SECURITIES & EXCHANGE COMMISSION EDGAR FILING

TENAX THERAPEUTICS, INC.

Form: 10-Q

Date Filed: 2020-11-16

Corporate Issuer CIK: 34956

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE QUARTERLY PERIOD ENDED September 30, 2020

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 12, 2020, the registrant had outstanding 12,619,369 shares of Common Stock.

TABLE OF CONTENTS

PART I - FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

TENAX THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2020	December 31, 2019
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	$ 8,235,532	$ 4,905,993
Marketable securities	472,648	493,884
Prepaid expenses	189,275	780,952
Total current assets	8,897,455	6,180,829
Right of use asset	87,285	169,448
Property and equipment, net	3,461	6,559
Other assets	8,435	8,435
Total assets	$ 8,996,636	$ 6,365,271
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,052,824	$ 1,661,054
Accrued liabilities	295,451	871,341
Note payable	30,900	-
Total current liabilities	1,379,175	2,532,395
Long term liabilities		
Note payable	213,757	-
Lease liability	-	60,379
Total long term liabilities	213,757	60,379
Total liabilities	1,592,932	2,592,774
Commitments and contingencies; see Note 7		
Stockholders' equity		
Preferred stock, undesignated, authorized 9,999,790 shares; See Note 8		
Series A Preferred stock, par value $.0001, issued and outstanding 210 and 38,606, respectively	-	4
Common stock, par value $.0001 per share; authorized 400,000,000 shares; issued and outstanding 12,619,369 and 6,741,860, respectively	1,262	674
Additional paid-in capital	250,591,604	239,939,797
Accumulated other comprehensive gain	903	458
Accumulated deficit	(243,190,065)	(236,168,436)
Total stockholders' equity	7,403,704	3,772,497
Total liabilities and stockholders' equity	$ 8,996,636	$ 6,365,271

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,	
	2020	2019	2020	2019
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Operating expenses				
General and administrative	$ 1,172,725	$ 1,343,429	$ 3,364,890	$ 3,692,843
Research and development	1,052,398	916,984	3,669,761	2,049,004
Total operating expenses	2,225,123	2,260,413	7,034,651	5,741,847
Net operating loss	2,225,123	2,260,413	7,034,651	5,741,847
Interest expense	610	-	1,016	-
Other income, net	(5,298)	(36,709)	(14,038)	(139,161)
Net loss	$ 2,220,435	$ 2,223,704	$ 7,021,629	$ 5,602,686
Unrealized loss (gain) on marketable securities	1,171	960	(445)	(803)
Total comprehensive loss	$ 2,221,606	$ 2,224,664	$ 7,021,184	$ 5,601,883
Net loss per share, basic and diluted	$ (0.18)	$ (0.33)	$ (0.73)	$ (0.93)
Weighted average number of common shares outstanding, basic and diluted	12,427,355	6,741,084	9,590,741	6,011,304

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, 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 loss 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**
Balance at December 31, 2019	**38,606**	**$ 4**	**6,741,860**	**$ 674**	**$ 239,939,797**	**$ 458**	**$ (236,168,436)**	**$ 3,772,497**
Common stock and pre-funded warrants sold, net of offering costs			750,000	75	2,129,930			2,130,005
Compensation on options issued				-	72,376			72,376
Common stock issued for services rendered			77,987	8	99,992			100,000
Common stock issued for convertible preferred stock	(38,396)	(4)	38,396	4	-			-
Exercise of pre-funded warrants			400,000	40	-			40
Unrealized loss on marketable securities						(1,622)		(1,622)
Net loss							(2,654,644)	(2,654,644)
Balance at March 31, 2020	**210**	**$ -**	**8,008,243**	**$ 801**	**$ 242,242,095**	**$ (1,164)**	**$ (238,823,080)**	**$ 3,418,652**

	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
Compensation on options issued				-	63,166			63,166
Exercise of pre-funded warrants			1,210,313	121	-			121
Exercise of warrants			877,202	88	1,690,455			1,690,543
Unrealized gain on marketable securities						3,238		3,238
Net loss							(2,146,550)	(2,146,550)
Balance at June 30, 2020	**210**	**$ -**	**10,095,758**	**$ 1,010**	**$ 243,995,716**	**$ 2,074**	**$ (240,969,630)**	**$ 3,029,170**
Common stock and pre-funded warrants sold, net of offering costs			2,523,611	252	6,532,727			6,532,979
Compensation on options issued				-	63,161			63,161
Unrealized loss on marketable securities						(1,171)		(1,171)
Net loss							(2,220,435)	(2,220,435)
Balance at September 30, 2020	**210**	**$ -**	**12,619,369**	**$ 1,262**	**$ 250,591,604**	**$ 903**	**$ (243,190,065)**	**$ 7,403,704**

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,	
	2020	2019
	(Unaudited)	(Unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (7,021,629)	$ (5,602,686)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	3,098	3,709
Interest on debt instrument	1,016	-
Amortization of right of use asset	82,163	75,942
Loss on disposal of property and equipment	-	522
Issuance and vesting of compensatory stock options and warrants	198,703	142,726
Issuance of common stock for services rendered	75,000	66,667
Amortization of premium on marketable securities	5,078	(1,778)
Changes in operating assets and liabilities		
Accounts receivable, prepaid expenses and other assets	616,676	57,230
Accounts payable and accrued liabilities	(1,185,136)	(498,145)
Long term portion of lease liability	(60,379)	(74,107)
Net cash used in operating activities	(7,285,410)	(5,829,920)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of marketable securities	(458,438)	(436,356)
Sale of marketable securities	475,041	455,026
Purchase of property and equipment	-	(3,574)
Net cash provided by investing activities	16,603	15,096
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common stock and pre-funded warrants, net of issuance costs	8,662,985	-
Proceeds from the exercise of warrants	1,690,704	96,500
Proceeds from the issuance of notes payable	244,657	-
Net cash provided by financing activities	10,598,346	96,500
Net change in cash and cash equivalents	3,329,539	(5,718,324)
Cash and cash equivalents, beginning of period	4,905,993	12,367,321
Cash and cash equivalents, end of period	$ 8,235,532	$ 6,648,997

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

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 7 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 on December 31, 2019 has been derived from the Company's audited consolidated financial statements included in its Annual Report on Form 10-K for the year ended December 31, 2019. 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, 2020 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 year ended December 31, 2019.

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 $243 million on September 30, 2020 and $236 million on December 31, 2019 and used cash in operations of $7.3 million and $5.8 million during the nine months ended September 30, 2020 and 2019, 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, 2020 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

On September 30, 2020, the Company had cash and cash equivalents, including the fair value of its marketable securities, of approximately $8.7 million. The Company used $7.3 million of cash for operating activities during the nine months ended September 30, 2020 and had stockholders' equity of $7.4 million, versus $3.8 million on December 31, 2019.

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, 2020, the Company believes that it has sufficient capital to fund its planned operations through the third quarter of calendar year 2021. 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 .

COVID-19 Impact and Related Risks

The continued spread of COVID-19 globally could adversely affect the Company's ability to retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. Further, some of these investigators and site staff may be unable to comply with clinical trial protocols if quarantines or travel restrictions impede movement or interrupt healthcare services, or if they become infected with COVID-19 themselves, which would delay the Company's ability to initiate and/or complete planned clinical and preclinical studies in the future.

The full extent to which the COVID-19 pandemic and the various responses to it might impact the Company's business, operations and financial results will depend on numerous evolving factors that are not subject to accurate prediction and that are beyond the Company's control.

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, convertible preferred shares and warrants.

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

	Nine months ended September 30,	
	2020	2019
Warrants to purchase common stock	26,213,228	10,521,195
Options to purchase common stock	451,186	244,214
Convertible preferred shares outstanding	210	38,606

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 condensed consolidated balance sheets. 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.

Recent Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board ("FASB") issued an accounting standard intended to simplify accounting for income taxes. It removes certain exceptions to the general principles in Topic 740, Income Taxes and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020 and early adoption is permitted. The Company is currently evaluating this standard, but it does not believe the adoption of the new guidance will have a material impact on its consolidated financial statements.

