

SECURITIES & EXCHANGE COMMISSION EDGAR FILING

TENAX THERAPEUTICS, INC.

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**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, 2018

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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-Accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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

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

As of November 12, 2018, the registrant had outstanding 1,465,496 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, 2018	December 31, 2017
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 3,347,183	\$ 1,604,810
Marketable securities	1,509,117	6,122,400
Accounts receivable	-	50,171
Prepaid expenses	284,857	285,512
Total current assets	5,141,157	8,062,893
Marketable securities	296,349	1,809,428
Property and equipment, net	8,178	9,945
Other assets	8,435	8,435
Total assets	<u>\$ 5,454,119</u>	<u>\$ 9,890,701</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 392,482	\$ 611,861
Accrued liabilities	104,300	363,306
Warrant liabilities	19,376	33,673
Total current liabilities	516,158	1,008,840
Total liabilities	516,158	1,008,840
Commitments and contingencies; see Note 6		
Stockholders' equity		
Common stock, par value \$.0001 per share; authorized 400,000,000 shares; issued and outstanding 1,465,496 and 1,411,840, respectively	147	141
Additional paid-in capital	223,029,293	222,397,198
Accumulated other comprehensive loss	(9,981)	(16,193)
Accumulated deficit	(218,081,498)	(213,499,285)
Total stockholders' equity	4,937,961	8,881,861
Total liabilities and stockholders' equity	<u>\$ 5,454,119</u>	<u>\$ 9,890,701</u>

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

TENAX THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Three months ended September 30,		Nine months ended September 30,	
	2018 (Unaudited)	2017 (Unaudited)	2018 (Unaudited)	2017 (Unaudited)
Operating expenses				
General and administrative	\$ 1,191,577	\$ 1,056,447	\$ 3,933,768	\$ 4,295,336
Research and development	362,628	253,973	732,365	3,528,338
Total operating expenses	1,554,205	1,310,420	4,666,133	7,823,674
Net operating loss	1,554,205	1,310,420	4,666,133	7,823,674
Other income	(23,400)	(76,226)	(83,920)	(327,725)
Net loss	\$ 1,530,805	\$ 1,234,194	\$ 4,582,213	\$ 7,495,949
Unrealized (gain)/loss on marketable securities	(6,515)	(3,767)	(6,212)	(12,969)
Total comprehensive loss	\$ 1,524,290	\$ 1,230,427	\$ 4,576,001	\$ 7,482,980
Net loss per share, basic and diluted	\$ (1.05)	\$ (0.87)	\$ (3.17)	\$ (5.32)
Weighted average number of common shares outstanding, basic and diluted	1,462,191	1,411,828	1,446,377	1,410,226

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

TENAX THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	Nine months ended September 30,	
	2018	2017
	(Unaudited)	(Unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	\$ (4,582,213)	\$ (7,495,949)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	7,574	10,599
Issuance and vesting of compensatory stock options and warrants	255,962	426,837
Issuance of common stock as compensation	136,921	79,525
Issuance of common stock for services rendered	75,271	-
Change in the fair value of warrants	(14,297)	(190,014)
Amortization of premium on marketable securities	82,574	158,209
Changes in operating assets and liabilities		
Accounts receivable, prepaid expenses and other assets	75,917	1,323,018
Accounts payable and accrued liabilities	(339,529)	(5,170,671)
Net cash used in operating activities	(4,301,820)	(10,858,446)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of marketable securities	-	(299,172)
Sale of marketable securities	6,050,000	2,930,082
Purchase of property and equipment	(5,807)	(4,536)
Net cash provided by investing activities	6,044,193	2,626,374
Net change in cash and cash equivalents	1,742,373	(8,232,072)
Cash and cash equivalents, beginning of period	1,604,810	9,995,955
Cash and cash equivalents, end of period	<u>\$ 3,347,183</u>	<u>\$ 1,763,883</u>

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

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)**NOTE 1. DESCRIPTION OF BUSINESS**

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

On October 18, 2013, the Company created a wholly owned subsidiary, Life Newco, Inc., a Delaware corporation ("Life Newco"), to acquire certain assets of Phyxius Pharma, Inc., a Delaware corporation ("Phyxius") pursuant to an Asset Purchase Agreement, dated October 21, 2013 (the "Asset Purchase Agreement"), by and among the Company, Life Newco, Phyxius and the stockholders of Phyxius (the "Phyxius Stockholders"). As further discussed in Note 5 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, 2017 has been derived from the Company's audited consolidated financial statements included in its Annual Report on Form 10-K for the period ended December 31, 2017. Certain footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States ("GAAP") have been condensed or omitted pursuant to Article 8 of Regulation S-X of the Securities and Exchange Commission ("SEC") rules and regulations. Operating results for the three- and nine-month periods ended September 30, 2018 are not necessarily indicative of results for the full year or any other future periods. As such, it is suggested that these condensed consolidated financial statements be read in conjunction with the consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the period ended December 31, 2017.

Reverse Stock Split

The Company initiated a 1-for-20 reverse stock split effective February 23, 2018. All shares and per share amounts in these condensed consolidated financial statements and notes thereto have been retroactively adjusted to give effect to the reverse stock split.

