Table of Contents

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, 2025

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, 2025, the last business day of the registrant's most recently completed second fiscal quarter, was $23,840,749.

The number of shares outstanding of the registrant's class of $0.0001 par value common stock as of March 6, 2026 was 17,197,613.

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 2026 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, 2025.

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 develop and ultimately commercialize our current product candidates, and any product candidate which we may develop or in-license in the future;
- delays in the commencement, enrollment and completion of clinical testing, as well as the analysis and reporting of results from such clinical testing;
- our ability, our partners' abilities, and third parties' abilities to protect and assert intellectual property rights;
- the success of nonclinical and clinical studies of our product candidates;
- the need and ability to obtain regulatory approval of our product candidates and any delays in such regulatory review;
- potential risks related to any collaborations we may enter into for our product candidates;
- 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;
- 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
- geopolitical uncertainties, including in the Middle East and the Russian invasion of and war against the country of Ukraine.

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", "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.

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 materializes (or if any of those listed elsewhere in this Annual Report on Form 10-K materialize), 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 Business 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, and in particular, oral levosimendan as our prioritized product candidate.
- We currently have no approved drug products for sale, and we cannot guarantee that we will ever have marketable drug products.
- 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 of our product candidates.
- We are conducting two Phase 3 clinical trials, LEVEL and LEVEL-2 for oral levosimendan, which are expensive and time consuming, and the outcomes of the clinical trials are uncertain.
- The market may not accept our products.
- Nonfinal results from our clinical trials announced or published from time to time on an interim, top-line, or preliminary basis, and conclusions that may be drawn from such results, may change as more patient data or analysis of this data become available, and these results are subject to audit and verification procedures that could result in material changes in the final data. Similarly, discrete observations during clinical trials may not reflect the general response to the products that will be revealed at the conclusion of the clinical trials or in future, widespread use of the product once marketed.
- 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.

Risks Related to Our Financial Position and Need for Additional Capital

- We will require substantial additional funding to further develop, file marketing authorization applications, and if approved, commercialize our product candidates, including to complete the open label extension stage of our ongoing Phase 3 LEVEL and LEVEL-2 trials of levosimendan; as well as to initiate or complete any future imatinib Phase 3 trial.
- Failure to obtain this necessary capital when needed on acceptable terms, or at all, or execute on an alternative strategic path, could force us to delay, limit, reduce or terminate our clinical trials, product development and marketing efforts, and business operations.
- We may be required to make milestone and royalty payments to the licensor of the levosimendan intellectual property in connection with the development and commercialization of levosimendan, which could adversely affect the profitability of levosimendan, if approved.
- 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 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 difficult to predict, expensive and time consuming, and we will not be able to sell our products without regulatory approval.
- We may not receive all of the anticipated market exclusivity benefits of imatinib's orphan drug designation, if we prioritize imatinib's development in the future.
- Even after products are commercialized, we would expect to spend considerable time and money complying with federal, state, and foreign 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 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 cybersecurity.

Risks Related to Our Dependence on Third Parties

- We have historically relied on and we will continue to rely on third parties substantially 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 depend on third parties to formulate and manufacture our products.
- If we fail to attract and retain senior management and key scientific and operational personnel, we may be unable to successfully develop and commercialize our product candidates.
- We expect to need to increase the size of our organization to further develop our product candidates, and we may experience difficulties in managing growth.
- We currently have very little marketing capabilities and no sales organization. If we are unable to establish sales and marketing capabilities on our own or through third parties, we will be unable to successfully commercialize our products, if approved, or generate product revenue.

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

- Our share price has been volatile, and may continue to be volatile, which may subject us to securities class action litigation in the future.
- Investors may experience dilution of their ownership interests because of the future issuance of additional shares of our common stock or securities convertible into common stock.

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

ITEM 1—BUSINESS

Overview

Tenax Therapeutics is a Phase 3, development-stage pharmaceutical company using clinical insights to develop novel cardiopulmonary therapies. We employ a clinician-driven drug development approach, led by key opinion leaders and heart failure experts and informed by their clinical insights to precisely target disease pathophysiology. We are currently actively conducting the LEVEL and LEVEL-2 clinical trials to evaluate levosimendan as our prioritized product candidate and have deprioritized a Phase 3 clinical trial of imatinib, two drugs supported by promising evidence that they may significantly improve the lives of patients with pulmonary hypertension. Importantly, both levosimendan and imatinib have already been approved in other indications and prescribed around the world for more than 20 years, and we believe their mechanisms of action are uniquely suitable to target and treat pulmonary hypertension. We believe this derisked approach of using already-approved drugs that provide well-established safety profiles from millions of patients, combined with a development path led by preeminent cardiovascular and pulmonary hypertension experts, puts us in a strong position to deliver breakthrough cardiopulmonary therapies designed to improve patients' functioning and quality of life.

In March 2025, we closed a private placement financing (the "March 2025 Offering") raising gross proceeds of $25.0 million. We intend to use the net proceeds from the March 2025 Offering, in addition to the approximately $100.0 million raised in August 2024, to advance our Phase 3 oral levosimendan program. Specifically, we plan to complete our ongoing Phase 3 LEVEL study of TNX-103 in pulmonary hypertension in heart failure with preserved ejection fraction ("PH-HFpEF"). We also plan to advance our second global Phase 3 study, LEVEL-2, which was initiated in December 2025. Following completion of the two Phase 3 levosimendan trials, we intend to submit marketing authorization applications. We also plan to submit an application for imatinib following a single Phase 3 trial, when appropriate.

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. 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, with the commencement of our focus on developing and ultimately commercializing levosimendan, we changed the Company name to Tenax Therapeutics, Inc.

Our Strategy

The key elements of our business strategy are outlined below.

Efficiently conduct clinical development to establish clinical proof of principle in new indications, refine dosage levels and dosing strategies, conduct other required clinical and nonclinical testing as U.S. Federal Drug Administration (the "FDA") and other regulators may require, and continue Phase 3 testing of oral levosimendan, as our prioritized product candidate.

Levosimendan and imatinib have already been approved and prescribed in other indications in many countries around the world. 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 provide benefit to patients with diseases for which either no pharmaceutical therapies are approved at all, or in the case of pulmonary arterial hypertension, where numerous, expensive therapies generally offer a modest reduction of symptoms. Our focus is primarily on designing and executing formulation and dosing regimen 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 the second Phase 3 trial of levosimendan, which we commenced in December 2025, as our prioritized drug candidate. 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 preclinical and clinical testing organizations to help expedite development, and continue expanding into complementary areas when opportunities arise through our development, research, and discoveries. We also intend to continue outsourcing to clinical research organizations, and seeking and acting upon the advice of preeminent scientists focused on cardiovascular and pulmonary drug development, 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 during its development and in the more than two decades following its approval. Our own Phase 2 study and open-label extension has demonstrated that levosimendan's property of relaxing the venous circulation, a formerly under-appreciated mechanism of action of levosimendan, brings durable improvements in exercise capacity and quality of life, as well as other clinical assessments, in patients with PH-HFpEF. The FDA has not approved a therapy for this disease. We are committed to exploring potential clinical indications in which our therapies may achieve best-in-class profile, demonstrate novelty, and where we can address significant unmet medical needs and maintain market exclusivity.

We believe these factors will support approval by the FDA of this product candidate based on positive Phase 3 data. Through our agreement with our licensor, Orion Corporation, 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. In order to achieve our objective of developing this medicine 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 candidate 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.

Continue to expand our intellectual property portfolio.

Our intellectual property, as more fully described below, 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 uses of our existing technologies, alone or in combination with existing therapies, as well as other product candidates.

Enter into licensing or product co-development arrangements.

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

We also continue to position ourselves to execute upon licensing and other partnering opportunities. To do so, we need to continue to maintain our strategic direction, manage and deploy our available cash efficiently, and strengthen our collaborative research development and partner relationships.

Our Pipeline and Drug Candidates

PH-HFpEF

Pulmonary hypertension in heart failure with preserved ejection fraction is the most common form of pulmonary hypertension in the world, according to the World Health Organization. Prevalence in the United States is currently estimated to be greater than 1.5 million, although PH-HFpEF may be significantly underdiagnosed because diagnosis typically requires catheterization. Currently, there are no therapies approved for treatment of PH-HFpEF. Even though many therapies have been studied in this indication in the past, none have proven to be effective in treating patients with the disease.

Levosimendan

Levosimendan is a novel, first-in-class K-ATP activator and calcium sensitizer developed for intravenous use in hospitalized patients with acutely decompensated heart failure. It has been granted market authorization in 60 countries for use in this indication, although it is not available in the United States or Canada. It is estimated that over 2.2 million patients have been treated worldwide with levosimendan to date.

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 patient symptoms as well as acute hemodynamic measurements such as increased cardiac output, reduced pulmonary capillary wedge pressure, reduced preload and reduced afterload.

The therapeutic effects of levosimendan are mediated through:

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

Importantly, several published studies provide evidence that levosimendan may improve right ventricular dysfunction, a common comorbidity in patients with pulmonary hypertension. While none of these studies 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 evaluation of potential clinical benefit in PH-HFpEF.

Phase 2 HELP Study

Insights from published studies led us to initiate the HELP Study (“Hemodynamic Evaluation of Levosimendan in PH-HFpEF”), a Phase 2, double-blind, randomized, placebo-controlled clinical study to evaluate the efficacy and safety of intravenous levosimendan (“TNX-101”) in patients with PH-HFpEF. The primary endpoint of the HELP Study was change from baseline in pulmonary capillary wedge pressure (“PCWP”) during exercise, along with various other secondary endpoints. The first patient was enrolled in the study in March 2019, and the enrollment and dosing of 44 patients was completed in March 2020.

The HELP Study design was novel in several respects. To date, no other multi-center study has evaluated levosimendan in PH-HFpEF patients, or any patients with an ejection fraction greater than 40%. Instead, all previous levosimendan heart failure studies have enrolled patients with heart failure with reduced ejection fraction (“HFrEF”), thereby excluding HFpEF patients from the study. 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.

In June 2020, we announced preliminary, top-line data from the HELP study. 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 responded to the degree required by the protocol in order to be randomized (including reduction of PCWP of at least 4mm Hg during exercise). In the randomized, placebo-controlled, double-blinded 6-week trial stage, levosimendan did not demonstrate a statistically significant reduction from baseline in PCWP during exercise, the primary endpoint. However, patients receiving levosimendan had statistically significant reductions from baseline at Week 6 in PCWP and PAP at rest or after leg raise ($p<0.05$). Furthermore, the study demonstrated a statistically significant reduction in PCWP compared to baseline ($p=<0.0017$) and placebo ($p=<0.0475$) when the three patient measurements (i.e., at rest, with legs up, and during exercise) were combined.

Levosimendan also demonstrated a statistically significant improvement in the change in 6-minute walk distance ("6MWD"), a secondary end-point commonly used in many pulmonary hypertension registration trials. Clinical efficacy was confirmed by a statistically significant improvement in 6-minute walk distance of 29 meters ($p=0.0329$).

The incidence rate of adverse events or serious adverse events between the treatment and placebo 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.

Detailed results from HELP were presented at the Heart Failure Society of America Virtual Annual Scientific Meeting in October 2020, at the American Heart Association Scientific Sessions in November 2020, and several subsequent scientific congresses.

Open-Label Extension Study of Oral Levosimendan (TNX-103)

Following completion of the randomized treatment phase of the HELP Study, patients were able to enter an open-label extension study ("OLE") to remain on intravenous therapy and to facilitate the continued evaluation of safety. Later, the HELP study protocol was modified to introduce a substudy within this open-label extension stage that allowed the investigators and Tenax to evaluate the safety and efficacy of an oral formulation of levosimendan ("TNX-103"). Patients who agreed to participate in the OLE substudy were safely transitioned from intravenous to oral formulation in late 2021, and the study was continued by the Company and our HELP investigators for over two years, concluding in the first half of 2023. Positive signs of efficacy were observed across all measured parameters during the OLE, which provided us with sufficient data to discuss further development of oral levosimendan with the FDA.

The transition of patients in the OLE from intravenous to oral formulation occurred safely. Improvements in all measures of efficacy taken in the transition from intravenous to 3mg daily oral levosimendan were observed.

We believe these findings from the HELP Study and the OLE IV-to-oral substudy represent important discoveries related to the use of levosimendan in PH-HFpEF patients. Not only is HELP the first study to evaluate levosimendan in PH-HFpEF patients, but to our knowledge it is also the first study conducted of any therapy in PH-HFpEF patients to show such positive improvements in hemodynamics and 6MWD. Taken together, the encouraging data to date demonstrate that levosimendan's property of relaxing the venous circulation, a formerly under-appreciated mechanism of action of levosimendan, brings durable improvements in exercise capacity and quality of life, as well as other clinical assessments, in patients with PH-HFpEF.

