

# SECURITIES & EXCHANGE COMMISSION EDGAR FILING

## TENAX THERAPEUTICS, INC.

**Form: 10-Q**

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Corporate Issuer CIK: 34956

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, 2017

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.)

ONE Copley Parkway, Suite 490, Morrisville, North Carolina 27560  
(Address of principal executive offices)

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

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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. (Check one):

Large Accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-Accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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

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

As of November 4, 2017, the registrant had outstanding 28,236,546 shares of Common Stock.

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## PART I - FINANCIAL INFORMATION

## ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

## TENAX THERAPEUTICS, INC.

## CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2017 (Unaudited)	December 31, 2016
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 1,763,883	\$ 9,995,955
Marketable securities	6,770,718	3,284,616
Accounts receivable	24,649	72,599
Prepaid expenses	103,960	275,005
Total current assets	<u>8,663,210</u>	<u>13,628,175</u>
Marketable securities	2,323,858	8,586,110
Property and equipment, net	13,043	19,105
Other assets	2,762	1,106,785
Total assets	<u>\$ 11,002,873</u>	<u>\$ 23,340,175</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities		
Accounts payable	\$ 579,386	\$ 727,599
Accrued liabilities	223,088	5,245,546
Warrant liabilities	36,078	226,092
Total current liabilities	<u>838,552</u>	<u>6,199,237</u>
Total liabilities	838,552	6,199,237
Commitments and contingencies; see Note 6		
Stockholders' equity		
Common stock, par value \$.0001 per share; authorized 400,000,000 shares; issued and outstanding 28,236,546 and 28,120,021, respectively	2,824	2,812
Additional paid-in capital	222,322,798	221,816,447
Accumulated other comprehensive loss	(5,749)	(18,718)
Accumulated deficit	<u>(212,155,552)</u>	<u>(204,659,603)</u>
Total stockholders' equity	<u>10,164,321</u>	<u>17,140,938</u>
Total liabilities and stockholders' equity	<u>\$ 11,002,873</u>	<u>\$ 23,340,175</u>

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

TENAX THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Three months ended September 30,		Nine months ended September 30,	
	2017 (Unaudited)	2016 (Unaudited)	2017 (Unaudited)	2016 (Unaudited)
Operating expenses				
General and administrative	\$ 1,056,447	\$ 1,265,880	\$ 4,295,336	\$ 4,267,218
Research and development	253,973	3,234,686	3,528,338	10,609,912
Total operating expenses	1,310,420	4,500,566	7,823,674	14,877,130
Net operating loss	1,310,420	4,500,566	7,823,674	14,877,130
Other income	(76,226)	(226,914)	(327,725)	(600,610)
Net loss	<u>\$ 1,234,194</u>	<u>\$ 4,273,652</u>	<u>\$ 7,495,949</u>	<u>\$ 14,276,520</u>
Unrealized (gain) / loss on marketable securities	(3,767)	39,324	(12,969)	(178,985)
Total comprehensive loss	<u>\$ 1,230,427</u>	<u>\$ 4,312,976</u>	<u>\$ 7,482,980</u>	<u>\$ 14,097,535</u>
Net loss per share, basic and diluted	\$ (0.04)	\$ (0.15)	\$ (0.27)	\$ (0.51)
Weighted average number of common shares outstanding, basic and diluted	28,236,546	28,119,848	28,204,511	28,119,797

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

## TENAX THERAPEUTICS, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Nine months ended September 30,	
	2017	2016
	(Unaudited)	(Unaudited)
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net Loss	\$ (7,495,949)	\$ (14,276,520)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	10,599	14,531
Gain on disposal of property and equipment	-	(74,388)
Issuance and vesting of compensatory stock options and warrants	426,837	366,129
Issuance of common stock as compensation	79,525	858
Change in the fair value of warrants	(190,014)	(214,065)
Amortization of premium on marketable securities	158,209	565,156
Changes in operating assets and liabilities		
Accounts receivable, prepaid expenses and other assets	1,323,018	182,605
Accounts payable and accrued liabilities	(5,170,671)	669,463
Net cash used in operating activities	<u>(10,858,446)</u>	<u>(12,766,231)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchase of marketable securities	(299,172)	(7,255,578)
Sale of marketable securities	2,930,082	17,011,392
Purchase of property and equipment	(4,536)	(2,884)
Proceeds from the sale of property and equipment	-	75,000
Net cash provided by investing activities	<u>2,626,374</u>	<u>9,827,930</u>
Net change in cash and cash equivalents	<u>(8,232,072)</u>	<u>(2,938,301)</u>
Cash and cash equivalents, beginning of period	9,995,955	3,660,453
Cash and cash equivalents, end of period	<u>\$ 1,763,883</u>	<u>\$ 722,152</u>

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

**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. Oxygen Biotherapeutics was formed on April 17, 2008 by Synthetic Blood International 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 to one share of Oxygen Biotherapeutics common stock. On September 19, 2014, the Company changed its name to Tenax Therapeutics, Inc.

On October 18, 2013, the Company created a wholly owned subsidiary, Life Newco, Inc., a Delaware corporation ("Life Newco"), to acquire 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 (the "Phyxius Stockholders"). As further discussed in Note 6 below, on November 13, 2013, under the terms and subject to the conditions of the Asset Purchase Agreement, Life Newco acquired certain assets, including a license granting Life Newco 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.

**NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES*****Basis of Presentation***

The accompanying unaudited condensed consolidated financial statements include all adjustments (consisting of normal and recurring adjustments) necessary for a fair presentation of these financial statements. The condensed consolidated balance sheet at December 31, 2016 has been derived from the Company's audited consolidated financial statements included in its Annual Report on Form 10-K for the period ended December 31, 2016. Certain footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States ("GAAP") have been condensed or omitted pursuant to Article 8 of Regulation S-X of the Securities and Exchange Commission ("SEC") rules and regulations. Operating results for the three- and nine- month periods ended September 30, 2017 are not necessarily indicative of results for the full year or any other future periods. As such, it is suggested that these condensed consolidated financial statements be read in conjunction with the consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the period ended December 31, 2016.

***Use of Estimates***

In preparing the unaudited condensed consolidated financial statements, management is required to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the dates of the unaudited condensed consolidated financial statements and the reported amounts of revenue and expenses during the reporting periods. Actual results could differ from these estimates and the operating results for the interim periods presented are not necessarily indicative of the results expected for the full year.

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

## Liquidity and Management's Plan

At September 30, 2017, the Company had cash and cash equivalents, including the fair value of its marketable securities, of approximately \$10.9 million. The Company used \$10.9 million of cash for operating activities during the nine months ended September 30, 2017 and had stockholders' equity of \$10.2 million, versus \$17.1 million at December 31, 2016.

The Company expects to continue to incur expenses related to development of levosimendan, as well as identifying and developing other potential product candidates. Based on its resources at September 30, 2017, the Company believes that it has sufficient capital to fund its planned operations through the fourth quarter of calendar year 2018. 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. The Company will continue to fund operations from cash on hand and through sources of capital similar to those previously described. The Company cannot assure that it will be able to secure such additional financing, or if available, that it will be sufficient to meet its needs.

To the extent that the Company raises additional funds by issuing shares of its common stock or other securities convertible or exchangeable for shares of common stock, stockholders will experience dilution, which may be significant. In the event the Company raises additional capital through debt financings, the Company may incur significant interest expense and become subject to covenants in the related transaction documentation that may affect the manner in which the Company conducts its business. To the extent that the Company raises additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to its technologies or product candidates, or grant licenses on terms that may not be favorable to the Company. Any or all of the foregoing may have a material adverse effect on the Company's business and financial performance.