Going Concern

Management believes the accompanying condensed consolidated financial statements have been prepared in conformity with GAAP, which contemplate continuation of the Company as a going concern. The Company has an accumulated deficit of \$218,081,498, at September 30, 2018 and \$213,499,285 at December 31, 2017, and used cash in operations of \$4,301,820 and \$10,858,446 during the nine months ended September 30, 2018 and 2017, respectively. The Company requires substantial additional funds to complete clinical trials and pursue regulatory approvals. Management is actively seeking additional sources of equity and/or debt financing; however, there is no assurance that any additional funding will be available.

In view of the matters described above, recoverability of a major portion of the recorded asset amounts shown in the accompanying September 30, 2018 balance sheet is dependent upon continued operations of the Company, which in turn is dependent upon the Company's ability to meet its financing requirements on a continuing basis, to maintain present financing, and to generate cash from future operations. These factors, among others, raise substantial doubt about the Company's ability to continue as a going concern. The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence.

Use of Estimates

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

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

Principles of Consolidation

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

Liquidity and Management's Plan

At September 30, 2018, the Company had cash and cash equivalents, including the fair value of its marketable securities, of approximately \$5.2 million. The Company used \$4.3 million of cash for operating activities during the nine months ended September 30, 2018 and had stockholders' equity of \$4.9 million, versus \$8.9 million at December 31, 2017.

The Company expects to continue to incur expenses related to development of levosimendan for pulmonary hypertension and other potential indications, as well as identifying and developing other potential product candidates. Based on its resources at September 30, 2018, the Company believes that it has sufficient capital to fund its planned operations through the first quarter of calendar year 2019. However, the Company will need substantial additional financing in order to fund its operations beyond such period and thereafter until it can achieve profitability, if ever. The Company depends on its ability to raise additional funds through various potential sources, such as equity and debt financing, or to license its product candidates to another pharmaceutical company. The Company will continue to fund operations from cash on hand and through sources of capital similar to those previously described. The Company cannot assure that it will be able to secure such additional financing, or if available, that it will be sufficient to meet its needs.

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

Net Loss per Share

Basic net 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 net loss per share considers the potential dilution that could occur from other equity instruments that would increase the total number of outstanding shares of common stock. Such amounts include shares potentially issuable under outstanding options, restricted stock and warrants.

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

	Nine months ended September 30,	
	2018	2017
Options to purchase common stock	241,744	189,558
Warrants to purchase common stock	120,773	120,773
Restricted stock	19,914	-

Recent Accounting Pronouncements

The SEC has released SEC Final Rule Release No. 33-10532 Disclosure Update and Simplification, which adopts amendments to certain disclosure requirements that have become redundant, duplicative, overlapping, outdated, or superseded, in light of other SEC disclosure requirements, GAAP, or changes in the information environment. The amendments also refer certain SEC disclosure requirements that overlap with but require information incremental to GAAP to the Financial Accounting Standards Board ("FASB") for potential incorporation into GAAP. The amendments are intended to facilitate the disclosure of information to investors and simplify compliance without significantly altering the total mix of information provided to investors. These amendments are part of an initiative by the Division of Corporation Finance to review disclosure requirements applicable to issuers to consider ways to improve the requirements for the benefit of investors and issuers. The amendments became effective on November 5, 2018 and did not have a material impact to the Company.

In June 2018, the FASB issued an accounting standard that provides guidance that aligns the accounting for share-based payment awards issued to employees and nonemployees. Under the new guidance, the existing employee guidance will apply to nonemployee share-based transactions. The cost of nonemployee awards will continue to be recorded as if the grantor had paid cash for the goods or services. In addition, the contractual term will be able to be used in lieu of an expected term in the option-pricing model for nonemployee awards. Equity-classified share-based payment awards issued to nonemployees will now be measured on the grant date, and, for performance conditions, compensation cost associated with the award will be recognized when achievement of the performance condition is probable, rather than upon achievement of the performance condition. The new guidance also clarifies that any share-based payment awards issued to customers should be evaluated under ASC 606, Revenue from Contracts with Customers. The standard will be effective for interim and annual reporting periods beginning after December 15, 2018. Early adoption is permitted. The Company does not believe adoption of this standard will have a material impact on its condensed consolidated financial statements and related disclosures.

In July 2017, the FASB issued an accounting standard that changes the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. The amendments also clarify existing disclosure requirements for equity-classified instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. The standard will be effective on January 1, 2019. Early adoption is permitted, including adoption in an interim period. The Company does not believe adoption of this standard will have a material impact on its condensed consolidated financial statements and related disclosures.

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

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

In June 2016, the FASB issued an accounting standard that amends how credit losses are measured and reported for certain financial instruments that are not accounted for at fair value through net income. This standard requires 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 does not believe adoption of this standard will have a material impact on its condensed consolidated financial statements and related disclosures.

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

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

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

NOTE 3: FAIR VALUE

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

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

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

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

Investments in Marketable Securities

The Company classifies all of its investments as available-for-sale. Unrealized gains and losses on investments are recognized in comprehensive income/(loss), unless an unrealized loss is considered to be other than temporary, in which case the unrealized loss is charged to operations. The Company periodically reviews its investments for other than temporary declines in fair value below cost basis and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company believes the individual unrealized losses represent temporary declines primarily resulting from interest rate changes. Realized gains and losses are reflected in 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, 2018, 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, 2018				
	Amortized Cost	Accrued Interest	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
Corporate debt securities	\$ 1,802,485	\$ 12,962	\$ -	\$ (9,981)	\$ 1,805,466

The following table summarizes the scheduled maturity for the Company's investments at September 30, 2018 and December 31, 2017.

