

[Table of Contents](#)

The following table summarizes the shares available for grant under the Plan for the years ended December 31, 2021 and 2020:

	Shares Available for Grant
Balances, at December 31, 2019	697,500
Options granted	(341,000)
Balances, at December 31, 2020	356,500
Additional shares reserved	750,000
Options granted	(378,750)
Options cancelled/forfeited	92,000
Balances, at December 31, 2021	<u>819,750</u>

2016 Plan Stock Options

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

The following table summarizes the outstanding stock options under the 2016 Plan for the years ended December 31, 2021 and 2020:

	Outstanding Options		Aggregate Intrinsic Value
	Number of Shares	Weighted Average Exercise Price	
Balances at December 31, 2019	52,500	\$ 5.89	
Options granted	341,000	\$ 1.18	
Balances at December 31, 2020	393,500	\$ 1.81	
Options granted	378,750	\$ 1.88	
Options exercised	(17,000)	\$ 1.18	
Options cancelled/forfeited	(92,000)	\$ 1.59	
Balances at December 31, 2021	663,250	\$ 1.90	\$ 190 ⁽¹⁾

(1) Amount represents the difference between the exercise price and \$1.04, the closing price of Tenax Therapeutics’ stock on December 31, 2021, as reported on the Nasdaq Capital Market, for all in-the-money options outstanding.

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

The Company used the following assumptions to estimate the fair value of options granted under the 2016 Plan for the years ended December 31, 2021 and 2020:

	For the year ended December 31,	
	2021	2020
Risk-free interest rate (weighted average)	0.72%	1.02%
Expected volatility (weighted average)	101.60%	97.63%
Expected term (in years)	6.7	7
Expected dividend yield	0.00%	0.00%

[Table of Contents](#)

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

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

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

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

Forfeitures As stock-based compensation expense recognized in the statement of operations for the years ended December 31, 2021 and 2020 is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on the Company’s historical experience.

The weighted-average grant-date fair value of options granted during the years ended December 31, 2021 and 2020 was \$1.53 and \$0.95, respectively.

The Company recorded compensation expense for these stock options grants of \$391,801 and \$218,148 for the years ended December 31, 2021 and 2020, respectively.

As of December 31, 2021, there were unrecognized compensation costs of approximately \$167,000 related to non-vested stock option awards under the 2016 Plan that will be recognized on a straight-line basis over the weighted average remaining vesting period of 0.82 years.

1999 Stock Plan

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

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

[Table of Contents](#)

The following table summarizes the outstanding stock options under the 1999 Plan for the years ended December 31, 2021 and 2020:

	Outstanding Options		Aggregate Intrinsic Value
	Number of Shares	Weighted Average Exercise Price	
Balances at December 31, 2019	191,706	\$ 93.40	
Options cancelled	(134,058)	\$ 113.64	
Balances at December 31, 2020	57,648	\$ 46.34	
Options cancelled	(21,331)	\$ 53.28	
Balances at December 31, 2021	<u>36,317</u>	<u>\$ 42.26</u>	\$ (1)

- (1) Amount represents the difference between the exercise price and \$1.04, the closing price of Tenax Therapeutics' stock on December 31, 2021, 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 recorded compensation expense for these stock options grants of \$1,290 and \$34,498 for the years ended December 31, 2021 and 2020, respectively.

As of December 31, 2021, there were no unrecognized compensation costs related to non-vested stock option awards under the 1999 Plan.

In connection with the retirement of the Company's former Chief Executive Officer ("CEO"), effective July 13, 2021 (the "Modification Date"), the Company modified the terms of the former CEO's outstanding stock awards to: (1) accelerate the 152,500 unvested shares underlying his outstanding stock awards immediately as of the Modification Date and (2) extend the period during which his outstanding stock awards for an aggregate of 218,706 shares may be exercised through the earlier of the stock award's original termination date or the five-year anniversary of the Modification Date.

The Company determined that the extension of the period during which the vested shares may be exercised was a Type 1 modification pursuant to ASC 718, Compensation-Stock Compensation. However, acceleration of vesting and extension of the exercise period for the remaining Stock Awards was a Type 3 modification pursuant to ASC 718 because absent the modification terms, those Stock Awards would have been forfeited as of the former CEO's retirement date.

On the Modification Date, the Company recognized approximately \$187,000 of compensation expense, which is included in General and administrative expense for the year ended December 31, 2021, with respect to these modifications.

Inducement Stock Options

The Company granted two employment inducement stock option awards, one for 100,000 shares of common stock and the other for 250,000 shares of common stock, to its new CEO on July 6, 2021.

The employment inducement stock option for 100,000 shares of common stock was awarded in accordance with the employment inducement award exemption provided by Nasdaq listing rule 5635(c)(4) and was therefore not awarded under the Company's stockholder approved equity plan. The option award will vest as follows: 50% upon initiation of a Phase 3 trial for levosimendan by June 30, 2022; and 50% upon initiation of a Phase 3 trial for imatinib by June 30, 2022. The options have a 10-year term and an exercise price of \$1.97 per share, the July 6, 2021 closing price of our common stock. As of December 31, 2021, none of the vesting milestones have been achieved. The estimated fair value of this inducement stock option award was \$178,291 using a Black-Scholes option pricing model based on market prices and the following assumptions at the date of inducement option grant: risk-free interest rate of 1.37%, dividend yield of 0%, volatility factor for our common stock of 103.50% and an expected life of 10 years.

[Table of Contents](#)

The employment inducement stock option award for 250,000 shares of common stock also was awarded in accordance with the employment inducement award exemption provided by Nasdaq listing rule 5635(c)(4) and was therefore not awarded under the Company's stockholder approved equity plan. The option award will vest as follows: 25% on the one-year anniversary of the CEO's employment start date and an additional 25% on each of the following three anniversaries of the CEO's employment start date, subject to continued employment. The options have a 10-year term and an exercise price of \$1.97 per share, the July 6, 2021 closing price of our common stock.

The estimated fair value of this inducement stock option award was \$403,180 using a Black-Scholes option pricing model based on market prices and the following assumptions at the date of inducement option grant: risk-free interest rate of 1.13%, dividend yield of 0%, volatility factor for our common stock of 99.36% and an expected life of 7 years.

The Company granted an employment inducement stock option award for 250,000 shares of common stock to our chief medical officer on January 15, 2021. This employment inducement stock option was awarded in accordance with the employment inducement award exemption provided by Nasdaq listing rule 5635(c)(4) and was therefore not awarded under the Company's stockholder approved equity plan. The option award will vest as follows: 25% upon initiation of a Phase 3 trial; 25% upon database lock; 25% upon acceptance for review of an investigational NDA; and 25% upon approval. The options have a 10-year term and an exercise price of \$1.78 per share, the January 15, 2021 closing price of our common stock. As of December 31, 2021, none of the vesting milestones have been achieved. The estimated fair value of the inducement stock option award granted was \$402,789 using a Black-Scholes option pricing model based on market prices and the following assumptions at the date of inducement option grant: risk-free interest rate of 1.11%, dividend yield of 0%, volatility factor for our common stock of 103.94% and an expected life of 10 years.

Inducement stock option compensation expense totaled \$194,143 for the year ended December 31, 2021. As of December 31, 2021, there was \$778,658 of remaining unrecognized compensation expense related to these inducement stock options.

NOTE G—COMMITMENTS AND CONTINGENCIES

Operating Leases

As described above in "NOTE B", the Company adopted ASC 842 as of January 1, 2019. Prior period amounts have not been adjusted and continue to be reported in accordance with the Company's historic accounting under ASC 840.

In January 2011, the Company entered into a lease with Concourse Associates, LLC for its headquarters in Morrisville, North Carolina (the "Lease"). The Lease was amended in August 2015 to extend the term for the 5,954 square foot rental. The current term began on March 1, 2016 and continued for 64 months to June 30, 2021. Rent payments began on July 1, 2016, following the conclusion of a four-month rent abatement period. The Company has two five-year options to extend the Lease and a one-time option to terminate the Lease thirty-six months after the commencement of the initial term if no additional space became available. On April 2, 2021, the Company negotiated a 3-year extension to the existing lease term, commencing July 1, 2021 (the "Commencement Date"). Beginning on the Commencement Date, the annual base rent was increased to \$125,034 and will increase 2.5% annually for lease years 2 and 3.

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

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

	December 31, 2021	December 31, 2020
Current portion included in accrued liabilities	\$ 107,192	\$ 60,379
Long term lease liability	183,589	-
	<u>\$ 290,781</u>	<u>\$ 60,379</u>

F-21

[Table of Contents](#)

As of December 31, 2021, the maturities of our operating lease liabilities were as follows:

Year ending December 31,	
2022	\$ 126,612
2023	129,797
2024	<u>65,702</u>
Total lease payments	<u>\$ 322,111</u>
Less: Imputed interest	<u>(31,330)</u>
Operating lease liability	<u>\$ 290,781</u>

Simdax license agreement

On November 13, 2013, the Company acquired, through its wholly-owned subsidiary, Life Newco, that certain License Agreement, dated September 20, 2013, as amended on October 9, 2020 and January 25, 2022, by and between Phyxius and Orion (as amended, the "License"), and that certain Side Letter, dated October 15, 2013 by and between Phyxius and Orion. The License grants the Company an exclusive, sublicenseable right to develop and commercialize pharmaceutical products containing levosimendan in the United States and Canada (the "Territory") and, pursuant to the October 9, 2020 amendment, also includes two product dose forms containing levosimendan, in capsule and solid dosage form, and a subcutaneously administered product containing levosimendan, subject to specified limitations in the License (together, the "Product"). Pursuant to the License, the Company and Orion will agree to a new trademark when commercializing levosimendan in either of these forms.

