

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

**FORM 10-Q**

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

FOR THE QUARTERLY PERIOD ENDED March 31, 2024

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 Number 001-34600

**TENAX THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

Delaware  
(State of incorporation)

26-2593535  
(I.R.S. Employer Identification No.)

101 Glen Lennox Drive, Suite 300, Chapel Hill, North Carolina 27517  
(Address of principal executive offices, including zip code)

(919) 855-2100  
(Registrant's telephone number, including area code)

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

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 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   
Non-accelerated Filer   
Emerging growth company

Accelerated filer   
Smaller reporting company

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

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

As of May 10, 2024, the registrant had outstanding 1,958,245 shares of Common Stock.

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**PART I - FINANCIAL INFORMATION**

**ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**TENAX THERAPEUTICS, INC.  
CONDENSED CONSOLIDATED BALANCE SHEETS**

	<b>March 31, 2024 (Unaudited)</b>	<b>December 31, 2023</b>
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 12,549,475	\$ 9,792,130
Prepaid expenses	1,843,047	1,639,797
Other current assets	66,625	251,583
Total current assets	<u>14,459,147</u>	<u>11,683,510</u>
Other assets	1,117	1,117
Total assets	<u>\$ 14,460,264</u>	<u>\$ 11,684,627</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$ 1,080,962	\$ 2,073,149
Accrued liabilities	536,443	1,012,468
Note Payable	413,174	500,903
Total current liabilities	<u>2,030,579</u>	<u>3,586,520</u>
Total liabilities	<u>2,030,579</u>	<u>3,586,520</u>
Commitments and contingencies; see Note 6		
Stockholders' equity		
Preferred stock, undesignated, authorized 4,818,654 shares; See Note 7		
Series A Preferred stock, par value \$. 0001, authorized 5,181,346 shares; issued and outstanding 210, as of March 31, 2024 and December 31, 2023, respectively	-	-
Common stock, par value \$0.0001 per share; authorized 400,000,000 shares; issued and outstanding 1,958,245 as of March 31, 2024 and 298,281 as of December 31, 2023, respectively	196	30
Additional paid-in capital	313,481,082	305,350,830
Accumulated deficit	<u>(301,051,593)</u>	<u>(297,252,753)</u>
Total stockholders' equity	<u>12,429,685</u>	<u>8,098,107</u>
Total liabilities and stockholders' equity	<u>\$ 14,460,264</u>	<u>\$ 11,684,627</u>

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

**TENAX THERAPEUTICS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(Unaudited)**

	<b>Three months ended March 31,</b>	
	<b>2024</b>	<b>2023</b>
Operating expenses		
General and administrative	\$ 1,232,674	\$ 1,273,730
Research and development	2,675,652	265,735
<b>Total operating expenses</b>	<b>3,908,326</b>	<b>1,539,465</b>
Net operating loss	3,908,326	1,539,465
Interest expense	7,963	7,350
Other expense (income), net	(117,449)	(140,055)
<b>Net loss</b>	<b>\$ 3,798,840</b>	<b>\$ 1,406,760</b>
Net loss per share, basic and diluted	\$ (3.12)	\$ (12.10)
Weighted average number of common shares outstanding, basic and diluted	1,219,139	116,259

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

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**TENAX THERAPEUTICS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**  
(Uaudited)

	Preferred Stock		Common Stock		Additional paid-in capital	Accumulated deficit	Total stockholders' equity
	Number of Shares	Amount	Number of Shares	Amount			
<b>Balance at December 31, 2022</b>	<b>210</b>	<b>\$ -</b>	<b>28,647</b>	<b>\$ 3</b>	<b>\$291,034,818</b>	<b>\$(289,542,080)</b>	<b>\$ 1,492,741</b>
Public offering sale of common stock and prefunded warrants	-	-	86,994	9	13,896,516	-	13,896,525
Offering costs	-	-	-	-	(282,647)	-	(282,647)
Exercise of pre-funded warrants for cash	-	-	18,076	2	511,309	-	511,311
Exercise of pre-funded warrants, cashless	-	-	3,259	-	-	-	-
Exercise of warrants, cashless	-	-	135,069	13	(13)	-	-
Stock split and fractional shares issued	-	-	174	-	-	-	-
Compensation on options issued	-	-	-	-	66,543	-	66,543
Net loss	-	-	-	-	-	(1,406,760)	(1,406,760)
<b>Balance at March 31, 2023</b>	<b>210</b>	<b>\$ -</b>	<b>272,219</b>	<b>\$ 27</b>	<b>\$305,226,526</b>	<b>\$(290,948,840)</b>	<b>\$ 14,277,713</b>
<b>Balance at December 31, 2023</b>	<b>210</b>	<b>\$ -</b>	<b>298,281</b>	<b>\$ 30</b>	<b>\$305,350,830</b>	<b>\$(297,252,753)</b>	<b>\$ 8,098,107</b>
Public offering sale of common stock and prefunded warrants, net	-	-	421,260	42	6,183,619	-	6,183,661
Exercise of pre-funded warrants for cash	-	-	973,240	97	1,827,036	-	1,827,133
Exercise of pre-funded warrants, cashless	-	-	205,467	21	(21)	-	-

Stock split and fractional shares issued	-	-	59,997	6	828	-	834	
Compensation on options issued	-	-	-	-	118,790	-	118,790	
Net loss	-	-	-	-	-	(3,798,840)	(3,798,840)	
<b>Balance at March 31, 2024</b>	<b>210</b>	<b>\$</b>	<b>1,958,245</b>	<b>\$</b>	<b>196</b>	<b>\$313,481,082</b>	<b>\$ (301,051,593)</b>	<b>\$ 12,429,685</b>

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

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TENAX THERAPEUTICS, INC.  
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

Three months ended March 31,	
2024	2023

	(Unaudited)	(Unaudited)
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net Loss	\$ (3,798,840)	\$ (1,406,760)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	-	895
Interest on debt instrument	7,963	4,443
Gain on sale of equipment	-	3,771
Issuance and vesting of compensatory stock options and warrants	118,790	66,543
Changes in operating assets and liabilities		
Accounts receivable, prepaid expenses and other assets	(18,292)	234,802
Accounts payable and accrued liabilities	(1,475,201)	(628,566)
Net cash used in operating activities	<u>(5,165,580)</u>	<u>(1,724,872)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Proceeds from sale of property and equipment	-	1,241
Net cash provided by investing activities	<u>-</u>	<u>1,241</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from issuance of common stock, warrants and pre-funded warrants	6,524,262	13,896,525
Offering cost	(340,643)	(282,647)
Proceeds from the exercise of warrants	1,827,036	511,311
Payments on short-term note	(87,730)	(110,396)
Net cash provided by financing activities	<u>7,922,925</u>	<u>14,014,793</u>
Net change in cash and cash equivalents	2,757,345	12,291,162
Cash and cash equivalents, beginning of period	<u>9,792,130</u>	<u>2,123,682</u>
Cash and cash equivalents, end of period	<u>\$ 12,549,475</u>	<u>\$ 14,414,844</u>

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

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**TENAX THERAPEUTICS, INC.**  
**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(Unaudited)**