	September 30, 2018	December 31, 2017
Maturing in one year or less	\$ 1,509,117	\$ 6,122,400
Maturing after one year through three years	296,349	1,809,428
Total investments	\$ 1,805,466	\$ 7,931,828

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"). As part of the offering, the Company issued 137,668 warrants at an exercise price of \$52.00 per share and contractual term of 6 years. On November 11, 2013, the Company satisfied certain contractual obligations pursuant to the Series C offering which caused certain "down-round" price protection clauses in the outstanding warrants to become effective on that date. In accordance with ASC 815-40-35-9, the Company reclassified these warrants as a current liability and recorded a warrant liability of \$1,380,883, which represents the fair market value of the warrants at that date. The initial fair value recorded as warrants within stockholders' equity of \$233,036 was reversed 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, 2018 and December 31, 2017:

Series C Warrants	September 30, 2018	December 31, 2017
Closing stock price	\$ 5.26	\$ 9.80
Expected dividend rate	0%	0%
Expected stock price volatility	90.00%	81.26%
Risk-free interest rate	2.50%	1.83%
Expected life (years)	0.81	1.56

As of September 30, 2018, the fair value of the warrant liability was \$19,376. The Company recorded a gain of \$5,175 and \$14,297 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, 2018, respectively.

As of September 30, 2018, there were 12,035 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, 2018 and December 31, 2017:

	Balance as of September 30, 2018	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	\$ 3,347,183	\$ 3,347,183	\$ -	\$ -
Marketable securities	\$ 1,509,117	\$ -	\$ 1,509,117	\$ -
Long-term Assets				
Marketable securities	\$ 296,349	\$ -	\$ 296,349	\$ -
Current Liabilities				
Warrant liabilities	\$ 19,376	\$ -	\$ -	\$ 19,376

	Balance as of December 31, 2017	Fair Value Measurements at Reporting Date Using		
		Quoted prices in Active Markets for Identical Securities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Current Assets				
Cash and cash equivalents	\$ 1,604,810	\$ 1,604,810	\$ -	\$ -
Marketable securities	\$ 6,122,400	\$ -	\$ 6,122,400	\$ -
Long-term Assets				
Marketable securities	\$ 1,809,428	\$ -	\$ 1,809,428	\$ -
Current Liabilities				
Warrant liabilities	\$ 33,673	\$ -	\$ -	\$ 33,673

There were no significant transfers between levels during the three and nine months ended September 30, 2018.

NOTE 4. BALANCE SHEET COMPONENTS

Property and equipment, net

Property and equipment consist of the following as of September 30, 2018 and December 31, 2017:

	September 30, 2018	December 31, 2017
Laboratory equipment	\$ 354,861	\$ 354,861
Computer equipment and software	94,804	88,998
Office furniture and fixtures	130,192	130,192
	<u>579,857</u>	<u>574,051</u>
Less: Accumulated depreciation	(571,679)	(564,106)
	<u>\$ 8,178</u>	<u>\$ 9,945</u>

Depreciation expense was approximately \$2,000 and \$3,000 for the three months ended September 30, 2018 and 2017, respectively, and approximately \$8,000 and \$11,000 for the nine months ended September 30, 2018 and 2017, respectively.

Accrued liabilities

Accrued liabilities consist of the following as of September 30, 2018 and December 31, 2017:

	September 30, 2018	December 31, 2017
Operating costs	\$ 56,345	\$ 39,252
Employee related	47,955	324,054
	<u>\$ 104,300</u>	<u>\$ 363,306</u>

NOTE 5. 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, 2018, the Company has not met any of the developmental milestones and, accordingly, has not recorded any liability for the contingent payments due to Orion.

NOTE 6. 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, 2018, 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, 2018, there were 1,465,496 shares of common stock issued and outstanding.

Warrants

As of September 30, 2018, the Company had 120,773 warrants outstanding. There was no warrant activity for the nine months ended September 30, 2018.

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 150,000 shares of common stock. As of September 30, 2018, the Company had 100,000 shares of common stock available for grant under the 2016 Plan.

The following table summarizes the shares available for grant under the 2016 Plan for the nine months ended September 30, 2018:

	Shares Available for Grant
Balances, at December 31, 2017	150,000
Options granted	(50,000)
Balances, at September 30, 2018	100,000

2016 Plan Stock Options

Stock options granted under the 2016 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 2016 Plan may be granted with a term of up to ten years and at prices no less than fair market value at the time of grant. Stock options granted generally vest over three to four years.

The following table summarizes the outstanding stock options under the 2016 Plan for the nine months ended September 30, 2018:

	Outstanding Options	
	Number of Shares	Weighted Average Exercise Price
Balances, at December 31, 2017	-	\$ -
Options granted	50,000	\$ 6.10
Balances, at September 30, 2018	50,000	\$ 6.10

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 \$29,732 and \$59,463 for the three and nine months ended September 30, 2018, respectively.

As of September 30, 2018, there were unrecognized compensation costs of approximately \$189,744 related to non-vested stock option awards under the 2016 Plan that will be recognized on a straight-line basis over the weighted average remaining vesting period of 2.17 years.

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 200,000 shares, up from 15,000 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 250,000 shares, up from 200,000 previously authorized. The 1999 Plan expired on June 17, 2018 and no new grants may be made under that plan after that date. However, unexpired awards granted under the 1999 Plan remain outstanding and subject to the terms of the 1999 Plan.