The License also grants the Company a right of first refusal to commercialize new developments of the Product, including developments as to the formulation, presentation, means of delivery, route of administration, dosage or indication (i.e., line extension products).

Orion's ongoing role under the License includes sublicense approval, serving as the sole source of manufacture, holding a first right to enforce intellectual property rights in the Territory, and certain regulatory participation rights. Orion must notify the Company before the end of 2024 if it chooses not to exercise its right to supply oral formulations of levosimendan to the Company for commercialization in the Territory. 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 term of the License extends until 10 years after the launch of the Product in the Territory, provided that the License will continue after the end of the term in each country in the Territory until the expiration of Orion's patent rights in the Product in such country. In the event that no regulatory approval for the Product has been granted in the United States on or before September 20, 2030, however, either party will have the right to terminate the License with immediate effect.

Pursuant to the terms of the License, on November 13, 2013, the Company paid to Orion a non-refundable up-front payment in the amount of \$1.0 million. The License also includes the following development milestones for which the Company must make non-refundable payments to Orion no later than 28 days after the occurrence of the applicable milestone event: (1) \$2.0 million upon the grant of United States Food and Drug Administration approval, including all registrations, licenses, authorizations and necessary approvals, to develop and/or commercialize the Product in the United States; and (2) \$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 to up to \$13.0 million, contingent upon achievement of certain cumulative net sales amounts in the Territory. The Company also must 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 License term, the Company must pay Orion a royalty based on net sales of the Product in the Territory for as long as the Company sells the Product in the Territory.

As of December 31, 2021, the Company has not met any of the developmental milestones under the License and, accordingly, has not recorded any liability for the contingent payments due to Orion.

[Table of Contents](#)

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 eighteen 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. A third-party trustee manages the 401(k) Plan.

For the years ended December 31, 2021 and 2020, the Company recorded \$73,855 and \$69,793 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, 2021 due to its history of net operating losses.

The reconciliation of income tax expense (benefit) at the statutory federal income tax rate of 21% for the periods ended December 31, 2021 and December 31, 2020 is as follows:

	December 31,	
	2021	2020
U.S. federal tax benefit at statutory rate	\$ (6,819,615)	\$ (2,068,792)
State income tax benefit, net of federal benefit	(641,368)	(194,565)
Stock compensation	171,269	57,611
Other nondeductible, including IPR&D expense	5,032,981	576
Change in state tax rate	1,768,013	-
Federal and state net operating loss adjustments	745,439	1,605,223
Other, including effect of tax rate brackets	(73)	(56,640)
Change in realizability of IPR&D	229,750	-
Change in valuation allowance	(486,396)	656,587
	<u>\$ -</u>	<u>\$ -</u>

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,	
	2021	2020
Deferred Tax Assets		
Net operating loss carryforwards	\$ 35,291,097	\$ 35,540,911
Accruals and other	308,296	545,225
Capital loss carryforwards	11,003	11,003
Valuation allowance	(35,610,396)	(36,096,792)
Net deferred tax assets	<u>-</u>	<u>347</u>
Deferred Tax Liabilities		
Other liabilities	-	(347)
Net Deferred Tax Liabilities	<u>\$ -</u>	<u>\$ -</u>

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 2021 was approximately \$0.49 million.

As of December 31, 2021, the Company had Federal and State net operating loss carryforwards of approximately \$159.3 million and \$119.0 million available to offset future federal and state taxable income, respectively. Federal net operating losses of \$125.2 million begin to expire in 2022, while the remaining \$34.2 million carryforward indefinitely. State net operating losses begin to expire in 2024.

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

The Company has U.S. federal net operating loss carryforwards, or NOLs, which expire in various years if not utilized. In addition, it has federal research and development credit carryforwards. The federal research and development credit carryforwards expire in various years if not utilized. Under Sections 382 and 383 of Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an “ownership change,” the corporation’s ability to use its pre-change NOLs and other pre-change tax attributes, such as research tax credits, to offset its future post-change income and taxes may be limited. In general, an “ownership change” occurs if there is a cumulative change in our ownership by “5% shareholders” that exceeds 50 percentage points over a rolling three-year period. Similar rules may apply under state tax laws. The Company has not performed a formal study to determine whether any of its NOLs are subject to these limitations. The Company has recorded deferred tax assets for our NOLs and research and development credits and have recorded a full valuation allowance against these deferred tax assets. In the event that it is determined that it has in the past experienced additional ownership changes, or if it experiences one or more ownership changes as a result of future transactions in its stock, then the Company may be further limited in its ability to use its NOLs and other tax assets to reduce taxes owed on the net taxable income that it earns in the event that The Company attains profitability. Any such limitations on the ability to use its NOLs and other tax assets could adversely impact its business, financial condition, and operating results in the event that the Company attain profitability.

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, 2021.

The Company files U.S. and state income tax returns with varying statutes of limitations. The tax years 2002 and forward remain open to examination due to the carryover of unused net operating losses or tax credits.

NOTE I—SUBSEQUENT EVENTS

On January 4, 2022, the Company was issued US Pat. No. 11,213,524, entitled **PHARMACEUTICAL COMPOSITIONS FOR SUBCUTANEOUS ADMINISTRATION OF LEVOSIMENDAN**, which is directed towards the use of levosimendan via subcutaneous administration for treating a subject having a health condition of any kind, such as heart failure, pulmonary hypertension including PH-HFpEF, chronic kidney disease, stroke, or other health conditions. The patent is expected to expire no earlier than 2039, exclusive of any possible extensions. The Company also has a PCT international application pending, with a U.S. counterpart already under examination, that describes and claims methods of treating the Company’s first intended clinical indication, PH-HFpEF, by providing levosimendan by any route of administration.

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

The authorized capital stock of Tenax Therapeutics, Inc. consists of 400,000,000 shares of common stock, \$0.0001 par value per share ("Common Stock"), and 10,000,000 shares of preferred stock, par value \$0.0001 per share ("Preferred Stock"). The following description summarizes the material terms of our capital stock. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description of our capital stock, you should refer to our certificate of incorporation, as amended, or our "Charter", and our third amended and restated bylaws, or our "Restated Bylaws", which are included as exhibits to this Annual Report on Form 10-K, and to the provisions of applicable Delaware law.

As used in this exhibit, the terms "Tenax Therapeutics, Inc.", "Tenax", the "Company," "we", "us", and "our" mean Tenax Therapeutics, Inc.

Common Stock

Our Charter authorizes the issuance of 400,000,000 shares of Common Stock.

Our authorized but unissued shares of Common Stock are available for issuance without further action by our stockholders unless such action is required by applicable law or the rules of any securities exchange or automated quotation system on which our securities may be listed or traded. Holders of our Common Stock are entitled to the following rights.

- *Voting Rights.* The holders of our Common Stock are entitled to one vote for each share of Common Stock held on all matters submitted to a vote of the stockholders, including the election of directors. Our Charter and our Restated Bylaws do not provide for cumulative voting rights.
- *Dividend Rights.* The holders of outstanding shares of our Common Stock are entitled to receive ratably any dividends declared by our board of directors out of assets legally available for the payment of dividends, at the times and in the amounts as our board may from time to time determine.
- *No Preemptive or Similar Rights.* The holders of our Common Stock have no preemptive, conversion, or subscription rights, and there are no redemption or sinking fund provisions applicable to our Common Stock.
- *Right to Receive Liquidation Distributions.* In the event of our liquidation, dissolution or winding up, holders of Common Stock are entitled to receive, pro rata, our assets which are legally available for distribution, after payments of all debts and other liabilities and subject to the preferential rights, if any, on any outstanding shares of Preferred Stock and payment of other claims of creditors.
- *Fully Paid and Non-Assessable.* All of the outstanding shares of our Common Stock are fully paid and non-assessable.
- *Potential Adverse Effect of Future Preferred Stock.* The rights, preferences and privileges of the holders of Common Stock are subject to, and might be adversely affected by, the rights of the holders of shares of any series of our Preferred Stock that we may designate and issue in the future.

Preferred Stock

Our board of directors has the authority, without further action by our stockholders, unless such action is required by applicable law or the rules of any securities exchange or automated quotation system on which our securities may be listed or traded, to issue up to 10,000,000 shares of Preferred Stock in one or more series and to fix the designations, powers, rights, preferences, qualifications, limitations and restrictions thereof. These designations, powers, rights and preferences could include voting rights, dividend rights, dissolution rights, conversion rights, exchange rights, redemption rights, liquidation preferences, and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of Common Stock. The issuance of Preferred Stock could adversely affect the voting power of holders of Common Stock and the likelihood that such holders will receive dividend payments and payments upon liquidation. In addition, the issuance of Preferred Stock could have the effect of delaying, deferring or preventing a change in our control or other corporate action.

Series A Convertible Preferred Stock

On December 10, 2018, we filed a certificate of designations (the "Certificate of Designations") with the Secretary of State of the State of Delaware creating our Series A Convertible Preferred Stock (the "Series A Preferred Stock") and establishing the designations, preferences, and other rights of the Series A Preferred Stock, which became effective upon filing.

