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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 3, 2025

Tenax Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-34600**	**26-2593535**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

101 Glen Lennox Drive, Suite 300
Chapel Hill, NC 27517
(Address of principal executive offices) (Zip Code)

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

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR 230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR 240.12b-2).

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. ☐

Item 1.01 Entry into a Material Definitive Agreement.

On September 3, 2025, Tenax Therapeutics, Inc. (the "Company") and Orion Corporation ("Orion") entered into an amendment (the "Amendment") to that certain License Agreement between the Company and Orion dated as of September 20, 2013, as previously amended on October 9, 2020, January 25, 2022, February 19, 2024, and October 2, 2024 (the "Agreement"). Under the Amendment, the Company's licenses from Orion have been expanded to include 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 or commercialize subcutaneously administered products containing levosimendan, to manufacture or have manufactured such products. The Amendment also calls for Orion to supply the Company with levosimendan to the extent reasonably necessary or useful to manufacture orally-administered products containing levosimendan for purposes of developing such products, and sets forth the terms for such supply, including the price of levosimendan ordered by the Company of low triple-digit thousands in Euros per kilogram, payment terms, and active pharmaceutical ingredient specifications.

The foregoing summary of the material terms of the Amendment is subject to the full and complete terms of the Amendment, a copy of which is attached to this Current Report on Form 8-K as Exhibit 10.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
10.1*	Amendment to the License Agreement of September 20, 2013 by and between Tenax Therapeutics, Inc. and Orion Corporation, dated as of September 3, 2025.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

*Portions of this Exhibit have been omitted pursuant to Items 601(b)(10)(iv) of Regulation S-K. The Company agrees to furnish supplementally an unredacted copy of this Exhibit to the Securities and Exchange Commission upon request.

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 hereunto duly authorized.

Date: September 9, 2025

Tenax Therapeutics, Inc.

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

CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL. SUCH EXCLUDED INFORMATION HAS BEEN MARKED WITH "[***]."

FIFTH AMENDMENT
TO THE LICENSE AGREEMENT OF SEPTEMBER 20, 2013

This Fifth Amendment to the License Agreement of September 20, 2013 (hereinafter referred to as the "Amendment") is made and executed as of this 3rd day of September, 2025 ("Effective Date of Amendment") by and between:

Orion Corporation, Business Identity Code 1999212-6, a company registered under the laws of Finland and having its principal office at Orionintie 1, 02200 Espoo, Finland (hereinafter referred to as "Orion"); and

Tenax Therapeutics, Inc., a company incorporated under the laws of the State of Delaware, and having its principal office at 101 Glen Lennox Drive, Suite 300, Chapel Hill, NC 27517, USA (hereinafter referred to as "Licensee").

Orion and Licensee are collectively referred to herein as the "Parties" and each individually as a "Party".

WHEREAS, this Amendment pertains to that certain agreement entitled "License Agreement" between the Parties, dated September 20, 2013, as amended October 9, 2020 (such amendment, the "First Amendment"), January 25, 2022 (such amendment, the "Second Amendment"), February 19, 2024 (such amendment, the "Third Amendment"), and October 2, 2024 (such amendment, the "Fourth Amendment"), and subject to that certain letter executed by the Parties August 6, 2024 (the "Side Letter"; the License Agreement, as amended by the First Amendment, Second Amendment, Third Amendment, and Fourth Amendment, and subject to the Side Letter, hereinafter, the "Agreement"); and

WHEREAS, the Parties now wish, for mutual convenience, to amend the Agreement by, inter alia, clarifying the definition of Modified Oral Product and granting manufacturing rights to Licensee with respect to the Modified Oral Products and the Subcutaneously Administered Product.

NOW, THEREFORE, the Parties, in consideration of the premises and of the mutual agreement, covenants and conditions hereinafter set forth, hereby agree and convene as follows:

1 TERMS USED IN THIS AMENDMENT

1.1 Unless otherwise explicitly agreed herein, all capitalized terms used herein shall have the same meaning as given to them under the Agreement.

2 AMENDMENTS TO THE AGREEMENT

2.1 The definition of "Initial Product" shall be established and added to the Agreement, and shall read as follows:

> "Initial 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).

2.2 The definition of "Modified Oral Product" of the Agreement, established by the First Amendment, shall be replaced with the following:

> "Modified Oral Product" means any orally-administered pharmaceutical product, other than the Oral Product, containing Levosimendan as an active pharmaceutical ingredient (alone or in combination with any other active pharmaceutical ingredient(s)).