In June 2016, the FASB issued an accounting standard that amends how credit losses are measured and reported for certain financial instruments that are not accounted for at fair value through net income. This standard requires that credit losses be presented as an allowance rather than as a write-down for available-for-sale debt securities and will be effective for interim and annual reporting periods beginning January 1, 2023, with early adoption permitted. A modified retrospective approach is to be used for certain parts of this guidance, while other parts of the guidance are to be applied using a prospective approach. The Company does not believe the adoption of this standard will have a material impact on its consolidated financial statements and related disclosures.

NOTE 3. FAIR VALUE

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

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

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

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

Investments in Marketable Securities

The Company classifies all of its investments as available-for-sale. Unrealized gains and losses on investments are recognized in comprehensive income/(loss), unless an unrealized loss is considered to be other than temporary, in which case the unrealized loss is charged to operations. The Company periodically reviews its investments for other than temporary declines in fair value below cost basis and whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company believes the individual unrealized losses represent temporary declines primarily resulting from interest rate changes. Realized gains and losses are reflected in other income in the condensed consolidated statements of comprehensive loss and are determined using the specific identification method with transactions recorded on a settlement date basis. Investments with original maturities at date of purchase beyond three months and which mature at or less than 12 months from the balance sheet date are classified as current. Investments with a maturity beyond 12 months from the balance sheet date are classified as long-term. As of September 30, 2020, 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, 2020				
	Amortized Cost	Accrued Interest	Gross Unrealized Gains	Gross Unrealized losses	Estimated Fair Value
Corporate debt securities	$ 469,409	$ 3,239	$ 993	$ (94)	$ 473,547
Total investments	$ 469,409	$ 3,239	$ 993	$ (94)	$ 473,547

All of the Company’s investments have scheduled maturities of less than one year as of September 30, 2020 and December 31, 2019.

The following tables summarize information regarding assets and liabilities measured at fair value on a recurring basis as of September 30, 2020 and December 31, 2019:

		Fair Value Measurements at Reporting Date Using		
	Balance as of September 30, 2020	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	$ 8,235,532	$ 8,235,532	$ -	$ -
Marketable securities	$ 472,648	$ -	$ 472,648	$ -

	Balance as of December 31, 2019	Fair Value Measurements at Reporting Date Using		
		Quoted prices in Active Markets for Identical Securities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Current Assets				
Cash and cash equivalents	$ 4,905,993	$ 4,905,993	$ -	$ -
Marketable securities	$ 493,884	$ -	$ 493,884	$ -

There were no significant transfers between levels in the nine months ended September 30, 2020.

NOTE 4. BALANCE SHEET COMPONENTS

Property and equipment, net

Property and equipment consist of the following as of September 30, 2020 and December 31, 2019:

	September 30, 2020	December 31, 2019
Office furniture and fixtures	$ 43,034	$ 130,192
Computer equipment and software	19,816	80,669
	62,850	210,861
Less: Accumulated depreciation	(59,389)	(204,302)
	$ 3,461	$ 6,559

Depreciation expense was approximately $900 and $1,300 for the three months ended September 30, 2020 and 2019, and approximately $3,100 and $3,700 for the nine months ended September 30, 2020 and 2019, respectively.

Accrued liabilities

Accrued liabilities consist of the following as of September 30, 2020 and December 31, 2019:

	September 30, 2020	December 31, 2019
Employee related	$ 105,337	$ 333,873
Operating costs	100,932	426,115
Lease liability	89,182	111,353
	$ 295,451	$ 871,341

NOTE 5. LEASE

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 June 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 the 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, 2020	December 31, 2019
Current portion included in accrued liabilities	$ 89,182	$ 111,353
Long term lease liability	-	60,379
	$ 89,182	$ 171,732

As of September 30, 2020, the maturities of our operating lease liabilities were as follows:

Year ending December 31,	
2020	$ 30,395
2021	61,803
Total lease payments	$ 92,198
Less: Imputed interest	(3,016)
Operating lease liability	$ 89,182

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, 2020, the remaining Lease term is 1 year and the discount rate used to determine the operating lease liability was 8.0%. For the nine months ending September 30, 2020, the Company paid $95,854 in total lease expenses, including $5,553 for common area maintenance charges.

NOTE 6. NOTE PAYABLE

Payroll Protection Program Loan

On April 30, 2020, the Company received a loan pursuant to the Paycheck Protection Program (the "PPP Loan") under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), as administered by the U.S. Small Business Administration. The PPP Loan in the principal amount of $244,657 was disbursed by First Horizon Bank (the "Lender") pursuant to a promissory note issued by us (the "Note").

The PPP Loan has a two-year term and bears interest at a rate of 1.00% per annum. Monthly principal and interest payments are deferred for sixteen months. Beginning September 30, 2021, the Company is required to make monthly payments of principal and interest of approximately $31,100 to the Lender. The Company did not provide any collateral or guarantees for the PPP Loan, nor did the Company pay any facility charge to obtain the PPP Loan. The Note provides for customary events of default, including, among others, those relating to failure to make payment, bankruptcy, breaches of representations, and material adverse effects. The Company may prepay the principal of the PPP Loan at any time, subject to certain notice requirements.

Under the terms of the CARES Act, Paycheck Protection Program loan recipients can apply for and be granted forgiveness for all or a portion of a loan granted under the program. Such forgiveness will be determined, subject to limitations, based on the use of loan proceeds for payment of payroll costs and any payments of mortgage interest, rent, and utilities. The Company is using the proceeds from the PPP Loan to fund payroll costs in accordance with the relevant terms and conditions of the CARES Act. However, no assurance is provided that forgiveness for any portion of the PPP Loan will be obtained.

As of September 30, 2020, the current and long-term portions of the PPP Loan were $30,900 and $213,757, respectively.

NOTE 7. COMMITMENTS AND CONTINGENCIES

Simdax license agreement

On November 13, 2013, the Company acquired, through its wholly owned subsidiary, Life Newco, that certain License Agreement (the “License”), dated September 20, 2013 by and between Phyxius and Orion Corporation, a global healthcare company incorporated under the laws of Finland (“Orion”), and that certain Side Letter, dated October 15, 2013 by and between Phyxius and Orion. The License grants the Company an exclusive, sublicenseable right to develop and commercialize pharmaceutical products containing levosimendan (the “Product”) in the United States and Canada (the “Territory”) from Orion. Pursuant to the License, the Company must use Orion’s “Simdax®” trademark to commercialize the Product. The License also grants to the Company a right of first refusal to commercialize new developments of the Product, including developments as to the formulation, presentation, means of delivery, route of administration, dosage or indication, 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: (1) $2.0 million upon the grant of United States Food and Drug Administration approval, including all registrations, licenses, authorizations and necessary approvals, to develop and/or commercialize the Product in the United States; and (2) $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, 2020, the Company has not met any of the developmental milestones and, accordingly, has not recorded any liability for the contingent payments due to Orion.

On July 3, 2019, Orion filed a request for arbitration against the Company under the Arbitration Rules of the Arbitration Institute of the Stockholm Chamber of Commerce 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 submitted its response to the request for arbitration on July 31, 2019 and rejected Orion’s position that the oral formation was not a line extension product under the License and requested Orion reimburse the Company for all legal fees associated with the arbitration. The hearing on this matter was held before the arbitral tribunal on April 7 and April 8, 2020. The Final Award was issued May 21, 2020 and held in favor of the Company. The tribunal determined that oral levosimendan was a line extension product under the License and ordered Orion to reimburse the Company approximately $358,000 for its direct arbitration costs, including legal fees incurred.

NOTE 8. 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 (1) one share of the Company's Series A convertible preferred stock, par value $0.0001 per share (the "Series A Stock"), (2) a two-year warrant to purchase one share of common stock at an exercise price of $1.93 (the "Series 1 Warrants"), and (3) 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, 2019.

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. The Company will not effect 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.

