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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2022

OR

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

For the transition period from ____ to _____

Commission File No. 001-34600

TENAX THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

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

101 Glen Lennox Drive, Suite 300, Chapel Hill, North Carolina 27517
(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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

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

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by checkmark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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 common equity held by non-affiliates computed by reference to the price at which the common equity was last sold as of June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter, was $5,004,960.

The number of shares outstanding of the registrant's class of $0.0001 par value common stock as of March 28, 2023 was 22,398,546.

On January 4, 2023, the registrant effected a 1-for-20 reverse stock split (the "Reverse Stock Split"). The Reverse Stock Split did not change the number of authorized shares of the registrant's capital stock or cause an adjustment to the par value of the registrant's capital stock. However, all other share amounts and references to stock prices in this Annual Report on Form 10-K have been retrospectively restated to reflect the reverse split. Pursuant to their terms, a proportionate adjustment also was made to the per share exercise price and number of shares issuable under the registrant's outstanding stock options and warrants and to the number of shares authorized for issuance pursuant to the registrant's equity incentive plans to reflect the Reverse Stock Split. The Company also has adjusted the financial statements in this Annual Report on Form 10-K to reflect the Reverse Stock Split.

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 2023 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, 2022.

TABLE OF CONTENTS

Table of Contents

PART I

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains various forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which represent our expectations or beliefs concerning future events. Forward-looking statements include statements that are predictive in nature, which depend upon or refer to future events or conditions, and/or which include words such as "believes," "plans," "intends," "anticipates," "estimates," "expects," "may," "will" or similar expressions. In addition, any statements concerning future financial performance, ongoing strategies or prospects, and possible future actions, including any potential strategic transaction involving us, which may be provided by our management, are also forward-looking statements. These statements are not guarantees of future performance, and we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by law.

Forward-looking statements are based on current expectations and projections about future events, actual events and results may differ materially from those expressed or forecasted in forward-looking statements due to a number of factors. You should understand that the following important factors, in addition to those discussed in under the heading "*Risk Factors*" included in Item 1A of Part I of this Annual Report on Form 10-K and in any of our filings with the U.S. Securities and Exchange Commission (the "SEC") pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, could affect our stock price or future results and could cause those results to differ materially from those expressed in such forward-looking statements:

- our ability to raise additional money to fund our operations for at least the next 12 months as a going concern;
- our ongoing evaluation of strategic alternatives;
- our ability to develop our current product candidates, and any product candidate which we may develop or in-license in the future;
- our ability, our partners' abilities, and third parties' abilities to protect and assert intellectual property rights;
- delays in the commencement, enrollment and completion of clinical testing, as well as the analysis and reporting of results from such clinical testing;
- the success of clinical trials of our product candidates;
- the need to obtain regulatory approval of our product candidates;
- potential risks related to any collaborations we may enter into for 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;
- our estimates regarding the potential market opportunity for our product candidates;
- 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 dependence on third-party manufacturers and clinical research organizations ("CROs");
- our ability to establish or maintain collaborations, licensing or other arrangements;
- 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 personnel, including our executive team, 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, any future epidemic, and geopolitical uncertainties, including the Russian invasion of and war against the country of Ukraine.

Table of Contents

The forward-looking statements in this Annual Report on Form 10-K represent our views as of the date such statements are made. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date such statements are made.

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 are not the only risks 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's report includes an explanatory paragraph stating that there is substantial doubt about our ability to continue as a going concern.
- We will require substantial additional funding to further develop our product candidates, including to complete any Phase 3 trials. Failure to obtain this necessary capital when needed on acceptable terms, or at all, or execute on alternative strategic paths, could force us to delay, limit, reduce or terminate our clinical trials, product development efforts and business operations.
- Our ongoing exploration of alternative strategic paths may not result in entering into or completing transactions, and the process of reviewing alternative strategic paths or their conclusion could adversely affect our stock price.
- In the event we do not successfully complete a strategic transaction, should this be deemed necessary, our Board of Directors may decide to pursue a dissolution and liquidation of our Company.
- Our failure to maintain compliance with Nasdaq's continued listing requirements could result in the delisting of our Common Stock.
- 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.
- We have incurred losses since our inception, expect to continue to incur losses in the foreseeable future, and may never become profitable.

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 another coronavirus or similar disrupting illness, may materially and adversely affect our business and our financial results.
- If we fail to attract and retain personnel, we may be unable to successfully develop and commercialize our product candidates.

Risks Related to Drug Development and Commercialization
- We currently do not have, and may never have, an approved drug products for sale.
- 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.
- Nonfinal results from our clinical trials announced or published from time to time on an interim, preliminary, or "top-line" basis, and conclusions drawn from these nonfinal results, 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.
- 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.
- Pending the outcome of our strategic process, 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.

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, which is expensive and time consuming, and we will not be able to sell our products without regulatory approval.

Table of Contents

- Pending the outcome of our strategic process, we may not receive all of the anticipated market exclusivity benefits of imatinib's orphan drug designation.
- Pending the outcome of our strategic process, even after products are commercialized, we would 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.

Risks Related to Our Dependence on Third Parties
- We have historically, and pending the outcome of our strategic process, we will continue to 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 to, or use, our technology.
- Under current law, we may not be able to enforce all employees' covenants not to compete.
- We may infringe or be alleged to infringe intellectual property rights of third parties.

Risks Related to Owning Our Common Stock
- Anti-takeover provisions in our corporate charter documents and under Delaware law could make an acquisition of us more difficult.
- Our bylaws contain an exclusive forum provision for certain disputes, 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. Any return on investment may be limited to the value of our common stock.
- 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

Having carefully considered alternatives within the ongoing strategic process announced in September 2022, and having raised capital to fund the Company through to the first quarter of 2024, the Company has recently elected to prioritize the Phase 3 testing of levosimendan, ahead of imatinib, with plans to commence a levosimendan Phase 3 study in 2023. Supporting this strategic decision is a U.S. Patent issued in March 2023, covering the use of IV levosimendan in patients with PH-HFpEF. This patent is the second levosimendan patent granted to Tenax since the start of 2022, and Tenax believes it provides strong precedent for the ongoing review of a third patent which might be granted in 2023 or 2024. This prioritization of the Phase 3 testing of levosimendan places the start of a Phase 3 imatinib trial likely outside the 2023 timeframe, pending fundraising to support that trial, as well as other strategic considerations.

The Company took steps to reduce its monthly operating expenses and conserve cash, as it commenced exploring strategic alternatives. The Company has cancelled substantially all of its non-essential operating expenses such as consulting, its office lease, and dues and subscriptions and office supplies associated with that leased office.

Prior to announcing the strategic process, our principal business objective has been to identify, develop, and commercialize late-stage pharmaceutical therapeutic products for serious cardiovascular and pulmonary diseases with high unmet medical need. The Company has been developing TNX-103 (oral levosimendan) for the treatment of Pulmonary Hypertension with Heart Failure with Preserved Ejection Fraction (PH-HFpEF) and TNX-201 (modified release imatinib) for the treatment of pulmonary arterial hypertension (PAH). Both TNX-103 and TNX-201 are Phase 3-ready assets, each with the potential to meaningfully impact the quality and longevity of patient lives.

Pending the outcome of our strategic process, the key elements of our long-term business strategy are outlined below.

Table of Contents

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 around the world 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 either one or two Phase 3 trials of levosimendan and, when appropriate, a single Phase 3 trial of imatinib. 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 biostatisticians and trialists, medical leaders, formulation 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 when designing and executing our research.

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 the two decades following its approval. Our own Phase 2 study and open-label extension has demonstrated that a formerly under-appreciated mechanism of action of levosimendan, its property of relaxing the venous circulation, brings about durable improvements 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 (the “FDA”) of these product candidates based on positive Phase 3 data. Through our agreement with our licensor, Orion Corporation (“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 we hope to generate in at least one indication, will support FDA approval of levosimendan. 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 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 help protect its value. Our research and development efforts, both through internal activities and through collaborative research activities with others, 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. On March 21, 2023, we received our second patent for this product, covering the IV formulation of levosimendan (TENX-101) tested in the Phase II HELP trial in patients with PH-HFpEF. At present, we have two patents pending, with additional decisions expected in 2023.

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.

Table of Contents

Our Current Programs

TNX-101 (IV), TNX-102 (subcutaneous) and TNX-103 (oral) ((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.

Several studies have demonstrated that levosimendan protects the heart and improves tissue perfusion while minimizing tissue damage during cardiac surgery.

In 2013, we acquired certain assets of Phyxius Pharma, Inc. (“Phyxius”), 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-101 (IV), TNX-102 (subcutaneous) and TNX-103 (oral) (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 (“mPAP”) of ≥25 mmHg, and a pulmonary capillary wedge pressure “(PCWP”) of >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.

