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

FORM 10-Q

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

FOR THE QUARTERLY PERIOD ENDED June 30, 2026

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.)**

101 Glen Lennox Drive, Suite 300, Chapel Hill, North Carolina 27517
(Address of principal executive offices, including zip code)

(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 July 28, 2026, the registrant had outstanding 37,423,917 shares of Common Stock.

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PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

TENAX THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(Amounts in thousands, except share and per share data)

	June 30, 2026 (unaudited)	December 31, 2025
ASSETS		
Current assets		
Cash and cash equivalents	$ 117,976	$ 97,565
Prepaid expenses	3,415	5,643
Other current assets	272	1,019
Total current assets	121,663	104,227
Total assets	$ 121,663	$ 104,227
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 6,795	$ 6,041
Accrued liabilities	1,278	1,115
Total current liabilities	8,073	7,156
Total liabilities	8,073	7,156
Commitments and contingencies; see Note 4		
Stockholders' equity		
Preferred stock, undesignated, authorized 4,818,654 shares		
Series A Preferred stock, par value $0.0001, authorized 5,181,346 shares; issued and outstanding 210, as of June 30, 2026 and December 31, 2025	-	-
Common stock, par value $0.0001 per share; authorized 400,000,000 shares; issued and outstanding 31,949,785 as of June 30, 2026 and 9,314,130 as of December 31, 2025, respectively	3	1
Additional paid-in capital	514,560	464,524
Accumulated deficit	(400,973)	(367,454)
Total stockholders' equity	113,590	97,071
Total liabilities and stockholders' equity	$ 121,663	$ 104,227

The accompanying notes are an integral part of these condensed consolidated financial statements.

TENAX THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(unaudited)
(Amounts in thousands, except share and per share data)

	For the three months ended June 30,		For the six months ended June 30,	
	2026	**2025**	**2026**	**2025**
Operating expenses				
Research and development	$ 12,850	$ 6,121	$ 24,389	$ 11,804
Selling, general and administrative	5,934	5,671	10,968	11,326
Total operating expenses	18,784	11,792	35,357	23,130
Net operating loss	(18,784)	(11,792)	(35,357)	(23,130)
Interest income	981	954	1,842	1,884
Other expense, net	-	(9)	(4)	(9)
Net loss	$ (17,803)	$ (10,847)	$ (33,519)	$ (21,255)
Net loss per share, basic and diluted	$ (0.35)	$ (0.27)	$ (0.70)	$ (0.56)
Weighted average number of common shares and prefunded warrants outstanding, basic and diluted	50,869,259	39,572,177	48,064,151	38,086,800

The accompanying notes are an integral part of these condensed consolidated financial statements.

TENAX THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(unaudited)
(Amounts in thousands, except share data)

	Preferred Stock		Common Stock				
	Number of Shares	Amount	Number of Shares	Amount	Additional paid-in capital	Accumulated deficit	Total stockholders' equity
Balance at December 31, 2024	**210**	**$ -**	**3,420,906**	**$ -**	**$ 406,848**	**$ (314,855)**	**$ 91,993**
Public offering sale of common stock and prefunded warrants, net of offering costs of $1,746	-	-	378,346	-	23,216	-	23,216
Exercise of pre-funded warrants	-	-	99,189	-	1	-	1
Exercise of warrants	-	-	71,944	-	347	-	347
Stock-based compensation expense	-	-	-	-	4,142	-	4,142
Net loss	-	-	-	-	-	(10,408)	(10,408)
Balance at March 31, 2025	**210**	**$ -**	**3,970,385**	**$ -**	**$ 434,554**	**$ (325,263)**	**$ 109,291**
Exercise of pre-funded warrants	-	-	116,693	-	1	-	1
Exercise of warrants	-	-	61,417	-	276	-	276
Stock-based compensation expense	-	-	-	-	4,609	-	4,609
Net loss	-	-	-	-	-	(10,847)	(10,847)
Balance at June 30, 2025	**210**	**$ -**	**4,148,495**	**$ -**	**$ 439,440**	**$ (336,110)**	**$ 103,330**

	Preferred Stock		Common Stock				
	Number of Shares	Amount	Number of Shares	Amount	Additional paid-in capital	Accumulated deficit	Total stockholders' equity
Balance at December 31, 2025	**210**	**$ -**	**9,314,130**	**$ 1**	**$ 464,524**	**$ (367,454)**	**$ 97,071**
Exercise of pre-funded warrants	-	-	8,533,958	1	52	-	53
Exercise of warrants	-	-	6,422,412	-	30,416	-	30,416
Exercise of options			5,000	-	30	-	30
Stock-based compensation expense	-	-	-	-	2,838	-	2,838
Net loss	-	-	-	-	-	(15,716)	(15,716)
Balance at March 31, 2026	**210**	**$ -**	**24,275,500**	**$ 2**	**$ 497,860**	**$ (383,170)**	**$ 114,692**
Exercise of pre-funded warrants			4,707,239	1	30		31
Exercise of warrants	-	-	2,964,546	-	13,340	-	13,340
Vesting of restricted stock units	-	-	2,500	-	-	-	-
Stock-based compensation expense	-	-	-	-	3,330	-	3,330
Net loss	-	-	-	-	-	(17,803)	(17,803)
Balance at June 30, 2026	**210**	**$ -**	**31,949,785**	**$ 3**	**$ 514,560**	**$ (400,973)**	**$ 113,590**

The accompanying notes are an integral part of these condensed consolidated financial statements.

TENAX THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)
(Amounts in thousands)

	Six months ended June 30,	
	2026	**2025**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (33,519)	$ (21,255)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation	6,168	8,751
Changes in operating assets and liabilities		
Prepaid expenses and other current assets	2,975	1,440
Accounts payable	754	(2,595)
Accrued liabilities	163	429
Net cash used in operating activities	(23,459)	(13,230)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of warrants and pre-funded warrants, net of issuance costs	-	23,216
Proceeds from the exercise of options	30	-
Proceeds from the exercise of warrants and pre-funded warrants	43,840	625
Net cash provided by financing activities	43,870	23,841
Net change in cash and cash equivalents	20,411	10,611
Cash and cash equivalents, beginning of period	97,565	94,851
Cash and cash equivalents, end of period	$ 117,976	$ 105,462

The accompanying notes are an integral part of these condensed consolidated financial statements.

TENAX THERAPEUTICS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

NOTE 1. DESCRIPTION OF BUSINESS

Tenax Therapeutics, Inc., together with its subsidiaries (collectively "Tenax" or the "Company"), is a Phase 3, development-stage pharmaceutical company using clinical insights to develop novel cardiopulmonary therapies. The Company is incorporated in Delaware and is headquartered in Chapel Hill, North Carolina.

Liquidity and Capital Resources

The Company has financed its operations since September 1990 primarily through the sale of equity and debt securities and loans from stockholders. The Company had an accumulated deficit of $401.0 million at June 30, 2026 and incurred losses of $33.5 million and $21.3 million during the six months ended June 30, 2026 and 2025, respectively. The Company expects to continue to incur expenses related to the development of levosimendan for pulmonary hypertension and other potential indications and, over the long term, imatinib for pulmonary arterial hypertension ("PAH"), as well as identifying and developing other potential product candidates. At June 30, 2026, the Company had cash and cash equivalents of $118.0 million. Based on its resources on June 30, 2026, Company management believes that it has sufficient funds for the Company to continue its operations over at least the next 12 months from the date these condensed consolidated financial statements were available to be issued.

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 in the related transaction documents that may affect the manner in which the Company conducts its business. To the extent that the Company raises additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to its technologies or product candidates or grant licenses on terms that may not be favorable to the Company. Any or all of the foregoing may have a material adverse effect on the Company's business and financial performance.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles ("GAAP") for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all the information and footnotes required by GAAP for complete financial statements. In the opinion of management, the unaudited condensed consolidated financial statements reflect all adjustments, which include only normal recurring adjustments necessary for the fair statement of the balances and results for the periods presented. Certain information and footnote disclosures normally included in the Company's annual financial statements prepared in accordance with GAAP have been condensed or omitted. These condensed consolidated financial statement results are not necessarily indicative of results to be expected for the full fiscal year or any future period.

The accompanying unaudited condensed consolidated financial statements and related disclosures have been prepared with the presumption that users of the unaudited condensed consolidated financial statements have read or have access to the audited financial statements for the preceding fiscal year. Accordingly, these unaudited condensed consolidated financial statements should be read in conjunction with the Company's Form 10-K, which was filed with the United States Securities and Exchange Commission ("SEC") on March 10, 2026, from which the Company derived the balance sheet data on December 31, 2025.

The condensed consolidated financial statements include the accounts of the Company and its subsidiaries. Intercompany balances and transactions have been eliminated upon consolidation.

Use of Estimates

The preparation of the accompanying unaudited condensed consolidated financial statements in conformity with GAAP requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the unaudited condensed consolidated financial statements and reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

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.

Significant Accounting Policies

There have been no material changes in the Company's significant accounting policies to those previously disclosed in its Annual Report on Form 10-K for the year ended December 31, 2025, other than the following:

Cash Concentration Risk

The Federal Deposit Insurance Corporation (the "FDIC") insurance limits are $250,000 per depositor per insured bank. The Company had cash balances of $117.7 million and $97.0 million uninsured by the FDIC as of June 30, 2026 and December 31, 2025, respectively.

Loss Per Share

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

The following outstanding options, restricted stock grants, 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.

	Six months ended June 30,	
	2026	**2025**
Warrants to purchase common stock	7,508,153	19,740,901
Options to purchase common stock, restricted stock grants (stock incentive plans and inducement grants)	9,262,744	6,306,747
Convertible preferred shares outstanding	210	210

NOTE 3. BALANCE SHEET COMPONENTS

Prepaid expenses and other current assets consist of the following (in thousands):

	June 30, 2026	**December 31, 2025**
Prepaid assets:		
Prepaid CRO expenses	$ 3,009	$ 4,841
Other prepaid expenses	406	802
Total prepaid expenses	$ 3,415	$ 5,643
Other current assets:		
Cash from warrant exercise held at transfer agent	$ -	$ 949
Miscellaneous other current assets	272	70
Total other current assets	$ 272	$ 1,019

Accrued liabilities consist of the following (in thousands):

	June 30, 2026	**December 31, 2025**
Accrued liabilities:		
Operating costs	$ 304	$ 217
Employee related	974	898
Total accrued liabilities	$ 1,278	$ 1,115

NOTE 4. COMMITMENTS AND CONTINGENCIES

Orion License and Supply Agreements

On November 13, 2013, the Company acquired certain assets of Phyxius Pharma, Inc. ("Phyxius") pursuant to an asset purchase agreement by and among the Company, Phyxius and the stockholders of Phyxius, dated October 21, 2013. Among these assets was a license with Orion Corporation ("Orion") for the 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 (as amended from time to time, the "License"). On October 9, 2020 and January 25, 2022, the Company entered into amendments to the License to include in the scope of the License two new product formulations containing levosimendan, in capsule and solid dosage form (TNX-103) and a subcutaneously administered dosage form (TNX-102), subject to specified limitations (together, the "Product").

On February 19, 2024, the Company entered into an amendment to the License providing global rights to oral and subcutaneous formulations of levosimendan used in the treatment of pulmonary hypertension in heart failure with preserved ejection fraction ("PH-HFpEF"). The amendment also reduced the tiered royalties based on worldwide net sales of the product by the Company and its sublicensees, increased the License's existing milestone payment due to Orion upon the grant of United States Food and Drug Administration (the "FDA") approval of a levosimendan-based product to $10.0 million and added a milestone payment to Orion of $5.0 million due upon the grant of regulatory approval for a levosimendan-based product in Japan. The amendment also (i) increased the Company's obligations to make certain non-refundable commercialization milestone payments to Orion, aggregating to up to $45.0 million, contingent upon achievement of certain cumulative worldwide sales of the product by the Company, and (ii) reduced the maximum price per capsule payable by the Company to Orion, under a supply agreement finalized in June 2026, for the commercial supply of oral levosimendan-based product. Pursuant to the License, the Company and Orion will agree to a new trademark when commercializing levosimendan in either of the dosage forms.

On September 3, 2025, the Company entered into an amendment to the License providing exclusive worldwide rights to develop, commercialize, manufacture, and have manufactured any orally-administered pharmaceutical product containing levosimendan and, in addition to the Company's existing rights to develop and commercialize subcutaneously administered products containing levosimendan, to manufacture or have manufactured such products.

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 but, pursuant to the February 2024 amendment, excluding new applications of levosimendan for neurological diseases and disorders developed by Orion.

On June 29, 2026, the Company further amended the License and extended to December 31, 2035, the date by which regulatory approval for the Product must be obtained in the United States, in order to avoid the effectiveness of a termination right for either party based on the failure to achieve such milestone. Pursuant to the amendment, the Company also is required to comply with certain information and cybersecurity requirements of Orion.

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.

As of June 30, 2026, 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.

On June 29, 2026, the Company and Orion also entered into a supply agreement to govern Orion's manufacture and supply of oral levosimendan for development and, if approved, commercial purposes ("Supply Agreement"). The Supply Agreement has an initial term of five years from the first delivery of supplied oral levosimendan with automatic three-year renewals unless either party provides 24 months' prior written notice of non-renewal. Either party may terminate the Supply Agreement for the other party's material breach, subject to a 60-day cure period, insolvency or in connection with a termination of the License. The Supply Agreement establishes forecasting, ordering, delivery, quality, pricing, and non-conforming product provisions and certain alternative manufacturing rights between Orion and the Company. The Supply Agreement also includes cost-sharing provisions with respect to scaling up Orion's manufacturing capabilities.

Litigation

The Company is subject to litigation in the normal course of business, none of which management believes will have a material adverse effect on the Company's consolidated financial statements.

NOTE 5. STOCKHOLDERS' EQUITY

Common Stock, Preferred Stock, and Warrants

Common Stock

The Company's Certificate of Incorporation, as amended, authorizes the issuance of 400,000,000 shares of $0.0001 par value common stock. As of June 30, 2026 and December 31, 2025, there were 31,949,785 and 9,314,130 shares of common stock issued and outstanding, respectively.