**NOTE 1. DESCRIPTION OF BUSINESS**

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

On November 13, 2013, the Company, through its wholly-owned subsidiary, Life Newco, Inc., a Delaware corporation ("Life NewCo"), acquired certain assets of Phyxius Pharma, Inc., a Delaware corporation ("Phyxius") pursuant to an Asset Purchase Agreement dated October 21, 2013 (the "Asset Purchase Agreement"), by and among the Company, Life Newco, Phyxius and the stockholders of Phyxius. Among these assets was a license with Orion Corporation, a global healthcare company incorporated under the laws of Finland ("Orion") for the exclusive, sublicensable right to develop and commercialize pharmaceutical products containing levosimendan, 2.5 mg/ml concentrate for solution for infusion / 5ml vial in the United States and Canada. On October 9, 2020 and January 25, 2022, the Company entered into an amendment to the license to include in the scope of the license two new oral 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"). In February 2024, the Company entered into an additional amendment to the license (as amended, 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"), revising the royalty structure, lowering the royalty rates, modifying milestones associated with certain regulatory and commercial achievements, and excluding from the Company's right of first refusal the right to commercialize new applications of levosimendan for neurological diseases and disorders developed by Orion. Pursuant to the License, the Company and Orion will agree to a new trademark when commercializing levosimendan in either of these forms. The term of the License has been extended until 10 years after the launch of the Product in the territory, provided that the License will continue after the end of the term in each country in the territory until the expiration of Orion's patent rights in the Product in such country. In the event that no regulatory approval for the Product has been granted in the United States on or before September 20, 2030, however, either party will have the right to terminate the License with immediate effect. The Company intends to conduct two

upcoming Phase 3 studies in pulmonary hypertension patients utilizing one of these oral formulations. See "Note 6 - Commitments and Contingencies" below for a further discussion of the License.

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

#### *Going Concern*

Management believes the accompanying unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"), which contemplate continuation of the Company as a going concern. The Company has an accumulated deficit of approximately \$301.1 million and \$297.2 million on March 31, 2024, and December 31, 2023, respectively, and expects to incur substantial operating losses for the foreseeable future. As such, the Company requires substantial additional funds to complete clinical trials and pursue regulatory approvals. Management is actively seeking additional sources of equity and/or debt financing; however, there is no assurance that any additional funding will be available.

In view of the matters described above, recoverability of a major portion of the recorded asset amounts shown in the accompanying March 31, 2024, balance sheet is dependent upon continued operations of the Company, which in turn is dependent upon the Company's ability to meet its financing requirements on a continuing basis, to maintain present financing, and to generate cash from future operations. These factors, among others, raise substantial doubt about the Company's ability to continue as a going concern. The unaudited condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence.

#### **NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

##### *Basis of Presentation*

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with GAAP for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all the information and footnotes required by GAAP for complete financial statements. In the opinion of management, the unaudited condensed consolidated financial statements reflect all adjustments, which include only normal recurring adjustments necessary for the fair statement of the balances and results for the periods presented. Certain information and footnote disclosures normally included in the Company's annual financial statements prepared in accordance with GAAP have been condensed or omitted. These condensed consolidated financial statement results are not necessarily indicative of results to be expected for the full fiscal year or any future period.

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The accompanying unaudited condensed consolidated financial statements and related disclosures have been prepared with the presumption that users of the unaudited condensed consolidated financial statements have read or have access to the audited financial statements for the preceding fiscal year. Accordingly, these unaudited condensed consolidated financial statements should be read in conjunction with the Company's Form 10-K, which was filed with the United States Securities and Exchange Commission ("SEC") on March 28, 2024, from which the Company derived the balance sheet data at December 31, 2023.

### **Use of Estimates**

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

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

### **Principles of Consolidation**

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

### **Reverse Stock Splits**

The Company has adjusted the financial statements to reflect that on January 2, 2024, we effected a 1-for-80 reverse stock split (the "Reverse Stock Split"). The Company has also adjusted the financial statements to reflect that on January 4, 2023, we effected a 1-for-20 reverse stock split (the "Prior Reverse Stock Split", together with the Reverse Stock Split, the "Reverse Stock Splits"). The Reverse Stock Splits did not change the number of authorized shares of capital stock or cause an adjustment to the par value of our capital stock. Pursuant to their terms, a proportionate adjustment was made to the per share exercise price and number of shares issuable under our outstanding stock options and warrants. The number of shares authorized for issuance pursuant to our equity incentive plans have also been adjusted proportionately to reflect the Reverse Stock Splits.

### **Cash and Cash Equivalents**

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

### **Cash Concentration Risk**

The Federal Deposit Insurance Corporation (the “FDIC”) insurance limits are \$ 250,000 per depositor per insured bank. The Company had cash balances of \$683,170 and \$2,383,498 uninsured by the FDIC as of March 31, 2024 and December 31, 2023, respectively. In August 2023, the Company, through its commercial bank began to utilize the IntraFi network of commercial banks. IntraFi deposits \$250,000 in each of its member banks to maintain the FDIC insurance limit. On March 31, 2024, the Company had \$11.6 million deposited in the network which is fully FDIC insured.

#### ***Liquidity and Capital Resources***

The Company has financed its operations since September 1990 through the issuance of debt and equity securities and loans from stockholders. The Company had total current assets of approximately \$14.5 million and \$11.7 million and working capital of \$ 12.4 million and \$8.1 million as of March 31, 2024, and December 31, 2023, respectively.

The Company's cash resources were approximately \$12.5 million as of March 31, 2024, compared to cash resources of approximately \$ 9.8 million as of December 31, 2023.

The Company expects to continue to incur expenses related to the development of levosimendan for PH-HFpEF and other potential indications and, over the long term, imatinib for PAH, as well as identifying and developing other potential product candidates. Based on its resources on March 31, 2024, the Company believes that it has sufficient capital to fund its planned operations through calendar year 2024. However, the Company will need substantial additional financing in order to fund its operations beyond such period and thereafter until it can achieve profitability, if ever. The Company depends on its ability to raise additional funds through various potential sources, such as equity and debt financing, or to license its product candidates to another pharmaceutical company. The Company intends to continue to fund operations from cash on hand and through sources of capital similar to those previously described. The Company cannot provide assurance that it will be able to secure such additional financing on reasonable terms, or if available, that it will be sufficient to meet its needs.

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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 documentation that may affect the manner in which the Company conducts its business. To the extent that the Company raises additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to its technologies or product candidates or grant licenses on terms that may not be favorable to the Company.

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

### **Stock-Based Compensation**

The Company accounts for stock-based awards to employees in accordance with Accounting Standards Codification ("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.

### **Equity-Based Payments to Non-Employees**

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

#### **Warrants for Common Shares and Derivative Financial Instruments**

Warrants for our 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 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.

#### **Loss Per Share**

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

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

	<b>Three months ended March 31,</b>	
	<b>2024</b>	<b>2023</b>
Warrants to purchase common stock	3,219,694	56,278
Pre-funded warrants to purchase common stock	-	-
Options to purchase common stock	936	946
Convertible preferred shares outstanding	210	210

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### **NOTE 3. BALANCE SHEET COMPONENTS**

#### **Property and equipment, net**

Property and equipment primarily consist of office furniture and fixtures.

