
**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: July 22, 2020
(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 7.01 Regulation FD Disclosure.

The Company issued a press release on July 22, 2020 (the “Press Release”) regarding a pre-clinical study which indicated the Company’s approach to its COVID-19 vaccine was producing neutralizing antibodies. A copy of the Press Release is attached hereto as Exhibit 99.1.

By filing this Current Report on Form 8-K and furnishing the information contained herein, the Company makes no admission as to the materiality of any information in this report that is required to be disclosed solely by reason of Regulation FD.

The information contained in the Press Release is intended to be considered in the context of the Company’s Securities and Exchange Commission (“SEC”) filings and other public announcements that the Company may make, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in this report, although it may do so from time to time as its management believes is warranted. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosure.

The information presented in Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, unless the Company specifically states that the information is to be considered “filed” under the Exchange Act or specifically incorporates it by reference into a filing under the Securities Act of 1933, as amended, or the Exchange Act.

Item 8.01. OTHER EVENTS.

The Company’s Press Release announced that the National Institutes of Health (the “NIH”) created stabilized pre-fusion spike protein (CoV-2 S-2P) licensed by the Company has generated neutralizing antibodies in mice during immunization against SARS-CoV-2, the virus that causes COVID-19. The NIH’s preclinical study shows that this spike protein, adjuvanted with the TLR-4-agonist Sigma Adjuvant System (a TLR-4 agonists that induces T cell activation), generates neutralizing antibody titers in both a pseudovirus neutralization assay and a plaque reduction neutralization titer (PRNT) assay. In addition, this immunization produced a balanced Th1/Th2 response.

Item 9.01. FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated July 22, 2020.

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 22nd day of July, 2020.

ORAGENICS, INC.
(Registrant)

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

Preclinical Study Shows SARS-CoV-2 Spike Protein Licensed by Orogenics from the NIH Produces Neutralizing Antibodies*Recently published paper supports the Company's approach to COVID-19 vaccine development*

TAMPA (July 22, 2020) – Orogenics, Inc. (NYSE American: OGEN) (“Orogenics” or the “Company”) announces that the National Institutes of Health (the “NIH”) created stabilized pre-fusion spike protein (CoV-2 S-2P) licensed by the Company has generated neutralizing antibodies in mice during immunization against SARS-CoV-2, the virus that causes COVID-19.

The NIH’s preclinical study shows that this spike protein, adjuvanted with the TLR-4-agonist Sigma Adjuvant System (a TLR-4 agonists that induces T cell activation), generates neutralizing antibody titers in both a pseudovirus neutralization assay and a plaque reduction neutralization titer (PRNT) assay. In addition, this immunization produced a balanced Th1/Th2 response. The results are reported in Corbett et al. *BioRxiv*. 2020 (<https://www.biorxiv.org/content/10.1101/2020.06.11.145920v1>).

“We are delighted that our licensed SARS-CoV-2 spike protein has been shown to hold promise in the creation of a COVID-19 vaccine, and believe this research affirms our development strategy with the Company’s lead vaccine candidate, Terra CoV2,” said Alan Joslyn, Ph.D., President and Chief Executive Officer of Orogenics. Dr. Joslyn continued, “We are particularly pleased to see a balanced Th1/Th2 response, which is one of the most critical parameters used to assess both safety and efficacy of this vaccine candidate.” TerraCoV2 is currently undergoing development and we anticipate conducting Phase 1 human clinical studies in early 2021.”

In March 2020 Noachis Terra Inc., a wholly owned subsidiary of Orogenics, acquired a non-exclusive license from the NIH for this stabilized prefusion CoV-2 spike protein. The Company recently announced that its spike protein has been successfully inserted into Chinese Hamster Ovary (“CHO”) cells and “mini-pool” production and analytical development are underway. CHO cells are used to produce a number of FDA approved recombinant proteins. The transfer to full scale manufacture is expected to commence pending a grant from the Biomedical Advanced Research and Development Authority (BARDA).

About Orogenics, Inc.

Orogenics, Inc. is focused on the creation of the TerraCoV2 vaccine candidate to combat the novel coronavirus pandemic and the further development of effective treatments for novel antibiotics against infectious disease. Through Noachis Terra, a wholly-owned subsidiary of Orogenics, the Company is dedicated to the development and commercialization of a vaccine candidate providing specific immunity from novel coronavirus. The TerraCoV2 immunization leverages coronavirus spike protein research conducted by the National Institute of Health. In addition, Orogenics also has an exclusive worldwide channel collaboration with ILH Holdings, Inc. (n/k/a Eleszto Genetika, Inc.), relating to the development of novel antibiotics.

For more information about Orogenics, please visit www.orogenics.com.

Safe Harbor Statement

Under the Private Securities Litigation Reform Act of 1995: This release includes forward-looking statements that reflect management's current views with respect to future events and performance. 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 TerraCoV2 under the timelines and in accord with the milestones it projects; the Company's ability to obtain funding for the development of Noachis Terra's TerraCoV2 vaccine, whether through its own cash on hand, a grant from BARDA, or another alternative source; the regulatory application process, research and development stages, and future clinical data and analysis relating to TerraCoV2, including any 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 COVID-19 immunization and therapeutic treatments; 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. Oragenics assumes no responsibility to update any forward-looking statements contained in this press release or with respect to the matters described herein.

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