1999 Plan Stock Options

Stock options granted under the 1999 Plan may be ISOs, or 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, 2018:

	Outstanding Options	
	Number of Shares	Weighted Average Exercise Price
Balances, at December 31, 2017	188,744	\$ 95.24
Options granted	3,000	\$ 6.23
Options cancelled	-	\$ -
Balances, at September 30, 2018	191,744	\$ 93.85

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 \$62,564 and \$196,499 for the three and nine months ended September 30, 2018, respectively.

As of September 30, 2018, there were unrecognized compensation costs of approximately \$178,962 related to non-vested stock option awards under the 1999 Plan that will be recognized on a straight-line basis over the weighted average remaining vesting period of 1.12 years. Additionally, there were unrecognized compensation costs of approximately \$5.9 million related to non-vested stock option awards under the 1999 Plan subject to performance-based vesting milestones with a weighted average remaining life of 1.5 years. As of September 30, 2018, 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, 2018 and 2017:

	For the nine months ended September 30,	
	2018	2017
Risk-free interest rate (weighted average)	2.85%	2.19%
Expected volatility (weighted average)	102.38%	99.59%
Expected term (in years)	7	7
Expected dividend yield	0.00%	0.00%

<i>Risk-Free Interest Rate</i>	The risk-free interest rate assumption was based on U.S. Treasury instruments with a term that is consistent with the expected term of the Company's stock options.
<i>Expected Volatility</i>	The expected stock price volatility for the Company's common stock was determined by examining the historical volatility and trading history for its common stock over a term consistent with the expected term of its options.
<i>Expected Term</i>	The expected term of stock options represents the weighted average period the stock options are expected to remain outstanding. It was calculated based on the Company's historical experience with its stock option grants.
<i>Expected Dividend Yield</i>	The expected dividend yield of 0% is based on the Company's history and expectation of dividend payouts. The Company has not paid and does not anticipate paying any dividends in the near future.
<i>Forfeitures</i>	Stock compensation expense recognized in the statements of operations for the nine months ended September 30, 2018 and 2017 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, 2018 .

	Outstanding Restricted Stock Grants	
	Number of Shares	Weighted Average Grant Date Fair Value
Balances, at December 31, 2017	-	\$ -
Restricted stock granted	85,900	\$ 5.82
Restricted stock vested	(37,420)	\$ 5.69
Restricted stock cancelled	(28,566)	\$ 5.66
Balances, at September 30, 2018	19,914	\$ 6.29

The Company recorded compensation expense for these restricted stock grants of approximately \$63,000 and \$188,000 for the three and nine months ended September 30, 2018, respectively.

As of September 30, 2018, there was approximately \$63,000 of unrecognized compensation costs related to the non-vested restricted stock grants.

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

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the "safe harbor" created by those sections. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to them. In some cases you can identify forward-looking statements by words such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. Examples of these statements include, but are not limited to, statements regarding: the implications of interim or final results of our clinical trials, the progress of our research programs, including clinical testing, the extent to which our issued and pending patents may protect our products and technology, our ability to identify new product candidates, the potential of such product candidates to lead to the development of commercial products, our anticipated timing for initiation or completion of our clinical trials for any of our product candidates, our future operating expenses, our future losses, our future expenditures for research and development, our ability to raise capital and the sufficiency of our cash resources. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the risks faced by us and described in Part II, Item 1A of this Quarterly Report on Form 10-Q, Part I, Item 1A of our Annual Report on Form 10-K, and our other filings with the Securities and Exchange Commission, or SEC. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Quarterly Report on Form 10-Q. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from those we expect. Except as required by law, we assume no obligation to update these forward-looking statements, whether as a result of new information, future events or otherwise.

The following discussion and analysis should be read in conjunction with the unaudited condensed consolidated financial statements and notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q and with the audited consolidated financial statements and related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2017.

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 and developing products that address diseases with high unmet medical needs. Our principal business objective is to identify, develop and commercialize novel therapeutic products for disease indications that represent significant areas of clinical need and commercial opportunity. Our lead product is levosimendan, which was acquired in an asset purchase agreement with Phyxius Pharma, Inc., or Phyxius. Levosimendan is a calcium sensitizer developed for intravenous use in hospitalized patients with acutely decompensated heart failure. The treatment is currently approved in more than 60 countries for this indication and not available in the United States or Canada.

The European Society of Cardiology, or the ESC, recommends levosimendan as a preferable agent over dobutamine to reverse the effect of beta blockade if it is thought to be contributing to hypotension. The ESC guidelines also state that levosimendan is not appropriate for patients with systolic blood pressure less than 85mmHg or in patients in cardiogenic shock unless it is used in combination with other inotropes or vasopressors. Other unique properties of levosimendan include sustained efficacy through the formation of a long acting metabolite, lack of impairment of diastolic function, and evidence of better compatibility with beta blockers than dobutamine.

We are currently developing levosimendan in North America for the treatment of patients with pulmonary hypertension associated with heart failure with preserved ejection fraction, or PH-HFpEF. PH-HFpEF is defined hemodynamically by a pulmonary artery pressure, or mPAP, ≥ 25 mmHg, a pulmonary capillary wedge pressure, or PCWP, >15 mmHg, and a diastolic pressure gradient, or diastolic PAP – PCWP, >7 mmHg. Pulmonary hypertension in these patients initially develops from a passive backward transmission of elevated filling pressures from left-sided heart failure. These mechanical components of pulmonary venous congestion may trigger pulmonary vasoconstriction, decreased nitric oxide availability, increased endothelin expression, desensitization to natriuretic peptide induced vasodilation, and vascular remodeling. Finally, these changes often lead to advanced pulmonary vascular disease, increased right ventricle, or RV, afterload, and RV failure.

