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, 2019

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	**26-2593535**
(State of incorporation)	**(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)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	TENX	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes ☒ No ☐

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

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

Large Accelerated filer	☐	Accelerated filer	☐
Non-Accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

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

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

As of November 11, 2019, the registrant had outstanding 6,741,860 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, 2019	December 31, 2018
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	$ 6,648,997	$ 12,367,321
Marketable securities	478,543	494,633
Prepaid expenses	434,390	458,286
Total current assets	7,561,930	13,320,240
Right of use asset	195,768	-
Property and equipment, net	7,868	8,525
Other assets	8,435	8,435
Total assets	$ 7,774,001	$ 13,337,200
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 225,523	$ 749,814
Accrued liabilities	903,512	815,855
Total current liabilities	1,129,035	1,565,669
Lease liability	108,421	-
Total liabilities	1,237,456	1,565,669
Commitments and contingencies; see Note 5		
Stockholders' equity		
Preferred stock, undesignated, authorized 4,818,654 shares; See Note 6		
Series A Preferred stock, par value $.0001, issued 5,181,346 shares; outstanding 38,606 and 2,854,593, respectively	4	285
Common stock, par value $.0001 per share; authorized 400,000,000 shares; issued and outstanding 6,741,860 and 3,792,249, respectively	674	379
Additional paid-in capital	239,911,307	239,572,094
Accumulated other comprehensive gain	1,319	516
Accumulated deficit	(233,376,759)	(227,801,743)
Total stockholders' equity	6,536,545	11,771,531
Total liabilities and stockholders' equity	$ 7,774,001	$ 13,337,200

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,	
	2019	2018	2019	2018
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Operating expenses				
General and administrative	$ 1,343,429	$ 1,191,577	$ 3,692,843	$ 3,933,768
Research and development	916,984	362,628	2,049,004	732,365
Total operating expenses	2,260,413	1,554,205	5,741,847	4,666,133
Net operating loss	2,260,413	1,554,205	5,741,847	4,666,133
Other income	(36,709)	(18,224)	(139,161)	(69,623)
Net loss	$ 2,223,704	$ 1,535,981	$ 5,602,686	$ 4,596,510
Unrealized (gain) loss on marketable securities	960	(6,515)	(803)	(6,212)
Total comprehensive loss	$ 2,224,664	$ 1,529,466	$ 5,601,883	$ 4,590,298
Net loss per share, basic and diluted	$ (0.33)	$ (1.05)	$ (0.93)	$ (3.18)
Weighted average number of common shares outstanding, basic and diluted	6,741,084	1,462,191	6,011,304	1,446,377

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

TENAX THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited)

	Preferred Stock		Common Stock					
	Number of Shares	Amount	Number of Shares	Amount	Additional paid-in capital	Accumulated other comprehensive gain (loss)	Accumulated deficit	Total stockholders' equity
Balance at December 31, 2017	**-**	**$ -**	**1,411,840**	**$ 141**	**$ 222,397,198**	**$ (16,193)**	**$ (213,499,285)**	**$ 8,881,861**
Compensation on options and restricted stock issued			25,600	3	209,442			209,445
Common stock issued for services rendered			10,241	1	100,361			100,362
Fractional shares of common stock due to reverse stock split			5,995					-
Unrealized gain on marketable securities						(10,857)		(10,857)
Net loss							(1,192,967)	(1,192,967)
Balance at March 31, 2018	**-**	**$ -**	**1,453,676**	**$ 145**	**$ 222,707,001**	**$ (27,050)**	**$ (214,692,252)**	**$ 7,987,844**
Compensation on options and restricted stock issued					93,078			93,078
Unrealized gain on marketable securities						10,555		10,555
Net loss							(1,867,563)	(1,867,563)
Balance at June 30, 2018	**-**	**$ -**	**1,453,676**	**$ 145**	**$ 222,800,079**	**$ (16,495)**	**$ (216,559,815)**	**$ 6,223,914**
Compensation on options and restricted stock issued			11,820	2	229,214			229,216
Unrealized gain on marketable securities						6,515		6,515
Net loss							(1,535,981)	(1,535,981)
Balance at September 30, 2018	**-**	**$ -**	**1,465,496**	**$ 147**	**$ 223,029,293**	**$ (9,980)**	**$ (218,095,796)**	**$ 4,923,664**