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 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 pulmonary capillary wedge pressure ("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, 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.

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 three minutes or until the patient tired). In the initial open-label phase, 84% of the patients had a significant reduction in right atrial pressure ("RAP"), pulmonary artery pressure, ("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.

Following their completion of the randomized treatment phase of the HELP trial, patients were able to enter a study extension. For over two years, Tenax and our HELP investigators continued 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 ("OLE"). We expect the OLE to come to a conclusion in the first half of 2023.

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 only need meet the minimum International Clinical Harmonization (ICH) standards for a chronic medication.

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 ("HFpEF") patients or PH-HFpEF patients. Instead, all previous levosimendan heart failure studies have enrolled heart failure patients with reduced ejection fraction ("HFrEF"), therefore specifically excluding 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 five 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 two 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 ("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.

Table of Contents

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 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 approved 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 ("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.

Current TNX-201 Development for Pulmonary Arterial Hypertension Patients

On May 30, 2019, PHPrecisionMed Inc., a Delaware corporation ("PHPM"), which was to be 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. This formulation was later optimized in preparation for a second Phase 1 study, completed in the second quarter of 2022. A Phase 3 study of TNX-201, this optimized modified release formulation of imatinib, would be the next clinical trial to commence in Tenax' development planning, pending the outcome of our strategic process and funding of the trial costs.

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 potential future clinical trials, and relied on such contractors for material contributing to TNX-201, for testing in our two completed Phase 1 trials.

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 (“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 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 two granted patents, and two U.S. patent applications pending, related to product candidates and proprietary process, method and technology. Our issued levosimendan patents expire in 2039 and late 2040.

On January 4, 2022, we received a patent 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 received on March 21, 2023 a patent for the use of IV levosimendan in the treatment of PH-HFpEF patients, based on several discoveries that have emerged from the HELP Study and the OLE.

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. Comprehensive risks related to our intellectual property are described under the heading “Risk Factors - Risks Related to Our Intellectual Property” included elsewhere in this Annual Report on Form 10-K.

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 (the “Territory”) 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 (together, the “Product”). 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.

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 cardiovascular, pulmonary, and related medical conditions, both rare and common. 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-101/102/103 (levosimendan) to treat patients with PH-HFpEF is novel, and the patent granted for this use in March 2023 demonstrates USPTO's concurrence. 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 (imatinib) 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 seven years of Orphan Drug exclusivity in the U.S., these alternative formulations of imatinib represent potential competitive threats.

Table of Contents

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

Government Regulation

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

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

The effects of government regulations on our business are discussed under the heading "Risk Factors - Risks Relating to Regulatory Matters" included elsewhere in this Annual Report on Form 10-K.

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, 2022, we had seven full-time employees and one part-time employee. In addition to our employees, we also rely on the service and support of outside consultants and advisors. None of our employees are represented by a union, and we believe relationships with our employees are good.

Available Information

Our website address is *www.tenaxthera.com*, and our investor relations website is located at *http://investors.tenaxthera.com*. Information on our website is not incorporated by reference herein. Copies of our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and our proxy statements for our 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.

Table of Contents

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's 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 elsewhere 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 for the fiscal year ended December 31, 2022 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 will require substantial additional funding to further develop our product candidates, including to complete Phase 3 testing of levosimendan in PH-HFpEF or to initiate or complete the imatinib Phase 3 trial. Failure to obtain this necessary capital when needed on acceptable terms, or at all, or execute on alternative strategic paths, could force us to delay, limit, reduce or terminate our clinical trials, product development efforts and business 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 studies additional to those we currently anticipate, in which case the timing of any potential product approval may be delayed.

As of December 31, 2022, we had $2.1 million of cash and cash equivalents on hand. We will need substantial additional capital in order to develop our product candidates, including to complete a Phase 3 trial, and to complete the regulatory approval process and commercialization of levosimendan, imatinib, or any future product candidates. As a result, we continue to evaluate strategic alternatives, including pursuing additional public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Such funding may not be available on favorable terms, if at all.

In addition, to the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional significant dilution; 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.

Table of Contents

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 and the impact that factors such as the rate of patient recruitment, the standard deviation of treatment effect, and the number of patients who have events or withdraw from therapy have on the expected timelines and the eventual required number of patients enrolled 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 also expect to continue our evaluation of additional strategic alternatives, including a sale of our Company, merger, other business combination or recapitalization. In the event we are unable to obtain additional capital as needed or execute on other strategic alternatives, we may further delay, limit, reduce or terminate our current development efforts and business operations.

Table of Contents

Our ongoing exploration of alternative strategic paths may not result in entering into or completing transactions, when necessary, and the process of reviewing alternative strategic paths or their conclusion could adversely affect our stock price.

We continue to evaluate strategic paths to provide the resources necessary to complete our product development and maximize stockholder value. Potential strategic paths may include multiple capital raises, a sale of our Company, merger, one or more license agreements, a co-development agreement, a combination of these, or other strategic transactions. There can be no assurance, however, that our evaluation will result in transactions or other alternatives, even when deemed necessary. There is no set timetable for our strategic process and we do not intend to provide updates unless or until the Board of Directors approves a specific action or otherwise determines that disclosure is appropriate or necessary. We have shifted the anticipated launch of the imatinib Phase 3 trial in PAH beyond 2023, and the initiation of that trial and continued development of our product candidates, including completion of a Phase 3 trial of levosimendan in PH-HFpEF, depend on the outcome of our ongoing strategic process.

There can be no assurance any transaction will result from the Company's ongoing evaluation of strategic paths. Any potential transaction would be dependent on a number of factors that may be beyond our control, including, among other things, market conditions, industry trends, the interest of third parties in a potential transaction with us, obtaining stockholder approval and the availability of financing to third parties in a potential transaction with us on reasonable terms. The process of reviewing alternative strategic paths may be time consuming and may involve the dedication of significant resources and may require us to incur significant costs and expenses. It could negatively impact our ability to attract, retain and motivate employees, and expose us to potential litigation in connection with this process or any resulting transaction. If we are unable to effectively manage the process, our financial condition and results of operations could be adversely affected. In addition, speculation regarding any developments related to the review of strategic alternatives and perceived uncertainties related to the future of our Company could cause our stock price to fluctuate significantly. Further, any alternative strategic paths that may be pursued and completed ultimately may not deliver the anticipated benefits or enhance stockholder value. There can be no guarantee that the process of evaluating alternative strategic paths will result in our Company entering into or completing potential transactions within the anticipated timing or at all.

Table of Contents

In the event we do not successfully complete a strategic transaction, should this be deemed necessary, our Board of Directors may decide to pursue a dissolution and liquidation of our Company. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no guarantee that the process to identify strategic transactions will result in successfully completed transactions when necessary. If additional transactions are not completed that enable us to continue the development of our product candidates and sustain our business operations, our Board of Directors may decide that it is in the best interest of our stockholders to dissolve our Company and liquidate our assets. In that event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, ultimately, such liquidation since the amount of cash available for distribution continues to decrease as we fund our operations and evaluate our strategic alternatives. In addition, if our Board were to approve and recommend, and our stockholders were to approve, a dissolution of our Company, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of our Company. If a dissolution and liquidation were pursued, our Board, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a dissolution, liquidation or winding up of our Company.

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 March 29, 2023, we received a notification letter from the Nasdaq Stock Market LLC ("Nasdaq") 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), the Company has a compliance period of 180 calendar days, or until September 25, 2023, to regain compliance with the Bid Price Rule. If at any time before September 25, 2023, the bid price of the Company's common stock closes at $1.00 per share or more for a minimum of ten consecutive business days, Nasdaq will provide the Company with a written confirmation of compliance with the Bid Price Rule.

While we intend to engage in efforts to regain compliance, and thus maintain our listing, there can be no assurance that we will be successful or continue to meet all applicable Nasdaq Capital Market requirements in the future. If our common stock were to be 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.

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

Table of Contents

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 raise additional money to fund our operations for at least the next 12 months as a going concern;
- our ongoing evaluation of strategic alternatives;
- our ability to develop our current product candidates, and any product candidate which we may develop or in-license in the future;
- delays in the commencement, recruitment and initiation of sites, enrollment of patients, and completion of clinical testing, as well as the analysis and reporting of results from such clinical testing;
- the success of clinical trials of our product candidates;
- the need to obtain regulatory approval of our product candidates;
- potential risks related to any collaborations we may enter into for 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 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 personnel, including our executive team, advisors and members of our Board of Directors; and
- volatility and uncertainty in the global economy and financial markets in light of the possibility of pandemics, global financial and geopolitical uncertainties, including the Russian invasion of and war against the country of Ukraine.

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

We 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, 2022 and 2021, we incurred net operating losses of $11.0 million and $32.7 million, respectively. 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 and other potential indications,, imatinib for PAH, 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.

