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: January 2, 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)

4902 Eisenhower Boulevard, Suite 125 Tampa, FL	33634
(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 January 2, 2024, the Company issued a press release announcing the closing of its Asset Purchase Agreement with Odyssey Health Inc. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release Dated January 02, 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 2nd day of January, 2024.

ORAGENICS, INC.
(Registrant)

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

Exhibit 99.1

Oragenics Completes Acquisition of Odyssey Health's Neurological Assets

January 02, 2024

Adds Clinical-Stage Product Pipeline, Expands Intranasal Drug Delivery Technologies,

Names Michael Redmond as President of Oragenics

TAMPA, Fla.--(BUSINESS WIRE)-- Oragenics, Inc. (NYSE American: OGEN) ("Oragenics" or the "Company") announces it has completed its previously announced acquisition of assets related to Odyssey Health, Inc.'s (OTCQB: ODYY) ("Odyssey") proprietary neurological drug therapies and technologies.

The acquired assets include ONP-002 and a unique nasal delivery device, Odyssey's lead concussion asset, believed to be a first-in-class intranasal drug under development for the treatment of moderate-to-severe concussion in the acute through subacute phases. In preclinical animal studies, the asset demonstrated rapid and broad biodistribution throughout the brain while simultaneously reducing swelling, inflammation and oxidative stress, along with an excellent safety profile. Results from animals treated with the drug post-concussion showed positive behavioral outcomes using various testing platforms including improved memory and sensory-motor performance, and reduced anxiety. ONP-002 has completed a Phase 1 clinical trial in healthy human subjects showing it is safe and well tolerated. Oragenics anticipates preparing for Phase 2 clinical trials to further evaluate ONP-002's safety and efficacy.

Also included in the acquired assets are all of Odyssey's rights and interest in ONP-001, believed to be a first-in-class neurosteroid being developed for the treatment of Niemann Pick Type-C Disease (NPC), as well as Odyssey's proprietary powder formulation and its intranasal delivery device. Odyssey will retain its other assets and operations.

"We are delighted to complete this pivotal transaction following a favorable vote of shareholders at both companies. We expect that Odyssey's neurological pipeline will significantly expand our market opportunity and believe its technology complements our expertise in intranasal drug delivery. This acquisition also addresses a significant and growing health concern. There are an estimated 5 million concussions annually in the U.S., with up to half going unreported, underscoring a substantial market opportunity for an efficacious treatment," said Kim Murphy, Chief Executive Officer of Oragenics.

"Our decision to invest in this innovative therapy is driven by our commitment to pioneering solutions that build upon our expertise in intranasal drug delivery and our dedication to improving patient outcomes. These new pipeline candidates hold potential to deliver innovative treatments for millions affected by mTBI and NPC, and introduce Oragenics into a market that is projected to grow to $8.9 billion annually by 2027," added Ms. Murphy.

In conjunction with the transaction, Michael Redmond, who has served as President and CEO of Odyssey since 2018, was named President of Oragenics. Mr. Redmond has 35 years of commercial experience with medical device companies, having held various sales and marketing leadership positions that helped accelerate growth at companies to multiples of their previous revenue and valuation. Mr. Redmond also has significant experience in raising capital and securing licensing and distribution deals with major biotech and pharmaceutical companies. In his new position, Mr. Redmond will oversee the growth of Oragenics' neurology product pipeline and intranasal drug delivery technologies.

Additionally, the Odyssey management and development team that led the ONP-002 clinical trial design and implementation for the treatment of concussion, will continue to oversee research and development of the newly acquired neurology assets at Oragenics. The team has experience in conducting clinical trials, developing drug formulations and commercializing pharmaceutical products across a broad range of indications.

"I'm proud to join the executive team at Oragenics and look forward to continuing the development of ONP-002 and ultimately utilizing my experience in commercializing therapeutics. We intend to leverage our joint expertise and resources to expedite the development of this drug, with the goal of filling a critical gap in concussion care as we prepare for a Phase 2 clinical study in the first half of 2024. We believe this transaction also strengthens Oragenics' research and development capabilities, including the integration of key members of Odyssey's research and development team with the Oragenics team," said Mr. Redmond.

About ONP-002

ONP-002 is a fully synthetic neurosteroid being developed to treat mTBI. In preclinical studies, the drug demonstrated equivalent or better neuroprotective effects compared with related neurosteroids. Animal models of concussion showed the drug reduces the behavioral pathology associated with brain injury symptoms such as memory impairment, anxiety and motor/sensory performance. Additionally, ONP-002 is lipophilic and can cross the blood-brain barrier to rapidly eliminate swelling, oxidative stress and inflammation while restoring proper blood flow.

About Mild Traumatic Brain Injury (mTBI)

Concussions are an unmet medical need that affects millions worldwide. Repetitive concussions can increase the risk of developing chronic traumatic encephalopathy and other neuropsychiatric disorders. It is estimated that 5 million concussions occur in the U.S. annually and that up to 50% go unreported. The worldwide incidence is estimated at 69 million per year. The global market for concussion treatment was valued at $6.9 billion in 2020 and is forecast to reach $8.9 billion by 2027, according to Grandview Research. Common settings for concussion include contact sports, military training and operations, motor vehicle accidents, children at play and elderly assistive-living facilities due to falls.

About Niemann-Pick Type C Disease

Niemann-Pick Type C disease is a rare neurodegenerative genetic disorder characterized by the inability of cells to metabolize and properly transport cholesterol and other lipids, leading to the abnormal accumulation in various tissues including brain tissue. The market for NPC therapeutics is expected to grow from $128 million in 2022 to $188 million in 2031 across the U.S., Germany and UK[i].

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 achieve the anticipated benefits of acquiring the Odyssey assets and the Company's future performance, business prospects, events and product development plans. 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 following: the Company's ability to advance the development of its product candidates under the timelines and in accord with the milestones it projects; the Company's ability to obtain funding, non-dilutive or otherwise, for the development of its product candidates, whether through its own cash on hand, or another alternative

source; the regulatory application process, research and development stages, and future clinical data and analysis, decisions by regulatory authorities, such as the FDA and investigational review boards, whether favorable or unfavorable; the potential application of our research and development candidates; 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, treatments for NPC and COVID-19 immunization and therapeutic treatments and demand for vaccines and antibiotics; the Company's expectations as to the outcome of preclinical studies, nasal administration, transmission, manufacturing, storage and distribution; other potential adverse impacts due to the global COVID-19 pandemic, such as delays in regulatory review, interruptions to manufacturers and supply chains, adverse impacts on healthcare systems and disruption of the global economy; 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 in this communication is as of the date hereof. You should consider these factors in evaluating the forward-looking statements included in this communication 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.

[i] Source: GlobalData https://www.globaldata.com/store/report/niemann-pick-type-c-market-analysis/

View source version on businesswire.com: https://www.businesswire.com/news/home/20231227658588/en/

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