	Preferred Stock		Common Stock					
	Number of Shares	Amount	Number of Shares	Amount	Additional paid-in capital	Accumulated other comprehensive gain (loss)	Accumulated deficit	Total stockholders' equity
Balance at December 31, 2018	**2,854,593**	**$ 285**	**3,792,249**	**$ 379**	**$ 239,572,094**	**$ 516**	**$(227,801,743)**	**$ 11,771,531**
Compensation on options and restricted stock issued			12,195	1	60,294			60,295
Common stock issued for convertible preferred stock	(2,299,990)	(230)	2,299,990	230				-
Exercise of warrants			50,000	5	96,495			96,500
Adoption of ASC Topic 842: Leases							27,670	27,670
Unrealized gain on marketable securities						1,289		1,289
Net loss							(1,617,445)	(1,617,445)
Balance at March 31, 2019	**554,603**	**$ 55**	**6,154,434**	**$ 615**	**$ 239,728,883**	**$ 1,805**	**$(229,391,518)**	**$ 10,339,840**
Compensation on options and restricted stock issued					41,666			41,666
Common stock issued for convertible preferred stock	(515,997)	(51)	515,997	52				1
Unrealized gain on marketable securities						474		474
Net loss							(1,761,537)	(1,761,537)
Balance at June 30, 2019	**38,606**	**$ 4**	**6,670,431**	**$ 667**	**$ 239,770,549**	**$ 2,279**	**(231,153,055)**	**$ 8,620,444**
Compensation on options and restricted stock issued					40,765			40,765
Common stock issued for services rendered			71,429	7	99,993			100,000
Unrealized gain on marketable securities						(960)		(960)
Net loss							(2,223,704)	(2,223,704)
Balance at September 30, 2019	**38,606**	**$ 4**	**6,741,860**	**$ 674**	**$ 239,911,307**	**$ 1,319**	**(233,376,759)**	**$ 6,536,545**

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,	
	2019	**2018**
	(Unaudited)	**(Unaudited)**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (5,602,686)	$ (4,596,510)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	3,709	7,574
Amortization of right to use asset	75,942	-
Loss (gain) on disposal of property and equipment	522	-
Issuance and vesting of compensatory stock options and warrants	142,726	255,962
Issuance of common stock as compensation	-	136,921
Issuance of common stock for services rendered	66,667	75,271
Amortization of premium on marketable securities	(1,778)	82,574
Changes in operating assets and liabilities		
Accounts receivable, prepaid expenses and other assets	57,230	75,917
Accounts payable and accrued liabilities	(498,145)	(339,529)
Long term portion of lease liability	(74,107)	-
Net cash used in operating activities	(5,829,920)	(4,301,820)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of marketable securities	(436,356)	-
Sale of marketable securities	455,026	6,050,000
Purchase of property and equipment	(3,574)	(5,807)
Net cash provided by investing activities	15,096	6,044,193
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from the exercise of warrants	96,500	-
Net cash provided by financing activities	96,500	-
Net change in cash and cash equivalents	(5,718,324)	1,742,373
Cash and cash equivalents, beginning of period	12,367,321	1,604,810
Cash and cash equivalents, end of period	$ 6,648,997	$ 3,347,183

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, 2018 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, 2018. 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 period ended September 30, 2019 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, 2018.

Reclassifications

Certain prior period amounts in the accompanying condensed consolidated financial statements have been reclassified to conform to current period presentation. The Company adjusted certain previously reported financial statements to reflect the adoption of ASU 2017-11 during the year ended December 31, 2018. The Company has determined the impact of the adjustment on its condensed consolidated financial statements for the three and nine months ended September 30, 2019 not to be material.

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 $233,376,759 at September 30, 2019 and $227,801,743 at December 31, 2018 and used cash in operations of $5,829,920 and $4,301,820 during the nine months ended September 30, 2019 and 2018, 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, 2019 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. All material intercompany transactions and balances have been eliminated in consolidation.

Liquidity and Management's Plan

At September 30, 2019, the Company had cash and cash equivalents, including the fair value of its marketable securities, of approximately $7.1 million. The Company used $5.8 million of cash for operating activities during the nine months ended September 30, 2019 and had stockholders' equity of $6.5 million, versus $11.8 million at December 31, 2018.

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, 2019, the Company believes that it has sufficient capital to fund its planned operations through the first quarter of calendar year 2020. 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,	
	2019	**2018**
Warrants to purchase common stock	10,521,195	120,773
Options to purchase common stock	244,214	241,744
Convertible preferred shares outstanding	38,606	-
Restricted stock grants	-	19,914

Leases

The Company determines if an arrangement includes a lease at inception. Operating leases are included in operating lease right-of-use assets, other current liabilities, and long-term lease liabilities in the Company's consolidated balance sheet as of September 30, 2019. Right-of-use assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the net present value of lease payments, the Company uses the incremental borrowing rate based on the information available at the lease commencement date. The operating lease right-of-use assets also include any lease payments made and exclude lease incentives. The Company's leases may include options to extend or terminate the lease which are included in the lease term when it is reasonably certain that the Company will exercise any such option. Lease expense is recognized on a straight-line basis over the expected lease term. The Company has elected to account for leases with an initial term of 12 months or less similar to previous guidance for operating leases, under which the Company will recognize those lease payments in the consolidated statements of operations and comprehensive loss on a straight-line basis over the lease term.

Prior period amounts continue to be reported in accordance with the Company's historic accounting under previous lease guidance, see "Recent Accounting Pronouncements" below, for more information about the impact of the adoption of the new lease standard.

