

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 SEPTEMBER 30, 2023

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  Accelerated filer   
Non-accelerated Filer  Smaller reporting company   
Emerging growth company

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

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

As of November 8, 2023 the registrant had outstanding 23,862,434 shares of Common Stock.

TABLE OF CONTENTS

	PAGE
<b>PART I. FINANCIAL INFORMATION</b>	
<a href="#">Item 1. Financial Statements</a>	3
<a href="#">Condensed Consolidated Balance Sheets as of September 30, 2023 (Unaudited) and December 31, 2022</a>	3
<a href="#">Condensed Consolidated Statement of Operations (Unaudited) for the Three and Nine Months Ended September 30, 2023 and 2022</a>	4

<a href="#">Condensed Consolidated Statements of Stockholders' Equity (Unaudited) for the Three and Nine Months Ended September 30, 2023 and 2022</a>	5
<a href="#">Condensed Consolidated Statements of Cash Flows (Unaudited) for the Nine Months Ended September 30, 2023 and 2022</a>	6
<a href="#">Notes to Condensed Consolidated Financial Statements (Unaudited)</a>	7
<a href="#">Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</a>	17
<a href="#">Item 3. Quantitative and Qualitative Disclosures About Market Risk</a>	26
<a href="#">Item 4. Controls and Procedures</a>	26
<b><a href="#">PART II. OTHER INFORMATION</a></b>	
<a href="#">Item 1. Legal Proceedings</a>	28
<a href="#">Item 1A. Risk Factors</a>	28
<a href="#">Item 6. Exhibits</a>	29
<b><a href="#">SIGNATURES</a></b>	30

[Table of Contents](#)**PART I - FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS**

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

	<u>September 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
	<u>(Unaudited)</u>	
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 11,141,136	\$ 2,123,682
Prepaid expenses	474,866	738,927
Other current assets	267,084	345,856
Total current assets	<u>11,883,086</u>	<u>3,208,465</u>
Right of use asset	-	179,503
Property and equipment, net	4,706	7,189
Other assets	1,117	9,552
Total assets	<u>\$ 11,888,909</u>	<u>\$ 3,404,709</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$ 134,787	\$ 448,425
Accrued liabilities	292,961	775,045
Note Payable	174,466	624,302
Total current liabilities	<u>602,214</u>	<u>1,847,772</u>
Long term liabilities		
Lease liability	-	64,196
Total long term liabilities	<u>-</u>	<u>64,196</u>
Total liabilities	<u>602,214</u>	<u>1,911,968</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 \$0.0001, authorized 259,068 shares; issued and outstanding 210, as of September 30, 2023 and December 31, 2022, respectively	-	-
Common stock, par value \$0.0001 per share; authorized 400,000,000 shares; issued and outstanding 23,862,434 as of September 30, 2023 and 2,291,809 as of December 31, 2022, respectively	2,386	229
Additional paid-in capital	305,311,462	291,034,592
Accumulated deficit	<u>(294,027,153)</u>	<u>(289,542,080)</u>
Total stockholders' equity	<u>11,286,695</u>	<u>1,492,741</u>
Total liabilities and stockholders' equity	<u>\$ 11,888,909</u>	<u>\$ 3,404,709</u>

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

[Table of Contents](#)

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

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Operating expenses				
General and administrative	\$ 1,051,524	\$ 1,377,283	\$ 3,363,511	\$ 4,255,454
Research and development	1,065,855	1,540,205	1,529,493	4,242,565
Total operating expenses	2,117,379	2,917,488	4,893,004	8,498,019
Net operating loss	2,117,379	2,917,488	4,893,004	8,498,019
Interest expense	5,337	372	21,813	4,443
Interest income	(150,741)	-	(366,877)	-
Other expense (income), net	-	(1,323)	(62,866)	(3,368)
Net loss	\$ 1,971,975	\$ 2,916,537	\$ 4,485,074	\$ 8,499,094
Net loss per share, basic and diluted	\$ (0.08)	\$ (2.22)	\$ (0.24)	\$ (6.64)
Weighted average number of common shares outstanding, basic and diluted	23,862,434	1,316,504	18,532,270	1,279,271

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

4

[Table of Contents](#)

