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 13, 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 3.01. NOTICE OF DELISTING OR FAILURE TO SATISFY A CONTINUED LISTING RULE OR STANDARD; TRANSFER OF LISTING.

On August 16, 2024, Oragenics, Inc. (the "Company") issued a press release announcing it received a notice from the NYSE American indicating that the Company remains in non-compliance with the Section 1003(a) of the NYSE American's continued listing standards. As previously disclosed, on April 16, 2024, the NYSE American notified the Company that it was not in compliance with subsections (ii) and (iii) of Section 1003(a). The NYSE American has now informed the Company that it also is not in compliance with subsection (i) Section 1003(a), which requires stockholders' equity of no less than $2,000,000 if the Company has sustained losses from continuing operations and/or net losses in two of its three most recent fiscal years. A copy of the Press Release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

ITEM 8.01. OTHER INFORMATION.

On August 16, 2024, the Company issued a press release announcing recent achievements related to the development of the Company's leading 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, August 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 16thh day of August, 2024.

ORAGENICS, INC.
(Registrant)

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

Exhibit 99.1

Oragenics, Inc. Provides Update on its Drug Intended to Treat Concussion and Non-Compliance with NYSE American Continued Listing Standards

SARASOTA, Fla., August 16, 2024 (GLOBE NEWSWIRE) Oragenics, Inc. (NYSE American: OGEN) ("the Company"), a company focused on developing unique, intranasal pharmaceuticals for the treatment of neurological disorders, today announced recent and key 2024 business progress. The Company continues to execute its business strategy to develop and advance its lead candidate, ONP-002, for the treatment of concussion. Phase 2 human trials are being planned with anticipation of starting in the fourth quarter of this year.

Achievements:

- **Stability of ONP-002 Across a Wide Temperature Range:** Demonstrated that ONP-002 is stable at high and low temperatures, eliminating the need for cumbersome cold storage. This stability is critical for field delivery in diverse environments, including for military training and contact sports that are often conducted in extreme temperatures.
- **Phase 2 Clinical Trial Preparation:** The Company made significant strides in preparing for a Phase 2 clinical trial regarding ONP-002, a new chemical entity (NCE) designed to target the brain through delivery into the nasal cavity and onward to the brain. In May, the company partnered with Avance Clinical to conduct the upcoming trial in Australia. Phase 1 data has been reviewed and accepted establishing that ONP-002 is safe to move into a Phase 2 trial to further evaluate safety and efficacy. Clinical sites are being identified and educated on the patient enrollment process. The spray dry drug formulation and filling of devices for use in Phase 2 clinical trials is near completion.
- **Improvements in Drug Formulation:** Improved the intranasal drug formulation, increasing the amount of ONP-002 per dose by 4X, thereby increasing the amount of drug that the brain will be exposed to with a single treatment.
- **Development of Automated Intranasal Device:** Completed the prototype for an automated intranasal device designed for use in concussed patients who are initially dazed, confused, or unconscious, facilitating drug administration during the acute phase of injury.
- **Successful Completion of FDA-Required Testing:** ONP-002 cleared FDA-required cardiotoxicity and genotoxicity testing, confirming the safety of the drug for further clinical development. These results strengthen the safety profile of ONP-002, paving the way for the upcoming Phase 2 trials. These were the final studies required to submit an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA). Currently, the IND package is being generated with the support of Syneos Health's regulatory team and will be the basis for starting a Phase 2b study in the U.S. to evaluate the effects of ONP-002 on clinical outcome measures following concussion.

- **Completed Public Offering:** Closed a public offering, raising approximately $1.1 million, to support the continued development of ONP-002 and other corporate needs.
- **Appointed Medical Advisors:** Dr. William 'Frank' Peacock, a leading expert in emergency medicine and diagnostic biomarkers, was named as Chief Clinical Officer, and Dr. James 'Jim' Kelly, a world renown neurologist and key opinion leader in concussion, joined as Chief Medical Officer. These new team members were appointed to oversee the upcoming Phase 2 clinical trial for treating concussion in the emergency department.

"We are pleased with the significant progress this year, particularly in advancing ONP-002 toward Phase 2 clinical trials," commented Michael Redmond, President of Oragenics. "Our team's efforts in enhancing drug safety, completing key FDA tests, and improving our delivery technology and formulation demonstrate our commitment to addressing the urgent need for concussion treatments. These advancements, along with the strategic leadership appointments, position Oragenics as a leader in the development of medical solutions for acute neurological trauma, bringing us closer to meeting this critical unmet need."

Continued Non-Compliance and NYSE Approved Plan to Gain Compliance

As previously disclosed, the Company is not in compliance with subsections (ii) and (iii) of Section 1003(a) of the NYSE American's continued listing standards. On August 13, 2024, the Company received a notice from the NYSE American LLC informing the Company that it also is not in compliance with subsection (i) Section 1003(a), which requires stockholders' equity of no less than $2,000,000 if the Company has sustained losses from continuing operations and/or net losses in two of its three most recent fiscal years. The Company previously submitted a Plan of Compliance (the "Plan") to the NYSE American. The NYSE American approved the Plan. The Company has until October 18, 2025 to regain compliance under the approved Plan. The NYSE non-compliance notices do not affect the listing or trading of Oragenics' stock, which will continue under the symbol "OGEN" with a ".BC" designation to indicate the status of the Common Stock as "below compliance". The Company remains committed to addressing this issue while advancing its business and clinical operations.

About Concussion

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, also known as concussion, and for treating Niemann Pick Disease Type C, 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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