Phase 3 LEVEL and LEVEL-2 Studies

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. Subsequently, a path to registration was agreed upon involving two confirmatory Phase 3 studies, as well as a plan to replace weekly intravenous levosimendan dosing with daily oral levosimendan doses in the upcoming clinical trials. In February 2022, the FDA provided a written response advising that the safety database required for filing a New Drug Application ("NDA") only needs to meet two of the three minimum International Clinical Harmonization ("ICH") standards for a chronic medication in treating a non-life-threatening condition: 300 patients treated for 6 months, and 100 patients treated for 12 months. Subsequently, based on the below-described continuing dialogue with FDA, Tenax introduced into the LEVEL-2 certain study design features intended to ensure 100 patients assigned to levosimendan are treated for 12 months with their treatment

assignment double-blinded. Tenax plans to continue to discuss with the FDA and other global regulators this requirement and other requirements that will determine the size and timing of its completed Phase 3 program, throughout the execution of its Phase 3 program.

On November 13, 2023, we announced that the FDA had reviewed and cleared our Investigational New Drug ("IND") application for oral levosimendan for the treatment PH-HFpEF, enabling us to proceed with the first of two Phase 3 studies.

In the fourth quarter of 2023, we initiated the LEVEL Study (LEVosimendan to Improve Exercise Limitation in PH-HFpEF Patients), an ongoing, registrational Phase 3, randomized, double-blind, placebo-controlled clinical trial to evaluate TNX-103 in patients with PH-HFpEF in the United States and Canada. The primary endpoint is change in 6MWD from baseline to Week 12.

On December 17, 2025, we announced that the prespecified Blinded Sample Size Re-estimation (BSSR) of the LEVEL Study, demonstrated the trial is powered at well over 90% to detect a 25 meter change in 6MWD, the primary endpoint. Based on these results, we confirmed the previously announced target enrollment number and expected enrollment completion timeframe as well as topline data timeframe.

On December 17, 2025, we also announced that we initiated LEVEL-2 (NCT07288398), the second registrational study of TNX-103 in patients with PH-HFpEF. LEVEL-2 (NCT07288398) in a global, Phase 3, double-blind, randomized, placebo-controlled study of TNX-103. Tenax plans to enroll approximately 540 PH-HFpEF patients in LEVEL-2, randomized 2:1 to receive TNX-103 or placebo. The primary endpoint of the study is change from baseline in 6MWD at Week 26. Secondary endpoints include change from baseline in Kansas City Cardiomyopathy Questionnaire and New York Heart Association Functional Class.

In addition, LEVEL-2, like LEVEL, includes an OLE phase following the completion of the randomized phase to treat patients under protocol can receive open label levosimendan, allowing for additional weeks of safety observation that will contribute to the safety data on TNX-103.

Patients who complete a total study duration of 104 weeks in both protocols can continue to receive oral levosimendan by subscribing in an open-level study to bridge them from LEVEL or LEVEL-2 to commercialized product. This protocol will begin to enroll subjects from LEVEL in the first half of 2026.

PAH

Pulmonary arterial hypertension ("PAH") is a type of pulmonary hypertension and a rare, progressive, and serious disease. Although several therapies are now available, none are cures for the disease and patients remain symptomatic with high morbidity and mortality. Importantly, all currently approved PAH therapies are pulmonary vasodilators, and there is no data supporting that these types of treatments halt progression or induce regression of the disease.

Imatinib

Imatinib (marketed in the United States as Gleevec®) is a tyrosine kinase inhibitor. It is the first curative treatment for chronic myeloid leukemia ("CML") and has significantly impacted patients since receiving FDA approval in 2001.

Separately, imatinib has been shown in animal models of pulmonary hypertension to induce disease reversal by affecting platelet derived growth factor, which may be causal in the disease. Several case reports and small case series of patients with advanced PAH failing combination pulmonary vasodilator therapy that were treated with imatinib were subsequently published, showing dramatic effects on disease stabilization and improvements in symptom and function.

These results 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. Novartis then sponsored a Phase 3 trial (IMPRES) which met its primary endpoint of significant increase in 6MWD (32 meters, p=0.002), an effect maintained in an 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 in the study. Consequently, Novartis chose to withdraw the IND application.

On May 30, 2019, PHPrecisionMed Inc. ("PHPM") met with the FDA to discuss a proposal for a Phase 3 trial of imatinib in PAH using change in 6MWD as the primary endpoint. 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 pharmacokinetic and bioavailability study.

In January 2021, Tenax acquired PHPM and renamed the modified release formulation of imatinib TNX-201. Given our prioritization of the LEVEL trials, we have suspended plans to launch an imatinib Phase 3 trial.

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.

As of the date of this filing, we have been granted four U.S. patents, and have been notified of the impending granting of a Canadian, a European, and a fifth U.S. patent, all related to product candidates and proprietary process, method and technology. Our issued levosimendan patents expire in 2039 and December 2040.

On January 4, 2022, we received a patent from the United States Patent and Trademark Office ("USPTO") for the subcutaneous administration of levosimendan (TNX-102), whether through the prototype formulation we have developed in collaboration with a formulation development partner, or other subcutaneous formulations meeting certain broad characteristics defined in the patent. This patent expires in 2039. On March 21, 2023, we were granted a patent for the use of IV levosimendan in the treatment of PH-HFpEF patients. This patent expires in 2040. On July 19, 2023, we announced the USPTO issuance of another patent, this one including claims covering the use of oral levosimendan in patients with PH-HFpEF. This issued patent provides exclusivity through December 2040. On February 6, 2024, we announced the fourth levosimendan USPTO patent broadening IP protection for oral, I.V., and subcutaneous use of levosimendan and its active metabolites in PH-HFpEF, at all therapeutic doses and in combination with various cardiovascular drugs.

On September 16, 2025, we announced that the European Patent Office (EPO) notified the Company of its Intention to Grant a patent to us that will provide intellectual property protection for TNX-103 and other formulations of levosimendan, as well as its active metabolites, for use in PH-HFpEF.This new patent will have a patent term until December 2040, and it may qualify for European patent supplementary protection certificates (SPC) that would extend the period of patent protection beyond 2040. Similarly, in 2025, the Canadian government notified us that it will issue a patent for the use of oral levosimendan for the treatment of PH-HFpEF. We also have multiple patent applications pending in Europe and other countries for the treatment of PH-HFpEF, for oral and combination products.

The U.S. trademark registration for Simdax® is owned by Orion Corporation ("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 certain assets of Phyxius Pharma, Inc. ("Phyxius") pursuant to an asset purchase agreement by and among the Company, Phyxius and the stockholders of Phyxius, dated October 21, 2013. Among these assets was a license with Orion Corporation ("Orion") for the 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 (as amended from time to time, the "License"). On October 9, 2020 and January 25, 2022, we entered into amendments to the License to include in the scope of the License two new product formulations containing levosimendan, in capsule and solid dosage form (TNX-103) and a subcutaneously administered dosage form (TNX-102), subject to specified limitations (together, the "Product").

On February 19, 2024, we entered into an amendment to the License providing global rights to oral and subcutaneous formulations of levosimendan used in the treatment of PH-HFpEF. The amendment also reduced the tiered royalties based on worldwide net sales of the product by the Company and its sublicensees, increased the License's existing milestone payment due to Orion upon the grant of FDA approval of a levosimendan-based product to $10.0 million and added a milestone payment to Orion of $5.0 million due upon the grant of regulatory approval for a levosimendan-based product in Japan. The amendment also (i) increased the Company's obligations to make certain non-refundable commercialization milestone payments to Orion, aggregating to up to $45.0 million, contingent upon achievement of certain cumulative worldwide sales of the product by the Company, and (ii) reduced the maximum price per capsule payable by the Company to Orion, under a yet-to-be-negotiated supply agreement, for the commercial supply of oral levosimendan-based product. Pursuant to the License, the Company and Orion will agree to a new trademark when commercializing levosimendan in either of the dosage forms.

On September 3, 2025, we entered into an amendment License providing exclusive worldwide rights to develop, commercialize, manufacture, and have manufactured any orally-administered pharmaceutical product containing levosimendan and, in addition to the Company's existing rights to develop and commercialize subcutaneously administered products containing levosimendan, to manufacture or have manufactured such products. The amendment also calls for Orion to supply the Company with levosimendan to the extent reasonably necessary or useful to manufacture orally-administered products containing levosimendan for purposes of developing such products, and sets forth the terms for such supply, including the price of levosimendan ordered by the Company of low triple-digit thousands in Euros per kilogram, payment terms, and active pharmaceutical ingredient specifications.

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.

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 but, pursuant to the February 2024 amendment, excluding new applications of levosimendan for neurological diseases and disorders developed by Orion.

As of December 31, 2025, 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.

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 drug manufacturing organizations ("CMOs") eliminates the need to directly invest in manufacturing facilities, equipment and additional employees.

Pursuant to the terms of the License, 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, a regulatory standard for the manufacture of pharmaceuticals.

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 staff and more extensive marketing and manufacturing organizations than we do. In addition, many 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 the 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, and 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. Other companies, including for example Astra Zeneca, Tectonic, and Merck, are currently conducting Phase 1 and Phase 2 clinical trials of potential new therapies to treat PH-HFpEF. Merck's sotatercept is approved for PAH and is being tested in a subset of PH patients with HFpEF, with a Phase 2 data readout predicted in the first quarter of 2026. Merck executives have confirmed their intention to conduct a Phase 3 program testing this product in PH-HFpEF patients with combined pre-capillary and post-capillary PH, among other characteristics to be shared with the public in future. GSK recently acquired a private company with a sotatercept-like compound that may in future be developed in Group 2 PH. These companies may be successful in their efforts to gain market approval for a product in some of the same patients we aim to treat with levosimendan, whether before or after we could do so. Some classes of medical therapy such as SGLT-2 inhibitors and GLP-1 agonists are or may be approved for use in patients with heart failure, and may or may not be developed specifically for PH-HFpEF, creating competition in the future. Some approved products to treat common conditions such as diabetes and obesity are theorized, or proven, to provide benefit in patients with heart failure, and are sometimes used in these patients, including off-label. Products approved for PAH, including endothelin receptor agonists (ERAs) and phosphodiesterase type 5 (PDE5) inhibitors, even though trials have not shown benefit and have sometimes demonstrated harm, and manufacturers of which have not sought approval in patients with PH-HFpEF by filing an NDA or BLA, are nevertheless prescribed off-label by some physician who care for patients with

PH associated with HFpEF, and who state in our own market research that they do so out of a desire to provide something helpful for patients with this disease.

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.

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 U.S. government authorities as well as those of other 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 to monitor for adverse effects, which can involve significant expense.

The effects of government regulations on our business are discussed under the heading “Risk Factors - Risks Relating to Our Industry” 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, 2025, we had 14 full-time employees and two part-time employees. 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.

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. 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 Business and Our 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.

At present we are 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 for regulatory approval for the treatment of pulmonary hypertension in patients with HFpEF. Depending on whether we raise additional funds in the future, as well as on decisions made by the USPTO, clinical trial results and other information revealed by competitors, and other factors, we will prioritize our funding and other resources accordingly. If as a consequence of the results of our planned Phase 3 trials for levosimendan, 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.

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 and our business depends on the successful development and commercialization of our product candidates. The research, testing, manufacturing, labeling, approval, selling, marketing, and distribution of drug products are extensively regulated 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. 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.

The process of developing new drugs and/or therapeutic products is inherently complex, unpredictable, time-consuming, expensive and uncertain. We must make long-term investments and commit significant resources before knowing whether our development programs will result in products that will receive regulatory approval and achieve market acceptance. Product candidates that appear to be promising at some or all stages of development may not receive approval or reach the market for reasons that may not be predictable based on results and data of the clinical program. Product candidates may be found ineffective or may cause harmful side effects during clinical trials, may take longer to progress through clinical trials than had been anticipated, may not be able to achieve the pre-defined clinical endpoints due to statistical anomalies even though clinical benefit may have been achieved, may fail to receive necessary regulatory approvals, may prove impracticable to manufacture in commercial quantities at reasonable cost and with acceptable quality, or may fail to achieve market acceptance. Even if we believe the preclinical or clinical data for our product candidates are favorable, such data may not be sufficient to support approval by the FDA and other regulatory authorities. Additionally, the FDA may 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.

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 to gain this approval in the timeline planned, 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 might already be engaged in other clinical trial programs for the same indication as our product candidates, might be required to withdraw from our clinical trial as a result of changing standards of care, might suffer from staff shortages at the institutional or clinic level that impact their ability to enroll and treat patients under our protocols, or might 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; and
- collecting, analyzing and reporting final data from the clinical trials.

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

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

Changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. Amendments may require us to resubmit our clinical trial protocols to IRBs for re-examination, which may impact the costs, design, 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 ultimately able to commercialize our product candidates, other therapies for the same or similar indications may have been introduced to the market and established a competitive advantage.

We are conducting two Phase 3 clinical trials, LEVEL and LEVEL-2 for oral levosimendan, which are expensive and time consuming, and the outcome of the clinical trials is uncertain.

We expect to commit a substantial portion of our financial and business resources for the foreseeable future to completing the LEVEL and LEVEL-2 trials and advancing this product through to regulatory approval for use in PH-HFpEF, and potentially other indications. We may in the future commit resources to clinical trials for our other product candidates, including imatinib. All of these clinical trials and product testing efforts 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.