PH-HFpEF is a common form of pulmonary hypertension with an estimated US prevalence exceeding 1.5 million patients. Currently, no pharmacologic therapies are approved for treatment of PH-HFpEF. Despite the fact that many therapies have been studied in PH-HFpEF patients, including therapies approved to treat pulmonary arterial hypertension patients, no therapies have been shown to be effective in treating PH-HFpEF patients.

Published pre-clinical and clinical studies indicate that levosimendan may provide important benefits to patients with pulmonary hypertension. Data from these published trials indicate that levosimendan may reduce pulmonary vascular resistance and improve important cardiovascular hemodynamics such as reduced pulmonary capillary wedge pressure in patients with pulmonary hypertension. In addition, several published studies provide evidence that levosimendan may improve right ventricular dysfunction which is a common comorbidity in patients with pulmonary hypertension. While none of these studies have focused specifically on PH-HFpEF patients, the general hemodynamic improvements in these published studies of various types of pulmonary hypertension provide an indication that levosimendan may be beneficial in PH-HFpEF patients.

In March 2018, we met with the United States Food and Drug Administration, or FDA, to discuss development of levosimendan in PH-HFpEF patients. The FDA was in agreement with our planned Phase 2 design, patient entry criteria, and endpoints. The study may be conducted under the existing investigational new drug application with no additional nonclinical studies required to support full development. The FDA recognized there were no approved drug therapies to treat PH-HFpEF patients and acknowledged this provided an opportunity for a limited Phase 3 clinical program. This topic will be discussed further at the End-of-Phase 2 Meeting following completion of the planned Phase 2 study in PH-HFpEF patients. We plan to begin enrollment of the Phase 2 trial in the fourth quarter of 2018.

Third Quarter 2018 Highlights

The following summarizes certain key financial measures for the three months ended September 30, 2018:

- Cash and cash equivalents, including the fair-value of our marketable securities, were \$5.2 million at September 30, 2018.
- Our net loss from operations was \$1.6 million for the third quarter of fiscal 2018 compared to \$1.3 million for the three months ended September 30, 2017.
- Net cash used in operating activities was \$1.6 million and \$1.3 million for the three months ended September 30, 2018 and 2017, respectively.

Opportunities and Trends

As we focus on the development of levosimendan, 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 2018, we are focused on the following initiatives:

- Working with collaborators and partners to accelerate product development, reduce our development costs, and broaden our commercialization capabilities;
- Gaining regulatory approval for the continued development and commercialization of levosimendan in the United States; and
- Identifying new products or product candidates for potential acquisitions.

Financial Overview

Results of Operations- Comparison of the Three Months Ended September 30, 2018 and 2017

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, 2018 and 2017, respectively, are as follows:

	Three months ended September 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2018	2017		
Personnel costs	\$ 719,870	\$ 599,289	\$ 120,581	20%
Legal and professional fees	289,893	284,470	5,423	2%
Other costs	144,333	136,096	8,237	6%
Facilities	35,720	34,024	1,696	5%
Depreciation and amortization	1,761	2,568	(807)	(31)%

Personnel costs:

Personnel costs increased approximately \$121,000 for the three months ended September 30, 2018 compared to the same period in the prior year. This increase was due primarily to the hiring of our CEO in the current year as well as an increase of approximately \$29,000 in recognized costs for stock-based compensation in 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 increased approximately \$5,000 for the three months ended September 30, 2018 compared to the same period in the prior year. This increase was due primarily to an increase in costs incurred for legal fees and investor relations fees, partially offset by decreases in costs incurred for consulting fees and fees paid to our Board of Directors, including the vested value of stock option grants.

- Legal fees increased approximately \$31,000 in the current period. This increase was due primarily to an increase in costs associated with levosimendan intellectual property, partially offset by a decrease in costs incurred in support of the Board of Directors Strategic Alternatives Committee in the current period as compared to same period of the prior year.
- Investor relations fees increased approximately \$43,000 in the current period. This increase was due primarily to additional fees paid to investor relations firms and conference fees and travel costs that were not incurred in the same period of the prior year.
- Consulting costs decreased approximately \$54,000 in the current period. This decrease was due primarily to the fees paid to third-party firms for FDA and Health Canada submissions as well as costs incurred in support of the Board of Directors Strategic Alternatives Committee in the prior year that were not incurred in the current period.
- Board of Directors fees decreased in the current period by approximately \$16,000. This decrease was due primarily to a member of the Board of Directors accepting the position of CEO, and a reduction in the recognized expense for the vesting of stock options awarded in the current period as compared to the recognized expense for stock options awarded in the same period of the prior year.

Other costs:

Other costs include costs incurred for travel, supplies, insurance and other miscellaneous charges. The approximately \$8,000 increase in other costs for the three months ended September 30, 2018 compared to the same period in the prior year was due primarily to approximately \$30,000 in relocation costs, an increase of approximately \$15,000 in travel related costs and an increase of approximately \$10,000 in insurance and other miscellaneous charges, partially offset by a decrease of approximately \$47,000 in franchise taxes paid in the current period as compared to the same period in the prior year.