The holders of our Series A Preferred Stock are entitled to the following rights.

- *Voting Rights.* Shares of Series A Preferred Stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the then outstanding Series A Preferred Stock will be required to amend the terms of the Series A Preferred Stock or to take other action that adversely affects the rights of the holders of Series A Preferred Stock.
- *Dividend Rights.* In the event the Company pays dividends on its shares of Common Stock, the holders of the Series A Preferred Stock will be entitled to receive dividends on shares of Series A Preferred Stock equal, on an as-if-converted basis, to and in the same form as paid on the Common Stock. No other dividends will be paid on the shares of Series A Preferred Stock.
- *No Preemptive or Similar Rights.* The holders of our Series A Preferred Stock have no preemptive, or subscription rights, and there are no

redemption or sinking fund provisions applicable to our Series A Preferred Stock.

- *Right to Receive Liquidation Distributions.* Upon any liquidation, dissolution or winding up of the Company after payment or provision for payment of debts and other liabilities of the Company, the holders of Series A Preferred Stock shall be entitled to be paid out of the assets of the Company available for distribution to its stockholders an amount equal to the amount that a holder of Common Stock would receive if the Series A Preferred Stock were fully converted to Common Stock, which amounts will be paid pari passu with all holders of Common Stock.
- *Conversion Rights.* Subject to the ownership limitations described below, the Series A Preferred Stock is convertible at any time at the option of the holder into shares of Common Stock at a conversion ratio determined by dividing the stated value of the Series A Preferred Stock by a conversion price of \$1.93 per share. The conversion price is subject to adjustment in the case of stock splits, stock dividends, combinations of shares and similar recapitalization transactions.
- *Forced Conversion.* Subject to the beneficial ownership limitation described below, the Company has the right to cause each holder of the Series A Preferred Stock to convert all or part of such holder's Series A Preferred Stock in the event that (i) the volume weighted average price of our Common Stock for any 30 consecutive trading days (the "Measurement Period"), exceeds \$5.79 (subject to typical adjustments), (ii) the average daily trading volume for such Measurement Period exceeds \$175,000 per trading day, and (iii) the holder is not in possession of any information that constitutes or might constitute, material non-public information which was provided by the Company.
- *Beneficial Ownership Limitation.* The Company will not effect any redemption or conversion of the Series A Preferred Stock, nor shall a holder convert its shares of Series A Preferred Stock, to the extent that such conversion would cause the holder to have acquired, through conversion of the Series A Preferred Stock or otherwise, beneficial ownership of a number of shares of Common Stock in excess of 4.99% (or, at the election of the holder prior to the issuance of any shares of Series A Preferred Stock, 9.99%) of the Common Stock outstanding after giving effect to such exercise.

CERTAIN PROVISIONS OF DELAWARE LAW,

OUR RESTATED CERTIFICATE AND RESTATED BYLAWS

The provisions of Delaware law, our Charter, and our Restated Bylaws may have the effect of delaying, deferring, or discouraging another person from acquiring control of our Company.

Delaware Law

We are governed by the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder unless:

prior to such time, the board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding shares owned by persons who are directors and also officers and by specified employee stock plans; or

at or subsequent to the date of the transaction, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

A "business combination" includes mergers, asset sales or other transactions resulting in a financial benefit to the stockholder. In general, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years did own, 15% or more of the corporation's outstanding voting stock. These provisions may have the effect of delaying, deferring, or preventing a change in our control.

Charter and Restated Bylaw Provisions

Various provisions of our Charter and Restated Bylaws could deter hostile takeovers or delay or prevent changes in control of our management team, including the following:

- *Undesignated Preferred Stock.* The ability to authorize undesignated preferred stock makes it possible for our board of directors to issue one or more series of preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of our company.
- *Removal of Directors and Filling of Vacancies.* Our Restated Bylaws require the vote of stockholders representing not less than two-thirds of our issued and outstanding capital stock entitled to voting power in order to remove a director from office, with or without cause. In addition, vacancies on our board of directors (including vacancies created by the removal of directors) may be filled by a majority of the remaining directors, even if less than a quorum, or by a sole remaining director, and each director so appointed shall hold office until his or her successor is elected at an annual or a special meeting of our stockholders.
- *Special Meeting of Stockholders.* Our Restated Bylaws provide that a special meeting of stockholders may be called only by a majority of our board of directors, our president, the chairperson of our board of directors or such other person as our board of directors may designate, in each

case, for the purpose specified in the notice of meeting. Our stockholders are not permitted to propose business to be brought before a special meeting of our stockholders.

- *Advance Notice Requirements.* Our Restated Bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of our board of directors or a committee of the board of directors. These provisions may have the effect of deterring unsolicited offers to acquire our company or delaying stockholder actions, even if they are favored by the holders of a majority of our outstanding voting securities.
- *No Cumulative Voting.* Our Charter does not permit cumulative voting. Without cumulative voting, a minority stockholder may not be able to gain as many seats on our board of directors as the stockholder would be able to gain if cumulative voting were permitted. The absence of cumulative voting makes it more difficult for a minority stockholder to gain a seat on our board of directors to influence our board of directors' decision regarding a takeover.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Issuer Direct Corporation.

Listing on the Nasdaq Capital Market

Our Common Stock is listed on the Nasdaq Capital Market under the symbol "TENX".

CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED PURSUANT TO REGULATION S-K ITEM 601(b)(10)(iv) OF THE SECURITIES ACT OF 1933, AS AMENDED AND REPLACED WITH [***]. SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (i) NOT MATERIAL AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED.

CONSULTING AGREEMENT

This Consulting Agreement (the "Agreement") is made as of October 14, 2021, by and between Tenax Therapeutics, Inc., a Delaware corporation, with its principal place of business being ONE Copley Parkway, Suite 490, Morrisville, NC 27560 (the "Company") and Danforth Advisors, LLC, a Massachusetts limited liability company, with its principal place of business being 91 Middle Road, Southborough, MA 01772 ("Danforth"). The Company and Danforth are herein sometimes referred to individually as a "Party" and collectively as the "Parties."

WHEREAS, the Company is a specialty pharmaceutical company focused on identifying, developing, and commercializing products that address cardiovascular and pulmonary diseases with high unmet medical need; and

WHEREAS, Danforth has expertise in financial and corporate operations and strategy; and

WHEREAS, Danforth desires to serve as an independent consultant for the purpose of providing the Company with certain strategic and financial advice and support services, using personnel described in Exhibit A attached hereto, (the "Services"); and

WHEREAS, the Company wishes to engage Danforth on the terms and conditions set forth herein.

NOW THEREFORE, in consideration of the foregoing and for other good and valuable consideration, the receipt of which are hereby acknowledged, the Parties agree and covenant as follows.

1. Services of Consultant. Danforth will assist the Company with matters relating to the Services. The Services are more fully described in Exhibit A attached hereto. Danforth and the Company will review the Services on a monthly basis to determine appropriate staffing requirements. Company shall have the right to request changes to the Danforth personnel at any time in writing. If Company makes a written request, Danforth shall replace such personnel subject to the Company's right of pre-approval.
2. Compensation for Services. In full consideration of Danforth's full, prompt and faithful performance of the Services, the Company shall compensate Danforth a consulting fee more fully described in Exhibit A (the "Consulting Fee"). Danforth shall, from time to time, but not more frequently than once per calendar month, invoice the Company for Services rendered, and such invoice will be paid upon 30 days of receipt. Each month the Parties shall evaluate jointly the current fee structure and scope of Services. Danforth reserves the right to an annual increase in consultant rates of up to 4%, effective January 1, 2023. Upon termination of this Agreement pursuant to Section 3, no compensation or benefits of any kind as described in this Section 2 shall be payable or issuable to Danforth after the effective date of such termination. In addition, the Company will reimburse Danforth for reasonable out-of-pocket business expenses, including but not limited to travel and parking, incurred by Danforth in performing the Services hereunder, upon submission by Danforth of supporting documentation reasonably acceptable to the Company. Any such accrued expenses in any given three (3) month period that exceed \$1,000 shall be submitted to the Company for its prior written approval.

All Danforth invoices and billing matters should be addressed to:

Company Accounts Payable Contact:

Name: Karen Miller
 Title: Senior Accountant
 Address: ONE Copley Parkway, Suite 490, Morrisville, NC 27560
 Phone: 919.855.2100
 E-mail:

All Company payments and billing inquiries should be addressed to:

Danforth Accounting: Betsy Sherr
 bsherr@danforthadvisors.com
 (508) 277-0031
 Danforth Advisors, LLC
 PO Box 335
 Southborough, MA 01772

3. Term and Termination. The term of this Agreement will commence on October 29, 2021 (the "Effective Date") and will continue until such time as either Party has given notice of termination pursuant to this paragraph 3 (the "Term"). This Agreement may be terminated by either Party hereto: (a) with Cause (as defined below), immediately upon written notice to the other Party; or (b) without Cause upon 30 days prior written notice to the other Party. For purposes of this Section 3, "Cause" shall include: (i) a material breach of the terms of this Agreement which, if curable, is not cured within 10 days of written notice of such default, or (ii) the commission of any act of fraud, embezzlement or deliberate disregard of a rule or policy of the Company.