As of December 31, 2019, there were 38,606 shares of Series A Stock outstanding. During the nine months ended September 30, 2020; an additional 38,396 shares of Series A Stock were converted into 38,396 shares of common stock. As of September 30, 2020, there were 210 shares of Series A Stock outstanding.

Common Stock

The Company's Certificate of Incorporation authorizes it to issue 400,000,000 shares of $0.0001 par value common stock. As of September 30, 2020, and December 31, 2019, there were 12,619,369 and 6,741,860 shares of common stock issued and outstanding, respectively.

On March 13, 2020, the Company completed a registered direct offering to a single healthcare-focused institutional investor (the "Investor") for the issuance and sale of 750,000 shares of its common stock at a purchase price of $1.1651 per share and pre-funded warrants to purchase up to 1,610,313 shares of its common stock, at a purchase price of $1.1650 per pre-funded warrant (which represents the per share offering price for the common stock less $0.0001, the exercise price of each pre-funded warrant), for gross proceeds of approximately $2.75 million, priced at-the-market under Nasdaq rules. Additionally, in a concurrent private placement, the Company issued to the Investor unregistered warrants to purchase up to 2,360,313 shares of its common stock. The unregistered warrants have an exercise price of $1.04 per share and exercise period commencing immediately upon the issuance date and a term of five and one-half years. The net proceeds from the offerings, after deducting placement agent fees and other direct offering expenses were approximately $2.125 million. The fair value allocated to the common stock, pre-funded warrants and warrants was $0.5 million, $1.1 million and $1.1 million, respectively.

On July 8, 2020, the Company completed a registered direct offering with the Investor for the issuance and sale of 2,523,611 shares of its common stock at a purchase price of $1.0278 per share and pre-funded warrants to purchase up to 652,313 shares of its common stock, at a purchase price of $1.0277 per pre-funded warrant (which represents the per share offering price for the common stock less $0.0001, the exercise price of each pre-funded warrant). The Company issued in a concurrent private placement unregistered pre-funded warrants to purchase up to 4,607,692 shares of common stock at the same purchase price as the registered pre-funded warrants, and unregistered common stock warrants to purchase up to 7,783,616 shares of common stock for aggregate gross proceeds of approximately $8.0 million, priced at-the-market under Nasdaq rules. The unregistered warrants have an exercise price of $0.903 per share and exercise period commencing immediately upon the issuance date and a term of five and one-half years. The net proceeds from the offerings, after deducting placement agent fees and other direct offering expenses were approximately $6.5 million. The fair value allocated to the common stock, pre-funded warrants and warrants was $1.5 million, $3.0 million and $3.5 million, respectively.

During the nine months ended September 30, 2020, the Company issued 1,610,313 shares of common stock upon the exercise of pre-funded warrants. As of September 30, 2020, there were 5,260,005 pre-funded warrants outstanding.

Warrants

March 2020 Warrants

As part of the March 2020 registered direct offering, the Company issued unregistered warrants to purchase 2,360,313 shares of its common stock at an exercise price of $1.04 per share and contractual term of five and one-half years. The unregistered warrants were offered in a private placement under Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"), and Regulation D promulgated thereunder and, along with the shares of common stock underlying the warrants, have not been registered under the Securities Act, or applicable state securities laws. In accordance with ASC 480, these warrants are classified as equity and their relative fair value of approximately $1.1 million was recognized as additional paid in capital. The estimated fair value is determined using the Black-Scholes Option Pricing Model which is based on the value of the underlying common stock at the valuation measurement date, the remaining contractual term of the warrants, risk-free interest rates, expected dividends and expected volatility of the price of the underlying common stock.

July 2020 Warrants

As part of the July 2020 offering, the Company issued unregistered warrants to purchase 7,783,616 shares of its common stock at an exercise price of $0.903 per share and contractual term of five and one-half years. The unregistered warrants were offered in a private placement under Section 4(a)(2) of the Securities Act, and Regulation D promulgated thereunder and, along with the shares of common stock underlying the warrants, have not been registered under the Securities Act, or applicable state securities laws. In accordance with ASC 480, these warrants are classified as equity and their relative fair value of approximately $3.5 million was recognized as additional paid in capital. The estimated fair value is determined using the Black-Scholes Option Pricing Model which is based on the value of the underlying common stock at the valuation measurement date, the remaining contractual term of the warrants, risk-free interest rates, expected dividends and expected volatility of the price of the underlying common stock.

Warrants Issued for Services

In connection with the March 2020 offering described above, the Company issued designees of the placement agent warrants to purchase 177,023 shares of common stock at an exercise price of $1.4564 and a contractual term of five years. In accordance with ASC 815, these warrants are classified as equity and its estimated fair value of $66,201 was recognized as additional paid in capital. Additionally, the Company issued to its previous underwriter a warrant to purchase 94,413 shares of common stock at an exercise price of $1.4564 per share and contractual term of five years. In accordance with ASC 815, this warrant is classified as equity and its estimated fair-value of $35,308 was recognized as additional paid in capital. The estimated fair value is determined using the Black-Scholes Option Pricing Model which is based on the value of the underlying common stock at the valuation measurement date, the remaining contractual term of the warrant, risk-free interest rates, expected dividends and expected volatility of the price of the underlying common stock.

In connection with the July 2020 offering described above, the Company issued designees of the placement agent warrants to purchase 583,771 shares of common stock at an exercise price of $1.2848 and a contractual term of five years. In accordance with ASC 815, these warrants are classified as equity and its estimated fair value of $399,445 was recognized as additional paid in capital. Additionally, the Company issued to its previous underwriter a warrant to purchase 311,345 shares of common stock at an exercise price of $1.2848 per share and contractual term of five years. In accordance with ASC 815, this warrant is classified as equity and its estimated fair-value of $213,038 was recognized as additional paid in capital. The estimated fair value is determined using the Black-Scholes Option Pricing Model which is based on the value of the underlying common stock at the valuation measurement date, the remaining contractual term of the warrant, risk-free interest rates, expected dividends and expected volatility of the price of the underlying common stock.

On June 2, 2020, the Company received approximately $1.7 million and issued 877,202 shares of common stock upon the exercise of previously outstanding warrants issued in connection with the Company's December 2018 offering.

As of September 30, 2020, the Company has 20,953,223 warrants outstanding. The following table summarizes the Company's warrant activity for the nine months ended September 30, 2020:

	Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2019	**10,519,945**	**$ 1.94**
Issued	11,310,480	0.98
Exercised	(877,202)	1.93
Outstanding at September 30, 2020	**20,953,223**	**$ 1.42**

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, 2020:

	Shares Available for Grant
Balances, at December 31, 2019	697,500
Options granted	(341,000)
Balances, at September 30, 2020	356,500

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, 2020:

	Outstanding Options	
	Number of Shares	Weighted Average Exercise Price
Balances at December 31, 2019	52,500	$ 5.89
Options granted	341,000	$ 1.18
Balances at September 30, 2020	393,500	$ 1.81

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 $52,659 and $16,279 for the three months ended September 30, 2020 and 2019, and $165,492 and $62,018 for the nine months ended September 30, 2020 and 2019, respectively.

As of September 30, 2020, there were unrecognized compensation costs of approximately $211,257 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 1.39 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, 2020:

	For the nine months ended September 30,	
	2020	2019
Risk-free interest rate (weighted average)	1.02%	2.39%
Expected volatility (weighted average)	97.63%	106.74%
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, 2020 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, 2020:

	Outstanding Options	
	Number of Shares	Weighted Average Exercise Price
Balances at December 31, 2019	191,706	$ 93.40
Options cancelled	(134,020)	$ 113.42
Balances at September 30, 2020	57,686	$ 46.89

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 $10,502 and $24,486 for the three months ended September 30, 2020 and 2019, and $33,211 and $80,708 for the nine months ended September 30, 2020 and 2019, respectively.

As of September 30, 2020, there were unrecognized compensation costs of approximately $2,896 related to non-vested stock option awards under the 1999 Plan that will be recognized on a straight-line basis over the weighted average remaining vesting period of 0.31 years.