Facilities:

Facilities expenses include costs paid for rent and utilities at our corporate headquarters in North Carolina. Facilities expenses remained relatively consistent for the three months ended September 30, 2018 and 2017.

Depreciation and Amortization:

Depreciation and amortization costs remained relatively consistent for the three months ended September 30, 2018 and 2017.

Research and Development Expenses

Research and development expenses include, but are not limited to, (i) expenses incurred under agreements with clinical research organizations, or 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) depreciation and direct and allocated expenses for rent and maintenance of equipment and other supplies. All research and development expenses are expensed as incurred. Research and development expenses and percentage changes for the three months ended September 30, 2018 and 2017, respectively, are as follows:

	<u>Three months ended September 30,</u>		<u>Increase/ (Decrease)</u>	<u>% Increase/ (Decrease)</u>
	<u>2018</u>	<u>2017</u>		
Clinical and preclinical development	\$ 310,158	\$ 226,225	\$ 83,933	37%
Personnel costs	48,329	25,993	22,336	86%
Consulting	2,900	-	2,900	- %
Other costs	1,241	1,755	(514)	(29)%

Clinical and preclinical development:

Clinical and preclinical development costs include, primarily, the costs associated with our Phase 3 LEVO-CTS clinical trial for levosimendan, which was completed during fiscal year 2017 and the costs associated with our Phase 2 PH-HFpEF clinical trial which we plan to initiate in the fourth quarter of the current fiscal year. The increase of approximately \$84,000 in clinical and preclinical development costs for the three months ended September 30, 2018 compared to the same period in the prior year, was primarily due to an increase of approximately \$274,000 in costs associated with initiating the Phase 2 PH-HFpEF clinical trial in the current period and approximately \$36,000 in preclinical costs associated with formulation development of levosimendan, partially offset by a decrease of approximately \$226,000 in CRO costs to manage the Phase 3 LEVO-CTS clinical trial in the same period of the prior year that were not incurred in the current period.

Personnel costs:

Personnel costs increased approximately \$22,000 in the current period due to headcount increases to manage the Phase 2 PH-HFpEF clinical trial which were not incurred in the same period in the prior year.

Consulting fees:

Consulting fees remained relatively consistent for the three months ended September 30, 2018 and 2017.

Other costs:

Other costs remained relatively consistent for the three months ended September 30, 2018 and 2017.

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

Other income and expense, net

Other income and expense include 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, 2018 and 2017, respectively, is as follows:

	Three months ended September 30,		(Increase)/ Decrease
	2018	2017	
Other income, net	\$ (23,400)	\$ (76,226)	\$ 52,826

Other income decreased approximately \$53,000 for the three months ended September 30, 2018 compared to the same period in the prior year. This decrease is due primarily to the change in fair value of our Series C warrant derivative liability in the current period and a reduction in the interest earned on our investment in marketable securities.

During the three months ended September 30, 2018, we recorded a derivative gain of approximately \$5,000 which compared to a derivative gain of approximately \$36,000 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, 2018, we recorded interest income of approximately \$17,000 from our investments in marketable securities. This income is derived from approximately \$20,000 in bond interest paid, partially offset by approximately \$3,000 in charges for amortization of premiums paid and fair-value adjustments measured each period, which compares to approximately \$84,000 in bond interest paid, partially offset by approximately \$44,000 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, 2018 and 2017

General and Administrative Expenses

General and administrative expenses and percentage changes for the nine months ended September 30, 2018 and 2017, respectively, are as follows:

	Nine months ended September 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2018	2017		
Personnel costs	\$ 2,311,185	\$ 2,510,569	\$ (199,384)	(8)%
Legal and professional fees	1,134,868	1,324,424	(189,556)	(14)%
Other costs	372,468	347,585	24,883	7%
Facilities	108,919	104,850	4,069	4%
Depreciation and amortization	6,328	7,908	(1,580)	(20)%

Personnel costs:

Personnel costs decreased approximately \$199,000 for the nine months ended September 30, 2018 compared to the same period in the prior year. This decrease was due primarily to the payment of \$430,000 in severance costs in the prior year, partially offset by and an overall increase in salaries and benefits paid of approximately \$11,000, an increase of approximately \$168,000 in bonuses paid and an increase of approximately \$50,000 in recognized costs for stock-based compensation in the current period as compared to the same period in the prior year.

Legal and professional fees:

Legal and professional fees decreased approximately \$190,000 for the nine months ended September 30, 2018 compared to the same period in the prior year. This decrease was due primarily to decreases in costs incurred for auditing fees, consulting fees, and the vested value of stock option grants to our Board of Directors, partially offset by an increase in costs incurred for legal fees and investor relations fees.

- Audit and accounting fees decreased approximately \$7,000 in the current period. This decrease was due primarily to the reduction in audit fees associated with our transition to “smaller reporting company” filer status for our fiscal year ended December 31, 2017 as compared to the same period in the prior year.
- Consulting costs decreased approximately \$209,000 in the current period. This decrease was due primarily to the fees paid to third-party firms for FDA and other regulatory submissions and costs incurred to support the Board of Directors Strategic Alternatives Committee in the prior year that were not incurred in the current period.
- Board of Directors fees decreased in the current period by approximately \$47,000. This decrease was due primarily to a member of the Board of Directors accepting the position of CEO in the current period, and a reduction in the recognized expense for the vesting of stock options awarded in the current period as compared to the recognized expense for stock options awarded in the same period of the prior year.
- Legal fees increased approximately \$39,000 in the current period. This increase was due primarily to the costs incurred for the filings associated with our Special Meeting of Stockholders and costs incurred in support of the Board of Directors Strategic Alternatives Committee in the current period that were not incurred in the prior year, as well as an increase in costs associated with levosimendan intellectual property in the current period as compared to same period of the prior year.
- Investor relations fees increased approximately \$34,000 in the current period. This increase was due primarily to the costs associated with our Special Meeting of Stockholders in the current period that were not incurred in the prior year.