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 and alternative treatments, if any;
- our ability to offer our products for sale at competitive prices and the availability of third-party coverage and adequate reimbursement;
- 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 or elsewhere;
- the strength of manufacturing, marketing and distribution support;
- 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, top-line, or preliminary 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 or reference interim, top-line, or preliminary results from our clinical trials, including from blinded or unblinded data. Interim or top-line results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcome measurements may materially change as patient enrollment and treatment extends and more patient experience is observed. Top-line or preliminary results also remain subject to audit and verification procedures that may result in the final data being materially different from the data we previously published. As a result, interim, top-line and preliminary data should be viewed with caution until the final and complete data are available. Differences between interim, top-line or preliminary data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

Likewise, statements made by investigators, patients, or others participating in our clinical trials as to the effect or effects of therapy they may have observed, should not be relied upon as applicable generally to all patients with the disease, or all or most patients participating in the trials. Statements made on social media or in scientific discussions of an ongoing clinical trial should not be reviewed as company statements. Such observations, made by an individual who by design is unaware of a patient's treatment assignment, or who is observing a patient's reaction outside the setting of controlled study, e.g. in an open-label setting, may not be reliable as predictors of a population's response. Such statements, while factual, should not be understood to be predictive of a larger population's eventual response to the therapy once study data from all participants is analyzed.

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

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

- we may not be able to control the amount and timing of resources that our partners may devote to the development or commercialization of our product candidates or to their marketing and distribution;
- partners may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- disputes may arise between us and our partners that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and resources;
- partners may experience financial difficulties;
- partners may not properly maintain or defend our intellectual property rights, or may use our proprietary information, in such a way as to invite litigation that could jeopardize or invalidate our intellectual property rights or proprietary information or expose us to potential litigation;
- business combinations or significant changes in a partner's business strategy may adversely affect a partner's willingness or ability to meet its obligations under any arrangement;
- a partner could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- the collaborations with our partners may be terminated or allowed to expire, which would delay the development and may increase the cost of developing our product candidates.

Risks Related to Our Financial Position and Need for Additional Capital

We will require substantial additional funding to further develop, file marketing authorization applications, and if approved, commercialize our product candidates, including to complete the open label extension stage of our ongoing Phase 3 LEVEL and LEVEL-2 trials of levosimendan; as well as to initiate or complete any future imatinib Phase 3 trial. Failure to obtain this necessary capital when needed on acceptable terms, or at all, or execute on an alternative strategic path, 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 continue to increase in connection with our ongoing activities, including the completion of the LEVEL and LEVEL-2 trials. 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, 2025, we had $97.6 million of cash and cash equivalents on hand and subsequent to year end, as of March 9, 2026 we have raised an additional $14.5 million of gross proceeds from the exercises of outstanding warrants and pre-funded warrants. We will need substantial additional capital in order to develop our product candidates, including to complete the LEVEL and LEVEL-2 trials, to complete the regulatory approval process and commercialization of levosimendan, and, potentially, imatinib, or any future product candidates. We continue to evaluate 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.

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, and evolving FDA and other regulator input and guidance, 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.

In the event we are unable to obtain additional capital as needed or execute on an alternative strategic path, we may further delay, limit, reduce or terminate our current development efforts and business operations.

We may be required to make milestone and royalty payments to the licensor of the levosimendan intellectual property in connection with the development and commercialization of levosimendan, which could adversely affect the profitability of levosimendan, if approved.

Under the terms of our license agreement with Orion, we are required to pay to Orion tiered royalties based on worldwide net sales of the product by the Company and any sublicensees, a $10.0 million milestone payment upon the grant of FDA approval of a levosimendan-based product, a $5.0 milestone payment upon the grant of regulatory approval for a levosimendan-based product in Japan, as well as certain non-refundable commercialization milestone payments, aggregating to up to $45.0 million, contingent upon achievement of certain cumulative worldwide sales of the product by the Company. In the event that no regulatory approval for a product containing 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.

These development and milestone obligations and royalties could impose substantial additional costs on us, divert resources from other aspects of the business, and adversely affect the overall profitability of levosimendan, if approved. We may need to obtain additional financing to satisfy these milestone and royalty payments, and cannot be sure that any additional funding, if needed, will be available on favorable terms, or at all.

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 develop and commercialize our current product candidates, and any product candidate which we may develop or in-license in the future;
- delays in the commencement of a trial, 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 costs and timing of regulatory approval, if any;
- the success of clinical trials of our product candidates;
- our ability to raise additional money to complete the development and commercialization of our current or future product candidates and support our operations;
- our ability to establish an effective sales and marketing infrastructure;
- competition from existing products or new products that may emerge;
- potential side effects or adverse events of our product candidates that could delay or prevent commercialization;
- 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 and risks related thereto;
- our ability, our partners' abilities, and third parties' abilities to protect and assert intellectual property rights;
- costs related to and outcomes of potential litigation, including any product liability claims;
- compliance with obligations under intellectual property licenses with third parties, including milestone payments and royalties;
- 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 in the Middle East and the Russian invasion of and war against the country of Ukraine, and fluctuations in biotechnology investor sentiment.

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, 2025 and 2024, we incurred net operating losses of $56.4 million and $19.5 million, respectively. We have funded our operations since 2013 principally through the issuance of equity securities. 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 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 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, or related indications. Currently, as an example, at least 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. While there are no products currently marketed to treat PH-HFpEF, specifically, some products such as sotatercept and relaxins under development by Astra Zeneca and others are under development to treat this prevalent disease, and some products marketed for other conditions or for HFpEF alone, are used in these patients and could constitute competition at the patient, payor, or overall market level in future.

Our activities are and will continue to be subject to extensive government regulation, which is difficult to predict, 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 regulation.

Product approval stage

During the product approval stage, we study and 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;
- at any time, the FDA and other regulatory agencies can provide evolving input into the design of our clinical program, and input from different regulators may be challenging to reconcile within an ongoing development program;
- at any time, review division staff and senior leadership within FDA and other regulatory agencies may reverse their policy or change the application of a policy to a given drug development program, resulting in faster or slower than expected approval, and this internal discussion may be time consuming and effect the Company's approach to study or applying for approval of a product;
- if a prolonged government shutdown occurs, reductions in staffing at the FDA, or similar impacts on medical review functions within global regulators, 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 the 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.

The FDA and other regulatory agencies continue to review products even after they receive agency approval. If 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 includes 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 any approved 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 nor regulatory review time of a drug and does not give the drug any advantage in the regulatory review or approval process. Furthermore, U.S. law and the application of law to the exclusivity of approved therapies for orphan diseases, has evolved, including with the Consolidated Appropriations Act of 2026, and this evolution may continue to evolve, impairing our ability to be assured of the same exclusivity and the resulting reimbursement for TNX-201 for its intended use.

Even after products are commercialized, we would expect to spend considerable time and money complying with federal, state, and foreign 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 recommendation 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.

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

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

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

Significant uncertainty exists as to the reimbursement status for newly approved drug products, including coding, coverage and payment. There is no uniform policy requirement for coverage and reimbursement for drug products among third-party payers in the United States; therefore, coverage and reimbursement for drug products can differ significantly by 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, including through such recent legislation as the Inflation Reduction Act in the United States, the effects of which are evolving over time, may adversely affect our ability to set as high a price for our products as we might otherwise and the rate and scope of adoption of our products by healthcare providers. We expect that federal, state and local governments in the United States, as well as governments in other countries, will continue to consider legislation directed at lowering the total cost of healthcare. In addition, in certain foreign markets, the pricing of drug products is subject to government control and reimbursement may in some cases be unavailable or insufficient. It is uncertain whether and how future legislation, whether domestic or abroad, could affect prospects for our product candidates or what actions governmental or private payers for healthcare treatment and services may take in response to any such healthcare reform proposals or legislation. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, may prevent or limit our ability to generate revenue, attain profitability or commercialize our product candidates.

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

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 worldwide distribution rights for levosimendan and 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, if our products are approved, the pricing of our products 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 pharmaceutical 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 $10 million. However, our profitability will be adversely affected by a successful product liability claim in excess of our insurance coverage. There can be no assurance that product liability insurance will be available in the future or be available on reasonable terms.

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

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 cybersecurity breach. However, a breakdown in existing controls and procedures around our cybersecurity 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. For more information, see Item 1C. Cybersecurity.

Risks Related to Our Dependence on Third Parties

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

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

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

We do not own or operate any manufacturing facilities for the clinical- or commercial-scale production of our products.

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 requires 24 months' notice to the Company in order to allow the Company to identify and engage an alternative manufacturer. 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 clinical trial conduct and other product development efforts and timelines, financial condition, results of operations and cash flows.

To potentially manufacture imatinib in the future, we have contracted with various third-party suppliers and 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.

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 December 31, 2025, we had fourteen full-time employees and two part-time employees. Numerous additional contract staff, separate to the CROs and vendors with whom we contract, support our administrative and R&D functions. Still, institutional knowledge is concentrated within this small group of employees and contract team members. 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.

We expect to need to increase the size of our organization to further develop our product candidates, and we may experience difficulties in managing growth.

We will need to manage our anticipated growth and increased operational activity, including as a result of the continuing development of levosimendan and any other product candidates. Our personnel, systems, and facilities

currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy will require that we:

- manage our research and development activities and our regulatory trials effectively;
- attract and motivate sufficient numbers of talented employees or consultants;
- manage our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors, collaborators and other third parties;
- develop internal sales and marketing capabilities or establish collaborations with third parties with such capabilities;
- commercialize our product candidates; and
- improve our operational, financial and management controls, reporting systems and procedures.

This planned future growth could place a strain on our administrative and operational infrastructure and may require our management to divert a disproportionate amount of its attention away from our day-to-day activities. We may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel, which may result in weaknesses in our infrastructure, and give rise to operational mistakes, loss of business opportunities, loss of employees and consultants and reduced productivity among remaining employees and consultants. We may not be able to make improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our ability to generate or increase our revenues could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to compete effectively will depend, in part, on our ability to effectively manage any future growth.

We currently have very limited marketing capabilities and no sales organization. If we are unable to establish sales and marketing capabilities on our own or through third parties, we will be unable to successfully commercialize our products, if approved, or generate product revenue.

To commercialize our products, if approved, in the United States and other jurisdictions in which we may seek approvals, we must build our marketing, sales, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. We have not decided upon a commercialization strategy in these areas. We have no experience in the sale and marketing of approved medical products and marketing the licensing of such products before FDA or other regulatory approval. We have not identified or engaged a third party that is prepared to distribute our products should they be approved. If we decide to establish our own commercialization capability, we will need to recruit, train and retain a marketing staff and sales force with sufficient technical expertise. We do not know whether we can establish a commercialization program at a cost that is acceptable in relation to revenue or whether we can be successful in commercializing our product. Factors that may inhibit our efforts to commercialize our products directly and without strategic partners include:

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

Further, we may pursue arrangements regarding the sales and marketing and distribution of one or more of our product candidates and our future revenues may depend, in part, on our ability to enter into and maintain arrangements with other companies having sales, marketing and distribution capabilities and the ability of such companies to successfully market and sell any such products. Any failure to enter into such arrangements and marketing alliances on favorable terms, if at all, could delay or impair our ability to commercialize our product candidates and could increase our costs of commercialization. Any use of distribution arrangements and marketing alliances to commercialize our product candidates will subject us to a number of risks, including the following:

- we may be required to relinquish important rights to our products or product candidates;

- we may not be able to control the amount and timing of resources that our distributors or collaborators may devote to the marketing and commercialization of our product candidates;
- our distributors or collaborators may experience financial difficulties; 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, Europe, and multiple other countries that, if granted, could protect various uses and formulations of levosimendan In January 2022, the USPTO granted us 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 2026, the USPTO issued Tenax a Notice of Allowance for claims directed to the subcutaneous administration of levosimendan in a broad range of indications. The range of indications includes but is not limited to PH-HFpEF. In addition, we received in March 2023 another U.S. patent protecting the use of levosimendan in the treatment of PH-HFpEF. Two subsequent U.S. patents expanded these protections on the use of levosimendan in the treatment of PH-HFpEF. Other patent applications are pending globally, or will be granted in 2026 according to patent authorities in Canada in Europe.

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, depending on evolving law and policy in this arena, could 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 may 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.

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.

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 and pharmaceutical industries have 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 USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions.

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

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

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

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

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

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

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

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, or comments made on the observed results of their, or our, 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, or on which development work is terminated for safety, efficacy or other reasons;
- 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;
- 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 disruptive events broadly affecting society, and as a result of geopolitical uncertainties, including in the Middle East and the Russian invasion of and war against the country of Ukraine.

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.

Investors may experience dilution of their ownership interests because of the future issuance of additional shares of our common stock or securities convertible into common stock.

For the foreseeable future, to finance our operations, including possible acquisitions or strategic transactions, we expect to issue equity securities, resulting in the dilution of the ownership interests of our present stockholders. We are currently authorized to issue an aggregate of 400,000,000 shares of common stock and 10,000,000 shares of preferred stock. As of December 31, 2025, there were 9,314,130 shares of common stock outstanding, 16,895,111 shares underlying warrants with a weighted average exercise price of $5.66 per share, 33,102,778 shares underlying pre-funded warrants with an exercise price of $0.01 per share, and 6,616,432 shares underlying options with a weighted average exercise price of $6.21 per share. We may also issue additional shares of our common stock or other securities that are convertible into or exercisable for common stock in connection with hiring or retaining employees, or for other business purposes. The future issuance of any such additional shares of common stock or common stock equivalents may create downward pressure on the trading price of our common stock.

