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

# FORM 10-Q

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

**FOR THE QUARTERLY PERIOD ENDED September 30, 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** | **26-2593535** |
|---|---|
| **(State of incorporation)** | **(I.R.S. Employer Identification No.)** |

**ONE Copley Parkway, Suite 490, Morrisville, North Carolina 27560**
**(Address of principal executive offices)**

**(919) 855-2100**
**(Registrant's telephone number, including area code)**

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

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

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

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

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

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

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

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

As of November 12, 2021, the registrant had outstanding 25,206,914 shares of Common Stock.

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## PART I - FINANCIAL INFORMATION

### ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

**TENAX THERAPEUTICS, INC.**

**CONDENSED CONSOLIDATED BALANCE SHEETS**

| | September 30, 2021 (Unaudited) | December 31, 2020 |
|---|---|---|
| **ASSETS** | | |
| Current assets | | |
| Cash and cash equivalents | $ 8,354,075 | $ 6,250,241 |
| Marketable securities | - | 462,687 |
| Prepaid expenses | 229,152 | 82,578 |
| Total current assets | 8,583,227 | 6,795,506 |
| Right of use asset | 313,443 | 58,778 |
| Property and equipment, net | 6,489 | 5,972 |
| Other assets | 8,435 | 8,435 |
| Total assets | $ 8,911,594 | $ 6,868,691 |
| **LIABILITIES AND STOCKHOLDERS EQUITY** | | |
| Current liabilities | | |
| Accounts payable | $ 776,247 | $ 757,856 |
| Accrued liabilities | 685,114 | 1,240,616 |
| Note payable | - | 120,491 |
| Total current liabilities | 1,461,361 | 2,118,963 |
| Long term liabilities | | |
| Lease liability | 211,590 | - |
| Note payable | - | 124,166 |
| Total long term liabilities | 211,590 | 124,166 |
| Total liabilities | 1,672,951 | 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 | 282,519,752 | 250,644,197 |
| Accumulated other comprehensive gain (loss) | 2 | (70) |
| Accumulated deficit | (275,283,631) | (246,019,827) |
| Total stockholders equity | 7,238,643 | 4,625,562 |
| Total liabilities and stockholders' equity | $ 8,911,594 | $ 6,868,691 |

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



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**TENAX THERAPEUTICS, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

| | Three months ended September 30, | | Nine months ended September 30, | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| | (Unaudited) | (Unaudited) | (Unaudited) | (Unaudited) |
| Operating expenses | | | | |
| General and administrative | $ 2,639,920 | $ 1,172,725 | $ 5,284,658 | $ 3,364,890 |
| Research and development | 1,162,370 | 1,052,398 | 24,231,794 | 3,669,761 |
| Total operating expenses | 3,802,290 | 2,225,123 | 29,516,452 | 7,034,651 |
| Net operating loss | 3,802,290 | 2,225,123 | 29,516,452 | 7,034,651 |
| Interest expense | - | 610 | 949 | 1,016 |
| Other income, net | (3,642) | (5,298) | (253,597) | (14,038) |
| Net loss | $ 3,798,648 | $ 2,220,435 | $ 29,263,804 | $ 7,021,629 |
| Unrealized (gain) loss on marketable securities | (276) | 1,171 | (72) | (445) |
| Total comprehensive loss | $ 3,798,372 | $ 2,221,606 | $ 29,263,732 | $ 7,021,184 |
| Net loss per share, basic and diluted | $ (0.15) | $ (0.18) | $ (1.54) | $ (0.73) |
| Weighted average number of common shares outstanding, basic and diluted | 25,201,312 | 12,427,355 | 19,017,311 | 9,590,741 |

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 | | | | |
| **Balance at December 31, 2019** | **38,606** | **$ 4** | **6,741,860** | **$ 674** | **$ 239,939,797** | **$ 458** | **$ (236,168,436)** | **$ 3,772,497** |
| Common stock and pre-funded warrants sold, net of offering costs | | | 750,000 | 75 | 2,129,930 | | | 2,130,005 |
| Compensation on options issued | | | | - | 72,376 | | | 72,376 |
| Common stock issued for services rendered | | | 77,987 | 8 | 99,992 | | | 100,000 |
| Common stock issued for convertible preferred stock | (38,396) | (4) | 38,396 | 4 | - | | | - |
| Exercise of pre-funded warrants | | | 400,000 | 40 | - | | | 40 |
| Unrealized loss on marketable securities | | | | | | (1,622) | | (1,622) |
| Net loss | | | | | | | (2,654,644) | (2,654,644) |
| **Balance at March 31, 2020** | **210** | **$ -** | **8,008,243** | **$ 801** | **$ 242,242,095** | **$ (1,164)** | **$ (238,823,080)** | **$ 3,418,652** |
| Compensation on options issued | | | | - | 63,166 | | | 63,166 |
| Exercise of pre-funded warrants | | | 1,210,313 | 121 | - | | | 121 |
| Exercise of warrants | | | 877,202 | 88 | 1,690,455 | | | 1,690,543 |
| Unrealized gain on marketable securities | | | | | | 3,238 | | 3,238 |
| Net loss | | | | | | | (2,146,550) | (2,146,550) |
| **Balance at June 30, 2020** | **210** | **$ -** | **10,095,758** | **$ 1,010** | **$ 243,995,716** | **$ 2,074** | **$ (240,969,630)** | **$ 3,029,170** |
| Common stock and pre-funded warrants sold, net of offering costs | | | 2,523,611 | 252 | 6,532,727 | | | 6,532,979 |
| Compensation on options issued | | | | | 63,161 | | | 63,161 |
| Unrealized loss on marketable securities | | | | | | (1,171) | | (1,171) |
| Net loss | | | | | | | (2,220,435) | (2,220,435) |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Balance at September 30, 2020** | **210** | **$ -** | **12,619,369** | **$ 1,262** | **$ 250,591,604** | **$ 903** | **$ (243,190,065)** | **$ 7,403,704** |
| **Balance at December 31, 2020** | **210** | **$ -** | **12,619,369** | **$ 1,262** | **$ 250,644,197** | **$ (70)** | **$ (246,019,827)** | **$ 4,625,562** |
| 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) |
| **Balance at March 31, 2021** | **10,442** | **$ 1** | **14,969,312** | **$ 1,497** | **$ 272,862,552** | **$ 402)** | **$ (269,767,967)** | **$ 3,095,681** |
| 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) |
| **Balance at June 30, 2021** | **210** | **$ -** | **25,201,312** | **$ 2,520** | **$ 272,953,869** | **$ (274)** | **$ (271,484,983)** | **$ 1,471,132** |
| Pre-funded warrants sold, net of offering costs | | | | | 9,192,624 | | | 9,192,624 |
| Compensation on options issued | | | | | 373,259 | | | 373,259 |
| Unrealized gain on marketable securities | | | | | | 276 | | 276 |
| Net loss | | | | | | | (3,798,648) | (3,798,648) |
| **Balance at September 30, 2021** | **210** | **$ -** | **25,201,312** | **$ 2,520** | **$ 282,519,752** | **$ 2** | **$ (275,283,631)** | **$ 7,238,643** |

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**

| | Nine Months ended September 30, | |
|---|---|---|
| | **2021** | **2020** |
| | **(Unaudited)** | **(Unaudited)** |
| CASH FLOWS FROM OPERATING ACTIVITIES | | |
| Net Loss | $ (29,263,804) | $ (7,021,629) |
| Adjustments to reconcile net loss to net cash used in operating activities | | |
| Depreciation and amortization | 3,037 | 3,098 |
| Interest on debt instrument | 949 | 1,016 |
| Amortization of right of use asset | 79,115 | 82,163 |
| 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 | 557,207 | 198,703 |
| Issuance of common stock for services rendered | - | 75,000 |
| Amortization of premium on marketable securities | 9,427 | 5,078 |
| Changes in operating assets and liabilities | | |
| Accounts receivable, prepaid expenses and other assets | (146,574) | 616,676 |
| Accounts payable and accrued liabilities | (644,311) | (1,185,136) |
| Long term portion of lease liability | (17,892) | (60,379) |
| Net cash used in operating activities | (8,087,748) | (7,285,410) |
| CASH FLOWS FROM INVESTING ACTIVITIES | | |
| Purchase of marketable securities | (345,540) | (458,438) |
| Sale of marketable securities | 803,401 | 475,041 |
| Purchase of property and equipment | (3,554) | - |
| Net cash provided by investing activities | 454,307 | 16,603 |
| CASH FLOWS FROM FINANCING ACTIVITIES | | |
| Proceeds from issuance of common stock and pre-funded warrants, net of issuance costs | 9,192,624 | 8,662,985 |
| Proceeds from the exercise of warrants | 544,651 | 1,690,704 |

| | | |
|---|---|---|
| Proceeds from the issuance of notes payable | - | 244,657 |
| Net cash provided by financing activities | 9,737,275 | 10,598,346 |
| | | |
| Net change in cash and cash equivalents | 2,103,834 | 3,329,539 |
| Cash and cash equivalents, beginning of period | 6,250,241 | 4,905,993 |
| Cash and cash equivalents, end of period | $ 8,354,075 | $ 8,235,532 |
| | | |
| Non-cash investing activity | | |
| 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**
**(Unaudited)**

## NOTE 1. DESCRIPTION OF BUSINESS

Tenax Therapeutics, Inc. (the "Company") was originally formed as a New Jersey corporation in 1967 under the name Rudmer, David & Associates, Inc., and subsequently changed its name to Synthetic Blood International, Inc. On June 17, 2008, the stockholders of Synthetic Blood International approved the Agreement and Plan of Merger dated April 28, 2008, between Synthetic Blood International and Oxygen Biotherapeutics, Inc., a Delaware corporation. Synthetic Blood International formed Oxygen Biotherapeutics on April 17, 2008 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 into 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, through its wholly owned subsidiary, Life Newco, Inc., a Delaware corporation, acquired 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. Among these assets was a license with Orion Corporation, a global healthcare company incorporated under the laws of Finland ("Orion") for the 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 (as amended, the "License"), to include two new oral products containing levosimendan, in capsule and solid dosage form, and a subcutaneously administered product containing levosimendan. The Amendment also amends the tiered royalty payments based on net sales of the Product in the Territory (each as defined below) 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. See "Note 8 – Commitments and Contingencies" below for a further discussion of the License.

On January 15, 2021, the Company, Life Newco II, Inc., a Delaware corporation and a wholly owned, subsidiary of the Company ("Life Newco II"), PHPrecisionMed Inc., a Delaware corporation ("PHPM") and Dr. Stuart Rich, solely in his capacity as holders' representative ( the "Representative"), entered into an Agreement and Plan of Merger (the "Merger Agreement") pursuant to which the Company acquired all of the equity of PHPM, a company developing pharmaceutical products containing imatinib for the treatment of pulmonary arterial hypertension ("PAH") in the United States and the rest of the world. Under the terms of the Merger Agreement, Life Newco II merged with and into PHPM, with PHPM surviving as a wholly owned subsidiary of the Company (the "Merger"). See "Note 7 – Merger" below for a further discussion of the Merger.

## 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, as amended. Certain footnote disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States ("GAAP") have been condensed or omitted pursuant to Article 8 of Regulation S-X of the Securities and Exchange Commission ("SEC") rules and regulations. Operating results for the three and nine-month period ended September 30, 2021 are not necessarily indicative of results for the full year or any other future periods. As such, these condensed consolidated financial statements should 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, as amended.



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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 $275 million on September 30, 2021 and $246 million on

December 31, 2020 and used cash in operations of $8.1 million and $7.3 million during the nine months ended September 30, 2021 and 2020, respectively.

In view of the matters described above, recoverability of a major portion of the recorded asset amounts shown in the accompanying September 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, maintain present financing, and generate cash from future operations. These factors, among others, raise substantial doubt about the Company's ability to continue as a going concern for at least one year from the date that these financial statements are issued. 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 PHPM. All material intercompany transactions and balances have been eliminated in consolidation.

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

On September 30, 2021, the Company had cash and cash equivalents of approximately $8.4 million. The Company used $8.1 million of cash for operating activities during the nine months ended September 30, 2021 and had stockholders' equity of $7.2 million, versus $4.6 million on December 31, 2020.

