

**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: April 9, 2025  
(Date of earliest event reported)

**Orogenics, Inc.**

(Exact name of registrant as specified in its charter)

FL  
(State or other jurisdiction  
of incorporation)

001-32188  
(Commission  
File Number)

59-3410522  
(IRS Employer  
Identification Number)

1990 Main Street  
Suite 750  
Sarasota, FL  
(Address of principal executive offices)

34236  
(Zip Code)

813-286-7900  
(Registrant's telephone number, including area code)

(Former Name or Former Address, if changed since last report)

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	OGEN	NYSE American

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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 8.01. OTHER INFORMATION.**

On April 9, 2025, Orogenics, Inc. (the "Company") issued a press release announcing that the Company had submitted its clinical trial protocol for regulatory review to the Health and Disability Ethics Committee (HDEC) in New Zealand in preparation for its Phase II clinical trial using ONP-002 in New Zealand. A copy of the Press Release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

**ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS.**

(d) Exhibits

Exhibit No.	Description
99.1	<a href="#">Press Release Dated, April 9, 2025.</a>

**SIGNATURES**

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on April 9, 2025.

**ORAGENICS, INC.**  
**(Registrant)**

BY: /s/ Janet Huffman  
Janet Huffman  
Chief Financial Officer

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**Oragenics, Inc. Announces Health and Disability Ethics Committee Submission for Phase IIa Concussion Trial**

**SARASOTA, Fla., Apr. 9, 2025** (GLOBE NEWSWIRE) — Oragenics, Inc. (NYSE American: OGEN), a biotechnology company focused on developing novel intranasal therapies for brain-related conditions, today announced that it has submitted a clinical trial protocol for regulatory review to the Health and Disability Ethics Committee (HDEC) in New Zealand.

This submission marks a critical milestone in advancing the Company’s Phase II clinical trial evaluating ONP-002, its proprietary neurosteroid therapy, for the treatment of mild traumatic brain injury (mTBI) or concussion. Pending approval, Oragenics expects to initiate patient enrollment in the region and expand the study’s geographic reach. The trial is expected to be conducted at Christchurch Hospital in New Zealand, the largest tertiary, teaching, and research hospital on the South Island. Christchurch Hospital provides a full range of emergency, acute, elective, and outpatient services, and its Emergency Department is one of the busiest in Australasia, treating more than 83,000 patients annually.

“Submitting our HDEC application is a pivotal step toward advancing ONP-002 and addressing the critical need for effective concussion treatments,” said Janet Huffman, Interim Chief Executive Officer of Oragenics. “With patient enrollment planned in both Australia and New Zealand, including at Christchurch Hospital—one of the region’s leading research institutions—we are hoping to expand our global clinical footprint. We look forward to regulatory feedback and moving closer to bringing this much-needed therapy to patients.”

No pharmaceutical therapy is available for treating concussion, an unmet medical need. These clinical trials mark the first time a novel chemical drug entity has been tested for efficacy in this patient population. ONP-002 is designed for intranasal administration, offering a non-invasive and efficient route for drug delivery to the brain. The therapy has demonstrated promising results in preclinical models, reducing inflammation, oxidative stress, and brain swelling associated with concussion. A Phase I clinical study proved the drug to be safe and well-tolerated in healthy human volunteers.

**Investor Contact**

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**About Oragenics, Inc.**

Oragenics is a biotechnology company focused on developing intranasal therapeutics for neurological disorders, including its lead candidate, ONP-002, for the treatment of mild traumatic brain injury (mTBI) or concussion. The Company is also advancing proprietary powder formulations and intranasal delivery technology to enhance drug administration. For more information, visit [www.oragenics.com](http://www.oragenics.com).

**Forward-Looking Statements**

This communication contains “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These forward-looking statements are based on management’s beliefs and assumptions and information currently available. The words “believe,” “expect,” “anticipate,” “intend,” “estimate,” “project” and similar expressions that do not relate solely to historical matters identify forward-looking statements. Investors should be cautious in relying on forward-looking statements because they are subject to a variety of risks, uncertainties, and other factors that could cause actual results to differ materially from those expressed in any such forward-looking statements. These factors include, but are not limited to, those described in our Form 10-K and other filings with the U.S. Securities and Exchange Commission. All information set forth in this press release is as of the date hereof. You should consider these factors in evaluating the forward-looking statements included in this press release and not place undue reliance on such statements. We do not assume any obligation to publicly provide revisions or updates to any forward-looking statements, whether as a result of new information, future developments or otherwise, circumstances should change, except as otherwise required by law.

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