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: February 5, 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 February 5, 2024, the Company issued a press release to announce it is preparing for a Phase II clinical trial using its novel drug - device combination for the treatment of mild Traumatic Brain Injury, aka concussion. A copy of the press release is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release Dated February 5, 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 5th day of February 2024.

ORAGENICS, INC.
(Registrant)

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

Exhibit 99.1

Oragenics, Inc. Preparing for Phase II Clinical Trials to Treat Concussion

February 05, 2024

SARASOTA, Fla.—(BUSINESS WIRE)—Oragenics, Inc. (NYSE American: OGEN), a company focused on developing unique, intranasal nanoparticle pharmaceuticals for the treatment of neurological disorders, today announced it is preparing for a Phase II clinical trial using its novel drug - device combination for the treatment of mild Traumatic Brain Injury, aka concussion. Oragenics' lead drug candidate, ONP-002, is a new chemical entity (NCE) designed to target the brain through self-propelled powdered delivery into the nasal cavity. A 40-patient Phase I study showed ONP-002 to be safe and well-tolerated.

Oragenics has begun the final process of synthesizing and formulating the drug needed for its Phase II clinical trial. It is expected that enrolled patients will be in the acute phase following concussions, after diagnosis the patient will quickly receive their first dose intranasally.

"Concussion is a serious unmet medical need. An acute treatment that can mitigate the pathological cascade could help so many people. We are excited to get the Phase II clinical trials underway," commented Dr. James "Jim" Kelly, Neurologist and Executive Director of the Marcus Institute of Brain Health and an advisor on the planned phase II trial.

ONP-002 has been shown to have a neuroprotective molecular profile and improve behavioral outcomes including memory and motor performance in animal models of brain injury. The drug has a large safety margin between dosages used in the animal toxicology program and those used in the Phase I study and planned for the upcoming Phase II clinical trial. Intranasal delivery of ONP-002 as a nanoparticle has been shown to enhance brain exposure in animals. "Intranasal delivery targeting the brain is our model for improving brain health while maintaining a strong safety margin," commented Michael Redmond, President of Oragenics.

Concussion is an unmet medical need. There is an estimated 69M concussions annually reported worldwide. Common causes of concussion include falls, motor vehicle accidents and contact sports. Other neurological disorders including Alzheimer's Disease, Parkinson's Disease and Chronic Traumatic Encephalopathy (CTE) have been linked to concussion. Post concussion syndrome is linked to long term disability and occurs in as high as 20% of concussed patients.

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 trial 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.

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