As further discussed in "Note 9—Stockholders' Equity" below, on July 6, 2021, 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 Company common stock, par value $0.0001 per share ("Common Stock") and one unregistered warrant to purchase one share of Common Stock for gross proceeds of approximately $10.0 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.

The Company expects to continue to incur expenses related to development of imatinib for PAH, levosimendan for pulmonary hypertension, and any other potential product candidates. Based on its resources on September 30, 2021, 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 licensing arrangements. 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 on reasonable terms, 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 restrictive covenants. 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 evolving COVID-19 pandemic and the various responses to it might impact the Company's business, operations and financial results continue to remain uncertain and will depend on numerous evolving factors that are not subject to accurate prediction and that are beyond the Company's control. We will continue to evaluate the nature and extent of these potential impacts to our business and condensed consolidated financial statements.

***Net Loss per Share***

Basic net loss per share, which excludes antidilutive securities, is computed by dividing net loss by the weighted-average number of common shares outstanding for that particular period. In contrast, diluted net loss per share considers the potential dilution that could occur from other equity instruments that would increase the total number of outstanding shares of Common Stock. Such amounts include shares potentially issuable under outstanding options, convertible preferred shares and warrants.

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

| | Nine months ended September 30, | |
|---|---|---|
| | 2021 | 2020 |
| Warrants to purchase common stock | 20,928,767 | 20,953,223 |
| Pre-funded warrants to purchase common stock | 10,033,274 | 5,260,005 |
| Options to purchase common stock | 1,330,366 | 451,186 |
| 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 accounting standard ASU-2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes, 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 condensed consolidated financial statements.

In June 2016, the FASB issued accounting standard ASU-2016-13, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, 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 condensed 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 September 30, 2021, the Company held no investments in marketable securities.

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



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| | | Fair Value Measurements at Reporting Date Using | | |
|---|---|---|---|---|
| | Balance as of September 30, 2021 | Quoted prices in Active Markets for Identical Securities (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| Current Assets | | | | |
| Cash and cash equivalents | $ 8,354,075 | $ 8,354,075 | $ - | $ - |
| Marketable securities | $ - | $ - | $ - | $ - |

| | | Fair Value Measurements at Reporting Date Using | | |
|---|---|---|---|---|
| | Balance as of December 31, 2020 | Quoted prices in Active Markets for Identical Securities (Level 1) | Significant Other Observable Inputs (Level 2) | Significant Unobservable Inputs (Level 3) |
| Current Assets | | | | |
| Cash and cash equivalents | $ 6,250,241 | $ 6,250,241 | $ - | $ - |
| Marketable securities | $ 462,687 | $ - | $ 462,687 | $ - |

There were no significant transfers between levels in the nine months ended September 30, 2021.

**NOTE 4. BALANCE SHEET COMPONENTS**

***Property and equipment, net***

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

| | September 30, 2021 | December 31, 2020 |
|---|---|---|
| Office furniture and fixtures | $ 43,033 | $ 43,033 |
| Computer equipment and software | 21,259 | 23,307 |
| | 64,292 | 66,340 |
| Less: Accumulated depreciation | (57,803) | (60,368) |
| | $ 6,489 | $ 5,972 |

Depreciation expense was approximately $1,000 for each of the three-month periods ended September 30, 2021 and 2020.
Depreciation expense was approximately $3,000 for each of the nine-month periods ended September 30, 2021 and 2020.

***Accrued liabilities***

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

| | September 30, 2021 | December 31, 2020 |
|---|---|---|
| Employee related | $ 462,444 | $ 860,629 |
| Operating costs | 118,372 | 319,608 |
| Lease liability | 104,298 | 60,379 |
| | $ 685,114 | $ 1,240,616 |

**NOTE 5. LEASE**

In January 2011, the Company entered into a lease with Concourse Associates, LLC for its headquarters 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 continued 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 became available. On April 2, 2021, the Company negotiated a 3-year extension to the existing lease term, commencing July 1, 2021 (the “Commencement Date”). Beginning on the Commencement Date, the annual base rent was 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, Leases, and determined that, except for the Lease described above, none of the Company's contracts contain a lease.

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

| | September 30, 2021 | December 31, 2020 |
|---|---|---|
| Current portion included in accrued liabilities | $ 104,298 | $ 60,379 |
| Long term lease liability | 211,590 | - |
| | $ 315,888 | $ 60,379 |

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

| **Year ending December 31,** | |
|---|---|
| 2021 | $ 31,259 |
| 2022 | 126,612 |
| 2023 | 129,797 |
| 2024 | 65,702 |
| Total lease payments | $ 353,370 |
| Less: Imputed interest | (37,482) |
| **Operating lease liability** | $ 315,888 |

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 its Lease's Commencement Date. As of September 30, 2021, the remaining Lease term is thirty-three months and the discount rate used to determine the operating lease liability was 8.0%. For the nine months ending September 30, 2021, the Company paid $100,058 in total lease expenses, including $6,997 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, 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.

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 our condensed consolidated statement of comprehensive loss.

**NOTE 7. MERGER**

On January 15, 2021, the Company, Life Newco II, PHPM, and Dr. Rich, as Representative, entered into the Merger Agreement, pursuant to which, the Company acquired all of the equity of PHPM. Under the terms of the Merger Agreement, Life Newco II merged with and into PHPM, with PHPM surviving as a wholly owned subsidiary of the Company.

As consideration for the Merger, the stockholders of PHPM received (i) 1,892,905 shares of Common Stock, and (ii) 10,232 shares of the Company's Series B convertible preferred stock ("Preferred Stock" or "Series B Stock"), which were convertible into up to an aggregate of 10,232,000 shares of Common Stock ("Preferred Stock") (collectively, the "Merger Consideration"). To satisfy the Company's post-closing rights to closing adjustments and indemnification by PHPM and the former stockholders of PHPM pursuant to the Merger Agreement, 1,212,492 shares of Common Stock issuable upon conversion of the Preferred Stock, which represented approximately 10% of the Merger Consideration, are subject to holdback restrictions for 24 months following closing of the transaction (the "Holdback Shares").



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Pursuant to the Merger Agreement, the Company's Board of Directors (the "Board"), 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. As a result, each share of Preferred Stock automatically converted into (i) 881.5 shares of Common Stock, and (ii) the right to receive up to 118.5 Holdback Shares, to be delivered 24 months after the date of issuance of the Preferred Stock, subject to reduction for indemnification claims.

Pursuant to the terms of the Merger Agreement, on February 25, 2021, the Board appointed three directors designated by the Representative to serve on the Board, Dr. Rich, the co-founder and Chief Executive Officer and a stockholder of PHPM, and Drs. Michael Davidson and Declan Doogan. In connection with the closing of the Merger, Dr. Rich also was 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 was 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 was concentrated in the single in-process research and development asset and the set was not a business.

The Company is planning to use the acquired asset to further its clinical development 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 was 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 | $ 21,582,331 |
| | |
| 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 | $ 21,582,331 |

**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, dated September 20, 2013, as amended on October 9, 2020, by and between Phyxius and Orion (the "License"), 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 in the United States and Canada (the "Territory") and, pursuant to the October 9, 2020 amendment, also includes two oral products containing levosimendan, in capsule and solid dosage form, and a subcutaneously administered product containing levosimendan subject to specified limitations in the License (together, the "Product"). Pursuant to the License, the Company must use Orion's "Simdax®" trademark to commercialize the Product. The License also grants 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 term of the License extends 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.



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Pursuant to the terms of the License, on November 13, 2013, 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 must make non-refundable payments to Orion no later than 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 to up to $13.0 million, contingent upon achievement of certain cumulative net sales amounts in the Territory. The Company also must 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 License term, the Company must pay Orion a royalty based on net sales of the Product in the Territory for as long as the Company sells the Product in the Territory.

As of September 30, 2021, the Company has not met any of the developmental milestones under the License 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.

*Series B Stock*

As further discussed in "Note 7—Merger" 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 on June 10, 2021 for the Conversion , each share of Series B Stock automatically converted into (i) 881.5 shares of Common Stock and (ii) the right to receive up to 118.5 Holdback Shares, to be delivered 24 months after the date of issuance of the Preferred Stock, subject to reduction for indemnification claims.

As of September 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 $9.0 million (the "2018 Offering"). Each unit consisted of (i) one share of the Company's Series A convertible preferred stock, par value $0.0001 per share (the "Series A Stock"), (ii) a two-year warrant to purchase one share of Common Stock at an exercise price of $1.93, and (iii) a five-year warrant to purchase one share of Common Stock at an exercise price of $1.93. In accordance with ASC 480, Distinguishing Liabilities from Equity, 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 | 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.<br><br>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. |



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| | |
|---|---|
| Dividends | In the event the Company pays dividends on its shares of Common Stock, the holders of the Series A Stock will be entitled to receive dividends on shares of Series A Stock equal, on an as-if-converted basis, to and in the same form as paid on the Common Stock. No other dividends will be paid on the shares of Series A Stock. |
| Liquidation | Upon any liquidation, dissolution or winding up of the Company after payment or provision for payment of debts and other liabilities of the Company, the holders of Series A Stock shall be entitled to be paid out of the assets of the Company available for distribution to its stockholders an amount equal to the amount that a holder of Common Stock would receive if the Series A Stock were fully converted to Common Stock, which amounts will be paid pari passu with all holders of Common Stock. |
| Voting rights | Shares of Series A Stock will generally have no voting rights, except as required by law and except that the consent of holders of a majority of the then outstanding Series A Stock will be required to amend the terms of the Series A Stock or to take other action that adversely affects the rights of the holders of Series A Stock. |

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

***Common Stock and Pre-Funded Warrants***

The Company's Certificate of Incorporation authorizes it to issue 400,000,000 shares of $0.0001 par value Common Stock. As of September 30, 2021, and December 31, 2020, there were 25,201,312 and 12,619,369 shares of Common Stock issued and outstanding, respectively. As of September 30, 2021, there were 10,033,274 pre-funded warrants outstanding.

*July 2021 Private Placement (the "July 2021 Offering")*

On July 6, 2021, the Company entered into a securities purchase agreement with an institutional investor ("Investor") pursuant to which the Company agreed to sell and issue to the Investor 4,773,269 Units in a private placement at a purchase price of $2.095 per unit. Each Unit consisted of (i) one unregistered pre-funded warrant to purchase one share of Common Stock and (ii) one unregistered warrant to purchase one share of Common Stock (together with the pre-funded warrants, the "2021 Warrants"). In the aggregate, 9,546,538 shares of the Company's Common Stock are underlying the 2021 Warrants. The net proceeds from the private placement, after deducting placement agent fees and other direct offering expenses, were approximately $9.2 million. The fair value allocated to the pre-funded warrants and warrants was $5.5 million and $4.5 million, respectively.

Also, on July 6, 2021 and in connection with the July 2021 Offering, the Company entered into a registration rights agreement (the "July 2021 Registration Rights Agreement") with the Investor, pursuant to which the Company agreed to register for resale the shares of Common Stock issuable upon exercise of the 2021 Warrants within 120 days following the effective date of the July 2021 Registration Rights Agreement. Pursuant to the July 2021 Registration Rights Agreement, on August 20, 2021, the Company filed a resale registration statement on Form S-3, which went effective on September 1, 2021.

*July 2020 Registered Direct Offering and Private Placement (the "July 2020 Offering")*

On July 6, 2020, the Company completed a registered direct offering with an 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.

Also, on July 6, 2020 and in connection with the concurrent private placement, the Company entered into a registration rights agreement (the "July 2020 Registration Rights Agreement") with the Investor, pursuant to which the Company agreed to register for resale the shares of Common Stock issuable upon exercise of the unregistered pre-funded warrants and the unregistered warrants within 120 days following the date of the Registration Rights Agreement. Pursuant to the Registration Rights Agreement, on August 20, 2020, the Company filed a resale registration statement on Form S-3, which went effective on September 30, 2020.



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*March 2020 Registered Direct Offering and Private Placement (the "March 2020 Offering")*

On March 13, 2020, the Company completed a registered direct offering to an 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 2,360,313shares 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 $2.1 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.