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 Amended and Restated Certificate of Incorporation (the "Charter") and our Fourth 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 of 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, 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.

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 or could result in increased costs for our stockholders to bring a claim in the chosen forum. 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.

ITEM 1B—UNRESOLVED STAFF COMMENTS

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

ITEM 1C—CYBERSECURITY

The Company has a cybersecurity strategy designed to protect our information systems and data from an evolving cyber-threat landscape. Our cybersecurity program, administered by the Company's Senior Network Administrator and overseen by the Audit and Compliance Committee, has the support of executive leadership and the Board of Directors, and the Company continues to invest in cybersecurity to protect the Company's systems.

Our cybersecurity program focuses on all areas of our business, including cloud-based environments, devices used by employees and contractors, facilities, networks, applications, vendors, disaster recovery, business continuity and controls and safeguards enabled through business processes and tools. We continuously monitor for threats and unauthorized access. We learn of security threats through automated detection solutions as well as reports from users and business partners. We draw on the knowledge and insight of external cybersecurity experts and vendors and employ an array of third-party tools to secure our information infrastructure and protect systems and information from unauthorized access.

As of the date of this Annual Report, we have not encountered any risks from cybersecurity threats that have materially affected or are reasonably likely to materially affect the Company, including its business strategy, results of operations, or financial condition. For more information on our cybersecurity related risks, see "Risk Factors - Risks Related to Our Industry" included elsewhere in this Annual Report on Form 10-K.

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 located at 101 Glen Lennox Drive, Suite 300, Chapel Hill, North Carolina 27517.

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 10, 2026:

Name	Age	Position
Christopher T. Giordano	52	President and Chief Executive Officer and Director
Thomas A. McGauley, CPA	53	Interim Chief Financial Officer
Stuart Rich, MD	76	Chief Medical Officer and Director

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 of several hundred 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.

Thomas McGauley joined the Company as our Interim Chief Financial Officer in December 2024. Mr. McGauley of Danforth Advisors, LLC is a senior life sciences financial executive with an extensive background in finance, life science companies, SEC reporting, and fundraising. Since July 2021, Mr. McGauley has been a member of Danforth Advisors, LLC, providing executive financial services to several public and private companies. From 2018 to 2022, Mr. McGauley was a director at CBIZ in their accounting advisory practice. Prior to that, from 2009 to 2018, he served as the chief financial officer and a consultant to several public and private life science companies, including Galectin Therapeutics Inc. (Nasdaq: GALT), where he was the interim chief financial officer from 2012 to 2013 and the company's financial/accounting and SEC consultant from 2009 to 2012. Prior to that, he was a senior financial executive for deCODE genetics, Inc., a formerly Nasdaq-listed company. Mr. McGauley began his financial career in public accounting working with several accounting firms, and was most recently a manager at PricewaterhouseCoopers LLP specializing in life sciences and technology companies. Prior to that, he was an officer in the U.S. Army and later the MA National Guard, ending his military career as a captain and company commander. Mr. McGauley holds a B.S.B.A in Accounting from Stonehill College and is a Certified Public Accountant in Massachusetts.

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 PHPrecisionMed Inc. (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 2023, a U.K. based charity. From July 2015 until January 2021 he also served as the Director of the Pulmonary Vascular Disease Program at the Bluhm Cardiovascular Institute of Northwestern University, and since January 2006 he has served as a 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
Member of the Board of Directors, Actinium Pharmaceuticals, Inc.
Co-founder and Executive, Chair, portfolio company, 82 Venture Studios (Exec. Venture Partner) and Member of Investment Advisory Board, Harrington Discovery Institute

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.

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 6, 2026, there were 1,328 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, 2025, 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 Part II, 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 is a Phase 3, development-stage pharmaceutical company leveraging clinical insights to develop novel cardiopulmonary therapies. We employ a clinician-driven drug development approach, led by key opinion leaders and advised by thought leaders who are pulmonary hypertension and heart failure experts and informed by their clinical insights to precisely target disease pathophysiology. We are currently actively conducting the LEVEL and LEVEL-2 clinical trials to evaluate levosimendan as our prioritized product candidate, and have deprioritized a Phase 3 clinical trial of imatinib, two drugs supported by promising evidence that they may significantly improve the lives of patients with pulmonary hypertension. Importantly, both levosimendan and imatinib have already been approved in other indications and prescribed around the world for more than 20 years, and we believe their mechanisms of action are uniquely suitable to target and treat pulmonary hypertension. We believe this derisked approach of using already-approved drugs that provide well-established safety profiles from millions of patients, combined with a development path led by preeminent cardiovascular and pulmonary hypertension experts, puts us in a strong position to deliver breakthrough cardiopulmonary therapies designed to improve patients' functioning and quality of life.

Recent Events

In March 2025, we closed a private placement financing raising gross proceeds of approximately $25.0 million. We intend to use the net proceeds from the March 2025 Offering, in addition to approximately $100.0 million raised in August 2024, to advance our Phase 3 oral levosimendan program. Specifically, we plan to complete our ongoing Phase 3 LEVEL study of TNX-103 in PH-HFpEF. We also plan to advance our second global Phase 3 study, LEVEL-2, which commenced in December 2025. Following completion of the two Phase 3 levosimendan trials, we intend to submit marketing authorization applications. We also plan to submit an application for imatinib following completion of a single Phase 3 trial, when appropriate.

Our Phase 3 LEVEL study continues, with high rates of study and therapy continuation during the blinded and open-label extension stages. We achieved our target enrollment of 230 patients in March of 2026. LEVEL is being conducted in the United States and Canada.

Based on our current operating plan, we believe that our existing cash and cash equivalents as of December 31, 2025 will be sufficient to fund our planned operations through at least the end of 2027.

Comparison of the Years Ended December 31, 2025 and 2024 (in thousands)

	The year ended December 31,		Increase/	% Increase/
	2025	2024	(Decrease)	(Decrease)
Operating expenses:				
Research and development	$ 32,672	$ 12,709	$ 19,963	157 %
General and administrative	23,713	6,785	16,928	249 %
Total operating expenses	$ 56,385	$ 19,494	$ 36,891	189 %
Net operating loss	(56,385)	(19,494)	(36,891)	189 %
Other segment items				
Interest income	3,819	1,914	1,905	100 %
Interest expense	-	(23)	23	(100) %
Other (expense) income, net	(33)	1	(34)	(3,400) %
Net loss	$ (52,599)	$ (17,602)	$ (34,997)	199 %

Research and Development Expenses

Research and development expenses include, but are not limited to, (i) expenses incurred under agreements with CROs and investigative sites, which conduct a substantial portion of our pre-clinical and our 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, 2025 and 2024, respectively, are as follows (in thousands):

	Year ended December 31,		Increase/	% Increase/
	2025	2024	(Decrease)	(Decrease)
Clinical and preclinical development	$ 26,064	$ 11,125	$ 14,939	134 %
Salary and benefits	2,133	1,048	1,085	104 %
Stock-based compensation	3,881	286	3,595	1257 %
Other costs	594	250	344	138 %
Total research and development expense	$ 32,672	$ 12,709	19,963	157 %

Clinical and preclinical development costs increased $14.9 million for the year ended December 31, 2025 as compared to the same period in the prior year. Clinical and preclinical development costs for the year ended December 31, 2025 consists primarily of expenses associated with our ongoing Phase 3 LEVEL trial and our second global Phase 3 study, LEVEL-2, which commenced in December 2025, compared with costs for the year ended December 31, 2024,

associated with the planning of LEVEL and the early progress initiating LEVEL sites and enrolling the first LEVEL patients.

Salary and benefits expense increased $1.1 million for the year ended December 31, 2025 as compared to the same period in the prior year primarily due the increased number of employees as we expanded our LEVEL trial and designed, planned, and commenced our LEVEL-2 trial. Stock-based compensation expense increased $3.6 million for the year ended December 31, 2025, as compared to the same period in the prior year due to stock option grants made late in 2024 and during 2025.

Other costs increased $0.3 million for the year ended December 31, 2025, as compared to the same period in the prior year, primarily due to higher regulatory costs over the prior year as we expanded our clinical trial during 2024.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation for executive, finance, legal and administrative personnel, including non-cash 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, 2025 and 2024, respectively, are as follows (in thousands):

	Year ended December 31,		Increase/	% Increase/
	2025	2024	(Decrease)	(Decrease)
Salary and benefits	$ 2,315	$ 2,257	$ 58	3 %
Stock-based compensation	15,282	839	14,443	1721 %
Legal and professional fees	4,388	2,692	1,696	63 %
Other costs	1,728	997	731	73 %
Total general and administrative expense	$ 23,713	$ 6,785	16,928	249 %

Salary and benefits expense remained relatively unchanged for the year ended December 31, 2025, as compared to the same period in the prior year due to lower bonuses offsetting salary increases and new employee salaries. Stock-based compensation expense increased $14.4 million for the year ended December 31, 2024 due to stock option grants in late 2024 and during 2025.

Legal fees consist of the cost of our legal counsel as well as legal costs related to our intellectual property. 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 and professional fees increased $1.7 million for the year ended December 31, 2025 compared to the same period in the prior year primarily related to increased capital market expenses, consulting expenses, and accounting expenses, offset by a decrease in intellectual property related legal costs.

Other costs increased $0.7 million for the year ended December 31, 2025 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 franchise and other taxes.

Interest Income, Interest Expense, and Other Income (Expense), net

Interest income increased $1.9 million for the year ended December 31, 2025 as compared to the same period in the prior year primarily related to higher interest income on increased cash deposits as a result of the March 2025 Offering and warrant exercises during 2025, and increased interest rates. The Company had no interest expense for the year ended December 31, 2025 and an immaterial amount for the prior year. Other income (expense) was immaterial.

Liquidity and Capital Resources

We have incurred losses since our inception and, as of December 31, 2025, we had an accumulated deficit of $367.5 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, over the long term, imatinib for

PAH, and other potential indications, as well as identifying and developing other potential product candidates, and as a result, we will need to generate significant net product sales, royalty and other revenues to achieve profitability.

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, and have prioritized levosimendan; however, we will need substantial additional capital in the future in order to finalize the development of levosimendan, commence its commercialization, potentially develop imatinib, and to continue with the development of other potential product candidates.

Liquidity

We have financed our operations since September 1990 through the issuance of debt and equity securities and loans from stockholders. We had total current assets of $104.2 million and $96.7 million and working capital of $97.1 million and $92.0 million as of December 31, 2025 and December 31, 2024, respectively. Our practice is to invest excess cash, where available, in short-term money market investment instruments and high quality corporate and government bonds.

We are currently conducting the LEVEL trial and intend to recruit patients into the first half of 2026 and we commenced our LEVEL-2 trial in December 2025 and are currently enrolling patients. Our ability to continue to pursue development of our products, including completion of a second Phase 3 oral levosimendan trial, beyond 2027, will depend on obtaining license income, income from warrants exercised by investors should they elect to do so, or outside financial resources. There is no assurance that we will obtain any license agreement or outside financing or that we will otherwise succeed in obtaining any necessary resources.

Financings

On March 5, 2025, we sold in the March 2025 Offering an aggregate of 378,346 shares of our common stock and pre-funded warrants to purchase an aggregate of 3,760,726 shares of our common stock at an offering price of $6.04 per share of common stock and $6.03 per pre-funded warrant, resulting in gross proceeds of $25.0 million. The pre-funded warrants do not expire and have an exercise price of $0.01. Net proceeds from the offering were $23.2 million, after deducting the placement agent fees and offering expenses payable by the Company.

On August 8, 2024, we sold in a private placement financing an aggregate of 1,450,661 shares of our common stock, and pre-funded warrants to purchase an aggregate of 31,882,671 shares of our common stock, and accompanying warrants to purchase up to an aggregate of 16,666,666 shares of our common stock with an exercise price of $4.50, at a combined offering price of $3.00 per share of common stock and accompanying warrant, or $2.99 per pre-funded warrant and accompanying warrant, resulting in gross proceeds of $99.7 million. Net proceeds from the offering were $92.3 million, after deducting the placement agent fees and offering expenses payable by the Company.

On February 8, 2024, we sold in a registered public offering (the "February 2024 Offering") an aggregate of 421,260 shares of our common stock and pre-funded warrants to purchase an aggregate of 1,178,740 shares of our common stock and (ii) accompanying warrants to purchase up to an aggregate of 3,200,000 shares of our common stock with an exercise price of $5.65, at a combined offering price of $5.65 per share of common stock and accompanying warrant, or $5.649 per pre-funded warrant and accompanying warrant, resulting in gross proceeds to the Company of $9.0 million. Net proceeds of the offering were $8.0 million, after deducting the placement agent fees and offering expenses payable by the Company.

