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: August 12, 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** **(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 August 12, 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. The Company announced that it successfully completed a study that indicates ONP-002 does not cause DNA damage and genotoxicity in an animal model. 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, August 12, 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 12th day of August, 2024.

ORAGENICS, INC.
(Registrant)

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

Exhibit 99.1

Oragenics, Inc. Announces Concussion Drug Successfully Completes FDA-Required Genotoxicity Study

● ONP-002 showed no cancer-causing DNA damage
● Phase II clinical trial being planned

SARASOTA, Fla., August 12, 2024 (GLOBE NEWSWIRE) Oragenics, Inc. (NYSE American: OGEN), a company focused on developing unique, intranasal pharmaceuticals for the treatment of neurological disorders, today announced its lead candidate for treating concussion, ONP-002, successfully completed a study that indicates it does not cause DNA damage and genotoxicity in an animal model. ONP-002 is a new chemical entity (NCE) designed to target the brain through delivery into the nasal cavity and onward to the brain. Prior to conducting a clinical trial, the U.S. Food and Drug Administration (FDA) requires that pharmaceuticals be tested on cells and animals to ensure they do not cause damage affecting cell division.

Oragenics conducted an *in vivo* (animal) study to determine if multi-day treatments of ONP-002 cause DNA damage and increased risk of cancer. Three concentrations of ONP-002 were used at a low, medium and high dose. Animal bone marrow was dissected and analysed for DNA damage. The results showed no evidence of genetic mutations, suggesting that ONP-002 does not affect the cell cycle and therefore does not disrupt cell division that could be cancer-causing. Oragenics partnered with VivoPharm, Inc. to conduct this study under Good Laboratory (GLP) conditions. These results suggest that multi-day treatment for concussion using ONP-002 will not cause genotoxicity.

“We continue to be pleased with the safety profile of ONP-002. We have now shown a safety margin in our two-species toxicology program, cardiac safety with GLP hERG testing and no issue with cancer-causing DNA damage using the *in vivo* micronucleus assay. Oragenics strongly believes that ONP-002 will be safe for concussed patients in our planned Phase II clinical trial. We will continue to monitor systemic and intranasal safety parameters throughout the drug development program,” commented Michael Redmond, President of Oragenics.

Concussion is an unmet medical need. There are an estimated 69 million 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 symptomology is linked to long-term disability and occurs in as high as 20% of concussed patients.

About Oragenics

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 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.

Oragenics, Inc.

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