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 our resources on developing levosimendan for the treatment of PH-HFpEF, while imatinib for the treatment of PAH remains part of our portfolio. We intend to commit most of our resources to advancing levosimendan to the point it receives regulatory approval for the treatment of pulmonary hypertension in patients with associated HFpEF. Depending on the funds raised and timing of the funding, as well as on decisions made by USPTO, clinical trial results and other information revealed by competitors, and other factors, we will prioritize our funding and other resources. Pending the outcome of our strategic process, 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.

Table of Contents

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 healthcare systems and has previously had an adverse impact on our business operations. COVID-19 or a similar global pandemic could in the future, directly or indirectly, materially and adversely affect our operations, including the potential interruption of our clinical trial activities and our supply chain. There could be continuing or new effects of COVID-19 or similar disrupting illnesses to the processes, timelines, resourcing, and other aspects of operations at FDA or other health authorities, which could result in delays of reviews and approvals, including with respect to our product candidates.

Additionally, the continued spread of COVID-19 or similar disrupting illnesses could adversely affect our future 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 respiratory illnesses if an outbreak occurs in their geography. 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.

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 five 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.

We face 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 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 an existing 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 insourcing and outsourcing strategies, which have 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 ("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, 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 in the short-term to completing a Phase 3 trial of levosimendan and advancing this product to regulatory approval for use in PH-HFpEF, and potentially other indications. We may in future commit resources to clinical trials for our other product candidates, including imatinib. 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.

Nonfinal results from our clinical trials announced or published from time to time on an interim, preliminary, or "top-line" basis, and conclusions that may be drawn from such results, 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 and complete 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.

Pending the outcome of our strategic process, 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:

- 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 ("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;
- collecting, analyzing and reporting final data from the clinical trials; and
- an epidemic 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;

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

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

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

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 areas 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, potentially in the future, 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 levosimendan, 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, if we prioritize imatinib development in the future.

TNX-201, our 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.

Pending the outcome of our ongoing strategic process, even after products are commercialized, we would 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 would 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.

Pending the outcome of our ongoing strategic process, 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.

Table of Contents

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.

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 our formulation of 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 $5 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.

Table of Contents

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 have historically, and pending the outcome of our ongoing strategic process, we will continue to 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 have historically, and pending the outcome of our strategic process, we will continue to 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.

Table of Contents

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.

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.

To potentially manufacture imatinib in the future, we have contracted with various third-party suppliers and clinical manufacturing organizations ("CMOs") making us highly dependent on these CMOs. We do not at present have alternative CMOs planned or contracted 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.

We currently have no marketing capabilities and no sales organization. Pending the outcome of our ongoing strategic process, 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.

Pending the outcome of our strategic process, 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.

Table of Contents

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.

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 various uses and formulations of levosimendan In January 2022, the USPTO granted Tenax Therapeutics a patent protecting claims for different uses of various cyclodextrin-based subcutaneous formulations of levosimendan, including a claim for its use in the treatment of PH-HFpEF patients. In addition, we received in March 2023 another patent protecting the use of levosimendan in treatment of PH-HFpEF.

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 patent applications to cover patentable subject matter that may result from 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.

Table of Contents

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

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

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

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

Our policy is to enter 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.

Table of Contents

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

patent and/or that the patent claims are invalid, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents by others covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the U.S. Patent and Trademark Office (the "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.

Table of Contents

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.

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

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;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- 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 epidemics or other disruptive events broadly affecting society, and as a result of geopolitical uncertainties, including the Russian invasion of and war against the country of 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.

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, as amended (the "Charter"), and our Third Amended and Restated Bylaws (the "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.

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 Securities and Exchange Act of 1934, as amended (the "Exchange Act") or the Securities Act of 1933, as amended (the "Securities Act"), or any other claim for which federal courts have exclusive jurisdiction.

Table of Contents

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 declared or paid any cash dividends on shares of our common stock and do not intend to pay any cash dividends in the foreseeable future. We anticipate that we will retain all of our future earnings for use in the development of our business and for general corporate purposes. Any determination to pay dividends in the future will be at the discretion of our Board of Directors. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments.

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 ("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 (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. Beginning November 1, 2022, we maintain a membership providing dedicated office space, as well as shared services and shared space for meetings, catering, and other business activities, at our principal executive office relocated to 101 Glen Lennox Drive, Suite 300, Chapel Hill, North Carolina 27517. The current rent is approximately $750 per month.

On February 7, 2023, we entered into a Lease Termination Agreement with CCP Concourse, LLC, a Virginia limited liability company (the "Landlord") with respect to the Company's prior principal executive office lease (the "Prior Lease). The Prior Lease, as amended, was originally entered into on January 27, 2011 and would have terminated on June 30, 2024. As consideration for the Landlord's entry into the Lease Termination Agreement, including a release of any claims the Landlord may have had against the Company under the Prior Lease, the Company has paid the Landlord $169,867.41. Pursuant to the Lease Termination Agreement, effective February 8, 2023, the Company has no remaining rent or further obligations to the Landlord pursuant to the Prior Lease.

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, 2023:

Name	Age	Position
Christopher T. Giordano	48	President and Chief Executive Officer
Eliot M. Lurier, CPA	64	Interim Chief Financial Officer
Stuart Rich, MD	73	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 medical device and small biotech companies, where he led an executive team that managed 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 operational roles at PPD, Inc., a global clinical research organization. Mr. Giordano holds a B.A. (*summa cum laude*) in English from the 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, MD 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. Beginning July 2015, Dr. Rich has served as Professor of Medicine (and since 2021, Professor Emeritus) at Northwestern University Feinberg School of Medicine. He was co-founder and a Trustee of the Pulmonary Vascular Research Institute from 2006 until 2013, a U.K. based charity. Since July 2015, he has also served as a Director of the Pulmonary Vascular Disease Program at the Bluhm Cardiovascular Institute, a U.K. based charity, and since January 2011, he has served as Director of the Cardiovascular Medical and Research Foundation, a U.S. based charity. He was a standing member of the Cardiovascular and Renal Advisory Committee of the U.S. Food and Drug Administration from 2002 through 2013. 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.

DIRECTORS

Gerald T. Proehl, Director and Chairman
Founder, President, Chief Executive Officer and Chair of the Board of Directors, Dermata Therapeutics, Inc.

June Almenoff, MD, PhD, Director
Chief Medical Officer, RedHill Biopharma Inc.

Michael Davidson, MD, Director
Chief Executive Officer, New Amsterdam Pharma B.V.

Declan Doogan, MD, Director
Co-founder and Chief Medical Officer, Juvenescence Ltd.

Christopher T. Giordano, Chief Executive Officer, President and Director
Tenax Therapeutics, Inc.

Robyn M. Hunter, Director
Global Chief Financial Officer, Sotio Biotech Inc.

Stuart Rich, MD, Chief Medical Officer and Director
Tenax Therapeutics, Inc.

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, 2023, there were approximately 1,339 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, 2022, 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

Business Strategy

Having carefully considered alternatives within the ongoing strategic process announced in September 2022, and having raised capital to fund the Company through to the first quarter of 2024, the Company has recently elected to prioritize the Phase 3 testing of levosimendan, ahead of imatinib, with plans to commence a levosimendan Phase 3 study in 2023. Supporting this strategic decision is a U.S. Patent issued in March 2023, covering the use of IV levosimendan in patients with PH-HFpEF. This patent is the second levosimendan patent granted to Tenax since the start of 2022, and Tenax believes it provides strong precedent for the ongoing review of a third patent which may be granted in 2023 or 2024. This prioritization of the Phase 3 testing of levosimendan places the start of a Phase 3 imatinib trial likely outside the 2023 timeframe, pending fundraising to support that trial, as well as other strategic considerations.

The Company took steps to reduce its monthly operating expenses and conserve cash, as it commenced exploring strategic alternatives in late 2022. The Company has cancelled substantially all of its non-essential operating expenses such as consulting, its office lease, and dues and subscriptions and office supplies associated with that leased office.

Pending the outcome of our ongoing strategic process, 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 around the world 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 either one or two Phase 3 trials of levosimendan and, when appropriate, a single Phase 3 trial of imatinib. 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 biostatisticians and trialists, medical leaders, formulation 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 when designing and executing our research.

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 the two decades following its approval. Our own Phase 2 study and open-label extension has demonstrated that a formerly under-appreciated mechanism of action of levosimendan, its property of relaxing the venous circulation, brings about durable improvements in exercise capacity and quality of life, as well as other clinical assessments, in patients with heart failure with 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 FDA of these product candidates based on positive Phase 3 data. Through our agreement with our licensor, 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 we hope to generate in at least one indication, will support FDA approval of levosimendan. 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 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 help protect its value. Our research and development efforts, both through internal activities and through collaborative research activities with others, 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.

