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: September 15, 2021
(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 (Address of principal executive offices)		33634 (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 September 15, 2021, Oragenics, Inc. ("Oragenics" or the "Company") issued a press release (the "Press Release") regarding the initiation of a study to evaluate the immunogenicity and viral load reduction impact of its SARS-CoV-2 vaccine candidate in a hamster challenge study.

A copy of the Press Release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated September 15, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 15th day of September, 2021.

ORAGENICS, INC.
(Registrant)

BY: */s/ Michael Sullivan*
Michael Sullivan
Interim Principal Executive Officer
and Chief Financial Officer

Exhibit 99.1

Oragenics Initiates COVID-19 Challenge Study Evaluating Multiple Formulations of its SARS-CoV-2 Vaccine Candidate

Intranasal and Intramuscular Formulations to be Assessed with Novel Adjuvants

TAMPA, Fla. (September 15, 2021) – Oragenics, Inc. (NYSE American: OGEN) ("Oragenics" or the "Company") today announced the initiation of a study to evaluate the immunogenicity and viral load reduction impact of its SARS-CoV-2 vaccine candidate in a hamster challenge study. The study will provide data for several vaccine formulations, using adjuvants specific for both intranasal and intramuscular routes of administration. An assessment of cross-neutralization titers against the Wuhan, Beta and Delta variants of COVID-19 and reduction in the viral load of the Wuhan challenge virus will be used to establish the most promising formulations to advance to human clinical studies. The study is being conducted by the Company's Canadian collaborator with results expected in November.

"We are delighted to have begun this important study on schedule and soon after receiving favorable results from our mouse immunogenicity study. We believe the results from this hamster challenge study will further affirm our development strategy for Terra CoV-2. We have particular interest for the intranasal delivery route. The findings from this second preclinical study will be a part of our Investigational New Drug filing to the U.S. Food and Drug Administration, expected to be made in the first quarter of 2022, to advance the most promising formulations into human clinical studies." said Frederick W. Telling, Ph.D., Executive Chairman of Oragenics.

About Oragenics, Inc.

Oragenics, Inc. is a development-stage company dedicated to fighting infectious diseases including coronaviruses and multidrug-resistant organisms. Its lead product is Terra CoV-2, a vaccine candidate to prevent COVID-19 and variants of the SARS-CoV-2 virus. The Terra CoV-2 program leverages coronavirus spike protein research licensed from the NIH and the NRC with a focus on addressing supply-chain challenges, and offering more patient-friendly administration, such as intranasal. Its lantibiotics program features a novel class of antibiotics against bacteria that have developed resistance to commercial antibiotics.

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. 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 Terra CoV-2 and lantibiotics 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 the vaccine product candidate, Terra CoV-2 and our lantibiotics, 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 relating to Terra CoV-2 and lantibiotics, including any meetings, decisions by regulatory authorities, such as the FDA and investigational review boards, whether favorable or unfavorable; the potential application of Terra CoV-2 to variants and other coronaviruses; the Company's ability to obtain, maintain and enforce necessary patent and other intellectual property protection; the nature of competition and development relating to COVID-19 immunization and therapeutic treatments and demand for vaccines and antibiotics; the Company's expectations as to administration, 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 press release is as of the date hereof. You should consider these factors in evaluating the forward-looking statements included in this press release 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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Or

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