NOTE 9. SUBSEQUENT EVENTS

On October 9, 2020, the Company entered into an Amendment (the "Amendment") to the License between the Company and Orion to include two new oral products containing levosimendan, in capsule and solid dosage form, and a subcutaneously administered product containing levosimendan to the scope of the License, subject to specified limitations. The Amendment also amends the tiered royalty payments based on net sales of the Product in the Territory (each as defined in the License, as amended by the Amendment) made by the Company and its sublicensees. Pursuant to the Amendment, the term of the License has been extended until 10 years after the launch of the Product in the Territory, provided that the License will continue after the end of the term in each country in the Territory until the expiration of Orion's patent rights in the Product in such country. In the event that no regulatory approval for the Product has been granted in the United States on or before September 20, 2028, however, either party will have the right to terminate the License with immediate effect.

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 (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (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 Corporation ("Orion"), our ability to raise capital, the sufficiency of our cash resources, the impacts of the current COVID-19 pandemic and the eligibility for forgiveness of our loan (the "PPP Loan") received pursuant to the Paycheck Protection Program under the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), as administered by the U.S. Small Business Administration (the "SBA"). 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 ("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, 2019.

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

The description or discussion, in this Quarterly Report on Form 10-Q, of any contract or agreement is a summary only and is qualified in all respects by reference to the full text of the applicable contract or agreement.

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. ("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 (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 (PH-HFpEF). PH-HFpEF is defined hemodynamically by a pulmonary artery pressure (mPAP) ≥25 mmHg, a pulmonary capillary wedge pressure (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, (RV) afterload, and RV failure.

PH-HFpEF is a common form of pulmonary hypertension with an estimated U.S. 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 RV 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 ("FDA") to discuss development of levosimendan in PH-HFpEF patients. The FDA agreed with our planned Phase 2 design, patient entry criteria, and endpoints. It was agreed the study could 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. In October 2020, we met with the FDA for an End-of-Phase 2 Meeting to discuss the phase 2 clinical data and further development of levosimendan in PH-HFpEF patients. The FDA agreed that one or two Phase 3 clinical studies with a primary endpoint of change in six minute walk distance over 12 weeks or clinical worsening (death, hospitalization for heart failure, or decline in exercise capacity) over 24 weeks will be sufficient to demonstrate the effectiveness of levosimendan in PH-HFpEF. The FDA also agreed to a plan to replace weekly intravenous levosimendan dosing with daily oral levosimendan doses in a Phase 3 clinical study. The FDA has requested that we submit a Risk Evaluation and Mitigation Strategy (REMS) with the Phase 3 study outline to determine if a post approval REMS can be used in lieu of a larger safety database in PH-HFpEF patients. We anticipate submission of the REMS and Phase 3 study outline in the first quarter of 2021.

We initiated the first of our expected 10-12 HELP Study clinical sites in November 2018 and the first of 36 patients was enrolled in the HELP Study in March 2019. Enrollment in the HELP Study was completed in March 2020. The primary endpoint of the HELP Study is based on change in PCWP vs baseline compared to placebo. The HELP Study utilized a double-blind randomized design following five weekly infusions of levosimendan.

The HELP Study design was novel in several respects. To date, no other multi-center levosimendan study has evaluated levosimendan in heart failure patients with preserved ejection fraction (HFpEF) or PH-HFpEF patients. Instead, all previous levosimendan heart failure studies have enrolled heart failure patients with reduced ejection fraction (HFrEF), which specifically excluded HFpEF patients. Also, the HELP Study utilizes a unique 24-hour weekly infusion regimen of 0.075-0.1µm/kg/min. Finally, the HELP Study employs a unique home-based IV infusion administration via an ambulatory infusion pump. This home-based weekly IV administration is unlike all other chronic dosing studies of levosimendan that have typically employed a shorter duration and less frequent infusion regimen administered in a hospital setting. Despite the unique patient population, weekly dosing, and home-based administration, there have been no reported serious adverse events.

On June 2, 2020, we announced preliminary, top-line data from the study. The primary efficacy analysis, pulmonary capillary wedge pressure (PCWP) during exercise did not demonstrate a statistically significant reduction from baseline. Levosimendan did demonstrate a statistically significant reduction in PCWP compared to baseline ($p=<0.0017$) and placebo ($p=<0.0475$) when the measurements at rest, with legs up and on exercise were combined. Levosimendan also demonstrated a statistically significant improvement in 6-minute walk distance (6MWD) as compared to placebo ($p=0.0329$).

Hemodynamic Results

Hemodynamic measurements were made at rest (supine), after leg raise on a supine bicycle (a test of rapid increase in ventricular filling) and during exercise (25 watts for 3 minutes or until the patient tired). Levosimendan demonstrated a statistically significant reduction in PCWP compared to baseline ($p=<0.0017$) and placebo ($p=<0.0475$) when the measurements at rest, with legs up and on exercise were combined. While there was no significant change in PCWP during exercise, patients receiving levosimendan had reductions from baseline at Week 6 in PCWP, pulmonary artery pressure (PAP), and right atrial pressure (RAP) that were significant when patients were "at rest" and/or with their "legs raised" ($p<0.05$).

Clinical Results (6-Minute Walk Distance)

The clinical efficacy was confirmed by a statistically significant improvement in 6-minute walk distance of 29 meters. (p=0.0329). The 6-minute walk distance was a secondary endpoint in the trial and is a validated and accepted endpoint used in many pulmonary hypertension registration trials. Levosimendan was given in once-weekly home infusions for six weeks.

Safety

The incidence of adverse events (AEs) or serious adverse events (SAEs) between the control and treated groups were similar. In addition, there were no arrhythmias observed, atrial or ventricular, when comparing baseline electrocardiographic monitoring with 72-hour monitoring after five weeks of treatment.

The detailed results from the Phase 2 HELP Study of levosimendan in PH-HFpEF were presented at the Heart Failure Society of America (HFSA) Virtual Annual Scientific Meeting on October 3, 2020 and at the American Heart Association (AHA) Scientific Sessions 2020 on November 13, 2020. Additionally, we have submitted a full manuscript for publication in a peer-reviewed journal.

Third Quarter 2020 Highlights

The following summarizes certain key financial measures for the three months ended September 30, 2020:

- Cash and cash equivalents, including the fair-value of our marketable securities, were $8.7 million on September 30, 2020.
- Our net loss from operations was $2.2 million for the third quarter of fiscal 2020 compared to $2.3 million for the three months ended September 30, 2019.
- Net cash used in operating activities was $2.4 million and $1.8 million for the three months ended September 30, 2020 and 2019, respectively.

Opportunities and Trends

On October 9, 2020, we entered into an Amendment (the “Amendment”) to the License between the Company and Orion to include two new oral products containing levosimendan, in capsule and solid dosage form, and a subcutaneously administered product containing levosimendan to the scope of the License, subject to specified limitations. The Amendment also amends the tiered royalty payments based on net sales of the Product in the Territory (each as defined in the License, as amended by the Amendment) made by the Company and its sublicensees. Pursuant to the Amendment, the term of the License has been extended until 10 years after the launch of the Product in the Territory, provided that the License will continue after the end of the term in each country in the Territory until the expiration of Orion’s patent rights in the Product in such country. In the event that no regulatory approval for the Product has been granted in the United States on or before September 20, 2028, however, either party will have the right to terminate the License with immediate effect. We believe we will be able to conduct an upcoming phase 3 study in PH-HFpEF patients utilizing one of these oral formulations.

The continued spread of COVID-19 globally could adversely affect our ability to retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. Further, some of these investigators and site staff may be unable to comply with clinical trial protocols if quarantines or travel restrictions impede movement or interrupt healthcare services, or if they become infected with COVID-19 themselves, which would delay our ability to initiate and/or complete planned clinical and preclinical studies in the future. The full extent to which the COVID-19 pandemic and the various responses to it might impact the Company’s business, operations and financial results will depend on numerous evolving factors that are not subject to accurate prediction and that are beyond the Company’s control.