Notice of Allowance and Patent

On February 1, 2023, the Company announced it was granted a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for its patent application with claims covering the use of IV levosimendan (TNX-101) in the treatment of PH-HFpEF. This patent was issued on March 21, 2023. At present, we have two patents pending, with additional decisions expected in 2023.
.

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.

As we focus on our strategic process, 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 a going concern. Management has implemented certain cost-cutting measures as described above and is actively exploring a diverse range of strategic options to help drive stockholder value including, among other things, capital raises, a sale of our Company, merger, one or more license agreements, a co-development agreement, a combination of these, or other strategic transactions; however, there is no assurance that these efforts will result in a transaction or other alternative or that any additional funding will be available. 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 complete a strategic transaction or secure additional capital, we may be required to curtail our research and development initiatives and take additional measures to reduce costs.

COVID-19

The COVID-19 pandemic or similar epidemics could in the future, directly or indirectly, adversely impact our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to such illnesses, which could negatively impact our trials, increase our operating expenses, and have a material adverse effect on our financial results. We will continue to assess the potential impact of the COVID-19 pandemic on our business and operations, including our clinical operations and manufacturing activities.

Comparison of Our Results of Operations for the Years Ended December 31, 2022 and 2021

	The year ended December 31,		Increase/(Decrease)
	2022	2021	
Operating expenses			
General and administrative	$ 5,675,231	$ 7,580,847	(1,905,616)
Research and development	5,377,412	25,147,394	(19,769,982)
Total operating expenses	11,052,643	32,728,241	(21,675,598)

General and Administrative Expenses

General and administrative expenses were $5.7 million for the year ended December 31, 2022, compared to $7.6 million for the same period in 2021. 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, 2022 and 2021, respectively, are as follows:

	Year ended December 31,		Increase/ (Decrease)	% Increase/ (Decrease)
	2022	2021		
Personnel costs	$ 2,370,362	$ 4,952,334	$ (2,581,972)	(52)%
Legal and professional fees	2,369,126	1,770,483	598,643	34%
Other costs	782,023	698,473	83,550	12%
Facilities	153,720	159,557	(5,837)	(4)%

Personnel costs decreased approximately $2.6 million for the year ended December 31, 2022, compared to the same period in the prior year. The decrease 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 in 2021, 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 $599,000 for the year ended December 31, 2022, 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 $245,000 for the year ended December 31, 2022, as compared to the same period in the prior year. The increase was primarily due to capital market activities and IP related costs.

Professional fees increased approximately $354,000 for the year ended December 31, 2022, compared to the same period in the prior year. The increase was primarily attributable to increased consulting fees offset by a decrease in accounting, capital markets, and investor relations costs.

Other costs increased approximately $84,000 for the year ended December 31, 2022, 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, 2022 and 2021.

Table of Contents

Research and Development Expenses

Research and development expenses were $5.4 million for the year ended December 31, 2022 as compared to $25.1 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, 2022 and 2021, respectively, are as follows:

	Year ended December 31,		Increase/ (Decrease)	% Increase/ (Decrease)
	2022	2021		
Clinical and preclinical development	$ 4,657,916	$ 2,653,571	$ 2,004,345	76%
Personnel costs	684,451	689,183	(4,732)	(1)%
Other costs	35,046	21,804,640	(21,769,594)	(100)%

Clinical and preclinical development costs increased approximately $2.0 million for the year ended December 31, 2022 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, the ongoing open label extension phase of this study, costs associated with our intravenous-to-oral levosimendan transition study, and development costs associated with the formulation for imatinib. The increase is primarily attributable to approximately $2.8 million in expenditures for CRO and development costs associated with imatinib offset by decreased costs of approximately $800,000 related to our modified release imatinib.

Personnel costs decreased $4,732 for the year ended December 31, 2022, as compared to the same period in the prior year. The decrease is primarily attributable to increased compensation costs offset by a decrease in annual bonus expense.

Other costs decreased approximately $21.8 million for the year ended December 31, 2022, as compared to the same period in the prior year. The decrease is primarily attributable to the recognition of in-process research and development acquired as part of the merger with PHPM in the prior period. There were no such expenses incurred in the current 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 decreased approximately $246,000 for the year ended December 31, 2022, compared to the same period in the prior year. This increase is due primarily to the forgiveness of our loan pursuant to the Paycheck Protection Program ("PPP Loan") in the prior period.

Liquidity, Capital Resources and Plan of Operation

We have incurred losses since our inception and, as of December 31, 2022, we had an accumulated deficit of approximately $290 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.

Table of Contents

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 approximately $3.2 million and $5.7 million and working capital of approximately $1.4 million and $4.1 million as of December 31, 2022 and December 31, 2021, 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 concluding an open label extension phase of the levosimendan HELP clinical trial, during which patients were transitioned from an intravenous to oral formulation of levosimendan for the treatment of pulmonary hypertension. We are also developing a new formulation of imatinib. Our ability to continue to pursue development of our products beyond the first quarter of calendar year 2024 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 COVID-19 pandemic or a similar epidemic could in the future, directly or indirectly, adversely affect our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to respiratory illnesses 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 February 3, 2023, we sold in a registered public offering (i) an aggregate of 6,959,444 shares of our common stock and pre-funded warrants to purchase an aggregate of 1,707,222 shares of our common stock and (ii) accompanying warrants to purchase up to an aggregate of 17,333,332 shares of our common stock at a combined offering price of $1.80 per share of common stock and associated warrant, or $1.799 per pre-funded warrant and associated warrant, resulting in gross proceeds to the Company of approximately $15.6 million. Net proceeds of the offering were approximately $14.1 million, after deducting the placement agent fees and estimated offering expenses payable by the Company.

On May 17, 2022, we sold 529,802 units in a private placement at a purchase price of $15.50 per unit for net proceeds of approximately $7.9 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, 2021, we sold 238,664 units in a private placement at a purchase price of $41.90 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.

Cash Flows

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

	Year ended December 31,	
	2022	**2021**
Net cash (used in) operating activities	$ (12,012,873)	$ (10,856,203)
Net cash (used in) provided by investing activities	(2,323)	452,609
Net cash provided by financing activities	8,554,956	9,737,275

Table of Contents

Net cash (used in) operating activities

Net cash used in operating activities was approximately $12.0 million for the year ended December 31, 2022 compared to approximately $10.9 million for the year ended December 31, 2021. The increase in cash used for operating activities was primarily due to an increase in our annual insurance premiums, trade accounts payable and accrued compensation as compared to the prior year.

Net cash (used in) provided by investing activities

Net cash used in or provided by investing activities was approximately $(2,323) for the year ended December 31, 2022, compared to approximately $454,000 in the year ended December 31, 2021. The decrease in cash provided by investing activities was primarily due to the purchase of fixed assets in the current period offset by sale of marketable securities in the prior period.

Net cash provided by financing activities

Net cash provided by financing activities was approximately $8.6 million for the year ended December 31, 2022 and is primarily attributable to net proceeds from the sale of stock units in our May 2022 private placement of $7.9 million and the exercise of stock warrants of $0.6 million.

Net cash provided by financing activities was approximately $9.7 million for the year ended December 31, 2021 and is 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.

Operating Capital and Capital Expenditure Requirements

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

- the initiation, progress, timing and completion of clinical trials for our product candidates and potential product candidates;
- the outcome, timing and cost of regulatory approvals and the regulatory approval process;
- delays that may be caused by changing regulatory requirements;
- the number of product candidates 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;
- delays that may be caused by the global coronavirus pandemic or similar global societal disruptions; and
- the possible costs of litigation.

Based on our working capital on December 31, 2022, and the financing completed on February 7, 2023 we believe we have sufficient capital on hand to continue to fund operations through to the first quarter of calendar year 2024.

Table of Contents

We will need substantial additional capital beyond the first quarter of calendar year 2024 and in the future in order to complete the regulatory approval and commercialization of 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, 2022 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.

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.

Table of Contents

Recent Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board, or the 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.

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, 2022, 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.

Table of Contents

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:

- 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, 2022. 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, 2022.

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.

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 2023 Annual Meeting of Stockholders currently scheduled to be held on June 9, 2023, 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 2023 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 available free of charge and 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, if any, concerning compliance with Section 16(a) of the Exchange Act will be 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.

