
**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 28, 2020
(Date of earliest event reported)

Orogenics, 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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 September 28, 2020, Oragenics, Inc. (the “Company”) announced that the Company received a response from Biomedical Advanced Research and Development Authority (“BARDA”) indicating that BARDA determined not to enter into negotiations with the Company, at this time, for the proposal concerning the development of the Company’s SARS-CoV-2 Vaccine, Terra CoV-2. The Company intends to continue to seek funding through other sources, including but not limited to, contracts and grants from various federal government agencies.

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 September 28, 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 28th day of September, 2020.

ORAGENICS, INC.
(Registrant)

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



Oragenics Provides an Update on Funding for its SARS-CoV-2 Vaccine

TAMPA (September 28, 2020) – Oragenics, Inc. (NYSE American: OGEN) (“Oragenics” or the “Company”) provides an update on U.S. federal government and other funding options the Company is pursuing in order to advance its SARS-CoV-2 vaccine, Terra CoV-2.

Oragenics has been informed by the Biomedical Advanced Research and Development Authority (“BARDA”) of BARDA’s determination not to enter into negotiation with the Company. While BARDA noted the Company’s submission aligned with its mission, a combination of factors, including availability of funds, precluded the agency from entering into negotiations at this time.

“We remain committed to our Terra CoV-2 vaccine candidate and expect to continue development through to the completion of a Phase 1 clinical trial,” said Alan Joslyn, Ph.D., President and Chief Executive Officer. “We have completed analytical method feasibility and qualification activities with our contract manufacturer and have advanced in creation of our research cell bank. Although we are disappointed with BARDA’s funding decision, we will continue to pursue other sources of non-dilutive funding of grants and corporate partnerships, and possibly equity capital to advance development of our promising vaccine.

BARDA noted that evaluation of vaccine development under the Operation Warp Speed (“OWS”) program continues and can be an avenue for promising vaccine candidates, which the Company believes Terra CoV-2 to be. In addition, BARDA has suggested that if promising vaccine candidates are identified, there is also an opportunity for a potential partnership with the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND). BARDA is part of the U.S. Department of Health and Human Services, OWS is a public-private partnership initiated by the White House in May 2020 and JPEO-CBRND is part of the U.S. Department of Defense.

“Our focus is on the stabilized prefusion spike protein that may confer lifetime immunity to COVID-19 along with other significant points of differentiation including storage and distribution at refrigerated temperatures versus other vaccines currently in development. We will be holding a pre-IND meeting with the FDA in the near future that we expect will help clarify the requirements to advance our program into the clinic. We believe that additional government funds could be made available during the federal government’s new fiscal year, which begins on October 1, that we can pursue for development of Terra CoV-2,” Dr. Joslyn added.

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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