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 2020, we are focused on the following initiatives:

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

Financial Overview

Results of Operations- Comparison of the Three Months Ended September 30, 2020 and 2019

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, 2020 and 2019, respectively, are as follows:

	Three months ended September 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2020	2019		
Personnel costs	$ 682,907	$ 610,640	$ 72,267	12%
Legal and professional fees	292,625	546,607	(253,982)	(46)%
Other costs	159,327	147,489	11,838	8%
Facilities	37,866	38,693	(827)	(2)%

Personnel costs:

Personnel costs increased approximately $72,000 for the three months ended September 30, 2020 compared to the same period in the prior year. This increase was due primarily to an increase of approximately $23,000 for the recognized expense for vested employee stock options, an increase of approximately $50,000 in bonuses paid 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, capital market expenses, consulting fees and investor relations services, as well as fees paid to our Board of Directors. Legal and professional fees decreased approximately $254,000 for the three months ended September 30, 2020 compared to the same period in the prior year. This decrease was due primarily to a reduction of legal fees incurred for arbitration proceedings related to our license agreement for levosimendan and a decrease in costs incurred for investor relations services.

- Legal fees decreased approximately $216,000 in the current period. This decrease was due primarily to a decrease of approximately $205,000 in costs incurred for arbitration and a decrease of approximately $24,000 in cost associated with our intellectual property portfolio, partially offset by an increase of approximately $13,000 in legal fees associated with registration statements and other filings in the current period as compared to the same period in the prior year.
- Investor relations costs decreased approximately $49,000 in the current period. This decrease was primarily due to fees paid to a third-party investor relations firm for direct outreach and communications in the prior year that were not incurred in the current period as well as a decrease in fees paid for conferences and presentations in the current period as compared to 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 increased approximately $12,000 in the current period due primarily to an increase of approximately $43,000 in insurance premiums paid, partially offset by decreases of approximately $17,000 in travel costs and approximately $11,000 in taxes paid in the current period as compared to the same period of the prior year.

Facilities:

Facilities expenses include costs paid for rent and utilities at our corporate headquarters in North Carolina. Facilities costs remained relatively consistent for the three months ended September 30, 2020 and 2019.

Research and Development Expenses

Research and development expenses include, but are not limited to, (1) expenses incurred under agreements with clinical research organizations (CROs) and investigative sites, which conduct our clinical trials and a substantial portion of our pre-clinical studies; (2) the cost of supplying clinical trial materials; (3) payments to contract service organizations, as well as consultants; (4) employee-related expenses, which include salaries and benefits; and (5) 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, 2020 and 2019, respectively , are as follows:

	Three months ended September 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2020	2019		
Clinical and preclinical development	$ 989,159	$ 846,895	$ 142,264	17%
Personnel costs	58,402	52,235	6,167	12%
Other costs	4,837	17,854	(13,017)	(73)%

Clinical and preclinical development:

Clinical and preclinical development costs include, primarily, the costs associated with our Phase 2 HELP Study for levosimendan, which was initiated during fiscal year 2018. The last patient was enrolled into the trial during the first quarter of the current fiscal year. The increase of approximately $142,000 in clinical and preclinical development costs for the three months ended September 30, 2020 compared to the same period in the prior year was primarily due to an increase of approximately $587,000 in expenditures for CRO costs, partially offset by a reduction of approximately $403,000 in enrolled patient costs and a decrease of approximately $37,000 in fees paid for clinical research associates to manage the Phase 2 HELP Study and other direct trial costs in the current period as compared to the same period in the prior year.

Personnel costs:

Personnel costs increased approximately $6,000 for the three months ended September 30, 2020 due primarily to an overall increase in salaries paid in the current period as compared to the same period in the prior year.

Other costs:

Other costs decreased approximately $13,000 for the three months ended September 30, 2020 due primarily to reductions in costs incurred for travel and consulting fees paid in the current period as compared to the same period in the prior year.

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, net

Other income includes non-operating income not otherwise recorded in our condensed consolidated statement of comprehensive loss. These 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, 2020 and 2019, respectively, is as follows:

	Three months ended September 30,		(Increase)/ Decrease
	2020	2019	
Other income, net	$ (5,298)	$ (36,709)	$ 31,411

Other income decreased approximately $31,000 for the three months ended September 30, 2020 compared to the same period in the prior year. This decrease is due primarily to a decrease in the interest earned on our investment in marketable securities.

During the three months ended September 30, 2020, we recorded interest income of approximately $2,000 from our investments in marketable securities. This income is derived from approximately $4,000 in bond interest paid partially offset by fair-value adjustments measured for the period, which compares to approximately $33,000 in bond interest paid during the same period in the prior year.

Results of Operations- Comparison of the Nine Months Ended September 30, 2020 and 2019

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, 2020 and 2019, respectively, are as follows:

	Nine months ended September 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2020	2019		
Personnel costs	$ 2,120,914	$ 1,956,465	$ 164,449	8%
Legal and professional fees	617,576	1,192,499	(574,923)	(48)%
Other costs	509,329	427,898	81,431	19%
Facilities	117,071	115,981	1,090	1%

Personnel costs:

Personnel costs increased approximately $164,000 for the nine months ended September 30, 2020 compared to the same period in the prior year. This increase was due primarily to an increase of approximately $60,000 for the recognized expense for vested employee stock options, an increase of approximately $50,000 in bonuses paid and an overall increase of approximately $54,000 in salaries paid 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, capital market expenses, consulting fees and investor relations services, as well as fees paid to our Board of Directors. Legal and professional fees decreased approximately $575,000 for the nine months ended September 30, 2020 compared to the same period in the prior year. This decrease was due primarily to reimbursement of direct costs and legal fees incurred for arbitration proceedings related to our license agreement for levosimendan, and a decrease in costs incurred for investor relations services in the current period.

- Legal fees decreased approximately $481,000 in the current period. This decrease was due primarily to the reimbursement of approximately $358,000 in costs incurred for arbitration in the current period, as well as a decrease of approximately $120,000 in fees incurred for arbitration proceedings related to our license agreement for levosimendan and a decrease of approximately $24,000 in costs associated with our intellectual property portfolio, partially offset by an increase of approximately $28,000 in legal fees associated with our financial and proxy filings in the current period as compared to the same period in the prior year.
- Investor relations costs decreased approximately $94,000 in the current period. This decrease was primarily due to fees paid to a third-party investor relations firm for direct outreach and communications in the prior year that were not incurred in the current period as well as a decrease in fees paid for conferences and presentations in the current period as compared to 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 increased approximately $81,000 for the nine months ended September 30, 2020 compared to the same period in the prior year. This increase was due primarily to an increase of approximately $128,000 for the cost of annual insurance premiums, partially offset by a reduction of approximately $40,000 in travel costs incurred and approximately $9,000 in taxes paid in the current period as compared to the same period in the prior year.

Facilities:

Facilities expenses include costs paid for rent and utilities at our corporate headquarters in North Carolina. Facilities costs remained relatively consistent for the nine months ended September 30, 2020 and 2019.

Research and Development Expenses

Research and development expenses include, but are not limited to, (1) expenses incurred under agreements with CROs and investigative sites, which conduct our clinical trials and a substantial portion of our pre-clinical studies; (2) the cost of manufacturing and supplying clinical trial materials; (3) payments to contract service organizations, as well as consultants; (4) employee-related expenses, which include salaries and benefits; and (5) 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, 2020 and 2019, respectively , are as follows:

	Nine months ended September 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2020	2019		
Clinical and preclinical development	$ 3,489,977	$ 1,858,034	$ 1,631,943	88%
Personnel costs	167,738	162,723	5,015	3%
Other costs	12,046	28,247	(16,201)	(57)%

Clinical and preclinical development:

Clinical and preclinical development costs include, primarily, the costs associated with our Phase 2 HELP Study for levosimendan, which was initiated during fiscal year 2018. The last patient was enrolled into the trial during the first quarter of the current fiscal year. The increase of approximately $1.6 million in clinical and preclinical development costs for the nine months ended September 30, 2020 compared to the same period in the prior year was primarily due to an increase of approximately $1.6 million in expenditures for CRO costs and an increase of approximately $307,000 in enrolled patient costs, partially offset by a reduction of approximately $147,000 in fees paid to clinical research associates to manage the Phase 2 HELP Study, as well as a reduction of approximately $82,000 in other direct costs, as well as a decrease of approximately $26,000 in nonclinical development costs for levosimendan in the current period as compared to the same period in the prior year.