4. Time Commitment. Danforth will devote such time to perform the Services under this Agreement as may reasonably be required. Danforth does not guarantee time and materials estimates in any way and such estimates are not fixed prices. Danforth will notify the Company as soon as practicable if an estimate will be exceeded.
 5. Place of Performance. Danforth will perform the Services at such locations upon which the Company and Danforth may mutually agree. Danforth will not, without the prior written consent of the Company, perform any of the Services at any facility or in any manner that might give anyone other than the Company any rights to or allow for disclosure of any Confidential Information (as defined below).
 6. Compliance with Policies and Guidelines. Danforth will perform the Services in accordance with all rules or policies adopted by the Company that the Company discloses in writing to Danforth.
 7. Confidential Information. Danforth acknowledges and agrees that during the course of performing the Services, the Company may furnish, disclose or make available to Danforth information, including, but not limited to, material, compilations, data, formulae, models, patent disclosures, procedures, processes, business plans, financial information, projections, protocols, results of experimentation and testing, specifications, strategies and techniques, and all tangible and intangible embodiments thereof of any kind whatsoever (including, but not limited to, any apparatus, biological or chemical materials, animals, cells, compositions, documents, drawings, machinery, patent applications, records and reports), which is owned or controlled by the Company and is marked or designated as confidential at the time of disclosure or is of a type that is customarily considered to be confidential information (collectively the "Confidential Information"). Danforth acknowledges that the Confidential Information or any part thereof is the exclusive property of the Company and shall not be disclosed to any third party without first obtaining the written consent of the Company. Danforth further agrees that the Confidential Information, and any part thereof, (i) shall not be disclosed or issued to its affiliates, agents or employees (the "Representatives"), except as necessary for the performance of the Services and provided that any such Representative is bound by terms and conditions no less restrictive than those terms and conditions applicable to Danforth under this Agreement and (ii) shall be used solely for the purposes of performing its obligations under this Agreement. The above provisions of confidentiality shall apply for a period of five years. Pursuant to the Defend Trade Secrets Act of 2016, Danforth acknowledges that Danforth will not have criminal or civil liability under any federal or state trade secret law for the disclosure of a trade secret that (i) is made (A) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney and (B) solely for the purpose of reporting or investigating a suspected violation of law; or (ii) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. In addition, if Danforth files a lawsuit for retaliation by Company for reporting a suspected violation of law, Danforth may disclose the trade secret to its attorney and may use the trade secret information in the court proceeding, if Danforth (i) files any document containing the trade secret under seal and (ii) does not disclose the trade secret, except pursuant to court order.
-
8. Use of Name and Logo. The Company agrees to permit the use of its name and logo in a roster of Danforth clients, which may appear on the Danforth website and in its marketing materials.
 9. Intellectual Property. Danforth agrees that all ideas, inventions, discoveries, creations, manuscripts, properties, innovations, improvements, know-how, designs, developments, apparatus, techniques, methods, and formulae that Danforth conceives, makes, develops or improves as a result of performing the Services, whether or not reduced to practice and whether or not patentable, alone or in conjunction with any other party and whether or not at the request or upon the suggestion of the Company (all of the foregoing being hereinafter collectively referred to as the "Inventions"), shall be the sole and exclusive property of the Company.
 10. Non Solicitation. All personnel representing Danforth are employees or contracted agents of Danforth. Accordingly, they are not retainable as employees or contractors by the Company and the Company hereby agrees not to solicit, hire or retain their services for so long as they are employees or contracted agents of Danforth and for two years thereafter. Should the Company violate this restriction, it agrees to pay Danforth liquidated damages equal to forty percent (40%) of the employee's starting annual base salary and target annual bonus for each Danforth contracted agent hired by the Company in violation of this Agreement plus Danforth's reasonable attorneys' fees and costs incurred in enforcing this agreement should the Company fail or refuse to pay the liquidated damages amount in full within 30 days following its violation. For purposes herein, "solicit" does not include broad-based recruiting efforts, including, without limitation, help wanted advertising and posting of open positions on a party's internet site.
 11. Placement Services. In the event that Danforth refers a potential employee to the Company and that individual is hired, Danforth shall receive a fee equal to 20% of the employee's starting annual base salary and target annual bonus. This fee is due and owing whether an individual is hired, directly or indirectly on a permanent basis or on a contract or consulting basis by the Company, as a result of Danforth's efforts within one year of the date applicant(s) are submitted to the Company. Such payment is due within 30 days of the employee's start date.
 12. Limited Warranty. Danforth represents and warrants that neither this Agreement nor the performance thereof will conflict with or violate any obligation of Danforth or right of any third party. Except for any express warranties stated herein, the Services are provided on an "as is" basis, and the Company disclaims any and all other warranties, conditions, or representations (express, implied, oral or written), relating to the Services or any part thereof. Further, in performing the Services, Danforth is not engaged to disclose illegal acts, including fraud or defalcations, which may have taken place. The foregoing notwithstanding, Danforth will promptly notify the Company if Danforth becomes aware of any such illegal acts during the performance of the Services. Because the Services do not constitute an examination in accordance with standards established by the American Institute of Certified Public Accountants (the "AICPA"), Danforth is precluded from expressing an opinion as to whether financial statements provided by the Company are in conformity with generally accepted accounting principles or any other standards or guidelines promulgated by the AICPA, or whether the underlying financial and other data provide a reasonable basis for the statements.
 13. Indemnification. Each Party hereto agrees to indemnify and hold the other Party hereto, its directors, officers, agents and employees harmless against any claim based upon circumstances alleged to be inconsistent with such representations and/or warranties contained in this Agreement. Further, the Company shall indemnify and hold harmless Danforth and any of its subcontractors against any claims, losses, damages or liabilities (or actions in respect thereof) that arise out of or are based on the Services performed hereunder, except for any such claims, losses, damages or liabilities arising out of the gross negligence or willful misconduct of Danforth or any of its subcontractors. The Company will endeavor to add Consultant and any

applicable subcontractor to its insurance policies as additional insureds. Furthermore, during the Term of this Agreement, if the Company desires that Danforth provide treasury services, the Company shall obtain and maintain a Crime and Cyber Insurance Policy that includes coverage for "Social Engineering" claims and extends coverage to Danforth.

14. **D&O Insurance.** The Company shall use its best efforts to specifically include and cover, as a benefit for their protection, Danforth staff serving as directors or officers of the Company or affiliates from time to time with direct coverage as named insureds under the Company's policy for directors' and officers' ("D&O") insurance. The Company will maintain such D&O insurance coverage for the period through which claims can be made against such persons. The Company disclaims a right to distribution from the D&O insurance coverage with respect to such persons. In the event that the Company is unable to include Danforth under the Company's policy or does not have first dollar coverage acceptable to Danforth in effect for at least \$10 million (e.g., such policy is not reserved based on actions that have been or are expected to be filed against officers and directors alleging prior acts that may give rise to a claim), Danforth may, at its option, attempt to purchase a separate D&O policy that will cover the Danforth staff only. The cost of same shall be invoiced to the Company as an out-of-pocket cash expense. If Danforth is unable to purchase such D&O insurance, then Danforth reserves the right to terminate the Agreement upon delivery of written notice.
15. **Independent Contractor.** Neither Danforth, nor any employee or agent of Danforth is, nor shall Danforth or any employee or agent of Danforth be deemed to be at any time during the term of this Agreement, an employee of the Company, and therefore neither Danforth nor any of its employees or agents shall be entitled to any benefits provided by the Company to its employees, if applicable. Danforth's status and relationship with the Company shall be that of an independent contractor and consultant. Danforth shall not state or imply, directly or indirectly, that Danforth is empowered to bind the Company without the Company's prior written consent. Nothing herein shall create, expressly or by implication, a partnership, joint venture or other association between the parties. Danforth will be solely responsible for (i) payment of all charges and taxes arising from its relationship to the Company as a consultant, and (ii) reporting, withholding and paying all applicable taxes of any nature that may be reportable or due on amounts paid to Danforth hereunder. Danforth further agrees to indemnify and hold the Company harmless from any and all claims, causes of action or other proceedings related to or resulting from Danforth's or any of its employees' or agents' failure to pay income taxes in compliance with applicable law. Except as expressly provided herein, nothing in this Agreement shall preclude Danforth from consulting for or being employed by any other person or entity.
16. **Records.** Upon termination of Danforth's relationship with the Company, Danforth shall deliver to the Company any property or Confidential Information of the Company relating to the Services which may be in its possession including products, project plans, materials, memoranda, notes, records, reports, laboratory notebooks, or other documents or photocopies and any such information stored using electronic medium.
17. **Notices.** Any notice under this Agreement shall be in writing (except in the case of verbal communications, emails and teleconferences updating either Party as to the status of work hereunder) and shall be deemed delivered upon personal delivery, one day after being sent via a reputable nationwide overnight courier service or two days after deposit in the mail or on the next business day following transmittal via facsimile. Notices under this Agreement shall be sent to the following representatives of the Parties:

 If to the Company:
 Name: Christopher T. Giordano
 Title: Chief Executive Officer
 Address: ONE Copley Parkway, Suite 490, Morrisville, NC 27560
 Phone: 919.855.2100
 E-mail:

 If to Danforth:

 Name: Gregg Beloff
 Title: Managing Director
 Address: 91 Middle Road
18. **Assignment and Successors.** This Agreement may not be assigned by a Party without the consent of the other which consent shall not be unreasonably withheld, except that each Party may assign this Agreement and the rights, obligations and interests of such Party, in whole or in part, to any of its Affiliates, to any purchaser of all or substantially all of its assets or to any successor corporation resulting from any merger or consolidation of such Party with or into such corporation.
19. **Force Majeure.** Neither Party shall be liable for failure of or delay in performing obligations set forth in this Agreement, and neither shall be deemed in breach of its obligations, if such failure or delay is due to natural disasters or any causes beyond the reasonable control of either Party. In the event of such force majeure, the Party affected thereby shall use reasonable efforts to cure or overcome the same and resume performance of its obligations hereunder.
20. **Headings.** The Section headings are intended for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.
21. **Integration; Severability.** This Agreement is the sole agreement with respect to the subject matter hereof and shall supersede all other agreements and understandings between the Parties with respect to the same. If any provision of this Agreement is or becomes invalid or is ruled invalid by any court of competent jurisdiction or is deemed unenforceable, it is the intention of the Parties that the remainder of the Agreement shall not be affected.
22. **Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, excluding choice of law principles. The Parties agree that any action or proceeding arising out of or related in any way to this Agreement shall be brought solely in a Federal or State court of competent jurisdiction sitting in the Commonwealth of Massachusetts.