Recent Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board ("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 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 requires the Company to recognize on its balance sheet the assets and liabilities for the rights and obligations created by all leased assets. The standard also requires 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 was effective for financial statements beginning after December 15, 2018, and interim periods within those annual periods. Early adoption was permitted.

The Company adopted this standard on January 1, 2019, using the required modified-retrospective approach as of the effective date. The Company elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allows it to carryforward the historical lease classification. The Company made an accounting policy election to account for leases with an initial term of 12 months or less similar to previous guidance for operating leases, under which the Company recognizes those lease payments in the consolidated statements of operations and comprehensive loss on a straight-line basis over the lease term. Results for the year ended December 31, 2018 continue to be reported in accordance with historical accounting under previous lease guidance, the FASB Accounting Standards Codification ("ASC") Topic 840: Leases (Topic 840).

The Company recorded a net reduction of $27,670 to opening accumulated deficit as of January 1, 2019, due to the cumulative impact of adopting the new leasing standard, with the impact relating to a change in the classification of the Company's office space. The adoption of the lease standard did not have a material impact on the Company's condensed consolidated balance sheets. The table below summarizes the impact of adopting the new standard on its condensed consolidated balance sheet as of January 1, 2019.

	As Previously Reported	New Lease Standard Adjustment	As Adjusted
Operating lease right-of-use asset	$ -	$ 271,710	$ 271,710
Operating lease liabilites	$ -	$ 271,710	$ 271,710
Deferred lease liabilities	$ 27,670	$ (27,670)	$ -

NOTE 3. FAIR VALUE

The Company determines the fair value of its financial assets and liabilities in accordance with the 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, 2019, 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 GAAP. These fair values are obtained from independent pricing services which utilize Level 2 inputs:

	September 30, 2019				
	Amortized Cost	Accrued Interest	Gross Unrealized Gains	Gross Unrealized losses	Estimated Fair Value
Obligations of U.S. Government and its agencies	$ 64,476	$ 288	$ 454	$ -	$ 65,218
Corporate debt securities	409,739	2,725	883	(22)	413,325
Total investments	$ 474,215	$ 3,013	$ 1,337	$ (22)	$ 478,543

All of the Company's investments have scheduled maturities of less than one year as of September 30, 2019 and December 31, 2018.

The following tables summarize information regarding assets and liabilities measured at fair value on a recurring basis as of September 30, 2019 and December 31, 2018:

	Fair Value Measurements at Reporting Date Using			
	Balance as of September 30, 2019	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	$ 6,648,997	$ 6,648,997	$ -	$ -
Marketable securities	$ 478,543	$ -	$ 478,543	$ -

	Fair Value Measurements at Reporting Date Using			
	Balance as of December 31, 2018	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	$ 12,367,321	$ 12,367,321	$ -	$ -
Marketable securities	$ 494,633	$ -	$ 494,633	$ -

There were no significant transfers between levels in the nine months ended September 30, 2019.

NOTE 4. BALANCE SHEET COMPONENTS

Property and equipment, net

Property and equipment consist of the following as of September 30, 2019 and December 31, 2018:

	September 30, 2019	December 31, 2018
Office furniture and fixtures	$ 130,192	$ 130,192
Computer equipment and software	80,669	96,593
Laboratory equipment	-	354,861
	210,861	581,646
Less: Accumulated depreciation	(202,993)	(573,121)
	$ 7,868	$ 8,525

Depreciation expense was approximately $1,300 and $2,000 for the three months ended September 30, 2019 and 2018, and approximately $3,700 and $8,000 for the nine months ended September 30, 2019 and 2018, respectively.

Accrued liabilities

Accrued liabilities consist of the following as of September 30, 2019 and December 31, 2018:

	September 30, 2019	December 31, 2018
Operating costs	$ 722,624	$ 244,456
Lease liability	89,182	-
Employee related	91,706	571,399
	$ 903,512	$ 815,855

NOTE 5. COMMITMENTS AND CONTINGENCIES

Leases

As described further in "NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES" above, the Company adopted ASC 842 as of January 1, 2019. Prior period amounts have not been adjusted and continue to be reported in accordance with the Company's historic accounting under ASC 840.

In January 2011, the Company entered into the Lease with Concourse Associates, LLC for office facilities located at the premises in Morrisville, North Carolina (the "Lease"). The Lease was amended in August 2015 to extend the term for the 5,954 square foot rental. The current term began on March 1, 2016 and continues for 64 months to September 30, 2021. Rent payments began on July 1, 2016, following the conclusion of a four-month rent abatement period. The Company has two five-year options to extend the Lease and a one-time option to terminate the Lease thirty-six months after the commencement of the initial term if no additional space ("Expansion Space") became available; none of these optional periods have been considered in the determination of the right-of-use asset or the lease liability for the Lease as the Company did not consider it reasonably certain that it would exercise any such options. The Lease further provides that the Company is obligated to pay to landlord certain variable costs, including taxes and operating expenses. The Company also has a right of first offer to lease the Expansion Space, of no less than 1,000 square feet, as that additional space becomes available adjacent to the premises over the remainder of the initial term of the Lease, at the same rate per square foot as the current premises, with an extension of the term of sixty additional months starting at the commencement date of acquiring the Expansion Space.

