
**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: October 6, 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 8.01 Other Events.

On October 6, 2020, Oragenics, Inc. (the “Company”) announced that the Company received a Pre-IND response from the Food and Drug Administration (“FDA”) for its SARS-CoV-2 Vaccine, Terra CoV-2. The Company intends to file its IND application with the FDA prior to the end of the first quarter of 2021.

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

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued on October 6, 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 6th day of October, 2020.

ORAGENICS, INC.
(Registrant)

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



FDA Broadly Supports Oragenics' Pre-IND Development Program for its SARS-CoV-2 Vaccine

Re-Affirms Plan to File IND Application by the End of 1Q21, Begin Phase 1 Study in Early 2Q21

TAMPA (October 6, 2020) – Oragenics, Inc. (NYSE American: OGEN) (“Oragenics” or the “Company”) announced receipt of feedback to its Type B Pre-IND Meeting Request from the U.S. Food and Drug Administration (“FDA”) that it is in broad agreement with the Company’s planned approach to clinical development of its SARS-CoV-2 vaccine, Terra CoV-2. As a result, the Company believes its timelines for both filing an Investigational New Drug (“IND”) application and the commencement of the Phase 1 study will proceed on schedule. Oragenics expects to file the IND by the end of the first quarter of 2021 and commence patient enrollment in the Phase 1 clinical study early in the second quarter of 2021.

“We are very pleased with the FDA’s response to our Type B Pre-IND meeting request as it permits us to maintain an aggressive development timeline for our Terra CoV-2 vaccine,” said Alan Joslyn, Ph.D., President and Chief Executive Officer of Oragenics. “Important points that are supportive of our planned approach received favorable feedback.”

Dr. Joslyn added, “The FDA’s response is an important step as we work to provide a vaccine against SARS-CoV-2 that is focused on the stabilized prefusion spike protein, with a potential profile that may include lifetime immunity to COVID-19, and storage and distribution at refrigerated temperatures. We believe the commercial opportunity for Terra CoV-2 is robust, and that our vaccine will find its place in the global fight against this deadly virus.”

The FDA has requested additional preclinical animal data for inclusion in the IND filing and plans to provide final comments upon reviewing that data and the Phase 1 trial protocol. Oragenics believes that generating the additional data will not impede the overall development timeline.

About Terra CoV-2

In March 2020, Oragenics acquired a non-exclusive license from the National Institutes of Health (“NIH”) for its stabilized prefusion Terra CoV-2 spike protein. Oragenics recently announced that its spike protein had 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.

About Oragenics, Inc.

Oragenics, Inc. is focused on the creation of the Terra CoV-2 vaccine candidate to combat the novel coronavirus pandemic and the further 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 antibiotics.

For more information about Oragenics, please visit www.oragenics.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 TerraCoV-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 TerraCoV-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 TerraCoV-2, including any meetings, 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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