The Company had no depreciation expense and depreciation expense of \$ 895 for the three months ended March 31, 2024, and 2023, respectively.

#### **Accrued liabilities**

Accrued liabilities consist of the following:

	March 31, 2024	December 31, 2023
Operating costs	\$ 253,517	\$ 236,878
Employee related	282,926	775,590
	<u>\$ 536,443</u>	<u>\$ 1,012,468</u>

### **NOTE 4. NOTE PAYABLE**

#### **Premium Finance Agreement**

On December 31, 2023, the Company executed a premium finance note agreement (the "Note") with Premium Funding Associates, Inc. The Note financed the Company's Directors and Officers Insurance Policy as well as the Errors and Omissions policy. The total amount financed was \$548,750. The Company paid a down payment of \$47,847 at execution leaving a balance of \$500,903 payable in monthly installments of \$47,847 through December 1, 2024. The Note has an interest rate of 9.95%. The Company recorded interest expense on the Note in the amount of \$ 7,963 for the three months ended March 31, 2024. The balance on the Note as of March 31, 2024, and December 31, 2023, was \$413,174 and \$500,903, respectively.

## **NOTE 5. LEASE**

In January 2011, the Company entered into a lease (the "Lease") with Concourse Associates, LLC (the "Landlord") for its headquarters located at ONE Copley Parkway, Suite 490, Morrisville, North Carolina (the "Premises"). The Lease was amended in August 2015, March 2016 and April 2021 to extend the term for the 5,954 square foot rental. Pursuant to the Amendment dated April 2021, the existing lease term was extended through June 30, 2024, and the annual base rent of \$125,034 would increase 2.5% annually for lease years two and three. On February 7, 2023, the Company entered into a Lease Termination Agreement with the Landlord, with respect to the Premises. As consideration for the Landlord's entry into the Lease Termination Agreement, including a release of any claims the Landlord may have had against the Company under the Lease, the Company paid the Landlord \$169,867. Pursuant to the Lease Termination Agreement, effective February 8, 2023, the Company has no remaining rent or further obligations to the Landlord pursuant to the Lease.

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

The Company owns no real property. Beginning November 1, 2022, we maintain a membership providing dedicated office space, as well as shared services and shared space for meetings, catering, and other business activities, at our principal executive office relocated to 101 Glen Lennox Drive, Suite 300, Chapel Hill, North Carolina 27517.

The current rent is approximately \$800 per month.

## **NOTE 6. COMMITMENTS AND CONTINGENCIES**

### ***Simdax license agreement***

On November 13, 2013, the Company, through its wholly-owned subsidiary, Life Newco, Inc., acquired certain assets of Phyxius pursuant to the Asset Purchase Agreement by and among the Company, Life Newco, Phyxius and the stockholders of Phyxius. Among these assets was a license with Orion 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. On October 9, 2020 and January 25, 2022, the Company entered into an amendment to the license to include in the scope of the license two new oral Product formulations containing levosimendan, in capsule and solid dosage form (TNX-103) and a subcutaneously administered dosage form (TNX-102), subject to specified limitations.

On February 19, 2024, the Company entered into an additional 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 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.

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.

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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 March 31, 2024, 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 7. STOCKHOLDERS' EQUITY**

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

#### **Series A Stock**

On December 11, 2018, the Company closed its underwritten offering of 5,181,346 units for net proceeds of approximately \$9.0 million (the "2018 Offering"). Each unit consisted of (i) one share of the Company's Series A convertible preferred stock, par value \$0.0001 per share (the "Series A Stock"), (ii) a two-year warrant to purchase 1/1600<sup>th</sup> of a share of common stock at an exercise price of \$1.93, and (iii) a five-year warrant to purchase 1/1600<sup>th</sup> of a share of common stock at an exercise price of \$1.93. In accordance with ASC 480, *Distinguishing Liabilities from Equity*, the estimated fair value of \$1,800,016 for the beneficial conversion feature was recognized as a deemed dividend on the Series A Stock during the year ended December 31, 2018.

As of March 31, 2024, there were 210 shares of Series A Stock outstanding convertible in the aggregate into one share of common stock.

#### **Common Stock and Pre-Funded Warrants**

The Company's Certificate of Incorporation authorizes it to issue 400,000,000 shares of \$0.0001 par value common stock. As of March 31, 2024, and December 31, 2023, there were 1,958,245 and 298,281 shares of common stock issued and outstanding, respectively. As of March 31, 2024, and December 31, 2023, there were no pre-funded warrants outstanding.

The Company has adjusted all share amounts and references to stock prices in this Quarterly Report on Form 10-Q, as well as our financial statements, to reflect the Reverse Stock Splits. The Reverse Stock Splits did not change the number of authorized shares of capital stock or cause an adjustment to the par value of our capital stock. Pursuant to their terms, a proportionate adjustment was made to the per share exercise price and number of shares issuable under our outstanding stock options and warrants. The number of shares authorized for issuance pursuant to our equity incentive plans have also been adjusted proportionately to reflect the Reverse Stock Splits.

#### **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 approximately \$9.0 million. The net proceeds of the February 2024 Offering after deducting placement agent fees and direct offering expenses were approximately \$8.0 million. The fair value allocated to the common stock, pre-funded warrants and warrants was \$ 0.9 million, \$2.4 million, and \$5.7 million, respectively.

*February 2023 Registered Public Offering (the "February 2023 Offering")*

On February 3, 2023, 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 86,994 shares of its common stock, and pre-funded warrants to purchase an aggregate of 21,341 shares of common stock and (ii) accompanying warrants to purchase up to an aggregate of 216,667 shares of its common stock at a combined offering price of \$144 per share of common stock and associated common warrant, or \$ 143.92 per pre-funded warrant and associated common warrant, resulting in gross proceeds of approximately \$15.6 million. The net proceeds of the February 2023 Offering after deducting placement agent fees and direct offering expenses were approximately \$14.1 million. The fair value allocated to the common stock, pre-funded warrants and warrants was \$5.0 million, \$1.2 million and \$9.4 million, respectively.

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

On May 17, 2022, the Company entered into a securities purchase agreement with an institutional investor, pursuant to which the Company agreed to sell and issue to the investor 6,623 units in a private placement at a purchase price of \$1,240 per unit. Each unit consisted of (i) one unregistered pre-funded warrant to purchase one share of common stock and (ii) one unregistered warrant to purchase one share of common stock (together with the pre-funded warrants, the "2022 Warrants"). In the aggregate, 13,246 shares of the Company's common stock are underlying the 2022 Warrants. The net proceeds from the private placement, after direct offering expenses, were approximately \$7.9 million. The fair value allocated to the pre-funded warrants and warrants was \$4.2 million and \$3.8 million, respectively.

Also, on May 17, 2022 and in connection with the May 2022 Offering, the Company entered into a registration rights agreement (the "May 2022 Registration Rights Agreement") with the investor, pursuant to which the Company agreed to register for resale the shares of common stock issuable upon exercise of the 2022 Warrants within 120 days following the effective date of the May 2022 Registration Rights Agreement. Pursuant to the May 2022 Registration Rights Agreement, on May 25, 2022, the Company filed a resale registration statement on Form S-3 with the SEC, which went effective on June 3, 2022.