Preferred Stock

Under the Company's Certificate of Incorporation, as amended, 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. Of the potential 10,000,000 shares of preferred stock, 5,181,346 are designated as Series A Stock and 4,818,654 remain undesignated. As of June 30, 2026 and December 31, 2025, there were 210 shares of Series A Stock outstanding, convertible in the aggregate into one share of common stock.

Common Stock and Warrants

March 2025 Private Placement Financing (the "March 2025 Offering")

On March 4, 2025, the Company entered into a securities purchase agreement with certain accredited investors for the purchase and sale, in a private placement financing by the Company, of (i) an aggregate of 378,346 shares of its common stock, and pre-funded warrants to purchase an aggregate of 3,760,726 shares of common stock at an offering price of $6.04 per share of common stock and $6.03 per pre-funded warrant, resulting in gross proceeds of $25.0 million. The pre-funded warrants do not expire and have an exercise price of $0.01. The net proceeds of the March 2025 Offering, after deducting placement agent fees and direct offering expenses were $23.2 million. The relative fair value allocated to the common stock and pre-funded warrants was $2.3 million and $22.7 million, respectively.

Also, on March 5, 2025 and in connection with the March 2025 Offering, the Company entered into a registration rights agreement (the "March 2025 Registration Rights Agreement") with the purchasers, pursuant to which the Company agreed to register for resale the shares of common stock issued in the March 2025 Offering and the shares of common stock issuable upon exercise of the pre-funded warrants issued in the March 2025 Offering within 45 days of the closing date. Pursuant to the March 2025 Registration Rights Agreement, on April 15, 2025, the Company filed a resale registration statement on Form S-3 with the SEC, which went effective on April 23, 2025.

The March 2025 Registration Rights Agreement includes liquidated damages provisions that meet the definition of a registration payment arrangement that is within the scope of ASC 825-20. The Company determined at the initial issuance of the pre-funded warrants that it is not probable that a payment would be required as it has both the intent and ability to satisfy the March 2025 Registration Rights Agreement. Therefore, the Company did not record a liability at inception but will evaluate the contingency at each reporting period. As of June 30, 2026, no events had occurred that would change our initial assessment of this provision.

Pre-Funded Warrant Activity

The following table summarizes the Company's pre-funded warrant activity for the six months ended June 30, 2026:

	Prefunded Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2025	**33,102,778**	**$ 0.01**
Exercised (Shares Issued)	(13,241,197)	0.01
Forfeited*	(3,538)	0.01
Outstanding at June 30, 2026	**19,858,043**	**$ 0.01**

*Represents shares forfeited as a result of the cashless exercise of pre-funded warrants during the period.

Warrant Activity

The following table summarizes the Company's warrant activity for the six months ended June 30, 2026, not including pre-funded warrants:

	Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2025	**16,895,111**	**$ 5.66**
Exercised (Shares Issued)	(9,386,958)	4.66
Outstanding at June 30, 2026	**7,508,153**	**$ 6.91**

August 2024 Warrants

As part of the Company's private placement in August 2024 (the "2024 Offering"), the Company issued unregistered common warrants to purchase 16,666,666 shares of its common stock at an exercise price of $4.50 per share (the "August 2024 Warrants") and pre-funded warrants to purchase an aggregate of 31,882,671 shares of common stock. The August 2024 Warrants expire at the earlier of (i) 30 trading days following the date of the Company's initial public announcement of topline data from its Phase 3 LEVEL trial (the "Topline Data Announcement"), (ii) immediately upon the exercise of the pre-funded warrants if such exercise is prior to the Topline Data Announcement, provided that if the pre-funded warrant is not exercised in full, the warrant expires proportionally to the extent the pre-funded warrant is exercised, and (iii) August 8, 2029. At June 30, 2026, 7,267,749 of the August 2024 Warrants remained outstanding.

February 2024 Warrants

As part of the Company's registered public offering in February 2024, the Company issued registered warrants to purchase 3,200,000 shares of its common stock at an exercise price of $5.65 per share and contractual term of five years. At June 30, 2026, 223,880 of the February 2024 Warrants remained outstanding.

Stock-Based Compensation

Summary of Stock Option and Restricted Stock Unit (RSU) Activity

Stock Incentive Plans

In June 2022, the Company adopted the 2022 Stock Incentive Plan, as amended on June 7, 2024 and October 25, 2024, (the "2022 Plan"), with the outstanding shares available for future grants under prior plans, as well as outstanding awards under prior plans that subsequently expire, terminate or are surrendered or forfeited, generally being assumed by the 2022 Plan. Unexpired awards granted under certain prior plans may be subject to the terms of such prior plans.

Under the 2022 Plan, with the approval of the Board's Compensation Committee, the Company may grant stock options, stock appreciation rights, restricted stock, restricted stock units ("RSUs"), performance shares, performance units, cash-based awards or other stock-based awards. Stock options granted under the 2022 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 2022 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 one to four years.

A total of 435,121 shares remained available for issuance under the 2022 Plan as of June 30, 2026.

Transactions during the six months ended June 30, 2026 related to stock options granted to employees and directors under Company option plans were as follows:

	Shares	Weighted average exercise price per Share	Weighted average remaining contractual life (years)	Aggregate intrinsic value (in thousands)
Options outstanding as of December 31, 2025	6,616,432	$ 6.21	9.19	$ 41,382
Granted	1,286,000	13.27		
Exercised	(5,000)	5.94		
Forfeited/Expired	(2)	87,040.00		
Options outstanding as of June 30, 2026	7,897,430	$ 7.34	8.79	$ 58,597
Options exercisable at June 30, 2026	3,903,535	$ 5.17	8.46	$ 33,312

The Company estimated the fair value of stock options granted during the six months ended June 30, 2026 using the Black-Scholes option pricing model and the following range of assumptions:

	For the six months ended June 30, 2026
Risk-free interest rate	3.5% - 4.1%
Expected volatility	61.0% - 122.2%
Expected term (in years)	1.7 - 7.0
Expected dividend yield	-

The Company recorded compensation expense for stock options granted under Company stock incentive plans of $2.8 million and $5.6 million for the three and six months ended June 30, 2026, respectively, and $4.5 million and $8.5 million for the three and six months ended June 30, 2025, respectively.

As of June 30, 2026, there were unrecognized compensation costs of $23.9 million related to non-vested stock option awards that will be recognized on a straight-line basis over the weighted average remaining vesting period of 2.89 years.

Inducement Awards

Transactions during the six months ended June 30, 2026 related to inducement stock options and an inducement RSU award granted to new employees. The inducement awards were granted in accordance with the employment inducement award exemption provided by Nasdaq Listing Rule 5635(c)(4) and were therefore not granted pursuant to the 2022 Plan.

Inducement Stock Options

Inducement stock option activity during the six months ended June 30, 2026 was as follows:

	Shares	Weighted average exercise price per Share	Weighted average remaining contractual life (years)	Aggregate intrinsic value (in thousands)
Options outstanding as of December 31, 2025	250,314	$ 10.20	9.10	$ 1,435
Granted	1,107,500	12.22		
Options outstanding as of June 30, 2026	1,357,814	$ 11.85	9.65	$ 4,602
Options exercisable at June 30, 2026	62,686	$ 16.09	8.60	$ 503

The Company estimated the fair value of inducement stock options granted during the six months ended June 30, 2026 using the Black-Scholes option pricing model and the following range of assumptions:

	For the six months ended June 30, 2026
Risk-free interest rate	4.2% - 4.3%
Expected volatility	115.3% - 115.4%
Expected term (in years)	7.0
Expected dividend yield	-

Inducement stock option compensation expense totaled $0.5 million for each of the three and six months ended June 30, 2026, and $0.1 million and $0.2 million for the three and six months ended June 30, 2025, respectively.

As of June 30, 2026, there was $12.6 million of remaining unrecognized compensation expense related to inducement stock options that will be recognized on a straight-line basis over the weighted average remaining vesting period of 3.77 years.

Inducement Restricted Stock Units

The Company granted an inducement RSU award to a new employee for 10,000 shares of common stock on May 11, 2026. One quarter of the RSU award vested 10 days after issuance and the remainder will vest in three equal installments on the four-month, eight-month, and twelve-month anniversaries of issuance.

Inducement RSU compensation expense totaled $40,000 for the three and six months ended June 30, 2026. No RSU compensation expense was recorded in the corresponding periods of 2025. As of June 30, 2026, there was $0.1 million of remaining unrecognized compensation expense related to inducement RSUs that will be recognized on a straight-line basis through May 2027.

NOTE 6. SEGMENTS

Operating segments are identified as components of an entity about which separate discrete financial information is available for evaluation by the Chief Operating Decision Maker ("CODM"), or decision-making group, in making decisions on how to allocate resources and assess performance. The Company's CODM, the President and Chief Executive Officer, views the Company's operations as one operating segment, which is focused on identifying and developing therapeutics that address cardiovascular and pulmonary diseases with high unmet medical need, with an initial therapeutic focus on pulmonary hypertension. The Company does not have revenue in the current comparative period, incurs expenses primarily in the United States and manages the business activities on a consolidated basis.

The accounting policies of the cardiovascular and pulmonary therapeutics segment are the same as those described in the summary of significant accounting policies.

The CODM assesses performance for the cardiovascular and pulmonary therapeutics segment and decides how to allocate resources based on net loss that also is reported on the income statement as consolidated net loss. The measure of segment assets is reported on the balance sheet as cash and cash equivalents.

The Company has not generated any product revenue in the current period and expects to continue to incur significant expenses and operating losses for the foreseeable future as the Company advances its product candidates through all stages of development and clinical trials.

As such, the CODM uses cash forecast models in deciding how to invest into the cardiovascular and pulmonary therapeutics segment. Such cash forecast models are reviewed to assess the entity-wide operating results and performance. Net loss is used to monitor budget versus actual results. Monitoring budgeted versus actual results, net cash used in operating activities for the period and cash on hand are used in assessing performance of the segment.

The table below summarizes the significant expense categories regularly reviewed by the CODM for the three and six months ended June 30, 2026 and 2025 (in thousands).

	For the three months ended June 30,		For the six months ended June 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 12,850	$ 6,121	$ 24,389	$ 11,804
Selling, general and administrative	5,934	5,671	10,968	11,326
Total operating expenses	$ 18,784	$ 11,792	$ 35,357	$ 23,130
Net operating loss	(18,784)	(11,792)	(35,357)	(23,130)
Other segment items (a)				
Interest income	981	954	1,842	1,884
Other expense, net	-	(9)	(4)	(9)
Net loss (b)	$ (17,803)	$ (10,847)	$ (33,519)	$ (21,255)

(a) Other segment items included in segment loss includes interest income.

(b) The Company is a single operating segment and therefore the measure of segment net loss is the same as consolidated net loss and does not require reconciliation.

For the six months ended June 30, 2026 and 2025, the net cash used in operating activities was $23.5 million and $13.2 million, respectively. The table below summarizes the significant asset categories regularly reviewed by the CODM at June 30, 2026 and June 30, 2025 (in thousands).

	As of June 30,	
	2026	2025
Assets:		
Cash and cash equivalents	$ 117,976	$ 105,462

NOTE 7. SUBSEQUENT EVENTS

Subsequent to June 30, 2026, the Company received a total of $8.1 million from the exercise of 3,667,440 pre-funded warrants and 1,797,973 warrants for the issuance of shares of common stock.

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, 2025. All references in this Quarterly Report to "Tenax Therapeutics," "we," "our" and "us" means Tenax Therapeutics, Inc.

Cautionary Note Regarding 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

Tenax Therapeutics is a Phase 3, development-stage pharmaceutical company using clinical insights to develop novel cardiopulmonary therapies. We employ a clinician-driven drug development approach, led by key opinion leaders and pulmonary hypertension and heart failure experts and informed by their clinical insights to precisely target disease pathophysiology. We are currently actively conducting the LEVEL and LEVEL-2 clinical trials to evaluate levosimendan as our prioritized product candidate, and have deprioritized a Phase 3 clinical trial of imatinib, two drugs supported by promising evidence that they may significantly improve the lives of patients with pulmonary hypertension. Currently, we do not have any significant imatinib development activities ongoing. Importantly, both levosimendan and imatinib have already been approved in other indications and prescribed around the world starting more than 25 years ago, and we believe their mechanisms of action are uniquely suitable to target and treat pulmonary hypertension. We believe this derisked approach of using already-approved drugs that provide well-established safety profiles from millions of patients, combined with a development path led by preeminent cardiovascular and pulmonary hypertension experts, puts us in a strong position to deliver breakthrough cardiopulmonary therapies designed to improve patients' functioning and quality of life.

Recent Events

In March 2025 and August 2024, we completed two private placement financings raising gross proceeds, in the aggregate, of approximately $125 million. We intend to use the net proceeds from these financings, together with proceeds received from the subsequent exercise of warrants and pre-funded warrants sold in the March 2025 and August 2024 offerings, to advance our Phase 3 oral levosimendan program. Specifically, we plan to complete our ongoing Phase 3 LEVEL clinical trial of TNX-103 in PH-HFpEF and make public before the end of 2026 the results of the 12-week randomized treatment period. The open-label stage of the trial will continue after this. We also plan to continue our second, global, Phase 3 clinical trial, LEVEL-2, which began in December 2025. Following completion of the two Phase 3 levosimendan trials, we intend to submit marketing authorization applications.

Our Phase 3 LEVEL clinical trial continues, with high rates of clinical trial and therapy continuation during the blinded and open-label extension stages. We completed randomization in the LEVEL clinical trial of more than 230 patients before the end of the first quarter of 2026, and we expect to report initial topline data in August of 2026. LEVEL is being conducted in the United States and Canada. Our second Phase 3 clinical trial, LEVEL-2, is ongoing globally, with enrollment completion anticipated by the end of 2027.

Based on our current operating plan, we believe that our existing cash and cash equivalents as of June 30, 2026, along with cash received from warrant exercises subsequent to quarter end, will be sufficient to fund our planned operations through the second quarter of 2028.