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

The balance sheet classification of our lease liabilities was as follows:

	September 30, 2019	December 31, 2018
Current portion included in accrued liabilities	$ 89,182	$ -
Long term lease liability	108,421	-
	$ 197,603	$ -

As of September 30, 2019, the maturities of our operating lease liabilities were as follows:

Year ending December 31,	
2019	$ 29,651
2020	121,084
2021	61,803
Total lease payments	$ 212,538
Less: Imputed interest	(14,935)
Operating lease liability	$ 197,603

Operating lease liabilities are based on the net present value of the remaining Lease payments over the remaining Lease term. In determining the present value of lease payments, the Company used the incremental borrowing rate based on the information available at the Lease commencement date. As of September 30, 2019, the remaining Lease term is 1.75 years and the discount rate used to determine the operating lease liability was 8.0%. For the nine months ending September 30, 2019, the Company paid $92,911 in total lease expenses, including $4,445 for common area maintenance charges.

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, i.e. line extension products. 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 the Company sells the Product in the Territory.

As of September 30, 2019, the Company has not met any of the developmental milestones and, accordingly, has not recorded any liability for the contingent payments due to Orion.

In June 2019, Orion filed a request for arbitration against the Company seeking a declaration regarding the correct interpretation of the line extension provisions of the License and whether or not such provisions apply to the oral form of levosimendan recently developed by Orion. Additionally, Orion requested the Company reimburse Orion for all legal fees associated with the arbitration. The Company recently submitted its response to the request for arbitration and rejected Orion's position that the oral formation was not a line extension product under the License.

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.

Series A Stock

On December 11, 2018, the Company closed its underwritten offering of 5,181,346 units for net proceeds of approximately $9 million. Each unit consists of (a) one share of the Company's Series A convertible preferred stock, par value $0.0001 per share (the "Series A Stock"), (b) a two-year warrant to purchase one share of common stock at an exercise price of $1.93 (the "Series 1 Warrants"), and (c) a five-year warrant to purchase one share of common stock at an exercise price of $1.93 (the "Series 2 Warrants"). In accordance with ASC 480, the estimated fair value of $1,800,016 for the beneficial conversion feature was recognized as a deemed dividend on the Series A Stock during the year ended December 31, 2018.

The table below sets forth a summary of the designation, powers, preferences and rights of the Series A Stock.

Conversion	Subject to the ownership limitations described below, the Series A Stock is convertible at any time at the option of the holder into shares of the Company's common stock at a conversion ratio determined by dividing the stated value of the Series A Stock by a conversion price of $1.93 per share. The conversion price is subject to adjustment in the case of stock splits, stock dividends, combinations of shares and similar recapitalization transactions. Until such time that 85% of the aggregate number of shares of Series A Stock issued to all holders on the original issue date have been converted to common stock, the Series A Stock has full ratchet price-based anti-dilution protection, subject to customary carve-outs, in the event of a down-round financing at a price per share below the conversion price of the Series A Stock. If during any 30 consecutive trading days (a "Measurement Period") the volume weighted average price of the Company's common stock exceeds 300% of the then-effective conversion price of the Series A Stock and the daily dollar trading volume for each trading day during such period exceeds $175,000, the anti-dilution protection in the Series A Stock will expire and cease to apply. Additionally, subject to certain exceptions, at any time after the issuance of the Series A Stock, and subject to the beneficial ownership limitations described below, the Company has the right to cause each holder of the Series A Stock to convert all or part of such holder's Series A Stock in the event that (i) the volume weighted average price of the Company's common stock for any Measurement Period exceeds 300% of the initial conversion price of the Series A Stock (subject to adjustment for forward and reverse stock splits, recapitalizations, stock dividends and similar transactions), (ii) the average daily trading volume for such Measurement Period exceeds $175,000 per trading day and (iii) the holder is not in possession of any information that constitutes or might constitute, material non-public information which was provided by the Company. The Company will not affect any conversion of the Series A Stock, nor shall a holder convert its shares of Series A Stock, to the extent that such conversion would cause the holder to have acquired, through conversion of the Series A Stock or otherwise, beneficial ownership of a number shares of common stock in excess of 4.99% (or, at the election of the holder prior to the issuance of any shares of Series A Stock, 9.99%) of the common stock outstanding after giving effect to such exercise.
Dividends	In the event the Company pays dividends on its shares of common stock, the holders of the Series A Stock will be entitled to receive dividends on shares of Series A Stock equal, on an as-if-converted basis, to and in the same form as paid on the common stock. No other dividends will be paid on the shares of Series A Stock.
Liquidation	Upon any liquidation, dissolution or winding up of the Company after payment or provision for payment of debts and other liabilities of the Company, the holders of Series A Stock shall be entitled to be paid out of the assets of the Company available for distribution to its stockholders an amount equal to the amount that a holder of common stock would receive if the Series A Stock were fully converted to common stock, which amounts will be paid pari passu with all holders of common stock.
Voting rights	Shares of Series A Stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the then outstanding Series A Stock will be required to amend the terms of the Series A Stock or to take other action that adversely affects the rights of the holders of Series A Stock.