## Net 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, warrants and restricted stock 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.

	Nine months ended September 30,	
	2017	2016
Options to purchase common stock	3,791,145	4,092,698
Warrants to purchase common stock	2,415,268	2,416,046
Restricted stock	-	367

## Recent Accounting Pronouncements

In July 2017, the Financial Accounting Standards Board (the "FASB"), issued an accounting standard that change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. The amendments also clarify existing disclosure requirements for equity-classified instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. The standard will be effective for the Company on January 1, 2019. Early adoption is permitted, including adoption in an interim period. The Company is currently evaluating the effect that the standard will have on its condensed consolidated financial statements and related disclosures.

In January 2017, the FASB issued an accounting standard that provides guidance for evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The guidance provides a screen to determine when an integrated set of assets and activities, or a set, does not qualify to be a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in an identifiable asset or a group of similar identifiable assets, the set is not a business. If the screen is not met, the guidance requires a set to be considered a business to include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create outputs and removes the evaluation as to whether a market participant could replace the missing elements. The standard will be effective for the Company on January 1, 2018 and will be adopted on a prospective basis. Early adoption is permitted. The Company does not believe adoption of this standard will have a material impact on its condensed consolidated financial statements and related disclosures.



In August 2016, the FASB issued an accounting standard that clarifies how companies present and classify certain cash receipts and cash payments in the statement of cash flows where diversity in practice exists. The standard is effective for the Company in its first quarter of fiscal 2018 and earlier adoption is permitted. The Company does not believe that adopting this updated standard will have a material impact on its condensed consolidated financial statements and related disclosures.

In June 2016, the FASB issued an accounting standard that amends how credit losses are measured and reported for certain financial instruments that are not accounted for at fair value through net income. This standard will require that credit losses be presented as an allowance rather than as a write-down for available-for-sale debt securities and will be effective for interim and annual reporting periods beginning January 1, 2020, with early adoption permitted, but not earlier than annual reporting periods beginning January 1, 2019. A modified retrospective approach is to be used for certain parts of this guidance, while other parts of the guidance are to be applied using a prospective approach. The Company is currently evaluating the impact that this new standard will have on its condensed consolidated financial statements and related disclosures .

In May 2014, the FASB issued an accounting standard that supersedes nearly all existing revenue recognition guidance under GAAP. The standard is principles-based and provides a five-step model to determine when and how revenue is recognized. The core principle of the standard is that revenue should be recognized when a company transfers promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. In March 2016, the FASB issued a standard to clarify the implementation guidance on principal versus agent considerations, and in April 2016, the FASB issued a standard to clarify the implementation guidance on identifying performance obligations and licensing. The standard also requires disclosure of qualitative and quantitative information surrounding the amount, nature, timing and uncertainty of revenues and cash flows arising from contracts with customers. In July 2015, the FASB agreed to defer the effective date of the standard from annual periods beginning after December 15, 2016, to annual periods beginning after December 15, 2017. Early application prior to the original effective date is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. The Company does not believe adoption of this standard will have a material impact on its condensed consolidated financial statements and related disclosures.

In February 2016, the FASB issued an accounting standard intended to improve financial reporting regarding leasing transactions. The standard will require the Company to recognize on the balance sheet the assets and liabilities for the rights and obligations created by all leased assets. The standard will also require it to provide enhanced disclosures designed to enable users of financial statements to understand the amount, timing, and uncertainty of cash flows arising from all leases, operating and capital, with lease terms greater than 12 months. The standard is effective for financial statements beginning after December 15, 2018, and interim periods within those annual periods. Early adoption is permitted. The Company is currently evaluating the impact that this standard will have on its condensed consolidated financial statements and related disclosures.

In January 2016, the FASB issued an accounting standard that will enhance the Company's reporting for financial instruments. The standard is effective for financial statements issued for annual periods beginning after December 15, 2017, and interim periods within those annual periods. Earlier adoption is permitted for interim and annual reporting periods as of the beginning of the fiscal year of adoption. The Company does not believe the adoption of this standard will have a material impact on its condensed consolidated financial statements.

### **NOTE 3: FAIR VALUE**

The Company determines the fair value of its financial assets and liabilities in accordance with the FASB Accounting Standards Codification ("ASC") 820 Fair Value Measurements. The Company's balance sheet includes the following financial instruments: cash and cash equivalents, investments in marketable securities, and warrant liabilities. The Company considers the carrying amount of its cash and cash equivalents to approximate fair value due to the short-term nature of these instruments.

Accounting for fair value measurements involves a single definition of fair value, along with a conceptual framework to measure fair value, with a fair value defined as "the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date." The fair value measurement hierarchy consists of three levels:

Level one	Quoted market prices in active markets for identical assets or liabilities;
Level two	Inputs other than level one inputs that are either directly or indirectly observable; and
Level three	Unobservable inputs developed using estimates and assumptions; which are developed by the reporting entity and reflect those assumptions that a market participant would use.

The Company applies valuation techniques that (1) place greater reliance on observable inputs and less reliance on unobservable inputs and (2) are consistent with the market approach, the income approach and/or the cost approach, and include enhanced disclosures of fair value measurements in the Company's condensed consolidated financial statements.

### **Investments in Marketable Securities**

The Company classifies all of its investments as available-for-sale. Unrealized gains and losses on investments are recognized in comprehensive income/(loss), unless an unrealized loss is considered to be other than temporary, in which case the unrealized loss is charged to operations. The Company periodically reviews its investments for other than temporary declines in fair value below cost basis and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company believes the individual unrealized losses represent temporary declines primarily resulting from interest rate changes. Realized gains and losses are reflected in interest and other income in the condensed consolidated statements of comprehensive loss and are determined using the specific identification method with transactions recorded on a settlement date basis. Investments with original maturities at date of purchase beyond three months and which mature at or less than 12 months from the balance sheet date are classified as current. Investments with a maturity beyond 12 months from the balance sheet date are classified as long-term. At September 30, 2017, the Company believes that the costs of its investments are recoverable in all material respects.

The following table summarizes the fair value of the Company's investments by type. The estimated fair value of the Company's fixed income investments is classified as Level 2 in the fair value hierarchy as defined in U.S. GAAP. These fair values are obtained from independent pricing services which utilize Level 2 inputs:

	September 30, 2017				Estimated Fair Value
	Amortized Cost	Accrued Interest	Gross Unrealized Gains	Gross Unrealized Losses	
Corporate debt securities	\$ 9,029,156	\$ 71,169	\$ 5,542	\$ (11,291)	\$ 9,094,576

The following table summarizes the scheduled maturity for the Company's investments at September 30, 2017 and December 31, 2016.

	September 30, 2017	December 31, 2016
Maturing in one year or less	\$ 6,770,718	\$ 3,284,616
Maturing after one year through three years	2,323,858	8,586,110
Total investments	<u>\$ 9,094,576</u>	<u>\$ 11,870,726</u>

### **Warrant liability**

On July 23, 2013, the Company issued common stock warrants in connection with the issuance of Series C 8% Preferred Stock (the "Series C Warrants"). These Series C Warrants contain certain "down-round" price protection clauses and in accordance with ASC 815-40-35-9, the Company classifies these warrants as a current liability and the subsequent changes in fair value are recorded as a component of other expense.