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

### **Warrants**

As of March 31, 2024, the Company has 3,219,694 warrants outstanding. The following table summarizes the Company's warrant activity for the three months ended March 31, 2024, not including pre-funded warrants:

	<b>Warrants</b>	<b>Weighted Average Exercise Price</b>
<b>Outstanding at December 31, 2023</b>	<b>19,694</b>	<b>\$ 1,095.27</b>
Issued	3,200,000	5.65
Exercised	-	-
<b>Outstanding at March 31, 2024</b>	<b>3,219,694</b>	<b>\$ 12.32</b>

### *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 approximately \$5.7 million was recognized as additional paid in capital. The estimated fair value is determined using the Black-Scholes Option Pricing Model which is based on the value of the underlying common stock at the valuation measurement date, the remaining contractual term of the warrants, risk-free interest rates, expected dividends and expected volatility of the price of the underlying common stock. The assumptions used in the Black-Scholes Option Pricing model were as follows:

Remaining contractual term	5 Years
Risk free interest rate	4.12%

Expected dividends	-
Expected Volatility	131.87%

#### February 2023 Warrants

As described above, as a part of the February 2023 Offering, the Company issued registered warrants to purchase 216,667 shares of its common stock at an exercise price of \$180.00 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 approximately \$10.6 million was recognized as additional paid in capital. The estimated fair value is determined using the Black-Scholes Option Pricing Model which is based on the value of the underlying common stock at the valuation measurement date, the remaining contractual term of the warrants, risk-free interest rates, expected dividends and expected volatility of the price of the underlying common stock. The assumptions used in the Black-Scholes Option Pricing model were as follows:

Remaining contractual term	5 Years
Risk free interest rate	2.23%
Expected dividends	-
Expected Volatility	105.69%

#### May 2022 Warrants

As described above, as a part of the May 2022 Offering, the Company issued unregistered warrants to purchase 6,623 shares of its common stock at an exercise price of \$1,008.00 per share and contractual term of five and one-half years. The unregistered warrants were offered in a private placement under Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act") and Regulation D promulgated thereunder. In accordance with *ASC 815, Derivatives and Hedging*, these warrants are classified as equity and their relative fair value of approximately \$ 3.8 million was recognized as additional paid in capital. The estimated fair value is determined using the Black-Scholes Option Pricing Model which is based on the value of the underlying common stock at the valuation measurement date, the remaining contractual term of the warrants, risk-free interest rates, expected dividends and expected volatility of the price of the underlying common stock.

### Stock Options

#### 2022 Stock Incentive Plan

In June 2022, the Company adopted the 2022 Stock Incentive Plan (the "2022 Plan"). Under the 2022 Plan, with the approval of the Board's Compensation Committee, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares, performance units, cash-based awards or other stock-based awards. On June 9, 2022, the Company's stockholders approved the 2022 Plan, which authorizes for issuance under the 2022 Plan a total of 688 shares of common stock. Upon approval by the stockholders, the 2022 Plan superseded and replaced the Tenax Therapeutics, Inc. 2016 Stock Incentive Plan, as amended (the "2016 Plan") and all shares of common stock remaining authorized and available for issuance under the 2016 Plan and any shares subject to outstanding awards under the 2016 Plan that subsequently expire, terminate, or are surrendered or forfeited for any reason without issuance of shares automatically become available for issuance under our 2022 Plan.

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The following table summarizes the shares available for grant under the 2022 Plan for the three months ended March 31, 2024.

	Shares Available for Grant
<b>Balances, at December 31, 2023</b>	1,000
Options cancelled/forfeited	-
<b>Balances, at March 31, 2024</b>	1,000

### *2022 Plan Stock Options*

Stock options granted under the 2022 Plan may be either incentive stock options ("ISOs") or nonqualified stock options ("NSOs"). ISOs may be granted only to employees. NSOs may be granted to employees, consultants and directors. Stock options under the 2022 Plan may be granted with a term of up to ten years and at prices no less than fair market value at the time of grant. Stock options granted generally vest over one to four years.

The following table summarizes the outstanding stock options under the 2022 Plan for the three months ended March 31, 2024.

	Outstanding Options	
	Number of Shares	Weighted Average Exercise Price
<b>Balances at December 31, 2023</b>	331	\$ 992.00
Options cancelled/forfeited	-	-
<b>Balances at March 31, 2024</b>	331	\$ 992.00

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

The Company recorded compensation expense for stock option grants of \$16,087 and \$34,380 for the three months ended March 31, 2024 and 2023, respectively.

As of March 31, 2024, there were unrecognized compensation costs of approximately \$55,626 related to non-vested stock option awards under the 2022 Plan that will be recognized on a straight-line basis over the weighted average remaining vesting period of 1.17 years.

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### **2016 Stock Incentive Plan**

In June 2016, the Company adopted the 2016 Stock Incentive Plan (the "2016 Plan"). Under the 2016 Plan, with the approval of the Board's Compensation Committee, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares, performance units, cash-based awards or other stock-based awards. On June 16, 2016, the Company's stockholders approved the 2016 Plan and authorized for issuance under the 2016 Plan a total of 94 shares of common stock. On June 13, 2019, the Company's stockholders approved an amendment to the 2016 Plan which increased the number of shares of common stock authorized for issuance under the 2016 Plan to a total of 469 shares, up from 94 shares previously authorized. On June 10, 2021, the Company's stockholders approved an amendment to the 2016 Plan which increased the number of shares of common stock authorized for issuance under the 2016 Plan to a total of 938 shares, up from 469 shares previously authorized. In June 2022, the 2016 Plan was superseded and replaced by the 2022 Plan and no new awards will be granted under the 2016 Plan going forward. Any awards outstanding under the 2016 Plan on the date of approval of the 2022 Plan remain subject to the 2016 Plan. Upon approval of the 2022 Plan, all shares of common stock remaining authorized and available for issuance under the 2016 Plan and any shares subject to outstanding awards under the 2016 Plan that subsequently expire, terminate, or are surrendered or forfeited for any reason without issuance of shares automatically become available for issuance under our 2022 Plan.

#### **2016 Plan Stock Options**

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

The following table summarizes the outstanding stock options under the 2016 Plan for the three months ended March 31, 2024.

	<b>Outstanding Options</b>	
	<b>Number of Shares</b>	<b>Weighted Average Exercise Price</b>
<b>Balances at December 31, 2023</b>	284	\$ 3,251.77
Options cancelled/forfeited	-	\$ -
<b>Balances at March 31, 2024</b>	284	\$ 3,251.77

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

The Company recorded no compensation expense for these stock option grants for the three months ended March 31, 2024 and \$ 7,867 for the three months ended March 31 2023, respectively. The Company granted no stock options for the three months ended March 31,2024.

As of March 31, 2024, there were no unrecognized compensation costs related to non-vested stock option awards under the 2016 Plan.

