

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 June 30, 2021

OR

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

FOR THE TRANSITION PERIOD FROM TO

Commission File Number 001-34600

## TENAX THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State of incorporation)

26-2593535

(I.R.S. Employer Identification No.)

ONE Copley Parkway, Suite 490, Morrisville, North Carolina 27560

(Address of principal executive offices)

(919) 855-2100

(Registrant's telephone number, including area code)

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

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

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

As of August 12, 2021, the registrant had outstanding 25,201,312 shares of Common Stock.

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	<b>June 30, 2021</b>	<b>December 31, 2020</b>
	<b>(Unaudited)</b>	
<b>ASSETS</b>		
Current assets		
Cash and cash equivalents	\$ 1,671,422	\$ 6,250,241
Marketable securities	510,943	462,687
Prepaid expenses	349,862	82,578
Total current assets	<u>2,532,227</u>	<u>6,795,506</u>
Right of use asset	338,698	58,778
Property and equipment, net	5,821	5,972
Other assets	8,435	8,435
Total assets	<u>\$ 2,885,181</u>	<u>\$ 6,868,691</u>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current liabilities		
Accounts payable	\$ 791,947	\$ 757,856
Accrued liabilities	383,063	1,240,616
Note payable	-	120,491
Total current liabilities	<u>1,175,010</u>	<u>2,118,963</u>
Long term liabilities		
Lease liability	239,039	-
Note payable	-	124,166
Total long term liabilities	<u>239,039</u>	<u>124,166</u>
Total liabilities	1,414,049	2,243,129
Commitments and contingencies; see Note 8		
Stockholders' equity		
Preferred stock, undesignated, authorized 9,999,790 shares; See Note 9 Series A Preferred stock, par value \$.0001, issued 5,181,346 shares; outstanding 210, respectively	-	-
Common stock, par value \$.0001 per share; authorized 400,000,000 shares; issued and outstanding 25,201,312 and 12,619,369 respectively	2,520	1,262
Additional paid-in capital	272,953,869	250,644,197
Accumulated other comprehensive loss	(274)	(70)
Accumulated deficit	(271,484,983)	(246,019,827)
Total stockholders equity	<u>1,471,132</u>	<u>4,625,562</u>
Total liabilities and stockholders' equity	<u>\$ 2,885,181</u>	<u>\$ 6,868,691</u>

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

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**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Operating expenses				
General and administrative	\$ 1,271,278	\$ 869,206	\$ 2,644,738	\$ 2,192,165
Research and development	693,222	1,274,837	23,069,424	2,617,363
Total operating expenses	1,964,500	2,144,043	25,714,162	4,809,528
Net operating loss	1,964,500	2,144,043	25,714,162	4,809,528
Interest expense	336	406	949	406
Other (income) expense, net	(247,820)	2,101	(249,955)	(8,740)
Net loss	\$ 1,717,016	\$ 2,146,550	\$ 25,465,156	\$ 4,801,194
Unrealized (gain) loss on marketable securities	(128)	(3,238)	204	(1,616)
Total comprehensive loss	\$ 1,716,888	\$ 2,143,312	\$ 25,465,360	\$ 4,799,578
Net loss per share, basic and diluted	\$ (0.10)	\$ (0.23)	\$ (1.60)	\$ (0.59)
Weighted average number of common shares outstanding, basic and diluted	17,218,103	9,339,309	15,874,062	8,156,848

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

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**TENAX THERAPEUTICS, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY  
(Unaudited)**

	Preferred Stock		Common Stock		Additional paid-in capital	Accumulated other comprehensive gain (loss)	Accumulated deficit	Total stockholders' equity
	Number of Shares	Amount	Number of Shares	Amount				
<b>Balance at December 31, 2019</b>	<b>38,606</b>	<b>\$ 4</b>	<b>6,741,860</b>	<b>\$ 674</b>	<b>\$ 239,939,797</b>	<b>\$ 458</b>	<b>\$ (236,168,436)</b>	<b>\$ 3,772,497</b>
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)
<b>Balance at March 31, 2020</b>	<b>210</b>	<b>\$ -</b>	<b>8,008,243</b>	<b>\$ 801</b>	<b>\$ 242,242,095</b>	<b>\$ (1,164)</b>	<b>\$ (238,823,080)</b>	<b>\$ 3,418,652</b>
Compensation on options issued				-	63,166			63,166
Exercise of warrants			2,087,515	209	1,690,455			1,690,664
Unrealized gain on marketable securities						3,238		3,238
Net loss							(2,146,550)	(2,146,550)
<b>Balance at June 30, 2020</b>	<b>210</b>	<b>\$ -</b>	<b>10,095,758</b>	<b>\$ 1,010</b>	<b>\$ 243,995,716</b>	<b>\$ 2,074</b>	<b>\$ (240,969,630)</b>	<b>\$ 3,029,170</b>
<b>Balance at December 31, 2020</b>	<b>210</b>	<b>\$ -</b>	<b>12,619,369</b>	<b>\$ 1,262</b>	<b>\$ 250,644,197</b>	<b>\$ (70)</b>	<b>\$ (246,019,827)</b>	<b>\$ 4,625,562</b>
Common stock and preferred stock issued for asset acquisition	10,232	1	1,892,905	189	21,582,141			21,582,331
Compensation on options issued					91,609			91,609
Exercise of warrants			457,038	46	544,605			544,651

Unrealized loss on marketable securities						(332)		(332)
Net loss							(23,748,140)	(23,748,140)
<b>Balance at March 31, 2021</b>	<b>10,442</b>	<b>\$ 1</b>	<b>14,969,312</b>	<b>\$ 1,497</b>	<b>\$272,862,552</b>	<b>\$ (402)</b>	<b>\$ (269,767,967)</b>	<b>\$ 3,095,681</b>
Common stock issued for convertible preferred stock	(10,232)	(1)	10,232,000	1,023	(1,022)			-
Compensation on options issued					92,339			92,339
Unrealized gain on marketable securities						128		128
Net loss							(1,717,016)	(1,717,016)
<b>Balance at June 30, 2021</b>	<b>210</b>	<b>\$ -</b>	<b>25,201,312</b>	<b>\$ 2,520</b>	<b>\$272,953,869</b>	<b>\$ (274)</b>	<b>\$ (271,484,983)</b>	<b>\$ 1,471,132</b>

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

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**TENAX THERAPEUTICS, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

	<b>Six Months ended June 30,</b>	
	<b>2021</b>	<b>2020</b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net Loss	\$ (25,465,156)	\$ (4,801,194)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	2,026	2,150
Interest on debt instrument	949	406
Amortization of right of use asset	53,859	54,223
Gain on debt settlement and extinguishment	(247,233)	-
Issuance of common stock and preferred stock for asset acquisition	21,582,331	-
Issuance and vesting of compensatory stock options and warrants	183,948	135,542
Issuance of common stock for services rendered	-	50,000
Amortization of premium on marketable securities	6,896	2,647
Changes in operating assets and liabilities		
Accounts receivable, prepaid expenses and other assets	(267,284)	170,046
Accounts payable and accrued liabilities	(923,295)	(453,406)
Long term portion of lease liability	6,720	(60,379)
Net cash used in operating activities	(5,066,239)	(4,899,965)
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchase of marketable securities	(345,540)	(351,138)
Sale of marketable securities	290,184	365,049
Purchase of property and equipment	(1,875)	-
Net cash (used in) provided by investing activities	(57,231)	13,911
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from the exercise of warrants	544,651	1,690,704
Proceeds from issuance of common stock and pre-funded warrants, net of issuance costs	-	2,130,005
Proceeds from the issuance of notes payable	-	244,657
Net cash provided by financing activities	544,651	4,065,366
Net change in cash and cash equivalents	(4,578,819)	(820,688)
Cash and cash equivalents, beginning of period	6,250,241	4,905,993
Cash and cash equivalents, end of period	<u>\$ 1,671,422</u>	<u>\$ 4,085,305</u>
<b>Non-cash investing activity</b>		
Addition to right of use asset obtained from new operating lease liability	\$ 333,779	\$ -

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

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**TENAX THERAPEUTICS, INC.**

**NOTES TO 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 8 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.