Financial assets or liabilities are considered Level 3 when their fair values are determined using pricing models, discounted cash flow methodologies or similar techniques and at least one significant model assumption or input is unobservable. The Series C Warrants are measured using the Monte Carlo valuation model which is based, in part, upon inputs for which there is little or no observable market data, requiring the Company to develop its own assumptions. The assumptions used in calculating the estimated fair value of the warrants represent the Company's best estimates; however, these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and different assumptions are used, the warrant liabilities and the change in estimated fair value of the warrants could be materially different.

Inherent in the Monte Carlo valuation model are assumptions related to expected stock-price volatility, expected life, risk-free interest rate and dividend yield. The Company estimates the volatility of its common stock based on historical volatility that matches the expected remaining life of the warrants. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected remaining life of the warrants. The expected life of the warrants is assumed to be equivalent to their remaining contractual term. The dividend rate is based on the historical rate, which the Company anticipates to remain at zero.

The Monte Carlo model is used for the Series C Warrants to appropriately value the potential future exercise price adjustments triggered by the anti-dilution provisions. This requires Level 3 inputs which are based on the Company's estimates of the probability and timing of potential future financings and fundamental transactions. The other assumptions used by the Company are summarized in the following table for the Series C Warrants that were outstanding as of September 30, 2017 and December 31, 2016

Series C Warrants	September 30, 2017	December 31, 2016
Closing stock price	\$ 0.36	\$ 1.95
Expected dividend rate	0%	0%
Expected stock price volatility	84.53%	79.60%
Risk-free interest rate	1.44%	1.35%
Expected life (years)	1.81	2.56

As of September 30, 2017, the fair value of the warrant liability was \$36,078. The Company recorded a gain of \$36,079 and \$190,014 for the change in fair value as a component of other income on the condensed consolidated statements of comprehensive loss for the three and nine months ended September 30, 2017, respectively.

As of September 30, 2017, there were 240,523 Series C Warrants outstanding.

The following tables summarize information regarding assets and liabilities measured at fair value on a recurring basis as of September 30, 2017 and December 31, 2016:

	Balance as of September 30, 2017	Fair Value Measurements at Reporting Date Using		
		Quoted prices in Active Markets for Identical Securities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Current Assets</b>				
Cash and cash equivalents	\$ 1,763,883	\$ 1,763,883	\$ -	\$ -
Marketable securities	\$ 6,770,718	\$ -	\$ 6,770,718	\$ -
<b>Long-term Assets</b>				
Marketable securities	\$ 2,323,858	\$ -	\$ 2,323,858	\$ -
<b>Current Liabilities</b>				
Warrant liabilities	\$ 36,078	\$ -	\$ -	\$ 36,078

	Balance as of December 31, 2016	Fair Value Measurements at Reporting Date Using		
		Quoted prices in Active Markets for Identical Securities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
<b>Current Assets</b>				
Cash and cash equivalents	\$ 9,995,955	\$ 9,995,955	\$ -	\$ -
Marketable securities	\$ 3,284,616	\$ -	\$ 3,284,616	\$ -
<b>Long-term Assets</b>				
Marketable securities	\$ 8,586,110	\$ -	\$ 8,586,110	\$ -
<b>Current Liabilities</b>				
Warrant liabilities	\$ 226,092	\$ -	\$ -	\$ 226,092

There were no significant transfers between levels in the nine months ended September 30, 2017.

#### NOTE 4. BALANCE SHEET COMPONENTS

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

Property and equipment consist of the following as of September 30, 2017 and December 31, 2016:

	September 30, 2017	December 31, 2016
Laboratory equipment	\$ 354,861	\$ 354,861
Computer equipment and software	101,015	101,677
Office furniture and fixtures	130,192	130,192
	586,068	586,730
Less: Accumulated depreciation	(573,025)	(567,625)
	<u>\$ 13,043</u>	<u>\$ 19,105</u>

Depreciation expense was approximately \$3,000 and \$5,000 for the three months ended September 30, 2017 and 2016, respectively, and \$11,000 and \$15,000 for the nine months ended September 30, 2017 and 2016, respectively.

##### *Accrued liabilities*

Accrued liabilities consist of the following as of September 30, 2017 and December 31, 2016:

	September 30, 2017	December 31, 2016
Operating costs	\$ 170,711	\$ 4,361,538
Employee related	52,377	884,008
	<u>\$ 223,088</u>	<u>\$ 5,245,546</u>

#### NOTE 5. INTANGIBLE ASSETS

The following table summarizes the Company's intangible assets as of September 30, 2017 and December 31, 2016:

Asset Category	Weighted Average Amortization Period (in Years)	Value Assigned	Accumulated Amortization	Impairments	Carrying Value (Net of Impairments and Accumulated Amortization)
IPR&D	N/A	22,000,000	-	(22,000,000)	-
Total		<u>\$ 22,000,000</u>		<u>\$ (22,000,000)</u>	<u>-</u>

The aggregate amortization expense on the above intangibles was \$0 for each of the three and nine months ended September 30, 2017 and 2016.

##### *In Process Research and Development*

The levosimendan product represents an in process research and development ("IPR&D") asset. The IPR&D asset is a research and development project rather than a product or process already in service or being sold. Research and development intangible assets are considered indefinite-lived until the abandonment or completion of the associated research and development efforts. If abandoned, the assets would be impaired. Research and development expenditures that are incurred after the acquisition, including those for completing the research and development activities related to the acquired intangible research and development assets, are generally expensed as incurred.

The LEVO-CTS trial was completed in December of 2016. Based on the data from the trial, I evosimendan, given prophylactically prior to cardiac surgery to patients with reduced left ventricular function, had no effect on the co-primary outcomes. The study did not achieve statistically significant reductions in the dual endpoint of death or use of a mechanical assist device at 30 days, nor in the quad endpoint of death, myocardial infarction, need for dialysis, or use of a mechanical assist device at 30 days. Based on the results of the LEVO-CTS trial, the Company does not anticipate additional development of levosimendan for the treatment of LCOS in patients undergoing cardiac surgery. As of December 31, 2016, the Company determined the IPR&D asset, and corresponding goodwill, was more than temporarily impaired.

During the quarter ended December 31, 2016, the Company recognized an impairment charge of \$33.3 million related to its levosimendan product in Phase III clinical trial, which represents approximately \$22 million for IPR&D assets and approximately \$11.3 million for goodwill.

## 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 Agreement (the "License"), dated September 20, 2013 by and between Phyxius and Orion Corporation, a global healthcare company incorporated under the laws of Finland ("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 (the "Product") in the United States and Canada (the "Territory") from Orion. Pursuant to the License, the Company must use Orion's "Simdax®" trademark to commercialize the Product. The License also grants to 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. Orion's ongoing role under the License includes sublicense approval, serving as the sole source of manufacture, holding a first right to enforce intellectual property rights in the Territory, and certain regulatory participation rights. Additionally, the Company must grant back to Orion a broad non-exclusive license to any patents or clinical trial data related to the Product developed by the Company under the License. The License has a fifteen (15) year term, provided, however, that the License will continue after the end of the fifteen year term in each country in the Territory until the expiration of Orion's patent rights in the Product in such country.

Pursuant to the terms of the License, the Company paid to Orion a non-refundable up-front payment in the amount of \$1.0 million. The License also includes the following development milestones for which the Company shall make non-refundable payments to Orion no later than twenty-eight (28) days after the occurrence of the applicable milestone event: (i) \$2.0 million upon the grant of FDA approval, including all registrations, licenses, authorizations and necessary approvals, to develop and/or commercialize the Product in the United States; and (ii) \$1.0 million upon the grant of regulatory approval for the Product in Canada. Once commercialized, the Company is obligated to make certain non-refundable commercialization milestone payments to Orion, aggregating up to \$13.0 million, contingent upon achievement of certain cumulative net sales amounts in the Territory. The Company must also pay Orion tiered royalties based on net sales of the Product in the Territory made by the Company and its sublicensees. After the end of the term of the License, the Company must pay Orion a royalty based on net sales of the Product in the Territory for as long as Life Newco sells the Product in the Territory.