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

	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, 2021</b>	<b>210</b>	<b>\$ -</b>	<b>1,260,346</b>	<b>\$ 126</b>	<b>\$ 282,738,727</b>	<b>\$ (278,494,185)</b>	<b>\$ 4,244,668</b>
Compensation on options issued	-	-	-	-	83,069	-	83,069
Net loss	-	-	-	-	-	(2,721,536)	(2,721,536)
<b>Balance at March 31, 2022</b>	<b>210</b>	<b>\$ -</b>	<b>1,260,346</b>	<b>\$ 126</b>	<b>\$ 282,821,796</b>	<b>\$ (281,215,721)</b>	<b>\$ 1,606,201</b>
Pre-funded warrants and warrants sold, net of offering costs	-	-	-	-	7,928,591	-	7,928,591
Compensation on options issued	-	-	-	-	110,031	-	110,031
Net loss	-	-	-	-	-	(2,861,021)	(2,861,021)
<b>Balance at June 30, 2022</b>	<b>210</b>	<b>\$ -</b>	<b>1,260,346</b>	<b>\$ 126</b>	<b>\$ 290,860,418</b>	<b>\$ (284,076,742)</b>	<b>\$ 6,783,802</b>
Exercise of pre-funded warrants	-	-	4,773,269	477	-	-	477
Compensation on options issued	-	-	-	-	86,109	-	86,109
Net loss	-	-	-	-	-	(2,916,537)	(2,916,537)
<b>Balance at September 30, 2022</b>	<b>210</b>	<b>\$ -</b>	<b>6,033,615</b>	<b>\$ 603</b>	<b>\$ 290,946,527</b>	<b>\$ (286,993,279)</b>	<b>\$ 3,953,851</b>
<b>Balance at December 31, 2022</b>	<b>210</b>	<b>\$ -</b>	<b>2,291,809</b>	<b>\$ 230</b>	<b>\$ 291,034,591</b>	<b>\$ (289,542,080)</b>	<b>\$ 1,492,741</b>
Public offering sale of common stock and warrants, net of offering costs	-	-	6,959,444	696	13,895,829	-	13,896,525
Offering costs	-	-	-	-	(282,647)	-	(282,647)
Exercise of pre-funded warrants for cash	-	-	1,446,110	145	511,166	-	511,311
Exercise of pre-funded warrants, cashless	-	-	260,722	26	(26)	-	-
Exercise of warrants, cashless	-	-	10,805,503	1,081	(1,081)	-	-
Stock split and fractional shares issued	-	-	13,846	-	-	-	-
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>21,777,434</b>	<b>\$ 2,178</b>	<b>\$ 305,224,375</b>	<b>\$ (290,948,840)</b>	<b>\$ 14,277,713</b>
Exercise of warrants, cashless	-	-	2,085,000	208	(208)	-	-
Compensation on options issued	-	-	-	-	50,283	-	50,283
Net loss	-	-	-	-	-	(1,106,338)	(1,106,338)
<b>Balance at June 30, 2023</b>	<b>210</b>	<b>\$ -</b>	<b>23,862,434</b>	<b>\$ 2,386</b>	<b>\$ 305,274,450</b>	<b>\$ (292,055,178)</b>	<b>\$ 13,221,658</b>
Compensation on options issued	-	-	-	-	37,012	-	37,012
Net loss	-	-	-	-	-	(1,971,975)	(1,971,975)
<b>Balance at September 30, 2023</b>	<b>210</b>	<b>\$ -</b>	<b>23,862,434</b>	<b>\$ 2,386</b>	<b>\$ 305,311,462</b>	<b>\$ (294,027,153)</b>	<b>\$ 11,286,695</b>

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

5

[Table of Contents](#)

**TENAX THERAPEUTICS, INC.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

	<b>Nine months ended September 30,</b>	
	<b>2023</b>	<b>2022</b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net Loss	\$ (4,485,074)	\$ (8,499,094)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	2,864	3,798
Interest on debt instrument	21,151	4,443
Amortization of right of use asset	-	80,332
Gain on sale of equipment	1,125	-
Issuance and vesting of compensatory stock options and warrants	153,838	279,686
Changes in operating assets and liabilities		
Accounts receivable, prepaid expenses and other assets	342,834	(606,559)
Accounts payable and accrued liabilities	(765,730)	(874,156)
Long term portion of lease liability	-	(88,241)
Net cash used in operating activities	(4,728,992)	(9,699,791)
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchase (proceeds) from sale of property and equipment	2,843	(6,323)
Net cash provided by (used in) investing activities	2,843	(6,323)
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from issuance of common stock, warrants and pre-funded warrants, net of issuance costs	14,193,439	7,928,591
Proceeds from the issuance of note payable	-	364,546
Payments on short-term note	(449,836)	(364,546)
Net cash provided by financing activities	13,743,603	7,928,591
Net change in cash and cash equivalents	9,017,454	(1,777,523)
Cash and cash equivalents, beginning of period	2,123,682	5,583,922
Cash and cash equivalents, end of period	<u>\$ 11,141,136</u>	<u>\$ 3,806,399</u>

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

[Table of Contents](#)

**TENAX THERAPEUTICS, INC.**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(Unaudited)**

**NOTE 1. DESCRIPTION OF BUSINESS**

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

On November 13, 2013, the Company, through its wholly-owned subsidiary, Life Newco, Inc., a Delaware corporation (“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, sublicenseable right to develop and commercialize pharmaceutical products containing levosimendan, 2.5 mg/ml concentrate for solution for infusion / 5ml vial in the United States and Canada (the “Territory”). On October 9, 2020 and January 25, 2022, the Company amended the license (as amended, the “License”), to include two new oral product dose forms containing levosimendan in capsule and solid dosage form, and a subcutaneously administered product containing levosimendan, subject to certain limitations (together, the “Product”). Pursuant to the License, the Company and Orion will agree to a new trademark when commercializing levosimendan in either of these forms. The term of the License has been extended until 10 years after the launch of the Product in the Territory, provided that the License will continue after the end of the term in each country in the Territory until the expiration of Orion’s patent rights in the Product in such country. In the event that no regulatory approval for the Product has been granted in the United States on or before September 20, 2030, however, either party will have the right to terminate the License with immediate effect. The Company intends to conduct 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 \$294.0 million at September 30, 2023, and used cash in operations of approximately \$4.7 million during the nine months ended September 30, 2023. 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 as part of its ongoing strategic process; 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 September 30, 2023 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.

### [Table of Contents](#)

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 31, 2023, from which the Company derived the balance sheet data at December 31, 2022.

### ***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 Therapeutics, Inc., Life Newco, Inc. and PHPM. All material intercompany transactions and balances have been eliminated in consolidation.