23. **Amendments and Waivers.** This Agreement may be amended or supplemented only by a written instrument duly executed by each of the Parties. No provision of this Agreement may be waived except by a written instrument signed by the Party hereto sought to be bound. No failure or delay by any Party in exercising any right or remedy hereunder or under applicable law will operate as a waiver thereof, and a waiver of a particular right or remedy on one occasion will not be deemed a waiver of any other right or remedy, or a waiver on any subsequent occasion.
24. **Counterparts.** This Agreement may be executed in counterparts, each of which will be deemed an original, but all of which together will constitute one agreement. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

If you are in agreement with the foregoing, please sign where indicated below, whereupon this Agreement shall become effective as of the Effective Date.

DANFORTH ADVISORS, LLC

Tenax Therapeutics, Inc.

By: /s/ Chris Connors

By: /s/ Christopher T. Giordano

Print Name: Chris Connors

Print Name: Christopher T. Giordano

Title: Chief Executive Officer

Title: Chief Executive Officer

Date: October 14, 2021

Date: October 14, 2021

EXHIBIT A

Description of Services and Schedule of Fees

Danforth will perform mutually agreed to finance and accounting functions which are necessary to support the management and operations of the Company.

Services and Fees:

Initial Staffing will be Eliot M. Lurier, who will act as Interim Chief Financial Officer of the Company, serving as its Principal Financial Officer and Principal Accounting Officer and performing all services related to such positions including, but not limited to, the following:

- Participation in financing activities;
- Overseeing the preparation and review of the Company's SEC filings and compliance with other regulatory documents;
- Certification of the Company's SEC filings;
- Support of investor relations activities;
- Overseeing the finance and accounting functions of the Company;
- Acting as Treasurer to the Company and its Subsidiaries;
- Board and Board Committee meeting support and attendance;
- Finance support for operational planning;
- Corporate and business development support;
- Financial modeling, planning and analysis;
- Strategic opportunity assessment; and
- Capitalization table management.

Mr. Lurier has been interviewed and approved by the Company. Additional personnel will be added in accordance with Section 1 of this Agreement.

Fees:

Mr. Lurier (Interim CFO): \$400/hr

Additional fee rates provided below:

<u>Role</u>	<u>Hourly Rate</u>	<u>Function</u>
Sr. Advisor	\$[***/hour	Senior Advisory
CFO	\$400/hour	CFO
Sr. Director	\$[***/hour	Principal Accounting Officer
Sr. HR Director	\$[***/hour	Human Resources
HR Director	\$[***/hour	Human Resources
Director	\$[***/hour	VP Finance
Sr HR Manager	\$[***/hour	Human Resources
Sr Manager	\$[***/hour	Sr Controller/FP&A
Manager	\$[***/hour	Controller
HR Manager	\$[***/hour	Human Resources
Sr. Consultant	\$[***/hour	Asst. Controller
Consultant	\$[***/hour	Staff Accountant

SEPARATION AND RELEASE AGREEMENT

This SEPARATION AND RELEASE AGREEMENT (the “Agreement”) is made and entered into this 14th day of October, 2021 (the “Effective Date”) by and between Michael B. Jebson, a citizen and resident of North Carolina (hereinafter “Employee”), and Tenax Therapeutics, Inc., a Delaware corporation with its principal place of business in North Carolina (the “Company”). (Employee and the Company are sometimes referred to herein each as a “Party” and together as the “Parties.”)

WHEREAS, Employee has been employed by the Company as its President and Chief Financial Officer; and

WHEREAS, in connection with his employment with the Company, the Parties entered into a Second Amended and restated Employment Agreement dated November 13, 2013 (the “Employment Agreement”); and

WHEREAS, pursuant to the Employment Agreement, upon the separation of his employment under certain circumstances, Employee would receive certain severance benefits conditioned upon Employee’s execution and non-revocation of an enforceable release of claims and his compliance with his ongoing obligations under Section 7 of the Employment Agreement; and

WHEREAS, Employee’s employment will end, effective as of October 29, 2021 (the “Separation Date”); and

WHEREAS, the Parties intend that this Agreement will set out the terms of Employee’s employment through the Separation Date and Employee’s severance benefits, and provide for the general release of the Company by Employee as contemplated by the Employment Agreement;

NOW, THEREFORE, in consideration of the promises and the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. Separation of Employment and Transition. Until the Separation Date, Employee will continue to perform his regular duties in a competent and professional manner, support the retention and motivation levels of employees of the Company, and reasonably cooperate with the Company in transitioning Employee’s duties to other employees or consultants of the Company as directed by the Company’s Chief Executive Officer. Effective as of the Separation Date, Employee’s employment with the Company will end and Employee will no longer serve as President and Chief Financial Officer of the Company or in any officer position at any of the Company’s subsidiaries, and Employee will resign from all of his positions, if any, on the Boards of Directors of the Company and any of its subsidiaries. Employee will receive his final paycheck for work through the Separation Date on the Company’s next regular pay day following the Separation Date. Except as expressly provided herein, as required by applicable law, or as may be vested under the Company’s plans, policies and arrangements, after the Separation Date, Employee will be entitled to no further compensation or employee benefits from the Company as an employee of the Company.

2. Severance Benefits. If, on the later of the Separation Date and twenty-one (21) days after his receipt of this Agreement, Employee signs this Agreement, the Company will provide Employee with the following payments and benefits (collectively the “Severance Benefits”):

a. Severance Pay. In accordance with the terms of the Employment Agreement and in consideration of Employee’s execution of this Agreement, the Company will pay Employee an amount equal to twelve (12) months of his regular base salary, minus applicable federal, state and local payroll taxes, and other withholdings required by law, paid out in a lump sum no later than on the thirtieth (30th) day following the Separation Date (the “Severance Pay”);

b. Target Bonus. The Company will pay to Employee an amount equal to his Target Bonus for fiscal year 2021, multiplied by a fraction, the numerator of which is the number of days during which the Employee was employed by the Company in fiscal year 2021 and the denominator of which is 365 (less applicable withholdings), with such payment to be made in lump sum payment on the Severance Pay date; and

c. Benefits. If Employee properly and timely applies for continuation coverage under the Consolidated Budget Reconciliation Act or applicable state health insurance continuation law (“COBRA”), the Company will reimburse Employee for premium payments Employee makes under COBRA to continue Employee, and if applicable, Employee’s family’s, health insurance coverage under the Company’s group health insurance plan for twelve (12) months from the Separation Date. Reimbursements for COBRA premium payments shall begin on the Severance Payment Date and shall be made as soon as possible following the Employee’s submission to the Company of proof of timely payments, but not later than thirty (30) days after the Employee’s submission of proof of timely payments; provided, however, all such claims for reimbursement shall be submitted by the Employee and paid by the Company no later than fifteen (15) months following the termination of the Employee’s employment. Any obligation for the Company to make payments for COBRA coverage under this Agreement shall immediately cease when Employee becomes eligible for health insurance from a subsequent employer, and Employee shall promptly notify the Company of such subsequent eligibility. Nothing herein shall constitute a guarantee of COBRA benefits.

Employee acknowledges and agrees that Employee’s receipt of the Separation Benefits is contingent upon his execution of an additional release in a form acceptable to the Company as contained in Exhibit A of this Agreement, to be presented to Employee after the Separation Date.

