

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, 2016

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 (§232.405 of this chapter) 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, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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 7, 2016, the registrant had outstanding 28,119,934 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, 2016	December 31, 2015
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 722,152	\$ 3,660,453
Marketable securities	6,756,130	16,528,494
Accounts receivable	72,600	49,448
Prepaid expenses	116,201	321,958
Total current assets	<u>7,667,083</u>	<u>20,560,353</u>
Marketable securities	17,649,434	18,019,054
Property and equipment, net	23,526	35,786
Intangible assets, net	22,000,000	22,000,000
Goodwill	11,265,100	11,265,100
Other assets	1,106,785	1,106,785
Total assets	<u>\$ 59,711,928</u>	<u>\$ 72,987,078</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,392,573	\$ 972,483
Accrued liabilities	3,354,180	3,104,807
Warrant liabilities	310,275	524,340
Total current liabilities	<u>5,057,028</u>	<u>4,601,630</u>
Deferred tax liability	7,962,100	7,962,100
Total liabilities	13,019,128	12,563,730
Commitments and contingencies; see Note 6		
Stockholders' equity		
Common stock, par value \$.0001 per share; authorized 400,000,000 shares; issued and outstanding 28,119,934 and 28,119,694, respectively	2,812	2,812
Additional paid-in capital	221,652,664	221,285,677
Accumulated other comprehensive gain/(loss)	49,543	(129,442)
Accumulated deficit	(175,012,219)	(160,735,699)
Total stockholders' equity	<u>46,692,800</u>	<u>60,423,348</u>
Total liabilities and stockholders' equity	<u>\$ 59,711,928</u>	<u>\$ 72,987,078</u>

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

TENAX THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
	<u>(Unaudited)</u>	<u>(Unaudited)</u>	<u>(Unaudited)</u>	<u>(Unaudited)</u>
Government grant revenue	\$ -	\$ -	\$ -	\$ 49,286
Operating expenses				
General and administrative	1,265,880	1,425,048	4,267,218	4,977,323
Research and development	3,234,686	1,678,517	10,609,912	5,208,518
Loss on impairment of long-lived assets	-	-	-	1,034,863
Total operating expenses	<u>4,500,566</u>	<u>3,103,565</u>	<u>14,877,130</u>	<u>11,220,704</u>
Net operating loss	4,500,566	3,103,565	14,877,130	11,171,418
Interest expense	-	571	-	3,795
Other income	(226,914)	(183,605)	(600,610)	(567,505)
Net loss	<u>\$ 4,273,652</u>	<u>\$ 2,920,531</u>	<u>\$ 14,276,520</u>	<u>\$ 10,607,708</u>
Unrealized loss (gain) on marketable securities	39,324	(12,651)	(178,985)	(122,612)
Total comprehensive loss	<u>\$ 4,312,976</u>	<u>\$ 2,907,880</u>	<u>\$ 14,097,535</u>	<u>\$ 10,485,096</u>
Net loss per share, basic and diluted	\$ (0.15)	\$ (0.10)	\$ (0.51)	\$ (0.38)
Weighted average number of common shares outstanding, basic and diluted	28,119,848	28,119,579	28,119,797	28,119,495

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

TENAX THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	<u>Nine months ended September 30,</u>	
	<u>2016</u>	<u>2015</u>
	(Unaudited)	(Unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	\$ (14,276,520)	\$ (10,607,708)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	14,531	74,461
Loss on impairment, disposal and write down of long-lived assets	-	1,081,131
Gain on disposal of property and equipment	(74,388)	-
Issuance and vesting of compensatory stock options and warrants	366,129	186,042
Issuance of common stock as compensation	858	1,189
Change in the fair value of warrants	(214,065)	(208,774)
Amortization of premium on marketable securities	565,156	699,435
Changes in operating assets and liabilities		
Accounts receivable, prepaid expenses and other assets	182,605	363,719
Accounts payable and accrued liabilities	669,463	(63,046)
Net cash used in operating activities	<u>(12,766,231)</u>	<u>(8,473,551)</u>
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of marketable securities	(7,255,578)	(15,809,329)
Sale of marketable securities	17,011,392	15,910,484
Purchase of property and equipment	(2,884)	(16,688)
Proceeds from the sale of property and equipment	75,000	-
Capitalization of patent costs and license rights	-	(20,056)
Net cash provided by investing activities	<u>9,827,930</u>	<u>64,411</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Payments on notes - short-term	-	(150,760)
Net cash used in financing activities	<u>-</u>	<u>(150,760)</u>
Net change in cash and cash equivalents	<u>(2,938,301)</u>	<u>(8,559,900)</u>
Cash and cash equivalents, beginning of period	<u>3,660,453</u>	<u>11,676,325</u>
Cash and cash equivalents, end of period	<u>\$ 722,152</u>	<u>\$ 3,116,425</u>
Cash paid for:		
Interest	\$ -	\$ 3,795

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

TENAX THERAPEUTICS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

NOTE 1. DESCRIPTION OF BUSINESS

Tenax Therapeutics, Inc. (the “Company”) was originally formed as a New Jersey corporation in 1967 under the name Rudmer, David & Associates, Inc., and subsequently changed its name to Synthetic Blood International, Inc. On June 17, 2008, the stockholders of Synthetic Blood International approved the Agreement and Plan of Merger dated April 28, 2008, between Synthetic Blood International and Oxygen Biotherapeutics, Inc., a Delaware corporation. 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, sublicenseable right to develop and commercialize pharmaceutical products containing levosimendan, 2.5 mg/ml concentrate for solution for infusion / 5ml vial in the United States and Canada.