As of September 30, 2017, the Company has not met any of the developmental milestones and, accordingly, has not recorded any liability for the contingent payments due to Orion.

## NOTE 7. STOCKHOLDERS' EQUITY

### *Preferred Stock*

Under the Company's Certificate of Incorporation, the Board of Directors is authorized, without further stockholder action, to provide for the issuance of up to 10,000,000 shares of preferred stock, par value \$0.0001 per share, in one or more series, to establish from time to time the number of shares to be included in each such series, and to fix the designation, powers, preferences and rights of the shares of each such series and the qualifications, limitations and restrictions thereof. As of September 30, 2017, no shares of preferred stock are designated, issued or outstanding.

### *Common Stock*

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, 2017, there were 28,236,546 shares of common stock issued and outstanding.

### *Warrants*

As of September 30, 2017, the Company has 2,415,268 warrants outstanding. The following table summarizes the warrant activity for the nine months ended September 30, 2017:

	Warrants	Weighted Average Exercise Price
<b>Outstanding at December 31, 2016</b>	<b>2,415,675</b>	<b>\$ 2.64</b>
Cancelled	(407)	123.00
<b>Outstanding at September 30, 2017</b>	<b>2,415,268</b>	<b>\$ 2.62</b>

## 2016 Stock Incentive Plan

In June 2016, the Company adopted the 2016 Stock Incentive Plan (the "2016 Plan"). Under the 2016 Plan, with the approval of the Compensation Committee of the Board of Directors, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares, performance units, cash-based awards or other stock-based awards. On June 16, 2016, the Company's stockholders approved the 2016 Plan and authorized for issuance under the 2016 Plan a total of 3,000,000 shares of common stock. As of September 30, 2017, no awards have been granted under the 2016 Plan.

## 1999 Amended Stock Plan

In October 2000, the Company adopted the 1999 Stock Plan, as amended and restated on June 17, 2008 (the "1999 Plan"). Under the 1999 Plan, with the approval of the Compensation Committee of the Board of Directors, the Company may 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 4,000,000 shares, up from 300,000 previously authorized. On September 15, 2015, the Company's stockholders approved an additional amendment to the 1999 Plan which increased the number of shares of common stock authorized for issuance under the 1999 Plan to a total of 5,000,000 shares, up from 4,000,000 previously authorized. As of September 30, 2017, the Company had 1,094,808 shares of common stock available for grant under the 1999 Plan.

The following table summarizes the shares available for grant under the 1999 Plan for the nine months ended September 30, 2017:

	<u>Shares Available for Grant</u>
<b>Balances, at December 31, 2016</b>	268,500
Options granted	(260,000)
Options cancelled/forfeited	1,202,553
Restricted stock granted	(213,420)
Restricted stock cancelled/forfeited	97,175
<b>Balances, at September 30, 2017</b>	<u>1,094,808</u>

### 1999 Plan Stock Options

Stock options granted under the 1999 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 1999 Plan may 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, 2017:

	<u>Outstanding Options</u>	
	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>
<b>Balances, at December 31, 2016</b>	4,733,698	\$ 4.98
Options granted	260,000	\$ 0.55
Options cancelled	(1,202,553)	\$ 4.76
<b>Balances, at September 30, 2017</b>	<u>3,791,145</u>	<u>\$ 4.75</u>

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 \$128,856 and \$426,837 for the three and nine months ended September 30, 2017, respectively.

As of September 30, 2017, there were unrecognized compensation costs of approximately \$465,000 related to non-vested stock option awards that will be recognized on a straight-line basis over the weighted average remaining vesting period of 1.6 years. Additionally, there were unrecognized compensation costs of approximately \$5.9 million related to non-vested stock option awards subject to performance-based vesting milestones with a weighted average remaining life of 2.5 years. As of September 30, 2017, none of these milestones have been achieved.

The Company used the following assumptions to estimate the fair value of options granted under its stock option plans for the nine months ended September 30, 2017 and 2016:

	For the nine months ended September 30,	
	2017	2016
Risk-free interest rate (weighted average)	2.19%	1.60%
Expected volatility (weighted average)	99.59%	84.53%
Expected term (in years)	7	7
Expected dividend yield	0.00%	0.00%

<i>Risk-Free Interest Rate</i>	The risk-free interest rate assumption was based on U.S. Treasury instruments with a term that is consistent with the expected term of the Company's stock options.
<i>Expected Volatility</i>	The expected stock price volatility for the Company's common stock was determined by examining the historical volatility and trading history for its common stock over a term consistent with the expected term of its options.
<i>Expected Term</i>	The expected term of stock options represents the weighted average period the stock options are expected to remain outstanding. It was calculated based on the Company's historical experience with its stock option grants.
<i>Expected Dividend Yield</i>	The expected dividend yield of 0% is based on the Company's history and expectation of dividend payouts. The Company has not paid and does not anticipate paying any dividends in the near future.
<i>Forfeitures</i>	Stock compensation expense recognized in the statements of operations for the nine months ended September 30, 2017 and 2016 is based on awards ultimately expected to vest, and it has been reduced for estimated forfeitures. ASC 718 requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on the Company's historical experience.

## Restricted Stock Grants

The following table summarizes the restricted stock grants under the 1999 Plan for the nine months ended September 30, 2017 .

	Outstanding Restricted Stock Grants	
	Number of Shares	Weighted Average Grant Date Fair Value
<b>Balances, at December 31, 2016</b>	214	\$ 2.72
Restricted stock granted	213,420	\$ 0.68
Restricted stock vested	(116,525)	\$ 0.68
Restricted stock cancelled	(97,109)	\$ 0.68
<b>Balances, at September 30, 2017</b>	-	\$ -

The Company recorded compensation expense for these restricted stock grants of \$35 and \$425 for the three and nine months ended September 30, 2017, respectively.

As of September 30, 2017, there was no unrecognized compensation costs related to the non-vested restricted stock grants.

### Inducement Stock Options

On February 15, 2015, an employment inducement stock option award for 25,000 shares of common stock was made to the Company's former chief medical officer. This employment inducement stock option was awarded in accordance with the employment inducement award exemption provided by Nasdaq Rule 5635(c)(4) and was therefore not awarded under the Company's stockholder approved equity plan. The option award was set to vest over a three-year period, with one-third vesting per year, beginning one year from the grant date. The options had a 10-year term and an exercise price of \$3.22 per share, the February 13, 2015 closing price of the Company's common stock.

The estimated weighted average fair value per inducement option share granted was \$2.57 in 2015 using a Black-Scholes option pricing model based on market prices and the following assumptions at the date of inducement option grant: weighted average risk-free interest rate of 1.84%, dividend yield of 0%, volatility factor for the Company's common stock of 93.90% and a weighted average expected life of 7 years for inducement options not forfeited.

A summary of the activity and related information for the inducement stock options follows:

	Number of Shares	Weighted Average Exercise Price
Inducement Stock Options outstanding at December 31, 2016	8,334	\$ 3.22
Options forfeited or expired	(8,334)	\$ 3.22
Inducement Stock Options outstanding at September 30, 2017	-	\$ -

Inducement stock option compensation expense totaled \$1,787 and \$4,468 for the three months ended September 30, 2017 and 2016, respectively, and \$6,255 and \$15,191 for the nine months ended September 30, 2017 and 2016, respectively.