***Warrants***

During the nine months ended September 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 nine months ended September 30, 2021, the Company issued 519,374 shares of Common Stock upon the cashless exercise of previously outstanding placement agent warrants issued in connection with the Company's July 2020 and March 2020 Offerings.

As of September 30, 2021, the Company has 20,928,767 warrants outstanding. The following table summarizes the Company's warrant activity for the nine months ended September 30, 2021:

| | Warrants | Weighted Average Exercise Price |
|---|---|---|
| **Outstanding at December 31, 2020** | **16,599,079** | **$ 1.29** |
| Issued | 5,131,264 | 2.00 |
| Exercised | (801,576) | 1.54 |
| **Outstanding at September 30, 2021** | **20,928,767** | **$ 1.45** |

*July 2021 Warrants*

As described above, as a part of the July 2021 Offering, the Company issued unregistered warrants to purchase 4,773,269 shares of its Common Stock at an exercise price of $1.97 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. In accordance with ASC 480, these warrants are classified as equity and their relative fair value of approximately $4.5 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.

*July 2020 Warrants*

As described above, as a 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. 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.

*March 2020 Warrants*

As part of the March 2020 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, and Regulation D promulgated thereunder. 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.

*Warrants Issued for Services*

In connection with the July 2021 Offering described above, the Company issued designees of the placement agent warrants to purchase 357,995 shares of Common Stock at an exercise price of $2.46 and a contractual term of five years. In accordance with ASC 815, Derivatives and Hedging, these warrants are classified as equity and its estimated fair value of $558,472 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 $1.2848and 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.

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.

***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 Board’s Compensation Committee, 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 nine months ended September 30, 2021:

| | Shares Available for Grant |
|---|---|
| **Balances, at December 31, 2020** | 356,500 |
| Additional shares reserved | 750,000 |
| Options granted | (378,750) |
| Options cancelled/forfeited | 91,000 |
| **Balances, at September 30, 2021** | 818,750 |





*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.

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

| | Outstanding Options | |
|---|---|---|
| | Number of Shares | Weighted Average Exercise Price |
| **Balances at December 31, 2020** | 393,500 | $ 1.81 |
| Options granted | 378,750 | $ 1.88 |
| Options cancelled/forfeited | (91,000) | $ 1.59 |
| **Balances at September 30, 2021** | 681,250 | $ 1.88 |

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 $139,983 and $52,659 for the three months ended September 30, 2021 and 2020, and $322,641 and $165,492 for the nine months ended September 30, 2021 and 2020, respectively.

As of September 30, 2021, there were unrecognized compensation costs of approximately $244,865 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 1.07 years.

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

| | For the nine months ended September 30, | |
|---|---|---|
| | 2021 | 2020 |
| Risk-free interest rate (weighted average) | 0.72% | 1.02% |
| Expected volatility (weighted average) | 101.60% | 97.63% |
| Expected term (in years) | 6.7 | 7 |
| Expected dividend yield | 0.00% | 0.00% |

| | |
|---|---|
| *Risk-Free Interest Rate* | The risk-free interest rate assumption was based on U.S. Treasury instruments with a term that is consistent with the expected term of the Company's stock options. |
| *Expected Volatility* | The expected stock price volatility for the Company's Common Stock was determined by examining the historical volatility and trading history for its Common Stock over a term consistent with the expected term of its options. |
| *Expected Term* | The expected term of stock options represents the weighted average period the stock options are expected to remain outstanding. It is calculated based on the Company's historical experience with its stock option grants. |
| *Expected Dividend Yield* | The expected dividend yield of 0% is based on the Company's history and expectation of dividend payouts. The Company has not paid and does not anticipate paying any dividends in the near future. |
| *Forfeitures* | Stock compensation expense recognized in the statements of operations for the nine months ended September 30, 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 Board's Compensation Committee, 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 can be granted only to employees. NSOs can 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 under the 1999 Plan generally vest over one to six years.

The following table summarizes the outstanding stock options under the 1999 Plan for the nine months ended September 30, 2021:

| | Outstanding Options | |
|---|---|---|
| | Number of Shares | Weighted Average Exercise Price |
| **Balances at December 31, 2020** | 57,648 | $ 46.34 |
| Options cancelled | (8,532) | $ 54.19 |
| **Balances at September 30, 2021** | 49,116 | $ 44.98 |

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 $10,502 for the three months ended September 30, 2021 and 2020, and $1,290 and $33,211 for the nine months ended September 30, 2021 and 2020, respectively.

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

In connection with the retirement of the Company's former Chief Executive Officer ("CEO"), effective July 13, 2021 (the "Modification Date"), the Company modified the terms of the former CEO's outstanding stock awards to: (1) accelerate the 152,500 unvested shares underlying his outstanding stock

awards immediately as of the Modification Date and (2) extend the period during which his outstanding stock awards for an aggregate of 218,706 shares may be exercised through the earlier of the stock award's original termination date or the five-year anniversary of the Modification Date.

The Company determined that the extension of the period during which the vested shares may be exercised was a Type 1 modification pursuant to ASC 718, Compensation-Stock Compensation. However, acceleration of vesting and extension of the exercise period for the remaining Stock Awards was a Type 3 modification pursuant to ASC 718 because absent the modification terms, those Stock Awards would have been forfeited as of the former CEO's retirement date.

On the Modification Date, the Company recognized approximately $187,000 of compensation expense, which is included in General and administrative expense for the three and nine months ended September 30, 2021, with respect to these modifications.



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***Inducement Stock Options***

The Company granted two employment inducement stock option awards, one for 100,000 shares of Common Stock and the other for 250,000 shares of Common Stock, to its new CEO on July 6, 2021.

The employment inducement stock option for 100,000 shares of Common Stock 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: 50% upon initiation of a Phase 3 trial for levosimendan by June 30, 2022; and 50% upon initiation of a Phase 3 trial for imatinib by June 30, 2022. The options have a 10-year term and an exercise price of $1.97 per share, the July 6, 2021 closing price of our Common Stock. As of September 30, 2021, none of the vesting milestones have been achieved. The estimated fair value of this inducement stock option award was $178,291 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 1.37%, dividend yield of 0%, volatility factor for our Common Stock of 103.50% and an expected life of 10 years.

The employment inducement stock option award for 250,000 shares of Common Stock also 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% on the one-year anniversary of the CEO's employment start date and an additional 25% on each of the following three anniversaries of the CEO's employment start date, subject to continued employment. The options have a 10-year term and an exercise price of $1.97 per share, the July 6, 2021 closing price of our Common Stock.

The estimated fair value of this inducement stock option award was $403,180 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 1.13%, dividend yield of 0%, volatility factor for our Common Stock of 99.36% and an expected life of 7 years.

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 our Common Stock. As of September 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 $46,723for the three and nine months ended September 30, 2021. As of September 30, 2021, there was $937,537 of remaining unrecognized compensation expense related to these inducement stock options.

**NOTE 10. SUBSEQUENT EVENTS**

On October 8, 2021, the Company and Michael B. Jebsen, the Company's President and Chief Financial Officer, agreed that Mr. Jebsen would separate from the Company effective October 29, 2021 (the "Separation Date").

In connection with Mr. Jebsen's separation from the Company, the Company and Mr. Jebsen entered into a separation and release agreement dated October 14, 2021 (the "Jebsen Separation Agreement"). Subject to Mr. Jebsen's execution of a general release of claims, Mr. Jebsen will receive severance in an amount equal to one year of his current base annual salary and a pro-rated amount of his target annual bonus that would have been received had 100% of his annual goals been achieved, aggregating to approximately $513,000 (less applicable taxes and withholdings)and payable in a lump sum on the 30th day following the Separation Date. The Company also will reimburse COBRA premiums for coverage of Mr. Jebsen and his eligible dependents for up to 12 months if Mr. Jebsen timely and properly elects continuation coverage.

The Company and Mr. Jebsen also entered into a consulting agreement dated October 14, 2021 (the "Jebsen Consulting Agreement") pursuant to which, for a period of six months following the Separation Date (the "Transition Period"), Mr. Jebsen will remain at the Company in an advisory role. The Transition Period can be terminated upon 30 days' notice by either party or immediately by the Company for cause (as defined in the Jebsen Consulting Agreement). During the Transition Period, the Company will pay Mr. Jebsen for his advisory services at a rate of $275 per hour.



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

*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 condensed 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, as amended. 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.*

**Forward-Looking Statements**

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 "might," "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. These statements reflect our current view with respect to future events and are subject to risks, uncertainties and assumptions related to various factors that could cause actual results and the timing of events to differ materially from future results expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in the section titled "Risk Factors" included in our most recent Annual report on Form 10-K filed with the SEC. Furthermore, such forward-looking statements speak only as of this Quarterly Report on Form 10-Q. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

**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 all of the equity of PHPrecisionMed Inc., a Delaware corporation, or PHPM, a company developing pharmaceutical products containing imatinib for the treatment of pulmonary arterial hypertension ("PAH") in the United States and the rest of the world. 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.

**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 sixty 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; and
- Opening of mitochondrial potassium channels in cardiomyocytes, resulting in a cardioprotective effect.



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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.

***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, ≥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 – **H**emodynamic **E**valuation of **L**evosimendan in **P**H-HFpEF.

We initiated the first of our expected 10 to 12 HELP Study clinical sites in November 2018 and the first of thirty-seven 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.



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***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.

***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, in May 2021, the manuscript was published in the peer-reviewed journal JACC: Heart Failure.

***Next Steps***

On October 9, 2020, we entered into an 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 have studied 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. The patients were successfully transitioned from the intravenous to an oral formulation. The investigators at the centers that participated in the HELP Study were the ones who participated and enrolled their patients into this study. The data from that open-label extension will inform as to the oral dosage of levosimendan for the Phase 3 trial.

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



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***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 manufactures Gleevec.

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

In 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 from the FDA 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 imatinib 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 twelve volunteers receiving a single dose of the modified release formulation to be compared to a single dose of the existing immediate release formulation. The Company is planning a Phase 3 study with the modified release formulation of imatinib.

***Third Quarter 2021 Highlights***

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

- Cash and cash equivalents were $8.4 million on September 30, 2021;

- Our net loss from operations was $3.9 million for the third quarter of fiscal 2021 compared to $2.2 million for the three months ended September 30, 2020; and
- Net cash used in operating activities was $3.0 million and $2.4 million for the three months ended September 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.



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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.

For the remainder of 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.

***Financial Overview***

***Results of Operations- Comparison of the Three Months Ended September 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 September 30, 2021 and 2020, respectively, are as follows:

| | Three months ended September 30, | | Increase/ (Decrease) | % Increase/ (Decrease) |
|---|---|---|---|---|
| | 2021 | 2020 | | |
| Personnel costs | $ 1,898,685 | $ 682,907 | $ 1,215,778 | 178% |
| Legal and professional fees | 527,603 | 292,625 | 234,978 | 80% |
| Other costs | 174,229 | 159,327 | 14,902 | 9% |
| Facilities | 39,403 | 37,866 | 1,537 | 4% |

*Personnel costs:*

Personnel costs increased approximately $1.2 million in the current period, compared to the same period in the prior year, primarily due to approximately $930,000 in severance costs associated with the retirement of our former CEO and other employees, as well as approximately $266,000 in noncash compensation expense resulting from the modification of the former CEO's outstanding options and the grant of an additional option on his separation date.

*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 members of our Board of Directors (the "Board"). Legal and professional fees increased approximately $235,000 for the three months ended September 30, 2021 compared to the same period in the prior year. This increase was primarily due to an increase of approximately $208,000 in legal fees associated with the filing of registration statements, and the CEO transition in the current period. Additionally, Board fees increased to approximately $14,000 in the current period due primarily to fees paid to new directors that were not incurred during the same period in the prior year.

*Other costs:*

Other costs include costs incurred for franchise and other taxes, travel, supplies, insurance, depreciation and other miscellaneous charges. Other costs increased approximately $15,000 in the current period primarily due to an increase of approximately $25,000 in insurance premiums paid, partially offset by a decrease of approximately $12,000 in franchise taxes paid in the current period as compared to the same period of the prior year.