On October 9, 2020, the Company entered into an Amendment (the "Amendment") to the License between the Company and Orion Corporation, a global healthcare company incorporated under the laws of Finland ("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. The Company intends to conduct an upcoming Phase 3 study in pulmonary hypertension patients utilizing one of these oral formulations.

On January 15, 2021, the Company, Life Newco II, Inc., a Delaware corporation and a wholly-owned, direct subsidiary of the Company ("Life Newco II"), PHPrecisionMed Inc., a Delaware corporation ("PHPM,") and Dr. Stuart Rich, solely in his capacity as holders' representative (in such capacity, the "Representative"), entered into an Agreement and Plan of Merger, dated January 15, 2021 (the "Merger Agreement"), pursuant to which, subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, the Company would acquire 100% of the equity of PHPM. Under the terms of the Merger Agreement, Life Newco II would merge with and into PHPM, with PHPM surviving as a wholly owned subsidiary of the Company (the "Merger"). On January 15, 2021, the Company completed the acquisition contemplated by the Merger Agreement (the "Acquisition"). As a result of the Acquisition the Company intends to develop pharmaceutical products containing imatinib for the treatment of pulmonary arterial hypertension in the United States and the rest of the world.

## 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, 2020 has been derived from the Company's audited consolidated financial statements included in its Annual Report on Form 10-K for the period ended December 31, 2020. 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 six-month period ended June 30, 2021 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, 2020.

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### *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 \$271 million on June 30, 2021 and \$246 million on December 31, 2020 and used cash in operations of \$5.1 million and \$4.9 million during the six months ended June 30, 2021 and 2020, respectively.

As further discussed in Note 10 below, the Company sold 4,773,269 units ("Units") in a private placement at a purchase price of \$2.095 per Unit. Each Unit consists of one unregistered pre-funded warrant to purchase one share of common stock and one unregistered warrant to purchase one share of common stock for gross proceeds of approximately \$10 million. The Company requires substantial additional funds to complete its planned clinical trials and to 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 June 30, 2021 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, Life Newco and Life Newco II. All material intercompany transactions and balances have been eliminated in consolidation.

## ***Liquidity and Management's Plan***

On June 30, 2021, the Company had cash and cash equivalents, including the fair value of its marketable securities, of approximately \$2.2 million. The Company used \$5.1 million of cash for operating activities during the six months ended June 30, 2021 and had stockholders' equity of \$1.5 million, versus \$4.6 million on December 31, 2020.

The Company expects to continue to incur expenses related to development of imatinib for pulmonary arterial hypertension and levosimendan for pulmonary hypertension and to continue with the development of other potential product candidates. Based on its resources on June 30, 2021 and including the net proceeds from its July 2021 offering (as discussed in Note 10 below), the Company believes that it has sufficient capital to fund its planned operations through the second quarter of calendar year 2022. 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.

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## ***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.

	<b>Six months ended June 30,</b>	
	<b>2021</b>	<b>2020</b>
Warrants to purchase common stock	15,797,503	12,274,492
Pre-funded warrants to purchase common stock	5,260,005	-
Options to purchase common stock	779,885	450,203
Convertible preferred shares outstanding	210	210

## ***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's adoption of this standard did not 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.

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### **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 June 30, 2021, 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:

	<b>June 30, 2021</b>				
	<b>Amortized Cost</b>	<b>Accrued Interest</b>	<b>Gross Unrealized Gains</b>	<b>Gross Unrealized losses</b>	<b>Estimated Fair Value</b>
Corporate debt securities	\$ 506,530	\$ 4,690	\$ 46	\$ (323)	\$ 510,943
Total investments	<u>\$ 506,530</u>	<u>\$ 4,690</u>	<u>\$ 46</u>	<u>\$ (323)</u>	<u>\$ 510,943</u>

All of the Company's investments have scheduled maturities of less than one year as of June 30, 2021 and December 31, 2020.

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The following tables summarize information regarding assets and liabilities measured at fair value on a recurring basis as of June 30, 2021 and December 31, 2020:

	Balance as of June 30, 2021	Fair Value Measurements at Reporting Date Using		
		Quoted prices in Active Markets for Identical Securities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Current Assets				
Cash and cash equivalents	\$ 1,671,422	\$ 1,671,422	\$ -	\$ -
Marketable securities	\$ 510,943	\$ -	\$ 510,943	\$ -

	Balance as of December 31, 2020	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	\$ 6,250,241	\$ 6,250,241	\$ -	\$ -
Marketable securities	\$ 462,687	\$ -	\$ 462,687	\$ -

There were no significant transfers between levels in the six months ended June 30, 2021.

#### NOTE 4. BALANCE SHEET COMPONENTS

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

Property and equipment consist of the following as of June 30, 2021 and December 31, 2020:

	June 30, 2021	December 31, 2020
Office furniture and fixtures	\$ 43,033	\$ 43,033
Computer equipment and software	23,631	23,307
	66,664	66,340
Less: Accumulated depreciation	(60,843)	(60,368)
	<u>\$ 5,821</u>	<u>\$ 5,972</u>

Depreciation expense was approximately \$1,000 for each of the three-month periods ended June 30, 2021 and 2020. Depreciation expense was approximately \$2,000 for each of the six-month periods ended June 30, 2021 and 2020.

##### *Accrued liabilities*

Accrued liabilities consist of the following as of June 30, 2021 and December 31, 2020:

	June 30, 2021	December 31, 2020
Employee related	\$ 127,551	\$ 860,629
Operating costs	154,051	319,608
Lease liability	101,461	60,379
	<u>\$ 383,063</u>	<u>\$ 1,240,616</u>

#### 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. On April 2, 2021, the Company negotiated a 3-year extension to the existing lease term, commencing July 1, 2021. Beginning on the commencement date, the annual base rent will be increased to \$125,034 and will increase 2.5% annually for lease years 2 and 3.

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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:

	June 30, 2021	December 31, 2020
Current portion included in accrued liabilities	\$ 101,461	\$ 60,379
Long term lease liability	239,039	-
	<u>\$ 340,500</u>	<u>\$ 60,379</u>

As of June 30, 2021, the maturities of our operating lease liabilities were as follows:

<b>Year ending December 31,</b>	
2021	\$ 62,517
2022	126,612
2023	129,797
2024	65,702
Total lease payments	<u>\$ 384,628</u>
Less: Imputed interest	<u>(44,128)</u>
<b>Operating lease liability</b>	<u><b>\$ 340,500</b></u>

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 June 30, 2021, the remaining Lease term is 36 months and the discount rate used to determine the operating lease liability was 8.0%. For the six months ending June 30, 2021, the Company paid \$67,765 in total lease expenses, including \$5,963 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 ("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, 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.

On May 28, 2021, the Company received notice from the SBA that the SBA had remitted \$244,657 in principal and \$2,576 in interest to the Lender in full forgiveness of the Company's PPP Loan pursuant to the Company's application to the SBA for forgiveness of the PPP Loan. The total amount was recorded as other income in the Company's condensed consolidated statement of comprehensive loss.

[Table of Contents](#)**NOTE 7. MERGER**

On January 15, 2021, the Company, Life Newco II, PHPM, and Dr. Stuart Rich, solely in his capacity as Representative, entered into the Merger Agreement, pursuant to which, subject to the satisfaction or waiver of the conditions set forth in the Merger Agreement, the Company would acquire 100% of the equity of PHPM. Under the terms of the Merger Agreement, Life Newco II would merge with and into PHPM, with PHPM surviving as a wholly owned subsidiary of the Company. On January 15, 2021, the Company completed the Acquisition.