Financial Overview – Three and Six Months Ended June 30, 2026 (in thousands)

	For the three months ended June 30,		Increase/ (Decrease)	% Increase/ (Decrease)	For the six months ended June 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2026	2025			2026	2025		
Operating expenses:								
Research and development	$ 12,850	$ 6,121	$ 6,729	110 %	$ 24,389	$ 11,804	$ 12,585	107 %
Selling, general and administrative	5,934	5,671	263	5 %	10,968	11,326	(358)	(3) %
Total operating expenses	$ 18,784	$ 11,792	$ 6,992	59 %	$ 35,357	$ 23,130	$ 12,227	53 %
Net operating loss	(18,784)	(11,792)	(6,992)	59 %	(35,357)	(23,130)	(12,227)	53 %
Other segment items								
Interest income	981	954	27	3 %	1,842	1,884	(42)	(2) %
Other expense, net	-	(9)	9	(100) %	(4)	(9)	5	(56) %
Net loss	$ (17,803)	$ (10,847)	$ (6,956)	64 %	$ (33,519)	$ (21,255)	$ (12,264)	58 %

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 a substantial portion of our pre-clinical and our clinical studies; (ii) the cost of supplying clinical trial materials; (iii) payments to CROs 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, and other supplies. All research and development expenses are expensed as incurred. Research and development expenses and percentage changes for the three and six months ended June 30, 2026 and 2025 are as follows (in thousands):

	For the three months ended June 30,		Increase/ (Decrease)	% Increase/ (Decrease)	For the six months ended June 30,		Increase/ (Decrease)	% Increase/ (Decrease)
	2026	2025			2026	2025		
Clinical and preclinical development	$ 11,004	$ 4,515	$ 6,489	144 %	$ 21,037	$ 8,788	$ 12,249	139 %
Salary and benefits	971	468	503	107 %	1,862	839	1,023	122 %
Stock-based compensation	674	982	(308)	(31) %	1,211	1,843	(632)	(34) %
Other costs	201	156	45	29 %	279	334	(55)	(16) %
Total research and development expense	$ 12,850	$ 6,121	6,729	110 %	$ 24,389	$ 11,804	12,585	107 %

Clinical and preclinical development costs increased $6.5 million and $12.2 million for the three and six months ended June 30, 2026, respectively, as compared to the same period in the prior year. Clinical and preclinical development costs for the three and six months ended June 30, 2026 consist primarily of expenses associated with our ongoing Phase 3 LEVEL trial and our second, larger, global, Phase 3 clinical trial, LEVEL-2, which began in December 2025, as compared to the three and six months ended June 30, 2025, which consisted primarily of costs associated with our Phase 3 LEVEL trial.

Salary and benefits costs increased by $0.5 million and $1.0 million for the three and six months ended June 30, 2026, respectively, as compared to the same period in the prior year primarily due to the hiring of additional development personnel resulting in higher salary and benefit costs.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of compensation for executive, commercial and administrative personnel, including non-cash stock-based compensation. Other selling, general and administrative expenses include facility costs not otherwise included in research and development expenses, legal and accounting services, and other professional and consulting services. Selling, general and administrative expenses and percentage changes for the three and six months ended June 30, 2026 and 2025 are as follows (in thousands):

	For the three months ended June 30,		Increase/	% Increase/	For the six months ended June 30,		Increase/	% Increase/
	2026	2025	(Decrease)	(Decrease)	2026	2025	(Decrease)	(Decrease)
Salary and benefits	$ 1,144	$ 673	$ 471	70 %	$ 1,983	$ 1,218	$ 765	63 %
Stock-based compensation	2,657	3,626	(969)	(27) %	4,957	6,907	(1,950)	(28) %
Legal and professional fees	1,612	1,050	562	54 %	2,978	2,309	669	29 %
Other costs	521	322	199	62 %	1,050	892	158	18 %
Total selling, general and administrative expense	$ 5,934	$ 5,671	263	5 %	$ 10,968	$ 11,326	(358)	(3) %

Salary and benefits increased $0.5 million and $0.8 million for the three and six months ended June 30, 2026, compared to the same period in 2025. The change was primarily attributable to increased personnel and their related compensation and benefits.

Non-cash stock-based compensation expense decreased $1.0 million and $1.9 million for the three and six months ended June 30, 2026, respectively, as compared to the same period in 2025 primarily due to stock options granted in December 2024, for which the expense was amortized over a one-year vesting term, which was partially offset by new option grants made in 2026.

Legal and professional fees consist of general legal costs, those related to our intellectual property, accounting fees, consulting fees and investor relations services, as well as fees paid to the members of our Board of Directors. Legal and professional fees increased $0.6 million and $0.7 million for the three and six months ended June 30, 2026, respectively, as compared to the same period in the prior year.

Other costs include expenses incurred for franchise and other taxes, travel, supplies, insurance, depreciation, and other miscellaneous charges. As we advance the development of levosimendan, our selling, general and administrative expenses have been increasing. We recently began to incur commercial costs, and with levosimendan continuing through Phase 3 development and progressing closer to commercial availability, we expect our selling, general and administrative expenses to increase in future periods.

Interest Income and Other Expense, net

Interest income and other expense was flat for the three and six months ended June 30, 2026, as compared to the same periods in the prior year.

Liquidity, Capital Resources and Plan of Operation

We have incurred losses since our inception and, as of June 30, 2026, we had an accumulated deficit of $401.0 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 additional expenses related to our development and potential commercialization of levosimendan and, potentially, imatinib for PAH, and other potential indications, as well as identifying and developing other potential product candidates, and as a result, we will need to generate significant product sales, royalty and other revenues to achieve profitability.

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, and have prioritized levosimendan. We will need substantial additional capital in the future in order to finalize the development of levosimendan, commence its commercialization, potentially reinitiate the development of imatinib, and to continue with the development of other potential product candidates.

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 $121.7 million and $104.2 million and working capital of $113.6 million and $97.1 million as of June 30, 2026 and December 31, 2025, respectively. Warrant exercises resulted in approximately $13.4 million and $43.8 million of cash for the Company in the three and six months ended June 30, 2026, respectively. There is the potential to raise an additional $34 million if all outstanding warrants from the August 2024 Offering and February 2024 Offering as of June 30, 2026 are exercised. Our practice is to invest excess cash, where available, in short-term money market investment instruments and high quality corporate and government bonds.

We completed randomization in the LEVEL trial at the end of the first quarter of 2026 and expect to report topline data in August 2026. We began our LEVEL-2 trial in December 2025 and are currently enrolling patients, with enrollment completion anticipated by the end of 2027. Our ability to continue to pursue development of our products beyond the second quarter of 2028, including completion of this second Phase 3 oral levosimendan trial (LEVEL-2), will depend on obtaining license income, income from warrants exercised by investors should they elect to do so, or other financial resources. There is no assurance that we will obtain any license agreement or other financing or that we will otherwise succeed in obtaining any necessary resources.

Financings

On March 5, 2025, we sold an aggregate of 378,346 shares of our common stock and pre-funded warrants to purchase an aggregate of 3,760,726 shares of our common stock at an offering price of $6.04 per share of common stock and $6.03 per pre-funded warrant, resulting in gross proceeds of $25.0 million. The pre-funded warrants do not expire and have an exercise price of $0.01. Net proceeds from the March 2025 Offering were $23.2 million, after deducting the placement agent fees and offering expenses payable by the Company.

On March 24, 2026, we filed a universal shelf registration statement on Form S-3 with the SEC, which the SEC declared effective on April 1, 2026. Pursuant to this registration statement, we have the ability to sell up to $300 million of any combination of our equity or debt securities in one or more public offerings, at prices and on terms that we will determine at the time of offering.

Cash Flows

The following table shows a summary of our cash flows for the periods indicated (in thousands):

	Six months ended June 30,	
	2026	**2025**
Net cash used in operating activities	$ (23,459)	$ (13,230)
Net cash provided by investing activities	-	-
Net cash provided by financing activities	43,870	23,841

Operating Activities

Net cash used in operating activities was $23.5 million for the six months ended June 30, 2026, compared to $13.2 million for the six months ended June 30, 2025. The increase in cash used in operating activities was primarily due to increased expenses as we expanded our clinical trials and increased payroll costs. The increase in payroll costs was primarily driven by the addition of new employees and targeted salary adjustments, reflecting a necessary investment to support our expanded clinical trial activity during the six months ended June 30, 2026 as compared to the prior year period.

Investing Activities

There was no net cash provided or consumed by investing activities for the six months ended June 30, 2026 or the six months ended June 30, 2025.

Financing Activities

Net cash provided by financing activities was $43.9 million for the six months ended June 30, 2026, compared to $23.8 million for the six months ended June 30, 2025, an increase of $20.0 million. During the six months ended June 30, 2026, the Company

received proceeds of $43.8 million from the exercise of warrants and pre-funded warrants. During the six months ended June 30, 2025, the Company received proceeds of $23.2 million net cash provided from the sale of common stock and pre-funded warrants in the March 2025 Offering and $0.6 million from the exercise of warrants and pre-funded 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, design, progress, timing and completion of clinical trials for our product candidates and potential product candidates;
- the outcome, timing and cost of regulatory approvals and the regulatory approval process;
- delays that may be caused by changing regulatory requirements and resource levels at regulators;
- the number of product candidates we pursue;
- the costs involved in filing and prosecuting patent applications and enforcing and defending patent claims;
- the timing and terms of future collaboration, licensing, consulting or other arrangements that we may enter into;
- the cost and timing of establishing sales, marketing, manufacturing and distribution capabilities;
- the cost of procuring clinical and commercial supplies of our product candidates;
- the extent to which we acquire or invest in businesses, products or technologies; and
- the possible costs of litigation.

Based on our working capital on June 30, 2026, and additional cash received subsequent to quarter end of $8.1 million, we believe we have sufficient capital on hand to fund operations through the second quarter of 2028.

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, 2025 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 (Principal Executive Officer) and our Chief Financial Officer (Principal Financial Officer and Principal Accounting 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 (Principal Executive Officer) and our Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer), concluded that our disclosure controls and procedures were effective as of June 30, 2026, 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 (Principal Executive Officer) and our Chief Financial Officer (Principal Financial Officer and Principal Accounting 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.

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, 2025.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

(a) During the three months ended June 30, 2026, we made certain unregistered stock option awards and an RSU award to new employees as an inducement material to each individual's acceptance of an offer of employment with us pursuant to the exemption from stockholder approval provided by Nasdaq Listing Rule 5635(c)(4). The vesting of each of the awards is subject to such employee's continued employment with the Company through the applicable vesting date. The exercise price for each option award is the closing price of the Company's common stock on the date of grant.

On May 11, 2026, the Company granted an inducement RSU award to an executive newly hired by the Company for 10,000 shares of common stock and an inducement stock option award of 450,000 shares of common stock. One quarter of the RSU award vested 10 days after issuance and the remainder will vest in three equal installments on the four-month, eight-month, and twelve-month anniversaries of issuance. One quarter of the option award will vest on the first anniversary of issuance with the remainder vesting in 36 approximately equal installments on the monthly anniversaries thereafter.

Additionally, between April 28, 2026 and June 1, 2026, the Company made four non-negotiated inducement stock option awards to non-executive individuals newly hired by the Company in various clinical operations, medical, product development, and commercial roles. The employees received, in the aggregate, stock option awards to purchase 657,500 shares of common stock. One quarter of each option award will vest on the first anniversary of issuance with the remainder vesting in 36 approximately equal installments on the monthly anniversaries thereafter.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. The sales of the above securities were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act as transactions by an issuer not involving any public offering. On May 12, 2026, we filed a registration statement on Form S-8 to register the shares of common stock underlying these inducement awards.

For additional information regarding the inducement awards, see Note 5 to our unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

(b) None.

(c) None.

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
10.1#	Executive Employment Agreement with Thomas R. Staab, II, dated April 9, 2026 (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the SEC on April 22, 2026).
10.2#	Amendment No. 1 to Employment Agreement, by and between Tenax Therapeutics, Inc. and Christopher Giordano (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the SEC on June 29, 2026).
10.3#	Amendment No. 1 to Employment Agreement, by and between Tenax Therapeutics, Inc. and Thomas Staab (incorporated by reference to Exhibit 10.2 to the Company's Form 8-K filed with the SEC on June 29, 2026).
10.4#	Amendment No. 3 to Employment Agreement, by and between Tenax Therapeutics, Inc. and Stuart Rich (incorporated by reference to Exhibit 10.3 to the Company's Form 8-K filed with the SEC on June 29, 2026).
10.5+	Sixth Amendment to the License Agreement, dated June 29,2026, between Tenax Therapeutics, Inc. and Orion Corporation (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the SEC on June 30, 2026).
10.6+Δ*	Supply Agreement, dated June 29, 2026, between Tenax Therapeutics, Inc. and Orion Corporation.
31.1*	Certification of President and Chief Executive Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer and Principal Accounting 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 Principal Financial Officer and Principal Accounting 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.

\+ Certain schedules, exhibits and similar attachments have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company agrees to furnish a copy of any omitted schedules to the SEC upon request.

Δ Certain confidential information has been redacted pursuant to Item 601(b)(10)(iv) of Regulation S-K by means of marking such portions with brackets because the information (i) is not material and (ii) would be competitively harmful if publicly disclosed. The Company agrees to furnish an unredacted copy of the exhibit and a copy of any omitted schedules to the SEC upon request.

\# Denotes a management contract.

* Filed herewith.

** Furnished herewith.

SIGNATURES

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

Date: July 31, 2026

TENAX THERAPEUTICS, INC.