Cash Flows

The following table shows a summary of our cash flows for the periods indicated (in thousands):

	Year ended December 31,	
	2025	2024
Net cash (used in) operating activities	$ (35,800)	$ (14,811)
Net cash provided by investing activities	-	-
Net cash provided by financing activities	38,514	99,870

Operating Activities

Net cash used in operating activities was $35.8 million for the year ended December 31, 2025, compared to $14.8 million for the year ended December 31, 2024. The increase in cash used for operating activities was primarily due to higher study expense activity and increased employee hiring in the year ended December 31, 2025 as compared to the prior year.

Investing Activities

There was no net cash provided or consumed by investing activities for the years ended December 31, 2025 and December 31, 2024.

Financing Activities

Net cash provided by financing activities was $38.5 million for the year ended December 31, 2025, as compared to $99.9 million in the year ended December 31, 2024. During the year ended December 31, 2025, the Company received proceeds of $23.2 million net cash provided from the sale of common stock and pre-funded warrants in the March 2025 Offering and $15.3 million from the exercise of warrants and pre-funded warrants. During the year ended December 31, 2024 the Company received proceeds of a total of $98.5 million from the August 8, 2024 and February 8, 2024 sales of common stock, and pre-funded warrants and accompanying warrants, and $1.8 million from the exercise of warrants and pre-funded warrants, offset by the principal payment of $0.5 million related to a short-term note.

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, design, 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; and
- the possible costs of litigation.

Based on our working capital on December 31, 2025, we believe we have sufficient capital on hand to continue to fund operations through the end of 2027.

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.

Warrants for Common Shares and Derivative Financial Instruments—Warrants for shares of common stock and other derivative financial instruments are classified as equity if the contracts: (i) require physical settlement or net-share settlement or (ii) give the Company a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement). Contracts are classified as equity or liabilities if the contracts: (i) require net-cash settlement (including a requirement to net cash settle the contract if an event occurs and if that event is outside the control of the Company), (ii) give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement), or (iii) contain reset provisions that do not qualify for the scope exception. The Company assesses the classification of its warrants for shares of common stock and other derivatives at each reporting date to determine whether a change in classification between equity and liabilities is required.

Recent Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which is intended to provide enhancements to annual income tax disclosures. The standard will require more detailed information in the rate reconciliation table and for income taxes paid, among other enhancements. The standard is effective for years beginning after December 15, 2024. The Company adopted and applied the amendments of this ASU to its disclosures. The application of this ASU did not have a material impact on the Company's financial position, results of operations or cash flows.

In November 2024, the FASB issued ASU 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Topic 220-40), which addresses the disaggregation of income statement expenses. This standard is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. The Company is evaluating this standard to determine if adoption will have a material impact on the Company’s consolidated financial statements.

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, 2025, 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.

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, 2025. 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, 2025.

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

(a) None.

(b) None.

ITEM 9C—DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

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 2026 Annual Meeting of Stockholders currently scheduled to be held on June 18, 2026, 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 2026 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.

We have also adopted an Insider Trading Policy governing the purchase, sale, and other dispositions of our securities by our directors, officers, and employees, and by the Company. We believe this policy is reasonably designed to promote compliance with insider trading laws, rules, and regulations and listing standards applicable to the Company. A copy of our Insider Trading Policy is filed as Exhibit 19.1 to this Annual Report on Form 10-K and is also available on our website at http://investors.tenaxthera.com/corporate-governance.

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.

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, 2025.

	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))
2022 Stock Incentive Plan	6,616,131	$	5.99	1,720,474
2016 Stock Incentive Plan, as amended	290	$	3,252.00	647
Amended and Restated 1999 Amended Stock Plan, as amended	11	$	50,830.55	-
Equity compensation plans not approved by security holders:				
Employee Inducement Stock Option Grants (1)	250,314	$	10.22	-
Total	6,866,746	$	6.36	1,721,121

(1) Consists of (a) an option award for 250,000 shares of common stock to a new employee on January 21, 2025, which vests in four equal annual installments beginning on the first anniversary of the date of issuance, subject to the employee's continued employment, with a 10-year term and an exercise price of $6.45 per share; and (b) options to purchase 314 shares of common stock, with a weighted average exercise price of $3,008, pursuant to the Plan for Employee Inducement Stock Options, which is filed as Exhibit 10.13 to this Annual Report on Form 10-K. The Plan became effective on July 6, 2021 when approved by the members of the Company's Compensation Committee. These option awards were each granted in accordance with the employment inducement award exemption provided by Nasdaq Listing Rule 5635(c)(4) and therefore were not awarded under the Company's stockholder approved equity plan.

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.

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	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
2.2	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	Amended and Restated Certificate of Incorporation, effective June 16, 2025.	8-K	001-34600	3.2	June 17, 2025
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	Fourth Amended and Restated Bylaws.	10-Q	001-34600	3.1	August 15, 2023
4.1	Form of Unregistered Warrant, dated March 13, 2020.	8-K	001-34600	4.2	March 13, 2020
4.2	Form of Placement Agent Warrant, dated March 13, 2020.	8-K	001-34600	4.3	March 13, 2020
4.3	Form of Unregistered Warrant, dated July 6, 2020.	8-K	001-34600	4.2	July 8, 2020
4.4	Form of Placement Agent Warrant, dated July 8, 2020.	8-K	001-34600	4.3	July 8, 2020
4.5	Form of Unregistered Warrant, dated July 6, 2021.	8-K	001-34600	4.2	July 8, 2021
4.6	Form of HCW Warrant, dated July 6, 2021.	8-K	001-34600	4.3	July 8, 2021

4.7	Form of Common Stock Warrant, dated May 19, 2022.	8-K	001-34600	4.2	May 20, 2022
4.8	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
4.9	Warrant Agency Agreement, dated February 3, 2023, by and between Tenax Therapeutics, Inc. and Direct Transfer LLC.	8-K	001-34600	4.1	February 7, 2023
4.10	Form of Common Stock Purchase Warrant, dated February 3, 2023.	8-K	001-34600	4.3	February 7, 2023
4.11	Warrant Agency Agreement, dated February 12, 2024, by and between Tenax Therapeutics, Inc. and Direct Transfer LLC.	8-K	001-34600	4.1	February 12, 2024
4.12	Form of Common Stock Purchase Warrant, dated February 12, 2024.	8-K	001-34600	4.3	February 12, 2024
4.13	Form of Pre-Funded Warrant to Purchase Common Stock, dated August 8, 2024.	8-K	001-34600	4.1	August 6, 2024
4.14	Form of Warrant to Purchase Shares of Common Stock or Pre-Funded Warrants, dated August 8, 2024.	8-K	001-34600	4.2	August 6, 2024
4.15	Form of Pre-Funded Warrant to Purchase Common Stock, dated March 5, 2025.	8-K	001-34600	4.1	March 6, 2025
4.16	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 under 1999 Amended Stock Plan.	10-K	002-31909	10.5	August 13, 2004
10.1.5+	Form of Option issued to Employees under 1999 Amended Stock Plan.	10-K	002-31909	10.6	August 13, 2004
10.1.6+	Form of Option Agreement with Form of Notice of Grant under 1999 Amended Stock Plan.	10-K	001-34600	10.9	March 16, 2017
10.2+	Form of Indemnification Agreement.	10-K	001-34600	10.36	July 15, 2011
10.3.1*	License Agreement dated September 20, 2013 by and between Phyxius Pharma, Inc. and Orion Corporation.	10-Q	001-34600	10.3	March 17, 2014

10.3.2*	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
10.3.3*	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
10.3.4*	Third Amendment to the License Agreement of September 20, 2013, by and between Tenax Therapeutics, Inc. and Orion Corporation, dated as of February 19, 2024.	8-K	001-34600	10.1	February 20, 2024
10.3.5*	Fourth Amendment to the License Agreement of September 20, 2013, by and between Tenax Therapeutics, Inc. and Orion Corporation, dated as of October 2, 2024.	10-K	001-34600	10.3.5	March 25, 2025
10.3.6*	Fifth Amendment to the License Agreement of September 20, 2013, by and between Tenax Therapeutics, Inc. and Orion Corporation, dated as of September 3, 2025.	8-K	001-34600	10.1	September 9, 2025
10.4.1+	Tenax Therapeutics, Inc. 2016 Stock Incentive Plan.	10-Q	001-34600	10.1	August 9, 2016
10.4.2+	Amendment No. 1 to Tenax Therapeutics, Inc. 2016 Stock Incentive Plan.	10-Q	001-34600	10.1	August 14, 2019
10.4.3+	Amendment No. 2 to Tenax Therapeutics, Inc. 2016 Stock Incentive Plan.	10-Q	001-34600	10.1	August 16, 2021
10.4.4+	Form of Option issued to Non-Employee Directors under Tenax Therapeutics, Inc. 2016 Stock Incentive Plan.	10-Q	001-34600	10.2	August 14, 2018
10.4.5+	Form of Option issued to Employees and Contractors under Tenax Therapeutics, Inc. 2016 Stock Incentive Plan.	10-Q	001-34600	10.3	August 14, 2018
10.4.6+	Form of Incentive Stock Option Agreement under Tenax Therapeutics, Inc. 2016 Stock Incentive Plan.	10-Q	001-34600	10.4	August 14, 2018
10.5	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
10.6	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
10.7.1	Form of Securities Purchase Agreement for Class E Units and Class F Units, dated as of July 6, 2020, by	8-K	001-34600	10.2	July 8, 2020

	and between Tenax Therapeutics, Inc. and the Investor.				
10.7.2	Waiver dated June 13, 2022.	8-K	001-34600	10.1	June 16, 2022
10.8	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
10.9.1+	Executive Employment Agreement with Dr. Stuart Rich dated January 15, 2021.	8-K	001-34600	10.1	January 19, 2021
10.9.2+	Amendment to Executive Employment Agreement with Dr. Stuart Rich dated June 12, 2024.	8-K	001-34600	10.2	June 13, 2024
10.9.3+	Second Amendment to Executive Employment Agreement with Dr. Stuart Rich, MD, dated January 6, 2026.	8-K	001-34600	10.1	January 6, 2026
10.10	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
10.11	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
10.12+	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
10.13+	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
10.14 +*	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
10.15	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
10.16	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
10.17.1+	Tenax Therapeutics, Inc. 2022 Stock Incentive Plan.	8-K	001-34600	10.1	June 10, 2022
10.17.2+	Amendment No. 1 to the Tenax Therapeutics, Inc. 2022 Stock Incentive Plan.	8-K	001-34600	10.1	June 13, 2024
10.17.3+	Amendment No. 2 to the Tenax Therapeutics, Inc. 2022 Stock Incentive Plan.	8-K	001-34600	10.1	October 30, 2024

10.17.4+	Form of Notice of Stock Option Grant and Award Agreement under the Tenax Therapeutics, Inc. 2022 Stock Incentive Plan.	8-K	001-34600	10.2	June 10, 2022
10.18	Placement Agency Agreement, dated as of February 3, 2023, by and between Tenax Therapeutics, Inc. and Roth Capital Partners, LLC.	8-K	001-34600	10.1	February 7, 2023
10.19	Form of Securities Purchase Agreement dated as of February 3, 2023 by and between Tenax Therapeutics, Inc. and the purchasers named therein.	8-K	001-34600	10.2	February 7, 2023
10.20	Form of Leak-Out Agreement, dated as of February 3, 2023 by and between Tenax Therapeutics, Inc. and the purchasers named therein.	8-K	001-34600	10.3	February 7, 2023
10.21	Placement Agency Agreement, dated as of February 8, 2024, by and between Tenax Therapeutics, Inc. and Roth Capital Partners, LLC.	8-K	001-34600	10.1	February 12, 2024
10.22	Form of Securities Purchase Agreement, dated as of February 8, 2024, by and between Tenax Therapeutics, Inc. and the purchasers named therein.	8-K	001-34600	10.2	February 12, 2024
10.23	Form of Securities Purchase Agreement, dated as of August 6, 2024, by and between Tenax Therapeutics, Inc. and the purchasers named therein.	8-K	001-34600	10.1	August 6, 2024
10.24	Form of Registration Rights Agreement, dated as of August 6, 2024, by and between Tenax Therapeutics, Inc. and the purchasers named therein.	8-K	001-34600	10.2	August 6, 2024
10.25+	Form of Inducement Stock Option Award Agreement	10-K	001-34600	10.26	March 25, 2025
10.26	Form of Securities Purchase Agreement, dated March 4, 2025, by and among Tenax Therapeutics, Inc. and the investors signatory thereto.	8-K	001-34600	10.1	March 6, 2025
10.27	Form of Registration Rights Agreement, dated as of March 5, 2025, by and between Tenax Therapeutics, Inc. and the purchasers named therein.	8-K	001-34600	10.2	March 6, 2025
19.1	Tenax Therapeutics, Inc. Insider Trading Policy, dated as of September 20, 2023.	10-K	001-34600	19.1	March 25, 2025
21.1	List of Subsidiaries of Registrant.	10-K	001-34600	21.1	March 31, 2023
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
97.1	Tenax Therapeutics, Inc. Compensation Recovery Policy, adopted September 20, 2023.	10-K	001-34600	97.1	March 28, 2024
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 10, 2026

TENAX THERAPEUTICS, INC.
By: /s/ Thomas A. McGauley
Thomas A. McGauley
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 10, 2026
/s/ Thomas A. McGauley Thomas A. McGauley	Interim Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 10, 2026
/s/ Gerald Proehl Gerald Proehl	Chairman of the Board and Director	March 10, 2026
/s/ June Almenoff, MD June Almenoff, MD	Director	March 10, 2026
/s/ Michael Davidson, MD Michael Davidson, MD	Director	March 10, 2026
/s/ Declan Doogan, MD Declan Doogan, MD	Director	March 10, 2026
/s/ Robyn M. Hunter Robyn M. Hunter	Director	March 10, 2026
/s/ Stuart Rich, MD Stuart Rich, MD	Director	March 10, 2026

TENAX THERAPEUTICS, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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, 2025and 2024, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2025, 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, 2025and 2024, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

Critical Audit Matters

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

Capital Raise Transaction Involving Equity Instruments

Description of Matter

As disclosed in Note 4 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 and pre-funded 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 the pre-funded warrants in the consolidated financial statements.