As consideration for the Merger, the stockholders of PHPM received (i) 1,892,905 shares of the Company's common stock ("Common Stock"), and (ii) 10,232 shares of the Company's Series B convertible preferred stock, which are convertible into up to an aggregate of 10,232,000 shares of Common Stock ("Preferred Stock") (collectively, the "Merger Consideration"). The issuance of 1,212,492 shares of Common Stock issuable upon conversion of the Preferred Stock, representing approximately 10% of the Merger Consideration, will be delayed as security for closing adjustments and post-closing indemnification obligations of PHPM and the stockholders of PHPM. Following receipt of the approval of the stockholders of the Company for the Conversion (as defined herein), each share of Preferred Stock will automatically convert into (i) 881.5 shares of Common Stock, and (ii) 118.5 shares of Common Stock to be delivered 24 months after the date of issuance of the Preferred Stock, subject to reduction for indemnification claims. The number of shares of Common Stock into which the Preferred Stock converts is subject to adjustment in the case of stock splits, stock dividends, combinations of shares and similar recapitalization transactions. The Preferred Stock does not carry dividends or a liquidation preference. The Preferred Stock carries voting rights aggregating 4.99% of the Company's Common Stock voting power immediately prior to the closing of the Merger. The rights, preferences and

privileges of the Preferred Stock are set forth in the Certificate of Designation of Series B Convertible Preferred Stock that the Company filed with the Secretary of State of the State of Delaware on January 15, 2021 (the “Certificate of Designation”).

Pursuant to the Merger Agreement, the Board of Directors, at its Annual Meeting of Shareholders held on June 10, 2021, recommended to the Company’s shareholders, and the shareholders approved, the conversion of the Preferred Stock pursuant to the Certificate of Designation (the “Conversion”). In addition, (i) at the Company’s first regularly scheduled Board meeting following the closing of the Merger, the Board must appoint one director designated by the Representative to serve on the Board, and (ii) as promptly as practicable after the Company has obtained stockholder approval for the Conversion, the Board must appoint two additional directors designated by the Representative to serve on the Board. Dr. Stuart Rich, the co-founder and Chief Executive Officer, and a stockholder of PHPM, and Dr. Michael Davidson and Dr. Declan Doogan, the two other designees of the Representative, were appointed to the Board on February 25, 2021. In connection with the closing of the Merger, Dr. Stuart Rich was also appointed Chief Medical Officer of the Company.

The Company evaluated this acquisition in accordance with ASC 805, Business Combinations, to determine whether the assets and operations of PHPM met the definition of a business. Included in the in-process research and development project is the historical know-how, formula protocols, designs, and procedures expected to be needed to complete the related phase of testing. The Company concluded that the in-process research and development project is an identifiable intangible asset that would be accounted for as a single asset in a business combination. The Company also qualitatively concluded that there is no fair value associated with the clinical research organization contract and the clinical manufacturing organization contract because the services are being provided at market rates and could be provided by multiple vendors in the marketplace. Therefore, all of the consideration in the transaction will be allocated to the in-process research and development project. As such, the Company concluded that substantially all of the fair value of the gross assets acquired is concentrated in the single in-process research and development asset and the set is not a business.

The Company is planning to use the acquired asset to further its clinical develop in an upcoming phase 3 clinical trial for the treatment of patients with PAH. Although the acquired asset may have utility in other patient populations, future development decisions for the acquired asset will be contingent upon the results of the contemplated phase 3 program for PAH. As such, the acquired asset does not have an alternative future use at the acquisition date. In accordance with ASC 730, Research and Development, the Company concluded the entire Purchase Price for the asset acquisition will be recorded as an expense on the acquisition date.

The consideration transferred, assets acquired and liabilities assumed were recognized as follows:

Fair value of shares of Common Stock issued	\$ 3,369,371
Fair Value of Series B Convertible Preferred Stock issued at closing	18,212,960
Total fair value of consideration transferred	<u>\$ 21,582,331</u>
Tangible assets acquired	\$ -
Accounts payable assumed	(150,000)
Total identifiable net assets	(150,000)
IPR&D expense recognized	21,732,331
Total fair value of consideration	<u>\$ 21,582,331</u>

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**NOTE 8. 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.

On October 9, 2020, the Company entered into the Amendment 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.

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 June 30, 2021, the Company has not met any of the developmental milestones and, accordingly, has not recorded any liability for the contingent payments due to Orion.

## NOTE 9. STOCKHOLDERS' EQUITY

### *Preferred Stock*

Under the Company's Certificate of Incorporation, the Board 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.

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#### *Series B Stock*

As further discussed in Note 7 above, on January 15, 2021 the Company issued 10,232 shares of its Series B Stock, which were convertible into an aggregate of 10,232,000 shares of common stock, to the stockholders of PHPM as partial consideration for the Merger with PHPM pursuant to the Merger Agreement.

The rights, preferences and privileges of the Series B Stock are set forth in the Certificate of Designation. Following receipt of the approval of the stockholders of the Company for the Conversion, each share of Series B Stock will automatically convert into (i) 881.5 shares of Common Stock and (ii) 118.5 shares of Common Stock, to be delivered 24 months after the date of issuance of the Preferred Stock, subject to reduction for indemnification claims. The number of shares of Common Stock into which the Preferred Stock converts is subject to adjustment in the case of stock splits, stock dividends, combinations of shares and similar recapitalization transactions. The Preferred Stock does not carry dividends or a liquidation preference. The Preferred Stock carries voting rights aggregating 4.99% of the Company's Common Stock voting power immediately prior to the closing of the Merger.

On June 10, 2021, the Company's shareholders approved the conversion of our outstanding Series B Stock into shares of common stock. As a result of the approval, all outstanding shares of Series B Stock were automatically converted into an aggregate of 10,232,000 shares of common stock.

As of June 30, 2021, there were no shares of Series B Stock outstanding.

#### *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, and (3) a five-year warrant to purchase one share of common stock at an exercise price of \$1.93. 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, 2020.

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

Conversion	<p>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.</p> <p>The Company will not affect any conversion of the Series A Stock, nor shall a holder convert its shares of Series A Stock, to the extent that such conversion would cause the holder to have acquired, through conversion of the Series A Stock or otherwise, beneficial ownership of a number shares of common stock in excess of 4.99% (or, at the election of the holder prior to the issuance of any shares of Series A Stock, 9.99%) of the common stock outstanding after giving effect to such exercise.</p>
Dividends	<p>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.</p>
Liquidation	<p>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.</p>
Voting rights	<p>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.</p>

As of June 30, 2021, there were 210 shares of Series A Stock outstanding.

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## **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 June 30, 2021, and December 31, 2020, there were 25,201,312 and 12,619,369 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.

As of June 30, 2021, 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.

During the six months ended June 30, 2021, the Company received approximately \$545,000 and issued 282,202 shares of common stock upon the exercise of previously outstanding warrants issued in connection with the Company's December 2018 offering.

During the six months ended June 30, 2021, the Company issued 119,491 shares of common stock upon the cashless exercise of previously outstanding placement agent warrants issued in connection with the Company's March 2020 offering.

During the six months ended June 30, 2021, the Company issued 399,883 shares of common stock upon the cashless exercise of previously outstanding placement agent warrants issued in connection with the Company's July 2020 offering.

As of June 30, 2021, the Company has 15,797,503 warrants outstanding. The following table summarizes the Company's warrant activity for the six months ended June 30, 2021:

	<b>Warrants</b>	<b>Weighted Average Exercise Price</b>
<b>Outstanding at December 31, 2020</b>	<b>16,599,079</b>	<b>\$ 1.29</b>
Exercised	(801,576)	1.54
<b>Outstanding at June 30, 2021</b>	<b>15,797,503</b>	<b>\$ 1.27</b>

#### **2016 Stock Incentive Plan**

In June 2016, the Company adopted the 2016 Stock Incentive Plan (the "2016 Plan"). Under the 2016 Plan, with the approval of the Compensation Committee of the Board of Directors, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units, performance shares, performance units, cash-based awards or other stock-based awards. On June 16, 2016, the Company's stockholders approved the 2016 Plan and authorized for issuance under the 2016 Plan a total of 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.

On June 10, 2021, 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 1.5 million shares, up from 750,000 previously authorized.