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*Facilities:*

Facilities expenses include costs paid for rent and utilities at our corporate headquarters in Morrisville, North Carolina. Facilities costs remained relatively consistent for the three months ended September 30, 2021 and 2020.

***Research and Development Expenses***

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

| | Three months ended September 30, | | Increase/ (Decrease) | % Increase/ (Decrease) |
|---|---|---|---|---|
| | 2021 | 2020 | | |
| Clinical and preclinical development | $ 1,014,124 | $ 989,159 | $ 24,965 | 3% |
| Personnel costs | 138,355 | 58,402 | 79,953 | 137% |
| Other costs | 9,891 | 4,837 | 5,054 | 104% |

*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 increase of approximately $25,000 in clinical and preclinical development costs for the three months ended September 30, 2021 compared to the same period in the prior year was primarily due to an increase of approximately $630,000 in costs associated with formulation development of imatinib in the current period that were not incurred in the same period in the prior year, partially offset by a decrease of approximately $605,000 in expenditures for CRO costs and other direct costs associated with the Phase 2 and IV to oral transition studies in the current period as compared to the same period in the prior year.

*Personnel costs:*

Personnel costs increased approximately $80,000 for the three months ended September 30, 2021 primarily due to the addition of our Chief Medical Officer in the current year.

*Other costs:*

Other costs remained relatively consistent for the three months ended September 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.

***Results of Operations- Comparison of the Nine Months Ended September 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 nine months ended September 30, 2021 and 2020, respectively, are as follows:



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| | Nine months ended September 30, | | Increase/ (Decrease) | % Increase/ (Decrease) |
|---|---|---|---|---|
| | 2021 | 2020 | | |
| Personnel costs | $ 3,405,369 | $ 2,120,914 | $ 1,284,455 | 61% |
| Legal and professional fees | 1,253,273 | 617,576 | 635,697 | 103% |
| Other costs | 505,097 | 509,329 | (4,232) | (1)% |
| Facilities | 120,919 | 117,071 | 3,848 | 3% |

*Personnel costs:*

Personnel costs increased approximately $1.3 million for the nine months ended September 30, 2021 compared to the same period in the prior year. This increase was primarily due to approximately $930,000 in severance costs associated with the retirement of the former CEO and other employees, as well as approximately $266,000 in noncash compensation expense resulting from the modification of the former CEO's outstanding options and the grant of an additional option on his separation date in the current period.

*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 members. Legal and professional fees increased approximately $636,000 for the nine months ended September 30, 2021 compared to the same period in the prior year.

- Legal fees increased approximately $519,000 in the current period. This increase was primarily due 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 costs associated with the CEO transition that were not incurred during the same period in the prior year.

- Accounting fees increased approximately $39,000 in the current period primarily due to fees associated with the PHPM transaction that were not incurred during the same period in the prior year.

- Board fees increased approximately $65,000 in the current period primarily due to fees paid to new directors that were not incurred during the same period in the prior year and an increase in the vested value of outstanding stock options as compared to the same period in the prior year.

- Capital market fees increased by approximately $25,000 in the current period. This increase was primarily due 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 $30,000 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 $4,000 in the current period due primarily to a decrease in franchise taxes paid, partially offset by an increase of approximately $76,000 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 nine months ended September 30, 2021 and 2020.

***Research and Development Expenses***

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



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| | Nine months ended September 30, | | Increase/ (Decrease) | % Increase/ (Decrease) |
|---|---|---|---|---|
| | 2021 | 2020 | | |
| Clinical and preclinical development | $ 2,063,211 | $ 3,489,977 | $ (1,426,766) | (41)% |
| Personnel costs | 417,304 | 167,738 | 249,566 | 149% |
| Other costs | 21,751,279 | 12,046 | 21,739,233 | 180,468% |

*Clinical and preclinical development:*

Clinical and preclinical development costs include costs associated with our Phase 2 HELP Study for levosimendan, which was completed during fiscal year 2020, costs associated with our IV to oral levosimendan transition study and development costs associated with the formulation for imatinib. The decrease of approximately $1.4 million in clinical and preclinical development costs for the nine months ended September 30, 2021 compared to the same period in the prior year was primarily due to a decrease of approximately $1.5 million in expenditures for CRO costs, a reduction of approximately $748,000 in enrolled patient and direct site costs and a decrease of approximately $122,000 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 $891,000 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 $250,000 for the nine months ended September 30, 2021 due primarily to the addition of our Chief Medical Officer in the current year.

*Other costs:*

Other costs increased approximately $21.7 million for the nine months ended September 30, 2021 primarily due 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, net***

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

| | Nine months ended September 30, | | (Increase)/ Decrease | % Increase/ (Decrease) |
|---|---|---|---|---|
| | 2021 | 2020 | | |
| Other income, net | $ (253,597) | $ (14,038) | $ (239,559) | 1707% |

Other income increased approximately $240,000 for the nine months ended September 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 September 30, 2021 we had an accumulated deficit of approximately $275 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 PAH, as well as identifying and developing other potential product candidates and, as a result, we will need to generate significant net product sales, royalty and other revenues to achieve profitability.

***Liquidity***

We have financed our operations since September 1990 through the issuance of debt and equity securities and loans from stockholders. We had total current assets of $8,583,227 and $6,795,506 and working capital of $7,121,866 and $4,676,543 as of September 30, 2021 and December 31, 2020, respectively. Based on our working capital and the value of our investments in marketable securities on September 30, 2021, we believe we have sufficient capital to fund our operations only through the second quarter of calendar year 2022.

***Cash Flows***

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

| | Nine months ended September 30, | |
|---|---|---|
| | 2021 | 2020 |
| Net cash used in operating activities | $ (8,087,748) | $ (7,285,410) |
| Net cash provided by investing activities | 454,307 | 16,603 |
| Net cash provided by financing activities | 9,737,275 | 10,598,346 |

*Net cash used in operating activities.*

Net cash used in operating activities was approximately $8.1 million for the nine months ended September 30, 2021 compared to net cash used in operating activities of approximately $7.3 million for the nine months ended September 30, 2020. The increase in cash used for operating activities was primarily due to an increase in our annual insurance premiums, employee severance and accrued bonuses paid in the current period as compared to the prior year.

*Net cash provided by investing activities*.

Net cash provided by investing activities was approximately $454,000 for the nine months ended September 30, 2021 compared to approximately $16,000 provided by investing activities for the nine months ended September 30, 2020. The increase in cash provided by investing activities was primarily due to the sale of marketable securities in the current period.

*Net cash provided by financing activities*.

Net cash provided by financing activities for the nine months ended September 30, 2021 totaled $9.7 million, which was attributable to net proceeds from the sale of units in our July 2021 private placement of $9.2 million and the exercise of stock warrants of $0.5 million.

Net cash provided by financing activities for the nine months ended September 30, 2020 totaled $10.6 million, which was attributable to aggregate net proceeds from the sale of common stock, warrants and pre-funded warrants in our July 2020 registered direct offering and concurrent private placement of $6.5 million, aggregate net proceeds from the sale of common stock and pre-funded warrants in our March 2020 registered direct offering and concurrent private placement of $2.1 million, $0.2 million in proceeds from a loan in connection with the Paycheck Protection Program under the Cares Act and $1.7 million of proceeds from the exercise of stock warrants.

***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;



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- 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.

The circumstances above raise substantial doubt about our ability to continue as a going concern for at least one year from the date that the financial statements included elsewhere in this Quarterly Report on Form 10-Q are issued. In fact, 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 only through the second quarter of calendar year 2022. Our financial statements do not include adjustments to the amounts and classification of assets and liabilities that may be necessary should we be unable to continue as a going concern. Further, 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 reasonable 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, as amended and Note 2 to our unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

***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**

Smaller reporting companies are not required to provide the information required by this item.

**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, under the supervision and with the participation of our management, including our President and Chief Executive Officer and our Interim Chief Financial Officer, we conducted an evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q, of the effectiveness of our disclosure controls and procedures as defined in Exchange Act Rules 13a-15(e) and 15d-15(e).

In designing and evaluating our disclosure controls and procedures, management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply its judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Based on their evaluation, our President and Chief Executive Officer and Interim Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2021, the end of the period covered by this Quarterly Report on Form 10-Q, 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 President and Chief Executive Officer and Interim 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 are 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.





## 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, as amended.

### ITEM 6. EXHIBITS

The following exhibits are being filed or furnished as part of this Quarterly Report on Form 10-Q and are numbered in accordance with Item 601 of Regulation S-K:

| Exhibit Number | Description |
|---|---|
| 4.1 | Form of Unregistered Pre-Funded Warrant (July 2021) (incorporated herein by reference to Exhibit 4.1 to our Current Report on Form 8-K filed with the SEC on July 8, 2021). |
| 4.2 | Form of Unregistered Warrant (July 2021) (incorporated herein by reference to Exhibit 4.2 to our Current Report on Form 8-K filed with the SEC on July 8, 2021). |
| 4.3 | Form of HCW Warrant (July 2021) (incorporated herein by reference to Exhibit 4.3 to our Current Report on Form 8-K filed with the SEC on July 8, 2021). |
| 10.1 | Securities Purchase Agreement for Unregistered Pre-Funded Warrant dated as of July 6, 2021, by and between Tenax Therapeutics, Inc. and the Investor (incorporated herein by reference to Exhibit 10.1 to our Current Report on Form 8-K filed with the SEC on July 8, 2021). |
| 10.2 | Registration Rights Agreement dated July 6, 2021, by and between Tenax Therapeutics, Inc. and the Investor (incorporated herein by reference to Exhibit 10.2 to our Current Report on Form 8-K filed with the SEC on July 8, 2021). |
| 10.3+ | Separation and General Release Agreement dated July 6, 2021, by and between Tenax Therapeutics, Inc. and Anthony A. DiTonno (incorporated herein by reference to Exhibit 10.3 to our Current Report on Form 8-K filed with the SEC on July 8, 2021). |
| 10.4+ | Executive Employment Agreement dated July 6, 2021, by and between Tenax Therapeutics, Inc. and Christopher T. Giordano (incorporated herein by reference to Exhibit 10.4 to our Current Report on Form 8-K filed with the SEC on July 8, 2021). |
| 10.5+ | Plan for Employee Inducement Stock Options adopted July 6, 2021 with Form of Stock Option Agreement (incorporated herein by reference to Exhibit 10.5 to our Current Report on Form 8-K filed with the SEC on July 8, 2021). |
| 10.6*+# | Consulting Agreement dated October 14, 2021, by and between Tenax Therapeutics, Inc. and Danforth Advisors, LLC. |
| 10.7*+ | Separation and Release Agreement dated October 14, 2021, by and between Tenax Therapeutics, Inc. and Michael B. Jebsen. |
| 10.8*+ | Consulting Agreement dated October 14, 2021, by and between Tenax Therapeutics, Inc. and Michael B. Jebsen. |
| 31.1* | Certification of President and Chief Executive Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002. |

| | |
|---|---|
| 31.2* | Certification of Interim Chief Financial Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002. |
| 32.1 | Certification of President and Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 32.2 | Certification of Interim Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |
| 101* | 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**
**#Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10)**



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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.

Date: November 15, 2021

**TENAX THERAPEUTICS, INC.**

By: /s/ Eliot M. Lurier
Eliot M. Lurier
Interim Chief Financial Officer
(On behalf of the Registrant and as Principal Financial and Accounting Officer)

CONFIDENTIAL PORTIONS OF THIS EXHIBIT HAVE BEEN OMITTED PURSUANT TO REGULATION S-K ITEM 601(b)(10)(iv) OF THE SECURITIES ACT OF 1933, AS AMENDED AND REPLACED WITH [***]. SUCH IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS (i) NOT MATERIAL AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED.

# CONSULTING AGREEMENT

This Consulting Agreement (the "Agreement") is made as of October 14, 2021, by and between Tenax Therapeutics, Inc., a Delaware corporation, with its principal place of business being ONE Copley Parkway, Suite 490, Morrisville, NC 27560 (the "Company") and Danforth Advisors, LLC, a Massachusetts limited liability company, with its principal place of business being 91 Middle Road, Southborough, MA 01772 ("Danforth"). The Company and Danforth are herein sometimes referred to individually as a "Party" and collectively as the "Parties."