### ***Reverse Stock Split***

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

### ***Cash and Cash Equivalents***

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

### ***Cash Concentration Risk***

The Federal Deposit Insurance Corporation (the “FDIC”) insurance limits are \$250,000 per depositor per insured bank. The Company had cash balances of \$345,000 and \$1.9 million uninsured by the FDIC as of September 30, 2023 and December 31, 2022, 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 September 30, 2023, the Company had \$10.5 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 \$11.9 million and \$3.2 million and working capital of \$11.3 million and \$1.4 million as of September 30, 2023 and December 31, 2022, respectively.

The Company's cash resources were approximately \$11.1 million as of September 30, 2023, compared to cash resources of approximately \$2.1 million as of December 31, 2022.

The Company expects to continue to incur expenses related to the development of oral levosimendan to treat pulmonary hypertension and heart failure with preserved ejection fraction (PH-HFpEF) in the Phase 3 LEVEL trial, and, potentially for other indications of levosimendan and imatinib for PAH, as well as identifying and developing other potential product candidates. Based on its resources on September 30, 2023, the Company believes that it has sufficient capital to fund its planned operations through to the first quarter of calendar year 2024. However, the Company will need substantial additional financing in order to fund its operations beyond such period and thereafter until it can achieve profitability, if ever. The Company depends on its ability to raise additional funds through various potential sources, such as equity and debt financing, or to license its product candidates to another pharmaceutical company. The Company 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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## **[Table of Contents](#)**

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.

The COVID-19 pandemic or a similar societal healthcare disruption could in the future, directly or indirectly, adversely affect the Company's clinical trial operations, including its ability to recruit and retain patients, principal investigators and site staff who, as healthcare providers, may have heightened exposure to or impact from infectious diseases if an outbreak occurs in their geography. Further, some patients may be unable to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services, or if the patients become infected with coronavirus or a similar virus themselves, which would delay the Company's ability to initiate and/or complete planned clinical and preclinical studies in the future. In May 2023, the World Health Organization declared that COVID-19 was no longer a global health emergency, however, any lingering impact or resurgence of COVID-19 cannot be estimated.

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.

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 (1) require physical settlement or net-share settlement or (2) give the Company a choice of net-cash settlement or settlement in its own shares (physical settlement or net-share settlement). Contracts which (1) 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), (2) give the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement), or (3) that contain reset provisions that do not qualify for the scope exception are classified as equity or liabilities. 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.

	2023	2022
Warrants to purchase common stock	1,722,240	1,576,240
Pre-funded warrants to purchase common stock	-	792,802
Options to purchase common stock	74,873	77,911
Convertible preferred shares outstanding	210	210

### **Recent Accounting Pronouncements**

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

### [Table of Contents](#)

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

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

Property and equipment primarily consist of office furniture and fixtures.

Depreciation expense was \$1,000 and \$1,200 for the three months ended September 30, 2023 and 2022, respectively. For the nine months ended September 30, 2023 and 2022, depreciation expense was \$2,900 and \$3,800, respectively.

### **Accrued liabilities**

Accrued liabilities consist of the following:

	September 30, 2023	December 31, 2022
Operating costs	\$ 245,545	\$ 245,391
Lease liability	-	119,393
Employee related	47,416	410,261
	<u>\$ 292,961</u>	<u>\$ 775,045</u>

## **NOTE 4. NOTE PAYABLE**

### **Premium Finance Agreement**

On December 31, 2022, the Company executed a premium finance note agreement (the “Note”) with AFCO Credit Corporation. The Note financed the Company’s Directors and Officers Insurance Policy as well as the Errors and Omissions policy. The total amount financed was \$693,669. The Company paid a down payment of \$69,367 at execution leaving a balance of \$624,302 payable in monthly installments of \$58,873 through December 1, 2023. The Note has an interest rate of 7.39%. The Company recorded interest expense on the Note in the amount of \$5,337 and \$21,151 for the three and nine months ended September 30, 2023. The balance on the Note as of September 30, 2023 and December 31, 2022 was \$174,466 and \$624,302, 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 \$750 per month.

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

### **Simdax license agreement**

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

[Table of Contents](#)

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

As of September 30, 2023, 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 259,068 units for net proceeds of approximately \$9.0 million (the "2018 Offering"). Each unit consisted of (i) 20 shares of the Company's Series A convertible preferred stock, par value \$0.0001 per share (the "Series A Stock"), (ii) a two-year warrant to purchase one share of common stock at an exercise price of \$38.60, and (iii) a five-year warrant to purchase one share of common stock at an exercise price of \$38.60. In accordance with ASC 480, Distinguishing Liabilities from Equity, the estimated fair value of \$1,800,016 for the beneficial conversion feature was recognized as a deemed dividend on the Series A Stock during the year ended December 31, 2020.

As of September 30, 2023, there were 210 shares of Series A Stock outstanding.

**Common Stock and Pre-Funded Warrants**

The Company's Certificate of Incorporation authorizes it to issue 400,000,000 shares of \$0.0001 par value common stock. As of September 30, 2023, and December 31, 2022, there were 23,862,434 and 2,291,809 shares of common stock issued and outstanding, respectively. As of September 30, 2023 and December 31, 2022, there were no pre-funded warrants outstanding.

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

*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 6,959,444 shares of its common stock, and pre-funded warrants to purchase an aggregate of 1,707,222 shares of common stock and (ii) accompanying warrants to purchase up to an aggregate of 17,333,332 shares of its common stock at a combined offering price of \$1.80 per share of common stock and associated common warrant, or \$1.799 per pre-funded warrant and associated common warrant, resulting in gross proceeds of approximately \$15.6 million. The net proceeds of the February 2023 Offering after deducting placement agent fees and direct offering expenses were approximately \$13.7 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 529,802 units in a private placement at a purchase price of \$15.50 per unit. Each unit consisted of (i) one unregistered pre-funded warrant to purchase one share of common stock and (ii) one unregistered warrant to purchase one share of common stock (together with the pre-funded warrants, the "2022 Warrants"). In the aggregate, 1,059,603 shares of the Company's common stock are underlying the 2022 Warrants. The net proceeds from the private placement, after direct offering expenses, were approximately \$7.9 million. The fair value allocated to the pre-funded warrants and warrants was \$4.2 million and \$3.8 million, respectively.