3. Release of Claims. In accordance with the terms of the Employment Agreement and in exchange for the Company’s agreement to provide Employee with the Severance Benefits described above, by signing this Agreement, Employee releases and forever discharges the Company, as well as its parent companies, affiliates, subsidiaries, divisions, officers, directors, stockholders, employees, agents, representatives, attorneys, lessors, lessees, licensors and licensees, and their respective successors, assigns, heirs, executors and administrators (collectively, the “Company Parties”), from any and all claims, demands, and causes of action of every kind and nature, whether known or unknown, direct or indirect, accrued, contingent or potential, that Employee ever had or now has, including but not limited to any claims arising out of or related to his employment with the Company and the end thereof (except where and to the extent that such a release is expressly prohibited or made void by law). The release includes, without limitation, Employee’s release of the Company and the Company Parties from any claims for lost wages or benefits, stock options, restricted stock, restricted stock units, compensatory damages, punitive damages, attorneys’ fees and costs, equitable relief or any other form of damages or relief. In addition, this release is meant to release the Company and the Company Parties from all common law claims, including claims in contract or tort, including, without limitation,

claims for breach of contract, wrongful or constructive discharge, intentional or negligent infliction of emotional distress, misrepresentation, tortious interference with contract or prospective economic advantage, invasion of privacy, defamation, negligence or breach of any covenant of good faith and fair dealing. Employee also specifically and forever releases the Company and the Company Parties (except where and to the extent that such a release is expressly prohibited or made void by law) from: all claims under North Carolina laws prohibiting discrimination, harassment and retaliation and all similar state and local laws; all claims under laws governing the payment of wages or protection of workers seeking payment for work performed and any other federal, state or local statutory and/or common laws governing the payment of wages; and/or and all claims under federal law based on unlawful employment discrimination, harassment or retaliation, including, but not limited to, claims for violation of Title VII of the Civil Rights Act, the Americans with Disabilities Act, the Genetic Information and Discrimination Act, and the Federal Age Discrimination In Employment Act (29 U.S.C. § 621 *et. seq.*).

Employee hereby acknowledges that this release applies both to known and unknown claims that may exist between Employee and the Company and the Company Parties. Employee expressly waives and relinquishes all rights and benefits which he may have under any state or federal statute or common law principle that would otherwise limit the effect of this Agreement to claims known or suspected prior to the date he executes this Agreement and does so understanding and acknowledging the significance and consequences of such specific waiver. Provided, however, that nothing in this Agreement extinguishes any claims Employee may have against the Company for breach of this Agreement or any claims arising from events that occur following the Effective Date of this Agreement.

4. No Admissions. Employee understands, acknowledges and agrees that the release set out above in Section 3 is a final compromise of potential claims, and is not an admission by the Company that any such claims exist or that the Company or the Company Parties are liable for any such claims. Unless prohibited by applicable law or regulation, Employee further agrees not to hereafter, directly or indirectly, sue, assist in or be a voluntary party to any litigation against Company or any one or more of the Company Parties for any claims relating to events occurring prior to or simultaneously with the execution of this Agreement.

Notwithstanding the foregoing, nothing in this Agreement prohibits Employee from filing a charge with, or participating in any investigation or proceeding conducted by, the U.S. Equal Employment Opportunity Commission or a comparable state or federal fair employment practices agency; provided, however, that this Agreement fully and finally resolves all monetary matters between Employee and the Company and the Company Parties, and by signing this Agreement, Employee acknowledges that he is waiving any right to monetary damages, attorneys' fees and/or costs related to or arising from any such charge, complaint or lawsuit filed by Employee or on Employee's behalf, individually or collectively.

5. Cooperation. By signing this Agreement, Employee promises and agrees, and for eighteen (18) months following the Separation Date, to the extent reasonably requested by the Company, to cooperate fully with the Company and its officers, directors, employees, agents and legal counsel in connection with any claim, complaint, charge, suit or action previously or hereafter asserted or filed by or against the Company or any of the Company Parties which relates to, arises out of or is connected directly or indirectly with (i) Employee's employment with the Company, (ii) any other relationship or dealings between Employee and the Company or any of the Company Parties, or (iii) any other matter relating to the Company or any of the Company Parties. Employee's cooperation with the Company shall continue throughout the pendency of any such claim, complaint, charge, suit or action; provided that the Company shall make reasonable efforts to minimize disruption of the Employee's other activities. Further, Employee promises and agrees that, in the event he is subject to a valid and enforceable subpoena or court order which compels his testimony at a trial, hearing or deposition concerning his relationship with the Company or any other matter relating to the Company or any of the Company Parties, he will provide reasonable and prompt notice to the Company of this fact and cooperate fully with the Company prior to and during his testimony, to the maximum extent possible, consistent with his obligation to provide truthful testimony. Employee further agrees that, in the event he is named as a defendant in a legal proceeding resulting from, arising out of, or connected directly or indirectly with Employee's employment with the Company, or any act, omission or conduct occurring during Employee's employment with the Company, he will provide reasonable and prompt notice of this fact to the Company. The Company agrees to reimburse Employee for reasonable out-of-pocket expenses as reasonably required for such cooperation and consultation, and to the extent Employee is required to spend more than five hours of such matters, the Company shall compensate Employee at an hourly rate based on the Employee's base salary on the Separation Date, and to the extent Employee is required to spend more than five hours of such matters, the Company shall compensate Employee at an hourly rate based on the Employee's base salary on the Separation Date.

Notwithstanding the foregoing, nothing in this Agreement prohibits Employee from reporting possible violations of federal law or regulation to any governmental agency or entity, including but not limited to the Department of Justice, the Securities and Exchange Commission, the Congress, and any agency Inspector General, or making other disclosures that are protected under the whistleblower provisions of federal law or regulation. Employee does not need the prior authorization of the Company to make any such reports or disclosures, and Employee is not required to notify the Company that he has made such reports or disclosures. The Company agrees that it will take no adverse action against Employee for truthful statements and testimony and that it will not seek to obtain any testimony or evidence that is not truthful and that it will not improperly seek to influence or modify any testimony of Employee.

6. Return of Property. On or before the Separation Date, Employee shall return all property of the Company in his possession, including, without limitation, any Company credit cards, Company-owned equipment, and all originals and any copies of all disks, tapes, files, correspondence, data, notes and other documents pertaining to the Company's proprietary products, customers and business and confidential and proprietary information as described in Section 7 of the Employment Agreement. Such property shall be in the same condition as when provided to Employee, reasonable wear and tear excepted.

7. Confidentiality and Competitive Business Activities. Employee hereby acknowledges and agrees that his post-employment duties and obligations under Section 7 of the Employment Agreement will remain in full force and effect in accordance with such terms, and that a breach of Section 7 of the Employment Agreement will also constitute a breach of this present Agreement.

8. No Disparagement. Employee agrees that he will not falsely denigrate, defame, disparage or cast aspersions upon the Company, its management, products, services, business and manner of doing business, and that he will instruct members of his immediate family not to engage in any such activity.

9. SECTION 409A.

a. The Parties hereby acknowledge and agree that all benefits or payments provided by the Company to Employee pursuant to this Agreement are intended either to be exempt from Section 409A of the Code, or to be in compliance with Section 409A, and the Agreement shall be interpreted to the greatest extent possible to be so exempt or in compliance. If there is an ambiguity in the language of the Agreement, or if Section 409A guidance indicates that a change to the Agreement is required or desirable to achieve exemption or compliance with Section 409A, Company and Employee agree to attempt to renegotiate in good faith to clarify the ambiguity or make such change.

b. If any severance or other payments that are required by the Agreement are to be paid in a series of installment payments, each individual payment in the series shall be considered a separate payment for purposes of Section 409A.

c. If any severance compensation or other benefit provided to Employee pursuant to this Agreement that constitutes “nonqualified deferred compensation” within the meaning of Section 409A is considered to be paid on account of “separation from service” within the meaning of Section 409A, and Employee is a “specified employee” within the meaning of Section 409A, no payments of any of such severance or other benefit shall be made for six (6) months plus one (1) day after the “separation from service” (the “New Payment Date”). The aggregate of any such payments that would have otherwise been paid during the period between the “separation from service” and the New Payment Date shall be paid to the Employee in a lump sum on the New Payment Date.

10. Relief and Enforcement. Employee understands and agrees that, in addition to any other remedies that the Company (or the Company Parties) has at law or in equity, upon any breach of this Agreement by Employee, the Company may immediately cease providing any or all of the Severance Benefits and/or seek recovery of Severance Benefits that have been paid to him pursuant to Section 2, above. Employee also understands and agrees that if he violates the terms of Sections 5, 6, 7 or 8 of this Agreement, Employee will cause injury to the Company and/or one or more of the Company Parties) that will be difficult to quantify or repair, so that the Company (and/or the Company Parties) will have no adequate remedy at law. Accordingly, Employee agree that if he violates Sections 5, 6, 7 or 8 of this Agreement, the Company (or the Company Parties) will be entitled as a matter of right to obtain an injunction from a court of law, restraining Employee from any further violation of this Agreement. The right to an injunction is in addition to any other remedies that the Company (or the Company Parties) has at law or in equity.

11. Assignment. This Agreement may not be assigned by Employee without the prior written consent of the Company. The Company shall have the right to assign this Agreement to its successors and assigns in connection with a change in control or business transaction requiring a general assignment, and all covenants and agreements hereunder shall inure to the benefit of and be enforceable by said successors or assigns. The term “Company” shall include any of the Company’s subsidiaries, subdivisions or affiliates.

12. No Modifications; Governing Law; Venue; Entire Agreement. This Agreement cannot be changed or terminated orally, and no modification or waiver of any of the provisions of this Agreement is effective unless in writing and signed by all of the Parties hereto. The Parties agree that this Agreement is to be governed by and construed in accordance with the laws of the State of North Carolina. The Parties agree that any litigation arising out of or related to this Agreement or Employee’s employment by Company will be brought exclusively in any state or federal court in Wake County, North Carolina. Each Party (a) consents to the personal jurisdiction of said courts, (b) waives any venue or inconvenient forum defense to any proceeding maintained in such courts and (c) agrees not to bring any proceeding arising out of or relating to this Agreement or Employee’s employment by Company in any other court.

