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: May 16, 2024
(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	34236
(Address of principal executive offices)	(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 May 16, 2024, the Company issued a press release announcing an update on the Company's drug development program related to its lead drug candidate, ONP-002, an innovative neurosteroid designed to treat mild Traumatic Brain Injury (mTBI), commonly referred to as concussion. 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, May 16 2024.
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 this May 16, 2024.

ORAGENICS, INC.
(Registrant)

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

Exhibit 99.1

Oragenics, Inc. Prepares Intranasal Pharmaceutical, ONP-002 for Phase II Concussion Trial

SARASOTA, Fla., May 16, 2024 (GLOBE NEWSWIRE) — Oragenics, Inc. (NYSE American: OGEN), a pioneering pharmaceutical company specializing in intranasal treatments for neurological disorders, today announced an update on the Company and its drug development program. Oragenics is designing an upcoming Phase II clinical trial conducted in acute and emergency departments. The company is preparing to initiate a Phase II clinical trial for its lead drug candidate, ONP-002, an innovative neurosteroid designed to treat mild Traumatic Brain Injury (mTBI), commonly referred to as concussion.

Advancements in Drug Formulation for Phase II Trial

Oragenics is focused on enhancing the formulation of ONP-002 by increasing the percentage of active compound in the final spray-dried intranasal powder. The formulation improvements aim to optimize the size of the emitted particles, ensuring they are large enough to prevent deep lung inhalation while maximizing intranasal absorption and brain targeting. This intranasal delivery method is crucial for bypassing the blood-brain barrier, facilitating rapid and efficient drug delivery to the brain within minutes.

Clinical Trial Preparations

In preparation for the Phase II clinical trial, Oragenics has secured an adequate supply of intranasal devices. The company has also partnered with Avance Clinical Pty Ltd, a renowned Clinical Research Organization (CRO) based in Adelaide, Australia. This collaboration will facilitate the implementation of the Phase IIa trial in emergency departments at level one trauma centers, which Oragenics anticipates will result in a robust and well-structured study.

Leadership Insights

“We are privileged to collaborate with exceptional GMP pre-clinical research teams dedicated to optimizing our drug formulation and intranasal device components,” stated Michael Redmond, President of Oragenics. “Our continued partnership with Avance Clinical has been instrumental in ensuring a seamless transition into our Phase II clinical trial.”

Preclinical studies have demonstrated that ONP-002 significantly improves molecular and behavioral outcomes following brain injury. Additionally, intranasal delivery of ONP-002 as a nanoparticle has shown enhanced brain exposure and metabolism, underlining the potential of this innovative treatment.

Dr. James Kelly, Chief Medical Officer of Oragenics, added, “Our Phase I human study has confirmed that ONP-002 is well tolerated in humans. We are encouraged by the progress and support we have received in optimizing our program, setting the stage for the launch of our Phase II trials.”

Addressing an Unmet Medical Need

Concussion remains an unmet medical need, with an estimated 69 million cases reported globally each year. Common causes include falls, motor vehicle accidents, and contact sports. Concussions are also associated with long-term neurological disorders such as Alzheimer’s Disease, Parkinson’s Disease, and Chronic Traumatic Encephalopathy (CTE). Post-concussion syndrome, which can lead to long-term disability, affects up to 20% of patients with concussion.

Oragenics remains committed to advancing its groundbreaking intranasal pharmaceutical solutions, aiming to provide effective treatments for neurological disorders and to improve patient outcomes worldwide.

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, including without limitation statements regarding the ability of the Company to timely and successfully undertake Phase II clinical trials using its novel drug-device combination for the treatment of mild Traumatic Brain Injury. 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: the Company’s ability to advance the development of its product candidates, including the neurology assets, under the timelines and in accord with the milestones it projects; the Company’s ability to raise capital and obtain funding, non-dilutive or otherwise, for the development of its product candidates; the regulatory application process, research and development stages, and future clinical data and analysis relating to its product candidates, including any meetings, decisions by regulatory authorities, such as the FDA and investigational review boards, whether favorable or unfavorable; the Company’s ability to obtain, maintain and enforce necessary patent and other intellectual property protection; the nature of competition and development relating to concussion treatments; the Company’s expectations as to the outcome of preclinical studies and clinical trials and the potential benefits, activity, effectiveness and safety of its product candidates including as to administration, transmission, manufacturing, storage and distribution; and general economic and market conditions and risks, as well as other uncertainties described in our filings with the U.S. Securities and Exchange Commission. All information set forth is as of the date hereof unless otherwise indicated. You should consider these factors in evaluating the forward-looking statements included 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, should circumstances change, except as otherwise required by law.

Contact:

Oragenics, Inc.