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

[Table of Contents](#)

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 September 30, 2023, the Company has 1,722,240 warrants outstanding. The following table summarizes the Company’s warrant activity for the nine months ended September 30, 2023:

	Warrants	Weighted Average Exercise Price
<b>Outstanding at December 31, 2022</b>	<b>1,576,240</b>	<b>\$ 17.13</b>
Issued	17,333,332	2.25
Exercised	(17,187,332)	2.25
<b>Outstanding at September 30, 2023</b>	<b>1,722,240</b>	<b>\$ 15.87</b>

### February 2023 Warrants

As described above, as a part of the February 2023 Offering, the Company issued unregistered warrants to purchase 17,333,332 shares of its common stock at an exercise price of \$2.25 per share and contractual term of five 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 \$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 529,802 shares of its common stock at an exercise price of \$12.60 per share and contractual term of five and one-half years. The unregistered warrants were offered in a private placement under Section 4(a)(2) of the Securities Act 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

On June 9, 2022, the Company’s stockholders approved the Tenax Therapeutics, Inc. 2022 Stock Incentive Plan (the “2022 Plan”), which authorizes for issuance a total of 55,000 shares of common stock. 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. 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 the 2022 Plan. At September 30, 2023 there were 51,487 shares that rolled over from the 2016 Plan and 28,488 shares remaining under the 2022 Plan resulting in an aggregate of 79,975 shares available for issuance under the 2022 Plan.

[Table of Contents](#)

The following table summarizes the shares available for grant under the 2022 Plan for the nine months ended September 30, 2023.

	Shares Available for Grant
<b>Balances, at December 31, 2022</b>	<b>77,616</b>
Options cancelled/forfeited	2,359
<b>Balances, at September 30, 2023</b>	<b>79,975</b>

## 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 nine months ended September 30, 2023.

	Outstanding Options	
	Number of Shares	Weighted Average Exercise Price
<b>Balances at December 31, 2022</b>	28,163	\$ 12.40
Options cancelled/forfeited	(1,650)	\$ 12.40
<b>Balances at September 30, 2023</b>	26,513	\$ 12.40

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 \$16,089 and \$68,586 for the three and nine months ended September 30, 2023, respectively. No compensation expense was recorded for the nine months ended September 30, 2022.

As of September 30, 2023, there were unrecognized compensation costs of approximately \$91,779 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 1.69 years.

## [Table of Contents](#)

### 2016 Stock Incentive Plan

On June 16, 2016, the Company’s stockholders approved the 2016 Plan and authorized for issuance under the 2016 Plan a total of 7,500 shares of common stock. Under the 2016 Plan, with the approval of the Board’s Compensation Committee, the Company could 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 13, 2019, the Company’s stockholders approved an amendment to the 2016 Plan which increased the number of shares of common stock authorized for issuance under the 2016 Plan to a total of 37,500 shares, up from 7,500 previously authorized. On June 10, 2021, the Company’s stockholders approved an additional amendment to the 2016 Plan which increased the number of shares of common stock authorized for issuance under the 2016 Plan to a total of 75,000 shares, up from 37,500 previously authorized. In June 2022, the 2016 Plan was superseded and replaced by the 2022 Plan and no new awards will be granted under the 2016 Plan going forward. Any awards outstanding under the 2016 Plan on the date of approval of the 2022 Plan remain subject to the 2016 Plan. Upon approval of the 2022 Plan, all shares of common stock remaining authorized and available for issuance under the 2016 Plan and any shares subject to outstanding awards under the 2016 Plan that subsequently expire, terminate, or are surrendered or forfeited for any reason without issuance of shares automatically become available for issuance under our 2022 Plan.

### 2016 Plan Stock Options

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

The following table summarizes the outstanding stock options under the 2016 Plan for the nine months ended September 30, 2023.

	Outstanding Options	
	Number of Shares	Weighted Average Exercise Price
<b>Balances at December 31, 2022</b>	23,373	\$ 40.13
Options cancelled/forfeited	(709)	\$ 23.60
<b>Balances at September 30, 2023</b>	22,664	\$ 40.64

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

The Company recorded compensation expense for these stock options grants of \$7,840 and \$23,574 for the three and nine months ended September 30, 2023, respectively.

As of September 30, 2023, there were unrecognized compensation costs of approximately \$8,805 related to non-vested stock option awards under the 2016 Plan that will be recognized on a straight-line basis over the weighted average remaining vesting period of 0.27 years.

### 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 10,000 shares, up from 750 previously authorized. On September 15, 2015, the Company's stockholders approved an additional amendment to the 1999 Plan which increased the number of shares of common stock authorized for issuance under the 1999 Plan to a total of 12,500 shares, up from 10,000 previously authorized. The 1999 Plan expired on June 17, 2018 and no new grants may be made under that plan after that date. However, unexpired awards granted under the 1999 Plan remain outstanding and subject to the terms of the 1999 Plan.