This Agreement, and the surviving provisions of the Employment Agreement, set forth the entire and fully integrated understanding between the Parties, and there are no representations, warranties, covenants or understandings, oral or otherwise, that are not expressly set out therein.

13. Voluntary Execution. By signing below, Employee acknowledges that he has read this Agreement, that he understands its contents and that he has relied upon or had the opportunity to seek the legal advice of his attorney, who is the attorney of his own choosing.

[Signature page follows.]

IN WITNESS WHEREOF, each of the Parties hereto acknowledges having read and understood the contents and effect of this Agreement and has executed this Agreement freely and with full authority duly given, all as of the Effective Date first above written.

THE COMPANY:

TENAX THERAPEUTICS, INC.

By: /s/ Christopher T. Giordano

Name: Christopher T. Giordano

Title: Chief Executive Officer

EMPLOYEE:

/s/ Michael B. Jebsen

Michael B. Jebsen

(SEAL)

EXHIBIT A

RELEASE

This RELEASE (the "Final Release") is hereby made and entered into this ___ day of October, 2021 by and between Tenax Therapeutics, Inc. (the "Company") and Michael B. Jebson ("Employee").

WHEREAS, the Company and Employee entered into a Separation and Release Agreement on or about [Date], 2021 (the "Agreement"); and

WHEREAS, in connection with the Agreement, Employee agreed to execute this Final Release in exchange for certain consideration as set out therein; and

NOW, THEREFORE, in consideration of the promises and the mutual covenants set out in the Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Company and Employee hereby agree that this Final Release will be an addendum to the Agreement and agree as follows:

1. Release of Claims. In exchange for the Company's providing Employee with the Separation Benefits described in Section 2 of the Agreement, by signing this Final Release, Employee releases and forever discharges the Company, as well as its parent companies, affiliates, subsidiaries, divisions, officers, directors, stockholders, employees, agents, representatives, attorneys, lessors, lessees, licensors and licensees, and their respective successors, assigns, heirs, executors and administrators (collectively, the "Company Parties"), from any and all claims, demands, and causes of action of every kind and nature, whether known or unknown, direct or indirect, accrued, contingent or potential, that Employee ever had or now has, including but not limited to any claims arising out of or related to his employment with the Company and the end thereof (except where and to the extent that such a release is expressly prohibited or made void by law). The release includes, without limitation, Employee's release of the Company and the Company Parties from any claims for lost wages or benefits, stock options, restricted stock, restricted stock units, compensatory damages, punitive damages, attorneys' fees and costs, equitable relief or any other form of damages or relief. In addition, this release is meant to release the Company and the Company Parties from all common law claims, including claims in contract or tort, including, without limitation, claims for breach of contract, wrongful or constructive discharge, intentional or negligent infliction of emotional distress, misrepresentation, tortious interference with contract or prospective economic advantage, invasion of privacy, defamation, negligence or breach of any covenant of good faith and fair dealing. Employee also specifically and forever releases the Company and the Company Parties (except where and to the extent that such a release is expressly prohibited or made void by law) from: all claims under North Carolina laws prohibiting discrimination, harassment and retaliation and all similar state and local laws; all claims under laws governing the payment of wages or protection of workers seeking payment for work performed and any other federal, state or local statutory and/or common laws governing the payment of wages; and/or and all claims under federal law based on unlawful employment discrimination, harassment or retaliation, including, but not limited to, claims for violation of Title VII of the Civil Rights Act, the Americans with Disabilities Act, the Genetic Information and Discrimination Act, and the Federal Age Discrimination In Employment Act.

Employee acknowledges that this release applies both to known and unknown claims that may exist between Employee and the Company and the Company Parties. Employee expressly waives and relinquishes all rights and benefits which Employee may have under any state or federal statute or common law principle that would otherwise limit the effect of this Final Release to claims known or suspected prior to the date Employee executes this Final Release, and Employee does so understanding and acknowledging the significance and consequences of such specific waiver. In addition, Employee hereby expressly understands and acknowledges that it is possible that unknown losses or claims exist or that present losses may have been underestimated in amount or severity, and Employee explicitly took that into account in giving this release.

Notwithstanding the foregoing, nothing in this Final Release prohibits Employee from filing a charge with, or participating in any investigation or proceeding conducted by, the U.S. Equal Employment Opportunity Company or a comparable state or federal fair employment practices agency; provided, however, that this Final Release fully and finally resolves all monetary matters between Employee and the Company and the Company Parties, and by signing this Final Release, Employee is waiving any right to monetary damages, attorneys' fees and/or costs related to or arising from any such charge, complaint or lawsuit filed by Employee or on Employee's behalf, individually or collectively. In addition, nothing in this Final Release extinguishes any claims Employee may have against the Company for breach of this Final Release or any claims arising from events that occur following the effective date of this Final Release.

2. No Modifications; Governing Law; Entire Agreement. This Agreement cannot be changed or terminated verbally, and no modification or waiver of any of the provisions of this Agreement will be effective unless it is in writing and signed by both parties. The parties agree that this Agreement is to be governed by and construed in accordance with the laws of the State of North Carolina, and that any suit, action or charge arising out of or relating to this Agreement will be adjudicated in the state or federal courts in Wake County, North Carolina. Together with the Agreement and the surviving provisions of the Employment Agreement (as that term is defined in the Agreement), this Final Release sets forth the entire and fully integrated understanding between the parties, and there are no representations, warranties, covenants or understandings, oral or otherwise, that are not expressly set out therein.

3. Miscellaneous.

(a) Should any portion, term or provision of this Final Release be declared or determined by any court to be illegal, invalid or unenforceable, the validity of the remaining portions, terms and provisions shall not be affected thereby, and the illegal, invalid or unenforceable portion, term or provision shall be deemed not to be part of this Final Release.

(b) The parties agree that the failure of a party at any time to require performance of any provision of this Final Release shall not affect, diminish, obviate or void in any way the party's full right or ability to require performance of the same or any other provision of this Final Release at any time thereafter.

(c) This Final Release shall inure to the benefit of and shall be binding upon Employee, his heirs, administrators, representatives, executors, successors and assigns and upon the successors and assigns of the Company.

(d) The headings of the paragraphs of this Final Release are for convenience only and are not binding on any interpretation of this Final Release. This Final Release may be executed in counterparts.

(e) Counterparts may be transmitted and/or signed by facsimile or electronic mail. The effectiveness of any such documents and signatures shall have the same force and effect as manually signed originals and shall be binding on the parties to the same extent as a manually signed original thereof.

(f) This Agreement, and the surviving provisions of the Employment Agreement, set forth the entire and fully integrated understanding between the Parties, and there are no representations, warranties, covenants or understandings, oral or otherwise, that are not expressly set out therein.

[Signatures follow on next page.]

TENAX THERAPEUTICS, INC.

By: _____

Name: _____

Title: _____

DATE: _____

Michael B. Jebsen (SEAL)

DATE: _____

CONSULTING AGREEMENT

This Consulting Agreement (the "Agreement") is entered into as of the 14th day of October, 2021, by and between Tenax Therapeutics, Inc. a Delaware corporation with its principal place of business in North Carolina ("the "Company"), and Michael B. Jebsen, a resident of North Carolina ("Consultant"). The Company and Consultant are sometimes referred to herein each as a "Party," and together as the "Parties."

WHEREAS, the Company desires to engage Consultant to provide services to the Company as a Special Advisor to the Company's Chief Executive Officer subject to the terms and conditions of this Agreement; and

WHEREAS, Consultant desires to provide those services to the Company subject to the terms and conditions of this Agreement;

NOW, THEREFORE, for and in consideration of the premises and mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and subject to the terms and conditions hereinafter set forth, the Parties hereto enter into this Agreement and agree as follows.

1. SERVICES. The services to be performed by Consultant as Special Advisor to the Chief Executive Officer under this Agreement will be as set forth on Exhibit A attached hereto and are hereafter referred to as the "Services." Consultant agrees to perform the Services in a timely and professional manner and at the direction of the Company's Chief Executive Officer.

2. TERM. The term of this Agreement will be for a period beginning as of October 29, 2021 (the "Effective Date") and continuing for six (6) months unless earlier terminated pursuant to Section 4 of this Agreement (the "Term"). The Term may be extended upon mutual agreement of the Parties.

3. COMPENSATION. During the Term of this Agreement, the Company will pay Consultant fees for the Services in accordance with the fee schedule that is attached to this Agreement as Exhibit B (the "Consultant Fees"). Consultant will submit monthly invoices to the Company detailing the Services provided, and the Company will make payments of the Consultant Fees earned on or before the tenth (10th) business day after receipt of such invoices. By signing this Agreement, Consultant acknowledges and agrees that he is solely responsible for payment of all required taxes on the Consultant Fees.