During the year ended December 31, 2018, 2,326,753 shares of Series A Stock were converted into 2,326,753 shares of common stock. As of December 31, 2018, there were 2,854,593 shares of Series A Stock outstanding.

During the nine months ended September 30, 2019, an additional 2,815,987 shares of Series A Stock were converted into 2,815,987 shares of common stock. As of September 30, 2019, there were 38,606 shares of Series A Stock outstanding, which represents approximately 1% of the aggregate number of shares of Series A Stock issued to all holders on the original issue date.

In accordance with the Series A Stock Certificate of Designations, following the conversion of 85% of the aggregate number of shares of Series A Stock issued to all holders on the original issue date, the full ratchet price-based anti-dilution protection in the event of a down-round financing at a price per share below the conversion price of the Series A Stock is no longer in effect for the remaining shares.

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, 2019, there were 6,741,860 shares of common stock issued and outstanding.

Warrants

As of September 30, 2019, the Company has 10,521,195 warrants outstanding. The following table summarizes the Company's warrant activity for the nine months ended September 30, 2019.

	Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2018	**10,690,718**	**$ 2.45**
Exercised	(50,000)	1.93
Forfeited	(119,523)	46.96
Outstanding at September 30, 2019	**10,521,195**	**$ 1.95**

On March 14, 2019, the Company received $96,500 and issued 50,000 shares of common stock upon the exercise of its outstanding Series 1 Warrants.

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. On June 13, 2019, the Company's stockholders approved an amendment to the 2016 Plan which increased the number of shares of common stock authorized for issuance under the 2016 Plan to a total of 750,000 shares, up from 150,000 previously authorized.

The following table summarizes the shares available for grant under the 2016 Plan for the nine months ended September 30, 2019:

	Shares Available for Grant
Balances, at December 31, 2018	100,000
Additional shares reserved	600,000
Options granted	(2,500)
Balances, at September 30, 2019	697,500

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, 2019:

	Outstanding Options	
	Number of Shares	Weighted Average Exercise Price
Balances at December 31, 2018	50,000	$ 6.10
Options granted	2,500	$ 1.72
Balances at September 30, 2019	52,500	$ 5.89

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 option grants of $16,279 and $29,732 for the three months ended September 30, 2019 and 2018, and $62,018 and $59,463 for the nine months ended September 30, 2019 and 2018, respectively.

As of September 30, 2019, there were unrecognized compensation costs of approximately $90,331 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 1.71 years.

The Company used the following assumptions to estimate the fair value of options granted under the 2016 Plan for the nine months ended September 30, 2019 and 2018:

	For the nine months ended September 30,	
	2019	2018
Risk-free interest rate (weighted average)	2.39%	2.85%
Expected volatility (weighted average)	106.74%	102.38%
Expected term (in years)	7	7
Expected dividend yield	0.00%	0.00%

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

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

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

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

Forfeitures Stock compensation expense recognized in the statements of operations for the nine months ended September 30, 2019 and 2018 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.

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 could grant stock options, restricted stock, stock appreciation rights and new shares of common stock upon exercise of stock options. On March 13, 2014, the Company's stockholders approved an amendment to the 1999 Plan which increased the number of shares of common stock authorized for issuance under the 1999 Plan to a total of 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 either ISOs or NSOs. ISOs could be granted only to employees. NSOs could be granted to employees, consultants and directors. Stock options under the 1999 Plan could be granted with a term of up to ten years and at prices no less than fair market value for ISOs and no less than 85% of the fair market value for NSOs. Stock options granted generally vest over one to six years.

The following table summarizes the outstanding stock options under the 1999 Plan for the nine months ended September 30, 2019:

	Outstanding Options	
	Number of Shares	Weighted Average Exercise Price
Balances at December 31, 2018	191,735	$ 93.72
Options cancelled	(21)	$ 2,136.00
Balances at September 30, 2019	191,714	$ 93.50

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 $24,486 and $62,564 for the three months ended September 30, 2019 and 2018, and $80,708 and $196,499 for the nine months ended September 30, 2019 and 2018, respectively.

As of September 30, 2019, there were unrecognized compensation costs of approximately $53,933 related to non-vested stock option awards that will be recognized on a straight-line basis over the weighted average remaining vesting period of 0.81 years. Additionally, there were unrecognized compensation costs of approximately $5.9 million related to non-vested stock option awards subject to performance-based vesting milestones with a weighted average remaining life of 0.51 years. As of September 30, 2019, none of these milestones have been achieved.

Restricted Stock Grants

The following table summarizes the restricted stock activity under the 1999 Plan for the nine months ended September 30, 2019.