Other costs:

The approximately \$25,000 increase in other costs for the nine months ended September 30, 2018 compared to the same period in the prior year was due primarily to increases of approximately \$43,000 in travel related costs, approximately \$30,000 in relocation costs and approximately \$12,000 in insurance costs, partially offset by an approximately \$60,000 decrease in franchise taxes paid in the current period as compared to the same period in the prior year.

Facilities:

Facilities expenses remained relatively consistent for the nine months ended September 30, 2018 and 2017.

Depreciation and Amortization:

Depreciation and amortization costs remained relatively consistent for the nine months ended September 30, 2018 and 2017.

Research and Development Expenses

Research and development expenses and percentage changes for the nine months ended September 30, 2018 and 2017, respectively, are as follows:

	Nine months ended September 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2018	2017		
Clinical and preclinical development	\$ 594,000	\$ 3,230,215	\$ (2,636,215)	(82)%
Personnel costs	122,340	177,615	(55,275)	(31)%
Other costs	9,991	7,572	2,419	32%
Consulting	6,034	112,936	(106,902)	(95)%

Clinical and preclinical development:

The decrease of approximately \$2.6 million in clinical and preclinical development costs for the nine months ended September 30, 2018 compared to the same period in the prior year, was primarily due to a decrease of approximately \$3.2 million in CRO costs to manage the Phase 3 LEVO-CTS clinical trial, partially offset by an increase of approximately \$531,000 in costs associated with initiating the Phase 2 PH-HFpEF clinical trial and approximately \$36,000 in preclinical costs associated with formulation development of levosimendan.

Personnel costs:

Personnel costs decreased approximately \$55,000 for the nine months ended September 30, 2018 compared to the same period in the prior year, primarily due to a reduction in headcount in the current period as compared to the same period in the prior year.

Other costs:

Other costs remained relatively consistent for the nine months ended September 30, 2018 and 2017.

Consulting fees:

Consulting fees decreased approximately \$107,000 for the nine months ended September 30, 2018 compared to the same period in the prior year, primarily due to a decrease in fees paid to third-party consulting firms for services provided for report-writing and regulatory submissions in support of our Phase 3 LEVO-CTS clinical trial in the prior year which were not incurred in the current period.

Other income and expense, net

Other income for the nine months ended September 30, 2018 and 2017, respectively, is as follows:

	<u>Nine months ended September 30,</u>		<u>(Increase)/ Decrease</u>
	<u>2018</u>	<u>2017</u>	
Other income	\$ (83,920)	\$ (327,725)	\$ 243,805

Other income decreased approximately \$244,000 for the nine months ended September 30, 2018 compared to the same period in the prior year. This decrease is due primarily to the change in fair value of our Series C warrant derivative liability in the current period and a reduction in the interest earned on our investment in marketable securities.

During the nine months ended September 30, 2018, we recorded a derivative gain of approximately \$14,000 which compared to a derivative gain of approximately \$190,000 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, 2018, we recorded interest income of approximately \$68,000 from our investments in marketable securities. This income is derived from approximately \$150,000 in bond interest paid, partially offset by approximately \$83,000 in charges for amortization of premiums paid and fair-value adjustments measured each period, which compares to approximately \$288,000 in bond interest paid, partially offset by approximately \$158,000 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, 2018, we had an accumulated deficit of approximately \$218 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 for pulmonary hypertension and other potential indications, as well as identifying and developing other potential product candidates and, as a result, we will need to generate significant net product sales, royalty and other revenues to achieve profitability.

Liquidity

We have financed our operations since September 1990 through the issuance of debt and equity securities and loans from stockholders. We had total current assets of \$5,141,157 and \$8,062,893 and working capital of \$4,624,999 and \$7,054,053 as of September 30, 2018 and December 31, 2017, respectively. Based on our working capital and the value of our investments in marketable securities at September 30, 2018, we believe we have sufficient capital to fund our operations through the first quarter of calendar year 2019.

We will need substantial additional capital in the future in order to continue the development of levosimendan and to fund the development and commercialization of other future product candidates. Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements. Such funding 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.

Cash Flows

The following table shows a summary of our cash flows for the nine months ended September 30, 2018 and 2017:

	Nine months ended September 30,	
	2018	2017
Net cash used in operating activities	\$ (4,301,820)	\$ (10,858,446)
Net cash provided by investing activities	6,044,193	2,626,374

Net cash used in operating activities. Net cash used in operating activities was approximately \$4.3 million for the nine months ended September 30, 2018 compared to net cash used in operating activities of approximately \$10.9 million for the nine months ended September 30, 2017. The decrease in cash used for operating activities was due primarily to a decrease in our accrued costs related to the Phase 3 clinical trial for levosimendan in the current period as compared to the same period in the prior year.