WHEREAS, the Company is a specialty pharmaceutical company focused on identifying, developing, and commercializing products that address cardiovascular and pulmonary diseases with high unmet medical need; and

WHEREAS, Danforth has expertise in financial and corporate operations and strategy; and

WHEREAS, Danforth desires to serve as an independent consultant for the purpose of providing the Company with certain strategic and financial advice and support services, using personnel described in Exhibit A attached hereto, (the "Services"); and

WHEREAS, the Company wishes to engage Danforth on the terms and conditions set forth herein.

NOW THEREFORE, in consideration of the foregoing and for other good and valuable consideration, the receipt of which are hereby acknowledged, the Parties agree and covenant as follows.

1. Services of Consultant. Danforth will assist the Company with matters relating to the Services. The Services are more fully described in Exhibit A attached hereto. Danforth and the Company will review the Services on a monthly basis to determine appropriate staffing requirements. Company shall have the right to request changes to the Danforth personnel at any time in writing. If Company makes a written request, Danforth shall replace such personnel subject to the Company's right of pre-approval.

2. Compensation for Services. In full consideration of Danforth's full, prompt and faithful performance of the Services, the Company shall compensate Danforth a consulting fee more fully described in Exhibit A (the "Consulting Fee"). Danforth shall, from time to time, but not more frequently than once per calendar month, invoice the Company for Services rendered, and such invoice will be paid upon 30 days of receipt. Each month the Parties shall evaluate jointly the current fee structure and scope of Services. Danforth reserves the right to an annual increase in consultant rates of up to 4%, effective January 1, 2023. Upon termination of this Agreement pursuant to Section 3, no compensation or benefits of any kind as described in this Section 2 shall be payable or issuable to Danforth after the effective date of such termination. In addition, the Company will reimburse Danforth for reasonable out-of-pocket business expenses, including but not limited to travel and parking, incurred by Danforth in performing the Services hereunder, upon submission by Danforth of supporting documentation reasonably acceptable to the Company. Any such accrued expenses in any given three (3) month period that exceed $1,000 shall be submitted to the Company for its prior written approval.



All Danforth invoices and billing matters should be addressed to:

Company Accounts Payable Contact:

Name: Karen Miller
Title: Senior Accountant
Address: ONE Copley Parkway, Suite 490, Morrisville, NC 27560
Phone: 919.855.2100
E-mail:

All Company payments and billing inquiries should be addressed to:

Danforth Accounting:
Betsy Sherr
bsherr@danforthadvisors.com
(508) 277-0031
Danforth Advisors, LLC
PO Box 335
Southborough, MA 01772

3. Term and Termination. The term of this Agreement will commence on October 29, 2021 (the "Effective Date") and will continue until such time as either Party has given notice of termination pursuant to this paragraph 3 (the "Term"). This Agreement may be terminated by either Party hereto: (a) with Cause (as defined below), immediately upon written notice to the other Party; or (b) without Cause upon 30 days prior written notice to the other Party. For purposes of this Section 3, "Cause" shall include: (i) a material breach of the terms of this Agreement which, if curable, is not cured within 10 days of written notice of such default, or (ii) the commission of any act of fraud, embezzlement or deliberate disregard of a rule or policy of the Company.

4. Time Commitment. Danforth will devote such time to perform the Services under this Agreement as may reasonably be required. Danforth does not guarantee time and materials estimates in any way and such estimates are not fixed prices. Danforth will notify the Company as soon as practicable if an estimate will be exceeded.

5. Place of Performance. Danforth will perform the Services at such locations upon which the Company and Danforth may mutually agree. Danforth will not, without the prior written consent of the Company, perform any of the Services at any facility or in any manner that might give anyone other than the Company any rights to or allow for disclosure of any Confidential Information (as defined below).

6. Compliance with Policies and Guidelines. Danforth will perform the Services in accordance with all rules or policies adopted by the Company that the Company discloses in writing to Danforth.



7. Confidential Information. Danforth acknowledges and agrees that during the course of performing the Services, the Company may furnish, disclose or make available to Danforth information, including, but not limited to, material, compilations, data, formulae, models, patent disclosures, procedures, processes, business plans, financial information, projections, protocols, results of experimentation and testing, specifications, strategies and techniques, and all tangible and intangible embodiments thereof of any kind whatsoever (including, but not limited to, any apparatus, biological or chemical materials, animals, cells, compositions, documents, drawings, machinery, patent applications, records and reports), which is owned or controlled by the Company and is marked or designated as confidential at the time of disclosure or is of a type that is customarily considered to be confidential information (collectively the "Confidential Information"). Danforth acknowledges that the Confidential Information or any part thereof is the exclusive property of the Company and shall not be disclosed to any third party without first obtaining the written consent of the Company. Danforth further agrees that the Confidential Information, and any part thereof, (i) shall not be disclosed or issued to its affiliates, agents or employees (the "Representatives"), except as necessary for the performance of the Services and provided that any such Representative is bound by terms and conditions no less restrictive than those terms and conditions applicable to Danforth under this Agreement and (ii) shall be used solely for the purposes of performing its obligations under this Agreement. The above provisions of confidentiality shall apply for a period of five years. Pursuant to the Defend Trade Secrets Act of 2016, Danforth acknowledges that Danforth will not have criminal or civil liability under any federal or state trade secret law for the disclosure of a trade secret that (i) is made (A) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney and (B) solely for the purpose of reporting or investigating a suspected violation of law; or (ii) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. In addition, if Danforth files a lawsuit for retaliation by Company for reporting a suspected violation of law, Danforth may disclose the trade secret to its attorney and may use the trade secret information in the court proceeding, if Danforth (i) files any document containing the trade secret under seal and (ii) does not disclose the trade secret, except pursuant to court order.

8. Use of Name and Logo. The Company agrees to permit the use of its name and logo in a roster of Danforth clients, which may appear on the Danforth website and in its marketing materials.

9. Intellectual Property. Danforth agrees that all ideas, inventions, discoveries, creations, manuscripts, properties, innovations, improvements, know-how, designs, developments, apparatus, techniques, methods, and formulae that Danforth conceives, makes, develops or improves as a result of performing the Services, whether or not reduced to practice and whether or not patentable, alone or in conjunction with any other party and whether or not at the request or upon the suggestion of the Company (all of the foregoing being hereinafter collectively referred to as the "Inventions"), shall be the sole and exclusive property of the Company.



10. Non Solicitation. All personnel representing Danforth are employees or contracted agents of Danforth. Accordingly, they are not retainable as employees or contractors by the Company and the Company hereby agrees not to solicit, hire or retain their services for so long as they are employees or contracted agents of Danforth and for two years thereafter. Should the Company violate this restriction, it agrees to pay Danforth liquidated damages equal to forty percent (40%) of the employee's starting annual base salary and target annual bonus for each Danforth contracted agent hired by the Company in violation of this Agreement **plus** Danforth's reasonable attorneys' fees and costs incurred in enforcing this agreement should the Company fail or refuse to pay the liquidated damages amount in full within 30 days following its violation. For purposes herein, "solicit" does not include broad-based recruiting efforts, including, without limitation, help wanted advertising and posting of open positions on a party's internet site.

11. Placement Services. In the event that Danforth refers a potential employee to the Company and that individual is hired, Danforth shall receive a fee equal to 20% of the employee's starting annual base salary and target annual bonus. This fee is due and owing whether an individual is hired, directly or indirectly on a permanent basis or on a contract or consulting basis by the Company, as a result of Danforth's efforts within one year of the date applicant(s) are submitted to the Company. Such payment is due within 30 days of the employee's start date.

12. Limited Warranty. Danforth represents and warrants that neither this Agreement nor the performance thereof will conflict with or violate any obligation of Danforth or right of any third party. Except for any express warranties stated herein, the Services are provided on an "as is" basis, and the Company disclaims any and all other warranties, conditions, or representations (express, implied, oral or written), relating to the Services or any part thereof. Further, in performing the Services, Danforth is not engaged to disclose illegal acts, including fraud or defalcations, which may have taken place. The foregoing notwithstanding, Danforth will promptly notify the Company if Danforth becomes aware of any such illegal acts during the performance of the Services. Because the Services do not constitute an examination in accordance with standards established by the American Institute of Certified Public Accountants (the "AICPA"), Danforth is precluded from expressing an opinion as to whether financial statements provided by the Company are in conformity with generally accepted accounting principles or any other standards or guidelines promulgated by the AICPA, or whether the underlying financial and other data provide a reasonable basis for the statements.

13. Indemnification. Each Party hereto agrees to indemnify and hold the other Party hereto, its directors, officers, agents and employees harmless against any claim based upon circumstances alleged to be inconsistent with such representations and/or warranties contained in this Agreement. Further, the Company shall indemnify and hold harmless Danforth and any of its subcontractors against any claims, losses, damages or liabilities (or actions in respect thereof) that arise out of or are based on the Services performed hereunder, except for any such claims, losses, damages or liabilities arising out of the gross negligence or willful misconduct of Danforth or any of its subcontractors. The Company will endeavor to add Consultant and any

applicable subcontractor to its insurance policies as additional insureds. Furthermore, during the Term of this Agreement, if the Company desires that Danforth provide treasury services, the Company shall obtain and maintain a Crime and Cyber Insurance Policy that includes coverage for "Social Engineering" claims and extends coverage to Danforth.



14. D&O Insurance. The Company shall use its best efforts to specifically include and cover, as a benefit for their protection, Danforth staff serving as directors or officers of the Company or affiliates from time to time with direct coverage as named insureds under the Company's policy for directors' and officers' ("D&O") insurance. The Company will maintain such D&O insurance coverage for the period through which claims can be made against such persons. The Company disclaims a right to distribution from the D&O insurance coverage with respect to such persons. In the event that the Company is unable to include Danforth under the Company's policy or does not have first dollar coverage acceptable to Danforth in effect for at least $10 million (e.g., such policy is not reserved based on actions that have been or are expected to be filed against officers and directors alleging prior acts that may give rise to a claim), Danforth may, at its option, attempt to purchase a separate D&O policy that will cover the Danforth staff only. The cost of same shall be invoiced to the Company as an out -of -pocket cash expense. If Danforth is unable to purchase such D&O insurance, then Danforth reserves the right to terminate the Agreement upon delivery of written notice.

15. Independent Contractor. Neither Danforth, nor any employee or agent of Danforth is , nor shall Danforth or any employee or agent of Danforth be deemed to be at any time during the term of this Agreement, an employee of the Company, and therefore neither Danforth nor any of its employees or agents shall be entitled to any benefits provided by the Company to its employees, if applicable. Danforth's status and relationship with the Company shall be that of an independent contractor and consultant. Danforth shall not state or imply, directly or indirectly, that Danforth is empowered to bind the Company without the Company's prior written consent. Nothing herein shall create, expressly or by implication, a partnership, joint venture or other association between the parties. Danforth will be solely responsible for (i) payment of all charges and taxes arising from its relationship to the Company as a consultant, and (ii) reporting, withholding and paying all applicable taxes of any nature that may be reportable or due on amounts paid to Danforth hereunder. Danforth further agrees to indemnify and hold the Company harmless from any and all claims, causes of action or other proceedings related to or resulting from Danforth's or any of its employees' or agents' failure to pay income taxes in compliance with applicable law. Except as expressly provided herein, nothing in this Agreement shall preclude Danforth from consulting for or being employed by any other person or entity.

16. Records. Upon termination of Danforth's relationship with the Company, Danforth shall deliver to the Company any property or Confidential Information of the Company relating to the Services which may be in its possession including products, project plans, materials, memoranda, notes, records, reports, laboratory notebooks, or other documents or photocopies and any such information stored using electronic medium.