The following table summarizes the shares available for grant under the 2016 Plan for the six months ended June 30, 2021:

	<b>Shares Available for Grant</b>
Balances, at December 31, 2020	356,500
Additional shares reserved	750,000
Options granted	(328,750)
Balances, at June 30, 2021	777,750

#### **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.

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The following table summarizes the outstanding stock options under the 2016 Plan for the six months ended June 30, 2021:

	<b>Outstanding Options</b>	
	<b>Number of Shares</b>	<b>Weighted Average Exercise Price</b>
Balances at December 31, 2020	393,500	\$ 1.81
Options granted	328,750	\$ 1.86
Balances at June 30, 2021	722,250	\$ 1.83

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 \$92,339 and \$52,672 for the three months ended June 30, 2021 and 2020, and \$182,658 and \$112,833 for the six months ended June 30, 2021 and 2020, respectively.

As of June 30, 2021, there were unrecognized compensation costs of approximately \$446,904 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 1.57 years.

The Company used the following assumptions to estimate the fair value of options granted under the 2016 Plan for the six months ended June 30, 2021:

<b>For the six months ended June 30,</b>	
<b>2021</b>	<b>2020</b>

Risk-free interest rate (weighted average)	0.70%	1.03%
Expected volatility (weighted average)	99.47%	97.61%
Expected term (in years)	7	7
Expected dividend yield	0.00%	0.00%

<i>Risk-Free Interest Rate</i>	The risk-free interest rate assumption was based on U.S. Treasury instruments with a term that is consistent with the expected term of the Company's stock options.
<i>Expected Volatility</i>	The expected stock price volatility for the Company's common stock was determined by examining the historical volatility and trading history for its common stock over a term consistent with the expected term of its options.
<i>Expected Term</i>	The expected term of stock options represents the weighted average period the stock options are expected to remain outstanding. It was calculated based on the Company's historical experience with its stock option grants.
<i>Expected Dividend Yield</i>	The expected dividend yield of 0% is based on the Company's history and expectation of dividend payouts. The Company has not paid and does not anticipate paying any dividends in the near future.
<i>Forfeitures</i>	Stock compensation expense recognized in the statements of operations for the six months ended June 30, 2021 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.

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**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 six months ended June 30, 2021:

	Outstanding Options	
	Number of Shares	Weighted Average Exercise Price
Balances at December 31, 2020	57,648	\$ 46.34
Options cancelled	(13)	\$ 775.85
Balances at June 30, 2021	57,635	\$ 46.18

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 \$0 and \$10,494 for the three months ended June 30, 2021 and 2020, and \$1,290 and \$22,709 for the six months ended June 30, 2021 and 2020, respectively.

As of June 30, 2021, there were no unrecognized compensation costs related to non-vested stock option awards under the 1999 Plan.

**Inducement Stock Options**

The Company granted an employment inducement stock option award for 250,000 shares of common stock to our chief medical officer on January 15, 2021. This employment inducement stock option was awarded in accordance with the employment inducement award exemption provided by NASDAQ Rule 5635(c)(4) and was therefore not awarded under the Company's stockholder approved equity plan. The option award will vest as follows: 25% upon initiation of a Phase 3 trial; 25% upon database lock; 25% upon acceptance for review of an NDA; and 25% upon approval. The options have a 10-year term and an exercise price of \$1.78 per share, the January 15, 2021 closing price of the Company's common stock. As of June 30, 2021, none of the vesting milestones have been achieved.

The estimated fair value of the inducement stock option award granted was \$402,789 using a Black-Scholes option pricing model based on market prices and the following assumptions at the date of inducement option grant: risk-free interest rate of 1.11%, dividend yield of 0%, volatility factor for our common stock of 103.94% and an expected life of 10 years.

Inducement stock option compensation expense totaled \$0 for the six months ended June 30, 2021. As of June 30, 2021, there was \$402,789 of remaining unrecognized compensation expense related to this inducement stock option.

## NOTE 10. SUBSEQUENT EVENTS

On July 6, 2021, Tenax Therapeutics, Inc. (the “Company”) entered into a securities purchase agreement (the “Purchase Agreement”) with an institutional investor (the “Investor”) pursuant to which the Company agreed to sell and issue to the Investor 4,773,269 units (“Units”) in a private placement at a purchase price of \$2.095 per Unit. Each Unit consisted of one unregistered pre-funded warrant to purchase one share of common stock, par value \$0.0001 (collectively the “Unregistered Pre-Funded Warrants”) and one unregistered warrant to purchase one share of common stock (collectively the “Unregistered Warrants” and together with the Unregistered Pre-Funded Warrants, the “Warrants”). In the aggregate, 9,546,538 shares of the Company’s common stock are underlying the Warrants. The aggregate gross proceeds to the Company of the Offering were approximately \$10 million.

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Each Unregistered Pre-Funded Warrant has an exercise price of \$0.0001 per share of common stock, is immediately exercisable, may be exercised at any time until exercised in full and is subject to customary adjustments. Each Unregistered Warrant has an exercise price of \$1.97 per share of common stock, is immediately exercisable, will expire five and one-half years from the date of issuance and is subject to customary adjustments. The Warrants may not be exercised if the aggregate number of shares of the Company’s common stock beneficially owned by the holder (together with its affiliates) would exceed 9.99% of the Company’s outstanding common stock immediately after exercise. However, the holder may increase (upon 61 days’ prior notice from the holder to the Company) or decrease such percentage, provided that in no event such percentage exceeds 9.99%.

The Company intends to use the net proceeds from the Offering to further its clinical trials of levosimendan and imatinib for research and development and for general corporate purposes, including working capital and potential acquisitions.

Also, on July 6, 2021 and in connection with the private placement, the Company entered into a registration rights agreement (the “Registration Rights Agreement”) with the Investor, pursuant to which the Company agreed to register for resale the shares of the Company’s common stock issuable upon exercise of the Warrants within 120 days following the date of the Registration Rights Agreement.

Under certain circumstances, including, but not limited to, (i) if the registration statement is not filed by the earlier of 45 days after the date of the Registration Rights Agreement or 10 days after the Company files its first Form 10-Q following the Registration Rights Agreement (ii) if the registration statement has not been declared effective (A) by the 120th day after the date of the Registration Rights Agreement (or, in the event of a “full review” by the Securities and Exchange Commission (the “SEC”), the 150th day after the date of the Registration Rights Agreement) or (B) within five trading days following the date the Company is notified by the SEC that the registration statement will not be reviewed or is no longer subject to further review and comments then the Company has agreed to pay the Investor, as partial liquidated damages, an amount equal to 1.0% of the Investor’s aggregate subscription amount paid pursuant to the Purchase Agreement.

H.C. Wainwright & Co., LLC (“HCW”) was entitled to fees related to the Offering under a tail provision in an engagement letter with the Company that relates to HCW’s assistance as a Placement Agent in a prior offering in July 2020 between the Investor and the Company (the “Tail Provision”). Pursuant to the Tail Provision, the Company paid HCW a cash fee equal to 7.5% of the gross proceeds received by the Company in the Offering, totaling approximately \$750,000. In addition, the Company has agreed to issue to HCW or its designees warrants to purchase up to 357,995 shares of common stock (representing 7.5% of the aggregate number of shares of common stock equivalents sold in the Offering) (the “HCW Warrants”). The HCW Warrants have substantially the same terms as the Unregistered Warrants, except that the HCW Warrants have an exercise price equal to \$2.46, or 125% of the offering price per share of common stock and will be exercisable for five years from the effective date of the Offering.

The issuance and sale of the Units, the Warrants, the HCW Warrants and the shares of common stock issuable upon exercise of the Warrants and the HCW Warrants were not registered under the Securities Act of 1933, as amended (the “Securities Act”), and were offered pursuant to the exemption provided in Section 4(a)(2) under the Securities Act and Rule 506(b) promulgated thereunder.

On July 13, 2021, Anthony A. DiTonno retired as the Chief Executive Officer of the Company and as a member of the Company’s Board of Directors (the “Board”) effective as of July 13, 2021 (the “Effective Separation Date”). In connection with his retirement, Mr. DiTonno entered into a Separation and General Release Agreement with the Company (the “Separation Agreement”), dated July 6, 2021. The terms of the Separation Agreement provided that Mr. DiTonno had the right to revoke the Separation Agreement until July 22, 2021.