2.3 Section 1.39. ("Product Trademark") of the Agreement shall be replaced with the following:

> 1.39. "Product Trademark" means (i) solely with respect to the Oral Product, the Modified Oral Product and the Subcutaneously Administered Product, any trademark other than Simdax® selected by Licensee, to be registered and owned by Licensee (or its Affiliate or sublicensee) to be used for the Oral Product, the Modified Oral Product or the Subcutaneously Administered Product (as applicable) in the Territory or (ii) with respect to the Initial Product, Simdax® or any other trademark selected by the Parties, registered or registerable and owned by Orion to be used for such Initial Product in the Territory.

2.4 Section 2.1. (Development and Commercialization Licenses) of the Agreement shall be replaced with the following:

> 2.1. Development and Commercialization Licenses. Subject to the terms and conditions of this Agreement, Orion hereby grants to Licensee under the Orion Patent Rights and Orion Proprietary Information during the Term (and thereafter, subject to the terms and conditions of this Agreement):
>
> (a) an exclusive right and license, with the right to grant sublicenses subject to Section 2.2, to conduct Development in support of obtaining Regulatory Approval for the Product in the Field in the Territory;
>
> (b) an exclusive right and license, with the right to grant sublicenses subject to Section 2.2, to Commercialize the Product in the Field in the Territory;
>
> (c) an exclusive right and license, with the right to grant sublicenses subject to Section 2.2, to manufacture or have manufactured Modified Oral Products and the Subcutaneously Administered Product (or Levosimendan for the manufacture of either of the foregoing) for

purposes of exercising the rights in clauses (a) and (b) above; and

(d) an exclusive right and license, with the right to grant sublicenses subject to Section 2.2, to import Products for purposes of exercising the rights above.

2.5 Section 2.3. (License to the Product Trademark) of the Agreement shall be replaced with the following:

2.3. License to the Product Trademark. The Product shall be Commercialized in the Territory under the Product Trademark. Subject to and in accordance with the terms and conditions of this Agreement, during the Term, Orion hereby grants to Licensee an exclusive license, with the right to sublicense subject to Section 2.2, to use and display the Product Trademark in the Territory solely in connection with the performance by Licensee of its Development and Commercialization obligations with respect to the Initial Product in the Territory. Licensee acknowledges that nothing in this Agreement shall give it any right, title or interest in or to the Product Trademark for the Initial Product other than the limited license granted herein for the duration of the Term.

2.6 Section 2.4. (Retention of Rights) of the Agreement shall be replaced with the following:

2.4. Retention of Rights. All rights not specifically granted to Licensee under this Agreement are expressly reserved and retained by Orion. Without limiting the generality of any of the foregoing, it is expressly understood and agreed that (i) Orion retains all rights under the Orion Patent Rights and Orion Proprietary Information outside the Territory; and (ii) except as set forth in clause (c) of Section 2.1, the grant of rights to Licensee under this Agreement excludes any rights whatsoever for Licensee to manufacture or have manufactured the Product.

2.7 Section 7.6. (Grant Back of Licensee's IPR) of the Agreement shall be replaced with the following:

The Parties acknowledges that as a result of this Agreement, Licensee may generate or have generated clinical trial data relating to the Product ("Licensee Clinical Data") and (ii) be issued patents covering inventions conceived and reduced to practice by Licensee related to the Product during the course of this Agreement ("Licensee Grant-Back Patents").

Without prejudice to and subject to Orion's rights to the Licensee Grant-Back Patents outside the Territory (as applicable), as set forth in Section 10.2.1., Licensee hereby grants to Orion an irrevocable, perpetual, transferable sublicensable, fully-paid-up, non-exclusive, royalty-free right and license under the Licensee Clinical Data and Licensee Grant-Back Patents for any and all purposes not in conflict with the rights granted to Licensee under this Agreement. Licensee agrees to promptly notify Orion of any Licensee Clinical Data generated and Licensee Grant-Back Patents issued and shall make available to Orion all Licensee Clinical Data.