17. Notices. Any notice under this Agreement shall be in writing (except in the case of verbal communications, emails and teleconferences updating either Party as to the status of work hereunder) and shall be deemed delivered upon personal delivery, one day after being sent via a reputable nationwide overnight courier service or two days after deposit in the mail or on the next business day following transmittal via facsimile. Notices under this Agreement shall be sent to the following representatives of the Parties:



If to the Company:

Name: Christopher T. Giordano
Title: Chief Executive Officer
Address: ONE Copley Parkway, Suite 490, Morrisville, NC 27560
Phone: 919.855.2100
E-mail:

If to Danforth:

Name: Gregg Beloff
Title: Managing Director
Address: 91 Middle Road
Southborough, MA 01772
Phone: (617) 686-7679
E-mail: gbeloff@danforthadvisors.com

18. Assignment and Successors. This Agreement may not be assigned by a Party without the consent of the other which consent shall not be unreasonably withheld, except that each Party may assign this Agreement and the rights, obligations and interests of such Party, in whole or in part, to any of its Affiliates, to any purchaser of all or substantially all of its assets or to any successor corporation resulting from any merger or consolidation of such Party with or into such corporation.

19. Force Majeure. Neither Party shall be liable for failure of or delay in performing obligations set forth in this Agreement, and neither shall be deemed in breach of its obligations, if such failure or delay is due to natural disasters or any causes beyond the reasonable control of either Party. In the event of such force majeure, the Party affected thereby shall use reasonable efforts to cure or overcome the same and resume performance of its obligations hereunder.

20. Headings. The Section headings are intended for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.

21. Integration; Severability. This Agreement is the sole agreement with respect to the subject matter hereof and shall supersede all other agreements and understandings between the Parties with respect to the same. If any provision of this Agreement is or becomes invalid or is ruled invalid by any court of competent jurisdiction or is deemed unenforceable, it is the intention of the Parties that the remainder of the Agreement shall not be affected.

22. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, excluding choice of law principles. The Parties agree that any action or proceeding arising out of or related in any way to this Agreement shall be brought solely in a Federal or State court of competent jurisdiction sitting in the Commonwealth of Massachusetts.



23. Amendments and Waivers. This Agreement may be amended or supplemented only by a written instrument duly executed by each of the Parties. No provision of this Agreement may be waived except by a written instrument signed by the Party hereto sought to be bound. No failure or delay by any Party in exercising any right or remedy hereunder or under applicable law will operate as a waiver thereof, and a waiver of a particular right or remedy on one occasion will not be deemed a waiver of any other light or remedy, or a waiver on any subsequent occasion.

24. Counterparts. This Agreement may be executed in counterparts, each of which will be deemed an original, but all of which together will constitute one agreement. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, e.g., www.docusign.com) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes.

If you are in agreement with the foregoing, please sign where indicated below, whereupon this Agreement shall become effective as of the Effective Date.

| **DANFORTH ADVISORS, LLC** | | **TENAX THERAPEUTICS, INC.** | |
|---|---|---|---|
| By: | /s/ Chris Connors | By: | /s/ Christopher T. Giordano |
| Print Name: | Chris Connors | Print Name: | Christopher T. Giordano |
| Title: | Chief Executive Officer | Title: | Chief Executive Officer |
| Date: | October 14, 2021 | Date: | October 14, 2021 |



## EXHIBIT A

Description of Services and Schedule of Fees

Danforth will perform mutually agreed to finance and accounting functions which are necessary to support the management and operations of the Company.

**Services and Fees:**

Initial Staffing will be Eliot M. Lurier, who will act as Interim Chief Financial Officer of the Company, serving as its Principal Financial Officer and Principal Accounting Officer and performing all services related to such positions including, but not limited to, the following:

- Participation in financing activities;
- Overseeing the preparation and review of the Company's SEC filings and compliance with other regulatory documents;
- Certification of the Company's SEC filings;
- Support of investor relations activities;
- Overseeing the finance and accounting functions of the Company;
- Acting as Treasurer to the Company and its Subsidiaries;
- Board and Board Committee meeting support and attendance;
- Finance support for operational planning;
- Corporate and business development support;
- Financial modeling, planning and analysis;
- Strategic opportunity assessment; and
- Capitalization table management.

Mr. Lurier has been interviewed and approved by the Company. Additional personnel will be added in accordance with Section 1 of this Agreement.



Fees:

Mr. Lurier (Interim CFO): $400/hr

Additional fee rates provided below:

| Role | Hourly Rate | Function |
|---|---|---|
| Sr. Advisor | $[***]/hour | Senior Advisory |
| CFO | $400/hour | CFO |
| Sr. Director | $[***]/hour | Principal Accounting Officer |
| Sr. HR Director | $[***]/hour | Human Resources |
| HR Director | $[***]/hour | Human Resources |
| Director | $[***]/hour | VP Finance |
| Sr HR Manager | $[***]/hour | Human Resources |
| Sr Manager | $[***]/hour | Sr Controller/FP&A |
| Manager | $[***]/hour | Controller |
| HR Manager | $[***]/hour | Human Resources |
| Sr. Consultant | $[***]/hour | Asst. Controller |
| Consultant | $[***]/hour | Staff Accountant |

# SEPARATION AND RELEASE AGREEMENT

This SEPARATION AND RELEASE AGREEMENT (the "Agreement") is made and entered into this 14th day of October, 2021 (the "Effective Date") by and between Michael B. Jebsen, a citizen and resident of North Carolina (hereinafter "Employee"), and Tenax Therapeutics, Inc., a Delaware corporation with its principal place of business in North Carolina (the "Company"). (Employee and the Company are sometimes referred to herein each as a "Party" and together as the "Parties.")

WHEREAS, Employee has been employed by the Company as its President and Chief Financial Officer; and

WHEREAS, in connection with his employment with the Company, the Parties entered into a Second Amended and restated Employment Agreement dated November 13, 2013 (the "Employment Agreement"); and

WHEREAS, pursuant to the Employment Agreement, upon the separation of his employment under certain circumstances, Employee would receive certain severance benefits conditioned upon Employee's execution and non-revocation of an enforceable release of claims and his compliance with his ongoing obligations under Section 7 of the Employment Agreement; and

WHEREAS, Employee's employment will end, effective as of October 29, 2021 (the "Separation Date"); and

WHEREAS, the Parties intend that this Agreement will set out the terms of Employee's employment through the Separation Date and Employee's severance benefits, and provide for the general release of the Company by Employee as contemplated by the Employment Agreement;

NOW, THEREFORE, in consideration of the promises and the mutual covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. Separation of Employment and Transition. Until the Separation Date, Employee will continue to perform his regular duties in a competent and professional manner, support the retention and motivation levels of employees of the Company, and reasonably cooperate with the Company in transitioning Employee's duties to other employees or consultants of the Company as directed by the Company's Chief Executive Officer. Effective as of the Separation Date, Employee's employment with the Company will end and Employee will no longer serve as President and Chief Financial Officer of the Company or in any officer position at any of the Company's subsidiaries, and Employee will resign from all of his positions, if any, on the Boards of Directors of the Company and any of its subsidiaries. Employee will receive his final paycheck for work through the Separation Date on the Company's next regular pay day following the Separation Date. Except as expressly provided herein, as required by applicable law, or as may be vested under the Company's plans, policies and arrangements, after the Separation Date, Employee will be entitled to no further compensation or employee benefits from the Company as an employee of the Company.



2. Severance Benefits. If, on the later of the Separation Date and twenty-one (21) days after his receipt of this Agreement, Employee signs this Agreement, the Company will provide Employee with the following payments and benefits (collectively the "Severance Benefits"):

a. Severance Pay. In accordance with the terms of the Employment Agreement and in consideration of Employee's execution of this Agreement, the Company will pay Employee an amount equal to twelve (12) months of his regular base salary, minus applicable federal, state and local payroll taxes, and other withholdings required by law, paid out in a lump sum no later than on the thirtieth ($30^{th}$) day following the Separation Date (the "Severance Pay");

b. Target Bonus. The Company will pay to Employee an amount equal to his Target Bonus for fiscal year 2021, multiplied by a fraction, the numerator of which is the number of days during which the Employee was employed by the Company in fiscal year 2021 and the denominator of which is 365 (less applicable withholdings), with such payment to be made in lump sum payment on the Severance Pay date; and

c. Benefits. If Employee properly and timely applies for continuation coverage under the Consolidated Budget Reconciliation Act or applicable state health insurance continuation law ("COBRA"), the Company will reimburse Employee for premium payments Employee makes under COBRA to continue Employee, and if applicable, Employee's family's, health insurance coverage under the Company's group health insurance plan for twelve (12) months from the Separation Date. Reimbursements for COBRA premium payments shall begin on the Severance Payment Date and shall be made as soon as possible following the Employee's submission to the Company of proof of timely payments, but not later than thirty (30) days after the Employee's submission of proof of timely payments; provided, however, all such claims for reimbursement shall be submitted by the Employee and paid by the Company no later than fifteen (15) months following the termination of the Employee's employment. Any obligation for the Company to make payments for COBRA coverage under this Agreement shall immediately cease when Employee becomes eligible for health insurance from a subsequent employer, and Employee shall promptly notify the Company of such subsequent eligibility. Nothing herein shall constitute a guarantee of COBRA benefits.

**Employee acknowledges and agrees that Employee's receipt of the Separation Benefits is contingent upon his execution of an additional release in a form acceptable to the Company as contained in Exhibit A of this Agreement, to be presented to Employee after the Separation Date.**



3. Release of Claims. In accordance with the terms of the Employment Agreement and in exchange for the Company's agreement to provide Employee with the Severance Benefits described above, by signing this Agreement, Employee releases and forever discharges the Company, as well as its parent companies, affiliates, subsidiaries, divisions, officers, directors, stockholders, employees, agents, representatives, attorneys, lessors, lessees, licensors and licensees, and their respective successors, assigns, heirs, executors and administrators (collectively, the "Company Parties"), from any and all claims, demands, and causes of action of every kind and nature, whether known or unknown, direct or indirect, accrued, contingent or potential, that

Employee ever had or now has, including but not limited to any claims arising out of or related to his employment with the Company and the end thereof (except where and to the extent that such a release is expressly prohibited or made void by law). The release includes, without limitation, Employee's release of the Company and the Company Parties from any claims for lost wages or benefits, stock options, restricted stock, restricted stock units, compensatory damages, punitive damages, attorneys' fees and costs, equitable relief or any other form of damages or relief. In addition, this release is meant to release the Company and the Company Parties from all common law claims, including claims in contract or tort, including, without limitation, claims for breach of contract, wrongful or constructive discharge, intentional or negligent infliction of emotional distress, misrepresentation, tortious interference with contract or prospective economic advantage, invasion of privacy, defamation, negligence or breach of any covenant of good faith and fair dealing. Employee also specifically and forever releases the Company and the Company Parties (except where and to the extent that such a release is expressly prohibited or made void by law) from: all claims under North Carolina laws prohibiting discrimination, harassment and retaliation and all similar state and local laws; all claims under laws governing the payment of wages or protection of workers seeking payment for work performed and any other federal, state or local statutory and/or common laws governing the payment of wages; and/or and all claims under federal law based on unlawful employment discrimination, harassment or retaliation, including, but not limited to, claims for violation of Title VII of the Civil Rights Act, the Americans with Disabilities Act, the Genetic Information and Discrimination Act, and the Federal Age Discrimination In Employment Act (29 U.S.C. § 621 et. seq.).

Employee hereby acknowledges that this release applies both to known and unknown claims that may exist between Employee and the Company and the Company Parties. Employee expressly waives and relinquishes all rights and benefits which he may have under any state or federal statute or common law principle that would otherwise limit the effect of this Agreement to claims known or suspected prior to the date he executes this Agreement, and does so understanding and acknowledging the significance and consequences of such specific waiver. Provided, however, that nothing in this Agreement extinguishes any claims Employee may have against the Company for breach of this Agreement or any claims arising from events that occur following the Effective Date of this Agreement.

4. No Admissions. Employee understands, acknowledges and agrees that the release set out above in Section 3 is a final compromise of potential claims, and is not an admission by the Company that any such claims exist or that the Company or the Company Parties are liable for any such claims. Unless prohibited by applicable law or regulation, Employee further agrees not to hereafter, directly or indirectly, sue, assist in or be a voluntary party to any litigation against Company or any one or more of the Company Parties for any claims relating to events occurring prior to or simultaneously with the execution of this Agreement.