	Outstanding Restricted Stock Grants	
	Number of Shares	Weighted Average Grant Date Fair Value
Balances, at December 31, 2018	19,914	$ 6.29
Restricted stock vested	(12,195)	$ 6.28
Restricted stock cancelled	(7,719)	$ 6.27
Balances, at September 30, 2019	-	$ -

The Company did not record compensation expense for these restricted stock grants for the nine months ended September 30, 2019.

As of September 30, 2019, there was no unrecognized compensation costs related to 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 relationship with Orion, 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, 2018.

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

Overview

Strategy

We are a specialty pharmaceutical company focused on identifying, developing and commercializing products that address cardiovascular and pulmonary diseases of high unmet medical need. 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.

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 conducting a Phase 2 clinical trial of 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, >7mmHg. 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 agreed 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 initiated the first of our 15 active clinical sites in November 2018, and, as of November 11, 2019, we have enrolled 17 of the trial's 36 patients.

Third Quarter 2019 Highlights

The following summarizes certain key financial measures for the three months ended September 30, 2019:

- Cash and cash equivalents, including the fair-value of our marketable securities, were $7.1 million at September 30, 2019.
- Our net loss from operations was $2.3 million for the third quarter of fiscal 2019 compared to $1.6 million for the three months ended September 30, 2018.
- Net cash used in operating activities was $1.8 million and $1.6 million for the three months ended September 30, 2019 and 2018, respectively.

Opportunities and Trends

We initiated the Phase 2 trial for levosimendan and activated the initial site in the fourth quarter of 2018. The trial is a multi-center, double-blind placebo-controlled study and is currently being conducted in 15 targeted major medical centers in North America. The trial is enrolling pulmonary hypertension patients with heart failure and preserved ejection fractions. We enrolled our first patient on March 11, 2019, and we anticipate enrollment will continue through the end of 2019. As of November 11, 2019, we have enrolled 17 of the trial's 36 patients.

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

During the remainder of calendar year 2019, 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 our product candidate in the United States; and
- Identifying products or product candidates for potential acquisitions.

Financial Overview

Results of Operations- Comparison of the Three Months Ended September 30, 2019 and 2018

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, 2019 and 2018, respectively, are as follows:

	Three months ended September 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2019	2018		
Personnel costs	$ 610,640	$ 719,870	$ (109,230)	(15)%
Legal and professional fees	546,607	289,893	256,714	89%
Other costs	147,489	146,094	1,395	1%
Facilities	38,693	35,720	2,973	8%

Personnel costs:

Personnel costs decreased approximately $109,000 for the three months ended September 30, 2019 compared to the same period in the prior year. This decrease was due primarily to a reduction of approximately $111,000 for the vested value of share-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, recruiting costs, consulting fees and investor relations services, as well as fees paid to our Board of Directors. Legal and professional fees increased approximately $257,000 for the three months ended September 30, 2019 compared to the same period in the prior year. This increase was due primarily to increases in costs incurred for legal fees and investor relations services.

- Legal fees increased approximately $236,000 in the current period. This increase was due primarily to costs incurred for arbitration and fees associated with the filing of patents for subcutaneous delivery of levosimendan in the current period that were not incurred in the prior year.
- Investor relations costs increased approximately $36,000 in the current period. This increase was primarily due to fees paid to a third-party investor relations firm in the current period that was not engaged during the same period in the prior year as well as fees paid for communication and shareholder outreach efforts in the current period that were not incurred in the same period in the prior year.

Other costs:

Other costs include costs incurred for franchise and other taxes, travel, supplies, insurance, depreciation and other miscellaneous charges. Other costs remained relatively consistent for the three months ended September 30, 2019 and 2018.

Facilities:

Facilities expenses include costs paid for rent and utilities at our corporate headquarters in North Carolina. Facilities costs remained relatively consistent for the three months ended September 30, 2019 and 2018.

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) facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, depreciation of leasehold improvements, equipment, laboratory and other supplies. All research and development expenses are expensed as incurred. Research and development expenses and percentage changes for the three months ended September 30, 2019 and 2018, respectively, are as follows:

	Three months ended September 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2019	2018		
Clinical and preclinical development	$ 846,895	$ 310,158	$ 536,737	173%
Personnel costs	52,235	48,329	3,906	8%
Other costs	9,154	1,241	7,913	638%
Consulting	8,700	2,900	5,800	200%

Clinical and preclinical development:

Clinical and preclinical development costs include, primarily, the costs associated with our Phase 2 HELP clinical trial for levosimendan, which was initiated during fiscal year 2018. The increase of approximately $537,000 in clinical and preclinical development costs for the three months ended September 30, 2019 compared to the same period in the prior year was primarily due to an increase of approximately $127,000 in expenditures for CRO costs and CRAs to manage the Phase 2 HELP clinical trial, as well as an increase of approximately $441,000 in the direct costs associated with clinical site activations and enrolled patient costs, partially offset by a reduction of approximately $36,000 in nonclinical development costs for levosimendan subcutaneous formulation in the current period.

Personnel costs:

Personnel costs remained relatively consistent for the three months ended September 30, 2019 and 2018.