Table of Contents

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, 2022.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuances under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders:			
2022 Stock Incentive Plan	28,163	$ 12.40	77,616
2016 Stock Incentive Plan, as amended	23,373	$ 40.13	--
Amended and Restated 1999 Amended Stock Plan, as amended	936	$ 1,123.00	--
Equity compensation plans not approved by security holders:			
Plan for Employee Inducement Stock Option Grants	25,000	$ 37.50	--
Total	77,472	$ 42.21	77,616

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

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

PART IV

ITEM 15—EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

i. 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.

ii. Financial Statement Schedules:

None.

iii. Exhibit Index

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

		Incorporated by Reference (Unless Otherwise Indicated)			
Exhibit Number	**Exhibit Title**	**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

Table of Contents

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 Stock, dated December 10, 2018.	8-K	001-34600	4.1	December 11, 2018
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	Form of Pre-Funded Warrant (2022)	8-K	001-34600	4.1	May 20, 2022
4.15	Form of Series E Common Stock Warrant (2022)	8-K	001-34600	4.2	May 20, 2022
4.16	Warrant Amendment Agreement, dated as of May 17, 2022, by and between the Company and the Investor	8-K	001-34600	4.3	May 20, 2022
4.17	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
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+	Description of Non-Employee Director Compensation, effective June 15, 2015.	10-Q	001-34600	10.1	September 9, 2015
10.6.1+	2016 Stock Incentive Plan.	10-Q	001-34600	10.1	August 9, 2016
10.6.2+	Amendment No. 1 to 2016 Stock Incentive Plan.	10-Q	001-34600	10.1	August 14, 2019
10.6.3+	Amendment No. 2 to 2016 Stock Incentive Plan.	10-Q	001-34600	10.1	August 16, 2021
10.6.4+	Form of Option issued to Non-Employee Directors under 2016 Stock Incentive Plan.	10-Q	001-34600	10.2	August 14, 2018
10.6.5+	Form of Option issued to Employees and Contractors under 2016 Stock Incentive Plan.	10-Q	001-34600	10.3	August 14, 2018
10.6.6+	Form of Incentive Stock Option Agreement under 2016 Stock Incentive Plan.	10-Q	001-34600	10.4	August 14, 2018
10.7	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
10.8	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
10.9	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

10.10	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
10.11+	Executive Employment Agreement with Dr. Stuart Rich dated January 15, 2021.	8-K	001-34600	10.1	January 19, 2021
10.12	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
10.13	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
10.14+	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
10.15+	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
10.16 +*	Consulting Agreement dated October 14, 2021, by and between Tenax Therapeutics, Inc. and Danforth Advisors, LLC.	10-K	001-34600	10.20	March 29, 2022
10.17	Securities Purchase Agreement for Units, dated as of May 17, 2022, by and between the Company and the Investor	8-K	001-34600	10.1	May 20, 2022
10.18	Registration Rights Agreement, dated as of May 17, 2022, by and between the Company and the Investor	8-K	001-34600	10.2	May 20, 2022
10.19+	Tenax Therapeutics, Inc. 2022 Stock Incentive Plan	8-K	001-34600	10.1	June 10, 2022

10.20+	Form of Tenax Therapeutics, Inc. Notice of Stock Option Grant and Award Agreement	8-K	001-34600	10.2	June 10, 2022
10.21	Waiver dated June 13, 2022	8-K	001-34600	10.1	June 16, 2022
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 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	-	-	-	Furnished herewith
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.

SIGNATURES

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

Date: March 30, 2023

TENAX THERAPEUTICS, INC.
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.

Name	Title	Date
/s/ Christopher T. Giordano Christopher T. Giordano	President and Chief Executive Officer and Director (Principal Executive Officer)	March 30, 2023
/s/ Eliot M. Lurier Eliot M. Lurier	Interim Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 30, 2023
/s/ Gerald Proehl Gerald Proehl	Chairman of the Board and Director	March 30, 2023
/s/ June Almenoff, MD June Almenoff, MD	Director	March 30, 2023
/s/ Michael Davidson, MD Michael Davidson, MD	Director	March 30, 2023
/s/ Declan Doogan, MD Declan Doogan, MD	Director	March 30, 2023
/s/ Robyn M. Hunter Robyn M. Hunter	Director	March 30, 2023
/s/ Stuart Rich, MD Stuart Rich, MD	Director	March 30, 2023

Table of Contents

TENAX THERAPEUTICS, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Table of Contents

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
Tenax Therapeutics, Inc
Chapel Hill, North Carolina

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Tenax Therapeutics, Inc and Subsidiaries (the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31 2022, 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 financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

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

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

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the 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 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 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.

Capital Raise Transaction Involving Equity Instruments

Description of Matter — 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, unregistered pre-funded warrants, and unregistered common stock 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.

How We Addressed the Matter in Our Audit — Our audit procedures included the following:

- 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, 2022.
- 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 30, 2023

Table of Contents

TENAX THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2022	December 31, 2021
ASSETS		
Current assets		
Cash and cash equivalents	$ 2,123,682	$ 5,583,922
Prepaid expenses	738,927	105,078

Other current assets	345,856	-
Total current assets	3,208,465	5,689,000
Right of use asset	179,503	287,692
Property and equipment, net	7,189	7,108
Other assets	9,552	8,435
Total assets	$ 3,404,709	$ 5,992,235
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 448,425	$ 859,638
Accrued liabilities	775,045	704,340
Note Payable	624,302	-
Total current liabilities	1,847,772	1,563,978
Long term liabilities		
Lease liability	64,196	183,589
Total long term liabilities	64,196	183,589
Total liabilities	1,911,968	1,747,567
Commitments and contingencies; see Note 7		
Stockholders' equity		
Preferred stock, undesignated, authorized 4,818,654 shares; See Note 8		
Series A Preferred stock, par value $.0001, issued 5,181,346 shares; outstanding 210, as of December 31, 2022 and December 31, 2021, respectively	-	-
Common stock, par value $.0001 per share; authorized 400,000,000 shares; issued and outstanding 2,291,809 as of December 31, 2022 and 1,260,346 as of December 31, 2021	4,584	2,521
Additional paid-in capital	291,030,237	282,736,332
Accumulated deficit	(289,542,080)	(278,494,185)
Total stockholders' equity	1,492,741	4,244,668
Total liabilities and stockholders' equity	$ 3,404,709	$ 5,992,235

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

Table of Contents

TENAX THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	The year ended December 31,	
	2022	**2021**
Operating expenses		
General and administrative	$ 5,675,231	$ 7,580,847
Research and development	5,377,412	25,147,394
Total operating expenses	11,052,643	32,728,241
Net operating loss	11,052,643	32,728,241
Interest expense	4,443	949
Other income, net	(9,191)	(254,832)
Net loss	$ 11,047,895	$ 32,474,358
Unrealized gain on marketable securities	-	(70)
Total comprehensive loss	$ 11,047,895	$ 32,474,288
Net loss per share, basic and diluted	$ (7.51)	$ (31.56)
Weighted average number of common shares outstanding, basic and diluted	1,471,303	1,028,862

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

Table of Contents

TENAX THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Preferred Stock		Common Stock		Additional paid-in	Accumulated other comprehensive	Accumulated	Total stockholders'
	Number	Amount	Number	Amount				

	of Shares		of Shares		capital	gain (loss)	deficit	equity
Balance at December 31, 2020	**210**	**$ -**	**630,968**	**$ 1,262**	**$ 250,644,197**	**$ (70)**	**$ (246,019,827)**	**$ 4,625,562**
Common stock and preferred stock issued for asset acquisition	10,232	1	94,645	189	21,582,141			21,582,331
Common stock issued for convertible preferred stock	(10,232)	(1)	511,600	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			22,852	46	544,605			544,651
Exercise of stock options			280	1				1
Unrealized loss on marketable securities						70		70
Net loss							(32,474,358)	(32,474,358)
Balance at December 31, 2021	**210**	**$ -**	**1,260,346**	**$ 2,521**	**$ 282,736,332**	**$ -**	**$ (278,494,185)**	**$ 4,244,668**
Pre-funded warrants and warrants sold, net of offering costs					7,928,591			7,928,591
Exercise of pre-funded warrants			1,031,463	2,063				2,063
Compensation on options issued					365,314			365,314
Net loss							(11,047,895)	(11,047,895)
Balance at December 31, 2022	**210**	**$ -**	**2,291,809**	**$ 4,584**	**$ 291,030,237**	**$ -**	**$ (289,542,080)**	**$ 1,492,741**

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

Table of Contents

TENAX THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,	
	2022	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (11,047,895)	$ (32,474,358)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	5,143	4,116
Interest on debt instrument	4,443	949
Amortization of right of use asset	108,189	104,866
Gain on sale of equipment	(2,901)	
Gain on debt settlement and extinguishment	-	(247,233)
Issuance and vesting of compensatory stock options and warrants	365,314	773,787
Issuance of common stock and preferred stock for asset acquisition	-	21,582,331
Amortization of premium on marketable securities	-	9,427
Changes in operating assets and liabilities		
Accounts receivable, prepaid expenses and other assets	(980,822)	(22,500)
Accounts payable and accrued liabilities	(344,951)	(544,589)
Long term portion of lease liability	(119,393)	(42,999)
Net cash used in operating activities	(12,012,873)	(10,856,203)
CASH FLOWS FROM INVESTING ACTIVITIES		
Sale of marketable securities	-	803,401
Purchase of marketable securities	-	(345,540)
Purchase of property and equipment	(2,323)	(5,252)
Net cash (used in) provided by investing activities	(2,323)	452,609
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of warrants and pre-funded warrants, net of issuance costs	7,928,591	9,192,624
Proceeds from the issuance of note payable	624,302	-
Proceeds from the exercise of warrants	2,063	544,651
Net cash provided by financing activities	8,554,956	9,737,275
Net change in cash and cash equivalents	(3,460,240)	(666,319)
Cash and cash equivalents, beginning of period	5,583,922	6,250,241

Cash and cash equivalents, end of period	$ 2,123,682	$ 5,583,922
Non-cash investing activity		
Addition to right of use asset obtained from new operating lease liability	$ -	$ 333,779

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 (the "Territory"). 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 (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 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 one or two upcoming Phase 3 studies in pulmonary hypertension patients utilizing one of these oral formulations. See "Note –G - 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 –E - 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 $289,542,080 and $278,494,185 on December 31, 2022 and 2021, respectively, and used cash in operations of $12,012,873 and $10,856,203 during the years ended December 31, 2022 and 2021, 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, 2022 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.