Notwithstanding the foregoing, nothing in this Agreement prohibits Employee from filing a charge with, or participating in any investigation or proceeding conducted by, the U.S. Equal Employment Opportunity Commission or a comparable state or federal fair employment practices agency; provided, however, that this Agreement fully and finally resolves all monetary matters between Employee and the Company and the Company Parties, and by signing this Agreement, Employee acknowledges that he is waiving any right to monetary damages, attorneys' fees and/or costs related to or arising from any such charge, complaint or lawsuit filed by Employee or on Employee's behalf, individually or collectively.

5. Cooperation. By signing this Agreement, Employee promises and agrees, and for eighteen (18) months following the Separation Date, to the extent reasonably requested by the Company, to cooperate fully with the Company and its officers, directors, employees, agents and legal counsel in connection with any claim, complaint, charge, suit or action previously or hereafter asserted or filed by or against the Company or any of the Company Parties which relates to, arises out of or is connected directly or indirectly with (i) Employee's employment with the Company, (ii) any other relationship or dealings between Employee and the Company or any of the Company Parties, or (iii) any other matter relating to the Company or any of the Company Parties. Employee's cooperation with the Company shall continue throughout the pendency of any such claim, complaint, charge, suit or action; provided that the Company shall make reasonable efforts to minimize disruption of the Employee's other activities. Further, Employee promises and agrees that, in the event he is subject to a valid and enforceable subpoena or court order which compels his testimony at a trial, hearing or deposition concerning his relationship with the Company or any other matter relating to the Company or any of the Company Parties, he will provide reasonable and prompt notice to the Company of this fact and cooperate fully with the Company prior to and during his testimony, to the maximum extent possible, consistent with his obligation to provide truthful testimony. Employee further agrees that, in the event he is named as a defendant in a legal proceeding resulting from, arising out of, or connected directly or indirectly with Employee's employment with the Company, or any act, omission or conduct occurring during Employee's employment with the Company, he will provide reasonable and prompt notice of this fact to the Company. The Company agrees to reimburse Employee for reasonable out-of-pocket expenses as reasonably required for such cooperation and consultation, and to the extent Employee is required to spend more than five hours of such matters, the Company shall compensate Employee at an hourly rate based on the Employee's base salary on the Separation Date, and to the extent Employee is required to spend more than five hours of such matters, the Company shall compensate Employee at an hourly rate based on the Employee's base salary on the Separation Date.

Notwithstanding the foregoing, nothing in this Agreement prohibits Employee from reporting possible violations of federal law or regulation to any governmental agency or entity, including but not limited to the Department of Justice, the Securities and Exchange Commission, the Congress, and any agency Inspector General, or making other disclosures that are protected under the whistleblower provisions of federal law or regulation. Employee does not need the prior authorization of the Company to make any such reports or disclosures, and Employee is not required to notify the Company that he has made such reports or disclosures. The Company agrees that it will take no adverse action against Employee for truthful statements and testimony and that it will not seek to obtain any testimony or evidence that is not truthful and that it will not improperly seek to influence or modify any testimony of Employee.



6. Return of Property. On or before the Separation Date, Employee shall return all property of the Company in his possession, including, without limitation, any Company credit cards, Company-owned equipment, and all originals and any copies of all disks, tapes, files, correspondence, data, notes and other documents pertaining to the Company's proprietary products, customers and business and confidential and proprietary information as described in Section 7 of the Employment Agreement. Such property shall be in the same condition as when provided to Employee, reasonable wear and tear excepted.

7. Confidentiality and Competitive Business Activities. Employee hereby acknowledges and agrees that his post-employment duties and obligations under Section 7 of the Employment Agreement will remain in full force and effect in accordance with such terms, and that a breach of Section 7

of the Employment Agreement will also constitute a breach of this present Agreement.

8. No Disparagement. Employee agrees that he will not falsely denigrate, defame, disparage or cast aspersions upon the Company, its management, products, services, business and manner of doing business, and that he will instruct members of his immediate family not to engage in any such activity.

9. SECTION 409A.

a. The Parties hereby acknowledge and agree that all benefits or payments provided by the Company to Employee pursuant to this Agreement are intended either to be exempt from Section 409A of the Code, or to be in compliance with Section 409A, and the Agreement shall be interpreted to the greatest extent possible to be so exempt or in compliance. If there is an ambiguity in the language of the Agreement, or if Section 409A guidance indicates that a change to the Agreement is required or desirable to achieve exemption or compliance with Section 409A, Company and Employee agree to attempt to renegotiate in good faith to clarify the ambiguity or make such change.

b. If any severance or other payments that are required by the Agreement are to be paid in a series of installment payments, each individual payment in the series shall be considered a separate payment for purposes of Section 409A.

c. If any severance compensation or other benefit provided to Employee pursuant to this Agreement that constitutes "nonqualified deferred compensation" within the meaning of Section 409A is considered to be paid on account of "separation from service" within the meaning of Section 409A, and Employee is a "specified employee" within the meaning of Section 409A, no payments of any of such severance or other benefit shall made for six (6) months plus one (1) day after the "separation from service" (the "New Payment Date"). The aggregate of any such payments that would have otherwise been paid during the period between the "separation from service" and the New Payment Date shall be paid to the Employee in a lump sum on the New Payment Date.



10. Relief and Enforcement. Employee understands and agrees that, in addition to any other remedies that the Company (or the Company Parties) has at law or in equity, upon any breach of this Agreement by Employee, the Company may immediately cease providing any or all of the Severance Benefits and/or seek recovery of Severance Benefits that have been paid to him pursuant to Section 2, above. Employee also understands and agrees that if he violates the terms of Sections 5, 6, 7 or 8 of this Agreement, Employee will cause injury to the Company and/or one or more of the Company Parties) that will be difficult to quantify or repair, so that the Company (and/or the Company Parties) will have no adequate remedy at law. Accordingly, Employee agree that if he violates Sections 5, 6, 7 or 8 of this Agreement, the Company (or the Company Parties) will be entitled as a matter of right to obtain an injunction from a court of law, restraining Employee from any further violation of this Agreement. The right to an injunction is in addition to any other remedies that the Company (or the Company Parties) has at law or in equity.

11. Assignment. This Agreement may not be assigned by Employee without the prior written consent of the Company. The Company shall have the right to assign this Agreement to its successors and assigns in connection with a change in control or business transaction requiring a general assignment, and all covenants and agreements hereunder shall inure to the benefit of and be enforceable by said successors or assigns. The term "Company" shall include any of the Company's subsidiaries, subdivisions or affiliates.

12. No Modifications; Governing Law; Venue; Entire Agreement. This Agreement cannot be changed or terminated orally, and no modification or waiver of any of the provisions of this Agreement is effective unless in writing and signed by all of the Parties hereto. The Parties agree that this Agreement is to be governed by and construed in accordance with the laws of the State of North Carolina. The Parties agree that any litigation arising out of or related to this Agreement or Employee's employment by Company will be brought exclusively in any state or federal court in Wake County, North Carolina. Each Party (a) consents to the personal jurisdiction of said courts, (b) waives any venue or inconvenient forum defense to any proceeding maintained in such courts and (c) agrees not to bring any proceeding arising out of or relating to this Agreement or Employee's employment by Company in any other court.

This Agreement, and the surviving provisions of the Employment Agreement, set forth the entire and fully integrated understanding between the Parties, and there are no representations, warranties, covenants or understandings, oral or otherwise, that are not expressly set out therein.

13. Voluntary Execution. By signing below, Employee acknowledges that he has read this Agreement, that he understands its contents and that he has relied upon or had the opportunity to seek the legal advice of his attorney, who is the attorney of his own choosing.

*[Signature page follows.]*



IN WITNESS WHEREOF, each of the Parties hereto acknowledges having read and understood the contents and effect of this Agreement and has executed this Agreement freely and with full authority duly given, all as of the Effective Date first above written.

THE COMPANY:

TENAX THERAPEUTICS, INC.

By: /s/ Christopher T. Giordano
Name: Christopher T. Giordano
Title: Chief Executive Officer

EMPLOYEE:

/s/ Michael B. Jebsen (SEAL)
Michael B. Jebsen

**EXHIBIT A**

**RELEASE**

This RELEASE (the "Final Release") is hereby made and entered into this __ day of October, 2021 by and between Tenax Therapeutics, Inc. (the "Company") and Michael B. Jebsen ("Employee").

WHEREAS, the Company and Employee entered into a Separation and Release Agreement on or about [Date], 2021 (the "Agreement"); and

WHEREAS, in connection with the Agreement, Employee agreed to execute this Final Release in exchange for certain consideration as set out therein; and

NOW, THEREFORE, in consideration of the promises and the mutual covenants set out in the Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Company and Employee hereby agree that this Final Release will be an addendum to the Agreement and agree as follows:

1. Release of Claims. In exchange for the Company's providing Employee with the Separation Benefits described in Section 2 of the Agreement, by signing this Final Release, Employee releases and forever discharges the Company, as well as its parent companies, affiliates, subsidiaries, divisions, officers, directors, stockholders, employees, agents, representatives, attorneys, lessors, lessees, licensors and licensees, and their respective successors, assigns, heirs, executors and administrators (collectively, the "Company Parties"), from any and all claims, demands, and causes of action of every kind and nature, whether known or unknown, direct or indirect, accrued, contingent or potential, that Employee ever had or now has, including but not limited to any claims arising out of or related to his employment with the Company and the end thereof (except where and to the extent that such a release is expressly prohibited or made void by law). The release includes, without limitation, Employee's release of the Company and the Company Parties from any claims for lost wages or benefits, stock options, restricted stock, restricted stock units, compensatory damages, punitive damages, attorneys' fees and costs, equitable relief or any other form of damages or relief. In addition, this release is meant to release the Company and the Company Parties from all common law claims, including claims in contract or tort, including, without limitation, claims for breach of contract, wrongful or constructive discharge, intentional or negligent infliction of emotional distress, misrepresentation, tortious interference with contract or prospective economic advantage, invasion of privacy, defamation, negligence or breach of any covenant of good faith and fair dealing. Employee also specifically and forever releases the Company and the Company Parties (except where and to the extent that such a release is expressly prohibited or made void by law) from: all claims under North Carolina laws prohibiting discrimination, harassment and retaliation and all similar state and local laws; all claims under laws governing the payment of wages or protection of workers seeking payment for work performed and any other federal, state or local statutory and/or common laws governing the payment of wages; and/or and all claims under federal law based on unlawful employment discrimination, harassment or retaliation, including, but not limited to, claims for violation of Title VII of the Civil Rights Act, the Americans with Disabilities Act, the Genetic Information and Discrimination Act, and the Federal Age Discrimination In Employment Act.



Employee acknowledges that this release applies both to known and unknown claims that may exist between Employee and the Company and the Company Parties. Employee expressly waives and relinquishes all rights and benefits which Employee may have under any state or federal statute or common law principle that would otherwise limit the effect of this Final Release to claims known or suspected prior to the date Employee executes this Final Release, and Employee does so understanding and acknowledging the significance and consequences of such specific waiver. In addition, Employee hereby expressly understands and acknowledges that it is possible that unknown losses or claims exist or that present losses may have been underestimated in amount or severity, and Employee explicitly took that into account in giving this release.

Notwithstanding the foregoing, nothing in this Final Release prohibits Employee from filing a charge with, or participating in any investigation or proceeding conducted by, the U.S. Equal Employment Opportunity Company or a comparable state or federal fair employment practices agency; provided, however, that this Final Release fully and finally resolves all monetary matters between Employee and the Company and the Company Parties, and by signing this Final Release, Employee is waiving any right to monetary damages, attorneys' fees and/or costs related to or arising from any such charge, complaint or lawsuit filed by Employee or on Employee's behalf, individually or collectively. In addition, nothing in this Final Release extinguishes any claims Employee may have against the Company for breach of this Final Release or any claims arising from events that occur following the effective date of this Final Release.

2. No Modifications; Governing Law; Entire Agreement. This Agreement cannot be changed or terminated verbally, and no modification or waiver of any of the provisions of this Agreement will be effective unless it is in writing and signed by both parties. The parties agree that this Agreement is to be governed by and construed in accordance with the laws of the State of North Carolina, and that any suit, action or charge arising out of or relating to this Agreement will be adjudicated in the state or federal courts in Wake County, North Carolina. Together with the Agreement and the surviving provisions of the Employment Agreement (as that term is defined in the Agreement), this Final Release sets forth the entire and fully integrated understanding between the parties, and there are no representations, warranties, covenants or understandings, oral or otherwise, that are not expressly set out therein.