#### **1999 Stock Plan, as Amended and Restated**

In October 2000, the Company adopted the 1999 Stock Plan, as amended and restated on June 17, 2008 (the "1999 Plan"). Under the 1999 Plan, with the approval of the Compensation Committee of the Board of Directors, the Company could grant stock options, restricted stock, stock appreciation rights and new shares of common stock upon exercise of stock options. On March 13, 2014, the Company's stockholders approved an amendment to the 1999 Plan which increased the number of shares of common stock authorized for issuance under the 1999 Plan to a total of 125 shares, up from 10 previously authorized. On September 15, 2015, the Company's stockholders approved an additional amendment to the 1999 Plan which increased the number of shares of common stock authorized for issuance under the 1999 Plan to a total of 157 shares, up from 125 previously authorized. The 1999 Plan expired on June 17, 2018 and no new grants may be made under that plan after that date. However, unexpired awards granted under the 1999 Plan remain outstanding and subject to the terms of the 1999 Plan.

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### **1999 Plan Stock Options**

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

The following table summarizes the outstanding stock options under the 1999 Plan for the three months ended March 31, 2024:

	<b>Outstanding Options</b>		
	<b>Number of Shares</b>	<b>Weighted Average Exercise Price</b>	
<b>Balances at December 31, 2023</b>	9	\$ 86,108.80	
Options cancelled/forfeited	-	\$ -	-
<b>Balances at March 31, 2024</b>	9	\$ 86,108.80	

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

The Company recorded no compensation expense for these stock option grants for the three months ended March 31, 2024 and 2023, respectively.

As of March 31, 2024, there were no unrecognized compensation costs related to non-vested stock option awards under the 1999 Plan.

### **Inducement Stock Options**

The Company granted two employment inducement stock option awards, one for 63 shares of common stock and the other for 156 shares of common stock, to its new CEO on July 6, 2021.

The employment inducement stock option for 63 shares of common stock was awarded in accordance with the employment inducement award exemption provided by Nasdaq Listing Rule 5635(c)(4) and was therefore not awarded under the Company's stockholder approved equity plan. The option award was to vest as follows: 50% upon initiation of a Phase 3 trial for levosimendan by June 30, 2022; and 50% upon initiation of a Phase 3 trial for imatinib by June 30, 2022. The options had a 10-year term and an exercise price of \$3,152.00 per share, the July 6, 2021 closing price of our common stock. As of December 31, 2022, none of the vesting milestones had been achieved and the options were subsequently cancelled. The estimated fair value of this inducement stock option award was \$178,291 using a Black-Scholes option pricing model based on market prices and the following assumptions at the date of inducement option grant: risk-free interest rate of 1.37%, dividend yield of 0%, volatility factor for our common stock of 103.50% and an expected life of 10 years.

The employment inducement stock option award for 156 shares of common stock also was awarded in accordance with the employment inducement award exemption provided by Nasdaq Listing Rule 5635(c)(4) and was therefore not awarded under the Company's stockholder approved equity plan. The option award will vest as follows: 25% on the one-year anniversary of the CEO's employment start date and an additional 25% on each of the following three anniversaries of the CEO's employment start date, subject to continued employment. The options have a 10-year term and an exercise price of \$3,152 per share, the July 6, 2021 closing price of our common stock. As of March 31, 2024, half of the vesting milestones have been achieved.

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

The Company granted an employment inducement stock option award for 156 shares of common stock to our Chief Medical Officer on January 15, 2021. This employment inducement stock option was awarded in accordance with the employment inducement award exemption provided by Nasdaq Listing Rule 5635(c)(4) and was therefore not awarded under the Company's stockholder approved equity plan. The option award will vest as follows: 25% upon initiation of a Phase 3 trial; 25% upon database lock; 25% upon acceptance for review of an investigational NDA; and 25% upon approval. The options have a 10-year term and an exercise price of \$2,848 per share, the January 15, 2021 closing price of our common stock. As of March 31, 2024, two of the vesting milestones have been achieved. The estimated fair value of the inducement stock option award granted was \$402,789 using a Black-Scholes option pricing model based on market prices and the following assumptions at the date of inducement option grant: risk-free interest rate of 11%, dividend yield of 0%, volatility factor for our common stock of 103.94% and an expected life of 10 years.

Inducement stock option compensation expense totaled \$102,703 for the three months ended March 31, 2024. As of March 31, 2024, there was \$252,362 remaining unrecognized compensation expense related to these inducement stock options.

**NOTE 8. SUBSEQUENT EVENTS**

None.

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### **ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*The following discussion and analysis should be read in conjunction with the unaudited condensed consolidated financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q and with the audited condensed consolidated financial statements and related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2023. All references in this Quarterly Report to "Tenax Therapeutics," "we," "our" and "us" means Tenax Therapeutics, Inc.*

#### **Cautionary Note Regarding Forward-Looking Statements**

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the "safe harbor" created by those sections. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to them. In some cases you can identify forward-looking statements by words such as "might," "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. These statements reflect our current view with respect to future events and are subject to risks, uncertainties and assumptions related to various factors that could cause actual results and the timing of events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section titled "Risk Factors" included in our most recent Annual Report on Form 10-K filed with the SEC. Furthermore, such forward-looking statements speak only as of this Quarterly Report on Form 10-Q. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

#### **Overview**

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, the Company changed its name to Tenax Therapeutics, Inc.

In November 2013, we acquired a license with Orion Corporation ("Orion") granting our wholly-owned subsidiary an exclusive, sublicensable right to develop and commercialize pharmaceutical products containing levosimendan, 2.5 mg/ml concentrate for solution for infusion / 5ml vial in the United

States and Canada. In October 2020 and January 2022, we entered into an amendment to the license agreement between the Company and Orion to include in the scope of the license two new oral product formulations containing levosimendan, in capsule and solid dosage form (TNX-103) and a subcutaneously administered dosage form (TNX-102), subject to specified limitations. In February 2024, we entered into an additional 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"), revising the royalty structure, lowering the royalty rates, modifying milestones associated with certain regulatory and commercial achievements, and excluding from our right of first refusal the right to commercialize new applications of levosimendan for neurological diseases and disorders developed by Orion.

In January 2021, we acquired 100% of the equity of PHPrecisionMed Inc., a Delaware corporation ("PHPM"), with PHPM surviving as our wholly-owned subsidiary. As a result of the merger, pending the outcome of our strategic process, we plan to commercialize pharmaceutical products containing imatinib for the treatment of pulmonary arterial hypertension ("PAH").

#### **Business Strategy**

Having carefully considered alternatives within the ongoing strategic process announced in September 2022, and having raised capital expected to fund the Company through calendar year 2024, the Company has elected to prioritize its LEVEL trial (Phase 3 testing of oral levosimendan), ahead of imatinib. Activity to initiate the LEVEL trial continued in the fourth quarter of 2023, and site qualification, selection, and initiation processes are ongoing, the Company having received U.S. Food and Drug Administration ("FDA") input into the oral levosimendan protocol and clinical development program in the third quarter of 2023. The Company began initiating sites in the fourth quarter of 2023 and commenced enrolling patients early in 2024. Additional funding will be needed to complete the LEVEL trial, which includes an open label extension phase following the completion of the randomized phase. The Company will complete efficacy and safety analyses of levosimendan versus placebo at the end of the randomized treatment phase, but many patients will continue to be treated under the protocol on open label levosimendan, beyond the completion of these analyses. Supporting this strategic decision to prioritize levosimendan development and commence Phase 3 trial work were two U.S. Patents issued in March and July 2023, covering the use of IV and oral levosimendan in patients with PH-HFpEF. These patents are the second and third levosimendan patents granted to us since the start of 2022. An additional new patent was issued in early 2024 which provides protections covering all therapeutic doses of all three formulations of the product in patients with PH-HFpEF. Given our prioritization of the Phase 3 testing of levosimendan, we have suspended plans to launch an imatinib Phase 3 trial.