[Table of Contents](#)

*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 nine months ended September 30, 2023:

	<b>Outstanding Options</b>	
	<b>Number of Shares</b>	<b>Weighted Average Exercise Price</b>
<b>Balances at December 31, 2022</b>	936	\$ 1,122.75
Options cancelled/forfeited	(240)	\$ 1,253.83
<b>Balances at September 30, 2023</b>	696	\$ 1,076.36

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 and nine months ended September 30, 2023 and 2022, respectively.

As of September 30, 2023, 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 5,000 shares of common stock and the other for 12,500 shares of common stock, to its new CEO on July 6, 2021.

The employment inducement stock option for 5,000 shares of common stock was awarded in accordance with the employment inducement award exemption provided by Nasdaq Listing Rule 5635(c)(4) and was therefore not awarded under the Company's stockholder approved equity plan. The option award was to vest as follows: 50% upon initiation of a Phase 3 trial for levosimendan by June 30, 2022; and 50% upon initiation of a Phase 3 trial for imatinib by June 30, 2022. The options had a 10-year term and an exercise price of \$39.40 per share, the July 6, 2021 closing price of our common stock. None of the vesting milestones were 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 12,500 shares of common stock also was awarded in accordance with the employment inducement award exemption provided by Nasdaq Listing Rule 5635(c)(4) and was therefore not awarded under the Company's stockholder approved equity plan. The option award will vest as follows: 25% on the one-year anniversary of the CEO's employment start date and an additional 25% on each of the following three anniversaries of the CEO's employment start date, subject to continued employment. The options have a 10-year term and an exercise price of \$39.40 per share, the July 6, 2021 closing price of our common stock.

[Table of Contents](#)

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

The Company granted an employment inducement stock option award for 12,500 shares of common stock to our chief medical officer on January 15, 2021. This employment inducement stock option was awarded in accordance with the employment inducement award exemption provided by Nasdaq Listing Rule 5635(c)(4) and was therefore not awarded under the Company's stockholder approved equity plan. The option award will vest as follows: 25% upon initiation of a Phase 3 trial; 25% upon database lock; 25% upon acceptance for review of an investigational NDA; and 25% upon approval. The options have a 10-year term and an exercise price of \$35.60 per share, the January 15, 2021 closing price of our common stock. 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 \$13,083 and \$61,678 for the three and nine months ended September 30, 2023, respectively. As of September 30, 2023, there was \$371,384 of remaining unrecognized compensation expense related to these inducement stock options.

## NOTE 8. SUBSEQUENT EVENTS

None.

[Table of Contents](#)

## 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, 2022. All references in this Quarterly Report to “Tenax Therapeutics,” “Tenax,” “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

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. Effective June 30, 2008, we changed the domiciliary state of the corporation to Delaware and changed the Company name to Oxygen Biotherapeutics, Inc. On September 19, 2014, we changed the Company name to Tenax Therapeutics, Inc.

On November 13, 2013, we acquired a license granting Life Newco Inc., our wholly-owned subsidiary, an exclusive, sublicensable right to develop and commercialize pharmaceutical products containing levosimendan, 2.5 mg/ml concentrate for solution for infusion / 5ml vial in the United States and Canada. On October 9, 2020 and January 25, 2022, we entered into amendments to the license to include two product dose forms containing levosimendan, in capsule and solid dosage form, and a subcutaneously administered product containing levosimendan, subject to specified limitations.

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

### Business Strategy

Having carefully considered alternatives within the ongoing strategic process announced in September 2022, and having raised capital to fund the Company through to the first quarter of 2024, the Company has elected to prioritize its LEVEL trial (Phase 3 testing of oral levosimendan to treat pulmonary hypertension and heart failure with preserved ejection fraction (PH-HFpEF)), ahead of imatinib. Activity to initiate the LEVEL trial continued in the third quarter of 2023, and site qualification and selection processes are ongoing, the Company having received FDA input into the oral levosimendan protocol and clinical development program in the third quarter of 2023. The Company plans to begin initiating sites in the fourth quarter of 2023 and enrolling patients early in 2024. Additional funding will be needed to complete the LEVEL trial. Supporting the strategic decision to prioritize levosimendan 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 Tenax since the start of 2022. This prioritization of the Phase 3 testing of levosimendan places the start of a Phase 3 imatinib trial outside the 2023 timeframe, pending strategic considerations.

[Table of Contents](#)

The Company took steps to reduce its monthly operating expenses and conserve cash, as it commenced exploring strategic alternatives in late 2022. The Company at that time cancelled many non-essential operating expenses such as its office lease, and dues and subscriptions and office supplies associated with that leased office. During the third quarter of 2023, the Company and its contracted clinical research organization (CRO) increased outreach to North American clinical trial sites, Institutional Review Boards, and other partners who will support the LEVEL trial, resulting in an increase in R&D expenses in the third quarter of 2023.

Pending the outcome of our ongoing strategic process, 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 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 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 when designing and executing our research.

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

Levosimendan has shown promise in multiple disease areas in the two decades following its approval. Our own Phase 2 study and open-label extension has demonstrated that a formerly under-appreciated mechanism of action of levosimendan, its property of relaxing the venous circulation, brings about durable improvements in exercise capacity and quality of life, as well as other clinical assessments, in patients with heart failure with PH-HFpEF. We believe this patient population today has no pharmaceutical therapies available and we are committed to exploring potential clinical indications where our therapies may achieve best-in-class profile, and where we can address significant unmet medical needs.

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

Continue to expand our intellectual property portfolio.

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

[Table of Contents](#)

[Notice of Allowance and Patent](#)

On February 1, 2023, the Company announced it was granted a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for its patent application with claims covering the use of IV levosimendan (TNX-101) in the treatment of PH-HFpEF. This patent (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. At present, Tenax Therapeutics has other patent applications pending, with additional decisions expected beyond 2023.