At September 30, 2017, there were no inducement stock options outstanding.



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

*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 "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. Examples of these statements include, but are not limited to, statements regarding: the implications of interim or final results of our clinical trials, the progress of our research programs, including clinical testing, the extent to which our issued and pending patents may protect our products and technology, our ability to identify new product candidates, the potential of such product candidates to lead to the development of commercial products, our anticipated timing for initiation or completion of our clinical trials for any of our product candidates, our future operating expenses, our future losses, our future expenditures for research and development, our ability to raise capital and the sufficiency of our cash resources. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the risks faced by us and described in Part II, Item 1A of this Quarterly Report on Form 10-Q, Part I, Item 1A of our Annual Report on Form 10-K, and our other filings with the Securities and Exchange Commission, or SEC. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from those we expect. Except as required by law, we assume no obligation to update these forward-looking statements, whether as a result of new information, future events or otherwise.*

*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 consolidated financial statements and related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2016.*

*All references in this Quarterly Report to "Tenax Therapeutics", "we", "our" and "us" means Tenax Therapeutics, Inc.*

### Overview

#### Strategy

We are a specialty pharmaceutical company focused on identifying, developing and commercializing drugs for critical care patients. Our principal business objective is to acquire or discover, develop, and commercialize novel therapeutic products for disease indications that represent significant areas of clinical need and commercial opportunity. Our lead product is levosimendan, which was acquired in an asset purchase agreement with Phyxius Pharma, Inc., or Phyxius. Levosimendan is a calcium sensitizer developed for intravenous use in hospitalized patients with acutely decompensated heart failure. The treatment is currently approved in more than 60 countries for this indication.

The United States Food and Drug Administration, or FDA, has granted Fast Track status for levosimendan for the reduction of morbidity and mortality in cardiac surgery patients at risk for developing Low Cardiac Output Syndrome, or LCOS. In addition, the FDA has agreed to the Phase III protocol design under Special Protocol Assessment, or SPA, and provided guidance that a single successful trial will be sufficient to support approval of levosimendan in this indication. On January 31, 2017, we announced top-line results from the Phase III LEVO-CTS trial. Levosimendan, given prophylactically prior to cardiac surgery to patients with reduced left ventricular function, had no effect on the co-primary outcomes. The study did not achieve statistically significant reductions in the dual endpoint of death or use of a mechanical assist device at 30 days, nor in the quad endpoint of death, myocardial infarction, need for dialysis, or use of a mechanical assist device at 30 days. However, the study results demonstrated statistically significant reductions in two of three secondary endpoints including reduction in LCOS and a reduction in postoperative use of secondary inotropes. Additionally, levosimendan was found to be safe with no clinically significant increases in hypotension or cardiac arrhythmias and the clinical data showed a non-significant numerical reduction in 90-day mortality.

Notwithstanding the fact that the trial's primary endpoints were not statistically significant, and given the statistically significant reductions in the secondary endpoints, we continue to believe levosimendan is an effective and safe inotrope to increase cardiac output in patients at risk for or with perioperative low cardiac output. Following the announcement of the Phase III LEVO-CTS top-line results, we held a meeting with the FDA to review the preliminary trial data and discuss a path forward to file a NDA for levosimendan. As a follow-up to this meeting, in May 2017, we participated in a pre-NDA meeting with the FDA to discuss the possibility of submitting an NDA for levosimendan in two indications: treatment of patients undergoing coronary artery bypass grafting (CABG) to reduce the risk of low cardiac output syndrome (LCOS) and treatment of patients with acute decompensated heart failure (ADHF) for improvement in symptoms. In July 2017, both the FDA and Health Canada determined that another trial would be necessary in order to support the filing of an NDA for levosimendan. We are currently evaluating clinical, regulatory and financial options with regard to continued development of the levosimendan program in the U.S. and Canada.

Additionally, our Board of Directors is conducting a comprehensive review of strategic alternatives focused on maximizing stockholder value and has formed a strategic committee of three independent board members to supervise management in this review. We have engaged Ladenburg Thalmann & Co. Inc. as our financial advisor to assist in the strategic review process; including, but not limited to a merger, a business combination, or a purchase, license or other acquisition of assets. This process may not result in any transaction and we do not intend to disclose additional details unless and until we determine further disclosure is appropriate or required.

### **Third Quarter 2017 Highlights**

The following summarizes certain key financial measures for the three months ended September 30, 2017:

- Cash and cash equivalents, including the fair-value of our marketable securities, were \$10.9 million at September 30, 2017.
- Our net loss from operations was \$1.3 million and \$4.5 million for the three months ended September 30, 2017 and 2016, respectively.
- Net cash used in operating activities was \$1.3 million and \$4.3 million for the three months ended September 30, 2017 and 2016, respectively.

### **Opportunities and Trends**

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

During the remainder of calendar year 2017, we are focused on the following initiatives:

- Working with collaborators and partners to accelerate product development, reduce our development costs, and broaden our commercialization capabilities; and
- Identifying strategic alternatives, including, but not limited to, the potential acquisition of additional products or product candidates.

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

There have been no significant changes in critical accounting policies, as compared to the critical accounting policies described in “*Item 7—Management’s Discussion and Analysis of Financial Condition and Results of Operations— Summary of Significant Accounting Policies*” in our Annual Report on Form 10-K for the year ended December 31, 2016.

### **Financial Overview**

#### **Results of Operations- Comparison of the Three Months Ended September 30, 2017 and 2016**

##### **General and Administrative Expenses**

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, other professional services, and consulting fees. General and administrative expenses and percentage changes for the three months ended September 30, 2017 and 2016, respectively, are as follows:

	Three months ended September 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2017	2016		
Personnel costs	\$ 599,289	\$ 629,187	\$ (29,898)	(5)%
Legal and professional fees	284,470	379,286	(94,816)	(25)%
Other costs	136,096	220,160	(84,064)	(38)%
Facilities	34,024	34,042	(18)	(0)%
Depreciation and amortization	2,568	3,205	(637)	(20)%

*Personnel costs:*

Personnel costs decreased approximately \$30,000 for the three months ended September 30, 2017 compared to the same period in the prior year. This decrease was due primarily to reductions in headcount, partially offset by an increase in the vested value of outstanding stock options during the current period as compared to the same period of the prior year.

*Legal and professional fees:*

Legal and professional fees consist of the costs incurred for legal fees, accounting fees, consulting fees, recruiting costs and investor relations services, as well as fees paid to our Board of Directors. Legal and professional fees decreased approximately \$95,000 for the three months ended September 30, 2017 compared to the same period in the prior year. This decrease was due primarily to a decrease in consulting fees paid to third-party firms for pre-launch commercialization preparations for LCOS and a reduction in the recognized expense for the vesting of stock options awarded in the current period as compared to the same period in the prior year.

*Other costs:*

Other costs include costs incurred for travel, supplies, insurance and other miscellaneous charges. The approximately \$84,000 decrease in other costs for the three months ended September 30, 2017 was due primarily to decreases in costs incurred for taxes, banking fees associated with our investments in marketable securities and general office expenses as compared to the same period in the prior year.

*Facilities:*

Facilities expenses include costs paid for rent and utilities at our corporate headquarters in North Carolina. Facilities costs remained relatively consistent for the three months ended September 30, 2017 and 2016.

*Depreciation and Amortization:*

Depreciation and amortization costs remained relatively consistent for the three months ended September 30, 2017 and 2016.