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

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

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

therapies may achieve best-in-class profile, and where we can address significant unmet medical needs.

We believe these factors will support approval by the FDA of this product candidate based on positive Phase 3 data. Through our agreement with our licensor, Orion, the originator of levosimendan for acute decompensated heart failure, we have access to a library of ongoing and completed trials and research projects, including certain documentation, which we believe, in combination with positive Phase 3 data we hope to generate in at least one indication, will support FDA approval of levosimendan. Likewise, the regulatory pathway for approval of imatinib for the treatment of PAH, as formulated by us at the dose shown to be effective in a prior Phase 3 trial conducted by Novartis, allows us to build on the dossier of research results already reviewed by the FDA. In order to achieve our objective of developing these medicines for new groups of patients, we have established collaborative research relationships with investigators from leading research and clinical institutions, and our strategic partners. These collaborative relationships have enabled us to explore where our product candidates may have therapeutic relevance, gain the advice and support of key opinion leaders in medicine and clinical trial science, and invest in development efforts to exploit opportunities to advance beyond current clinical care.

[Continue to expand our intellectual property portfolio.](#)

Our intellectual property and the confidentiality of all our Company information is important to our business and we take significant steps to help protect its value. Our research and development efforts, both through internal activities and through collaborative research activities with others, aim to develop new intellectual property and enable us to file patent applications that cover new uses of our existing technologies, alone or in combination with existing therapies, as well as other product candidates.

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### [Notice of Allowance and Patents](#)

On February 1, 2023, the Company announced it was granted a Notice of Allowance from the United States Patent and Trademark Office ("USPTO") for its patent application with claims covering the use of IV levosimendan (TNX-101) in the treatment of PH-HFpEF. This patent (U.S. Patent No. 11,607,412) was issued on March 21, 2023. On July 19, 2023, the Company announced USPTO issuance of another patent, this one including claims covering the use of oral levosimendan (TNX-103) in patients with PH-HFpEF. This issued patent (U.S. Patent No. 11,701,355) provides exclusivity through December 2040. On February 6, 2024, the Company announced it was granted a Notice of Allowance from the USPTO for its patent application 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. At present, the Company has other patent applications pending, with additional decisions expected in the future. Patents pending in Europe may lead to intellectual property protections on the use of levosimendan in patients with PH-HFpEF in 2024.

### [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.

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

Historically, we have financed our operations principally through equity and debt offerings, including private placements and loans from our stockholders. Based on our current operating plan, there is substantial doubt about our ability to continue as a going concern. Management has implemented certain cost-cutting measures as described above and is actively exploring a diverse range of strategic options to help drive stockholder value including, among other things, capital raises, a sale of our Company, merger, one or more license agreements, a co-development agreement, a combination of these, or other strategic transactions; however, there is no assurance that these efforts will result in a transaction or other alternative or that any additional funding will be available. Our ability to continue as a going concern depends on our ability to raise additional capital, through the sale of equity or debt securities and through collaboration and licensing agreements, to support our future operations. If we are unable to complete a strategic transaction or secure additional capital, we may be required to curtail our research and development initiatives and take additional measures to reduce costs.

**Financial Overview – Three Months Ended March 31, 2024**

**Operating Expenses**

	Three months ended March 31,		Increase/ (Decrease)	% Increase/ (Decrease)
	2024	2023		
Operating expenses				
General and administrative	\$ 1,232,674	\$ 1,273,730	\$ (41,056)	(3)%
Research and development	2,675,652	265,735	2,409,917	907%
Total operating expenses	\$ 3,908,326	\$ 1,539,465	\$ 2,368,861	154%

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**General and Administrative Expenses**

General and administrative expenses were \$1.2 million for the three months ended March 31, 2024, compared to \$1.3 million for the same period in 2023. General and administrative expenses consist primarily of compensation for executive, finance, legal and administrative personnel, including stock-based compensation. Other general and administrative expenses include facility costs not otherwise included in research and development expenses, legal and accounting services, and other professional and consulting services. General and administrative expenses and percentage changes for the three months ended March 31, 2024 and 2023, respectively, are as follows:

	Three months ended March 31,		Increase/ (Decrease)	% Increase/ (Decrease)
	2024	2023		
Personnel costs	\$ 551,336	\$ 600,056	\$ (48,720)	(8)%
Legal and professional fees	436,487	431,722	4,765	1%
Other costs	241,109	223,569	17,540	8%
Facilities	3,742	18,383	(14,641)	(80)%
<b>Total general and administrative expenses</b>	<b>\$ 1,232,674</b>	<b>\$ 1,273,730</b>	<b>\$ (41,056)</b>	<b>(3)%</b>

Personnel costs decreased approximately \$49,000 for the three months ended March 31, 2024, compared to the same period in 2023. The change was primarily due to decreased employment-related costs due to lower headcount in the current period compared to the same period in the prior year.

Legal and professional fees increased approximately \$5,000 for the three months ended March 31, 2024, compared to the same period in the prior year. Professional fees consist of the costs incurred for accounting fees, capital market expenses, consulting fees and investor relations services, as well as fees paid to the members of our Board of Directors.

Legal fees increased approximately \$31,000 for the three months ended March 31, 2024, compared to the same period in the prior year. The change was primarily due to increased legal fees associated with general corporate matters, fundraising activities and IP costs compared to the same period in the prior year.

Professional fees decreased approximately \$26,000 for the three months ended March 31, 2024, compared to the same period in the prior year. The change was primarily attributable to decreased capital market expenses, consulting expenses and accounting expenses.

Other costs increased approximately \$18,000 for the three months ended March 31, 2024, compared to the same period in 2023. Other costs include expenses incurred for franchise and other taxes, travel, supplies, insurance, depreciation, and other miscellaneous charges. The change was primarily attributable to increases in franchise tax fees offset by lower costs for insurance and general office supplies.

Facilities costs include costs paid for rent and utilities at our corporate headquarters in North Carolina. Facilities costs decreased approximately \$15,000 for the three months ended March 31, 2024, compared to the same period in 2023. The decrease is the result of the Company's relocation to new shared office space resulting in lower rent costs.