2.8 The following new Section 7.9. (Supply of Levosimendan for the Modified Oral Product) shall be added to the Agreement:

7.9. Supply of Levosimendan for the Modified Oral Product. Orion shall, promptly following Licensee's written order(s) from time to time, supply Licensee or its designee with, to the extent reasonably necessary or useful to manufacture Modified Oral Products for use in the Development thereof, Levosimendan conforming to the specifications set forth on Schedule 7.9. hereto, which shall be manufactured, stored, handled, and shipped in accordance with current FDA standards of Good Manufacturing Practices, and which will have a retest date no earlier than thirty-six (36) months following the shipment thereof to Licensee or its designee. The minimum order amount of such Levosimendan shall be [***] grams.

Licensee shall pay Orion a price of [***] Euros (€[***]) per kilogram of such Levosimendan ordered by Licensee and delivered by Orion, with such payment to be made within forty-five (45) days of Licensee's receipt of an invoice therefor, with such invoice not to be provided prior to delivery of such product.

2.9 Section 9.2. (Inclusion of Orion's Name on Marketing Materials) of the Agreement shall be replaced with the following:

9.2. (Inclusion of Orion's Name on Marketing Materials). Licensee agrees that, to the extent consistent with and subject to regulatory requirements in the Territory, appropriate language shall be included in the advertising, promotion and marketing materials for the Product identifying the Product as being licensed from and, if supplied to Licensee in finished form by Orion, manufactured by Orion.

2.10 Section 11.1. (Ownership) of the Agreement shall be replaced with the following:

11.1. (Ownership). Licensee acknowledges that Orion is the sole and exclusive owner of the Product Trademark with respect to the Initial Product within the Territory. All goodwill resulting from use of such Product Trademark by or on behalf of Licensee shall at all times inure solely to the benefit of Orion. Licensee may not register or cause to be registered such Product Trademark or any mark confusingly similar thereto with any national, state or provincial or other governmental authority. Licensee agrees that it will not at any time dispute or contest (i) the validity of such Product Trademark and/or any registrations thereof, whether now existing or hereafter obtained; (ii) the exclusive ownership by Orion of such Product Trademark and/or of any registrations thereof, whether now existing or hereafter obtained; (iii) the exclusive ownership by Orion of the present and future goodwill pertaining to such Product Trademark; or (iv) Orion's right to grant to Licensee the rights conferred by this Agreement as to such Product Trademark.

2.11 Section 11.2 (Product Trademark on Materials) of the Agreement shall be replaced with the following:

11.2. Product Trademark on Materials. It shall be clearly indicated on the Product's labels, packaging and inserts, and all sales, marketing and promotional materials that the Product Trademark is a registered trademark using the symbol ® or any other appropriate symbol indicating the registration status of the Product Trademark. Orion retains the right to review and approve all intended uses of the Initial Product's Product Trademark prior to the first use thereof, such approval not to be unreasonably withheld, conditioned or delayed. It is expressly understood and agreed that Orion's review of such materials shall not be deemed a qualification of or otherwise release Licensee of its sole and exclusive responsibility relating to any use of the Product Trademark.

2.12 Section 11.3. (Domain Names) of the Agreement shall be replaced with the following:

11.3. Domain Names. Licensee shall have the right to apply for, acquire and/or register domain names specific to the countries comprised in the Territory that incorporate the Initial Product's Product Trademark in Orion's name and at Licensee's own cost. Any such domain names shall be owned by Orion.

2.13 The Agreement shall be amended by adding Schedule 7.9, attached to this Amendment, as Schedule 7.9 of the Agreement.

3 EFFECTIVE DATE

3.1 The amendments to the Agreement agreed upon herein shall become effective as of the Effective Date of Amendment.

4 OTHER PROVISIONS

4.1 For the avoidance of doubt it is stated that except for what has been stipulated herein above, all other terms and conditions of the Agreement will remain unchanged.

4.2 The terms and conditions of the Agreement with regard to the choice of law and dispute resolution will apply to this Amendment.

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

IN WITNESS WHEREOF, the Parties, through their authorized representatives, have executed two (2) identical counterparts of this Amendment.

Orion Corporation

By: /s/ p.p. Satu Ahomäki

Name: p.p. Satu Ahomäki

Title: EVP

By: /s/ p.p. Patrik Kass

Name: p.p. Patrik Kass

Title: Director Generics business

Tenax Therapeutics, Inc.

By: /s/ Christopher T. Giordano

Name: Christopher T. Giordano

Title: President & CEO

SCHEDULE 7.9.
MODIFIED ORAL PRODUCT API SPECIFICATIONS

Specifications, Levosimendan milled

Test	Acceptance criterion	Test method
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