Personnel costs:

Personnel costs remained relatively consistent for the nine months ended September 30, 2020 and 2019 .

Other costs:

Other costs decreased approximately $16,000 for the nine months ended September 30, 2020 due primarily to reductions in costs incurred for travel and consulting fees paid in the current period as compared to the same period in the prior year.

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, net

Other income includes non-operating income not otherwise recorded in our condensed consolidated statement of comprehensive loss. These 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, 2020 and 2019, respectively, is as follows:

	Nine months ended September 30,		(Increase)/ Decrease
	2020	2019	
Other income, net	$ (14,038)	$ (139,161)	$ 125,123

Other income decreased approximately $125,000 for the nine months ended September 30, 2020 compared to the same period in the prior year. This decrease is due primarily to a decrease in the interest earned on our investment in marketable securities.

During the nine months ended September 30, 2020, we recorded interest income of approximately $15,000 from our investments in marketable securities. This income is derived from approximately $19,000 in bond interest paid partially offset by fair-value adjustments measured for the period, which compares to approximately $118,000 in bond interest paid 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, 2020 we had an accumulated deficit of approximately $243 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 $8,897,455 and $6,180,829 and working capital of $7,518,280 and $3,648,434 as of September 30, 2020 and December 31, 2019, respectively. Based on our working capital and the value of our investments in marketable securities on September 30, 2020, we believe we have sufficient capital to fund our operations through the third quarter of calendar year 2021.

Cash Flows

Financings

On March 11, 2020, we entered into a definitive agreement with a single healthcare-focused institutional investor (the “Investor“) for the issuance and sale of 750,000 shares of our common stock at a purchase price of $1.1651 per share and pre-funded warrants to purchase up to 1,610,313 shares of common stock, at a purchase price of $1.1650 per pre-funded warrant (which represents the per share offering price for the common stock less $0.0001, the exercise price of each pre-funded warrant), for gross proceeds of approximately $2.75 million, in a registered direct offering priced at-the-market under Nasdaq rules. Additionally, in a concurrent private placement, we also agreed to issue to the Investor unregistered warrants to purchase up to 2,360,313 shares of common stock. The unregistered warrants have an exercise price of $1.04 per share and exercise period commencing immediately upon the issuance date and a term of five and one-half years. The offering closed on March 13, 2020.

We agreed to pay H.C. Wainwright & Co., LLC (the "Placement Agent"), a cash fee equal to 7.5% of the gross proceeds of the March 2020 offering, totaling approximately $206,250. We also agreed to pay the Placement Agent $75,000 for non-accountable expenses, a management fee equal to 1.0% of the gross proceeds and up to $12,900 for clearing fees. In addition, we issued designees of the Placement Agent warrants to purchase 177,023 shares of common stock (representing 7.5% of the aggregate number of shares of common stock (or common stock equivalents) sold in the March 2020 offering). The Placement Agent warrants have substantially the same terms as the unregistered warrants, except that the Placement Agent warrants have an exercise price equal to $1.4564, or 125% of the offering price per share of common stock, and will be exercisable for five years from the effective date of the March 2020 offering.

The shares of common stock and pre-funded warrants offered in the registered direct offering (including the shares of common stock underlying the pre-funded warrants) were offered and sold pursuant to a "shelf" registration statement on Form S-3, which was declared effective by the SEC on May 23, 2018. The unregistered warrants described above were offered in a private placement under Section 4(a)(2) of the Securities Act, and Regulation D promulgated thereunder and, along with the shares of common stock underlying the warrants, have not been registered under the Securities Act, or applicable state securities laws. The net proceeds from the March 2020 offering, after deducting placement agent fees and other direct offering expenses, were approximately $2.125 million. We are using the net proceeds to further our clinical trials of levosimendan, for research and development and general corporate purposes, including working capital and potential acquisitions.

On July 6, 2020 entered into a definitive agreement with the Investor for the issuance and sale of 2,523,611 shares of our common stock at a purchase price of $1.0278 per share and pre-funded warrants to purchase up to 652,313 shares of common stock, at a purchase price of $1.0277 per pre-funded warrant (which represents the per share offering price for the common stock less $0.0001, the exercise price of each pre-funded warrant), in a registered direct offering priced at-the-market under Nasdaq rules. Additionally, in a concurrent private placement, we agreed to issue to the Investor unregistered pre-funded warrants to purchase up to 4,607,692 shares of common stock, at the same purchase price as the registered pre-funded warrants, as well as unregistered warrants to purchase up to an aggregate of 7,783,616 shares of common stock. The unregistered warrants have an exercise price of $0.903 per share, were immediately exercisable upon issuance, and expire five and one-half years from the date of issuance. The aggregate gross proceeds to the Company of both offerings was approximately $8.0 million. As part of the offerings and subject to Nasdaq rules, the Investor will have the right to designate two directors to the Company's Board of Directors. The offerings closed on July 8, 2020.

We agreed to pay the Placement Agent a cash fee equal to 7.5% of the gross proceeds of the July 2020 offering, totaling approximately $600,000. We also agreed to pay the Placement Agent $75,000 for non-accountable expenses, a management fee equal to 1.0% of the gross proceeds and up to $12,900 for clearing fees. In addition, we issued designees of the Placement Agent warrants to purchase 583,771 shares of common stock (representing 7.5% of the aggregate number of shares of common stock (or common stock equivalents) sold in the July 2020 offering). The Placement Agent warrants have substantially the same terms as the unregistered warrants, except that the Placement Agent warrants have an exercise price equal to $1.2848, or 125% of the offering price per share of common stock, and will be exercisable for five years from the effective date of the July 2020 offering.

The shares of common stock and pre-funded warrants offered in the registered direct offering (including the shares of common stock underlying the pre-funded warrants) were offered and sold pursuant to a "shelf" registration statement on Form S-3 which was declared effective by the SEC on May 23, 2018. The unregistered pre-funded warrants and unregistered warrants described above were offered in a private placement under Section 4(a)(2) of the Securities Act and Regulation D promulgated thereunder and, along with the shares of common stock underlying the pre-funded warrants and the warrants, have not been registered under the Securities Act, or applicable state securities laws. The net proceeds from the July 2020 offering, after deducting placement agent fees and other direct offering expenses, were approximately $6.5 million. We are using the net proceeds to further our clinical trials of levosimendan, for research and development and general corporate purposes, including working capital and potential acquisitions.

Paycheck Protection Program Loan

On April 30, 2020, we received the PPP Loan under the CARES Act, as administered by the SBA. The PPP Loan in the principal amount of $244,657 was disbursed by First Horizon Bank (the "Lender"), pursuant to a promissory note issued by us (the "Note").

The PPP Loan has a two-year term and bears interest at a rate of 1.00% per annum. Monthly principal and interest payments are deferred for sixteen months. Beginning September 30, 2021, we are required to make monthly payments of principal and interest of approximately $31,100 to the Lender. We did not provide any collateral or guarantees for the PPP Loan, nor did we pay any facility charge to obtain the PPP Loan. The Note provides for customary events of default, including, among others, those relating to failure to make payment, bankruptcy, breaches of representations, and material adverse effects. We may prepay the principal of the PPP Loan at any time, subject to certain notice requirements.

Under the terms of the CARES Act, Paycheck Protection Program loan recipients can apply for and be granted forgiveness for all or a portion of a loan granted under the program. Such forgiveness will be determined, subject to limitations, based on the use of loan proceeds for payment of payroll costs and any payments of mortgage interest, rent, and utilities. We are using the proceeds from the PPP Loan to fund payroll costs in accordance with the relevant terms and conditions of the CARES Act. However, no assurance is provided that forgiveness for any portion of the PPP Loan will be obtained.