Reverse Stock Split

The Company has adjusted the financial statements to reflect that on January 4, 2023, we effected a 1-for-20 reverse stock split (the "Reverse Stock Split"). The Reverse Stock Split did not change the number of authorized shares of capital stock or cause an adjustment to the par value of our capital stock. Pursuant to their terms, a proportionate adjustment was made to the per share exercise price and number of shares issuable under our outstanding stock options and warrants. The number of shares authorized for issuance pursuant to our equity incentive plans have also been adjusted proportionately to reflect the Reverse Stock Split.

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 $1,877,589 and $5,127,956 uninsured by the FDIC as of December 31, 2022 and 2021, 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 approximately $3.2 million and $5.7 million and working capital of $1.4 million and $4.1 million as of December 31, 2022 and 2021, respectively.

The Company's cash resources were approximately $2.1 million as of December 31, 2022, compared to cash resources of approximately $5.6 million as of December 31, 2021.

The Company expects to continue to incur expenses related to development of levosimendan for pulmonary hypertension and other potential indications and imatinib for PAH, as well as identifying and developing other potential product candidates. Based on its resources on December 31, 2022, the Company believes that it has sufficient capital to fund its planned operations through to the first quarter of calendar year 2024. 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 COVID-19 pandemic or a similar societal disruption could in the future, directly or indirectly, 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 infectious diseases 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 do or may conduct and manage preclinical and clinical trials on its behalf. The financial terms of the agreements vary from contract to contract, may be estimated by Tenax Therapeutics and outside advisors prior to contracting with a CRO, 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 and clinical 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,	
	2022	**2021**
Warrants to purchase common stock	1,576,240	1,046,438
Pre-funded warrants to purchase common stock	-	501,664
Options to purchase common stock	77,472	64,978
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, 2022. 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 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.

NOTE C—BALANCE SHEET COMPONENTS

Property and equipment, net

Property and equipment primarily consist of office furniture and fixtures.

Table of Contents

Depreciation and amortization expense were $5,143 and $4,116 for the years ended December 31, 2022 and 2021, respectively.

Accrued liabilities

Accrued liabilities consist of the following:

	December	December

	31, 2022	31, 2021
Operating costs	$ 245,391	$ -
Lease liability	119,393	107,192
Employee related	410,261	597,148
	$ 775,045	$ 704,340

NOTE D—NOTE PAYABLE

Premium Finance Agreement

On December 31, 2022, the Company executed a premium finance agreement with Premium Funding Associates, Inc.
The agreement financed the Company's Directors and Officers Insurance Policy as well as the Errors and Omissions policy. The total amount financed was $693,669. The Company paid a down payment of $69,367 at execution leaving a balance of $624,302 payable in monthly installments of $58,873 through December 1, 2023. The agreement has an interest rate of 7.39%.

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, were 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, which were delivered 24 months after the date of issuance of the Series B Stock, subject to reduction for indemnification claims.

Table of Contents

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 a potential future 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.

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	$ 21,582,331
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	$ 21,582,331

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, where were delivered 24 months after the date of issuance of the Series B Stock and were subject to reduction for indemnification claims.

Table of Contents

As of December 31, 2022, 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.
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, 2022, 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, 2022, and December 31, 2021, there were 2,291,809 and 1,260,346 shares of common stock issued and outstanding, respectively. As of December 31, 2022 and 2021, there were 0 and 501,664 respectively of pre-funded warrants outstanding.

Table of Contents

May 2022 Private Placement (the "May 2022 Offering")

On May 17, 2022, 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 529,802 units in a private placement at a purchase price of $0.155 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 "2022 Warrants"). In the aggregate, 1,059,603 shares of the Company's common stock are underlying the 2022 Warrants. The net proceeds from the private placement, after direct offering expenses, were approximately $7.9 million. The fair value allocated to the pre-funded warrants and warrants was $4.2 million and $3.8 million, respectively.

Also, on May 17, 2022 and in connection with the May 2022 Offering, the Company entered into a registration rights agreement (the "May 2022 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 2022 Warrants within 120 days following the effective date of the May 2022 Registration Rights Agreement. Pursuant to the May 2022 Registration Rights Agreement, on May 25, 2022, the Company filed a resale registration statement on Form S-3 with the SEC, which went effective on June 3, 2022.

Additionally, in connection with the May 2022 Offering, the Company entered into a warrant amendment agreement (the "Warrant Amendment Agreement") with the investor, in consideration for the investor's purchase of units in the May 2022 Offering, pursuant to which the Company agreed to amend certain previously issued warrants held by the investor. The terms of the amended and restated warrants are described further below under "Note 8—Stockholders Equity—Warrants".

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 238,664 units in a private placement at a purchase price of $41.90 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, 477,327 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.

Warrants

During the year ended December 31, 2022, the Company received approximately $526 and issued 263,000 shares of common stock upon the exercise of previously outstanding pre-funded warrants issued in connection with the Company's July 2020 offering.

During the year ended December 31, 2022, the Company received approximately $477 and issued 238,664 shares of common stock upon the exercise of previously outstanding pre-funded warrants issued in connection with the Company's July 2021 Offering.

During the year ended December 31, 2022, the Company received approximately $1,060 and issued 529,802 shares of common stock upon the exercise of previously outstanding pre-funded warrants issued in connection with the Company's May 2022 Offering.

During the year ended December 31, 2021, the Company received approximately $545,000 and issued 14,110 shares of common stock upon the exercise of previously outstanding warrants issued in connection with the Company's December 2018 offering.

Table of Contents

During the year ended December 31, 2021, the Company issued 25,969 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, 2022, the Company has 1,576,240 warrants outstanding. The following table summarizes the Company's warrant activity for the year ended December 31, 2021 and 2022:

	Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2021	**1,046,438**	**$ 29.04**
Issued	529,801	12.60
Amended and restated	(460,306)	34.46
Amended and restated	460,306	12.60
Outstanding at December 31, 2022	**1,576,240**	**$ 17.13**

May 2022 Warrants

As described above, as a part of the May 2022 Offering, the Company issued unregistered warrants to purchase 529,802 shares of its common stock at an exercise price of $12.60 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 815, Derivatives and Hedging*, these warrants are classified as equity and their relative fair value of approximately $3.8 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.

July 2021 Warrants

As described above, as a part of the July 2021 Offering, the Company issued unregistered warrants to purchase 238,664 shares of its common stock at an exercise price of $39.40 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.

July 2020 Warrants

As described above, as a part of the July 2020 offering, the Company issued unregistered warrants to purchase 389,181 shares of its common stock at an exercise price of $18.06 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.

Table of Contents

March 2020 Warrants

As described above, as part of the March 2020 Offering, the Company issued unregistered warrants to purchase 118,016 shares of its common stock at an exercise price of $20.80 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 17,890 shares of common stock at an exercise price of $49.20 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.