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**Research and Development Expenses**

Research and development expenses were approximately \$2.6 million for the three months ended March 31, 2024, compared to \$0.3 million for the same period in the prior year. Research and development expenses include, but are not limited to, (i) expenses incurred under agreements with contract research organizations and investigative sites, which conduct our clinical trials and a substantial portion of our pre-clinical studies; (ii) the cost of supplying clinical trial materials; (iii) payments to contract service organizations, as well as consultants; (iv) employee-related expenses, which include salaries and benefits; and (v) facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, depreciation of leasehold improvements, equipment, and other supplies. All research and development expenses are expensed as incurred. Research and development expenses and percentage changes for the three months ended March 31, 2024, and 2023, respectively, are as follows:

<u>Three months ended March 31,</u>	<u>Increase/(Decrease)</u>	<u>% Increase/(Decrease)</u>
-------------------------------------	----------------------------	------------------------------

	2024	2023		
Clinical and preclinical development	\$ 2,402,226	\$ 84,032	\$ 2,318,194	2759%
Personnel costs	264,917	171,367	93,550	55%
Other costs	8,509	10,336	(1,827)	(18)%
Total research and development expenses	<u>\$ 2,675,652</u>	<u>\$ 265,735</u>	<u>\$ 2,409,917</u>	<u>907%</u>

Clinical and preclinical development costs increased approximately \$2.3 million for the three months ended March 31, 2024, compared to the same period in the prior year. Clinical and preclinical development costs for the three months ended March 31, 2024, consist of expenses associated with our Phase 2 HELP Open Label Extension Study and Phase 3 LEVEL trial for oral levosimendan, compared with costs for the three months ended March 31, 2023 associated with our imatinib Phase 1 Pharmacokinetics Study, imatinib Phase 3 IMPROVE Study, and development costs associated with the formulation for imatinib. The increase is primarily attributable to the receipt of refunded costs associated with formulation development and Phase 1 and Phase 3 costs for imatinib in the prior year period as a result of the Company pausing its clinical development activities to focus on its strategic process.

Personnel costs increased approximately \$94,000 for the three months ended March 31, 2024, compared to the same period in the prior year, primarily attributable to vesting of options associated with the commencement of the Phase 3 LEVEL trial for oral levosimendan.

Other costs decreased approximately \$1,800 for the three months ended March 31, 2024, compared to the same period in the prior year, primarily due to decreased regulatory consulting costs.

#### **Other Income and Expense**

Other income and expenses include non-operating income and expense items not otherwise recorded in our consolidated statement of comprehensive loss. These items include but are not limited to interest income earned and fixed asset disposals. Interest expenses were approximately \$8,000 and \$7,400 for the three months ended March 31, 2024, and 2023, respectively. The change is due primarily to an increase in the interest rate associated with the premium finance note agreement (the "Note") with Premium Funding Associates, Inc. Other income decreased approximately \$23,000 primarily related to higher licensing fees earned in the prior year offset by the interest income on cash deposits as a result of the February 2024 offering.

#### **Liquidity, Capital Resources and Plan of Operation**

We have incurred losses since our inception and, as of March 31, 2024, we had an accumulated deficit of approximately \$301.1 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 in the LEVEL trial 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 in the short-term; however, we will need substantial additional capital in the future in order to complete the development and potential commercialization of levosimendan and imatinib, and to continue with the development of other potential product candidates.

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### **Liquidity**

We have financed our operations since September 1990 through the issuance of debt and equity securities and loans from stockholders. We had total current assets of approximately \$14.5 million and \$11.7 million and working capital of approximately \$12.4 million and \$8.1 million as of March 31, 2024 and December 31, 2023, respectively. Our practice is to invest excess cash, where available, in short-term money market investment instruments and high quality corporate and government bonds.

### *Clinical and Preclinical Product Development*

We are currently conducting the LEVEL trial and intend to recruit patients throughout 2024 and into at least the first half of 2025. Our ability to continue to pursue development of our products, including completing the LEVEL trial, beyond 2024 will depend on obtaining license income or outside financial resources. There is no assurance that we will obtain any license agreement or outside financing or that we will otherwise succeed in obtaining any necessary resources.

### *Financings*

On February 8, 2024, we sold in a registered public offering (i) 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 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 to the Company of approximately \$9.0 million. Net proceeds of the offering were approximately \$8.0 million, after deducting the placement agent fees and offering expenses payable by the Company.

As retrospectively adjusted for the Reverse Stock Split, on February 3, 2023, we sold in a registered public offering (i) an aggregate of 86,994 shares of our common stock and pre-funded warrants to purchase an aggregate of 21,341 shares of our common stock and (ii) accompanying warrants to purchase up to an aggregate of 216,667 shares of our common stock at a combined offering price of \$144.00 per share of common stock and associated warrant, or \$143.92 per pre-funded warrant and associated warrant, resulting in gross proceeds to the Company of approximately \$15.6 million. Net proceeds of the offering were approximately \$14.1 million, after deducting the placement agent fees and offering expenses payable by the Company.

As retrospectively adjusted for the Reverse Stock Splits, on May 17, 2022, we sold 6,623 units in a private placement at a purchase price of \$1,240.00 per unit for net proceeds of approximately \$7.9 million. Each unit consisted of one unregistered pre-funded warrant to purchase one share of our common stock and one unregistered warrant to purchase one share of common stock.

### *Cash Flows*

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

	<b>Three months ended March 31,</b>	
	<b>2024</b>	<b>2023</b>
Net cash (used in) operating activities	\$ (5,165,580)	\$ (1,724,872)
Net cash provided by investing activities	-	1,241
Net cash provided by financing activities	7,922,925	14,014,793

*Net cash used in operating activities.* Net cash used in operating activities was approximately \$5.2 million for the three months ended March 31, 2024,

compared to approximately \$1.7 million for the three months ended March 31, 2023. The increase in cash used for operating activities was primarily due to higher study expense activity in the current period as compared to the prior year.

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*Net cash provided by investing activities.* There was no net cash provided or consumed by investing activities for the three months ended March 31, 2024, compared to net cash provided by investing activities of approximately \$1,200 in the three months ended March 31, 2023. The decrease in cash

provided by investing activities was primarily due to the sale of all remaining office furniture related to the Company's headquarters in the prior year.

*Net cash provided by financing activities.* Net cash provided by financing activities was approximately \$7.9 million for the three months ended March 31, 2024, compared to approximately \$14.0 million in the three months ended March 31, 2023. The decrease in cash provided by financing activities was due to lower net proceeds received from the February 8, 2024 sale of common stock and warrants compared to the February 3, 2023 sale of common stock and warrants and the exercise of warrants.

#### ***Operating Capital and Capital Expenditure Requirements***

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

- the initiation, progress, timing and completion of clinical trials for our product candidates and potential product candidates;
- the outcome, timing and cost of regulatory approvals and the regulatory approval process;
- delays that may be caused by changing regulatory requirements;
- the number of product candidates we pursue;
- the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims;
- the timing and terms of future collaboration, licensing, consulting or other arrangements that we may enter into;
- the cost and timing of establishing sales, marketing, manufacturing and distribution capabilities;
- the cost of procuring clinical and commercial supplies of our product candidates;
- the extent to which we acquire or invest in businesses, products or technologies;
- delays that may be caused by another outbreak of an infectious disease or other global societal disruptions; and
- the possible costs of litigation.

Based on our working capital on March 31, 2024, we believe we have sufficient capital on hand to continue to fund operations through the remainder of the 2024 calendar year.