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

By: /s/ Thomas R. Staab, II
Thomas R. Staab, II
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

CERTAIN INFORMATION IDENTIFIED WITH THE MARK "[***]" HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE SUCH INFORMATION IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED

SUPPLY AGREEMENT

This Supply Agreement (hereinafter the/this "**Agreement**")
has been made and executed as of this
29th day of June, 2026
(hereinafter the "**Effective Date**")

by and between

Orion Corporation
a company organised under the laws of Finland,
(Business Identity Code FI 19992126),
with its principal offices at Orionintie 1, 02200 Espoo, Finland,
(hereinafter "**Orion**")

and

Tenax Therapeutics, Inc.
a company organized under the laws of Delaware
Business Identity Code EIN number 26-2593535
with its principal offices at 101 Glen Lennox Drive, Suite 300, Chapel Hill, NC, 27517, USA

(hereinafter "**Licensee**")

(each referred to herein after as a "**Party**" and collectively as the "**Parties**")

WITNESSETH

WHEREAS, Orion Corporation and Phyxius Pharma, Inc. entered into that certain License Agreement dated September 20, 2013, as subsequently amended on October 9, 2020 (the "First Amendment"), January 25, 2022 (the "Second Amendment"), February 19, 2024 (the "Third Amendment"), October 2, 2024 (the "Fourth Amendment"), September 3, 2025 (the "Fifth Amendment"), and June 29, 2026 (the "Sixth Amendment"; that certain License Agreement, as amended by all of the foregoing, the "License Agreement"), and Tenax Therapeutics, Inc. is the successor in interest to Phyxius Pharma, Inc. under the License Agreement;

WHEREAS, among other things, the First Amendment added an orally administered levosimendan product (as defined in more detain therein, the "Oral Product") to the scope of the License Agreement and established a supply framework for the Oral Product, including Orion's right (but not obligation) to supply the Oral Product for commercialization (as defined in more detain therein, the "Supply Option") and pricing parameters for clinical and commercial supply;

WHEREAS, the Second Amendment, as relevant to the Oral Product, adjusted timing for the Phase III Study and confirmed the Supply Option construct, including notice requirements and Licensee's right to source the Oral Product from a third-party manufacturer if Orion elects not to supply or later terminates its supply, with technical transfer cost sharing as set forth therein;

WHEREAS, the Third Amendment further amended the License Agreement as it pertained to the Oral Product, including revising the Oral Product commercial transfer price cap applicable if Orion exercises the Supply Option, and amending the definition of Territory for the Oral Product;

WHEREAS, the Fourth Amendment and Fifth Amendment include additional changes relevant to the Oral Product, including matters relating to Oral Product branding and provisions related to the transfer and handling of certain types of data or information;

WHEREAS, the Sixth Amendment amended Section 16.1 of the License Agreement to amend certain termination rights and add certain cybersecurity requirements; and

WHEREAS, the Parties desire to enter into this Supply Agreement to set forth the terms and conditions governing Orion's manufacture and supply of the Oral Product and Placebo Products (as defined below) to Licensee as contemplated by, consistent with, and subject to, the License Agreement.

NOW, THEREFORE, Licensee and Orion, in consideration of the premises and of the mutual agreement, covenants and conditions hereinafter set forth, agree and covenant as follows:

1. DEFINITIONS

1.1. In this Agreement, the following capitalized words and expressions have the meanings set out below:

"Affiliate" means, with respect to either Party, any Person that directly or indirectly through one or more Affiliates controls, is controlled by or is under common control with such Party. For the purposes of this definition, 'control' means the ownership of greater than fifty percent (50%) of the shares or such other arrangement as constitutes the direct or indirect ability to direct the management, affairs or actions of such Person.

"Applicable Law" means all applicable laws and regulations of the Country of Manufacture, as well as current Good Manufacturing Practice ("cGMP"), which is hereby defined to mean the following regulations and published guidelines related to current good manufacturing practices that relate to the testing, manufacturing, processing, packaging, holding or distribution of drug or biologic drug substances and finished drugs or biologics: (a) the regulations set forth in 21 CFR 210 and 211 promulgated by the FDA; and (b) the EU good manufacturing practices set forth in the European Community directive 2003/94/EC and the respective EU GMP Guide, Directive 2001/83/EC.

"Approved Facility" means Orion's manufacturing facility/ies approved by competent authorities having jurisdiction thereover (which shall include but not be limited to the United States Food and Drug Administration, European Medicines Agency, or any successor agency to either of the foregoing) as an approved site of manufacture for the Supplied Products.

"Business Day" means a day (not being a Saturday or Sunday) on which banks are open for business in Finland and the State of North Carolina (USA).

"Certificate of Analysis" means a certificate supplied with delivered Supplied Product, which states details of the relevant Supplied Product batch(es) covered by the certificate and contains the agreed manufacturing data.

"Commercial Oral Product" means Oral Product to be sold for commercial human use in a country of the Territory following Regulatory Approval thereof for human use in such country.

"Confidential Information" means any and all information, documentation, know-how and data disclosed and/or made available under this Agreement by or on behalf of a Party to the other Party or any Affiliate thereof relating to any Supplied Product, the business affairs, trade secrets and/or other activities of such Party and/or its Affiliates, which may include but may not be limited to specifications, ideas, know-how, formulas, technology, practices, processes, methods of production, manufacturing processes documentation, manufacturing formulae, instructions, specifications, standards and analytical procedures, whether technical or non-technical, verbal or written, patented or patentable, as well as product samples and specifications.

"Costs of Industrialization of the Oral Product" means those documented direct costs and expenses described in the budget set forth on Schedule 3 (the "**Industrialization Budget**") and incurred by Orion or an Affiliate thereof following the Effective Date with respect to the activities, labor, equipment, machinery, materials and creating of documentation necessary for the Industrialization of the Oral Product.

"Country of Manufacture" means Finland.

"Development Oral Product" means Oral Product to be used in human clinical trials, other research or development activity, or for compassionate or charitable use in a country prior to Regulatory Approval thereof for human use in such country.

"Independent Improvements" means any and all inventions, improvements, modifications, adaptations, enhancements or new applications, techniques or processes conceived, derived, first reduced to practice, or developed by or on behalf of Orion in connection with the Manufacture of the Supplied Products hereunder or arising as a result thereof, the use and/or application of which in no way exploits or utilises any, and can be used independently of, Licensee's IPRs or Licensee's Confidential Information.

"Industrialization of the Oral Product" means building the capability of manufacturing commercial scale batches of Oral Product, consisting of Steps 1 and 2 as described in Schedule 3.

"**IV Product**" means the pharmaceutical product containing levosimendan as an active pharmaceutical ingredient and intended for human use or administration in a hospital or critical care setting (i.e., 2.5 mg/ml concentrate for solution for infusion/ 5ml vial)**.**

"Intellectual Property Rights" or **"IPRs"** means all inventions, patent applications, patents, registered or unregistered design rights, copyrights, database rights, trade marks, trade names, know-how and other industrial or intellectual property rights of whatever kind and all rights of a similar nature throughout the world.

"Manufacture" means the manufacture of the Supplied Products, and assurance and verification of product quality and compliance of the Supplied Products, as applicable to their respective Product Specifications (in accordance with the Quality Agreement), including but not limited to the quality control and quality assurance, packaging (if any) and storage and handling of the Supplied Products.

"Oral Product" means the orally administered pharmaceutical product in capsule formulation, containing levosimendan as an active pharmaceutical ingredient and having a strength of 1mg/capsule, the composition of which is described in Schedule 1, Part A (attached hereto).

"Placebo Oral Product" means a product which is by visual inspection identical with the Oral Product in terms of packaging and appearance but contains no active ingredients.

"**Placebo Product**" means the Placebo Oral Product.

"Product Specification" means the agreed specifications for each Supplied Product as set out in Schedule 1, Part B.

"Quality Agreement" means the agreement between Orion and Licensee which sets out the quality-related roles and responsibilities of each Party with respect to Manufacture of the Supplied Products, as may be amended from time to time in writing between the Parties.

"**Supplied Product**" means the Development Oral Product, Commercial Oral Product, or Placebo Product in their respective final sales or similar packages.

"Territory" means (as provided under the License Agreement with respect to the Oral Product) the entire world.

"Third Party" means any person or entity other than a Party or an Affiliate of a Party.

2. SCOPE OF THIS AGREEMENT

2.1. General. This Agreement governs Orion's manufacture and supply of the Supplied Products to Licensee for development and commercial purposes in the Territory, and sets forth, inter alia, the Parties' forecasting, ordering, delivery, quality, pricing, and non-conformance procedures and certain alternative manufacturing rights of Licensee and its Affiliates with respect thereto. For clarity, the License Agreement sets forth the terms and conditions under which Licensee is authorized to Develop and Commercialize the Supplied Products in the applicable Territory (including license grants, Field, Territory, exclusivity, economics, trademarks, and other commercialization matters).

2.2. Exercise of the Supply Option. Upon the execution of this Agreement, Orion exercises the Supply Option for the Oral Product and will be the primary supplier to Licensee of the Supplied Products for development and commercial purposes on the terms and conditions of this Agreement. Licensee shall be entitled to source from Third Parties and/or manufacture or have manufactured the Supplied Products, in each case as provided in this Agreement (and, where applicable, the License Agreement). For clarity, this Agreement establishes supply rights permitting Licensee to source Supplied Products from third parties to an extent defined or permitted in this Agreement; these rights do not, as set out in Section 2.3, amend the License Agreement's allocation of license grants, intellectual property ownership, Field, Territory, royalties, or trademarks.

2.3. Priority of Agreements. This Agreement is expressly subject to and subordinate to the License Agreement in the following manner: In the event of any conflict between this Agreement and the License Agreement, this Agreement controls with respect to Sections 7.8 and 8.9 as well as Exhibits D and E of the License

Agreement, in each case to the extent concerning Supplied Products. Except as expressly stated in the preceding sentence, the License Agreement controls in the event of any conflict, unless this Agreement expressly provides otherwise with respect to supply-related matters for Supplied Products or Licensee's rights to make or have made Supplied Products. Capitalized terms used but not defined herein have the meanings given in the License Agreement, and definitions established above or elsewhere in this Agreement apply solely for purposes of this Agreement.

2.4. IV Product. If Licensee notifies Orion that Licensee wishes to pursue the further Development or Commercialization of the IV Product, the Parties shall, in accordance with Sections 7.8 and/or 8.9 of the License Agreement, enter into a supply agreement concerning Orion's supply of the IV Product to Licensee. To facilitate the execution of such aforesaid supply agreement for the IV Product, the Parties shall initiate good faith negotiations on the terms for such supply agreement, and use reasonable efforts to execute such an agreement, without undue delay following Licensee's aforesaid notification to Orion.

3. INDUSTRIALIZATION OF THE ORAL PRODUCT

3.1. The Parties have agreed to share the Costs of the Industrialization of the Oral Product as set out below. For clarity, the Parties agree and confirm that the cost-sharing and reimbursement mechanisms detailed in this Section 3, [***], are separate from the Supply Price provisions of this Agreement. The Parties expressly acknowledge that this allocation of costs may result in a total effective price for the Commercial Oral Product that exceeds the Supply Price, and that this arrangement constitutes a permitted deviation from the supply terms set forth in the License Agreement as contemplated by Section 2.3 of this Agreement.

3.1.1. Orion shall begin performing Step 1 of the Industrialization of the Oral Product no later than the Effective Date and complete Step 1 of Industrialization of the Oral Product as soon as reasonably possible thereafter in accordance with any schedule or timeline therefor set forth on Schedule 3 hereto. Costs of the Industrialization of the Oral Product incurred in performing Step 1 thereof and incurred in accordance with the Industrialization Budget shall be [***].

3.1.2. Orion shall not begin performing Step 2 of the Industrialization of the Oral Product unless and until requested by Licensee in writing. Upon such request by Licensee, Orion shall begin performing Step 2 of the Industrialization of the Oral Product as soon as possible and complete Step 2 of Industrialization of the Oral Product as soon as reasonably possible thereafter in accordance with the schedule or timeline therefor set forth on Schedule 3 hereto, which shall, using reasonable efforts, be amended and clarified by the Parties, acting in good faith, once the Step 1 of the Industrialization of the Oral Product has been completed. Costs of the Industrialization of the Oral Product incurred in performing Step 2 thereof and in accordance with the Industrialization Budget (the "**Step 2 Costs of the Industrialization of the Oral Product**"), shall be shared as follows:

(a) [***]

(b) [***]

3.1.3. Licensee shall pay its share of the Step 2 Costs of the Industrialization of the Oral Product, as set forth in Section 3.1.2 above, to Orion as follows:

(a) [***]

(b) [***]

(c) [***]

3.1.4 Orion shall provide Licensee a detailed monthly report of the progress of the Industrialization of the Oral Product, any tasks accomplished with respect thereto since the previous such report, all Costs of Industrialization of the Oral Product incurred with respect to such tasks, and, with respect to any Step 2 Costs of the Industrialization of the Oral Product, a reconciliation of the amounts paid by Licensee with respect thereto under Section 3.1.3(a) and 3.1.3(b) as compared to the total Step 2 Costs of the Industrialization of the Oral Product through the date of such report.

4. SUPPLIED PRODUCT FORECASTING

4.1. Licensee shall by the [***] furnish Orion with a rolling [***] forecast concerning Licensee's requirements for Supplied Products to be ordered from Orion for the following [***]. Such rolling forecast shall be regarded as a good faith estimate of Licensee's requirements for Supplied Products, but shall not be deemed binding on Licensee, except that, of each such forecast submitted by the Licensee, [***], shall be binding upon Licensee. With respect to such binding portions, Licensee shall submit a Purchase Order to Orion for quantities of Supplied Products to be delivered during each calendar month that equal or exceed such percentage, as applicable.

4.2. Licensee shall by the end of the [***] during the Term furnish Orion with a nonbinding (except as set forth in Section 4.1 above) [***] forecast concerning Licensee's requirements for Commercial Oral Products.

5. MANUFACTURE AND SUPPLY OF THE SUPPLIED PRODUCT

5.1. Purchase Orders. Subject to Section 5.3, Orion shall Manufacture and supply to Licensee the amounts of each Supplied Product ordered by Licensee from time to time. Each order for Supplied Product by Licensee (hereinafter "Purchase Order") shall contain:

(a) the quantity of each Supplied Product being purchased; and

(b) the delivery date(s) for the Supplied Products (in compliance with the agreed delivery time period).

5.2. Approved Facility. The Supplied Products shall be Manufactured only at an Approved Facility. Orion shall not change the Approved Facility without the prior written consent of Licensee, such consent not to be unreasonably withheld, conditioned or delayed.

5.3. Supply Obligations. Notwithstanding any other provision of this Agreement, Orion shall only be obligated to Manufacture and supply quantities of each Supplied Product that correspond to the first [***] placed by Licensee in accordance with Section 4.1 of this Agreement (such first [***], the "**Fully-Binding Portion"** of a forecast). For the avoidance of doubt, Orion's firm supply obligation hereunder shall be [***].