How We Addressed the Matter in Our Audits

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, 2025.
- 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.
- We tested management's application of the relevant accounting guidance.

Prepaid or Accrued Clinical Trial Expenses

Description of Matter

The Company's total prepaid expenses and other current assets totaled $5.6 million, which included amounts in advance of services incurred pursuant to clinical trials in the amount of approximately $4.8 million.

As discussed in Note 2 to the consolidated financial statements, when the third party contract research organizations and other vendor billing terms do not coincide with the Company's period-end, the Company is required to make estimates of its obligations to those vendors, including personnel costs, allocated facility costs, lab supplies, outside services, contract laboratory costs related to manufacturing drug product, clinical trials, and preclinical studies costs incurred in a given accounting period and record accruals at the end of the period.

The Company bases its estimates on its knowledge of the research and development programs, services performed for the period, past history for related activities, and the expected duration of the vendor service contracts, where applicable. Payments for these activities are based on the terms of the individual arrangements and may result in payment terms that differ from the pattern of costs incurred. There may be instances in which payments made to vendors will exceed the level of services provided and result in a prepayment of the clinical expense.

Auditing the Company's prepaid or accrued clinical trial expenses is especially challenging due to the large volume of information received from multiple vendors that perform services on the Company's behalf. While the Company's estimates of prepaid or accrued clinical trial expenses are primarily based on information received related to each study from its vendors, the Company may need to make an estimate for additional costs incurred. Additionally, due to the long duration of clinical trials and the timing of invoicing received from vendors, the actual amounts incurred are not typically known at the time the consolidated financial statements are issued.

How We Addressed the Matter in Our Audits

Our audit procedures included, among others, the following:

- Obtained an understanding of the internal controls and processes in place over the Company's process used in determining the existence and completeness of prepaid or accrued clinical trial expenses.
- Tested the accuracy and completeness of the underlying data used in determining the prepaid or accrued clinical trial expenses and evaluating the assumptions and estimates used by management to adjust the actual information received. We corroborated the schedules of the underlying data used in the accrual calculation with the Company's third party contract research organizations who oversees the clinical trials. To evaluate the

completeness of any required accrual, we also tested subsequent invoices received to assess the impact to the accrual.

/s/ Cherry Bekaert LLP

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

Raleigh, North Carolina

March 10, 2026

TENAX THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS
(Amounts in thousands, except share and per share data)

	December 31, 2025	December 31, 2024
ASSETS		
Current assets		
Cash and cash equivalents	$ 97,565	$ 94,851
Prepaid expenses	5,643	1,771
Other current assets	1,019	64
Total current assets	104,227	96,686
Total assets	$ 104,227	$ 96,686
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 6,041	$ 3,157
Accrued liabilities	1,115	1,536
Total current liabilities	7,156	4,693
Total liabilities	7,156	4,693
Commitments and contingencies; see Note 5		
Stockholders' equity		
Preferred stock, undesignated, authorized 4,818,654 shares		
Series A Preferred stock, par value $0.0001, issued 5,181,346 shares; outstanding 210, as of December 31, 2025 and December 31, 2024	-	-
Common stock, par value $0.0001 per share; authorized 400,000,000 shares; issued and outstanding 9,314,130 as of December 31, 2025 and 3,420,906 as of December 31, 2024, respectively	1	-
Additional paid-in capital	464,524	406,848
Accumulated deficit	(367,454)	(314,855)
Total stockholders' equity	97,071	91,993
Total liabilities and stockholders' equity	$ 104,227	$ 96,686

The accompanying notes are an integral part of these consolidated financial statements.

TENAX THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS
(Amounts in thousands, except share and per share data)

	For the Year Ended December 31,	
	2025	**2024**
Operating expenses		
Research and development	$ 32,672	$ 12,709
General and administrative	23,713	6,785
Total operating expenses	56,385	19,494
Net operating loss	(56,385)	(19,494)
Interest income	3,819	1,914
Interest expense	-	(23)
Other (expense) income, net	(33)	1
Net loss	$ (52,599)	$ (17,602)
Net loss per share, basic and diluted	$ (1.34)	$ (1.15)
Weighted average number of common shares and prefunded warrants outstanding, basic and diluted	39,217,244	15,271,705

The accompanying notes are an integral part of these consolidated financial statements.

TENAX THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Amounts in thousands, except share data)

	Preferred Stock		Common Stock				
	Number of Shares	Amount	Number of Shares	Amount	Additional paid-in capital	Accumulated deficit	Total stockholders' equity
Balance at December 31, 2023	**210**	**$ -**	**298,281**	**$ -**	**$ 305,351**	**$ (297,253)**	**$ 8,098**
Public offering sale of common stock, warrants, and prefunded warrants, net of offering costs of $8,416	-	-	1,871,921	-	100,303	-	100,303
Exercise of pre-funded warrants	-	-	1,178,707	-	1	-	1
Exercise of warrants	-	-	12,000	-	68	-	68
Stock split and fractional shares issued	-	-	59,997	-	-	-	-
Stock-based compensation expense	-	-	-	-	1,125	-	1,125
Net loss	-	-	-	-	-	(17,602)	(17,602)
Balance at December 31, 2024	**210**	**$ -**	**3,420,906**	**$ -**	**$ 406,848**	**$ (314,855)**	**$ 91,993**
Public offering sale of common stock, warrants, and prefunded warrants, net of offering costs of $1,746	-	-	378,346	-	23,216	-	23,216
Exercise of pre-funded warrants	-	-	2,538,799	-	12	-	12
Exercise of warrants	-	-	2,976,079	1	15,285	-	15,286
Stock-based compensation expense	-	-	-	-	19,163	-	19,163
Net loss	-	-	-	-	-	(52,599)	(52,599)
Balance at December 31, 2025	**210**	**$ -**	**9,314,130**	**$ 1**	**$ 464,524**	**$ (367,454)**	**$ 97,071**

The accompanying notes are an integral part of these consolidated financial statements.

TENAX THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands)

	Year ended December, 31	
	2025	**2024**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (52,599)	$ (17,602)
Adjustments to reconcile net loss to net cash used in operating activities		
Interest on debt instrument	-	23
Stock-based compensation	19,163	1,125
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	(4,827)	58
Accounts payable	2,884	1,062
Accrued liabilities	(421)	523
Net cash used in operating activities	(35,800)	(14,811)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common stock, warrants and pre-funded warrants, net of issuance costs	23,216	100,303
Proceeds from the exercise of warrants	15,298	68
Payments on short-term note	-	(501)
Net cash provided by financing activities	38,514	99,870
Net change in cash and cash equivalents	2,714	85,059
Cash and cash equivalents, beginning of period	94,851	9,792
Cash and cash equivalents, end of period	$ 97,565	$ 94,851
Supplemental Disclosures:		
Cash paid for interest	$ -	$ 23

The accompanying notes are an integral part of these consolidated financial statements.

TENAX THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1—DESCRIPTION OF BUSINESS

Tenax Therapeutics, Inc., together with its subsidiaries (collectively "Tenax" or the "Company"), is a Phase 3, development-stage pharmaceutical company using clinical insights to develop novel cardiopulmonary therapies.

The Company is incorporated in Delaware and is headquartered in Chapel Hill, North Carolina.

Liquidity and Capital Resources

The Company has financed its operations since September 1990 primarily through the sale of equity and debt securities and loans from stockholders. The Company had an accumulated deficit of $367.5 million at December 31, 2025 and incurred losses of $52.6 million and $17.6 million during the years ended December 31, 2025 and 2024, respectively. The Company expects to continue to incur expenses related to the development of levosimendan for pulmonary hypertension and other potential indications and, over the long term, imatinib for pulmonary arterial hypertension ("PAH"), as well as identifying and developing other potential product candidates. At December 31, 2025, the Company had cash and cash equivalents of $97.6 million and received an additional $14.5 million subsequent to year end from the exercise of pre-funded warrants and warrants. Based on its resources on December 31, 2025 and cash received subsequent to year end, Company management believes that it has sufficient funds for the Company to continue its operations over at least the next 12 months from the date these consolidated financial statements were available to be issued.

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 restrictive covenants in the related transaction documents that may affect the manner in which the Company conducts its business. To the extent that the Company raises additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to its technologies or product candidates or grant licenses on terms that may not be favorable to the Company. Any or all of the foregoing may have a material adverse effect on the Company's business and financial performance.

NOTE 2—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Principles of Consolidation

The Company has prepared its consolidated financial statements in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASUs") promulgated by the Financial Accounting Standards Board ("FASB").

The consolidated financial statements include the accounts of the Company and its subsidiaries. Intercompany balances and transactions have been eliminated upon consolidation.

Use of Estimates

The preparation of consolidated financial statements in accordance with U.S. 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.

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. The Company's cash and cash equivalents include holdings in money market funds, checking and overnight sweep accounts at December 31, 2025 and bank certificates of deposit through CDARS (Certificate of Deposit Account Registry Service), as well as money market funds, at December 31, 2024. These accounts are measured at fair value on a recurring basis. As of December 31, 2025 and 2024, the balances of cash and cash equivalents were $97.6 million and $94.9 million, respectively, which approximate fair value and were determined based upon Level 1 inputs. The money market and sweep accounts are valued using quoted market prices with no valuation adjustments applied. Accordingly, these financial instruments are categorized as Level 1.

Concentrations of Credit Risk and Off-Balance Sheet Risk

The Federal Deposit Insurance Corporation (the "FDIC") insurance limits are $250 thousand per depositor per insured bank. The Company had cash balances of $97.0 million and $1.0 million uninsured by the FDIC as of December 31, 2025 and 2024, respectively. At December 31, 2024, the Company utilized the IntraFi network of commercial banks which deposits $250,000 in each of its member banks to maintain the FDIC insurance limit.

Financial instruments that potentially subject the Company to credit risk consist primarily of cash and cash equivalents. The Company mitigates its risk with respect to cash and cash equivalents by maintaining its deposits and investments at high-quality financial institutions. The Company invests any excess cash in money market funds and certificates of deposit, and the management of these investments is not discretionary on the part of the financial institution. Substantially all of the Company's cash and cash equivalents are held at JP Morgan and First Horizon Bank, and the amounts frequently exceed federally insured limits.

The Company has no off-balance-sheet concentration of credit risk such as foreign exchange contracts, option contracts or other foreign hedging arrangements.

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 the Company 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.

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, Equity-Based Payments to Non-Employees. The Company records equity instruments at their fair value on the measurement date and periodically adjust them as the underlying equity instruments vest.

Warrants for Common Shares and Derivative Financial Instruments

Warrants for shares of common stock and other derivative financial instruments are classified as equity if the contracts: (i) require physical settlement or net-share settlement or (ii) give the Company a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement). Contracts are classified as equity or liabilities if the contracts: (i) require net-cash settlement (including a requirement to net cash settle the contract if an event occurs and if that event is outside the control of the Company), (ii) give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement), or (iii) contain reset provisions that do not qualify for the scope exception. The Company assesses the classification of its warrants for shares of common stock and other derivatives at each reporting date to determine whether a change in classification between equity and liabilities is required.

Offering Costs

Offering costs consists of the costs incurred with the issuance of common stock. warrants, and pre-funded warrants. Costs include placement agent, legal, advisory, accounting and filing fees.

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, 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,	
	2025	**2024**
Warrants to purchase common stock	16,895,111	19,874,360
Options to purchase common stock	6,866,746	3,126,750
Convertible preferred shares outstanding	210	210

Leases

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease. Leases with a term greater than one year are recognized on the consolidated balance sheet as a right-of-use ("ROU") asset and current and non-current lease liabilities, as applicable. The Company has made an accounting policy election,

known as the short-term lease recognition exemption, which allows the Company to not recognize ROU assets and lease liabilities that arise from short-term leases (12 months or less); The Company has applied this election to all classes of underlying assets. The Company typically only includes an initial lease term in its assessment of a lease arrangement. Options to renew or options to cancel a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew or will not cancel, respectively. The Company monitors its material leases on a quarterly basis.

Operating lease liabilities and their corresponding ROU assets are recorded based on the present value of future lease payments over the expected remaining lease term. Lease cost for operating leases is recognized on a straight-line basis over the lease term as an operating expense. Certain adjustments to the ROU asset may be required for items such as lease prepayments or incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. The Company has elected to account for the lease and non-lease components together for all leases.