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, 2015 has been derived from the Company’s audited consolidated financial statements included in its transition report on Form 10-KT for the transition period ended December 31, 2015. 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 the Securities and Exchange Commission (“SEC”) rules and regulations. Operating results for the three and nine month periods ended September 30, 2016 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 transition report on Form 10-KT for the transition period ended December 31, 2015.

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 fiscal 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.

Goodwill

Acquired businesses are accounted for using the acquisition method of accounting, which requires that assets acquired, including identifiable intangible assets, and liabilities assumed be recorded at fair value, with limited exceptions. Any excess of the purchase price over the fair value of the net assets acquired is recorded as goodwill. If the acquired net assets do not constitute a business, the transaction is accounted for as an asset acquisition and no goodwill is recognized.

Goodwill is reviewed for impairment on an annual basis or more frequently if events or circumstances indicate potential impairment. The Company's goodwill evaluation is based on both qualitative and quantitative assessments regarding the fair value of goodwill relative to its carrying value. The Company assesses qualitative factors to determine if its sole reporting unit's fair value is more likely than not to exceed its carrying value, including goodwill. In the event the Company determines that it is more likely than not that its reporting unit's fair value is less than its carrying amount, quantitative testing is performed comparing recorded values to estimated fair values. If the fair value exceeds the carrying value, goodwill is not impaired. If the carrying value exceeds the fair value, an impairment charge is recognized through a charge to operations based upon the excess of the carrying value of goodwill over the implied fair value. There was no impairment to goodwill recognized during the three and nine months ended September 30, 2016.

Liquidity and Management's Plan

At September 30, 2016, the Company had cash and cash equivalents, including the fair value of its marketable securities, of approximately \$25.1 million. The Company used \$12.8 million of cash for operating activities during the nine months ended September 30, 2016 and had stockholders' equity of \$46.7 million, versus \$60.4 million at December 31, 2015. The Company expects that it has sufficient cash to manage the business through calendar year 2017, although this assumes that the Company does not accelerate the development of other opportunities that are available to the Company or otherwise face unexpected events, costs or contingencies, any of which could affect the Company's cash requirements.

Additional capital will likely be required to support the Company's future commercialization activities, including the anticipated commercial launch of levosimendan for low cardiac output syndrome ("LCOS"), and the development of other products or indications which may be acquired or licensed by the Company, and general working capital requirements. Based on product development timelines the ability to scale up or reduce personnel and associated costs are factors considered throughout the product development life cycle. Available resources may be consumed more rapidly than currently anticipated, potentially resulting in the need for additional funding. Additional funding, capital or loans (including, without limitation, milestone or other payments from commercialization agreements) may be unavailable on favorable terms, if at all.

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 way 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.

	<u>Nine months ended September 30,</u>	
	<u>2016</u>	<u>2015</u>
Options to purchase common stock	4,092,698	3,802,698
Warrants to purchase common stock	2,416,046	2,728,236
Restricted stock	367	367

Recent Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board (the “FASB”), issued a new 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 new 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 March 2016, the FASB, issued a new accounting standard intended to simplify various aspects related to how share-based payments are accounted for and presented in the financial statements. The new guidance includes provisions to reduce the complexity related to income taxes, statement of cash flows, and forfeitures when accounting for share-based payment transactions. The new standard is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted. 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 a new accounting standard that supersedes nearly all existing revenue recognition guidance under GAAP. The new standard is principles-based and provides a five-step model to determine when and how revenue is recognized. The core principle of the new 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 new standard to clarify the implementation guidance on principal versus agent considerations, and in April 2016, the FASB issued a new standard to clarify the implementation guidance on identifying performance obligations and licensing. The new 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, with an option that permits companies to adopt the standard as early as the original effective date. 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 has not yet selected a transition method and it 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 a new accounting standard intended to improve financial reporting regarding leasing transactions. The new 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 new 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 new 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 new standard will have on its financial statements and related disclosures.

In January 2016, the FASB issued a new accounting standard that will enhance the Company’s reporting for financial instruments. The new 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 records 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, 2016, 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, 2016				
	<u>Amortized Cost</u>	<u>Accrued Interest</u>	<u>Gross Unrealized Gains</u>	<u>Gross Unrealized losses</u>	<u>Estimated Fair Value</u>
Corporate debt securities	\$ 24,173,901	\$ 182,120	\$ 58,081	\$ (8,538)	\$ 24,405,564

The following table summarizes the scheduled maturity for the Company's investments at September 30, 2016 and December 31, 2015.

	<u>September 30, 2016</u>	<u>December 31, 2015</u>
Maturing in one year or less	\$ 6,756,130	\$ 16,528,494
Maturing after one year through three years	17,649,434	18,019,054
Total investments	<u>\$ 24,405,564</u>	<u>\$ 34,547,548</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, 2016 and December 31, 2015:

Series C Warrants	September 30, 2016	December 31, 2015
Closing stock price	\$ 2.32	\$ 3.28
Expected dividend rate	0%	0%
Expected stock price volatility	85.07%	84.08%
Risk-free interest rate	0.86%	1.44%
Expected life (years)	2.81	3.56

As of September 30, 2016, the fair value of the warrant liability was \$310,275. The Company recorded a gain of \$60,130 and \$214,065 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, 2016, respectively.