Under the Separation Agreement, Mr. DiTonno is entitled to receive severance in an amount equal to one year of his current base annual salary, and a pro-rated amount of his annual bonus that would have been received had 100% of his annual goals been achieved, approximately \$563,000 (less applicable taxes and withholdings), payable in a lump sum on the 60th day following the Effective Separation Date. The Company will also reimburse COBRA premiums for coverage of Mr. DiTonno and his eligible dependents for up to 18 months if Mr. DiTonno timely and properly elects continuation coverage. The foregoing payments were contingent on Mr. DiTonno’s standard release of employment claims. In connection with his retirement and in order to ensure a smooth transition to the new CEO, Mr. DiTonno has received a stock option grant for 50,000 shares of common stock. All of Mr. DiTonno’s outstanding stock options for common stock of the Company accelerated upon the Effective Separation Date, becoming fully vested, and are exercisable until the earlier of: (i) the original expiration date of each option under such option’s respective option agreement; or (ii) July 13, 2026. The Company is additionally reimbursing Mr. DiTonno for up to \$5,000 in legal expenses related to the Separation Agreement. The Separation Agreement also contains such non-competition, non-solicitation, and confidentiality provisions and other terms and conditions as are usual and customary for agreements of this type. All of Mr. DiTonno’s obligations under his Employee Non-Disclosure, Inventions Assignment, and Competitive Business Activities Agreement, dated June 1, 2018, regarding confidentiality and proprietary information will continue.

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

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the “safe harbor” created by those sections. Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to them. In some cases you can identify forward-looking statements by words such as “may,” “will,” “should,” “could,” “would,” “expects,” “plans,” “anticipates,” “believes,” “estimates,” “projects,” “predicts,” “potential” and similar expressions intended to identify forward-looking statements. Examples of these statements include, but are not limited to, statements regarding: the implications of interim or final results of our clinical trials, the progress of our research programs, including clinical testing, the extent to which our issued and pending patents may protect our products and technology, our ability to identify new product candidates, the potential of such product candidates to lead to the development of commercial products, our anticipated timing for initiation or completion of our clinical trials for any of our product candidates, our future operating expenses, our future losses, our future expenditures for research and development, our relationship with Orion Corporation, or Orion, our ability to raise capital, the sufficiency of our cash resources, our ability to successfully integrate operations pursuant to our merger with PH Precision Med, the impacts of the current COVID-19 pandemic and the eligibility for forgiveness of our loan, or the PPP Loan, received pursuant to the Paycheck Protection Program under the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, as administered by the U.S. Small Business Administration, or 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, or the 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, 2020.

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. On November 13, 2013, through our wholly owned subsidiary, Life Newco, Inc., or Life Newco, we acquired a license granting Life Newco an exclusive, sublicensable right to develop and commercialize pharmaceutical products containing levosimendan, 2.5 mg/ml concentrate for solution for infusion / 5ml vial in the United States and Canada. On October 9, 2020, we entered into an amendment to the license 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.

On January 15, 2021, through our wholly owned subsidiary, Life Newco II, Inc., or Life Newco II, we acquired 100% of the equity of PHPrecisionMed Inc., a Delaware corporation, or PHPM. In accordance with the terms of the merger agreement between Life Newco II and PHPM, Life Newco II merged with and into PHPM, with PHPM surviving as our wholly owned subsidiary. As a result of the merger, we plan to develop and commercialize pharmaceutical products containing imatinib for the treatment of pulmonary arterial hypertension.

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## Our Current Programs

### Levosimendan Background

Levosimendan was discovered and developed by Orion Corporation, a Finnish company, or Orion. Levosimendan is a *calcium sensitizer/K-ATP activator* developed for intravenous use in hospitalized patients with acutely decompensated heart failure. It is currently approved in over 60 countries for this indication and not available in the United States or Canada. It is estimated that to date over 1.5 million patients have been treated worldwide with levosimendan.

Levosimendan is a novel, first in class *calcium sensitizer/K-ATP activator*. The therapeutic effects of levosimendan are mediated through:

- Increased cardiac contractility by calcium sensitization of troponin C, resulting in a positive inotropic effect which is not associated with substantial increases in oxygen demand.
- Opening of potassium channels in the vasculature smooth muscle, resulting in a vasodilatory effect on all vascular beds.
- Opening of mitochondrial potassium channels in cardiomyocytes, resulting in a cardioprotective effect.

This triple mechanism of action helps to preserve heart function during cardiac surgery. Several studies have demonstrated that levosimendan protects the heart and improves tissue perfusion while minimizing tissue damage during cardiac surgery.

In 2013, we acquired certain assets of Phyxius Pharma, Inc., or Phyxius, including its North American rights to develop and commercialize levosimendan for any indication in the United States and Canada. In the countries where levosimendan is marketed, levosimendan is indicated for the short-term treatment of acutely decompensated severe chronic heart failure in situations where conventional therapy is not sufficient, and in cases where inotropic support is considered appropriate. In acute decompensated heart failure patients, levosimendan has been shown to significantly improve patients’ symptoms as well as acute hemodynamic measurements such as increased cardiac output, reduced preload and reduced afterload.

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

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### ***Levosimendan Development for Pulmonary Hypertension Patients***

We recently completed a Phase 2 clinical trial of levosimendan in North America for the treatment of patients with pulmonary hypertension associated with heart failure with preserved ejection fraction, or PH-HFpEF. PH-HFpEF is defined hemodynamically by a mean pulmonary artery pressure, or mPAP,  $\geq 25$  mmHg, and a pulmonary capillary wedge pressure, or PCWP,  $> 15$  mmHg. Pulmonary hypertension in these patients is believed to arise 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. Over time, these changes often lead to advanced pulmonary arterial and venous disease, increased right ventricle afterload, and right ventricle 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 and pulmonary artery pressure in patients with pulmonary hypertension. In addition, several published studies provide evidence that levosimendan may improve right ventricular dysfunction which is a common comorbidity in patients with pulmonary hypertension. While none of these studies have focused specifically on PH-HFpEF patients, the general hemodynamic improvements in these published studies of various types of pulmonary hypertension provide a basis to believe that levosimendan may be beneficial in PH-HFpEF patients.

In March 2018, we met with the United States Food and Drug Administration, or FDA, to discuss development of levosimendan in PH-HFpEF patients. The FDA agreed with our planned Phase 2 design, patient entry criteria, and endpoints. 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. This topic was discussed further at the End-of-Phase 2 Meeting following completion of the Phase 2 study in PH-HFpEF patients, which is known as the HELP Study – **Hemodynamic Evaluation of Levosimendan in PH-HFpEF**.

We initiated the first of our expected 10-12 HELP Study clinical sites in November 2018 and the first of 37 patients were 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 was based on the change in PCWP during exercise versus baseline compared to placebo. The HELP Study utilized a double-blind randomized design following five weekly outpatient infusions of levosimendan.

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 as compared to placebo ( $p = 0.0329$ ). These findings from the HELP Study represent important discoveries related to the use of levosimendan in PH-HFpEF patients since this is the first study to evaluate levosimendan in PH-HFpEF patients and this is the first study ever conducted of any therapy in PH-HFpEF patients to show such positive improvements in hemodynamics and 6-minute walk distance.

#### ***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). In the initial open-label phase, 84% of the patients had a significant reduction in right atrial pressure, or RAP, pulmonary artery pressure, or PAP and PCWP at rest and during exercise. In the randomized double-blinded 6-week trial, 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, PAP, and 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.

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### ***Safety***

The incidence of adverse events or serious adverse events 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 Virtual Annual Scientific Meeting on October 3, 2020 and at the American Heart Association Scientific Sessions 2020 on November 13, 2020. Additionally, the full manuscript has been accepted for publication in the peer-reviewed journal JACC:Heart Failure.

### **Next Steps**

On October 9, 2020, we entered into an amendment, or the Amendment, to the License between the Company and Orion to include two new product formulations containing levosimendan, in a capsule solid oral dosage form, and a subcutaneously administered dosage form containing levosimendan, to the scope of the License, subject to specified limitations.

