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: March 6, 2025
(Date of earliest event reported)

Oragenics, Inc.
(Exact name of registrant as specified in its charter)

FL	**001-32188**	**59-3410522**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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 March 6, 2025, Oragenics, Inc. (the "Company") issued a press release announcing that the Company had submitted its Investigator's Brochure (IB) application in preparation for its Phase II clinical trial using ONP-002 in Australia. 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	Press Release Dated, March 6, 2025.
104	Cover page Interactive Data File (embedded in the cover page formatted in Inline XBRL)

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 March 6, 2025.

ORAGENICS, INC.
(Registrant)

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

Exhibit 99.1

Oragenics, Inc. Submits Investigator's Brochure for Phase II Clinical Trial of ONP-002 in Mild Traumatic Brain Injury (mTBI)

SARASOTA, FL – March. X, 2025 (GLOBE NEWSWIRE) – Oragenics, Inc. (NYSE American: OGEN), a biotechnology company advancing innovative treatments for concussion and brain-related health conditions, today announced the submission of its Investigator's Brochure (IB) application in preparation for its Phase II clinical trial using ONP-002 in Australia. This milestone represents an important step in advancing ONP-002, a novel intranasal neurosteroid, as a potential treatment for mild traumatic brain injury (mTBI), commonly known as concussion.

ONP-002 has demonstrated promising preclinical results, showing the potential to reduce inflammation, oxidative stress, and brain swelling. A prior Phase I study in healthy adults confirmed the drug's safety and tolerability at multiple intranasal doses. This upcoming Phase II study aims to establish the feasibility of acute intranasal administration in mTBI patients and generate initial proof-of-concept data through cognitive testing, visual motor testing, and biomarker analysis.

The IB provides investigators with comprehensive clinical and non-clinical data on ONP-002, including its safety, pharmacokinetics, and pharmacodynamics. This document serves as a critical foundation for the study, guiding investigators on protocol requirements such as dosing, intranasal administration protocols, blood biomarker analysis, and safety monitoring. Additionally, the submission enables updates to ClinicalTrials.gov, providing a transparent record of the trial's details and progress as regulatory approvals advance.

Mild TBI, commonly known as a concussion, is a form of head trauma that temporarily disrupts brain function. Symptoms often include headache, dizziness, confusion, and cognitive impairment. Despite the high incidence of concussions, no FDA-approved drug therapies currently exist, leaving a significant unmet medical need.

"The submission of our Investigator's Brochure application marks a critical step forward in advancing our clinical program for ONP-002," said Janet Huffman, Interim CEO of Oragenics. "This submission brings us closer to initiating our clinical trial, and we remain committed to delivering a much-needed therapeutic option for patients suffering from mTBI. We anticipate receiving final regulatory approvals that should allow us to initiate our clinical trial in the coming weeks, and are focused on ensuring a smooth trial launch and look forward to sharing updates as we progress."

About the Phase II Study

The randomized, double-blind, placebo-controlled Phase II trial is designed to assess the feasibility, safety, tolerability, blood biomarker response, and pharmacokinetics/pharmacodynamics of ONP-002 in adults with mTBI. The study is designed to enroll up 40 participants across two treatment arms—20 receiving ONP-002 and 20 receiving a placebo. It is anticipated that participants will receive a total of nine doses over five days, with the first dose administered within 12 hours of injury. Cognitive testing, visual motor testing, and blood biomarker analysis will be used to evaluate the impact of ONP-002 on brain function and recovery.

Investor Contact

Rich Cockrell
404.736.3838
ogen@cg.capital

About Oragenics, Inc.

Oragenics is a development-stage biotechnology company focused on nasal delivery of pharmaceutical medications in neurology and fighting infectious diseases, including drug candidates for treating mild traumatic brain injury (mTBI), also known as concussion, and for treating Niemann Pick Disease Type C (NPC), as well as proprietary powder formulation and an intranasal delivery device. For more information, please visit 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.