As of September 30, 2020, the current and long-term portions of the PPP Loan were $30,900 and $213,757, respectively.

The following table shows a summary of our cash flows for the nine months ended September 30, 2020 and 2019:

	Nine months ended September 30,	
	2020	2019
Net cash used in operating activities	$ (7,285,410)	$ (5,829,920)
Net cash provided by investing activities	16,603	15,096
Net cash provided by financing activities	10,598,346	96,500

Net cash used in operating activities. Net cash used in operating activities was approximately $7.3 million for the nine months ended September 30, 2020 compared to net cash used in operating activities of approximately $5.8 million for the nine months ended September 30, 2019. The increase in cash used for operating activities was due primarily to an increase in our costs related to the Phase 2 Help Study in the current period.

Net cash provided by investing activities. Net cash provided by investing activities was approximately $17,000 for the nine months ended September 30, 2020 compared to approximately $15,000 used in the nine months ended September 30, 2019. The increase in cash in investing activities was primarily due to the sale of marketable securities in the current period.

Net cash provided by financing activities. Net cash provided by financing activities was approximately $10.6 million for the nine months ended September 30, 2020 compared to approximately $97,000 for the nine months ended September 30, 2019. The increase in cash provided by financing activities was due primarily to net proceeds of approximately $6.5 million from the July 2020 offering, net proceeds of approximately $2.1 million from the March 2020 offering, the issuance of 877,203 shares of common stock upon the exercise of approximately $1.7 million of outstanding warrants and the receipt of approximately $245,000 under the PPP Loan 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 candidate and potential product candidates;
-the outcome, timing and cost of regulatory approvals and the regulatory approval process;
-the impacts of COVID-19, including delays that may be caused by COVID-19;
-delays that may be caused by changing regulatory requirements;
-the number of product candidates that we pursue;
-the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims;
-the timing and terms of future collaboration, licensing, consulting or other arrangements that we may enter into;
-the cost and timing of establishing sales, marketing, manufacturing and distribution capabilities;
-the cost of procuring clinical and commercial supplies of our product candidates;
-the extent to which we acquire or invest in businesses, products or technologies; and
-the possible costs of litigation.

We believe that our existing cash and cash equivalents, along with our investment in marketable securities, will be sufficient to fund our projected operating requirements through the third quarter of calendar year 2021. 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 unaudited condensed consolidated financial statements have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the expenses during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions. For information regarding our critical accounting policies and estimates, please refer to “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Summary of Critical Accounting Policies” contained in our Annual Report on Form 10-K for the year ended December 31, 2019, and Note 2 to our unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Recent Accounting Pronouncements

In December 2019, FASB issued an accounting standard intended to simplify accounting for income taxes. It removes certain exceptions to the general principles in Topic 740, Income Taxes and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020 and early adoption is permitted. We are currently evaluating this standard, but we do not believe the adoption of the new guidance will have a material impact on our consolidated financial statements.

In June 2016, the FASB issued an accounting standard that amends how credit losses are measured and reported for certain financial instruments that are not accounted for at fair value through net income. This standard requires that credit losses be presented as an allowance rather than as a write-down for available-for-sale debt securities and will be effective for interim and annual reporting periods beginning January 1, 2023, with early adoption permitted. A modified retrospective approach is to be used for certain parts of this guidance, while other parts of the guidance are to be applied using a prospective approach. We do not believe the adoption of this standard will have a material impact on our consolidated financial statements and related disclosures.

Off-Balance Sheet Arrangements

Since our inception, we have not engaged in any off-balance sheet arrangements, including the use of structured finance, special purpose entities or variable interest entities.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As required by paragraph (b) of Rules 13a-15 and 15d-15 promulgated under the Exchange Act, our management, including our Chief Executive Officer and Chief Financial Officer, conducted an evaluation as of the end of the period covered by this report, of the effectiveness of our disclosure controls and procedures as defined in Exchange Act Rules 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, 2020, 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 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, 2019, except as set forth below:

A pandemic, epidemic, or outbreak of an infectious disease, such as COVID-19, or coronavirus, may materially and adversely affect our business and our financial results.

The spread of COVID-19 has affected segments of the global economy and may affect our operations, including the potential interruption of our clinical trial activities and our supply chain. The continued spread of COVID-19 may result in a period of business disruption, including delays in our clinical trials or delays or disruptions in our supply chain. In addition, there could be a potential effect of COVID-19 to the business at FDA or other health authorities, which could result in delays of reviews and approvals, including with respect to our product candidates.

The continued spread of COVID-19 globally could adversely affect our clinical trial operations in the United States and elsewhere, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. Further, some patients may be unable to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services, or if the patients become infected with COVID-19 themselves, which would delay our ability to initiate and/or complete planned clinical and preclinical studies in the future. COVID-19 may also affect employees of third-party CROs located in affected geographies that we rely upon to carry out our clinical trials, which could result in inefficiencies due to reductions in staff and disruptions to work environments.

The spread of COVID-19, or another infectious disease, could also negatively affect the operations at our third-party manufacturers, which could result in delays or disruptions in the supply of our product candidates. In addition, we have taken temporary precautionary measures intended to help minimize the risk of the virus to our employees, including temporarily requiring all employees to work remotely, suspending all non-essential travel worldwide for our employees, and discouraging employee attendance at industry events and in-person work-related meetings, which could negatively affect our business.

We cannot presently predict the scope and severity of any potential business shutdowns or disruptions. If we or any of the third parties with whom we engage, however, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business and our results of operation and financial condition.

Our PPP Loan may not be forgiven or may subject us to challenges and investigations regarding qualification for the loan.

On April 30, 2020, we received the PPP Loan in the principal amount of $244,657 pursuant to the Paycheck Protection Program under the CARES Act, as administered by the SBA. The PPP Loan matures in April 2022 and has an annual interest rate of 1.00%. Monthly principal and interest payments are deferred for sixteen months. Beginning September 30, 2021, the Company is required to make monthly payments of principal and interest of approximately $31,100 to the Lender. Pursuant to the terms of the CARES Act, we may apply for and be granted forgiveness for all or a portion of the PPP Loan. Such forgiveness will be determined, subject to limitations, based on the use of the loan proceeds for qualifying expenses, which include payroll costs, rent, and utility costs. We cannot provide any assurance that we will be eligible for loan forgiveness, that we will ultimately apply for forgiveness, or that any amount of the PPP Loan will ultimately be forgiven by the SBA.

Additionally, the PPP Loan application required us to certify that the current economic uncertainty made the PPP Loan request necessary to support our ongoing operations. While we made this certification in good faith after analyzing, among other things, our financial situation and access to alternative forms of capital, and believe that we satisfied all eligibility criteria for the PPP Loan and that our receipt of the PPP Loan is consistent with the broad objectives of the Paycheck Protection Program of the CARES Act, the certification described above does not contain any objective criteria and is subject to interpretation. In addition, the SBA has stated that it is unlikely that a public company with substantial market value and access to capital markets will be able to make the required certification in good faith. The lack of clarity regarding loan eligibility under the program has resulted in significant media coverage and controversy with respect to public companies applying for and receiving loans. If, despite our good faith belief that we satisfied all eligibility requirements for the PPP Loan, we are found to have been ineligible to receive the PPP Loan or in violation of any of the laws or regulations that apply to us in connection with the PPP Loan, including the False Claims Act, we may be subject to penalties, including significant civil, criminal and administrative penalties and could be required to repay the PPP Loan. In the event that we seek forgiveness of all or a portion of the PPP Loan, we will also be required to make certain certifications which will be subject to audit and review by governmental entities and could subject us to significant penalties and liabilities if found to be inaccurate. In addition, our receipt of the PPP Loan may result in adverse publicity and damage to our reputation, and a review or audit by the SBA or other government entity or claims under the False Claims Act could consume significant financial and management resources. Any of these events could harm our business, results of operations and financial condition.