[Enter into licensing or product co-development arrangements.](#)

In addition to our internal development efforts, an important part of our product development strategy is to work with collaborators and partners to accelerate product development, maintain our low development and business operations costs, and broaden our commercialization capabilities globally. We believe this strategy will help us to develop a portfolio of high-quality product development opportunities, enhance our clinical development and commercialization capabilities, and increase our ability to generate value from our proprietary technologies.

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

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

## COVID-19

The COVID-19 pandemic or similar epidemics as well as other societal/healthcare disruptions could in the future, directly or indirectly, adversely impact our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to or impact of such illnesses, which could negatively impact our trials, increase our operating expenses, and have a material adverse effect on our financial results. In

May 2023, the World Health Organization declared that COVID-19 was no longer a global health emergency, however, any lingering impact or resurgence of COVID-19 cannot be estimated. We will continue to assess the potential impact of the COVID-19 pandemic on our business and operations, including our clinical operations and manufacturing activities.

### Financial Overview – Three Months Ended September 30, 2023

#### Operating Expenses

	Three months ended September 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2023	2022		
Operating expenses				
General and administrative	\$ 1,051,524	\$ 1,377,283	\$ (325,759)	(24)%
Research and development	1,065,855	1,540,205	(474,350)	(31)%
Total operating expenses	\$ 2,117,379	\$ 2,917,488	\$ (800,109)	(27)%

19

#### [Table of Contents](#)

#### General and Administrative Expenses

General and administrative expenses were \$1.0 million for the three months ended September 30, 2023, compared to \$1.4 million for the same period in 2022. 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 September 30, 2023 and 2022, respectively, are as follows:

	Three months ended September 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2023	2022		
Personnel costs	\$ 439,622	\$ 489,369	\$ (49,747)	(10)%
Legal and professional fees	412,121	668,172	(256,051)	(38)%
Other costs	196,820	180,390	16,430	9%
Facilities	2,961	39,352	(36,391)	(92)%
Total general and administrative expenses	\$ 1,051,524	\$ 1,377,283	\$ (325,759)	(24)%

Personnel costs decreased approximately \$50,000 for the three months ended September 30, 2023, compared to the same period in the prior year. 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 decreased approximately \$256,000 for the three months ended September 30, 2023, 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 decreased approximately \$24,000 for the three months ended September 30, 2023, compared to the same period in the prior year. The change was primarily due to decreased legal fees associated with general corporate matters, fundraising activities and IP costs that were incurred during the same period in the prior year.

Professional fees decreased approximately \$232,000 for the three months ended September 30, 2023, compared to the same period in the prior year. The change was primarily attributable to decreased capital market expenses and consulting expenses offset by increases in accounting costs.

Other costs increased approximately \$16,000 for the three months ended September 30, 2023, compared to the same period in the prior year. Other costs include expenses incurred for franchise and other taxes, travel, supplies, insurance, depreciation and other miscellaneous charges. The change was primarily attributable to increased costs for insurance and general office supplies offset by decreases in dues, franchise and other taxes and banking fees.

Facilities costs include costs paid for rent and utilities at our corporate headquarters in North Carolina. Facilities costs decreased approximately \$36,000 for the three months ended September 30, 2023, compared to the same period in the prior year. The decrease is the result of the Company's relocation to new shared office space resulting in lower rent costs.

20

#### [Table of Contents](#)

#### Research and Development Expenses

Research and development expenses were approximately \$1.1 million for the three months ended September 30, 2023, compared to \$1.5 million for the same period in the prior year. Research and development expenses include, but are not limited to, (i) expenses incurred under agreements with CROs and investigative sites, which conduct our clinical trials and a substantial portion of our pre-clinical studies; (ii) the cost of supplying clinical trial materials; (iii) payments to contract service organizations, as well as consultants; (iv) employee-related expenses, which include salaries and benefits; and (v) facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, depreciation of leasehold improvements, equipment, and other supplies. All research and development expenses are expensed as incurred. Research and development expenses and percentage changes for the three months ended September 30, 2023 and 2022, respectively, are as follows:

	Three months ended September 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2023	2022		
Clinical and preclinical development	\$ 978,767	\$ 1,376,795	\$ (398,028)	(29)%
Personnel costs	71,898	146,685	(74,787)	(51)%
Other costs	15,190	16,725	(1,535)	(9)%
Total research and development expenses	\$ 1,065,855	\$ 1,540,205	\$ (474,350)	(31)%

Clinical and preclinical development costs decreased approximately \$398,000 for the three months ended September 30, 2023 compared to the same period in the prior year. Clinical and preclinical development costs for the three months ended September 30, 2023 consist of start-up costs related to the LEVEL trial, compared with costs for the three months ended September 30, 2022 associated with our imatinib Phase 1 Pharmacokinetics Study, imatinib Phase 3 IMPROVE Study, and development costs associated with the formulation for imatinib. The decrease is primarily attributable to lower Phase 1 and Phase 3 costs for imatinib, since the Company paused clinical development activities for this product candidate in 2022, offset by increased LEVEL trial costs in the third quarter of 2023.

Personnel costs decreased approximately \$75,000 for the three months ended September 30, 2023, compared to the same period in the prior year, primarily attributable to the timing of general employment costs.

Other costs decreased approximately \$1,500 for the three months ended September 30, 2023, compared to the same period in the prior year, primarily attributable to decreased regulatory consulting costs.