With respect to any quantities of each Supplied Product ordered with respect to the Fully-Binding Portion of a forecast that exceed [***] of the amount set forth in such forecast therefor, Orion undertakes to use commercially reasonable efforts to Manufacture and supply such excess quantities; provided, however, that Orion does not guarantee supply of any such excess quantities and shall have no liability to Licensee for any failure to supply any such excess quantities. In the event Licensee anticipates a need, during the

Fully-Binding Portion of a forecast, for quantities of a Supplied Product from Orion in excess of the corresponding quantities set forth in such Fully-Binding Portion, Licensee shall provide Orion with as much advance notice as reasonably practicable, and the Parties shall cooperate in good faith to determine the feasibility of fulfilling such excess requirements.

5.4. Order Placement and Delivery Obligations. Orion shall Manufacture and supply Supplied Products only against Licensee's written firm orders and Orion shall confirm in writing each Licensee firm order for Supplied Products, and the time of delivery of such order, within [***] Business Days from the date of receipt of such order, provided that Orion shall not be required to confirm any such order for Supplied Product to the extent exceeding [***] of the applicable amount set forth in the applicable Fully-Binding Portion. Delivery of Supplied Products so ordered shall take place within [***] from the date of Orion's order confirmation. Firm orders shall be placed, and are only required to be fulfilled, in full batch sizes (or multiples thereof). The minimum packaging order size is [***].

5.5. Delivery Terms and Payment Conditions. The Supplied Products shall be delivered FCA Approved Facility, [***] (as per Incoterms 2020, made part of this Agreement by reference), unless the Parties agree in writing in connection with Product(s) order, and on a case by case basis, on delivery to another destination. Title to the Supplied Products shall transfer to Licensee upon delivery. Payment term is [***] from the date of Orion's invoice. Overdue amounts shall accrue interest at a rate corresponding to the interest rate on the main refinancing operations of the European Central Bank, increased [***]. Without limiting any other rights or remedies Orion may have by law or under this Agreement, Orion reserves the right to withhold delivery of the Supplied Products whether based on an accepted order of Licensee or not, in the event Licensee is in default of any of its undisputed payment obligations hereunder until such breach is fully cured.

5.6. Audits; Records.

5.6.1. Licensee shall during the term of this Agreement or thereafter for a maximum period of [***] from the termination or expiration of this Agreement, but not more often than [***] consecutive calendar years (or more often as requested by Licensee for cause), be entitled, upon reasonable advance notice and during normal business hours, to audit Orion's facilities used, or intended to be used, for the Manufacture, handling, and storage of the Supplied Products hereunder, and any records of Orion thereof related thereto, solely to verify compliance with this Agreement and accuracy of the calculation of any Costs of the Industrialization of the Oral Product.

5.6.2. Orion shall notify Licensee in writing as soon as reasonably possible (and in any event within [***]) of any inquiries, notifications, correspondence or inspection activity by, from, or with any governmental or regulatory authority directly related to Supplied Product, the manufacture, handling, storage, or shipment thereof under this Agreement, or Approved Facilities. Orion shall be responsible for handling and responding to any appropriate governmental agency inspections, requests, or inquiries applicable to manufacturers (and not regulatory approval holders or parties submitting regulatory filings with respect to a particular product or drug) with respect to its manufacturing of the Supplied Product, subject to any applicable terms of this Agreement (including but not limited to, any FDA Form 483 Establishment Inspection Reports, warning letters, or similar items). Orion shall, within [***] of receipt by Orion or any Affiliate thereof, provide to Licensee redacted copies and a reasonably detailed description of any (i) request, inquiry, or inspection made by, or correspondence from, any governmental or regulatory authority directly related to Supplied Product or its manufacture, shipping, handling, or storage, or Approved Facility involved with any

of the foregoing, and (ii) any response thereto or information provided in response with respect to the foregoing by Orion. Orion shall within [***] (i) advise Licensee of any requests by any governmental or regulatory authority for any inspections with respect to the manufacture, shipping, handling, or storage directly relating to Supplied Products, or with respect to Approved Facility involved with any of the foregoing, and (ii) provide Licensee with redacted copies of any correspondence related thereto. In the event any such authorities request information or data during an inspection of a manufacturing site of Orion thereof that are in the possession or control of Licensee, Licensee shall use commercially reasonable efforts to promptly provide such information or data to such governmental or regulatory authority or Orion.

5.6.3. Orion shall maintain accurate and complete records with respect to its costs, obligations and performance under this Agreement. All such records, including those relating to the manufacture, stability and quality control of all Supplied Products, shall be available for Licensee's audit, inspection and reproduction during normal business hours upon reasonable written request. All records described above shall be retained by Orion for the longer of (i) [***] or (ii) such period as is required by Applicable Law, provided that, prior to the destruction of any such record, written notice shall be provided to Licensee by Orion, and Licensee shall have the right to request and retain said record (and, in such event, Orion shall promptly provide such record to Licensee).

6. MATERIALS

6.1. Responsibility for Materials. Orion shall be responsible for procuring, at its sole cost and expense all necessary packaging and other materials (including active pharmaceutical ingredient) for the Supplied Products supplied hereunder (hereinafter "**Materials**"). Orion shall ensure that all Materials conform to the respective Material specifications (hereinafter referred to as "**Material Specification**") and shall allow no changes or deviations from the Material Specifications without the prior written consent of Licensee, such consent not to be unreasonably withheld or delayed.

6.2. Material Costs. For the avoidance of doubt, the Parties agree that the price for the Materials, and all costs and expenses incurred by the Orion in fulfilling its obligations under this Section 6, shall be deemed included in the Supply Price payable by Licensee for the Supplied Products. Licensee acknowledges that Orion will order Materials based upon the first [***] of Licensee's forecast referred to in Section 4, and agrees to reimburse Orion for the reasonable, documented direct costs (including destruction costs) incurred in connection with any Materials so ordered that comply with the applicable Material Specifications and are rendered obsolete or unusable due to Licensee's failure to order Supplied Products in accordance with the most recent forecast therefor, and not due to negligence, intentional misconduct, breach of this Agreement, or failure to comply with Applicable Law on Orion's or its Affiliate's part, despite Orion's reasonable efforts to use such Materials for other purposes in its and its Affiliates' businesses.

7. WARRANTIES; NONCONFORMITIES

7.1. Mutual Representations and Warranties. Each Party represents and warrants to the other that, as of the date hereof:

7.1.1. it is duly organized and validly existing under the laws of its jurisdiction of organization, and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof;

7.1.2. it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the person or persons executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate action;

7.1.3. this Agreement is legally binding upon it and enforceable in accordance with its terms. The execution, delivery and performance of this Agreement by it does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any law or regulation of any governmental authority having jurisdiction over it;

7.1.4. it is aware of no action, suit or inquiry or investigation instituted by any governmental agency or other Third Party that questions or threatens the validity of this Agreement; and

7.1.5. all necessary consents, approvals and authorizations of all governmental authorities and Third Parties required to be obtained by such Party to enter into this Agreement and to perform under and pursuant to this Agreement have been obtained (provided, however, that the foregoing shall not be construed as a representation or warranty concerning non-infringement of intellectual property rights of Third Parties).

7.2. Orion Warranties. Orion represents and warrants that:

7.2.1. (i) the manufacture and packaging of the Supplied Products under this Agreement will not infringe on or constitute misappropriation of any Third Party's intellectual property, provided however that the aforesaid representation and warranty is qualified by Orion's actual knowledge with respect to other countries and territories other than the Country of Manufacture, and (ii) any patents or other intellectual property rights that Orion or an Affiliate thereof owns or has in-licensed with respect to the manufacture of any Supplied Products are included, without breach of any agreement Orion may have with any Third Party, in the rights granted under Section 9.4;

7.2.2. on of the Effective Date, neither it nor any Affiliate thereof is the subject of any for-cause inquiries, notifications, or inspection activity by any governmental or regulatory authority with respect to the Approved Facility or the Supplier Products in any manner that would, or could reasonably be anticipated to, materially adversely affect Orion's performance of its obligations under, or compliance with, this Agreement; and

7.2.3. all amounts of the Supplied Products delivered and supplied to Licensee under this Agreement:

(a) shall have been Manufactured only in the Approved Facility in accordance with (i) the Quality Agreement and (ii) all Applicable Laws (including cGMP);

(b) shall, upon delivery, (i) comply with the applicable Product Specifications, (ii) not be adulterated within the meaning of the U.S. Food, Drug and Cosmetic Act or similar provisions under Applicable Law, and (iii) be free from any security interest, liens, or other encumbrances; and

(c) shall on the date of delivery have, at minimum, [***] of its validated shelf life remaining

(items (a), (b), and (c) collectively referred to as the "**Agreed Quality**").

Orion shall furnish Licensee with a Certificate of Analysis for each batch of Supplied Products delivered.

7.3 Disclaimers.

7.3.1 EXCEPT FOR THE EXPRESS WARRANTIES AND CONFIRMATIONS SET FORTH IN THIS SECTION 7, (I) ORION MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, WITH RESPECT TO ANY SUPPLIED PRODUCT UNDER THIS AGREEMENT, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE, NON-INFRINGEMENT, QUALITY, OR ACCURACY, AND, WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, (II) ORION DOES NOT WARRANT THAT THE SUPPLIED PRODUCTS WILL MEET LICENSEE'S REQUIREMENTS OR EXPECTATIONS, OR THAT THEIR MANUFACTURE, USE, SALE, OFFER FOR SALE, OR IMPORTATION WILL NOT INFRINGE THE PATENT RIGHTS OR OTHER INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY. LICENSEE ACKNOWLEDGES THAT IT HAS NOT RELIED UPON ANY REPRESENTATION OR WARRANTY MADE BY ORION, OR ANY OTHER PERSON ON ORION'S BEHALF, EXCEPT SUCH REPRESENTATIONS SPECIFICALLY PROVIDED IN THIS AGREEMENT OR THE LICENSE AGREEMENT. NOTWITHSTANDING THE FOREGOING DISCLAIMERS, NOTHING IN THIS SECTION SHALL LIMIT OR EXCLUDE ANY OTHER RIGHTS OR REMEDIES EXPRESSLY PROVIDED TO LICENSEE ELSEWHERE IN THIS AGREEMENT OR THE LICENSE AGREEMENT.

7.3.2 Licensee Disclaimer. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, LICENSEE DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT OF THE INTELLECTUAL PROPERTY OF ANY THIRD PARTY.

7.4. Defect Notification and Claim Review Process. Licensee shall notify Orion within [***] of the receipt by Licensee at its destination facility of any Supplied Product if Licensee finds out that any such Supplied Product delivered does not comply with the Agreed Quality, or, in the event of any such failure to comply is not readily ascertainable upon reasonable visual inspection, within [***] of Licensee becoming aware of such non-compliance. If Licensee fails to timely notify Orion as set out above, Licensee shall be deemed having accepted the Supplied Products concerned. Any claims by Licensee regarding any failure of the Supplied Products delivered to comply with the Agreed Quality shall specify the nature and basis for the claim and cite relevant Orion's batch control numbers or other information to enable specific identification of the Supplied Products involved. Orion agrees to review any such written claim made by Licensee regarding the Supplied Products and provide Licensee with the results of such review within [***] after Orion's receipt of such written claim.

7.5. Remedies for Non-Conforming Product. If the review and testing by Orion referred to in Section 7.4 confirms that a claimed quantity of Supplied Products did not as of the date of delivery meet the Agreed Quality, then Licensee shall have the right to reject such batch of non-conforming Supplied Products, and shall at Orion's expense dispose of or deliver such quantity involved to such destination as Orion shall direct in writing, provided that such directions are in compliance with applicable environmental laws and regulations, and Orion shall, as the Licensee's sole and exclusive remedy for such nonconformity (but in any event without limitation of Licensee's rights and Orion's obligations under Sections 10 and 18), at Licensee's option, either make a replacement delivery of corresponding conforming Supplied Products, free of charge, as soon as practicable or reimburse Licensee for any payments made for such non-conforming Supplied Products.

7.6. Independent Laboratory. If the Parties hereto fail to agree within a reasonable period of time as to whether a delivered quantity of Supplied Products complies with the Agreed Quality, then the Parties

may, subject to separate written agreement thereof (if any), have the batch in dispute tested and further analysed by an independent, neutral testing laboratory approved by both Parties, such approval not to be unreasonably withheld. Such separate written agreement shall expressly stipulate whether the laboratory's testing results shall or shall not be binding on the Parties or merely serve as an expert opinion, and, unless expressly otherwise agreed in writing, the cost thereof shall be borne to the Party not prevailing in such dispute.

7.7. Quality Agreement. The Parties shall enter into a separate Quality Agreement, such agreement to be compiled preferably to Orion's standard quality agreement template and entered into prior to the first delivery of Supplied Products under this Agreement. Such agreement shall be an integral part of this Agreement.

8. PRICE AND TERMS OF PAYMENT

8.1. Supply Price. Licensee shall pay to Orion for the Manufacture and supply of the Supplied Products the prices stipulated in Schedule 2 of this Agreement therefore (hereinafter, the "**Supply Price**" for each Supplied Product). For the sake of good order, the Parties acknowledge that the supply price for the Oral Product stated in the License Agreement has been for Oral Product in bulk form, and that the Parties have under this Agreement agreed that Orion shall supply the Supplied Products in final packages and the Supply Price has been agreed upon accordingly.

9. SUPPLY COMMITMENT; NON-SUPPLY EVENTS; CONTINGENT SOURCING RIGHT OF LICENSEE

9.1. Order Commitment. Licensee shall, except in the event of a Supply Failure, place Purchase Orders with Orion for at least the lesser of (x) [***] of its needs for each of the Development Oral Product, corresponding Placebo Product, and Commercial Oral Product in each calendar year or (y) in the case of Commercial Oral Product, such amount of each of Licensee's total needs of Commercial Oral Product that would reasonably enable Licensee, as reasonably determined in good faith thereby, to have manufactured by Licensee, an Affiliate, or a third party (i) [***] thereof for delivery during each [***] period prior to the [***] or the [***] (as defined in the License Agreement) of Commercial Oral Product, (ii) [***] of Commercial Oral Product for delivery during the [***] period following such [***], (iii) [***] of Commercial Oral Product during each [***] period thereafter, and (iv) any validation, registration, or similar batches thereof that, as reasonably determined in good faith by Licensee, are reasonably necessary or useful to enable such manufacture by Licensee, an Affiliate, or a third party and the use or sale of such Commercial Oral Product manufactured by Licensee, an Affiliate, or a third party. For purposes of this Section 9.1, a single (1) "batch" shall mean the then-current manufacturing batch size of the respective Supplied Product applied by Orion at the Approved Facility. Licensee's order commitment established under this Section 9.1 is hereinafter referred to as the "**Order Commitment**").