As of September 30, 2016, 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, 2016 and December 31, 2015:

	Balance as of September 30, 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)
Current Assets				
Cash and cash equivalents	\$ 722,152	\$ 722,152	\$ -	\$ -
Marketable securities	\$ 6,756,130	\$ -	\$ 6,756,130	\$ -
Long-term Assets				
Marketable securities	\$ 17,649,434	\$ -	\$ 17,649,434	\$ -
Current Liabilities				
Warrant liabilities	\$ 310,275	\$ -	\$ -	\$ 310,275

	Balance as of December 31, 2015	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)
Current Assets				
Cash and cash equivalents	\$ 3,660,453	\$ 3,660,453	\$ -	\$ -
Marketable securities	\$ 16,528,494	\$ -	\$ 16,528,494	\$ -
Long-term Assets				
Marketable securities	\$ 18,019,054	\$ -	\$ 18,019,054	\$ -
Current Liabilities				
Warrant liabilities	\$ 524,340	\$ -	\$ -	\$ 524,340

There were no significant transfers between levels in the nine months ended September 30, 2016.

NOTE 4. BALANCE SHEET COMPONENTS

Property and equipment, net

Property and equipment consist of the following as of September 30, 2016 and December 31, 2015:

	September 30, 2016	December 31, 2015
Laboratory equipment	\$ 354,861	\$ 514,214
Computer equipment and software	142,868	139,984
Office furniture and fixtures	130,192	130,192
	627,921	784,390
Less: Accumulated depreciation	(604,395)	(748,604)
	<u>\$ 23,526</u>	<u>\$ 35,786</u>

Depreciation expense was approximately \$5,000 and \$12,000 for the three months ended September 30, 2016 and 2015, and \$15,000 and \$50,000 for the nine months ended September 30, 2016 and 2015, respectively.

Accrued liabilities

Accrued liabilities consist of the following as of September 30, 2016 and December 31, 2015:

	<u>September 30, 2016</u>	<u>December 31, 2015</u>
Operating costs	\$ 3,270,252	\$ 2,559,092
Employee related	83,928	545,715
	<u>\$ 3,354,180</u>	<u>\$ 3,104,807</u>

NOTE 5. INTANGIBLE ASSETS

The following table summarizes the Company's intangible assets as of September 30, 2016 and December 31, 2015:

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

The aggregate amortization expense on the above intangibles was \$0 for each of the three months ended September 30, 2016 and 2015, and \$0 and \$25,000, for the nine months ended September 30, 2016 and 2015, respectively.

In-Process Research and Development

The levosimendan product in Phase III clinical trial 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.

Patents and License Rights

The Company currently holds, has filed for, or owns exclusive rights to, U.S. and worldwide patents covering 3 various methods and uses of its perfluorocarbon ("PFC") technology and one which covers the methods and uses of its licensed drug, levosimendan, in patients undergoing cardiac surgery. It capitalizes amounts paid to third parties for legal fees, application fees and other direct costs incurred in the filing and prosecution of its patent applications. These capitalized costs are amortized on a straight-line method over their useful life or legal life, whichever is shorter. The Company capitalized patent costs of approximately \$0 and \$20,000, for the nine months ended September 30, 2016 and 2015, respectively.

During the quarter ended April 30, 2015, the Company completed its annual impairment test of its patents and license rights. The Company wrote-off approximately \$929,000 of capitalized costs for patent applications that were withdrawn or abandoned during the fiscal year ended April 30, 2015. These asset impairment charges primarily related to the Company's PFC formulations which were determined not to be a core component of the Company's development strategy.

Trademarks

The Company currently holds, or has filed for, trademarks to protect the use of names and descriptions of its products and technology. It capitalizes amounts paid to third parties for legal fees, application fees and other direct costs incurred in the filing and prosecution of its trademark applications. These trademarks are evaluated annually for impairment in accordance with ASC 350, Intangibles – Goodwill and Other. The Company evaluates (i) its expected use of the underlying asset, (ii) any laws, regulations, or contracts that may limit the useful life, (iii) the effects of obsolescence, demand, competition, and stability of the industry, and (iv) the level of costs to be incurred to commercialize the underlying asset. The Company did not capitalize any trademark costs for the nine months ended September 30, 2016 and 2015.

The Company wrote-off trademark costs of approximately \$106,000 for the fiscal year ended April 30, 2015. These asset impairment charges primarily related to the Company's PFC formulations which were determined not to be a core component of the Company's development strategy.

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, sublicenseable 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, 2016, the Company has not met any of the developmental milestones and, accordingly, has not recorded any liability for the contingent payments due to Orion.

Agreement with Virginia Commonwealth University

In May 2008, the Company entered into a license agreement with Virginia Commonwealth University ("VCU") whereby it obtained a worldwide, exclusive license to valid claims under three of VCU's patent applications that relate to methods for non-pulmonary delivery of oxygen to tissue and the products based on those valid claims used or useful for therapeutic and diagnostic applications in humans and animals. The license included the right to sub-license to third parties. The term of the agreement was the life of the patents covered by the patent applications unless the Company elected to terminate the agreement prior to patent expiration. Under the agreement the Company had an obligation to diligently pursue product development and pursue, at its own expense, prosecution of the patent applications covered by the agreement. As part of the agreement, the Company was required to pay to VCU non-refundable payments upon achieving development and regulatory milestones. Prior to termination of the license agreement, as discussed below, the Company had not met any of the developmental milestones.

