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 18, 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 March 18, 2024, the Company issued a press release announcing that it has retained Dr. James "Jim" Kelly as its Chief Medical Officer, pursuant to an independent contractor agreement, to oversee its upcoming Phase II clinical trial. Dr. Kelly has committed to providing twenty hours of service per month to the Company (at $400 per hour). 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 18, 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 18th day of March, 2024.

ORAGENICS, INC.
(Registrant)

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

Exhibit 99.1

Oragenics Appoints James Kelly MD, Chief Medical Officer to Lead Phase II Clinical Trials for Treating Concussion

(March 18, 2024, Sarasota, FL) Oragenics, Inc. (NYSE American: OGEN), a company focused on developing unique, intranasal pharmaceuticals for the treatment of neurological disorders, today announced it has appointed Dr. James "Jim" Kelly, Neurologist, as its Chief Medical Officer, to oversee its upcoming Phase II clinical trial. Oragenics' lead drug candidate, ONP-002 is combined with its intranasal device intended for the treatment of mild Traumatic Brain Injury (TBI), aka concussion. ONP-002 is a new chemical entity (NCE) designed to target the brain through delivery into the nasal cavity and onward to the brain. A 40-patient Phase I study was completed and showed the drug to be safe and well-tolerated.

In the recent past, Dr. Kelly served as the Executive Director of the Marcus Institute for Brain Health (MIBH) and Professor of Neurology at the University of Colorado Anschutz Medical Campus in Aurora, Colorado. The MIBH specialized treatment program is funded by the Marcus Foundation to care for US military veterans with persistent symptoms of TBI. Dr. Kelly was also National Director of the Avalon Action Alliance TBI Programs for which the MIBH serves as the clinical coordinating center.

"I am excited to join Oragenics as its Chief Medical Officer at such an important and pivotal time in the drug development process. I have been involved with the drug for many years now and look forward to testing the drug and showing it can improve patient outcomes in our upcoming Phase II clinical trials," said Dr Kelly."

Prior to these recent positions, Dr. Kelly was the Director of the National Intrepid Center of Excellence (NICoE) at Walter Reed National Military Medical Center in Bethesda, MD. As its founding Director, he led the creation of an innovative interdisciplinary team of healthcare professionals who blended high-tech diagnosis and treatment with complementary and alternative medical interventions in a holistic, integrative approach to the care of US military personnel with the complex combination of TBI and psychological conditions, such as post-traumatic stress, depression, and anxiety. In this role, Dr. Kelly was frequently called upon by leaders of the Military Health System at the Pentagon, the US Congress, the Department of Veterans Affairs, and numerous military facilities in the continental US and abroad. Dr. Kelly has interacted with the FDA and clinical trials for brain injury throughout his esteemed career. He is a strong advocate for treatments in the acute phase of brain injury and understands the value of protecting the brain early on from inflammation, swelling and oxidative stress to gain better clinical outcomes.

"We are fortunate to have such an esteemed neurologist as Dr. Kelly join our team in this important role at Oragenics. Dr. Kelly is recognized as a leading expert in concussion and other brain injuries and and we are fortunate to have him lead our drug trials going forward. We are currently completing the drug manufacturing and formulation at GMP facilities to ensure the integrity of the drug before and during the trials, and we look forward to completing this work in the short-term and getting the Phase II trial underway," stated Michael Redmond, President of Oragenics.

In preclinical animal models, the drug has been shown to acutely improve molecular and behavioral outcomes following brain injury. In addition, intranasal delivery of the drug as a nanoparticle has been shown to enhance brain exposure and metabolism in animals. "Our Phase I human study has shown ONP-002 to be well tolerated in humans. Our mission now is to show that the ONP-002 brain protective mechanisms in animals translates to humans. Our Phase II study is designed to establish time to first dose, relationships between drug application and blood biomarkers, and the evaluation of clinical endpoints to determine improved in patient outcomes, " said Dr. Kelly.

Concussion is an unmet medical need. There is 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 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 the 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 retain its key employees and independent contractors necessary to continue to develop its product candidates and in particular ONP-002 and the availability of those key employees and independent contractors; the Company's ability to raise capital and obtain funding, non-dilutive or otherwise, for the development of its product candidates; the Company's expectations as to the outcome of the Phase II clinical trial 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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LHA Investor Relations

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