We will need substantial additional capital beyond 2024, assuming ongoing preparation, planning activities, and other outsourced activities associated with the LEVEL trial continue at the expected pace. In addition, we will need additional funding in the future in order to complete the regulatory approval and commercialization of levosimendan, as well as to fund the development and commercialization of other future product candidates. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Such funding, if needed, may not be available on favorable terms, if at all. In the event we are unable to obtain additional capital, we may delay or reduce the scope of our current research and development programs and other expenses. As a result of our historical operating losses and expected future negative cash flows from operations, we have concluded that there is substantial doubt about our ability to continue as a going concern. Similarly, the report of our independent registered public accounting firm on our December 31, 2023 consolidated financial statements include an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern. Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock and make it more difficult to obtain financing.

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

### ***Critical Accounting Policies and Significant Judgments and Estimates***

Our unaudited condensed consolidated financial statements have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the expenses during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions. For information regarding our critical accounting policies and estimates, please refer to "Management's Discussion and Analysis of Financial Condition and Results of Operations—Summary of Critical Accounting Policies" contained in our Annual Report on Form 10-K for the year ended December 31, 2023 and Note 2 to our unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

### ***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.

### **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

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

### **ITEM 4. CONTROLS AND PROCEDURES**

#### ***Evaluation of 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 Quarterly Report on Form 10-Q, 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.

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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 March 31, 2024, the end of the period covered by this Quarterly Report on Form 10-Q, 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 Control over Financial Reporting***

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

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

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**PART II – OTHER INFORMATION**

**ITEM 1. LEGAL PROCEEDINGS**

There are no material pending legal proceedings to which we are a party or to which any of our property is subject.

**ITEM 1A. RISK FACTORS**

The risks we face have not materially changed from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2023.

**ITEM 6. EXHIBITS**

The following exhibits are being filed or furnished as part of this Quarterly Report on Form 10-Q and are numbered in accordance with Item 601 of Regulation S-K:

Exhibit Number	Description
3.1.1	<a href="#">Certificate of Incorporation of Oxygen Biotherapeutics, Inc., dated April 17, 2008 (incorporated herein by reference to Exhibit 3.01 to our Current Report on Form 8-K filed with the SEC on June 30, 2008).</a>

3.1.2	<a href="#">Certificate of Amendment of the Certificate of Incorporation, effective November 9, 2009 (incorporated herein by reference to Exhibit 3.1 to our Current Report on Form 8-K filed with the SEC on November 13, 2009).</a>
3.1.3	<a href="#">Certificate of Amendment of the Certificate of Incorporation, effective May 10, 2013 (incorporated herein by reference to Exhibit 3.1 to our Current Report on Form 8-K filed with the SEC on May 15, 2013).</a>
3.1.4	<a href="#">Certificate of Amendment of the Certificate of Incorporation, effective September 19, 2014 (incorporated herein by reference to Exhibit 3.4 to our Quarterly Report on Form 10-Q filed with the SEC on December 15, 2014).</a>
3.1.5	<a href="#">Certificate of Amendment of the Certificate of Incorporation, effective February 23, 2018 (incorporated herein by reference to Exhibit 3.1 to our Current Report on Form 8-K filed with the SEC on February 23, 2018).</a>
3.1.6	<a href="#">Certificate of Amendment to Certificate of Incorporation, as amended of Tenax Therapeutics, Inc., effective January 4, 2023 (incorporated herein by reference to Exhibit 3.1 to our Current Report on Form 8-K filed with the SEC on January 4, 2023).</a>
3.1.7	<a href="#">Certificate of Amendment of Certificate of Incorporation of Tenax Therapeutics, Inc. (incorporated herein by reference to Exhibit 3.1 to our Current Report on Form 8-K filed with the SEC on January 5, 2024).</a>
3.2	<a href="#">Certificate of Designation of Series A Convertible Preferred Stock, dated December 10, 2018 (incorporated herein by reference to Exhibit 4.1 to our Current Report on Form 8-K filed with the SEC on December 11, 2018).</a>
3.3	<a href="#">Certificate of Designation of Series B Convertible Preferred Stock, dated January 15, 2021 (incorporated herein by reference to Exhibit 4.1 to our Current Report on Form 8-K filed with the SEC on January 19, 2021).</a>
4.1	<a href="#">Warrant Agency Agreement, dated as of February 12, 2024, by and between Tenax Therapeutics, Inc. and Direct Transfer LLC (incorporated herein by reference to Exhibit 4.1 to our Current Report on Form 8-K filed with the SEC on February 12, 2024).</a>
4.2	<a href="#">Form of February 2024 Pre-Funded Common Stock Purchase Warrant (incorporated herein by reference to Exhibit 4.2 to our Current Report on Form 8-K filed with the SEC on February 12, 2024).</a>
4.3	<a href="#">Form of February 2024 Common Stock Purchase Warrant. (incorporated herein by reference to Exhibit 4.3 to our Current Report on Form 8-K filed with the SEC on February 12, 2024).</a>
10.1	<a href="#">Placement Agency Agreement, dated as of February 8, 2024, by and between Tenax Therapeutics, Inc. and Roth Capital Partners, LLC (incorporated herein by reference to Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on February 12, 2024).</a>
10.2	<a href="#">Form of Securities Purchase Agreement by and between Tenax Therapeutics, Inc. and the purchasers named therein (incorporated herein by reference to Exhibit 10.2 to our Current Report on Form 8-K filed with the SEC on February 12, 2024).</a>
10.3+	<a href="#">Amendment to the License Agreement of September 20, 2013 by and between Tenax Therapeutics, Inc. and Orion Corporation, dated as of February 19, 2024 (incorporated herein by reference to Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on February 20, 2024).</a>
31.1*	<a href="#">Certification of President and Chief Executive Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002.</a>
31.2*	<a href="#">Certification of Interim Chief Financial Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002.</a>
32.1**	<a href="#">Certification of 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.</a>
32.2**	<a href="#">Certification of 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.</a>
101*	Inline XBRL Document Set for the condensed consolidated financial statements and accompanying notes in Part I, Item 1, "Financial Statements" of this Quarterly Report on Form 10-Q.
104*	Inline XBRL for the cover page of this Quarterly Report on Form 10-Q, included in the Exhibit 101 Inline XBRL Document Set.

\* Filed herewith

\*\* Furnished herewith

+ Portions of this Exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K. The Company agrees to furnish supplementally an unredacted copy of this Exhibit to the SEC upon request.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: May 14, 2024

**TENAX THERAPEUTICS, INC.**

By: /s/Lawrence R. Hoffman  
Lawrence R. Hoffman  
Interim Chief Financial Officer  
(On behalf of the Registrant and as Principal  
Financial and Accounting Officer)

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

I, Christopher T. Giordano, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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: May 14, 2024

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

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

I, Lawrence R. Hoffman, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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: May 14, 2024

/s/ Lawrence R. Hoffman  
Lawrence R. Hoffman  
*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 Quarterly Report of Tenax Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2024 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: May 14, 2024

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

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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

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

In connection with the Quarterly Report of Tenax Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended March 31, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Lawrence R. Hoffman, 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: May 14, 2024

*/s/* Lawrence R. Hoffman

Lawrence R. Hoffman

*Interim Chief Financial Officer*

*(Principal Financial Officer)*

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, 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.