9.2. Supply Failure. If Orion fails to deliver at least [***] of the quantities of each of the Development Oral Product, Placebo Product, or Commercial Oral Product covered by confirmed purchase orders during any period of [***], then a "**Supply Failure**" will be deemed to have occurred. Upon the occurrence of a Supply Failure, Orion shall without undue delay provide Licensee with a written notification (a "**Supply Failure Notification**") that includes (A) a description of the circumstances leading to such Supply Failure and (B) Orion's good faith best estimate of the expected duration of such Supply Failure (the "**Estimated Supply Failure Duration**"). Orion shall keep Licensee informed regarding the status and expected duration of the Supply Failure by issuing updated Supply Failure Notifications to Licensee no less frequently [***] following the initial Supply Failure Notification, and more frequently if Orion deems it useful to do so.

Upon the occurrence of a Supply Failure, the application of Section 9.1 shall be suspended but, subject to the limitations set forth below in this Section 9.2, solely to the extent necessary to allow Licensee to source such quantities of the Supplied Products as are needed to cover Licensee's requirements for the applicable Supplied Products during a period equal to the Estimated Supply Failure Duration plus [***] (such quantities, "**Cover Quantities**"). For the avoidance of doubt, if Orion subsequently shortens the Estimated Supply Failure Duration as compared to the Estimated Supply Failure Duration set forth in the initial Supply Failure Notification, such shortening shall not reduce or otherwise affect the duration of Licensee's right to source Cover Quantities as determined based on the initial Estimated Supply Failure Duration. Licensee shall be entitled to source Cover Quantities from Third Party manufacturers or through its own or its Affiliates' manufacturing capabilities, and any orders placed by Licensee with a Third Party manufacturer in respect of Cover Quantities shall be permitted to be fulfilled notwithstanding any subsequent Supply Restoration. For any quantities of the Development Oral Product, Placebo Product, or Commercial Oral Product that Orion is capable to supply, Licensee's obligation set out in Section 9.1 (Order Commitment) shall apply. Notwithstanding the foregoing, during any Supply Failure, Licensee shall continue to provide Orion with rolling forecasts of its total requirements from Orion for Development Oral Product, corresponding Placebo Product, and Commercial Oral Product in accordance with the forecasting provisions of this Agreement to enable Orion to assess its readiness to remedy such Supply Failure.

9.3. Resumption of Order Commitment. After Orion having remedied a given Supply Failure and restored its ability to fully satisfy its supply obligations under this Agreement ("**Supply Restoration**"), Orion shall notify Licensee thereof in writing, by which notification Licensee's obligation to source the Supplied Products from Orion in accordance with Section 9.1 of this Agreement is, subject to Licensee's rights to purchase Cover Quantities as set forth in Section 9.2, restored.

9.4. Licensee's Alternative Sourcing Right. Licensee will have the right, upon written notice to Orion, to manufacture and/or have manufactured (by an Affiliate or through one or more Third Parties) in maximum such amounts of its needs for the Supplied Products that are not covered by Licensee's Order Commitment (under Section 9.1), or otherwise permitted by Section 9.2 in the event of a Supply Failure. Upon such notice, Orion hereby grants Licensee and its Affiliates a royalty-free, fully-paid license, with rights of sublicense solely to the applicable Affiliate or alternative Third Party manufacturer (however, such sublicense not being further sublicensable), and which license shall be transferable to a permitted assignee of this Agreement pursuant to Section 16.1, under all IPRs owned, licensed, or otherwise controlled by Orion or its Affiliates necessary or useful for the manufacture of Supplied Products, to make and have made Supplied Products; such right shall be valid during the term of this Agreement, and thereafter as set forth in Section 15 (Effects of Expiration or Termination).

9.5. Technical Transfer.

(a) *Proactive Technical Transfer*. Orion shall, upon any written request of Licensee, undertake and perform, in cooperation with Licensee as requested thereby, a technical transfer to Licensee, an Affiliate thereof, or any designated third-party manufacturer of Licensee of all relevant information, documentation, and materials in Orion's or its Affiliates' possession or control that is necessary or reasonably useful to enable the manufacture, testing, release, packaging, and supply of one or more Supplied Products, including CMC documentation, batch records, specifications, analytical methods, validation and stability data, lists of qualified suppliers and contract manufacturing organizations, and reasonable manufacturing know-how, which transfer shall include using reasonable efforts in addition to the transfer of such documentation to enable Licensee, its Affiliate, or such alternative manufacturer to manufacture the applicable Supplied Products in accordance with applicable

processes and applicable Product Specifications (the "**Technical Transfer**"), as set out in this Section 9.5. The purpose of the Technical Transfer is to enable Licensee or such other party(ies) to be capable of manufacturing the Supplied Products.

(b) *Technical Transfer Plan*. Orion shall perform such Technical Transfer upon request of Licensee pursuant to a separate technology transfer plan (the "**Tech Transfer Plan**"), which the Parties shall negotiate in good faith and execute as soon as reasonably feasible after the Effective Date, and which, once executed, shall constitute and be included in Schedule 5 attached hereto. The Tech Transfer Plan shall detail, among other things:

i. the scope, process, and procedures for the Technical Transfer;

ii. the timeline and milestones for completion of the Technical Transfer; and

iii. the roles and responsibilities of each Party and any possible third-party recipients.

The Parties shall use reasonable efforts to update the Tech Transfer Plan to include additional detail and/or process- or method-specific steps or information if and when any additional or altered methods/processes for the manufacture of Commercial Oral Product have been developed or established. The Tech Transfer Plan shall be subordinate to, and shall not conflict with, the terms and conditions of this Agreement and the License Agreement and in the event of any conflict or inconsistency between the Tech Transfer Plan and this Agreement or the License Agreement, the terms of this Agreement and the License Agreement shall prevail.

Notwithstanding the foregoing, due to the lack of a Tech Transfer Plan as of Effective Date, Orion shall, prior to the execution of the Tech Transfer Plan provide to Licensee certain documentation that would allow a Third Party manufacturer to plan and prepare for a Technical Transfer before a more detailed Tech Transfer Plan is agreed upon, which documentation will comprise of (A) a batch record of the current manufacturing processes for the Supplied Products, (B) a list of excipient suppliers and grades therefor, and (C) a description of Orion's planned process improvements for such manufacturing processes, it being expressly acknowledged that such aforesaid documentation will facilitate the initiation of the Technical Transfer but the Technical Transfer needs to be supported thereafter by the subsequent more detailed Tech Transfer Plan.

(c) *Costs and Expenses*. Notwithstanding any provision to the contrary in this Agreement or the License Agreement, [***]. With respect to any Technical Transfer, and without limiting the generality of the foregoing:

i. Licensee shall, for the Oral Product (and any corresponding Placebo Product), [***]; and

ii. Licensee shall be [***];

provided that, in the case of a Technical Transfer requested by Licensee in connection with or as a result of a Supply Failure or termination of this Agreement (in whole or in part) by Licensee for Orion's uncured material breach, Licensee shall not be responsible for any costs or expenses of any kind incurred by Orion with respect to such Technical Transfer. Orion shall provide Licensee with reasonably detailed invoices for reimbursable costs and expenses due under this subsection (c) on a [***], and Licensee shall pay such invoices within [***] of receipt.

(d) *Standard of Performance; No Guarantee*. Orion shall use commercially reasonable efforts to perform each Technical Transfer in accordance with the Tech Transfer Plan and this Agreement. Notwithstanding the foregoing, Licensee acknowledges and agrees that, provided such efforts are performed by Orion:

i. the successful implementation of the technology and manufacturing processes depends in part on the capabilities, facilities, and technical expertise of the receiving entity (whether Licensee, Its Affiliate, or Licensee's designated third-party manufacturer);

ii. Orion does not guarantee the successful implementation of the Technical Transfer or the ability of the receiving entity to manufacture the Supplied Products to applicable Product Specifications following completion of the Technical Transfer; and

iii. Orion shall have no liability to Licensee for any failure to achieve successful technology implementation, except to the extent such failure is directly caused by Orion's gross negligence, wilful misconduct, or breach of its obligations under this Section 9.5 or failure to perform the Tech Transfer Plan.

(e) *Cooperation*. The Parties shall cooperate in good faith throughout the Technical Transfer process. Licensee shall ensure that the receiving entity provides reasonable access, resources, and support as necessary to facilitate the Technical Transfer. Each Party shall designate a qualified representative to serve as the primary point of contact for matters relating to the Technical Transfer.

9.6. Confidentiality of Technical Transfer Materials; Third-Party Recipients. All documents, data, materials and information provided by or on behalf of Orion in connection with any Technical Transfer, regardless of form or medium and whether or not marked confidential, constitutes, subject to (and without limitation of) Section 13.3, Orion's Confidential Information under the License Agreement and this Agreement subject to the protections of Section 13 hereof. Licensee may disclose such Confidential Information only to its and its Affiliates' and contractors' personnel who have a need to know for the manufacture of Supplied Products (to the extent permitted herein) and who are bound by written obligations of confidentiality and non-use at least as substantially protective as those set forth herein. If the Technical Transfer is made to any third party designated by Licensee (each, a "**Third-Party Recipient**"), Licensee remains responsible and liable to Orion for all acts and omissions of any Third-Party Recipient and its personnel with respect to confidentiality and permitted use with respect to the applicable Confidential Information of Orion as if they were the acts and omissions of Licensee with respect thereto.

9.7. Protection for Technical Transfer Materials. The below obligations in this Section 9.7 are in addition to the general obligations of confidentiality and non-use set out in Section 13:

(a) *Scope of Restrictions*. All Technical Transfer materials, including without limitation manufacturing know-how, CMC documentation, batch records, specifications, analytical methods, validation and stability data, lists of qualified suppliers and CMOs, formulas, processes, techniques, and any other information or documentation, provided by Orion in connection with any Technical Transfer that constitute Confidential Information of Orion (collectively, "Technical Transfer Materials") constitute Orion's valuable trade secrets. Licensee acknowledges that the Technical Transfer Materials represent significant investment by Orion in research, development, and manufacturing expertise, and that any unauthorized disclosure or use may cause irreparable harm to Orion.

(b) *Strict Non-Use Obligation*. Licensee shall not, and shall ensure that its Affiliates and any third-party recipients do not, use any Technical Transfer Materials for any purpose other than the manufacture, testing, release, packaging, and supply of the Supplied Product in accordance with this Agreement and the License Agreement. Without limiting the generality of the foregoing, Licensee shall not use Technical Transfer Materials to (i) develop, manufacture, or commercialize any product other than the Supplied Product; (ii) reverse engineer, analyze, or deconstruct the manufacturing processes or formulations disclosed therein; (iii) seek patent protection or other intellectual property rights that are based on or derived from the Technical Transfer Materials; or (iv) provide services to any third party (other than a licensee or sublicensee of Licensee or an Affiliate thereof for purposes of the supply of Supplied Products by Tenax to such licensee or sublicensee to the extent permitted by this Agreement).

(c) *Restrictions on Third-Party Recipients*. Tenax may disclose Technical Transfer Materials to third parties solely to the extent permitted under this Agreement. Moreover, prior to any disclosure of Technical Transfer Materials to such permitted third-party recipient, Licensee shall ensure that such third-party recipient executes a written agreement containing confidentiality and non-use terms substantially as protective as those set forth herein and in Section 13 and which agreement shall expressly name Orion as a third party beneficiary with the right to enforce its terms directly against the third-party recipient; and provide Orion with a copy of such executed agreement upon request. The number of third-party recipients shall be limited to the minimum necessary to accomplish the permitted purpose.

(d) *Return or Destruction*. Upon any early termination (but not expiration) of the License Agreement, as well as upon the termination of Licensee's rights to Manufacture or have Manufactured the Supplied Products granted under this Agreement, Licensee shall, and shall cause its Affiliates and third-party recipients to, promptly (and in any event within [***]) return to Orion or destroy (at Orion's election) all Technical Transfer Materials in their possession or control, including all copies, summaries, and extracts thereof, and shall certify such return or destruction in writing to Orion. Notwithstanding the foregoing, (i) Licensee (and each Affiliate thereof and third-party recipient) may retain one (1) archival copy of Technical Transfer Materials solely for legal or regulatory compliance purposes and (ii) the obligations of this subsection (d) shall not apply to automatic electronic or digital backups, provided that each copy in (i) and (ii) remains subject to the confidentiality and non-use obligations herein.

(e) *Injunctive Relief*. Licensee acknowledges and agrees that any breach or threatened breach of the confidentiality and non-use obligations set forth in this Section 9.7and Section 13 may cause Orion irreparable harm for which monetary damages may be inadequate. Accordingly, Orion shall be entitled to seek injunctive or other equitable relief to prevent or restrain any such breach or threatened breach, without the necessity of proving actual damages or posting any bond or other security.

(f) *Survival*. The obligations set forth in this Section 9.7 shall survive in accordance with the survival provisions under Section 13.5, or for so long as the Technical Transfer Materials remain trade secrets under Applicable Law, whichever is longer.

9.8. For clarity, Licensee's rights contained in this Section 9 shall be Licensee's sole remedy in case of any Non-Supply Event.