### Other Income and Expense

Other income and expense include non-operating income and expense items not otherwise recorded in our consolidated statement of comprehensive loss. These items include but are not limited to interest income earned and fixed asset disposals. Interest expense increased approximately \$4,965 for the three months ended September 30, 2023, compared to the same period in the prior year. The change is due primarily to interest expense paid on the premium finance note agreement (the "Note") with AFCO Credit Corporation. Other income increased approximately \$149,000 primarily related to interest income on cash deposits as a result of the February 2023 offering.

### Financial Overview – Nine Months Ended September 30, 2023

#### Operating Expenses

	Nine months ended September 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2023	2022		
Operating expenses				
General and administrative	\$ 3,363,511	\$ 4,255,454	\$ (891,943)	(21)%
Research and development	1,529,493	4,242,565	(2,713,072)	(64)%
Total operating expenses	\$ 4,893,004	\$ 8,498,019	\$ (3,605,015)	(42)%

#### [Table of Contents](#)

#### General and Administrative Expenses

General and administrative expenses were \$3.3 million for the nine months ended September 30, 2023, compared to \$4.3 million for the same period in 2022. 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 nine months ended September 30, 2023 and 2022, respectively, are as follows:

	Nine months ended September 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2023	2022		
Personnel costs	\$ 1,446,549	\$ 1,617,284	\$ (170,735)	(11)%
Legal and professional fees	1,299,021	1,918,403	(619,382)	(32)%
Other costs	592,174	606,538	(14,364)	(2)%
Facilities	25,767	113,229	(87,462)	(77)%
Total general and administrative expenses	\$ 3,363,511	\$ 4,255,454	\$ (891,943)	(21)%

Personnel costs decreased approximately \$171,000 for the nine months ended September 30, 2023, compared to the same period in the prior year. The change was primarily due to decreased employment related costs in the current period compared to the same period in the prior year.

Legal and professional fees decreased approximately \$619,000 for the nine months ended September 30, 2023, 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 decreased approximately \$335,000 for the nine months ended September 30, 2023, compared to the same period in the prior year. The change was primarily due to decreased legal fees associated with general corporate matters, fundraising activities and IP costs that were incurred during the same period in the prior year.

Professional fees decreased approximately \$284,000 for the nine months ended September 30, 2023, compared to the same period in the prior year. The decrease was primarily attributable to decreased investor relations and consulting fees offset by increases in capital market fees and accounting costs.

Other costs decreased approximately \$14,000 for the nine months ended September 30, 2023, compared to the same period in the prior year. Other costs include expenses incurred for franchise and other taxes, travel, supplies, insurance, depreciation and other miscellaneous charges. The change was primarily attributable to decreased costs for travel, dues, taxes and general office supplies offset by increased costs for insurance.

Facilities costs include costs paid for rent and utilities at our corporate headquarters in North Carolina. Facilities costs decreased approximately \$87,000 for the nine months ended September 30, 2023, compared to the same period in the prior year. The decrease is the result of the Company's relocation to new shared office space resulting in lower rent costs.

[Table of Contents](#)

**Research and Development Expenses**

Research and development expenses were \$1.5 million for the nine months ended September 30, 2023, compared to \$4.2 million for the same period in the prior year. Research and development expenses include, but are not limited to, (i) expenses incurred under agreements with CROs and investigative sites, which conduct our clinical trials and a substantial portion of our pre-clinical studies; (ii) the cost of supplying clinical trial materials; (iii) payments to contract service organizations, as well as consultants; (iv) employee-related expenses, which include salaries and benefits; and (v) facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, depreciation of leasehold improvements, equipment, and other supplies. All research and development expenses are expensed as incurred. Research and development expenses and percentage changes for the nine months ended September 30, 2023 and 2022, respectively, are as follows:

	<b>Nine months ended September 30,</b>		<b>Increase/ (Decrease)</b>	<b>% Increase/ (Decrease)</b>
	<b>2023</b>	<b>2022</b>		
Clinical and preclinical development	\$ 1,119,920	\$ 3,751,696	\$ (2,631,776)	(70)%
Personnel costs	340,625	466,223	(125,598)	(27)%
Other costs	68,948	24,646	44,302	180%
Total research and development expenses	\$ 1,529,493	\$ 4,242,565	\$ (2,713,072)	(64)%

Clinical and preclinical development costs decreased approximately \$2.6 million for the nine months ended September 30, 2023 compared to the same period in the prior year. Clinical and preclinical development costs for the nine months ended September 30, 2023 consist of start-up costs related to the LEVEL trial, compared to costs incurred in the same period in the prior year related to the Phase 2 HELP Open Label Extension Study for levosimendan, and costs associated with our imatinib Phase 1 Pharmacokinetics Study, imatinib Phase 3 IMPROVE Study, and development costs associated with the formulation for imatinib. The decrease is primarily attributable to lower Phase 1 and Phase 3 costs for imatinib, since the Company paused clinical development activities for this product candidate in 2022, offset by increased LEVEL trial costs in the third quarter of 2023.

Personnel costs decreased approximately \$126,000 for the nine months ended September 30, 2023, compared to the same period in the prior year, primarily attributable to the timing of general employment costs.

Other costs increased approximately \$44,000 for the nine months ended September 30, 2023, compared to the same period in the prior year, primarily attributable to increased regulatory consulting costs.

**Other Income and Expense**

Other income and expense include non-operating income and expense items not otherwise recorded in our consolidated statement of comprehensive loss. These items include but are not limited to interest income earned and fixed asset disposals. Interest expense increased approximately \$17,000 for the nine months ended September 30, 2023, compared to the same period in the prior year. This increase is due primarily to interest expense paid on the Note. Other income increased \$426,000 primarily related to an earned license fee and interest income earned on higher cash balances resulting from our securities offering offset, offset by the lease loss of \$140,000.