3. Miscellaneous.

(a) Should any portion, term or provision of this Final Release be declared or determined by any court to be illegal, invalid or unenforceable, the validity of the remaining portions, terms and provisions shall not be affected thereby, and the illegal, invalid or unenforceable portion, term or provision shall be deemed not to be part of this Final Release.

(b) The parties agree that the failure of a party at any time to require performance of any provision of this Final Release shall not affect, diminish, obviate or void in any way the party's full right or ability to require performance of the same or any other provision of this Final Release at any time thereafter.



(c) This Final Release shall inure to the benefit of and shall be binding upon Employee, his heirs, administrators, representatives, executors, successors and assigns and upon the successors and assigns of the Company.

(d) The headings of the paragraphs of this Final Release are for convenience only and are not binding on any interpretation of this Final Release. This Final Release may be executed in counterparts.

(e) Counterparts may be transmitted and/or signed by facsimile or electronic mail. The effectiveness of any such documents and signatures shall have the same force and effect as manually signed originals and shall be binding on the parties to the same extent as a manually signed original thereof.

(f) This Agreement, and the surviving provisions of the Employment Agreement, set forth the entire and fully integrated understanding between the Parties, and there are no representations, warranties, covenants or understandings, oral or otherwise, that are not expressly set out therein.

[*Signatures follow on next page.*]



**TENAX THERAPEUTICS, INC.**

By: _____
Name:
Title:

DATE: _____

EMPLOYEE:

_____ (SEAL)
Michael B. Jebsen

DATE: _____

**EXHIBIT 10.3**

**CONSULTING AGREEMENT**

This Consulting Agreement (the "Agreement") is entered into as of the 14th day of October, 2021, by and between Tenax Therapeutics, Inc. a Delaware corporation with its principal place of business in North Carolina ("the "Company"), and Michael B. Jebsen, a resident of North Carolina ("Consultant"). The Company and Consultant are sometimes referred to herein each as a "Party" and together as the "Parties."

WHEREAS, the Company desires to engage Consultant to provide services to the Company as a Special Advisor to the Company's Chief Executive Officer subject to the terms and conditions of this Agreement; and

WHEREAS, Consultant desires to provide those services to the Company subject to the terms and conditions of this Agreement;

NOW, THEREFORE, for and in consideration of the premises and mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and subject to the terms and conditions hereinafter set forth, the Parties hereto enter into this Agreement and agree as follows.

1. SERVICES. The services to be performed by Consultant as Special Advisor to the Chief Executive Officer under this Agreement will be as set forth on Exhibit A attached hereto and are hereafter referred to as the "Services." Consultant agrees to perform the Services in a timely and professional manner and at the direction of the Company's Chief Executive Officer.

2. TERM. The term of this Agreement will be for a period beginning as of October 29, 2021 (the "Effective Date") and continuing for six (6) months unless earlier terminated pursuant to Section 4 of this Agreement (the "Term"). The Term may be extended upon mutual agreement of the Parties.

3. COMPENSATION. During the Term of this Agreement, the Company will pay Consultant fees for the Services in accordance with the fee schedule that is attached to this Agreement as Exhibit B (the "Consultant Fees"). Consultant will submit monthly invoices to the Company detailing the Services provided, and the Company will make payments of the Consultant Fees earned on or before the tenth (10th) business day after receipt of such invoices. By signing this Agreement, Consultant acknowledges and agrees that he is solely responsible for payment of all required taxes on the Consultant Fees.

4. TERMINATION.

a. Termination by Notice. At any time during the Term, either Party hereto may terminate this Agreement by providing at least thirty (30) days advance written notice of termination to the other Party ("Termination by Notice"). Upon Termination by Notice, the Company will pay Consultant only that portion of the Consultant Fees due to Consultant for Services performed through the effective date of the termination.



b. Termination for Cause. At any time during the Term, the Company may terminate this Agreement immediately and without advanced notice for "Cause." For purposes of this Agreement, "Cause" shall mean and include: (i) Consultant's material breach of this Agreement; (ii) Consultant's commission of a felony or crime involving moral turpitude; (iii) any act by Consultant involving dishonesty in the performance of the Services, including, without limitation, fraud, misappropriation or embezzlement; (iv) Consultant's repeated failure or refusal to perform the Services; or (v) any willful or grossly negligent act or omission by Consultant that is injurious to the Company or the Company, including injury to the Company's reputation. If the Company terminates this Agreement for Cause, the Company will pay Consultant only that portion of the Consultant Fees due to Consultant for Services performed through the effective date of the termination.

c. Other Termination. This Agreement shall terminate immediately upon Consultant's death or "Disability." For purposes of this Agreement, "Disability" is defined as Consultant's inability due to a physical or mental impairment to perform the Services for a period of thirty (30) consecutive days. If this Agreement is terminated due to Consultant's death or Disability, the Company will pay Consultant only that portion of the Consultant Fees due to Consultant for Services performed through the effective date of the termination.

5. Independent Contractor Status. During the Term, Consultant will be an independent contractor and not the Company's employee for any purpose, including, but not limited to, the application of the Fair Labor Standards Act's minimum wage and overtime provisions, the Federal Insurance Contribution Act, the Social Security Act, the Federal Unemployment Tax Act, the provisions of the Internal Revenue Code, and all federal, state and local laws and regulations. Consultant understands that the Company will not be responsible for withholding or paying any federal or state income, social security or other taxes in connection with any compensation paid under this Agreement, and Consultant agrees to pay all such taxes when due. The Company will provide Consultant with a Form 1099 to the extent required by law. Consultant hereby agrees to indemnify and hold the Company harmless from any and all claims, causes of action or other proceedings related to or resulting from Consultant's failure to pay taxes in compliance with applicable law. Consultant further understands and agrees that Consultant will not be entitled to any medical, disability, pension or other employment benefits made available by the Company to its employees. During the Term, Consultant will retain sole and absolute discretion and judgment in the manner and means of carrying out the Services. Consultant further agrees that during the Term, he has a full opportunity to find other business (so long as such other business is not in violation of this Agreement), and that he will use a high level of skill necessary to perform the Services. During the Term, Consultant will not have the authority to enter into any contract on behalf of the Company or otherwise to bind the Company to any agreement unless expressly authorized in writing to do so, and the Company will not be liable for any obligation incurred by Consultant during the Term. During the Term, Consultant shall indemnify and hold the Company harmless from all claims, losses, injuries or damages, and wages or any other form of compensation (including, without limitation, reasonable attorneys' fees and costs) arising in connection with any claim, suit or proceeding alleging that Consultant has or had a relationship with the Company other than an independent contracting relationship during the Term.

6. NO CONFLICTING OBLIGATIONS. Consultant hereby represents that his agreement to the terms of this Agreement will not breach any prior agreement not to compete or solicit customers or employees or to keep in confidence any proprietary information acquired by Consultant in confidence or in trust prior to the execution of this Agreement. Consultant further represents that he has not entered into, and agrees he will not enter into, any agreement, either written or oral, in conflict with this Agreement.

7. WAIVER OF BREACH. Any waiver by the Company of a breach of any provision of this Agreement will not operate as a waiver of any subsequent breach of that provision or any other provision of this Agreement.

8. CHOICE OF LAW; VENUE. This Agreement is to be governed by the laws of the State of North Carolina without regard to its choice of law provisions. The Parties agree that any litigation arising out of or related to this Agreement will be brought exclusively in any state or federal court in Wake County, North Carolina. Each Party (i) consents to the personal jurisdiction of said courts, (ii) waives any venue or inconvenient forum defense to any proceeding maintained in such courts, and (iii) agrees not to bring any proceeding arising out of or relating to this Agreement or Consultant's engagement by the Company in any other court.

9. COMPLETE AND FINAL AGREEMENT. This Agreement, including any exhibits, represents the complete and final agreement of the Parties and will control over any other statement, representation or agreement by the Company. This Agreement supersedes any prior negotiations or discussions between the Parties with regard to the subject matter hereof. This Agreement may be amended only in a writing signed by each of the Parties hereto.

10. HEADINGS. The headings or titles to the paragraphs of this Agreement are solely for convenience of reference and shall be ignored when interpreting this Agreement.

11. SEVERABILITY AND CONSTRUCTION. Should any part of this Agreement be declared invalid for any reason by any court of competent jurisdiction, such decision or determination shall not affect the validity of any remaining portion, and such remaining portion shall remain in force and effect as if this Agreement had been executed with the invalid portion eliminated; provided, that, in the event of a declaration of invalidity, the provision declared invalid shall not be invalidated in its entirety, but shall be observed and performed by the Parties to the extent such provision is valid and enforceable. The Parties hereby agree that any such provision shall be deemed to be altered and amended to the extent necessary to effect such validity and enforceability.

12. VOLUNTARY EXECUTION. Consultant hereby acknowledges that he has read the foregoing Agreement, that he understands its contents, and that he has relied upon or had the opportunity to seek the legal advice of his attorney, who is the attorney of his choosing.

13. COUNTERPARTS. This Agreement may be executed in any number of counterparts and all of such counterparts shall for all purposes constitute one and the same instrument.

14. NOTICES. All notices or demands by any Party relating to this Agreement shall be in writing and shall be deemed effectively given: (a) upon person delivery to the Party to be notified; (b) five (5) days after having been sent by registered mail, postage prepaid, return receipt requested; or (c) one (1) day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt, at its addresses set forth below:



If to the Company: Tenax Therapeutics, Inc.
ONE Copley Parkway, Suite 490
Morrisville, NC 27560
Attention: Christopher T. Giordano

If to Consultant: Michael B. Jebsen

The Parties hereto may change the address at which they are to receive notice hereunder, by notice in writing in the foregoing manner given to the other.

*[Signature page follows.]*



IN WITNESS WHEREOF, each of the Parties hereto acknowledges having read and understood the contents and effect of this Agreement and has executed this Agreement freely and with full authority duly given, all as of the date first above written.

THE COMPANY:

TENAX THERAPEUTICS, INC.

By: /s/ Christopher T. Giordano
Name: Christopher T. Giordano
Title: Chief Executive Officer

CONSULTANT:

/s/ Michael B. Jebsen (SEAL)
Michael B. Jebsen

**EXHIBIT A**

THE “SERVICES” DEFINED

Consultant shall make himself available to the Company’s Chief Executive Officer for special projects and requests. Consultant shall be expected to devote no more than twenty (20) hours per week in performing the Services. The Services will include:

- Assist with questions related to daily operations of the accounting department
- Assist with processes and procedures related to filing financial statements and other documents with the SEC
- Assist with other accounting and finance related questions as they arise
- Any other reasonable assistance to the Company, including to the Chief Financial Officer, as requested by the Chief Executive Officer



**EXHIBIT B**

CONSULTANT FEES

Consultant will receive Consulting Fee at the rate of Two Hundred And Seventy Five Dollars ($275.00) per hour.

**EXHIBIT 31.1**

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

I, Christopher T. 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 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 financial statements for external purposes in accordance with generally accepted accounting principles;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 15, 2021

/s/ Christopher T. Giordano
Christopher T. Giordano
*President and Chief Executive Officer*
*(Principal Executive Officer)*

**EXHIBIT 31.2**

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

I, Eliot M. Lurier, 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 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 financial statements for external purposes in accordance with generally accepted accounting principles;

   c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 15, 2021

/s/ Eliot M. Lurier
Eliot M. Lurier
*Interim Chief Financial Officer*
*(Principal Financial and Accounting Officer)*

**EXHIBIT 32.1**

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

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

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods covered by the Report.

Date: November 15, 2021

/s/ Christopher T. Giordano
Christopher T. Giordano
*President and 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, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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

**EXHIBIT 32.2**

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

In connection with the Quarterly Report of Tenax Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Eliot M. Lurier, Interim Chief Financial Officer (Principal Financial and Accounting 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, to my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods covered by the Report.

Date: November 15, 2021

/s/ Eliot M. Lurier
Eliot M. Lurier
*Interim Chief Financial Officer*
*(Principal Financial and Accounting Officer)*

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350 , as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 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.