We plan to study the utility of the levosimendan oral capsule dosage form in patients who have participated in the open-label extension of the HELP Study and who continue to receive weekly infusions of intravenous levosimendan. These patients are now eligible to participate in the amendment to the HELP Study that will transition them from the intravenous to an oral formulation. The investigators at the centers that participated in the HELP Study have been invited to participate and enroll their patients into this study.

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 (depending on the size) with a primary endpoint of change in 6-minute walk distance over 12 weeks or a single Phase 3 trial with clinical worsening (e.g., death, hospitalization for heart failure, or decline in exercise capacity) over 24 weeks would 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 expressed concern about a safety database as potentially necessary and indicated that the need for a further safety database could be dependent on the final design of the Phase 3 study. We expect that this will be addressed when the final Phase 3 protocol is submitted which will better characterize the trial design and primary endpoints.

The HELP Study design was novel in several respects. To date, no other multi-center study has evaluated levosimendan in heart failure patients with preserved ejection fraction, or HFpEF, patients or PH-HFpEF patients. Instead, all previous levosimendan heart failure studies have enrolled heart failure patients with reduced ejection fraction, or HFrEF, which specifically excluded HFpEF patients. Also, the HELP Study utilized a unique 24-hour weekly infusion regimen of 0.075- 0.1µm/kg/min. Finally, the HELP Study employed a unique home-based intravenous infusion administration via an ambulatory infusion pump. This home-based weekly intravenous 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.

We believe that the combination of the unique HELP Study patient population, innovative weekly 24-hour dosing, unique home-based site of administration, and novel findings of efficacy and safety in PH-HFpEF patients represent unique discoveries and significant intellectual property. These discoveries, among others from the HELP Study, form the basis for a U.S. patent application that we have filed.

### **Imatinib Background**

Imatinib (also known as “Gleevec”), is a tyrosine kinase inhibitor, which revolutionized the treatment of chronic myeloid leukemia, or CML, in 2001. The first clinical trial of imatinib took place in 1998 and the drug received FDA approval in May 2001. Encouraged by the success of Imatinib in treating CML patients, scientists explored its effect in other cancers, and it was found to produce a similar positive effect in other cancers where tyrosine kinases were overexpressed.

Tyrosine kinases are important mediators of the signaling cascade, determining key roles in diverse biological processes like growth, differentiation, metabolism, and apoptosis in response to external and internal stimuli. Deregulation of protein kinase activity has been shown to play a central role in the pathogenesis of human cancers. Imatinib, a 2-phenyl amino pyrimidine derivative, is a tyrosine kinase inhibitor with activity against ABL, BCR-ABL, PDGFRA, and c-KIT. Imatinib works by binding close to the ATP binding site therefore inhibiting the enzyme activity of the protein. Imatinib also inhibits the ABL protein of noncancer cells. Imatinib is well absorbed after oral administration with a bioavailability exceeding 90%. It is extensively metabolized, principally by cytochrome P450 (CYP)3A4 and CYP3A5 and can competitively inhibit the metabolism of drugs that are CYP3A4 or CYP3A5 substrates. Imatinib is generally well tolerated in cancer patients. Common side effects include fluid retention, headache, diarrhea, loss of appetite, weakness, nausea and vomiting, abdominal distention, edema, rash, dizziness, and muscle cramps. Serious side effects may include myelosuppression, heart failure, and liver function abnormalities. Novartis is the manufacturer of Gleevec.

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### **Previous Imatinib Development for Pulmonary Arterial Hypertension Patients**

In pulmonary arterial hypertension, or PAH, a rare disease, subjects who remain symptomatic despite available therapies have a high morbidity and mortality. Though several therapies are now available, there is no cure for the disease, and there is no data supporting that the existing therapies, all of which are pulmonary vasodilators, halt progression or induce regression of the disease. Imatinib is a tyrosine kinase inhibitor that has been shown in animal models of pulmonary hypertension to induce disease reversal by an effect on platelet derived growth factor, or PDGF, which appears to be causal in the disease. After that discovery was made, several case reports and small case series of patients with advanced PAH failing combination pulmonary vasodilator therapy were published showing a dramatic effect of imatinib on stabilizing and improving these patients. This led Novartis to develop imatinib as a treatment of PAH.

Novartis sponsored a Phase 2 proof-of-concept trial to evaluate the safety, tolerability, and efficacy of imatinib as an adjunct to PAH specific therapy in patients with PAH. This was a 24-week randomized, double-blind, placebo-controlled study of PAH subjects who remained symptomatic on one or more PAH therapies in WHO Functional Class (FC) II-IV. The Phase 2 trial of imatinib in PAH caused significant hemodynamic improvement in some patients but failed to meet the primary endpoint of an increase in 6-minute walk distance (22 meters, p=NS). Novartis then sponsored a Phase 3 trial (IMPRES) which met its primary endpoint of significant increase in 6-minute walk (32 meters, p=0.002), an effect maintained in the extension study in patients remaining on imatinib. However, the data were confounded by a high rate of dropouts in the patients randomized to imatinib attributed largely to gastric

intolerance during the first eight weeks. The sponsor proposed consideration of a surrogate endpoint under the subpart H provision as a basis for approval but was denied. Consequently, Novartis chose to withdraw the Investigational New Drug application as the drug went off patent.

### **Current Imatinib Development for Pulmonary Arterial Hypertension Patients**

On May 30, 2019, PHPM met with the FDA to discuss a proposal for a Phase 3 trial of imatinib for PAH. At that meeting, PHPM received agreement for a single Phase 3 trial using change in 6-minute walk distance as the primary endpoint ( $p < 0.05$ ). PHPM also received agreement for submission under the 505(b)(2) regulatory pathway, and thereafter received orphan designation. In August of 2019, PHPM was given preliminary advice on its plans to submit an application for Breakthrough Therapy Designation. In July 2020, PHPM received agreement from the FDA for the development of a modified release formulation that would require only a small comparative PK/bioavailability study in 12 volunteers receiving a single dose of the modified release formulation to be compared to a single dose of the existing immediate release formulation. A Phase 3 study is planned with the modified release formulation of imatinib.

### **Second Quarter 2021 Highlights**

The following summarizes certain key financial measures for the three months ended June 30, 2021:

- Cash and cash equivalents, including the fair-value of our marketable securities, were \$2.2 million on June 30, 2021.
- Our net loss from operations was \$2.0 million for the second quarter of fiscal 2021 compared to \$2.1 million for the three months ended June 30, 2020.
- Net cash used in operating activities was \$1.9 million and \$2.2 million for the three months ended June 30, 2021 and 2020, respectively.

### **Opportunities and Trends**

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, 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.

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

During 2021, we are focused on the following initiatives:

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

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### **Financial Overview**

#### **Results of Operations- Comparison of the Three Months Ended June 30, 2021 and 2020**

##### **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 June 30, 2021 and 2020, respectively, are as follows:

	<b>Three months ended June 30,</b>		<b>Increase/ (Decrease)</b>	<b>% Increase/ (Decrease)</b>
	<b>2021</b>	<b>2020</b>		
Personnel costs	\$ 711,174	\$ 700,737	\$ 10,437	1%
Legal and professional fees	343,122	(32,879)	376,001	1,144%
Other costs	176,223	160,409	15,814	10%
Facilities	40,759	40,939	(180)	(0)%

##### *Personnel costs:*

Personnel costs remained relatively consistent for the three months ended June 30, 2021 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 increased approximately \$376,000 for the three months ended June 30, 2021 compared to the same period in the prior year. This increase was due primarily to the reimbursement of approximately \$358,000 in legal fees associated with arbitration proceedings in the prior year, as well as increases in Board of Directors fees and capital market expenses, partially offset by a reduction in investor relations services.

- Board of Director fees increased approximately \$40,000 in the current period due primarily to fees paid to new directors that were not incurred during the same period in the prior year.
- Capital market fees increased approximately \$35,000 in the current period. This increase was due primarily to an increase in proxy related costs incurred in the current period as compared to the same period in the prior year.
- Investor relations costs decreased approximately \$21,000 in the current period. This decrease was primarily due to fees paid to third-party investor relations firms for direct outreach and communications in the prior year that were not incurred in the current period.