The agreement with VCU also required the Company to pay royalties to VCU at specified rates based on annual net sales derived from the licensed technology. Pursuant to the agreement, the Company was required make minimum annual royalty payments to VCU totaling \$70,000 as long as the agreement is in force. These payments were fully creditable against royalty payments due for sales and sublicense revenue earned during the fiscal year as described above. In the prior year, this fee was recorded as an other current asset and was amortized over the fiscal year. Amortization expense was approximately \$0 for each of the three months ended September 30, 2016 and 2015; and \$0 and \$23,500 for the nine months ended September 30, 2016 and 2015, respectively.

In September 2014, the Company discontinued the development of its PFC product candidates. As part of this change in business strategy, on May 5, 2015 the Company provided VCU its 90-day notice terminating the license agreement entered into with VCU. The license agreement gave the Company exclusive rights to intellectual property that was used for the development and commercialization of its PFC product candidates and was therefore no longer needed.

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, 2016, 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, 2016, there were 28,119,934 shares of common stock issued and outstanding.

Warrants

As of September 30, 2016, the Company has 2,416,046 warrants outstanding.

The following table summarizes the warrant activity for the nine months ended September 30, 2016:

	<u>Warrants</u>	<u>Weighted Average Exercise Price</u>
Outstanding at December 31, 2015	2,728,236	\$ 4.39
Cancelled	(312,190)	17.79
Outstanding at September 30, 2016	2,416,046	\$ 2.66

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, 2016, 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, 2016, the Company had 934,500 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, 2016:

	Shares Available for Grant
Balances, at December 31, 2015	994,713
Options granted	(60,000)
Restricted stock granted	(430)
Restricted stock cancelled/forfeited	217
Balances, at September 30, 2016	934,500

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, 2016:

	Outstanding Options	
	Number of Shares	Weighted Average Exercise Price
Balances, at December 31, 2015	4,007,698	\$ 5.50
Options granted	60,000	\$ 2.72
Balances, at September 30, 2016	4,067,698	\$ 5.46

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 \$111,127 and \$366,129 for the three and nine months ended September 30, 2016, respectively.

As of September 30, 2016, there were unrecognized compensation costs of approximately \$298,000 related to non-vested stock option awards that will be recognized on a straight-line basis over the weighted average remaining vesting period of 1.09 years. Additionally, there were unrecognized compensation costs of approximately \$7.9 million related to non-vested stock option awards subject to performance-based vesting milestones with a weighted average remaining life of 3.51 years. As of September 30, 2016, 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, 2016 and 2015:

	For the nine months ended September 30,	
	2016	2015
Risk-free interest rate (weighted average)	1.60%	1.87%
Expected volatility (weighted average)	84.53%	87.46%
Expected term (in years)	7	7
Expected dividend yield	0.00%	0.00%

Risk-Free Interest Rate The risk-free interest rate assumption was based on U.S. Treasury instruments with a term that is consistent with the expected term of the Company's stock options.

Expected Volatility The expected stock price volatility for the Company's common stock was determined by examining the historical volatility and trading history for its common stock over a term consistent with the expected term of its options.

Expected Term The expected term of stock options represents the weighted average period the stock options are expected to remain outstanding. It was calculated based on the Company's historical experience with its stock option grants.

Expected Dividend Yield The expected dividend yield of 0% is based on the Company's history and expectation of dividend payouts. The Company has not paid and does not anticipate paying any dividends in the near future.

Forfeitures Stock compensation expense recognized in the statements of operations for the nine months ended September 30, 2016 and 2015 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, 2016:

	Outstanding Restricted Stock Grants	
	Number of Shares	Weighted Average Grant Date Fair Value
Balances, at December 31, 2015	394	\$ 3.34
Restricted stock granted	430	\$ 2.72
Restricted stock vested	(240)	\$ 3.36
Restricted stock cancelled	(217)	\$ 3.38
Balances, at September 30, 2016	367	\$ 2.58

The Company recorded compensation expense for these restricted stock grants of \$439 and \$1,417 for the three and nine months ended September 30, 2016, respectively.

As of September 30, 2016, there were unrecognized compensation costs of approximately \$731 related to the non-vested restricted stock grants that will be recognized on a straight-line basis over the remaining vesting period of one year.

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 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 will vest over a three-year period, with one-third vesting per year, beginning one year from the grant date. The options have 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.

Inducement stock option compensation expense was approximately \$4,468 and \$9,830 for the three months ended September 30, 2016 and 2015, respectively, and \$15,191 and \$26,213 for the nine months ended September 30, 2016 and 2015, respectively.

At September 30, 2016, there was \$13,109 of remaining unrecognized compensation expense related to the inducement stock options. Inducement stock options outstanding as of September 30, 2016 had a weighted average remaining contractual life of 8.38 years.

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.

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, 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 Transition Report on Form 10-KT, 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 Transition Report on Form 10-KT for the transition period ended December 31, 2015.

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 Phylisus Pharma, Inc., or Phylisus. 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.

Our current strategy is to:

- Efficiently conduct clinical development to establish clinical proof of concept with our lead product candidates;
- Efficiently explore new high-potential therapeutic applications, leveraging third-party research collaborations and our results from related areas;
- Continue to expand our intellectual property portfolio; and
- Enter into licensing or product co-development arrangements in certain areas, while out-licensing opportunities in non-core areas.

We believe that this strategy will allow us to develop a portfolio of high quality product development opportunities, expand our clinical development and commercialization capabilities, and enhance our ability to generate value from our proprietary technologies.