**Research and Development Expenses**

Research and development expenses include, but are not limited to, (i) expenses incurred under agreements with CROs and investigative sites, which conduct our clinical trials and a substantial portion of our pre-clinical studies; (ii) the cost of manufacturing and 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, laboratory 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, 2017 and 2016, respectively, are as follows:

	Three months ended September 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2017	2016		
Clinical and preclinical development	\$ 226,225	\$ 2,959,210	\$ (2,732,985)	(92)%
Personnel costs	25,993	179,032	(153,039)	(85)%
Other costs	1,755	4,043	(2,288)	(57)%
Consulting	-	92,401	(92,401)	(100)%

*Clinical and preclinical development:*

Clinical and preclinical development costs include, primarily, the costs associated with our Phase III clinical trial for levosimendan. The decrease of approximately \$2.7 million in clinical and preclinical development costs for the three months ended September 30, 2017, compared to the same period in the prior year, was primarily due to decreased expenditures for CRO costs to manage the Levo-CTS Phase III clinical trial. For the three months ended September 30, 2017, we recorded CRO costs of approximately \$205,000 for the management of the Phase III trial, compared to CRO costs of \$3.0 million, which included approximately \$1.2 million in pass-through site activation and enrolled patient costs, during the same period in the prior year.

*Personnel costs:*

Personnel costs decreased approximately \$153,000 for the three months ended September 30, 2017 primarily due to a reduction in headcount in the current period as compared to the same period in the prior year.

*Other costs:*

Other costs remained relatively consistent for the three months ended September 30, 2017 and 2016.

*Consulting fees:*

Consulting fees decreased approximately \$92,000 for the three months ended September 30, 2017 compared to the same period in the prior year, primarily due to a decrease in fees paid to a third-party consulting firm for services provided to improve training and communication with active sites in support of our Phase III Levo-CTS clinical trial and contract labor for additional clinical trial support services in the prior year which were not incurred in the current period.

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 will need substantial additional capital in the future in order to continue with the development of our potential product candidates.

***Other income and expense, net***

Other income and expense includes non-operating income and expense items not otherwise recorded in our condensed consolidated statement of comprehensive loss. These items include, but are not limited to, changes in the fair value of financial assets and derivative liabilities, interest income earned and fixed asset disposals. Other income for the three months ended September 30, 2017 and 2016, respectively, is as follows:

	Three months ended September 30,		(Increase)/ Decrease
	2017	2016	
Other income, net	\$ (76,226)	\$ (226,914)	\$ 150,688

Other income decreased approximately \$151,000 for the three months ended September 30, 2017 compared to the same period in the prior year. This decrease is due primarily to the change in fair value of our Series C warrant derivative liability in the current period and by a reduction in the interest earned on our investment in marketable securities.

During the three months ended September 30, 2017, we recorded a derivative gain of approximately \$36,000 which compared to a derivative gain of approximately \$60,000 for the same period in the prior year. These charges to income are derived from the free standing Series C warrants which are measured at their fair market value each period using the Monte Carlo simulation model.

During the three months ended September 30, 2017, we recorded interest income of approximately \$40,000 from our investments in marketable securities. This income is derived from approximately \$84,000 in bond interest paid, partially offset by approximately \$44,000 in charges for amortization of premiums paid and fair-value adjustments measured each period, which compares to approximately \$229,000 in bond interest paid, partially offset by approximately \$137,000 in charges for amortization of premiums paid and fair-value adjustments during the same period in the prior year.

## Results of Operations- Comparison of the Nine Months Ended September 30, 2017 and 2016

### General and Administrative Expenses

General and administrative expenses and percentage changes for the nine months ended September 30, 2017 and 2016, respectively, are as follows:

	Nine months ended September 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2017	2016		
Personnel costs	\$ 2,510,569	\$ 1,964,135	\$ 546,434	28%
Legal and professional fees	1,324,424	1,495,868	(171,444)	(11)%
Other costs	347,585	691,883	(344,298)	(50)%
Facilities	104,850	105,794	(944)	(1)%
Depreciation and amortization	7,908	9,538	(1,630)	(17)%

#### Personnel costs:

Personnel costs increased approximately \$546,000 for the nine months ended September 30, 2017 compared to the same period in the prior year. This increase was due primarily to the recognized expense for the vesting of outstanding stock options and the severance costs incurred upon the resignation of our former chief executive officer during the current period as compared to the same period of the prior year.

#### Legal and professional fees:

Legal and professional fees decreased approximately \$171,000 for the nine months ended September 30, 2017 compared to the same period in the prior year. This decrease was due primarily to decreases in costs incurred for auditing and consulting fees, and the vested value of stock option grants to our Board of Directors, partially offset by an increase in costs incurred for investor relations services.

- Audit and accounting fees decreased approximately \$40,000 in the current period. This decrease was due primarily to the costs incurred for the change in our fiscal year, which necessitated the filing of our audited transitional financial statements in the prior year which were not incurred in the current period.
- Consulting fees decreased approximately \$102,000 in the current period. This decrease was due primarily to the fees paid to third-party firms for pre-launch commercialization preparations for LCOS, nationwide registrations for drug distribution and market analysis and research for septic shock in the prior year which were not incurred in the current period, partially offset by an increase in fees paid for medical consulting services in the current period.
- Costs associated with investor relations and communication increased approximately \$34,000 in the current period. This increase was due primarily to fees paid to a third-party investor relations firm providing marketing and corporate communications services to us in the current period, which were not incurred in the same period of the prior year.
- Board of Directors fees decreased in the current period by approximately \$55,000. This decrease was due primarily to a reduction in the recognized expense for the vesting of stock options awarded in the current period as compared to the recognized expense for stock options awarded in the same period of the prior year.

#### Other costs:

The approximately \$344,000 decrease in other costs for the nine months ended September 30, 2017 was due primarily to a reduction of approximately \$204,000 in franchise taxes paid, a reduction of approximately \$30,000 in travel related costs, a reduction of approximately \$25,000 in costs incurred for online database research subscriptions, a reduction of approximately \$38,000 in bank fees associated with the management of our investments in marketable security and an overall decrease in supplies expenses, insurance and other miscellaneous charges in the current period as compared to the same period in the prior year.

#### Facilities:

Facilities costs remained relatively consistent for the nine months ended September 30, 2017 and 2016.

*Depreciation and Amortization:*

Depreciation and amortization costs remained relatively consistent for the nine months ended September 30, 2017 and 2016.

**Research and Development Expenses**

Research and development expenses and percentage changes for the nine months ended September 30, 2017 and 2016, respectively, are as follows:

	Nine months ended September 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2017	2016		
Clinical and preclinical development	\$ 3,230,215	\$ 9,609,182	\$ (6,378,967)	(66)%
Personnel costs	177,615	451,760	(274,145)	(61)%
Consulting	112,936	522,725	(409,789)	(78)%
Other costs	7,572	26,245	(18,673)	(71)%

*Clinical and preclinical development:*

The decrease of approximately \$6.4 million in clinical and preclinical development costs for the nine months ended September 30, 2017, compared to the same period in the prior year, was primarily due to decreased expenditures for CRO costs to manage the Levo-CTS Phase III clinical trial. For the nine months ended September 30, 2017, we recorded CRO costs of approximately \$3.2 million for the management of the Phase III trial, compared to CRO costs of \$9.6 million, which included approximately \$4.5 million in pass-through site activation and enrolled patient costs, during the same period in the prior year.

*Personnel costs:*

Personnel costs decreased approximately \$274,000 for the nine months ended September 30, 2017 compared to the same period in the prior year, primarily due to a reduction in headcount in the current period.