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

We have incurred losses since our inception and, as of September 30, 2023, we had an accumulated deficit of approximately \$294.0 million. We will continue to incur losses until we generate sufficient revenue to offset our expenses, and we anticipate 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 imatinib for pulmonary hypertension and other potential indications, as well as identifying and developing other potential product candidates, and as a result, we will need to generate significant net product sales, royalty and other revenues to achieve profitability.

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

[Table of Contents](#)

## Liquidity

We have financed our operations since September 1990 through the issuance of debt and equity securities and loans from stockholders. We had total current assets of approximately \$11.9 million and \$3.2 million and working capital of approximately \$11.3 million and \$1.4 million as of September 30, 2023 and December 31, 2022, 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 have completed the open label extension phase of the levosimendan HELP clinical trial, during which patients were transitioned from an intravenous to oral formulation of levosimendan for the treatment of pulmonary hypertension. In the third quarter of 2023, we also began site qualification and selection processes for the LEVEL trial. Our ability to continue to pursue development of our products beyond the first quarter of calendar year 2024, including completing the LEVEL trial, will depend on obtaining license income or outside financial resources. There is no assurance that we will obtain any license agreement or outside financing or that we will otherwise succeed in obtaining any necessary resources.

The COVID-19 pandemic or a similar epidemic could in the future, directly or indirectly, adversely affect our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to or impact from respiratory illnesses or other similar widespread infections if an outbreak occurs in their geography. Further, some patients may be unable to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services, or if the patients become infected with COVID-19 or a similar disease themselves, which would delay our ability to complete our clinical trials or release clinical trial results.

## Financings

On February 3, 2023, we sold in a registered public offering (i) an aggregate of 6,959,444 shares of our common stock and pre-funded warrants to purchase an aggregate of 1,707,222 shares of our common stock and (ii) accompanying warrants to purchase up to an aggregate of 17,333,332 shares of our common stock at a combined offering price of \$1.80 per share of common stock and associated warrant, or \$1.799 per pre-funded warrant and associated warrant, resulting in gross proceeds to the Company of approximately \$15.6 million. Net proceeds of the offering were approximately \$13.6 million, after deducting the placement agent fees and offering expenses payable by the Company.

On May 17, 2022, we sold 529,802 units in a private placement at a purchase price of \$15.50 per unit for net proceeds of approximately \$7.9 million. Each unit consisted of one unregistered pre-funded warrant to purchase one share of our common stock and one unregistered warrant to purchase one share of common stock.

## Cash Flows

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

	Nine months ended	
	September 30,	
	2023	2022
Net cash (used in) operating activities	\$ (4,728,992)	\$ (9,699,791)
Net cash provided by (used in) investing activities	2,843	(6,323)
Net cash provided by financing activities	13,743,603	7,928,591

*Net cash used in operating activities.* Net cash used in operating activities was approximately \$4.7 million for the nine months ended September 30, 2023, compared to approximately \$9.7 million for the nine months ended September 30, 2022. The decrease in cash used for operating activities was primarily due to lower expense activity in the current period as compared to the prior year.

## [Table of Contents](#)

*Net cash provided by (used in) investing activities.* Net cash provided by investing activities was approximately \$2,843 for the nine months ended September 30, 2023, compared to net cash used in investing activities of approximately \$6,300 in the nine months ended September 30, 2022. The increase in cash provided by investing activities was primarily due to the sale of office furniture related to the relocation of the Company's headquarters.

*Net cash provided by financing activities.* Net cash provided by financing activities was approximately \$14.0 million for the nine months ended September 30, 2023, compared to approximately \$8.0 million in the nine months ended September 30, 2022. The increase in cash provided by financing activities was due to the net proceeds from 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 the global coronavirus pandemic or similar global societal disruptions; and
- the possible costs of litigation.

Based on our working capital on September 30, 2023, we believe we have sufficient capital on hand to continue to fund operations through to the first quarter of calendar year 2024.

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

[Table of Contents](#)

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, 2022 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.

[Table of Contents](#)

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 September 30, 2023, 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.

[Table of Contents](#)**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, 2022.

[Table of Contents](#)**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:

<b>Exhibit Number</b>	<b>Description</b>
<a href="#">3.1</a>	<a href="#">Fourth Amended and Restated Bylaws 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 August 15, 2023).</a>
<a href="#">31.1*</a>	<a href="#">Certification of President and Chief Executive Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002.</a>
<a href="#">31.2*</a>	<a href="#">Certification of Interim Chief Financial Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002.</a>
<a href="#">32.1**</a>	<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>
<a href="#">32.2**</a>	<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

[Table of Contents](#)**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.

**TENAX THERAPEUTICS, INC.**

By: Eliot M. Lurier  
Eliot M. Lurier  
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: November 13, 2023

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

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

I, Eliot M. Lurier, 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: November 13, 2023

Eliot M. Lurier  
*Interim Chief Financial Officer*  
*(Principal Financial and Accounting Officer)*

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

In connection with the Quarterly Report of Tenax Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2023 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: November 13, 2023

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 September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Eliot M. Lurier, Interim Chief Financial Officer (Principal Financial and Accounting Officer) of the Company, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods covered by the Report.

Date: November 13, 2023

Eliot M. Lurier  
*Interim Chief Financial Officer*  
*(Principal Financial and Accounting Officer)*

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

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