Net cash provided by investing activities. Net cash provided by investing activities was approximately \$6.0 million for the nine months ended September 30, 2018 compared to approximately \$2.6 million for the nine months ended September 30, 2017. The increase in cash provided by investing activities was primarily due to an increase in the sale of marketable securities in the current period.

Operating Capital and Capital Expenditure Requirements

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

- the initiation, progress, timing and completion of clinical trials for our product candidates and potential product candidates;
- the outcome, timing and cost of regulatory approvals and the regulatory approval process;
- delays that may be caused by changing regulatory requirements;
- the number of product candidates that we pursue;
- the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims;
- the timing and terms of future 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 the first quarter of calendar year 2019. We will need substantial additional capital in the future in order 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 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 and Significant Judgments and Estimates

Our condensed consolidated financial statements have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the expenses during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions. For information regarding our critical accounting policies and estimates, please refer to "Management's Discussion and Analysis of Financial Condition and Results of Operations—Summary of Significant Accounting Policies" contained in our Annual Report on Form 10-K for the year ended December 31, 2017. During the nine months ended September 30, 2018, there were no material changes to the critical accounting policies previously disclosed in that report.

Recent Accounting Pronouncements

The SEC has released SEC Final Rule Release No. 33-10532 Disclosure Update and Simplification, which adopts amendments to certain disclosure requirements that have become redundant, duplicative, overlapping, outdated, or superseded, in light of other SEC disclosure requirements, GAAP, or changes in the information environment. The amendments also refer certain SEC disclosure requirements that overlap with but require information incremental to GAAP to the Financial Accounting Standards Board, or the FASB, for potential incorporation into GAAP. The amendments are intended to facilitate the disclosure of information to investors and simplify compliance without significantly altering the total mix of information provided to investors. These amendments are part of an initiative by the Division of Corporation Finance to review disclosure requirements applicable to issuers to consider ways to improve the requirements for the benefit of investors and issuers. The amendments became effective on November 5, 2018 and did not have a material impact on our condensed consolidated financial statements and related disclosures.

In June 2018, the FASB issued an accounting standard that provides guidance that aligns the accounting for share-based payment awards issued to employees and nonemployees. Under the new guidance, the existing employee guidance will apply to nonemployee share-based transactions. The cost of nonemployee awards will continue to be recorded as if the grantor had paid cash for the goods or services. In addition, the contractual term will be able to be used in lieu of an expected term in the option-pricing model for nonemployee awards. Equity-classified share-based payment awards issued to nonemployees will now be measured on the grant date, and, for performance conditions, compensation cost associated with the award will be recognized when achievement of the performance condition is probable, rather than upon achievement of the performance condition. The new guidance also clarifies that any share-based payment awards issued to customers should be evaluated under ASC 606, Revenue from Contracts with Customers. The standard will be effective for interim and annual reporting periods beginning after December 15, 2018. Early adoption is permitted. We do not believe adoption of this standard will have a material impact on our condensed consolidated financial statements and related disclosures.

In July 2017, the FASB issued an accounting standard that changes the classification analysis of certain equity-linked financial instruments (or embedded features) with down round features. When determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. The amendments also clarify existing disclosure requirements for equity-classified instruments. As a result, a freestanding equity-linked financial instrument (or embedded conversion option) no longer would be accounted for as a derivative liability at fair value as a result of the existence of a down round feature. The standard will be effective on January 1, 2019. Early adoption is permitted, including adoption in an interim period. We do not believe adoption of this standard will have a material impact on our condensed consolidated financial statements and related disclosures.

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

In August 2016, the FASB issued an accounting standard that clarifies how companies present and classify certain cash receipts and cash payments in the statement of cash flows where diversity in practice exists. The standard is effective in our first quarter of fiscal 2018. Adoption of this standard did not have a material impact on our condensed consolidated financial statements and related disclosures.

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

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

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

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

Contractual Obligations

There have been no material changes, outside of the ordinary course of business, to our contractual obligations as previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2017.

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

Not applicable.

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, 2018, the end of the period covered by this report in that they provide reasonable assurance that the information we are required to disclose in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods required by the SEC and is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

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

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

The risks we face have not materially changed from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2017.

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, 2018 of any of our securities registered under Section 12 of the Exchange Act by or on behalf of us or any affiliated purchaser.

Issuer Purchases of Equity Securities

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, 2018 - July 31, 2018	8,325	\$ 6.25	-	\$ -
August 1, 2018 - August 31, 2018	-	\$ -	-	\$ -
September 1, 2018 - September 30, 2018	-	\$ -	-	\$ -
Total	8,325	\$ 6.25	-	\$ -

(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 6. EXHIBITS

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

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

SIGNATURES

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

Date: November 14, 2018

TENAX THERAPEUTICS, INC.

By: /s/ Michael B. Jebsen

Michael B. Jebsen

President and Chief Financial Officer

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

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

I, Anthony DiTonno, 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 14, 2018

/s/ Anthony DiTonno
Anthony DiTonno
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 14, 2018

/s/ Michael B. Jebsen

Michael B. Jebsen

*President and Chief Financial Officer
(Principal Financial Officer)*

**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**

In connection with the Quarterly Report of Tenax Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Anthony DiTonno, 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 14, 2018

/s/ Anthony DiTonno

Anthony DiTonno

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 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**

In connection with the Quarterly Report of Tenax Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael B. Jebsen, President and 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 14, 2018

/s/ Michael B. Jebsen

Michael B. Jebsen

President and 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.