10. INDEMNITY AND LIMITATION OF LIABILITY

10.1. Indemnification by Orion. Orion shall indemnify, defend and hold Licensee, its Affiliates, and its and their directors, officers, employees, agents, and other representatives (hereinafter "**Licensee Indemnitees**") harmless from and against any and all loss, damage, liability, costs and expenses claimed by a third party pursuant to any claims, demands, legal actions, suits, or proceedings, including but not limited to those for personal injury or death, against any of the Licensee Indemnitees (and including reasonable attorney's fees incurred by any Licensee Indemnitee with respect to such claim, demand, action, suit, or proceeding) arising out of (i) Orion's breach of the warranties under Section 7.2.1, Section 7.2.2 and Section 7.2.3 hereof, (ii) Orion's negligence, wilful misconduct or criminal wrongdoing with respect to the Manufacture of any Supplied Product or otherwise related to the subject matter of this Agreement, (iii) breach of this Agreement by Orion, or (iv) failure to comply with Applicable Law by Orion, provided that such obligation shall not apply to the extent any such third party claim, demand, action, suit, or proceeding results from the circumstances described in clause (i) or (iii) of Section 10.2.

10.2. Indemnification by Licensee. Licensee shall indemnify, defend and hold Orion, its Affiliates, and each of their respective directors, officers, employees, agents, and other representatives (hereinafter "**Orion Indemnitees**") harmless from and against all loss, damage, liability, costs and expenses claimed by a third party pursuant to any claims, demands, legal actions, suits, or proceedings, including but not limited to those for personal injury or death, against any of the Orion Indemnitees (and including reasonable attorney's fees incurred by any Orion Indemnitees with respect to such claim, demand, action, suit, or proceeding) arising out of (i) Licensee's negligence, wilful misconduct, or criminal wrongdoing with respect to any Supplied Product or subject matter of this Agreement, (ii) Licensee's, its Affiliates', its or their sublicensees, or any of the foregoing's third party contractors' use, sale, offer for sale, or import of any Supplied Product or the use thereof, or (iii) any breach of this Agreement by Licensee, provided that such obligation shall not apply to the extent any third party claim, demand, action, suit, or proceeding results from the circumstances described in clause (i), (ii), (iii), or (iv) of Section 10.1.

10.3. Indemnification Procedures. With respect to any indemnification obligation of either Party under this Section 10, the conditions to be met for such indemnification obligation to become applicable are as follows:

(a) If any third party shall notify a Party (the "**Indemnified Party**") with respect to any matter (a "**Third Party Claim**") which may give rise to a claim for indemnification against the other Party (the "**Indemnifying Party**") under this Agreement, then the Indemnified Party shall promptly notify the Indemnifying Party thereof in writing, provided that any failure to so notify the Indemnifying Party will not relieve it of its indemnification obligations except to the extent the failure or delay is prejudicial thereto.

(b) The Indemnifying Party shall have sole control of the defence of the Third Party Claim and all negotiations for its settlement or compromise (provided that any such settlement or compromise shall be subject to the consent of the Indemnified Party, such consent not to be unreasonably withheld, conditioned or delayed). Notwithstanding the foregoing, the Indemnifying Party shall be entitled to compromise or settle the Third Party Claim without the consent of the Indemnified Party if (i) there is no admission of fault, violation of law, or violation of the rights of any Third Party as part of such compromise or settlement and (ii) the sole relief provided in such compromise or settlement is monetary damages that are paid in full by the Indemnifying Party. For the avoidance of doubt, any settlement or compromise that imposes non-monetary relief on the Indemnified Party (including,

without limitation, injunctive relief, specific performance, conduct restrictions, product recalls or modifications, or other ongoing obligations) shall require the prior written consent of the Indemnified Party, which consent may be withheld in the Indemnified Party's sole discretion.

(c) No Indemnified Party with respect to a particular Third Party Claim subject to indemnification under this Section 10 shall enter into any compromise or settlement thereof without the applicable Indemnifying Party's prior written consent, such consent not to be unreasonably withheld.

(d) The Indemnified Party shall render reasonable assistance, information, cooperation and authority to permit the Indemnifying Party to defend the Third Party Claim; provided that the Indemnifying Party shall promptly reimburse all out-of-pocket expenses (including reasonable attorneys' fees and expenses) actually incurred by the Indemnified Party in connection therewith.

10.4. Limitation of Liability. SUBJECT TO AND WITHOUT PREJUDICE TO OR LIMITATION OF THE INDEMNIFICATION OBLIGATIONS OF EACH PARTY SET OUT ABOVE IN THIS SECTION 10, IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR ANY INDIRECT, PUNITIVE, INCIDENTAL, SPECIAL, EXEMPLARY, OR CONSEQUENTIAL DAMAGES, INCLUDING WITHOUT LIMITATION DAMAGE IN THE FORM OF LOST PROFITS, LOST BUSINESS, OR LOST GOODWILL, IN CONNECTION WITH THIS AGREEMENT OR ANY BREACH THEREOF. NOTWITHSTANDING THE FOREGOING, THE AFORESAID LIMITATION OF LIABILITY SHALL NOT APPLY TO ANY BREACHES OF THE CONFIDENTIALITY AND NON-USE OBLIGATIONS CONCERNING THE PARTIES' CONFIDENTIAL INFORMATION CONTAINED IN THIS AGREEMENT.

11. IMPROVEMENTS

11.1. Any Independent Improvements shall be the sole and exclusive property of Orion.

12. NO IMPLIED RIGHTS

12.1. Except as expressly set forth in this Agreement, nothing in this Agreement grants to Licensee any license, right or interest (whether by implication, estoppel, exhaustion or otherwise) under any patents, know-how, data, trademarks or other intellectual property of Orion, and all such rights are expressly reserved. Moreover, subject to Section 2.3, this Agreement does not amend, expand or otherwise affect the scope of rights granted under the License Agreement, including without limitation license grants, ownership and allocation of intellectual property and data, Field, Territory, exclusivity/competing product covenants, Development and Commercialization responsibilities, economics (including royalties and other payments), and trademark matters. Any use by Licensee or its Affiliates of Orion's IPRs or Confidential Information under this Agreement is limited to the rights explicitly set forth herein.

13. CONFIDENTIALITY

13.1. Each Party shall itself, and shall cause its Affiliates and its and their directors, officers, employees, agents, and other representatives (hereinafter "**Employees**"), to hold and treat all Confidential Information disclosed to it by or on behalf of the other Party in the strictest confidence and not, and cause its Employees not to, publish it or disclose it to any third party, nor use such Confidential Information, for any purposes other than the performance of its obligations or exercise of rights pursuant to this Agreement or the License Agreement, without the express prior written consent of the disclosing Party.

13.2. Each Party shall make available the other Party's Confidential Information only to those of its Employees, its Affiliates' Employees, and, in the case of Licensee, its and its Affiliates' contractors who need to know

that Confidential Information for the purpose of exercising rights or performing obligations granted or provided this Agreement or the License Agreement, provided that such Employees or other parties are bound to confidentiality and non-use obligations materially no less stringent that those included herein.

13.3. Notwithstanding anything to the contrary set forth herein, no information disclosed or otherwise made available under this Agreement shall constitute Confidential Information for the purposes hereof to the extent the same:

(a) is or becomes generally available to the public through no breach of this Agreement by the receiving Party or any of its Employees;

(b) was lawfully in the receiving Party's possession, without obligation of confidentiality, prior to the time of disclosure of the same information to the receiving Party by or on behalf of the disclosing Party;

(c) is obtained by the receiving Party, without obligation of confidentiality, from a Third Party lawfully entitled to possession of such information and under no obligation of confidentiality towards the disclosing Party or its Affiliates in respect of such information; or

(d) is or has been independently developed by or for the receiving Party without reference to, aid from or reliance upon Confidential Information obtained by the receiving Party from the disclosing Party under this Agreement.

13.4. In the event a receiving Party or its Employee is required under law or regulation or order of government or judicial authority to disclose all or any part of the disclosing Party's Confidential Information, such Party shall a) to the extent legally permissible, promptly and without undue delay notify the disclosing Party of the existence, terms and circumstances surrounding such requirement so that the disclosing Party may, at its sole discretion, seek a protective order, confidential treatment, or other appropriate relief or remedy or waive compliance with the terms hereof, b) reasonably cooperate with the disclosing Party, as reasonably requested thereby, in seeking such order, treatment, or relief, and c) if disclosure of such information is required, disclose such information only to the minimum extent so required to be disclosed. If and whenever any Confidential Information is disclosed in accordance with this Section 13.4, such disclosure shall not cause any such information to cease to be Confidential Information.

13.5. The obligations of confidentiality and non-use under this Section 13 shall survive the termination or expiration of this Agreement for whatsoever reason and shall continue in full force and effect for (i) [***], or (ii) [***], whichever is longer.

14. TERM AND TERMINATION

14.1. Term and Renewal. Subject to Sections 14.2, 14.3, and 14.4, this Agreement shall become effective on the Effective Date and continue in full force and effect for an initial period of five (5) years after from the first delivery of any Supplied Product from Orion to Licensee under this Agreement (hereinafter, the "Initial Period"). The Agreement shall thereafter be automatically renewed for successive three (3) year periods (each, a "Renewal Period"), unless notice of non-renewal is provided by either of the Parties in writing at least twenty-four (24) months before the end of the Initial Period or the then-current Renewal Period (as applicable), in which case, this Agreement shall expire upon the end of the Initial Period or then-current Renewal Period, as applicable.

14.2. Termination for Insolvency. This Agreement may be terminated immediately by either of the Parties upon written notice if the other Party becomes insolvent, is adjudged bankrupt, applies for judicial or extra-judicial settlement with its creditors, makes an assignment for the benefit of its creditors, voluntarily files for bankruptcy or has a receiver or trustee or the like in bankruptcy appointed by reason of its insolvency (who is not dismissed within sixty (60) days), or in the event an involuntary bankruptcy action is filed against the other Party and not dismissed within sixty (60) days, or if the other Party becomes the subject of liquidation or dissolution proceedings (which, if not initiated by such Party, are not dismissed within sixty (60) days), or otherwise discontinues business.

14.3. Termination for Breach. In the event a Party materially breaches any of the material terms or conditions of this Agreement (the "**Defaulting Party**"), the other Party (the "**Non-Defaulting Party**") may give written notice of such breach to the Defaulting Party, specifying the nature of the breach and requesting a cure. If the Defaulting Party fails to cure such breach within sixty (60) days of receipt of written notice from the Non-Defaulting Party, then the Non-Defaulting Party shall be entitled to terminate this Agreement upon written notice to the Defaulting Party, such termination to be effective upon the Defaulting Party's receipt of such notice.

14.4. Termination Triggered by License Agreement. If the License Agreement expires or is terminated for any reason, either Party may terminate this Agreement upon written notice to the other Party effective on the effective date of such expiration or termination of the License Agreement. Any termination under this Section 14.4 will be without prejudice to: (a) accrued and unpaid payment obligations; (b) the Parties' rights and obligations that are reasonable intended or anticipated (due to their nature) to, or expressly, survive such termination, to the extent consistent with the License Agreement.

15. EFFECTS OF EXPIRATION OR TERMINATION

15.1. Preservation of Accrued Rights. Termination of this Agreement, for whatever reason, shall be without prejudice to any rights, claims or obligations of either Party which may have accrued prior to the effective date of such termination.

15.2. Effects of Expiration.

(a) *Expiration Following Licensee's Notice*. If this Agreement expires as a result of Licensee providing a notice of non-renewal or termination in accordance with Section 14.1, then, upon such expiration, all rights granted to Licensee under this Agreement (except those expressly surviving expiration or termination pursuant to Section 15.5) shall immediately terminate, including any rights related to the Technical Transfer, contingent manufacturing rights, and sourcing rights for the Oral Product. Orion shall have no further obligations to Licensee under this Agreement, except for those obligations that expressly survive expiration or termination pursuant to Section 15.5 (Survival).

(b) *Expiration Following Orion's Notice*. If this Agreement expires as a result of Orion providing a notice of non-renewal or termination in accordance with Section 14.1, then, notwithstanding such expiration, Licensee shall continue to retain and may exercise its manufacturing and sourcing rights for the Supplied Products as set forth in this Agreement, including:

i. the right to receive and utilize the Technical Transfer in accordance with Section 9.55;

ii. the right to manufacture or have manufactured the Supplied Products using the transferred technology and know-how; and

iii. the right to source the Supplied Products from alternative manufacturers.

The foregoing rights, and the license granted under Section 9.4, shall continue in effect for so long as (X) the License Agreement remains in effect or (Y) Licensee's right and license under Section 16.6 of the License Agreement remain in effect; provided, however, that in the event Licensee breaches this Agreement in a manner that would allow Orion to terminate this Agreement on the basis of such breach if this Agreement had not expired, then Orion shall have the right at its sole discretion to revoke and terminate the foregoing rights and the license granted under Section 9.4 with immediate effect by notifying Licensee thereof in writing. .

15.3. Effects of Termination.

a) *Termination of this Agreement for Licensee's Breach or Insolvency*. If this Agreement is terminated by Orion pursuant to Section 14.2 (Termination for Insolvency) or Section 14.3 (Termination for Breach), all rights granted to Licensee under this Agreement shall immediately terminate, including any rights related to the Technical Transfer, manufacturing rights, and sourcing rights for the Supplied Products. Orion shall have no further obligations to Licensee under this Agreement, except for those obligations that expressly survive expiration or termination pursuant to Section 15.5 (Survival).

b) *Termination of this Agreement for Orion's Breach or Insolvency*. If this Agreement is terminated by Licensee pursuant to Section 14.2 or 14.3, Licensee shall continue to retain and may exercise its manufacturing and sourcing rights for the Supplied Products as set forth in this Agreement, including:

i. the right to receive and utilize the Technical Transfer in accordance with Section 9.5;

ii. the right to manufacture or have manufactured the Supplied Products using the transferred technology and know-how; and

iii. the right to source the Supplied Products from alternative manufacturers;

and such rights, and the license granted under Section 9.4, shall continue in effect for so long as (X) the License Agreement remains in effect or (Y) Licensee's right and license under Section 16.6 of the License Agreement remain in effect; provided, however, that in the event Licensee breaches this Agreement in a manner that would allow Orion to terminate this Agreement on the basis of such breach if this Agreement had not been terminated, then Orion shall have the right at its sole discretion to revoke and terminate the foregoing rights and the license granted under Section 9.4 with immediate effect by notifying Licensee thereof in writing.

c) *Termination of this Agreement for Termination or Expiration of License Agreement.* If this Agreement is terminated pursuant to Section 14.4 (Termination Triggered by License Agreement), such termination will be without prejudice to (i) any accrued and unpaid payment obligations; and (ii) the Parties' rights and obligations that are reasonable intended or anticipated (due to their nature) to, or expressly, survive such termination pursuant to Section 15.5 (Survival), to the extent

consistent with the License Agreement. Moreover, notwithstanding such aforesaid termination, Licensee shall continue to retain and may exercise its manufacturing and sourcing rights for Supplied Products as set forth in this Agreement, including (without limitation):

i. the right to receive and utilize a Technical Transfer in accordance with Section 9.5;

ii. the right of Licensee and its Affiliates to manufacture or have manufactured the Supplied Products using the transferred technology, know-how, and other IPRs; and

iii. the right to source the Supplied Products from alternative manufacturers;

However, notwithstanding the foregoing, the foregoing rights (which shall include the license granted under Section 9.4) shall continue in effect only to the extent and for so long as the rights granted to Licensee with respect to Supplied Products, as applicable under the License Agreement, remain in effect.