Third Quarter 2016 Highlights

The following summarizes certain key financial measures for the three months ended September 30, 2016:

- Cash and cash equivalents, including the fair-value of our marketable securities, were \$25.1 million at September 30, 2016.
- Our net loss from operations was \$4.3 million for the third quarter of fiscal 2016 compared to \$2.9 million for the three months ended September 30, 2015.
- Net cash used in operating activities was \$4.3 million and \$3.1 million for the three months ended September 30, 2016 and 2015, respectively.

After reviewing the endpoint data from the first 600 patients enrolled in our Phase III LCOS clinical trial, we are now projecting that we will need to enroll a total of 880 patients in the trial. The increase in 120 patients over the initial projection of 760 is necessary to obtain the 201 events needed to finish the trial. The reason for the increase is due to several factors including, approximately 4% of the patients randomized have not received the study drug; approximately 4% of the patients enrolled are missing end point data; and the event rate through the 600 patients is slightly lower than anticipated. As of November 8, 2016, we have enrolled 858 patients. At the current rate of enrollment, we expect to complete enrollment by the end of November 2016.

Opportunities and Trends

We initiated the Phase III trial for levosimendan and activated the initial sites in the three months ended July 31, 2014. Duke University's Duke Clinical Research Institute, or DCRI, is conducting the Phase III trial. DCRI is the world's largest academic clinical research organization, or CRO, with substantial experience in conducting cardiac surgery trials. The DCRI is serving as the coordinating center and Drs. John H. Alexander and Rajendra Mehta are serving as lead investigators for this trial.

The Phase III trial is being conducted in approximately 60 targeted major cardiac surgery centers in North America. The trial is enrolling patients undergoing coronary artery bypass graft, or CABG, and/or mitral valve surgery, CABG and aortic valve surgery who are at risk for developing LCOS. The trial is a double blind, randomized, placebo controlled study designed to enroll approximately 880 patients, up from the original projection for 760 patients. We enrolled our first patient on September 18, 2014, and we anticipate enrollment will continue through the end of November 2016.

As we focus on the development of our existing products and product candidates, 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 2016 and into calendar year 2017, we are focused on the following four key initiatives:

- Conducting well-designed studies early in the clinical development process to establish a robust foundation for subsequent development, partnership and expansion into complementary areas;
- Working with collaborators and partners to accelerate product development, reduce our development costs, and broaden our commercialization capabilities;
- Gaining regulatory approval for the continued development and commercialization of our products in the United States; and
- Developing new intellectual property to enable us to file patent applications that cover new applications of our existing technologies and 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 Transition Report on Form 10-KT for the transition period ended December 31, 2015.

Financial Overview

Results of Operations- Comparison of the Three Months Ended September 30, 2016 and 2015

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, 2016 and 2015, respectively, are as follows:

	Three months ended September 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2016	2015		
Personnel costs	\$ 629,187	\$ 593,964	\$ 35,223	6%
Legal and professional fees	379,286	487,940	(108,654)	(22)%
Other costs	220,160	295,685	(75,525)	(26)%
Facilities	34,042	38,337	(4,295)	(11)%
Depreciation and amortization	3,205	9,122	(5,917)	(65)%

Personnel costs:

Personnel costs increased approximately \$35,000 for the three months ended September 30, 2016 compared to the same period in the prior year. The increase was due primarily to an increase of approximately \$70,000 in the recognized expense for the vesting of outstanding stock option awards, partially offset by an overall decrease of approximately \$35,000 in salaries and benefits paid during the current period as compared to the same period in 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 \$109,000 for the three months ended September 30, 2016 compared to the same period in the prior year. This decrease was primarily due to a reduction in costs incurred for investor relations services, legal fees and accounting fees, partially offset by an increase in consulting costs.

- Costs associated with investor relations and communication decreased approximately \$46,000 in the current period. This decrease was due primarily to fees paid in the prior year to a third-party investor relations firm that is no longer providing marketing and corporate communications services to us in the current period, as well as the costs incurred for conferences and presentations during the same period in the prior year.
- Legal fees and accounting fees combined decreased in the current period by approximately \$95,000. This decrease was due primarily to additional costs incurred in the prior year related to our filing of a Form 10-KT to transition to a calendar year filer which were not incurred in the current period.
- Consulting costs increased approximately \$48,000 in the current period. The increase in costs was due primarily to services performed for market research and channel strategy and implementation which were not incurred during the same period in the prior year.

Other costs:

Other costs include costs incurred for banking fees, travel, supplies, insurance, taxes and licenses and other miscellaneous charges. The approximately \$76,000 decrease in other costs for the three months ended September 30, 2016 was due primarily to an approximately \$35,000 decrease in franchise taxes paid and an approximately \$33,000 decrease in expenses related to bank fees, supplies and shipping, as compared to the same period in the prior year.

Facilities:

Facilities costs 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, 2016 and 2015.

Depreciation and Amortization:

Depreciation and amortization costs remained relatively consistent for the three months ended September 30, 2016 and 2015.

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, 2016 and 2015, respectively, are as follows:

	<u>Three months ended September 30,</u>		<u>Increase/ (Decrease)</u>	<u>% Increase/ (Decrease)</u>
	<u>2016</u>	<u>2015</u>		
Clinical and preclinical development	\$ 2,959,210	\$ 1,389,764	\$ 1,569,446	113%
Personnel costs	179,032	121,494	57,538	47%
Consulting	92,401	157,353	(64,952)	(41)%
Other costs	4,043	9,906	(5,863)	(59)%

Clinical and preclinical development:

Clinical and preclinical development costs include, primarily, the costs associated with our Phase III clinical trial for levosimendan and, in previous years, a Phase II clinical trial and preclinical trials for Oxycyte. The increase of approximately \$1.6 million in clinical and preclinical development costs for the three months ended September 30, 2016, compared to the same period in the prior year, was primarily due to increased expenditures for CRO costs to manage the Levo-CTS Phase III clinical trial.