4. TERMINATION.

a. Termination by Notice. At any time during the Term, either Party hereto may terminate this Agreement by providing at least thirty (30) days advance written notice of termination to the other Party ("Termination by Notice"). Upon Termination by Notice, the Company will pay Consultant only that portion of the Consultant Fees due to Consultant for Services performed through the effective date of the termination.

b. Termination for Cause. At any time during the Term, the Company may terminate this Agreement immediately and without advanced notice for "Cause." For purposes of this Agreement, "Cause" shall mean and include: (i) Consultant's material breach of this Agreement; (ii) Consultant's commission of a felony or crime involving moral turpitude; (iii) any act by Consultant involving dishonesty in the performance of the Services, including, without limitation, fraud, misappropriation or embezzlement; (iv) Consultant's repeated failure or refusal to perform the Services; or (v) any willful or grossly negligent act or omission by Consultant that is injurious to the Company or the Company, including injury to the Company's reputation. If the Company terminates this Agreement for Cause, the Company will pay Consultant only that portion of the Consultant Fees due to Consultant for Services performed through the effective date of the termination.

c. Other Termination. This Agreement shall terminate immediately upon Consultant's death or "Disability." For purposes of this Agreement, "Disability" is defined as Consultant's inability due to a physical or mental impairment to perform the Services for a period of thirty (30) consecutive days. If this Agreement is terminated due to Consultant's death or Disability, the Company will pay Consultant only that portion of the Consultant Fees due to Consultant for Services performed through the effective date of the termination.

5. Independent Contractor Status. During the Term, Consultant will be an independent contractor and not the Company's employee for any purpose, including, but not limited to, the application of the Fair Labor Standards Act's minimum wage and overtime provisions, the Federal Insurance Contribution Act, the Social Security Act, the Federal Unemployment Tax Act, the provisions of the Internal Revenue Code, and all federal, state and local laws and regulations. Consultant understands that the Company will not be responsible for withholding or paying any federal or state income, social security or other taxes in connection with any compensation paid under this Agreement, and Consultant agrees to pay all such taxes when due. The Company will provide Consultant with a Form 1099 to the extent required by law. Consultant hereby agrees to indemnify and hold the Company harmless from any and all claims, causes of action or other proceedings related to or resulting from Consultant's failure to pay taxes in compliance with applicable law. Consultant further understands and agrees that Consultant will not be entitled to any medical, disability, pension or other employment benefits made available by the Company to its employees. During the Term, Consultant will retain sole and absolute discretion and judgment in the manner and means of carrying out the Services. Consultant further agrees that during the Term, he has a full opportunity to find other business (so long as such other business is not in violation of this Agreement), and that he will use a high level of skill necessary to perform the Services. During the Term, Consultant will not have the authority to enter into any contract on behalf of the Company or otherwise to bind the Company to any agreement unless expressly authorized in writing to do so, and the Company will not be liable for any obligation incurred by Consultant during the Term. During the Term, Consultant shall indemnify and hold the Company harmless from all claims, losses, injuries or damages, and wages or any other form of compensation (including, without limitation, reasonable attorneys' fees and costs) arising in connection with any claim, suit or proceeding alleging that Consultant has or had a relationship with the Company other than an independent contracting relationship during the Term.

6. NO CONFLICTING OBLIGATIONS. Consultant hereby represents that his agreement to the terms of this Agreement will not breach any prior agreement not to compete or solicit customers or employees or to keep in confidence any proprietary information acquired by Consultant in confidence or in trust prior to the execution of this Agreement. Consultant further represents that he has not entered into, and agrees he will not enter into, any agreement, either written or oral, in conflict with this Agreement.

7. WAIVER OF BREACH. Any waiver by the Company of a breach of any provision of this Agreement will not operate as a waiver of any subsequent breach of that provision or any other provision of this Agreement.

8. CHOICE OF LAW; VENUE. This Agreement is to be governed by the laws of the State of North Carolina without regard to its choice of law provisions. The Parties agree that any litigation arising out of or related to this Agreement will be brought exclusively in any state or federal court in Wake County, North Carolina. Each Party (i) consents to the personal jurisdiction of said courts, (ii) waives any venue or inconvenient forum defense to any proceeding maintained in such courts, and (iii) agrees not to bring any proceeding arising out of or relating to this Agreement or Consultant's engagement by the Company in any other court.

9. COMPLETE AND FINAL AGREEMENT. This Agreement, including any exhibits, represents the complete and final agreement of the Parties and will control over any other statement, representation or agreement by the Company. This Agreement supersedes any prior negotiations or discussions between the Parties with regard to the subject matter hereof. This Agreement may be amended only in a writing signed by each of the Parties hereto.

10. HEADINGS. The headings or titles to the paragraphs of this Agreement are solely for convenience of reference and shall be ignored when interpreting this Agreement.

11. SEVERABILITY AND CONSTRUCTION. Should any part of this Agreement be declared invalid for any reason by any court of competent jurisdiction, such decision or determination shall not affect the validity of any remaining portion, and such remaining portion shall remain in force and effect as if this Agreement had been executed with the invalid portion eliminated; provided, that, in the event of a declaration of invalidity, the provision declared invalid shall not be invalidated in its entirety, but shall be observed and performed by the Parties to the extent such provision is valid and enforceable. The Parties hereby agree that any such provision shall be deemed to be altered and amended to the extent necessary to effect such validity and enforceability.

12. VOLUNTARY EXECUTION. Consultant hereby acknowledges that he has read the foregoing Agreement, that he understands its contents, and that he has relied upon or had the opportunity to seek the legal advice of his attorney, who is the attorney of his choosing.

13. COUNTERPARTS. This Agreement may be executed in any number of counterparts and all of such counterparts shall for all purposes constitute one and the same instrument.

14. NOTICES. All notices or demands by any Party relating to this Agreement shall be in writing and shall be deemed effectively given: (a) upon person delivery to the Party to be notified; (b) five (5) days after having been sent by registered mail, postage prepaid, return receipt requested; or (c) one (1) day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt, at its addresses set forth below:

If to the
Company: Tenax Therapeutics, Inc.

 ONE Copley Parkway, Suite 490

 Morrisville, NC 27560

 Attention: Christopher T. Giordano

If to Consultant: Michael B. Jebsen

The Parties hereto may change the address at which they are to receive notice hereunder, by notice in writing in the foregoing manner given to the other.

[Signature page follows.]

IN WITNESS WHEREOF, each of the Parties hereto acknowledges having read and understood the contents and effect of this Agreement and has executed this Agreement freely and with full authority duly given, all as of the date first above written.

THE COMPANY:

TENAX THERAPEUTICS, INC.

By: /s/ Christopher T. Giordano

Name: Christopher T. Giordano

Title: Chief Executive Officer

CONSULTANT:

 /s/ Michael B. Jebsen

(SEAL)

Michael B. Jebsen

EXHIBIT A

THE "SERVICES" DEFINED

Consultant shall make himself available to the Company's Chief Executive Officer for special projects and requests. Consultant shall be expected to devote no more than twenty (20) hours per week in performing the Services. The Services will include:

- Assist with questions related to daily operations of the accounting department
 - Assist with processes and procedures related to filing financial statements and other documents with the SEC
 - Assist with other accounting and finance related questions as they arise
 - Any other reasonable assistance to the Company, including to the Chief Financial Officer, as requested by the Chief Executive Officer
-

EXHIBIT B

CONSULTANT FEES

Consultant will receive Consulting Fee at the rate of Two Hundred And Seventy-Five Dollars (\$275.00) per hour.

SUBSIDIARIES OF TENAX THERAPEUTICS, INC.

Company Name	Jurisdiction
Life Newco, Inc.	Delaware
PHPrecisionMed Inc.	Delaware

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-167175, 333-196464, 333-210182, 333-224120, 333-233571, and 333-259266), Form S-3 (Nos. 333-248201 and 333-258981), and Form S-1 (No. 333-228212) of our report dated March 29, 2022 included in this Annual Report on Form 10-K of Tenax Therapeutics, Inc. and Subsidiaries (the “Company”), relating to the consolidated balance sheets of the Company as of December 31, 2021 and 2020, and the related consolidated statements of operations and comprehensive loss, stockholders’ equity, and cash flows, and the related notes (which report expresses an unqualified opinion and contains an explanatory paragraph regarding substantial doubt about the Company’s ability to continue as a going concern) for each of the years in the two-year period ended December 31, 2021.

/s/ CHERRY BEKAERT LLP

Raleigh, North Carolina

March 29, 2022

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Christopher T. Giordano, certify that:

1. I have reviewed this Annual Report on Form 10-K of Tenax Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 29, 2022

By: /s/ Christopher T. Giordano
Christopher T. Giordano
President and Chief Executive Officer
(Principal Executive Officer)

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Eliot M. Lurier, certify that:

1. I have reviewed this Annual Report on Form 10-K of Tenax Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 29, 2022

By: /s/ Eliot M. Lurier

Eliot M. Lurier
Interim Chief Financial Officer
(Principal Financial Officer)

**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, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Christopher T. Giordano, President and Chief Executive Officer (Principal Executive Officer) of the Company, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

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

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

Date: March 29, 2022

/s/ Christopher T. Giordano

Christopher T. Giordano

President and Chief Executive Officer

(Principal Executive Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 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.

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

In connection with the Annual Report of Tenax Therapeutics, Inc. (the "Company") on Form 10-K for the period year December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Eliot M. Lurier, Interim Chief Financial Officer (Principal Financial and Accounting 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, to my knowledge:

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

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

Date: March 29, 2022

/s/ Eliot M. Lurier

Eliot M. Lurier

*Interim Chief Financial Officer
(Principal Financial and Accounting Officer)*

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 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.