

**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: February 2, 2021
(Date of earliest event reported)

Oragenics, Inc.

(Exact name of registrant as specified in its charter)

FL
(State or other jurisdiction
of incorporation)

001-32188
(Commission
File Number)

59-3410522
(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 February 2, 2021, Oragenics, Inc. (the "Company") issued a press release announcing that the stabilized pre-fusion spike protein CoV-2 S-2P created by the National Institutes of Health and licensed by the Company demonstrates protective immunity in immunized mice challenged with mouse-adapted SARS-CoV-2 virus.

A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated February 2, 2021.

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 February, 2021.

ORAGENICS, INC.
(Registrant)

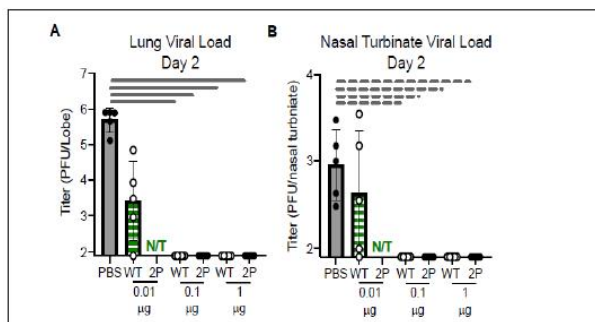
BY: /s/ Michael Sullivan
Michael Sullivan
Chief Financial Officer

SARS-CoV-2 Spike Protein Licensed by Oragenics from the NIH Demonstrates Protective Immunity in Mice

Data supports the Company's approach to COVID-19 vaccine development

TAMPA, Fla. (February 2, 2021) – Oragenics, Inc. (NYSE American: OGEN) (“Oragenics” or the “Company”) announces that the stabilized pre-fusion spike protein CoV-2 S-2P created by the National Institutes of Health (“NIH”) and licensed by the Company demonstrates protective immunity in immunized mice challenged with mouse-adapted SARS-CoV-2 virus.

The NIH data shows that the NIH – created COVID-19 spike protein when dosed at either 0.1 or 1.0 mcg and combined with an adjuvant completely inhibited virus growth in the nasal cavities and lungs of mice when the animals were infected four weeks after their second immunization, compared to the unvaccinated control animals. The adjuvant used was TLR-4-agonist Sigma Adjuvant System - a TLR-4 agonist that induces T cell activation in mice. Adjuvants are added to vaccines to boost immune responses.



Gray dashed line = $p < 0.05$ Gray solid line = $p < 0.01$

See Dinnon et al for details on the mouse-adapted challenge model - Dinnon et al, *Nature* **586**, 560–566 (2020) located at - <https://doi.org/10.1038/s41586-020-2708-8>.

The Company previously disclosed that the NIH-produced spike protein adjuvanted with the TLR-4-agonist Sigma Adjuvant System generated neutralizing antibody titers, measured using a pseudovirus neutralization assay and a plaque-reduction neutralization titer assay. In addition, this immunization produced a balanced Th1/Th2 (T helper cells) response. In a well-functioning immune system both groups of T helper cells work together to keep the system balanced.

“We are encouraged that our licensed SARS-CoV-2 spike protein has been shown to hold promise in the creation of a COVID-19 vaccine, and believe these additional animal data supports our continued development of Terra CoV-2, our lead COVID-19 vaccine candidate,” said Alan Joslyn, Ph.D., President and Chief Executive Officer of Oragenics. Dr. Joslyn continued, “Our successful pre-IND meeting with the FDA has allowed us a clear path towards an Investigational New Drug application. We continue to aggressively move forward with our development strategy for this vaccine candidate, as we believe the global need for vaccines against SARS-CoV-2 is estimated to be between 12 billion to 14 billion doses and the vaccines currently being administered are only a first step towards addressing the COVID-19 pandemic.”

About Oragenics, Inc.

Oragenics, Inc. is focused on the creation of the Terra CoV-2 development of effective treatments for novel antibiotics against infectious disease. The Company is dedicated to the development and commercialization of a vaccine candidate providing specific immunity from novel coronavirus. The Terra CoV-2 immunization leverages coronavirus spike protein research conducted by the National Institute of Health. In addition, Oragenics has an exclusive worldwide channel collaboration with ILH Holdings, Inc. (n/k/a Eleszto Genetika, Inc.), relating to the development of novel lantibiotics.

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 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 Noachis Terra’s Terra CoV-2 vaccine, 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, 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 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; the Company’s expectations as to storage and distribution, potential market and impact of other vaccines being administered; 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 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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