Fair Value

The Company determines the fair value of its financial assets and liabilities in accordance with ASC 820, Fair Value Measurements. The Company's balance sheet includes the following financial instruments: cash and cash equivalents and money market funds. The Company considers the carrying amount of its cash and cash equivalents and money market funds 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.

Recent Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures, which is intended to provide enhancements to annual income tax disclosures. The standard will require more detailed information in the rate reconciliation table and for income taxes paid, among other enhancements. The standard is effective for years beginning after December 15, 2024. The application of this ASU did not have a material impact on the Company's financial position, results of operations or cash flows.

In November 2024, the FASB issued ASU 2024-03, Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Topic 220-40), which addresses the disaggregation of income statement expenses. This standard is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. The Company is evaluating this standard to determine if adoption will have a material impact on the Company's consolidated financial statements.

NOTE 3—BALANCE SHEET COMPONENTS

Prepaid expenses and other current assets consist of the following (in thousands):

	December 31, 2025	December 31, 2024
Prepaid assets:		
Prepaid CRO expenses	$ 4,841	$ 1,086
Other prepaid expenses	802	685
Total prepaid expenses	$ 5,643	$ 1,771
Other current assts:		
Cash from warrant exercise held at transfer agent	$ 949	$ -
Miscellaneous other current assets	70	64
Total other current assets	$ 1,019	$ 64

Accrued liabilities consist of the following (in thousands):

	December 31, 2025	December 31, 2024
Operating costs	$ 217	$ 200
Employee related	898	1,336
	$ 1,115	$ 1,536

NOTE 4—STOCKHOLDERS' EQUITY

Common Stock and Preferred Stock

Common Stock

The Company's Certificate of Incorporation, as amended, authorizes it to issue 400,000,000 shares of $0.0001 par value common stock. As of December 31, 2025, and December 31, 2024, there were 9,314,130 and 3,420,906 shares of common stock issued and outstanding, respectively.

Preferred Stock

Under the Company's Certificate of Incorporation, as amended, the Board of Directors is authorized, without further stockholder action, to provide for the issuance of up to 10,000,000 shares of preferred stock, par value $0.0001 per share, in one or more series, to establish from time to time the number of shares to be included in each such series, and to fix the designation, powers, preferences and rights of the shares of each such series and the qualifications, limitations and restrictions thereof. Of the potential 10,000,000 shares of preferred stock, 5,181,346 are designated as Series A Stock and 4,818,654 remain undesignated. As of December 31, 2025 and 2024, there were 210 shares of Series A Stock outstanding, convertible into an aggregate of one share of common stock.

Common Stock and Pre-Funded Warrants

March 2025 Private Placement Financing (the "March 2025 Offering")

On March 4, 2025, the Company entered into a securities purchase agreement with certain accredited investors for the purchase and sale, in a private placement financing by the Company, of an aggregate of 378,346 shares of its common stock, and pre-funded warrants to purchase an aggregate of 3,760,726 shares of common stock at an offering price of $6.04 per share of common stock and $6.03 per pre-funded warrant, resulting in gross proceeds of $25.0 million. The pre-funded warrants do not expire and have an exercise price of $0.01. The net proceeds of the March 2025 Offering, after deducting placement agent fees and direct offering expenses were $23.2 million. The relative fair value allocated to the common stock and pre-funded warrants was $2.3 million and $22.7 million, respectively.

Also, on March 5, 2025 and in connection with the March 2025 Offering, the Company entered into a registration rights agreement (the "March 2025 Registration Rights Agreement") with the purchasers, pursuant to which the Company agreed to register for resale the shares of common stock issued in the March 2025 Offering and the shares of common stock issuable upon exercise of the pre-funded warrants issued in the March 2025 Offering within 45 days of the closing date. Pursuant to the March 2025 Registration Rights Agreement, on April 15, 2025, the Company filed a resale registration statement on Form S-3 with the SEC, which went effective on April 23, 2025.

The March 2025 Registration Rights Agreement includes liquidated damages provisions that meet the definition of a registration payment arrangement that is within the scope of ASC 825-20. The Company determined at the initial issuance of the pre-funded warrants that it is not probable that a payment would be required as it has both the intent and ability to satisfy the March 2025 Registration Rights Agreement. Therefore, the Company did not record a liability at inception but will evaluate the contingency at each reporting period. As of December 31, 2025, no events had occurred that would change our initial assessment of this provision.

August 2024 Private Placement Financing (the "August 2024 Offering")

On August 6, 2024, the Company entered into a securities purchase agreement with certain accredited investors for the purchase and sale, in a private placement financing by the Company, of (i) an aggregate of 1,450,661 shares of its common stock and pre-funded warrants to purchase an aggregate of 31,882,671 shares of common stock and (ii) accompanying warrants to purchase up to an aggregate of 16,666,666 shares of its common stock (or, in lieu thereof, additional pre-funded warrants) at a combined offering price of $3.00 per share of common stock and accompanying warrant, or $2.99 per pre-funded warrant and accompanying warrant, resulting in gross proceeds of $99.7 million. The pre-funded warrants do not expire and have an exercise price of $0.01. The net proceeds of the August 2024 Offering after deducting placement agent fees and direct offering expenses were $92.3 million. The relative fair value allocated to the common stock, pre-funded warrants, and warrants was $3.2 million, $69.4 million, and $27.1 million, respectively.

Also, on August 6, 2024 and in connection with the August 2024 Offering, the Company entered into a registration rights agreement (the "August 2024 Registration Rights Agreement") with the purchasers, pursuant to which the Company agreed to register for resale the shares of common stock issued in the August 2024 Offering and the shares of common stock issuable upon exercise of the warrants issued in the August 2024 Offering within 60 days following the effective date of the August 2024 Registration Rights Agreement. Pursuant to the August 2024 Registration Rights Agreement, on August 30, 2024, the Company filed a resale registration statement on Form S-3 with the SEC, which went effective on September 12, 2024.

The August 2024 Registration Rights Agreement includes liquidated damages provisions that meet the definition of a registration payment arrangement that is within the scope of ASC 825-20. The Company determined at the initial issuance of the pre-funded warrants and accompanying warrant that it is not probable that a payment would be required as it has both the intent and ability to satisfy the August 2024 Registration Rights Agreement. Therefore, the Company did not record a liability at inception but will evaluate the contingency at each reporting period. As of December 31, 2025 no events have occurred that would change our initial assessment of this provision.

February 2024 Registered Public Offering (the "February 2024 Offering")

On February 8, 2024, the Company entered into a securities purchase agreement with certain purchasers for the purchase and sale, in a registered public offering by the Company, of (i) an aggregate of 421,260 shares of its common stock and pre-funded warrants to purchase an aggregate of 1,178,740 shares of common stock and (ii) accompanying warrants to purchase up to an aggregate of 3,200,000 shares of its common stock at a combined offering price of $5.65 per share of common stock and associated warrant, or $5.649 per pre-funded warrant and associated warrant, resulting in gross proceeds of $9.0 million. The net proceeds of the February 2024 Offering after deducting placement agent fees and direct offering expenses were $8.0 million. The relative fair value allocated to the common stock, pre-funded warrants and warrants was $0.9 million, $2.4 million, and $5.7 million, respectively.

Pre-Funded Warrants Activity

The following table summarizes the Company's pre-funded warrant activity for the years ended December 31, 2025 and 2024:

	Prefunded Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2023	**-**	**$ —**
Issued	33,061,411	0.01
Exercised	(1,178,740)	0.01
Canceled	-	—
Outstanding at December 31, 2024	**31,882,671**	**$ 0.01**
Issued	3,760,726	0.01
Exercised	(2,538,799)	0.01
Canceled	(1,820)	0.01
Outstanding at December 31, 2025	**33,102,778**	**$ 0.01**

Warrants

The following table summarizes the Company's warrant activity for the years ended December 31, 2025 and 2024, not including pre-funded warrants:

	Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2023	**19,694**	**$ 1,095.27**
Issued	19,866,666	4.69
Exercised	(12,000)	5.65
Canceled	—	—
Outstanding at December 31, 2024	**19,874,360**	**$ 5.77**
Issued	—	—
Exercised	(2,976,079)	5.14
Canceled/Expired	(3,170)	1,151.33
Outstanding at December 31, 2025	**16,895,111**	**$ 5.66**

August 2024 Warrants

As described above, as part of the August 2024 Offering, the Company issued unregistered warrants to purchase 16,666,666 shares of its common stock at an exercise price of $4.50 per share. The warrants expire at the earlier of (i) 30 trading days following the date of the Company's initial public announcement of topline data from its Phase 3 LEVEL trial (the "Topline Data Announcement"), (ii) immediately upon the exercise of the August 2024 pre-funded warrants if such exercise is prior to the Topline Data Announcement, provided that if the pre-funded warrant is not exercised in full, the warrant expires proportionally to the extent the pre-funded warrant is exercised, and (iii) August 8, 2029. The warrants have an estimated term of 1.8 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 $27.1 million was recognized as additional paid in capital. The estimated fair value is determined using the Black-Scholes option pricing model using the following assumptions: remaining estimated term of 1.8 years, risk free interest rate of 3.83%, expected dividends of zero, and expected volatility of 177.27%.

February 2024 Warrants

As described above, as a part of the February 2024 Offering, the Company issued registered warrants to purchase 3,200,000 shares of its common stock at an exercise price of $5.65 per share and contractual term of five years. In accordance with ASC 815, Derivatives and Hedging, these warrants are classified as equity and their relative fair value of $5.7 million was recognized as additional paid in capital. The estimated fair value was determined using the Black-Scholes option pricing model using the following assumptions: remaining estimated term of 5.0 years, risk free interest rate of 4.12%, expected dividends of zero, and expected volatility of 131.87%.

Stock-Based Compensation

Stock Incentive Plans

In June 2022, the Company adopted the 2022 Stock Incentive Plan, as amended on June 7, 2024 and October 25, 2024, (the "2022 Plan"), with the outstanding shares available for future grants under prior plans, as well as outstanding awards under prior plans that subsequently expire, terminate or are surrendered or forfeited, generally being assumed by the 2022 Plan. Unexpired awards granted under certain prior plans may be subject to the terms of such prior plans.

Under the 2022 Plan, with the approval of the Board of Director'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. 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 number of shares of common stock authorized for issuance under the 2022 Plan is 8,337,252 shares and a total of 1,721,121 shares remained available for issuance as of December 31, 2025.

Summary of Stock Option Activity

Transactions during the years ended December 31, 2025 and 2024 related to stock options granted to employees and directors under Company option plans were as follows:

	Shares	Weighted average exercise price per Share	Weighted average remaining contractual life (years)	Aggregate intrinsic value (in thousands)
Options outstanding as of December 31, 2023	646	$ 4,509.71	7.42	$ -
Granted	3,125,794	5.94		
Exercised	-	-		
Canceled or forfeited	(4)	159,600.00		
Options outstanding as of December 31, 2024	3,126,436	$ 6.66	9.95	$ 783
Granted	3,490,000	5.93		
Exercised	-	-		
Canceled or forfeited	(4)	107,360.00		
Options outstanding as of December 31, 2025	6,616,432	$ 6.21	9.19	$ 41,382
Options exercisable at December 31, 2025	3,125,754	$ 6.50	8.95	$ 19,533

The following table summarizes all options issued under the Company's stock plans that are outstanding as of December 31, 2025:

				Options Outstanding at December 31, 2025		Options Exercisable and Vested at December 31, 2025	
Exercise Price				Number of Options	Weighted Average Remaining Contractual Life (Years)	Number of Options	Weighted Average Exercise Price
$ 3.55	to	$ 7.10		6,615,794	9.2	3,125,196	$ 5.94
$ 992.00	to	$ 87,040.00		638	5.4	558	$ 3,148.70
				6,616,432	9.2	3,125,754	$ 6.50

The Company used the following assumptions to estimate the fair value of options granted for the year ended December 31, 2025.

	For the year ended December 31,	
	2025	2024
Risk-free interest rate (weighted average)	4.18%	4.09%
Expected volatility (weighted average)	122.16%	131.33%
Expected term (in years)	5.9	5.0
Expected dividend yield	0.00%	0.00%

The Company recorded compensation expense for non-inducement stock options of $18.8 million and $1.0 million for the years ended December 31, 2025 and 2024, respectively.

As of December 31, 2025, there were unrecognized compensation costs of $14.7 million related to non-vested stock option awards that will be recognized on a straight-line basis over the weighted average remaining vesting period of 1.47 years.

Inducement Stock Options

The Company granted an employment inducement stock option award for 250,000 shares of common stock to a new employee on January 21, 2025. 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 vests in four equal annual installments beginning on the first anniversary of the date of issuance, subject to the employee's continued employment with the Company through each applicable vesting date. The option has a 10-year term and an exercise price of $6.45 per share, the January 21, 2025 closing price of the Company's common stock. The estimated fair value of the inducement stock option award was $1.4 million using the 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 4.49%, dividend yield of 0%, volatility factor for our common stock of 123.41% and an expected life of 6 years.