Other costs:

Other costs remained relatively consistent for the three months ended September 30, 2019 and 2018.

Consulting fees:

Consulting fees remained relatively consistent for the three months ended September 30, 2019 and 2018.

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, 2019 and 2018, respectively, is as follows:

	Three months ended September 30,		(Increase)/ Decrease
	2019	2018	
Other income, net	$ (36,709)	$ (18,224)	$ (18,485)

Other income increased approximately $18,000 for the three months ended September 30, 2019 compared to the same period in the prior year. This increase is due primarily to an increase in the interest earned on our investment in marketable securities.

During the three months ended September 30, 2019, we recorded interest income of approximately $37,000 from our investments in marketable securities. This income is derived from approximately $35,000 in bond interest paid and approximately $1,500 in fair-value adjustments measured for the period, which compares to approximately $20,000 in bond interest paid, partially offset by approximately $3,000 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, 2019 and 2018

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 nine months ended September 30, 2019 and 2018, respectively, are as follows:

	Nine months ended September 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2019	2018		
Personnel costs	$ 1,956,465	$ 2,311,185	$ (354,720)	(15)%
Legal and professional fees	1,192,499	1,134,868	57,631	5%
Other costs	427,898	378,796	49,102	13%
Facilities	115,981	108,919	7,062	6%

Personnel costs:

Personnel costs decreased approximately $355,000 for the nine months ended September 30, 2019 compared to the same period in the prior year. This decrease was due primarily to a reduction of approximately $250,000 in bonuses paid in the prior year that were not incurred in the current period as well as a reduction of approximately $294,000 for the vested value of share based compensation in the current period as compared to the same period in the prior year, partially offset by an increase of approximately $190,000 in salaries and benefits paid due primarily to the salary of the CEO not incurred in the prior year.

Legal and professional fees:

Legal and professional fees consist of the costs incurred for legal fees, accounting fees, recruiting costs, consulting fees and investor relations services, as well as fees paid to our Board of Directors. Legal and professional fees increased approximately $58,000 for the nine months ended September 30, 2019 compared to the same period in the prior year. This increase was due primarily to increases in costs incurred for legal fees and investor relations services, partially offset by a reduction in consulting costs, accounting fees, and Board of Directors costs.

- Legal fees increased approximately $151,000 in the current nine-month period. This increase was due primarily to approximately $201,000 in costs incurred for arbitration in the current nine-month period that were not incurred in the same period in the prior year, partially offset by a reduction in fees paid for filings associated with our Special Meeting of Stockholders in the prior year that were not incurred in the current period.
- Investor relations costs increased approximately $135,000 in the current nine-month period. This increase was primarily due to fees paid to a third-party investor relations firm in the current nine-month period that was not engaged during the same period in the prior year as well as fees paid for communication and shareholder outreach efforts in the current period.
- Accounting fees decreased approximately $22,000 in the current nine-month period. This decrease was due primarily to the costs incurred for the filings associated with our Special Meeting of Stockholders in the same period in the prior year that were not incurred in the current period.
- Consulting costs decreased approximately $83,000 in the current nine-month period. This decrease was due primarily to recruiting costs of approximately $28,000, approximately $39,000 in costs associated with market research and approximately $18,000 in payments to our scientific advisory board members in the same period in the prior year which were not incurred in the current period.
- Capital market expenses decreased approximately $91,000 in the current nine-month period. This decrease was due primarily to the Special Meeting of Shareholders and the costs associated with the proxy solicitation services in the same period in the prior year that were not incurred in the current period.
- Board of Directors fees decreased in the current nine-month period by approximately $31,000. This decrease was due primarily the transition of a director to CEO and a reduction in the recognized expense for the vesting of outstanding stock options in the current period as compared to the same period of the prior year.

Other costs:

Other costs include costs incurred for franchise and other taxes, travel, supplies, insurance, depreciation and other miscellaneous charges. The approximately $49,000 increase in other costs for the nine months ended September 30, 2019 compared to the same period in the prior year was due primarily to an increase of $120,000 in franchise taxes paid partially offset by decreases of approximately $24,000 in travel costs, approximately $30,000 in relocation costs and approximately $18,000 for bank fees 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 costs remained relatively consistent for the nine months ended September 30, 2019 and 2018.

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) facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, depreciation of leasehold improvements, equipment, laboratory and other supplies. All research and development expenses are expensed as incurred. Research and development expenses and percentage changes for the nine months ended September 30, 2019 and 2018, respectively, are as follows:

	Nine months ended September 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2019	2018		
Clinical and preclinical development	$ 1,858,034	$ 594,000	$ 1,264,034	213%
Personnel costs	162,723	122,340	40,383	33%
Other costs	15,447	6,034	9,413	156%
Consulting	12,800	9,991	2,809	28%

Clinical and preclinical development:

Clinical and preclinical development costs include, primarily, the costs associated with our Phase 2 HELP clinical trial for levosimendan, which was initiated during fiscal year 2018. The increase of approximately $1.3 million in clinical and preclinical development costs for the nine months ended September 30, 2019 compared to the same period in the prior year was primarily due to an increase of approximately $490,000 in expenditures for CRO costs and CRAs to manage the Phase 2 HELP clinical trial, as well as an increase of approximately $801,000 in the direct costs associated with clinical site activations and enrolled patient costs.