Levosimendan

We incurred approximately \$3.0 million in research and development costs for levosimendan during the three months ended September 30, 2016, an increase of approximately \$1.6 million compared to the same period in the prior year. The increase in levosimendan development costs is due primarily to the direct costs of our Phase III Levo-CTS clinical trial for LCOS. For the three months ended September 30, 2016, we recorded CRO costs of approximately \$3.0 million for the management of the Phase III trial which includes approximately \$1.2 million in pass-through site activation and enrolled patient costs, compared to CRO costs of approximately \$1.4 million during the same period in the prior year.

Personnel costs:

Personnel costs increased approximately \$58,000 for the three months ended September 30, 2016 compared to the same period in the prior year. This increase was primarily due to headcount additions during the period to support the clinical development of levosimendan.

Consulting fees:

Consulting fees decreased approximately \$65,000 for the three months ended September 30, 2016 compared to the same period in the prior year. This decrease was primarily due to a decrease of approximately \$82,000 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, partially offset by approximately \$20,000 in costs incurred for potential future regulatory filings.

Other costs:

Other costs remained relatively consistent for the three months ended September 30, 2016 and 2015.

Conducting a significant amount of research and development is central to our business model. Product candidates in later-stage clinical development generally have higher development costs than those in earlier stages of development, primarily due to the significantly increased size and duration of clinical trials. We plan to incur substantial research and development expenses for the foreseeable future to complete development of our most advanced product candidate, levosimendan, and to continue with the development of other potential product candidates.

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. Because of the uncertainties discussed above, uncertainty associated with clinical trial enrollment and risks inherent in the development process, we are unable to determine the duration and completion costs of current or future clinical stages of our product candidates or when, or to what extent, we will generate revenues from the commercialization and sale of any of our product candidates. Development timelines, probability of success and development costs vary widely. We are currently focused on developing our most advanced product candidate, levosimendan; however, we will need substantial additional capital in the future to complete the development and potential commercialization of levosimendan, and to continue with the development of other potential product candidates.

Other income, net

Other income 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, 2016 and 2015, respectively, is as follows:

	<u>Three months ended September 30,</u>		<u>(Increase)/ Decrease</u>
	<u>2016</u>	<u>2015</u>	
Other income	\$ (226,914)	\$ (183,605)	\$ (43,309)

Other income increased approximately \$43,000 for the three months ended September 30, 2016 compared to the same period in the prior year. This increase is due primarily to an approximately \$74,000 gain on the disposal of fixed assets previously used in the manufacturing of Oxycyte, partially offset by the change in fair value of our Series C warrant derivative liability and a decrease in interest income earned in the current period as compared to the same period in the prior year.

During the three months ended September 30, 2016, we recorded a derivative gain of approximately \$60,000 which compared to a derivative gain of approximately \$69,000 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, 2016, we recorded interest income of approximately \$92,000 from our investments in marketable securities. This income is derived from approximately \$229,000 in bond interest paid, partially offset by approximately \$137,000 in charges for amortization of premiums paid and fair-value adjustments measured each period, which compares to approximately \$321,000 in bond interest paid, partially offset by approximately \$207,000 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, 2016 and 2015

General and Administrative Expenses

General and administrative expenses and percentage changes for the nine months ended September 30, 2016 and 2015, respectively, are as follows:

	<u>Nine months ended September 30,</u>		<u>Increase/ (Decrease)</u>	<u>% Increase/ (Decrease)</u>
	<u>2016</u>	<u>2015</u>		
Personnel costs	\$ 1,964,135	\$ 2,295,079	\$ (330,944)	(14)%
Legal and professional fees	1,495,868	1,624,731	(128,863)	(8)%
Other costs	691,883	885,921	(194,038)	(22)%
Facilities	105,794	116,913	(11,119)	(10)%
Depreciation and amortization	9,538	54,679	(45,141)	(83)%

Personnel costs:

Personnel costs decreased approximately \$331,000 for the nine months ended September 30, 2016 compared to the same period in the prior year. The decrease was due primarily to approximately \$525,000 in bonuses paid in the prior year as well as an overall decrease of approximately \$19,000 in salaries and benefits paid during the current period, partially offset by an increase of approximately \$213,000 in the recognized expense for the vesting of outstanding stock option awards as compared to the same period in the prior year.

Legal and professional fees:

Legal and professional fees decreased approximately \$129,000 for the nine months ended September 30, 2016 compared to the same period in the prior year. This decrease was primarily due to a reduction in costs incurred for investor relations services, legal fees and accounting fees, partially offset by an increase in consulting costs.

- Costs associated with investor relations and communication decreased approximately \$219,000 in the current period. This decrease was due primarily to fees paid in the prior year to a third-party investor relations firm that is no longer providing marketing and corporate communications services to us in the current period, as well as the costs incurred for conferences and presentations during the same period in the prior year.
- Legal fees and accounting fees combined decreased in the current period by approximately \$68,000. This decrease was due primarily to additional costs incurred in the prior year related to our filing of a Form 10-KT to transition to a calendar year filer which were not incurred in the current period.
- Consulting costs increased approximately \$231,000 in the current period. The increase in costs was due primarily to services performed for market research and channel strategy and implementation which were not incurred during the same period in the prior year.