Stock Options

The following table summarizes all options outstanding as of December 31, 2022:

				Options Outstanding at December 31, 2022		Options Exercisable and Vested at December 31, 2022	
Exercise Price				**Number of Options**	**Weighted Average Remaining Contractual Life (Years)**	**Number of Options**	**Weighted Average Exercise Price**
$ 12.40	to	$ 37.00		47,847	8.7	11,549	$ 25.89
$ 39.40	to	$ 224.00		3,789	6.4	3,789	$ 97.49
$ 828.00	to	$ 1,264.00		603	3.5	603	$ 994.17
$ 1,368.00		$ 2,260.00		238	1.4	238	$ 1,825.97
				52,477	8.4	16,179	$ 105.22

The following table summarizes options outstanding that have vested and are expected to vest based on options outstanding as of December 31, 2022:

	Number of Options	**WA Exercise Price**	**Aggregate Intrinsic Value**	**Weighted Average Remaining Contractual Life (Years)**
Vested	16,179	$ 105.22	$ -	7.1

Vested & expected to vest	48,486	$ 46.78	$ -	9.0

Table of Contents

2022 Stock Incentive Plan

In June 2022, the Company adopted the 2022 Stock Incentive Plan (the "2022 Plan"). Under the 2022 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 9, 2022, the Company's stockholders approved the 2022 Plan, which authorizes for issuance under the 2022 Plan a total of 55,000 shares of common stock. Upon approval by the stockholders, the 2022 Plan superseded and replaced the Tenax Therapeutics, Inc. 2016 Stock Incentive Plan, as amended (the "2016 Plan") and all shares of common stock remaining authorized and available for issuance under the 2016 Plan and any shares subject to outstanding awards under the 2016 Plan that subsequently expire, terminate, or are surrendered or forfeited for any reason without issuance of shares automatically become available for issuance under our 2022 Plan.

	Shares Available for Grant
Balances, at December 31, 2021	-
Shares reserved under 2022 Plan	55,000
Shares rolled over from 2016 Plan	40,988
Options granted	(28,563)
Options cancelled/forfeited	10,191
Balances, at December 31, 2022	77,616

2022 Plan Stock Options

Stock options granted under the 2022 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 2022 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 one to four years.

The following table summarizes the outstanding stock options under the 2022 Plan for the year ended December 31, 2022.

	Outstanding Options		
	Number of Shares	**Weighted Average Exercise Price**	**Aggregate Intrinsic Value**
Balances at December 31, 2021	-	$ -	
Options granted	28,563	$ 12.40	
Options cancelled/forfeited	(400)	$ 12.40	
Balances at December 31, 2022	28,163	$ 12.40	$ -(1)

(1) Amount represents the difference between the exercise price and $2.22, the closing price of Tenax Therapeutics' stock on December 31, 2022, 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 7,500 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 37,500 shares, up from 7,500 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 75,000 shares, up from 37,500 previously authorized. In June 2022, the 2016 Plan was superseded and replaced by the 2022 Plan and no new awards will be granted under the 2016 Plan going forward. Any awards outstanding under the 2016 Plan on the date of approval of the 2022 Plan remain subject to the 2016 Plan. Upon approval of the 2022 Plan, all shares of common stock remaining authorized and available for issuance under the 2016 Plan and any shares subject to outstanding awards under the 2016 Plan that subsequently expire, terminate, or are surrendered or forfeited for any reason without issuance of shares automatically become available for issuance under our 2022 Plan.

2016 Plan Stock Options

Stock options granted under the 2016 Plan could be either ISOs or NSOs. ISOs could be granted only to employees. NSOs could be granted to employees, consultants and directors. Stock options under the 2016 Plan could 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 year ended December 31, 2022.

	Outstanding Options		
	Number of Shares	**Weighted Average Exercise Price**	**Aggregate Intrinsic Value**
Balances at December 31, 2020	19,675	$ 23.60	

Options granted	18,939	$	37.60	
Options exercised	(850)	$	23.60	
Options cancelled/forfeited	(4,600)	$	31.80	
Balances at December 31, 2021	33,164	$	38.00	
Options cancelled/forfeited	(9,791)	$	32.42	
Balances at December 31, 2022	23,373	$	40.13	$ -(1)

(1) Amount represents the difference between the exercise price and $2.22, the closing price of Tenax Therapeutics' stock on December 31, 2022, 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, 2022 and 2021:

	For the year ended December 31,	
	2022	**2021**
Risk-free interest rate (weighted average)	3.08%	0.72%
Expected volatility (weighted average)	102.01%	101.60%
Expected term (in years)	7.0	6.7
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, 2022 and 2021 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, 2022 and 2021 was $12.40 and $30.60, respectively.

The Company recorded compensation expense for these stock options grants of $223,277 and $391,801 for the years ended December 31, 2022 and 2021, respectively.

As of December 31, 2022, there were unrecognized compensation costs of approximately $214,175 related to non-vested stock option awards under the 2022 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 10,000 shares, up from 750 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 12,500 shares, up from 10,000 previously authorized. The 1999 Plan expired on June 17, 2018 and no new grants may be made under that plan after that date. However, unexpired awards granted under the 1999 Plan remain outstanding and subject to the terms of the 1999 Plan.

1999 Plan Stock Options

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

Table of Contents

The following table summarizes the outstanding stock options under the 1999 Plan for the years ended December 31, 2022 and 2021:

	Outstanding Options		
	Number of Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value
Balances at December 31, 2020	2,883	$ 926.80	
Options cancelled	(1,067)	$ 1,065.60	
Balances at December 31, 2021	1,816	$ 845.20	
Options cancelled	(880)	$ 558.34	
Balances at December 31, 2022	936	$ 1,122.75	$ -(1)

(1) Amount represents the difference between the exercise price and $2.22, the closing price of Tenax Therapeutics' stock on December 31, 2022, 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 $0 and $1,290 for the years ended December 31, 2022 and 2021, respectively.

As of December 31, 2022, 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, 2022, with respect to these modifications.

Inducement Stock Options

The Company granted two employment inducement stock option awards, one for 5,000 shares of common stock and the other for 12,500 shares of common stock, to its new CEO on July 6, 2021.

The employment inducement stock option for 5,000 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 was to 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 had a 10-year term and an exercise price of $39.40 per share, the July 6, 2021 closing price of our common stock. As of December 31, 2022, none of the vesting milestones had been achieved and the options were subsequently cancelled. 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 12,500 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 $39.40 per share, the July 6, 2021 closing price of our common stock. As of December 31, 2022, none of the vesting milestones have been achieved.

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 12,500 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 $35.60 per share, the January 15, 2021 closing price of our common stock. As of December 31, 2022, 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 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 $142,037 for the year ended December 31, 2022. As of December 31, 2022, there was $440,682 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 "Prior Lease"). 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 increased 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 Prior 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, 2022	December 31, 2021
Current portion included in accrued liabilities	$ 119,393	$ 107,192
Long term lease liability	64,196	183,589
	$ 183,589	$ 290,781

Table of Contents

As of December 31, 2022, the maturities of our operating lease liabilities were as follows:

Year ending December 31,	
2023	129,797
2024	65,702
Total lease payments	$ 195,499
Less: Imputed interest	(11,910)
Operating lease liability	$ 183,589

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 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. 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, 2022, 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.

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.

Table of Contents

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, 2022 and 2021, the Company recorded $90,873 and $73,855 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, 2022 due to its history of net operating losses.

The reconciliation of income tax expenses (benefit) at the statutory federal income tax rate of 21% for the periods ended December 31, 2022 and December 31, 2021 is as follows:

	December 31,	
	2022	**2021**
U.S. federal tax benefit at statutory rate	$ (2,320,057)	$ (6,819,615)
State income tax benefit, net of federal benefit	(218,196)	(641,368)
Stock compensation	79,090	171,269
Other nondeductible, including IPR&D expense	-	5,032,981
Change in state tax rate	116,392	1,768,013
Federal and state net operating loss adjustments	423,066	745,439
Other, including effect of tax rate brackets	8,850	(73)
Change in realizability of IPR&D	-	229,750
Change in valuation allowance	1,910,855	(486,396)
	$ -	$ -

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

	December 31,	
Deferred Tax Assets	**2022**	**2021**
Net operating loss carryforwards	$ 36,106,727	$ 35,291,097
Accruals and other	1,412,267	308,296
Capital loss carryforwards	2,258	11,003
Valuation allowance	(37,521,252)	(35,610,396)
Net deferred tax assets	-	-
Deferred Tax Liabilities		
Other liabilities	-	-
Net Deferred Tax Liabilities	$ -	$ -

The Company has established a valuation allowance against net deferred tax assets due to the uncertainty that such assets will be realized. The Company periodically evaluates the recoverability of the deferred tax assets. At such time that it is determined that it is more likely than not that deferred tax assets will be realizable, the valuation allowance will be reduced. The net increase in the valuation allowance during 2022 was approximately $1.9 million.

Table of Contents

As of December 31, 2022, the Company had Federal and State net operating loss carryforwards of approximately $163.2 million and $125.1 million available to offset future federal and state taxable income, respectively. Federal net operating losses of $122.9 million begin to expire in 2023, while the remaining $40.3 million carryforward indefinitely. State net operating losses begin to expire in 2023.

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.

We have U.S. federal net operating loss carryforwards, or NOLs, which 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.

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, 2022.