*Consulting fees:*

Consulting fees decreased approximately \$410,000 for the nine months ended September 30, 2017 compared to the same period in the prior year, primarily due to a decrease in fees paid to a third-party consulting firm for services provided to improve training and communication with active sites in support of our Phase III Levo-CTS clinical trial and contract labor for additional clinical trial support services in the prior year which were not incurred in the current period.

*Other costs:*

Other costs decreased approximately \$19,000 for the nine months ended September 30, 2017 as compared to the same period in the prior year due primarily to a reduction in travel related costs in the current period.

**Other income and expense, net**

Other income for the nine months ended September 30, 2017 and 2016, respectively, is as follows:

	Nine months ended September 30,		(Increase)/ Decrease
	2017	2016	
Other income	\$ (327,725)	\$ (600,610)	\$ 272,885

Other income decreased approximately \$273,000 for the nine months ended September 30, 2017 compared to the same period in the prior year. This decrease is due primarily to the change in fair value of our Series C warrant derivative liability in the current period and a reduction in the interest earned on our investment in marketable securities.

During the nine months ended September 30, 2017, we recorded interest income of approximately \$137,000 from our investments in marketable securities. This income is derived from approximately \$287,000 in bond interest paid, partially offset by approximately \$158,000 in charges for amortization of premiums paid and fair-value adjustments measured each period, which compares to approximately \$816,000 in bond interest paid, partially offset by approximately \$464,000 in charges for amortization of premiums paid and fair-value adjustments during the same period in the prior year.

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

We have incurred losses since our inception and as of September 30, 2017 we had an accumulated deficit of approximately \$212 million. We will continue to incur losses until we generate sufficient revenue to offset our expenses, and we anticipate that we will continue to incur net losses for at least the next several years. We expect to incur additional expenses related to our development of levosimendan 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.

### **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 \$8,663,210 and \$13,628,175 and working capital of \$7,824,658 and \$7,428,938 as of September 30, 2017 and December 31, 2016, respectively. Based on our working capital and the value of our investments in marketable securities at September 30, 2017, we believe we have sufficient capital to fund our operations through the fourth quarter of calendar year 2018.

We recently completed a Phase III clinical trial for levosimendan. In July 2017, after presenting data from the LEVO-CTS trial, both the FDA and Health Canada determined that another trial would be necessary in order to support the filing of an NDA for levosimendan. We are currently evaluating clinical regulatory and financial options with regard to continued development of the levosimendan program in the U.S. and Canada. Our ability to continue to pursue testing and development of levosimendan or other potential products depends 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 the necessary resources.

Our common stock is currently listed on The Nasdaq Capital Market. In order to maintain this listing, we must satisfy minimum financial and other requirements. On March 15, 2017, we received a notification letter from Nasdaq's Listing Qualifications Department indicating that we were not in compliance with Nasdaq Listing Rule 5550(a)(2), because the minimum bid price of our common stock on the Nasdaq Capital Market had closed below \$1.00 per share for 30 consecutive business days. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were given 180 calendar days, or until September 11, 2017, to regain compliance with the minimum \$1.00 bid price per share requirement.

On September 12, 2017, we received a notice from Nasdaq's Listing Qualifications Department indicating that, while we had not regained compliance with the minimum bid price requirement, we were eligible for an additional 180-day compliance period, or until March 12, 2018, to regain compliance with the minimum \$1.00 bid price per share requirement for continued listing on the Nasdaq Capital Market due to our meeting the continued listing requirement for market value of publicly held shares and all other applicable requirements for initial listing on the Nasdaq Capital Market, with the exception of the bid price requirement, and due to our written notice of our intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary.

To regain compliance, any time before March 12, 2018, the bid price of our common stock must close at \$1.00 per share or more for a minimum of 10 consecutive business days. If we do not regain compliance by March 12, 2018, we expect that Nasdaq will provide written notification to us that our common stock will be subject to delisting. Upon such notice, we may appeal Nasdaq's delisting determination to a Nasdaq hearings panel, pursuant to the procedures set forth in the applicable Nasdaq Marketplace Rules. There can be no assurance that, if we appeal the Nasdaq Staff's determination, such appeal would be successful.

We are currently evaluating our alternatives to resolve this listing deficiency. However, there can be no assurance that we will be able to regain compliance during the applicable time periods set forth above. If we fail to continue to meet all applicable Nasdaq Capital Market requirements in the future and Nasdaq determines to delist our common stock, the delisting could substantially decrease trading in our common stock; adversely affect the market liquidity of our common stock as a result of the loss of market efficiencies associated with Nasdaq and the loss of federal preemption of state securities laws; adversely affect our ability to obtain financing on acceptable terms, if at all; and may result in the potential loss of confidence by investors, suppliers, customers, and employees and fewer business development opportunities. Additionally, the market price of our common stock may decline further and shareholders may lose some or all of their investment.

## Cash Flows

The following table shows a summary of our cash flows for the nine months ended September 30, 2017 and 2016:

	Nine months ended September 30,	
	2017	2016
Net cash used in operating activities	\$ (10,858,446)	\$ (12,766,231)
Net cash provided by investing activities	2,626,374	9,827,930

*Net cash used in operating activities.* Net cash used in operating activities was approximately \$10.9 million for the nine months ended September 30, 2017 compared to net cash used in operating activities of approximately \$12.8 million for the nine months ended September 30, 2016. The decrease in cash used in operating activities was due primarily to a decrease in our accrued costs related to the Phase III clinical trial for levosimendan in the current period.

*Net cash provided by investing activities.* Net cash provided by investing activities was approximately \$2.6 million for the nine months ended September 30, 2017 compared to approximately \$9.8 million for the nine months ended September 30, 2016. The decrease in cash provided by investing activities was primarily due a reduction in the sale of marketable securities in the current period.

### 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 that we pursue;
- the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims;
- the timing and terms of future collaboration, licensing, consulting or other arrangements that we may enter into;
- the cost and timing of establishing sales, marketing, manufacturing and distribution capabilities;
- the cost of procuring clinical and commercial supplies of our product candidates;
- the extent to which we acquire or invest in businesses, products or technologies; and
- the possible costs of litigation.

We believe that our existing cash and cash equivalents, along with our investment in marketable securities, will be sufficient to fund our projected operating requirements through the fourth quarter of calendar year 2018. We will need substantial additional capital in the future in order to continue the development of levosimendan and 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.

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.

### Critical Accounting Policies

Our consolidated financial statements have been prepared in accordance with GAAP. 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 Significant Accounting Policies" contained in our Annual Report on Form 10-K for the year ended December 31, 2016. There have not been material changes to the critical accounting policies previously disclosed in that report.



## **Recent Accounting Pronouncements**

In July 2017, the Financial Accounting Standards Board, or the FASB, issued an accounting standard that change the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. The amendments also clarify existing disclosure requirements for equity-classified instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. The standard will be effective for us on January 1, 2019. Early adoption is permitted, including adoption in an interim period. We are currently evaluating the effect that the standard will have on our condensed consolidated financial statements and related disclosures.

In January 2017, the FASB, issued an accounting standard that provides guidance for evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The guidance provides a screen to determine when an integrated set of assets and activities, or a set, does not qualify to be a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in an identifiable asset or a group of similar identifiable assets, the set is not a business. If the screen is not met, the guidance requires a set to be considered a business to include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create outputs and removes the evaluation as to whether a market participant could replace the missing elements. The standard will be effective for us on January 1, 2018 and will be adopted on a prospective basis. Early adoption is permitted. We do not believe the adoption of this standard will have a material impact on our condensed consolidated financial statements and related disclosures.