Other costs:

The approximately \$194,000 decrease in other costs for the nine months ended September 30, 2016 was due primarily to an approximately \$185,000 decrease in franchise taxes paid and \$19,000 banking fees, partially offset by an increase of approximately \$31,000 in insurance costs, as compared to the same period in the prior year.

Facilities:

Facilities costs remained relatively consistent for the nine months ended September 30, 2016 and 2015.

Depreciation and Amortization:

Depreciation and amortization costs decreased approximately \$45,000 for the nine months ended September 30, 2016 compared to the same period in the prior year. The decrease in costs was due primarily to amortization costs incurred in the same period of the prior year on our PFC-based intellectual property portfolio that was fully impaired as of April 30, 2015.

Research and Development Expenses

Research and development expenses and percentage changes for the nine months ended September 30, 2016 and 2015, respectively, are as follows:

	Nine months ended September 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2016	2015		
Clinical and preclinical development	\$ 9,609,182	\$ 4,611,668	\$ 4,997,514	108%
Consulting	522,725	177,229	345,496	195%
Personnel costs	451,760	376,895	74,865	20%
Other costs	26,245	42,726	(16,481)	(39)%

Clinical and preclinical development:

The increase of approximately \$5.0 million in clinical and preclinical development costs for the nine months ended September 30, 2016, compared to the same period in the prior year, was primarily due to increased expenditures for CRO costs to manage the Levo-CTS Phase III clinical trial, partially offset by a reduction in costs incurred in the current period for the development and clinical testing of Oxycyte, which development we decided to suspend in September 2014.

Levosimendan

We incurred approximately \$9.6 million in research and development costs for levosimendan during the nine months ended September 30, 2016, an increase of approximately \$5.6 million compared to the same period in the prior year. The increase in levosimendan development costs is due primarily to the direct costs of our Phase III Levo-CTS clinical trial for LCOS. For the nine months ended September 30, 2016, we recorded CRO costs of approximately \$9.6 million for the management of the Phase III trial which includes approximately \$4.5 million in pass-through site activation and enrolled patient costs, compared to CRO costs of approximately \$4.0 million during the same period in the prior year.

Oxycyte

We incurred approximately \$4,000 in research and development costs for Oxycyte during the nine months ended September 30, 2016, a decrease of approximately \$577,000 compared to the same period in the prior year. The decrease in Oxycyte development costs was due to our decision to suspend development of the Oxycyte product in September 2014 and close out all our sites for the Phase II-B clinical trial for TBI. We do not anticipate any significant additional costs in the future related to this clinical trial or other close-out activities related to the discontinuance of the Oxycyte product development.

Consulting fees:

Consulting fees increased approximately \$345,000 for the nine months ended September 30, 2016 compared to the same period in the prior year, primarily due to an increase 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 as well as fees paid for pharmacokinetic study analysis and LCOS and septic shock cost and incidence studies.

Personnel costs:

Personnel costs increased approximately \$75,000 for the nine months ended September 30, 2016 compared to the same period in the prior year. This increase was primarily due to headcount additions during the period to support the clinical development of levosimendan, partially offset by bonuses of approximately \$15,000 recorded during the same period of the prior year.

Other costs:

Other costs decreased approximately \$16,000 for the nine months ended September 30, 2016 compared to the same period in the prior year. This decrease was due primarily to depreciation of lab equipment that was written off and disposed of on April 30, 2015 as well as other lab related costs during the same period in the prior year.

Other income, net

Other income for the nine months ended September 30, 2016 and 2015, respectively, is as follows:

	<u>Nine months ended September 30,</u>		<u>(Increase)/</u>
	<u>2016</u>	<u>2015</u>	<u>Decrease</u>
Other income	\$ (600,610)	\$ (567,505)	\$ (33,105)

Other income increased approximately \$33,000 for the nine months ended September 30, 2016 compared to the same period in the prior year. This increase is due to primarily to a gain of approximately \$74,000 on the disposal of fixed assets previously used in the manufacturing of Oxycyte, partially offset by the change in fair value of our Series C warrant derivative liability and a decrease in interest income earned in the current period as compared to the same period in the prior year.

During the nine months ended September 30, 2016, we recorded a derivative gain of approximately \$214,000 which compared to a derivative gain of approximately \$209,000 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 nine months ended September 30, 2016, we recorded interest income of approximately \$310,000 from our investments in marketable securities. This income is derived from approximately \$816,000 in bond interest paid, partially offset by approximately \$506,000 in charges for amortization of premiums paid and fair-value adjustments measured each period, which compares to approximately \$1.0 million in bond interest paid, partially offset by approximately \$650,000 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, 2016 we had an accumulated deficit of \$175 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 increased expenses related to our development and potential commercialization of levosimendan and other product candidates and, thus, 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 \$7,667,083 and \$20,560,353 of total current assets and working capital of \$2,610,055 and \$15,958,723 as of September 30, 2016 and December 31, 2015, respectively. Based on our working capital and the value of our investments in marketable securities at September 30, 2016, we believe we have sufficient capital to fund our operations through calendar year 2017.

We are in the clinical trial stages in the development of our product candidates. We are currently conducting a Phase III clinical trial for levosimendan, and we expect our primary focus will be on funding the Phase III clinical trial for levosimendan, since this product is the furthest along in the regulatory review process. Our ability to continue to pursue testing and development of our products beyond calendar year 2017 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.