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

i. The Company filed a Certificate of Amendment to the Company's Certificate of Incorporation, as amended (the "Certificate of Amendment") with the Secretary of State of Delaware for the purpose of effecting the Reverse Stock Split. The Reverse Stock Split was approved by our stockholders at the annual meeting of stockholders held on June 9, 2022 and the Company's Board of Directors approved the Certificate of Amendment with a 1-for-20 ratio on December 15, 2022. The Reverse Stock Split was effective at 5:00 p.m. on January 4, 2023. The Reverse Stock Split was effected primarily to enable the Company to regain compliance with Nasdaq Listing Rule 5550(a)(2) regarding the minimum $1.00 per share closing bid price requirement (the "Bid Price Rule"). The Company regained compliance with the Bid Price Rule on January 20, 2023.

ii. On March 29, 2023, Nasdaq notified the Company that it was no longer in compliance with the Bid Price Rule given that for the prior 30 consecutive business days, the bid price for the Company's common stock had closed below the minimum $1.00 per share requirement. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), the Company has a compliance period of 180 calendar days, or until September 25, 2023, to regain compliance with the Bid Price Rule. If at any time before September 25, 2023, the bid price of the Company's common stock closes at $1.00 per share or more for a minimum of ten consecutive business days, Nasdaq will provide the Company with a written confirmation of compliance with the Bid Price Rule.

Table of Contents

iii. On February 3, 2023, the Company entered into a placement agency agreement (the "Placement Agency Agreement") with Roth Capital Partners, LLC (the "Placement Agent") and a securities purchase agreement (the "Purchase Agreement") with certain purchasers for the purchase and sale, in a registered public offering by the Company (the "February 2023 Public Offering"), of (i) an aggregate of 6,959,444 shares of its common stock, par value $0.0001 per share and pre-funded warrants to purchase an aggregate of 1,707,222 shares of Common Stock and (ii) accompanying warrants to purchase up to an aggregate of 17,333,332 shares of its Common Stock at a combined offering price of $1.80 per share of common stock and associated common warrant, or $1.799 per pre-funded warrant and associated common warrant, resulting in gross proceeds of approximately $15.6 million. Estimated net proceeds of the February 2023 Public Offering were approximately $14.1 million, after deducting the Placement Agent fees and estimated offering expenses payable by the Company. The February 2023 Public Offering closed on February 7, 2023.

The Company's stockholders' equity at December 31, 2022 was $1.5 million which is lower than the minimum requirement for continued listing on the Nasdaq Capital Market of $2.5 million. The Company believes that, after taking into account the February 2023 Public Offering for net proceeds of $14.1 million, and based on interim financial data available to the Company, the Company's stockholders' equity at March 28, 2023 exceeds $2.5 million, which is the minimum stockholders' equity requirement under the Nasdaq Listing Rules. In addition, the Company's cash balance at March 28, 2023 is approximately $14.6 million.

iv. On February 7, 2023, the Company entered into a Lease Termination Agreement with CCP Concourse, LLC, a Virginia limited liability company (the "Landlord") with respect to the prior lease of its headquarters formerly located at ONE Copley Parkway, Suite 490, Morrisville, North Carolina (the "Premises"). The prior lease, as amended, was originally entered into on January 27, 2011 and would have terminated on June 30, 2024.

As consideration for the Landlord's entry into the Lease Termination Agreement, including a release of any claims the Landlord may have had against the Company under the prior lease, the Company has paid the Landlord $169,867.41. Pursuant to the Lease Termination Agreement, effective February 8, 2023, the Company has no remaining rent or further obligations to the Landlord pursuant to the prior lease.

v. On March 21, 2023, the U.S. Patent and Trademark Office (USPTO) issued to Tenax Therapeutics a patent covering the use of IV levosimendan in patients with PH-HFpEF.

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.

The information contained herein and in the Annual Report on Form 10-K for the period ended December 31, 2022, including the financial statements included therein, has been retrospectively adjusted to reflect that on January 4, 2023, we effected a 1-for-20 reverse stock split (the "Reverse Stock Split"). The Reverse Stock Split did not change the number of authorized shares of capital stock or cause an adjustment to the par value of our capital stock. Pursuant to their terms, a proportionate adjustment was made to the per share exercise price and number of shares issuable under our outstanding stock options and warrants. The number of shares authorized for issuance pursuant to our equity incentive plans have also been adjusted proportionately to reflect the Reverse Stock Split.

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 have the following rights and limitations:

- *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.

Warrants

As of December 31, 2022, the following warrants were outstanding:

- Warrants to purchase 136,334 shares of Common Stock, issued in December 2018, with an exercise price of $38.60 per share and set to expire in December 2023;
- Amended warrants to purchase 103,627 shares of Common Stock, issued in December 2018, with an exercise price of $12.60 per share and set to expire in December 2025;
- Placement agent warrants to purchase 10,363 shares of Common Stock, issued in December 2018, with an exercise price of $29.128 per share and set to expire in December 2023;
- Amended warrants to purchase 118,016 shares of Common Stock, issued in March 2020, with an exercise price of $12.60 per share and set to expire in September 2027;
- Placement agent warrants to purchase 7,599 shares of Common Stock, issued in March 2020, with an exercise price of $29.128 per share and set to expire in March 2025;
- Amended warrants to purchase 389,181 shares of Common Stock, issued in July 2020, with an exercise price of $18.06 per share and set to expire in January 2028;
- Placement agent warrants to purchase 24,761 shares of Common Stock, issued in July 2020, with an exercise price of $25.696 per share and

set to expire in July 2025;

- Amended warrants to purchase 238,664 shares of Common Stock, issued in July 2021, with an exercise price of $12.60 per share and set to expire in January 2029; and

- Placement agent warrants to purchase 17,902 shares of Common Stock, issued in July 2021, with an exercise price of $49.20 per share and set to expire in July 2026.

Each of these warrants contains customary provisions for the adjustment of the exercise price and the aggregate number of shares issuable upon the exercise of the warrant in the event of dividends, share splits, reorganizations and reclassifications and consolidations.

Options

As of December 31, 2022, the following options were outstanding:

- Pursuant to our Amended and Restated 1999 Stock Plan, as amended, options to purchase 936 shares of Common Stock, issuable with a weighted average exercise price of $1,123.00, of which 936 options are exercisable immediately. No additional grants will be made under the 1999 Plan.

- Pursuant to our Amended and Restated 2016 Stock Incentive Plan, as amended (the "2016 Plan"), options to purchase 23,373 shares of Common Stock, issuable with a weighted average exercise price of $40.13, of which 13,924 options are exercisable immediately. No additional grants will be made under the 2016 Plan.

- Pursuant to our Plan for Employee Inducement Stock Option Grants ("Inducement Plan"), options to purchase 30,000 shares of Common Stock, issuable with a weighted average exercise price of $37.50, of which no options are exercisable immediately. There are no shares of Common Stock reserved for future issuance under the Inducement Plan.

- Pursuant to our 2022 Stock Incentive Plan (the "2022 Plan"), options to purchase 28,163 shares of Common Stock, issuable with a weighted average exercise price of $12.40, of which 1,313 options are exercisable immediately. There are 77,616 shares of Common Stock reserved for future issuance under the 2022 Plan.

- The terms of each of our 1999 Plan, 2016 Plan, Inducement Plan and 2022 Plan include customary provisions for the adjustment of the exercise price and the aggregate number of shares issuable upon the exercise of the option in the event of dividends, share splits, reorganizations and reclassifications and consolidations.

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.

As of December 31, 2022, there were 210 shares of Series A Preferred Stock outstanding, convertible into 11 shares of Common Stock.

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 $38.60 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 $115.80 (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 or such other person as our board 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. 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 to influence our board's 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".

EXHIBIT 21.1

SUBSIDIARIES OF TENAX THERAPEUTICS, INC.

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

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the Registration Statements on Form S-8 (Nos. 333-167175, 333-196464, 333-210182, 333-224120, 333-233571, 333-259266, and 333-266833), Form S-3 (Nos. 333-248201, 333-258981, and 333-265209), and Form S-1 (No. 333-228212 and 333-269363) of our report dated March 30, 2023 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, 2022 and 2021, 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, 2022.

/s/ CHERRY BEKAERT LLP

Raleigh, North Carolina
March 30, 2023

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT EXCHANGE ACT RULE 13a-14(a)/15d-14(a) AS ADOPTED 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 30, 2023

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

EXHIBIT 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO EXCHANGE ACT RULE 13a-14(a)/15d-14(a) AS ADOPTED 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 30, 2023

By: /s/ Eliot M. Lurier
Eliot M. Lurier
Interim Chief Financial Officer
(Principal Financial Officer)

EXHIBIT 32.1

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

In connection with the Annual Report of Tenax Therapeutics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2022 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 30, 2023

/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.

EXHIBIT 32.2

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

In connection with the Annual Report of Tenax Therapeutics, Inc. (the "Company") on Form 10-K for the period year December 31, 2022 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 30, 2023

/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.