*Other costs:*

Other costs include costs incurred for franchise and other taxes, travel, supplies, insurance, depreciation and other miscellaneous charges. Other costs increased approximately \$16,000 in the current period due primarily to an increase of approximately \$25,000 in insurance premiums paid, partially offset by a decrease of approximately \$11,000 in franchise 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 June 30, 2021 and 2020.

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**Research and Development Expenses**

Research and development expenses include, but are not limited to, (i) expenses incurred under agreements with clinical research organizations, or CROs, and investigative sites, which conduct our clinical trials and a substantial portion of our pre-clinical studies; (ii) the cost of manufacturing and supplying clinical trial materials; (iii) payments to contract service organizations, as well as consultants; (iv) employee-related expenses, which include salaries and benefits; and (v) facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, depreciation of leasehold improvements, equipment, laboratory and other supplies. All research and development expenses are expensed as incurred. Research and development expenses and percentage changes for the three months ended June 30, 2021 and 2020, respectively, are as follows:

	<b>Three months ended June 30,</b>		<b>Increase/ (Decrease)</b>	<b>% Increase/ (Decrease)</b>
	<b>2021</b>	<b>2020</b>		
Clinical and preclinical development	\$ 548,909	\$ 1,218,156	\$ (669,247)	(55)%
Personnel costs	142,707	54,193	88,514	163%
Other costs	1,606	2,488	(882)	(35)%

*Clinical and preclinical development:*

Clinical and preclinical development costs include the costs associated with our Phase 2 HELP Study for levosimendan, which was completed during fiscal year 2020, the costs associated with our IV to oral levosimendan transition study and development costs associated with the formulation for imatinib. The decrease of approximately \$670,000 in clinical and preclinical development costs for the three months ended June 30, 2021 compared to the same period in the prior year was primarily due to a decrease of approximately \$524,000 in expenditures for CRO costs and a reduction of approximately \$261,000 in enrolled patient costs in the current period as compared to the same period in the prior year. These cost reductions were partially offset by an increase of approximately \$114,000 in costs associated with formulation development of imatinib in the current period that were not incurred in the same period in the prior year.

*Personnel costs:*

Personnel costs increased approximately \$89,000 for the three months ended June 30, 2021 due primarily to the addition of our Chief Medical Officer in the current period.

*Other costs:*

Other costs remained relatively consistent for the three months ended June 30, 2021 and 2020.

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 two product candidates, levosimendan and imatinib; however, we will need substantial additional capital in the future in order to complete the development and potential commercialization of levosimendan and imatinib, and to continue with the development of other potential product candidates.

**Other income and expense, net**

Other income and expense include non-operating income and expense items not otherwise recorded in our condensed consolidated statement of comprehensive loss. These items include, but are not limited to, changes in the fair value of financial assets and derivative liabilities, interest income earned and fixed asset disposals. Other income and expense for the three months ended June 30, 2021 and 2020, respectively, are as follows:

<b>Three months ended June 30,</b>	<b>(Increase)/ Decrease</b>
<b>2021</b>	<b>2020</b>

Other (income) expense, net	\$	(247,820)	\$	2,101	\$	(249,921)
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Other income increased approximately \$250,000 for the three months ended June 30, 2021 compared to the same period in the prior year. This increase is due primarily to the forgiveness of our PPP Loan in the current period.

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**Results of Operations- Comparison of the Six Months Ended June 30, 2021 and 2020**

**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 six months ended June 30, 2021 and 2020, respectively, are as follows:

	<u>Six months ended June 30,</u>		<u>Increase/ (Decrease)</u>	<u>% Increase/ (Decrease)</u>
	<u>2021</u>	<u>2020</u>		
Personnel costs	\$ 1,506,684	\$ 1,438,007	\$ 68,677	5%
Legal and professional fees	725,670	324,951	400,719	123%
Other costs	330,868	350,002	(19,134)	(5)%
Facilities	81,516	79,205	2,311	3%

*Personnel costs:*

Personnel costs increased approximately \$69,000 for the six months ended June 30, 2021 compared to the same period in the prior year. This increase was due primarily an increase of approximately \$27,000 in salaries and benefits paid and an increase of approximately \$42,000 in expense recognized for vested employee stock options 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 increased approximately \$401,000 for the six months ended June 30, 2021 compared to the same period in the prior year. This increase was due primarily to the reimbursement of approximately \$358,000 in legal fees associated with arbitration proceedings in the prior year, as well as an increase in accounting fees, legal fees, capital market expenses and Board of Directors fees, partially offset by a reduction in investor relations services.

- Legal fees increased approximately \$311,000 in the current period. This increase was due primarily to the reimbursement of approximately \$358,000 in legal fees associated with arbitration proceedings in the prior year, as well as an increase in fees paid associated with the PHPM acquisition and our intellectual property portfolio, partially offset by costs incurred for arbitration in the prior year.
- Accounting fees increased approximately \$42,000 in the current period due primarily to fees associated with the PHPM transaction that were not incurred during the same period in the prior year.
- Board of Director fees increased approximately \$51,000 in the current period due primarily to fees paid to new directors that were not incurred during the same period in the prior year.
- Capital market fees increased approximately \$25,000 in the current period. This increase was due primarily to an increase in proxy related costs incurred in the current period as compared to the same period in the prior year
- Investor relations costs decreased approximately \$33,000 in the current period. This decrease was primarily due to fees paid to third-party investor relations firms for direct outreach and communications in the prior year that were not incurred in the current period.

*Other costs:*

Other costs include costs incurred for franchise and other taxes, travel, supplies, insurance, depreciation and other miscellaneous charges. Other costs decreased approximately \$19,000 in the current period due primarily to a decrease in franchise taxes paid, partially offset by an increase of approximately \$51,000 in insurance premiums 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 six months ended June 30, 2021 and 2020.

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**Research and Development Expenses**

Research and development expenses include, but are not limited to, (i) expenses incurred under agreements with clinical research organizations, or CROs, and investigative sites, which conduct our clinical trials and a substantial portion of our pre-clinical studies; (ii) the cost of manufacturing and supplying

clinical trial materials; (iii) payments to contract service organizations, as well as consultants; (iv) employee-related expenses, which include salaries and benefits; and (v) facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent and maintenance of facilities and equipment, depreciation of leasehold improvements, equipment, laboratory and other supplies. All research and development expenses are expensed as incurred. Research and development expenses and percentage changes for the six months ended June 30, 2021 and 2020, respectively, are as follows:

	<u>Six months ended June 30,</u>		<u>Increase/ (Decrease)</u>	<u>% Increase/ (Decrease)</u>
	<u>2021</u>	<u>2020</u>		
Clinical and preclinical development	\$ 1,049,087	\$ 2,500,817	\$ (1,451,730)	(58)%
Personnel costs	278,949	109,336	169,613	155%
Other costs	21,741,388	7,210	21,734,178	301,445%

*Clinical and preclinical development:*

Clinical and preclinical development costs include the costs associated with our Phase 2 HELP Study for levosimendan, which was completed during fiscal year 2020, the costs associated with our IV to oral levosimendan transition study and development costs associated with the formulation for imatinib. The decrease of approximately \$1.5 million in clinical and preclinical development costs for the six months ended June 30, 2021 compared to the same period in the prior year was primarily due to a decrease of approximately \$859,000 in expenditures for CRO costs, a reduction of approximately \$764,000 in enrolled patient costs and a decrease of approximately \$139,000 in fees paid for clinical research associates and other direct costs to manage the Phase 2 HELP Study in the current period as compared to the same period in the prior year. These cost reductions were partially offset by an increase of approximately \$260,000 in costs associated with formulation development of imatinib in the current period that were not incurred in the same period in the prior year.

*Personnel costs:*

Personnel costs increased approximately \$170,000 for the six months ended June 30, 2021 due primarily to the addition of our Chief Medical Officer in the current period.