Cash Flows

The following table shows a summary of our cash flows for the nine months ended September 30, 2016 and 2015:

	<u>Nine months ended September 30,</u>	
	<u>2016</u>	<u>2015</u>
Net cash used in operating activities	\$ (12,766,231)	\$ (8,473,551)
Net cash provided by investing activities	9,827,930	64,411
Net cash used in financing activities	-	(150,760)

Net cash used in operating activities. Net cash used in operating activities was approximately \$12.8 million for the nine months ended September 30, 2016 compared to net cash used in operating activities of approximately \$8.5 million for the nine months ended September 30, 2015. The increase in cash used for operating activities was due primarily to an increase in our costs incurred for the Phase III clinical trial for levosimendan.

Net cash provided by investing activities. Net cash provided by investing activities was approximately \$9.8 million for the nine months ended September 30, 2016 compared to approximately \$64,000 for the nine months ended September 30, 2015. The increase in cash provided by investing activities was primarily due the sale of marketable securities that were purchased during the same period of the prior year.

Net cash used in financing activities. Net cash used in financing activities was \$0 for the nine months ended September 30, 2016 compared to approximately \$151,000 for the nine months ended September 30, 2015. The decrease of approximately \$151,000 in net cash used by financing activities was due primarily to the payment of a note in the prior year.

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 in-licensing and out-licensing transactions;
- 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 calendar year 2017. We will need substantial additional capital in the future to complete the development and commercialization 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 Transition Report on Form 10-KT for the transition period ended December 31, 2015. There have not been material changes to the critical accounting policies previously disclosed in that report.

Recent Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board, or FASB, issued a new 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 new 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 new standard will have on our condensed consolidated financial statements and related disclosures.

In March 2016, the FASB issued a new accounting standard intended to simplify various aspects related to how share-based payments are accounted for and presented in the financial statements. The new guidance includes provisions to reduce the complexity related to income taxes, statement of cash flows, and forfeitures when accounting for share-based payment transactions. The new standard is effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted. We are currently evaluating the impact that this new standard will have on our condensed consolidated financial statements and related disclosures.

In May 2014, the FASB issued a new accounting standard that supersedes nearly all existing revenue recognition guidance under GAAP. The new standard is principles-based and provides a five-step model to determine when and how revenue is recognized. The core principle of the new 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 new standard to clarify the implementation guidance on principal versus agent considerations, and in April 2016, the FASB issued a new standard to clarify the implementation guidance on identifying performance obligations and licensing. The new 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, with an option that permits companies to adopt the standard as early as the original effective date. 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 have not yet selected a transition method and we do not believe adoption of this standard will have a material impact on our condensed consolidated financial statements and related disclosures.

In February 2016, the FASB issued a new accounting standard intended to improve financial reporting regarding leasing transactions. The new 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 new 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 new 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 new standard will have on our financial statements and related disclosures.

In January 2016, the FASB issued a new accounting standard that will enhance our reporting for financial instruments. The new 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 condensed 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 transition report on Form 10-KT for the transition period ended December 31, 2015.

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 transition report on Form 10-KT for the transition period ended December 31, 2015.

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 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 Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2016, 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 the 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 Transition Report on Form 10-KT for the transition period ended December 31, 2015.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Repurchases of Common Stock

The following table lists all repurchases during the three months ended September 30, 2016 of any of our securities registered under Section 12 of the Exchange Act by or on behalf of us or any affiliated purchaser.

Period	Total Number of Shares Purchased (1)	Average Price Paid per Share (2)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs
July 1, 2016 - July 31, 2016	-	\$ -	-	\$ -
August 1, 2016 - August 31, 2016	-	\$ -	-	\$ -
September 1, 2016 - September 30, 2016	59	\$ 2.32	-	\$ -
Total	<u>59</u>	<u>\$ 2.32</u>	<u>-</u>	<u>\$ -</u>

(1) Represents shares repurchased in connection with tax withholding obligations under the 1999 Amended Stock Plan.

(2) Represents the average price paid per share for the shares repurchased in connection with tax withholding obligations under the 1999 Amended Stock Plan.

ITEM 5. OTHER INFORMATION

On October 31, 2016, Paula Bokesch, M.D. voluntarily resigned from her position as Chief Medical Officer, effective November 5, 2016.

ITEM 6. EXHIBITS

The exhibits listed in the accompanying exhibit index are filed as part of this quarterly report on Form 10-Q, and such exhibit index is incorporated by reference herein.

SIGNATURES

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

TENAX THERAPEUTICS, INC.

Date: November 9, 2016

By: /s/ Michael B. Jebsen

Michael B. Jebsen

Chief Financial Officer

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

EXHIBIT INDEX

No.	Description
31.1	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes Oxley Act of 2002. *
31.2	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes Oxley Act of 2002. *
32.1	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *
32.2	Certification of 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

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

I, John P. Kelley, 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. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of 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 our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2016

By: /s/ John P. Kelley

John P. Kelley

Chief Executive Officer

(Principal Executive Officer)

**CERTIFICATION OF 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. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of 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 our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 9, 2016

By: /s/ Michael B. Jebsen

Michael B. Jebsen
Chief Financial Officer
(Principal Financial Officer)

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

In connection with the Quarterly Report of Tenax Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, John P. Kelley, Chief Executive Officer (Principal Executive Officer) of the Company, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (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, 2016

By: /s/ John P. Kelley

John P. Kelley
Chief Executive Officer
(Principal Executive Officer)

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

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

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

In connection with the Quarterly Report of Tenax Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2016 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael B. Jebsen, Chief Financial Officer (Principal 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, 2016

By: /s/ Michael B. Jebsen

Michael B. Jebsen
Chief Financial Officer
(Principal Financial Officer)

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