The Company granted an employment inducement stock option award for 157 shares of common stock, to its then-new President and Chief Executive Officer on July 6, 2021. The employment inducement stock option award was granted 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. This award vested in four equal installments beginning on the first anniversary of the date of issuance, subject to continued employment. The option has a 10-year term and an exercise price of $3,152 per share, the July 6, 2021 closing price of our common stock. As of December 31, 2025, the option was fully vested. The estimated fair value of this inducement stock option award was $403 thousand using the 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 also granted an employment inducement stock option award for 157 shares of common stock to its then-new 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 option has a 10-year term and an exercise price of $2,848 per share, the January 15, 2021 closing price of our common stock, as adjusted for the subsequent reverse stock splits. As of December 31, 2025, two of the vesting milestones have been achieved. The estimated fair value of the inducement stock option award granted was $403 thousand using the 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 $0.4 million and $0.1 million for the years ended December 31, 2025 and December 31, 2024, respectively. As of December 31, 2025, there was $1.1 million of remaining unrecognized compensation expense related to these inducement stock options.

NOTE 5—COMMITMENTS AND CONTINGENCIES

Operating Leases

The Company owns no real property. Beginning November 1, 2022, the Company maintains a membership providing dedicated office space, as well as shared services and shared space for meetings, catering, and other business activities, at its' principal executive office.

Simdax License Agreement

On November 13, 2013, the Company acquired certain assets of Phyxius Pharma, Inc. ("Phyxius") pursuant to an asset purchase agreement by and among the Company, Phyxius and the stockholders of Phyxius, dated October 21, 2013. Among these assets was a license with Orion Corporation ("Orion") for the 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 (as amended from time to time, the "License"). On October 9, 2020 and January 25, 2022, the Company entered into amendments to the License to include in the scope of the License two new product formulations containing levosimendan, in capsule and solid dosage form (TNX-103) and a subcutaneously administered dosage form (TNX-102), subject to specified limitations (together, the "Product").

On February 19, 2024, the Company entered into an amendment to the License providing global rights to oral and subcutaneous formulations of levosimendan used in the treatment of pulmonary hypertension in heart failure with preserved ejection fraction ("PH-HFpEF"). The amendment also reduced the tiered royalties based on worldwide net sales of the product by the Company and its sublicensees, increased the License's existing milestone payment due to Orion upon the grant of United States Food and Drug Administration approval of a levosimendan-based product to $10.0 million and added a milestone payment to Orion of $5.0 million due upon the grant of regulatory approval for a levosimendan-based product in Japan. The amendment also (i) increased the Company's obligations to make certain non-refundable commercialization milestone payments to Orion, aggregating to up to $45.0 million, contingent upon achievement of certain cumulative worldwide sales of the product by the Company, and (ii) reduced the maximum price per capsule payable by the Company to Orion, under a yet-to-be-negotiated supply agreement, for the commercial supply of oral levosimendan-based product. Pursuant to the License, the Company and Orion will agree to a new trademark when commercializing levosimendan in either of the dosage forms.

On September 3, 2025, the Company entered into an amendment License providing exclusive worldwide rights to develop, commercialize, manufacture, and have manufactured any orally-administered pharmaceutical product containing levosimendan and, in addition to the Company's existing rights to develop and commercialize subcutaneously administered products containing levosimendan, to manufacture or have manufactured such products. The amendment also calls for Orion to supply the Company with levosimendan to the extent reasonably necessary or useful to manufacture orally-administered products containing levosimendan for purposes of developing such products, and sets forth the terms for such supply, including the price of levosimendan ordered by the Company of low triple-digit thousands in Euros per kilogram, payment terms, and active pharmaceutical ingredient specifications.

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.

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 but, pursuant to the February 2024 amendment, excluding new applications of levosimendan for neurological diseases and disorders developed by Orion.

As of December 31, 2025, 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.

NOTE 6—401(k) BENEFIT PLAN

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

For the years ended December 31, 2025 and 2024, the Company recorded $118 thousand and $63 thousand for matching contributions expense, respectively.

NOTE 7—INCOME TAXES

The Company has not recorded any income tax expense (benefit) for the period ended December 31, 2025 due to its history of net operating losses. The Company has adopted ASU 2023-09 "Income Taxes (Topic 740) Improvements to Income Tax Disclosures for the year-ended December 31, 2025.

The amounts of cash income taxes paid (received) by the Company for both federal and state income tax for the years ended December 31, 2025 and December 31, 2024 was zero.

The reconciliation of income tax expenses (benefit) at the statutory federal income tax rate of 21% for the period ended December 31, 2024 is as follows (in thousands):

	December 31, 2024
U.S. federal tax benefit at statutory rate	$ (3,696)
State income tax benefit, net of federal benefit	(94)
Stock compensation	256
Other nondeductible, including IPR&D expense	1
Change in state tax rate	-
Expiration of NOL Carryforward	564
Net operating loss adjustments	-
Other, including effect of tax rate brackets	(54)
Change in valuation allowance	3,023
	$ -

The reasons for the difference between actual income tax benefit for the years ended December 31, 2025 and the amount computed by applying the statutory federal income tax rate to losses before income tax benefit after the adoption of ASU 2023-09 are as follows (in thousands):

	Year Ended December 31, 2025	
	Amount	% of Pre-Tax Loss
U.S. federal statutory tax rate	$ (11,045)	21.0%
State and local income taxes, net of federal income tax	(51)	0.1%
Effect of changes in tax laws or rates enacted in the current period	-	-
Tax credits	-	-
Change in valuation allowance	8,682	(16.51%)
Nontaxable or nondeductible items		
Incentive stock option expense	167	(0.32%)
Sec. 162(m) impact on stock compensation	2,775	(5.27%)
Changes in Unrecognized Tax Benefits	-	-
Other adjustments		
Provision to return	-	-
Other	(528)	1.0%
Effective tax Rate	$ -	0.0%

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

	December 31,	
Deferred Tax Assets	2025	2024
Net operating loss carryforwards	$ 45,621	$ 37,639
Accruals and other	81	329
Capitalized R&D	3,315	3,732
Capital loss carryforwards	-	1
Stock compensation	1,366	-
Valuation allowance	(50,383)	(41,701)
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 2025 was approximately $8.7 million.

As of December 31, 2025, the Company had federal and state net operating loss carryforwards of approximately $208.5 million and $172.4 million available to offset future federal and state taxable income, respectively. Federal net operating losses of $120.7 million begin to expire in 2026, while the remaining $87.8 million carryforward indefinitely. State net operating losses begin to expire in 2026. The Company’s only material state income tax activity for the years 2025 and 2024 is related to the North Carolina jurisdiction.

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 or substantial restrictions on the use of such net operating losses.

On July 4, 2025, the U.S. government enacted the One Big Beautiful Bill Act (OBBBA), which includes several changes to U.S. federal income tax law, including temporary and permanent extension, of expiring provisions of the Tax Cuts and Jobs Act of 2017. Significant provisions for corporate taxpayers include permanent 100% bonus

depreciation for qualified property, immediate expensing of domestic R&D expenditures, and changes to the limitation on business interest expense deductions under Section 163(j). None of these provisions have a material impact on the Company's 2025 income tax provision. The main provision impacting the Company's tax profile is the allowance for current expensing of domestic R&D expenditures.

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.

The Company follows the provisions of ASC Topic 740-10, "Accounting for Uncertainty in Income Taxes" which clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements and prescribes a recognition threshold and measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. This topic also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure, and transition. There were no uncertain tax positions as of December 31, 2025 and 2024.

The Company files U.S. and state income tax returns with varying statutes of limitations. The tax years 2005 and forward remain open to examination due to the carryover of unused net operating losses or tax credits.

NOTE 8—SEGMENTS

Operating segments are identified as components of an entity about which separate discrete financial information is available for evaluation by the CODM, or decision-making group, in making decisions on how to allocate resources and assess performance. The Company's CODM, the President and Chief Executive Officer, views the Company's operations as one operating segment, which is focused on identifying and developing therapeutics that address cardiovascular and pulmonary diseases with high unmet medical need, with an initial therapeutic focus on pulmonary hypertension. The Company does not have revenue in the current comparative period, incurs expenses primarily in North America and manages the business activities on a consolidated basis.

The accounting policies of the cardiovascular and pulmonary therapeutics segment are the same as those described in the summary of significant accounting policies.

The CODM assesses performance for the cardiovascular and pulmonary therapeutics segment and decides how to allocate resources based on net loss that also is reported on the income statement as consolidated net loss. The measure of segment assets is reported on the balance sheet as cash and cash equivalents.

The Company has not generated any product revenue in the current period and expects to continue to incur significant expenses and operating losses for the foreseeable future as the Company advances its product candidates through all stages of development and clinical trials.

As such, the CODM uses cash forecast models in deciding how to invest into the cardiovascular and pulmonary therapeutics segment. Such cash forecast models are reviewed to assess the entity-wide operating results and performance. Net loss is used to monitor budget versus actual results. Monitoring budgeted versus actual results, net cash used in operating activities for the period and cash on hand are used in assessing performance of the segment.

The table below summarizes the significant expense categories regularly reviewed by the CODM for the years ended December 31, 2025 and 2024 (in thousands).

	The year ended December 31,	
	2025	**2024**
Operating expenses:		
Research and development	32,672	12,709
General and administrative	23,713	6,785
Total operating expenses	56,385	19,494
Net operating loss	(56,385)	(19,494)
Other segment items (a)		
Interest income	3,819	1,914
Interest expense	-	(23)
Other income, net	(33)	1
Net loss (b)	$ (52,599)	$ (17,602)

(a) Other segment items included in segment loss includes interest income and interest expense.

(b) The Company is a single operating segment and therefore the measure of segment net loss is the same as consolidated net loss and does not require reconciliation.

For the year ended December 31, 2025 and 2024, the net cash used in operating activities was $35.8 million and $14.8 million, respectively. The table below summarizes the significant asset categories regularly reviewed by the CODM for the years ended December 31, 2025 and 2024 (in thousands).

	The year ended December 31,	
	2025	**2024**
Assets:		
Cash and cash equivalents	97,565	94,851

NOTE 9—SUBSEQUENT EVENTS

Subsequent to December 31, 2025, the Company received a total of $14.5 million from the exercise of pre-funded warrants for 4,730,575 shares of common stock and warrants for 3,152,908 shares of common stock.

EXHIBIT 4.16

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

We are authorized to issue 410,000,000 shares of our capital stock consisting of (a) 400,000,000 shares of common stock, par value $0.0001 per share ("Common Stock"), and (b) 10,000,000 shares of preferred stock, par value $0.0001 per share ("Preferred Stock"), consisting of (i) 4,818,654 shares of undesignated "blank check" preferred stock, par value $0.0001 per share, and (ii) 5,181,346 shares of Series A Preferred Stock, par value $0.0001 per share. 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 amended and restated certificate of incorporation (the "Charter") and our fourth amended and restated bylaws (the "Restated Bylaws"), which are included as exhibits to this Annual Report on Form 10-K, and to the provisions of applicable Delaware law.

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

Common Stock

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

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

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 consisting of: (a) 4,818,654 shares of undesignated "blank check" Preferred Stock, par value $0.0001 per share, and (b) 5,181,346 shares of Series A Preferred Stock, par value $0.0001 per share. The "blank check" Preferred Stock may be issued in one or more series and our board of directors has the authority 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.

CERTAIN PROVISIONS OF DELAWARE LAW, OUR CHARTER 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 ("DGCL"). 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 a majority 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.

- *Limitation on Liability of Directors and Officers.* Our Charter provides that no director or officer of the Company shall be personally liable to the Company or its stockholders for monetary damages for breach of fiduciary duty, except, if required by DGCL, as amended from time to time, for liability (i) for any breach of the director's or officer's duty of loyalty to the Company or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) for a director under Section 174 of the DGCL, (iv) for any transaction from which the director or officer derived an improper personal benefit, or (v) for an officer, in any action by or in the right of the Company. Our Charter further provides that if the DGCL is amended to authorize corporate action further eliminating or limiting personal liability of directors or officers, such liability shall be eliminated or limited to the fullest extent permitted by the DGCL, as amended.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Equiniti Trust Company, LLC.

Listing on the Nasdaq Capital Market

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

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. 333-266833, 333-167175, 333-196464, 333-210182, 333-224120, 333-233571, 333-259266, 333-283482, and 333-281874), Form S-3 (Nos. 333-286557, 333-281873, 333-265209, 333-258981, and 333-248201), and Form S-1 (Nos. 333-275856 and 333-269363) of our report dated March 10, 2026, 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, 2025 and 2024, and the related consolidated statements of operations, stockholders' equity, and cash flows, and the related notes (which report expresses an unqualified opinion for each of the years in the two-year period ended December 31, 2025.

/s/ CHERRY BEKAERT LLP

Raleigh, North Carolina
March 10, 2026

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE 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, 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 10, 2026

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, Thomas A. McGauley, 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 10, 2026

By:/s/ Thomas A. McGauley
Thomas A. McGauley
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, 2025 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 10, 2026

/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, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Thomas A. McGauley, 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 10, 2026

/s/ Thomas A. McGauley
Thomas A. McGauley
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.