*Other costs:*

Other costs increased approximately \$21.7 million for the six months ended June 30, 2021 due primarily to the recognition of in-process research and development acquired as part of the merger with PHPM in the current period that was not incurred in 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 two product candidates, levosimendan and imatinib; however, we will need substantial additional capital in the future in order to complete the development and potential commercialization of levosimendan and imatinib, and to continue with the development of other potential product candidates.

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

Other income and expense include non-operating income and expense items not otherwise recorded in our condensed consolidated statement of comprehensive loss. These items include, but are not limited to, changes in the fair value of financial assets and derivative liabilities, interest income earned and fixed asset disposals. Other income for the six months ended June 30, 2021 and 2020, respectively, are as follows:

	<u>Six months ended June 30,</u>		<u>(Increase)/ Decrease</u>
	<u>2021</u>	<u>2020</u>	
Other income, net	\$ (249,955)	\$ (8,740)	\$ (241,215)

Other income increased approximately \$241,000 for the six months ended June 30, 2021 compared to the same period in the prior year. This increase is due primarily to the forgiveness of our PPP Loan in the current period.

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

We have incurred losses since our inception, and as of June 30, 2021 we had an accumulated deficit of approximately \$271 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 imatinib for pulmonary arterial hypertension, 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 \$2,532,227 and \$6,795,506 and working capital of \$1,357,217 and \$4,676,543 as of June 30, 2021 and December 31, 2020, respectively. Based on our working capital and the value of our investments in marketable securities on June 30, 2021 and the net proceeds from our July 2021 offering, we believe we have sufficient capital to fund our operations through the second quarter of calendar year 2022.

***Cash Flows***

The following table shows a summary of our cash flows for the six months ended June 30, 2021 and 2020:

	<b>Six months ended June 30,</b>	
	<b>2021</b>	<b>2020</b>
Net cash used in operating activities	\$ (5,066,239)	\$ (4,899,965)
Net cash (used in) provided by investing activities	(57,231)	13,911
Net cash provided by financing activities	544,651	4,065,366

*Net cash used in operating activities.* Net cash used in operating activities was approximately \$5.1 million for the six months ended June 30, 2021 compared to net cash used in operating activities of approximately \$4.9 million for the six months ended June 30, 2020. The increase in cash used for operating activities was due primarily to an increase in our annual insurance premiums and accrued bonuses paid in the current period as compared to the prior year.

*Net cash (used in) provided by investing activities.* Net cash used in investing activities was approximately \$57,000 for the six months ended June 30, 2021 compared to approximately \$14,000 provided by investing activities for the six months ended June 30, 2020. The increase in cash used investing activities was primarily due to the purchase of marketable securities in the current period.

*Net cash provided by financing activities.* Net cash provided by financing activities was approximately \$545,000 for the six months ended June 30, 2021 compared to approximately \$4.1 million for the six months ended June 30, 2020. The decrease in cash provided by financing activities was due primarily to net proceeds of approximately \$2.1 million from the March 2020 offering, and the issuance of 877,203 shares of common stock upon the exercise of approximately \$1.7 million of outstanding warrants in the prior period, as compared with approximately \$545,000 received upon the exercise of warrants in the current period.

### **Operating Capital and Capital Expenditure Requirements**

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

- the initiation, progress, timing and completion of clinical trials for our product 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.

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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 second quarter of calendar year 2022. We will need substantial additional capital in the future in order to complete the development and commercialization of levosimendan and imatinib, 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, 2020, 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, the 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. Our adoption of this new guidance did not 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 June 30, 2021, 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.

During the most recently completed fiscal quarter, management reviewed all work generated in support of the financial statements and corresponding footnotes in order to determine areas which may be susceptible to human error. The review focused on limiting manual inputs into work papers wherever possible and tying inputs to external source documents. In addition, management also enhanced its work paper review to compare figures to prior year amounts or source documents and increased the number of calculations in the work papers that are reviewed and re-performed.

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## **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, 2020.

### **ITEM 5. OTHER INFORMATION**

On June 10, 2021, the Company's stockholders approved Amendment No. 2 to amend the 2016 Plan to increase the number of shares that may be issued under the 2016 Plan by 750,000 shares (the "Plan Amendment").

The foregoing description of the Plan Amendment is qualified in its entirety by reference to the Plan Amendment, which is attached to this Quarterly Report on Form 10-Q as Exhibit 10.1 and is incorporated herein by reference.

### **ITEM 6. EXHIBITS**

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

<b>No.</b>	<b>Description</b>
<a href="#">10.1</a>	<a href="#">Amendment No. 2 to 2016 Stock Incentive Plan*+</a>
<a href="#">31.1</a>	<a href="#">Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes Oxley Act of 2002</a>
<a href="#">31.2</a>	<a href="#">Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes Oxley Act of 2002</a>
<a href="#">32.1</a>	<a href="#">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</a>
<a href="#">32.2</a>	<a href="#">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</a>

101\* Inline XBRL Document Set for the condensed consolidated financial statements and accompanying notes in Part I, Item 1, "Financial Statements" of this Quarterly Report on Form 10-Q.

104\* Inline XBRL for the cover page of this Quarterly Report on Form 10-Q, included in the Exhibit 101 Inline XBRL Document Set.

**\*Filed herewith**

**+ Management contract or compensatory plan or arrangement**

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### 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: August 16, 2021

By: /s/ Michael B. Jebsen

Michael B. Jebsen

President and Chief Financial Officer

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

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**AMENDMENT NO. 2 TO  
TENAX THERAPEUTICS, INC.  
2016 STOCK INCENTIVE PLAN**

This Amendment No. 2 (the "Amendment") to the Tenax Therapeutics, Inc. 2016 Stock Incentive Plan (the "Plan") to increase the number of shares of common stock issuable under the Plan is made on April 27, 2021, effective as of the time provided below.

**WHEREAS**, Tenax Therapeutics, Inc. (the "Company") has heretofore adopted the Plan;

**WHEREAS**, as a result of the February 23, 2018 reverse stock split, the number of shares of the Company's common stock issuable under the Plan was reduced from 3,000,000 to 150,000; and

**WHEREAS**, on June 13, 2019, the stockholders approved Amendment No. 1 to the 2016 Plan, increasing the number of shares of common stock authorized for issuance under the 2016 Plan to a total of 750,000 shares; and

**WHEREAS**, on April 27, 2021, our Board of Directors approved, subject to stockholder approval, Amendment No. 2 to the 2016 Plan to increase the number of shares of common stock authorized for issuance under the 2016 Plan to a total of 1.5 million shares, representing an increase of 750,000 shares; and

**WHEREAS**, the Board of Directors of the Company has approved the Amendment contingent upon the approval of the Amendment by the stockholders of the Company.

**NOW, THEREFORE, BE IT RESOLVED**, that, pursuant to Section 17.1 of the Plan, the Plan is hereby amended as follows, effective as of such time as the Amendment is approved by the stockholders of the Company:

Section 4.1 of the Plan is amended by replacing "seven hundred and fifty thousand (750,000) Shares" with one million five hundred thousand (1,500,000) Shares."

Except as expressly amended hereby, all provisions of the Plan shall remain unamended and shall continue to be, and shall remain, in full force and effect in accordance with their respective terms.

The Amendment shall have no effect until such time as it is approved by the stockholders of the Company.

The provisions of the Amendment shall be governed by and interpreted in accordance with the laws of the State of Delaware.

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

I, Christopher Giordano, 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: August 16, 2021

*/s/ Christopher Giordano*

Christopher Giordano

Chief Executive Officer

(Principal Executive Officer)

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

I, Michael B. Jebsen, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Tenax Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the 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: August 16, 2021

*/s/ Michael B. Jebsen*

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Michael B. Jebsen

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

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

In connection with the Quarterly Report of Tenax Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Christopher Giordano, 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: August 16, 2021

*/s/ Christopher Giordano*

\_\_\_\_\_  
Christopher Giordano

*Chief Executive Officer*

*(Principal Executive Officer)*

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

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

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

In connection with the Quarterly Report of Tenax Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2021 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: August 16, 2021

*/s/ Michael B. Jebsen*

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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.