Personnel costs:

Personnel costs increased approximately $40,000 for the nine months ended September 30, 2019 compared to the same period in the prior year, primarily due to an increase 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, 2019 and 2018.

Consulting fees:

Consulting fees remained relatively consistent for the nine months ended September 30, 2019 and 2018.

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 nine months ended September 30, 2019 and 2018, respectively, is as follows:

	Nine months ended September 30,		(Increase)/ Decrease
	2019	2018	
Other income, net	$ (139,161)	$ (69,623)	$ (69,538)

Other income increased approximately $70,000 for the nine months ended September 30, 2019 compared to the same period in the prior year. This increase is due primarily to an increase in the interest earned on our investment in marketable securities.

During the nine months ended September 30, 2019, we recorded interest income of approximately $124,000 from our investments in marketable securities. This income is derived from approximately $122,000 in bond interest paid and approximately $2,000 in fair-value adjustments for the period, which compares to approximately $150,000 in bond interest paid, partially offset by approximately $83,000 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, 2019 we had an accumulated deficit of approximately $233 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 $7,561,930 and $13,320,240 and working capital of $6,432,895 and $11,754,571 as of September 30, 2019 and December 31, 2018, respectively. Based on our working capital and the value of our investments in marketable securities at September 30, 2019, we believe we have sufficient capital to fund our operations through the first quarter of calendar year 2020.

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, 2019 and 2018:

	Nine months ended September 30,	
	2019	**2018**
Net cash used in operating activities	$ (5,829,920)	$ (4,301,820)
Net cash provided by investing activities	15,096	6,044,193
Net cash provided by financing activities	96,500	-

Net cash used in operating activities. Net cash used in operating activities was approximately $5.8 million for the nine months ended September 30, 2019 compared to net cash used in operating activities of approximately $4.3 million for the nine months ended September 30, 2018. The increase in cash used for operating activities was due primarily to an increase in our accrued costs related to the Phase 2 clinical trial for levosimendan in the current period.

Net cash (used in) provided by investing activities. Net cash provided by investing activities was approximately $15,000 for the nine months ended September 30, 2019 compared to approximately $6 million provided for the nine months ended September 30, 2018. The decrease in cash provided by investing activities was primarily due to a decrease in the sale of marketable securities in the current period.

Net cash provided by financing activities. Net cash provided by financing activities was approximately $97,000 for the nine months ended September 30, 2019 compared to $0 for the nine months ended September 30, 2018. The increase in cash provided by financing activities was due to an exercise of warrants 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 2020. 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, 2018. During the nine months ended September 30, 2019, there were no material changes to the critical accounting policies previously disclosed in that report.

Recent Accounting Pronouncements

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 February 2016, the FASB issued an accounting standard intended to improve financial reporting regarding leasing transactions. The standard requires us to recognize on our balance sheet the assets and liabilities for the rights and obligations created by all leased assets. The standard also requires 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 was effective for financial statements beginning after December 15, 2018, and interim periods within those annual periods. Early adoption was permitted.

We adopted this standard on January 1, 2019, using the required modified-retrospective approach as of the effective date. We elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allows us to carryforward the historical lease classification. We made an accounting policy election to account for leases with an initial term of 12 months or less similar to previous guidance for operating leases, under which we recognize those lease payments in the consolidated statements of operations and comprehensive loss on a straight-line basis over the lease term. Results for the year ended December 31, 2018 continue to be reported in accordance with historical accounting under previous lease guidance, ASC Topic 840: Leases (Topic 840).

We recorded a net reduction of $27,670 to opening accumulated deficit as of January 1, 2019, due to the cumulative impact of adopting the new leasing standard, with the impact relating to a change in the classification of our office space. The adoption of the lease standard did not have a material impact on our condensed consolidated balance sheets.

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, 2018.

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 Interim Chief Executive Officer and Chief Financial Officer, conducted an evaluation as of the end of the period covered by this report, of the effectiveness of our disclosure controls and procedures as defined in Exchange Act Rule 13a-15(e) and 15d-15(e). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2019, 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 have 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, 2018 and the Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2019.

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

SIGNATURES

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

TENAX THERAPEUTICS, INC.

Date: November 14, 2019

By: Michael B. Jebsen
Michael B. Jebsen
President and Chief Financial Officer
(On behalf of the Registrant and as Principal Financial Officer)

Exhibit 31.1

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, 2019

/s/ Anthony DiTonno
Anthony DiTonno
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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, 2019

/s/ Michael B. Jebsen

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

Exhibit 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

In connection with the Quarterly Report of Tenax Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2019 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, 2019

/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.

Exhibit 32.2

CERTIFICATION OF INTERIM CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Tenax Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2019 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, 2019

/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.