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

Our common stock is currently listed on The Nasdaq Capital Market. In order to maintain this listing, we must satisfy minimum financial and other requirements. On April 24, 2020, we received a notification letter from Nasdaq's Listing Qualifications Department indicating that we were not in compliance with Nasdaq Listing Rule 5550(a)(2), because the minimum bid price of our common stock on the Nasdaq Capital Market closed below $1.00 per share for 30 consecutive business days. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we would have had 180 calendar days to regain compliance with the minimum bid requirement; however, due to the market disruption caused by the ongoing COVID-19 pandemic, Nasdaq tolled the requirement for meeting the minimum bid price until June 30, 2020. As such, we would have had 180 days from July 1, 2020, or until December 28, 2020, to achieve compliance with the minimum bid price requirement. To regain compliance, the closing bid price of our common stock had to meet or exceed $1.00 per share for at least ten consecutive business days before December 28, 2020.

On June 2, 2020, we received a letter from Nasdaq notifying us that Nasdaq determined that our stock price traded above at least $1.00 for at least 10 consecutive business days since the April 24, 2020 notice, and therefore, we have regained compliance with Nasdaq listing rule 5550(a)(2).

While we intend to engage in efforts to maintain compliance, and thus maintain our listing, there can be no assurance that we will continue to meet all applicable Nasdaq Capital Market requirements in the future. In the event of future noncompliance, and if Nasdaq determines to delist our common stock, the delisting could substantially decrease trading in our common stock; adversely affect the market liquidity of our common stock as a result of the loss of market efficiencies associated with Nasdaq and the loss of federal preemption of state securities laws; adversely affect our ability to obtain financing on acceptable terms, if at all; and may result in the potential loss of confidence by investors, suppliers, customers, and employees and fewer business development opportunities. Additionally, the market price of our common stock may decline and shareholders may lose some or all of their investment.

We have a significant securityholder, which could exert substantial influence over our business.

As of November 12, 2020, to our knowledge, Armistice Capital, LLC ("Armistice") held 2,019,995 shares of our common stock, warrants to purchase up to 4,145,076 shares of our common stock at an exercise price of $1.93 per share, warrants to purchase up to 2,360,313 shares of our common stock at an exercise price of $1.04 per share, warrants to purchase up to 7,783,616 shares of our common stock at an exercise price of $0.903 per share, and pre-funded warrants to purchase up to 5,260,005 shares of our common stock at an exercise price of $0.0001 per share. In addition, two members of our Board of Directors are affiliates of Armistice. Under the terms of the warrants and pre-funded warrants issued to Armistice, Armistice is not permitted to exercise such warrants to the extent that such exercise would result in Armistice (and its affiliates) beneficially owning more than 19.99% (or 4.99% in the case of the warrants with the $1.04 and $1.93 exercise prices per share) of the number of shares of our common stock outstanding immediately after giving effect to the issuance of shares of common stock issuable upon exercise of such warrants. After giving effect to the beneficial ownership limitations currently in effect with respect to the warrants and pre-funded warrants held by Armistice to our knowledge, as of November 12, 2020, Armistice beneficially owned 19.99% of our outstanding common stock. If the warrants and pre-funded warrants held by Armistice could be exercised without the beneficial ownership limitations, then as of November 12, 2020, Armistice would have beneficially owned 67.05% of our common stock. Although there are contractual limitations on the beneficial ownership of Armistice, if Armistice were to exercise its warrants for common stock, it could be able to exert substantial influence over our business, including, for example, the ability to delay, defer or prevent a change of control, entrench our management and the Board of Directors or delay or prevent a merger, consolidation or other business combination.

Our bylaws contain an exclusive forum provision, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees, or agents.

Our bylaws provide that, unless we consent in writing to the selection of an alternative forum, any North Carolina state court that has jurisdiction, or the Delaware Court of Chancery shall, to the fullest extent permitted by law, be the sole and exclusive forum any internal corporate claims, including without limitation (1) any derivative action or proceeding brought on behalf of us, (2) any action asserting a claim of breach of a fiduciary duty owed by any director, officer or other employee of us to us or our stockholders, (3) any action asserting a claim arising pursuant to any provision of the General Corporation Law of the State of Delaware, and (4) any action asserting a claim governed by the internal affairs doctrine, in each case subject to said court having personal jurisdiction over the indispensable parties named as defendants in such action.

For the avoidance of doubt, the exclusive forum provision described above does not apply to any claims arising under the Securities Act or the Exchange Act. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder, and Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder.

The exclusive forum provision in our bylaws may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers, employees, or agents, which may discourage such lawsuits against us and our directors, officers, employees, and agents even though an action, if successful, might benefit our stockholders. The applicable courts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments or results may be more favorable to us than to our stockholders. With respect to the provision making the state courts of North Carolina with jurisdiction or the Delaware Court of Chancery the sole and exclusive forum for certain types of actions, stockholders who do bring a claim in North Carolina state court or in the Delaware Court of Chancery could face additional litigation costs in pursuing any such claim, particularly if they do not reside in or near North Carolina or Delaware. Finally, if a court were to find this provision of our bylaws inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could have a material adverse effect on us.

ITEM 6. EXHIBITS

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

No.	Description
4.1	Form of Pre-Funded Warrant (incorporated herein by reference to Exhibit 4.1 to our current report on Form 8-K filed with the SEC on March 13, 2020)
4.2	Form of Unregistered Warrant (incorporated herein by reference to Exhibit 4.2 to our current report on Form 8-K filed with the SEC on March 13, 2020)
4.3	Form of Placement Agent Warrant (incorporated herein by reference to Exhibit 4.3 to our current report on Form 8-K filed with the SEC on March 13, 2020)
4.4	Form of Pre-Funded Warrant (incorporated herein by reference to Exhibit 4.1 to our current report on Form 8-K filed with the SEC on July 8, 2020)
4.5	Form of Unregistered Warrant (incorporated herein by reference to Exhibit 4.2 to our current report on Form 8-K filed with the SEC on July 8, 2020)
4.6	Form of Placement Agent Warrant (incorporated herein by reference to Exhibit 4.3 to our current report on Form 8-K filed with the SEC on July 8, 2020)
10.1	Form of Securities Purchase Agreement, dated as of March 11, 2020, by and between Tenax Therapeutics, Inc. and the investor named therein (incorporated herein by reference to Exhibit 10.1 to our current report on Form 8-K filed with the SEC on March 13, 2020)
10.2	Note, dated April 30, 2020, between Tenax Therapeutics, Inc. and First Horizon Bank (incorporated herein by reference to Exhibit 10.1 to our quarterly report on Form 10-Q filed with the SEC on May 15, 2020)
10.3	Form of Securities Purchase Agreement for Class C Units and Class D Units, dated as of July 6, 2020, by and between Tenax Therapeutics, Inc. and the investor named therein (incorporated herein by reference to Exhibit 10.1 to our current report on Form 8-K filed with the SEC on July 8, 2020)
10.4	Form of Securities Purchase Agreement for Class E Units and Class F Units, dated as of July 6, 2020, by and between Tenax Therapeutics, Inc. and the investor named therein (incorporated herein by reference to Exhibit 10.2 to our current report on Form 8-K filed with the SEC on July 8, 2020)
10.5	Form of Registration Rights Agreement, dated as of July 6, 2020, by and between Tenax Therapeutics, Inc. and the investor named therein (incorporated herein by reference to Exhibit 10.3 to our current report on Form 8-K filed with the SEC on July 8, 2020)
10.6 †	Amendment to License Agreement, dated as of October 9, 2020, by and between Tenax Therapeutics, Inc. and Orion Corporation (incorporated herein by reference to Exhibit 10.1 to our current report on Form 8-K filed with the SEC on October 15, 2020).
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

† Portions of this exhibit have been omitted pursuant to Item 601 of Regulation S-K promulgated under the Securities Act because the information is not material and would likely cause competitive harm to the registrant if publicly disclosed.

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 16, 2020

By: /s/ 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 condensed 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 condensed 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 16, 2020

By: /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 condensed 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 condensed 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 16, 2020

By: /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, 2020 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 16, 2020

By: /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 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, 2020 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 16, 2020

By: /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.