15.4 Return of Confidential Information. In the event of termination or expiration of this Agreement, each Party shall promptly return to the other, unless otherwise agreed, all of the other Party's Confidential Information received hereunder, except, in the case of Licensee, to the extent necessary or useful to exercise Licensee's rights or perform Licensee's obligations under this Agreement or the License Agreement following such expiration or termination. Such return shall be completed as soon as practicable after completing and delivering all outstanding orders of the Supplied Products.

15.5 Survival. Termination of this Agreement, for whatever reason, shall not affect this Section 15 and other clauses which by their nature should reasonably survive the termination or expiration of this Agreement, including but not limited to Sections 1, 2.3, 5.6, 6.1 (with respect to the second sentence thereof), 7.1-7.6, 8, 9.6, 9.7, 9.8, 10, 11, 12, 13, 15-18, 19, and 20-29, which shall continue in full force and effect in accordance with their terms after such termination.

15.6 Payment of Ordered Supplied Products. For clarity, the expiration or termination of this Agreement for any reason shall not relieve Licensee from its obligation to pay the Supply Price (and any other outstanding payments to Orion, if any) for all Supplied Products ordered by Licensee from Orion.

16. ASSIGNMENT

16.1. Neither this Agreement nor any right, obligation, commitment or liability hereunder may be assigned by either Party without the other Party's express written consent, such consent not to be unreasonably withheld, provided, however, that each Party may assign this Agreement to (i) to an Affiliate of such Party (provided, however, that such assigning Party and the Affiliate concerned shall thereafter be jointly and severally liable and responsible to the other Party for compliance with this Agreement by such Affiliate and for any breach hereof by any such Affiliate) or (ii) a Third Party to whom all or substantially all of its business or assets are transferred or assigned by means of sale, merger, divestiture or any bona fide restructuring of operations.

16.2. Orion may subcontract the Manufacture of the Supplied Products to a third party only with Licensee's prior written consent. Notwithstanding the above, Orion shall, upon prior notice thereof to Licensee, have the right to subcontract the Manufacture of the Supplied Products to its Affiliate, and use

subcontractors in the performance of ancillary obligations related to the Manufacture of Supplied Products, including activities related to analytics and quality assurance of Supplied Products, as applicable, provided that Orion shall remain responsible for all such Affiliates and Third Parties' compliance with this Agreement and performance of Orion's obligations hereunder.

16.3. Any attempted assignment in violation of this Section 16 shall be null and void. Subject to the terms of this Agreement, this Agreement will be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.

17. FORCE MAJEURE

17.1 Neither of the Parties to this Agreement shall have any liability whatsoever or be in default for any delays or failures in performance under this Agreement resulting from any occurrence of an event of Force Majeure. For purposes hereof, "**Force Majeure**" shall be deemed to be any future event or condition, which (i) is beyond the reasonable control, and without the fault, of the Party affected thereby, (ii) was not foreseeable by such Party at the time this Agreement was entered into, and (iii) the effect(s) of which the Party affected thereby could not have prevented, mitigated or overcome by reasonable measures. The occurrence or existence of any event of Force Majeure shall be promptly notified by the affected Party to the other. The affected Party shall use all reasonable endeavours to remove, as quickly as possible, the effect of said event of Force Majeure.

18. PRODUCT RECALL

18.1 Notice of Recall. Each Party shall promptly notify the other Party in writing of any facts reasonably relating to the advisability of the recall, withholding or withdrawal from the market, or field correction of any Supplied Product(s) (hereinafter, a "**Recall**").

18.2 Performance and Costs of Recall. Licensee shall have full discretion and control over whether to execute any Recall and any actions to be taken with respect thereto. Orion shall cooperate with Licensee as reasonably requested thereby in performing any such Recall, which cooperation will be at Licensee's expense except as set forth below. Orion shall bear the direct out-of-pocket costs and expenses of any Recall, including replacement of any Supplied Product subject to such Recall, any such costs and expenses of Licensee or any Affiliate thereof with respect thereto, and the costs and expenses of any cooperation rendered by Orion with respect thereto, if and only to the extent such Recall is the result of any breach by Orion of this Agreement or negligence or misconduct or Orion or any Affiliate or Third Party subcontractor thereof (and Orion shall pay any such costs and expenses invoiced thereto by Licensee within sixty (60) days of receipt of such invoice). Licensee shall bear all costs and expenses of any Recall in all other circumstances.

19. COMPLIANCE WITH LAW AND GOOD BUSINESS PRACTICE, PROCESSING OF PERSONAL DATA

19.1 Ethical Business Practices and Anti-Corruption Compliance. At all times during the term of this Agreement, each Party agrees to comply with all applicable laws, rules and regulations. Without limiting the generality of the foregoing, each Party shall comply with the anti-corruption laws of the United Kingdom (i.e. the Bribery Act 2010) and the country/ies in which such Party is located or is operating. In addition, the Licensee undertakes to comply with Orion's Third Party Code of Conduct appended hereto as Schedule 4.

19.2 Compliance with Data Protection Laws. In the performance of the pharmacovigilance and other activities under this Agreement, both Parties shall comply with their respective obligations under all currently applicable laws and regulations relating to protection of personal data, including without limitation, to the extent applicable, Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 (General Data Protection Regulation), as amended from time to time, and/or any subsequent European Union and its Member States' legislation in relation to the protection of personal data.

i. Personal Data. For the purposes of this Agreement "personal data" shall mean information that the Parties process and/or control based on this Agreement that can be used by itself or in combination with other available information to identify a specific individual, as defined in detail under applicable European Union data protection legislation.

ii. Both Parties shall implement all reasonable physical, technical and administrative safeguards appropriate to the nature of the information to prevent any use or disclosure of personal data other than as provided for by this Agreement. Both Parties will also take reasonable precautions to protect the personal data from alteration or destruction.

iii. Each Party shall notify the other Party promptly after discovery of any accidental, unauthorized, or unlawful destruction, loss, alteration, or disclosure of, or access to, the personal data ("**Personal Data Breach**"), and shall take immediate steps to rectify any Personal Data Breach.

iv. To the extent either Party transfers Personal Data subject to Regulation (EU) 2016/679 (the "**GDPR**") from the European Economic Area (or a country recognized by the European Commission as ensuring an adequate level of protection under GDPR Article 45) to a recipient in a country that does not benefit from an adequacy decision, the Parties will rely on appropriate safeguards under GDPR Article 46, including the European Commission's Standard Contractual Clauses adopted by Commission Implementing Decision (EU) 2021/914 of 4 June 2021, as amended or replaced from time to time (the "**EU SCCs**"). If the European Commission issues updated or successor standard contractual clauses, or if a supervisory authority or court requires modifications to the Parties' transfer mechanism(s), the Parties will promptly take all steps reasonably necessary to replace or amend the EU SCCs to maintain a valid transfer mechanism under GDPR Article 46 (as amended or replaced).

20. WAIVER

20.1 The failure by either Party at any time to enforce any of the terms, provisions or conditions of this Agreement or to exercise any right hereunder shall not constitute or be construed to constitute a waiver of the same or affect that Party's rights thereafter to enforce or exercise the same. No waiver of any term, provision or condition of this Agreement shall be effective unless it is in writing and signed by a duly authorised person on behalf of the waiving Party.

21. SEVERABILITY

21.1 In case one or more of the provisions contained in this Agreement shall, for any reason, be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provision of this Agreement, but this Agreement shall be construed by limiting such invalid, illegal or unenforceable provision, or if such is not possible, by deleting such invalid, illegal or unenforceable provision from this Agreement; provided that should this Agreement as a result of any such deleting not any more reasonably correspond to the good faith intent of the Parties, either Party may propose to the

other Party amendments also to the other provisions of this Agreement in order to have the Agreement correspond to such good faith intent and negotiate in good faith on such amendment(s).

22. ENTIRE AGREEMENT

22.1 Entire Agreement. This Agreement, together with the attached Schedules, represents the entire agreement between the Parties relating to the subject matter hereof and supersedes except as otherwise expressly reserved, excluded or modified herein, all prior arrangements, understandings, correspondence, notes, minutes and agreements between the Parties whether written or oral.

22.2 Amendments. No supplement, modification or amendment of this Agreement shall be binding unless executed by the Parties in writing and signed by the duly authorized representatives of both Parties hereto.

23. INDEPENDENT CONTRACTORS

23.1 The status of Licensee and Orion under the business arrangement established by this Agreement is that of independent contractors. It is expressly agreed that for tax, legal or other purposes (i) this Agreement or any portion of this Agreement shall not be considered to be a partnership agreement, and (ii) the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither Party has any authority whatsoever to act as an agent or representative of the other, nor has either any authority or power to contract for, or create or assume any obligation or liability in the other's name or on behalf of the other or otherwise bind the other in any way for any purpose, nor shall either Party hereto represent to any third parties it possesses any such authority to bind the other Party.

24. NOTICES

24.1 Notices provided hereunder to be given by either Party to the other shall be in writing and shall be delivered by recognized overnight delivery service or sent by government mail service (certified or registered air mail) to the following respective addresses or to such other addresses as the Parties may hereafter communicate to each other in writing:

If to Orion:

[***]

If to Licensee:

[***]

With a copy (which shall not constitute notice) to:

[***]

24.2 The notices shall be deemed to have been received as follows: (a) when delivered by hand (with written confirmation of receipt) or (b) received by the addressee, if sent by an internationally recognized overnight or two-day delivery service (confirmation receipt requested), in each case, to the appropriate addresses set forth above (or to such other addresses as a Party may designate by notice).

24.3 Nothing contained herein shall justify or excuse failure to give oral notice for the purpose of informing the other Party hereto when prompt notification is required, but, it is understood that such oral notice shall in no way satisfy the requirement of a written notice.

25 GOVERNING LAW AND DISPUTE RESOLUTION

25.1 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of Sweden, without giving effect to its conflict of laws provisions. It is specifically agreed that the United Nations Convention on Contracts for the International Sale of Goods is not applicable to this Agreement.

25.2 Dispute Resolution. Any dispute, controversy or claim arising out of or in connection with this Agreement, including the breach, termination or invalidity thereof, shall be finally settled by arbitration in accordance with the Arbitration Rules of the Arbitration Institute of the Stockholm Chamber of Commerce. The arbitral tribunal shall be composed of three (3) arbitrators appointed in accordance with the said rules. The seat of arbitration shall be London, England, and the language to be used in the arbitral proceedings shall be English.

26 PUBLICITY

26.1 Unless agreed upon in writing beforehand by the Parties, neither Party shall discuss with any third party or originate any publicity, news release or other public announcement, written or oral, whether to the public press, stockholders or otherwise, regarding the content or terms of this Agreement, or any amendment hereto, except for such announcement as based on the advice of legal counsel to the Party making such announcement is required under applicable law, regulation, or stock exchange regulations, in which event such Party shall (i) give the other Party an opportunity reasonable under the circumstances to review the form and content of the announcement before such legally required disclosure is made and (ii) use reasonable efforts to seek protective or confidential treatment of the terms hereof if and as reasonably requested by the other Party.

27 SCHEDULES

27.1 The following Schedules are attached to this Agreement:

Schedule 1, Part A Description of the Oral Product

Schedule 1, Part B Product Specifications

Schedule 2. Supply Price

Schedule 3. Description of the Industrialization of the Oral Product

Schedule 4. Orion’s Third Party Code of Conduct

Schedule 5. Tech Transfer Plan

The Schedules constitute an integral part of this Agreement. In case of discrepancies between the Agreement and a Schedule, the provisions of the Agreement shall prevail.

28 HEADINGS

28.1 The headings in this Agreement are inserted for the convenience of the Parties only and may not be used in the interpretation of any provisions hereof.

29 COUNTERPARTS

29.1 This Agreement may be executed in any number of counterparts and by the Parties to it on separate counterparts, each of which when so executed and delivered shall be an original, but all the counterparts shall together constitute one and the same instrument. Execution and delivery of this Agreement may be effected by electronic means, including by electronic signature (such as via DocuSign or similar electronic signature technology), and any such electronic signature shall be deemed an original signature and shall have the same legal validity and enforceability as a manually executed signature.

****Balance of page left blank. Signature page follows.****

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed in duplicate by their duly authorised representatives.

Orion Corporation

By: /s/ Ms. Satu Ahomäki

Name: Ms. Satu Ahomäki

Title: Executive Vice President

By: /s/ p.p. Patrik Kass

Name: p.p. Patrik Kass

Title: Vice President

Tenax Therapeutics, Inc.

By: /s/ Chris Giordano

Name: Chris Giordano

Title: President and CEO

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: July 31, 2026

/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, Thomas R. Staab, II, 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: July 31, 2026

/s/ Thomas R. Staab, II
Thomas R. Staab, II
Chief Financial Officer
(Principal Financial Officer and Principal 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 June 30, 2026 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: July 31, 2026

/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 June 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Thomas R. Staab, II, Chief Financial Officer (Principal Financial Officer and Principal 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: July 31, 2026

/s/ Thomas R. Staab, II
Thomas R. Staab, II
Chief Financial Officer
(*Principal Financial Officer and Principal 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.