In August 2016, the FASB issued an accounting standard that clarifies how companies present and classify certain cash receipts and cash payments in the statement of cash flows where diversity in practice exists. The standard is effective for us in our first quarter of fiscal 2018 and earlier adoption is permitted. We do not believe that adopting this updated standard will have a material impact on our condensed consolidated financial statements and related disclosures.

In June 2016, the FASB, issued an accounting standard that amends how credit losses are measured and reported for certain financial instruments that are not accounted for at fair value through net income. This standard will require that credit losses be presented as an allowance rather than as a write-down for available-for-sale debt securities and will be effective for interim and annual reporting periods beginning January 1, 2020, with early adoption permitted, but not earlier than annual reporting periods beginning January 1, 2019. A modified retrospective approach is to be used for certain parts of this guidance, while other parts of the guidance are to be applied using a prospective approach. We are currently evaluating the impact that this standard will have on our condensed consolidated financial statements and related disclosures.

In May 2014, the FASB issued an accounting standard that supersedes nearly all existing revenue recognition guidance under GAAP. The standard is principles-based and provides a five-step model to determine when and how revenue is recognized. The core principle of the standard is that revenue should be recognized when a company transfers promised goods or services to customers in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services. In March 2016, the FASB issued a standard to clarify the implementation guidance on principal versus agent considerations, and in April 2016, the FASB issued a standard to clarify the implementation guidance on identifying performance obligations and licensing. The standard also requires disclosure of qualitative and quantitative information surrounding the amount, nature, timing and uncertainty of revenues and cash flows arising from contracts with customers. In July 2015, the FASB agreed to defer the effective date of the standard from annual periods beginning after December 15, 2016, to annual periods beginning after December 15, 2017. Early application prior to the original effective date is not permitted. The standard permits the use of either the retrospective or cumulative effect transition method. We do not believe the adoption of this standard will have a material impact on our condensed consolidated financial statements and related disclosures.

In February 2016, the FASB issued an accounting standard intended to improve financial reporting regarding leasing transactions. The standard will require us to recognize on our balance sheet the assets and liabilities for the rights and obligations created by all leased assets. The standard will also require us to provide enhanced disclosures designed to enable users of financial statements to understand the amount, timing, and uncertainty of cash flows arising from all leases, operating and capital, with lease terms greater than 12 months. The standard is effective for financial statements beginning after December 15, 2018, and interim periods within those annual periods. Early adoption is permitted. We are currently evaluating the impact that this standard will have on our condensed consolidated financial statements and related disclosures.

In January 2016, the FASB issued an accounting standard that will enhance our reporting for financial instruments. The standard is effective for financial statements issued for annual periods beginning after December 15, 2017, and interim periods within those annual periods. Earlier adoption is permitted for interim and annual reporting periods as of the beginning of the fiscal year of adoption. We do not believe the adoption of this standard will have a material impact on our consolidated financial statements.

## **Contractual Obligations**

There have been no material changes, outside of the ordinary course of business, to our contractual obligations as previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2016.

### ***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**

There have been no material changes to our quantitative and qualitative disclosures about market risk as compared to the quantitative and qualitative disclosures about market risk described in our Annual Report on Form 10-K for the year ended December 31, 2016 .

### **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, our management, including our Interim Chief Executive Officer and Chief Financial Officer, conducted an evaluation as of the end of the period covered by this report, of the effectiveness of our disclosure controls and procedures as defined in Exchange Act Rule 13a-15(e) and 15d-15(e). Based on that evaluation, our Interim Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2017, the end of the period covered by this report 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 Interim Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

#### ***Changes in Internal Control over Financial Reporting***

There were no significant changes in our internal control over financial reporting during our most recently completed fiscal quarter that has materially affected, or is 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.

## 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, 2016, except as set forth below:

#### ***Our failure to maintain compliance with Nasdaq's continued listing requirements could result in the delisting of our common stock.***

Our common stock is currently listed on The Nasdaq Capital Market. In order to maintain this listing, we must satisfy minimum financial and other requirements. On March 15, 2017, we received a notification letter from Nasdaq's Listing Qualifications Department indicating that we were not in compliance with Nasdaq Listing Rule 5550(a)(2), because the minimum bid price of our common stock on the Nasdaq Capital Market had closed below \$1.00 per share for 30 consecutive business days. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were given 180 calendar days, or until September 11, 2017, to regain compliance with the minimum \$1.00 bid price per share requirement.

On September 12, 2017, we received a notice from Nasdaq's Listing Qualifications Department indicating that, while we had not regained compliance with the minimum bid price requirement, we were eligible for an additional 180-day compliance period, or until March 12, 2018, to regain compliance with the minimum \$1.00 bid price per share requirement for continued listing on the Nasdaq Capital Market due to our meeting the continued listing requirement for market value of publicly held shares and all other applicable requirements for initial listing on the Nasdaq Capital Market, with the exception of the bid price requirement, and due to our written notice of our intention to cure the deficiency during the second compliance period by effecting a reverse stock split, if necessary.

To regain compliance, anytime before March 12, 2018, the bid price of our common stock must close at \$1.00 per share or more for a minimum of 10 consecutive business days. If we do not regain compliance by March 12, 2018, we expect that Nasdaq will provide written notification to us that our common stock will be subject to delisting. Upon such notice, we may appeal Nasdaq's delisting determination to a Nasdaq hearings panel, pursuant to the procedures set forth in the applicable Nasdaq Marketplace Rules. There can be no assurance that, if we appeal the Nasdaq Staff's determination, such appeal would be successful.

We are currently evaluating our alternatives to resolve this listing deficiency. However, there can be no assurance that we will be able to regain compliance during the applicable time periods set forth above. If we fail to continue to meet all applicable Nasdaq Capital Market requirements in the future and Nasdaq determines to delist our common stock, the delisting could substantially decrease trading in our common stock; adversely affect the market liquidity of our common stock as a result of the loss of market efficiencies associated with Nasdaq and the loss of federal preemption of state securities laws; adversely affect our ability to obtain financing on acceptable terms, if at all; and may result in the potential loss of confidence by investors, suppliers, customers, and employees and fewer business development opportunities. Additionally, the market price of our common stock may decline further and shareholders may lose some or all of their investment.

### ITEM 6. EXHIBITS

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

No.	Description
<a href="#">31.1</a>	Certification of Interim Chief Executive Officer and Chief Financial Officer Pursuant to Section 302 of the Sarbanes Oxley Act of 2002.*
<a href="#">32.1</a>	Certification of Interim Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

\* Filed herewith

**SIGNATURES**

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

Date: November 9, 2017

**TENAX THERAPEUTICS, INC.**

By: /s/ Michael B. Jebsen

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Michael B. Jebsen

Interim Chief Executive Officer, President and Chief Financial Officer

(On behalf of the Registrant and as Principal Executive and Financial Officer)

**CERTIFICATION OF INTERIM CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Michael B. Jebsen, 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 consolidated 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. I am 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 my supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to me 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 my supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated 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 my 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. I have disclosed, based on my 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 9, 2017

/s/ Michael B. Jebsen

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Michael B. Jebsen

*Interim Chief Executive Officer, President and Chief Financial Officer  
(Principal Executive and Financial Officer)*

**CERTIFICATION OF INTERIM CHIEF EXECUTIVE OFFICER AND  
CHIEF FINANCIAL OFFICER 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, 2017 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael B. Jebsen, Interim Chief Executive Officer and Chief Financial Officer (Principal Executive and Financial 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:

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

Date: November 9, 2017

/s/ Michael B. Jebsen  
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Michael B. Jebsen  
*Interim Chief Executive Officer, President and Chief Financial Officer*  
*(Principal Executive and Financial Officer)*

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