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: January 14, 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	33634
(Address of principal executive offices)	(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 January 14, 2021, Oragenics, Inc. ("Oragenics" or the "Company") issued a letter to its shareholders updating the shareholders on the Company's progress of its Terra CoV-2 vaccine.

A copy of the letter 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 Letter dated January 14, 2021 from Oragenics to its shareholders.

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 14th day of January, 2021.

ORAGENICS, INC.
(Registrant)

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

Exhibit 99.1

January 14, 2021

Oragenics Issues Letter to Stockholders

Provides update on competitive positioning of Terra CoV-2 vaccine against SARS-CoV-2, expects to file IND in 3Q21

TAMPA (January 14, 2021) – Oragenics, Inc. (NYSE American: OGEN) today issued the following letter to stockholders from its President and Chief Executive Officer, Alan Joslyn, Ph.D.:

To My Fellow Stockholders,

With so much encouraging news recently around COVID-19 vaccine development, this is an excellent time to update you on Oragenics' progress with our own vaccine, Terra CoV-2. Recent news heightens our confidence in our scientific approach. As a reminder, we added this vaccine candidate as a result of our May 2020 acquisition of Noachis Terra, and immediately began preclinical work. Noachis Terra is now a wholly-owned subsidiary of Oragenics.

Both Pfizer and Moderna have announced preliminary safety and efficacy data from their Phase 3 vaccine studies and recent Emergency Use Authorizations. We hold a nonexclusive intellectual property license from the National Institutes of Health (NIH) to the prefusion stabilized spike protein vaccine candidate. The Company's license covers stabilizing the spike protein in the pre-fusion state, which may permit the number of immunogenic centers to be increased. This could allow for a greater likelihood of successful antibody binding, resulting in improved immunogenic responses. We believe that recent Phase 3 data reported relating to the Moderna vaccine supports the concept of utilizing the stabilized spike protein.

In terms of our development of Terra CoV-2, as recently announced we held a successful pre-Investigational New Drug (IND) meeting with the U.S. Food and Drug Administration (FDA), with agreements that allow us to save three to six months on pre-IND development timelines. The broad support for our approach by the FDA included a number of activities, including:

- Use of the Research Cell Bank in the early manufacturing process development;
- Use of early pilot batch manufacture under Good Manufacturing Processes (GMP) for the anticipated Phase 1 clinical trials; and,
- Submission of draft toxicology reports during IND filing.

We are optimistic that our vaccine will ultimately prove to have several advantages.

1. **The NIH-created stabilized pre-fusion spike protein.** The Covid-19 spike protein is a Class 1 fusion (S) protein which exists in a somewhat unstable but better immunogenic "prefusion" tertiary conformation, which in the process of receptor binding and fusion with a cell changes conformation to a more stable but weaker immunogenic post-fusion conformation. We believe that using the stabilized pre-fusion spike protein antigen will lead to a greater immune response as measured by neutralizing antibody titers.

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2. **Access to a novel rationally designed adjuvant.** We have recently signed an agreement with Adjuvance Technologies Inc. for the use of TQL1055, a novel, rationally designed semi-synthetic analogue of the saponin adjuvant QS-21 with potential improved attributes, including stability and manufacturing efficiency. We also anticipate that our Terra CoV-2 vaccine will provide long lasting protection from the SARS-CoV-2 virus with only one or two doses, with a more rapid immune response compared to vaccines developed without the inclusion of an adjuvant.

3. **Standard vaccine storage and distribution conditions**. As presently designed, we believe the Terra CoV-2 vaccine permits cost effective storage and distribution at refrigerated temperatures, which should facilitate the distribution and thereby avoid challenges facing the two mRNA vaccines currently approved under Emergency Use Authorization in the U.S.

The creation of the Research Cell Bank is now complete and manufacturing has been transferred to our dedicated biologics contract development and manufacturing organization Avid Bioservices, Inc. for upstream and downstream processing. Creation of the Master Cell Bank, required for later stage manufacturing will begin in the coming weeks. This work supports our expectation to file the IND mid-year with commencement of patient enrollment in the Phase 1 clinical study immediately thereafter. The proposed Phase 1 study protocol is under development. We will provide details of the final protocol when the IND is approved.

While the world's attention is on COVID-19, we also believe that our vaccine may provide some benefit against other coronaviruses that, unfortunately, may emerge or strengthen in the coming years.

In November and December of 2020, we completed financing transactions, raising cumulative gross proceeds of $12.5 million. These funds, when combined with our current cash and cash equivalents, should allow us to advance our vaccine through IND-enabling studies, including immunogenicity, viral challenge studies and the toxicology study. We also continue to pursue non-dilutive funding options as recommended by the Biomedical Advanced Research and Development Authority (BARDA). In late-September we announced that BARDA declined to provide funds to support the development of the Terra CoV-2 vaccine, but noted that evaluation of vaccine development under the Operation Warp Speed program, as well as other U.S. government-supported funding initiatives, can be an avenue for promising vaccine candidates, which we believe Terra CoV-2 to be.

We firmly believe that even with two or more vaccines projected to be on the market in the coming months, given the size of the worldwide pandemic there will be plenty of demand for the Terra CoV-2 vaccine, once development is successfully completed. Managing the global COVID-19 pandemic and follow up maintenance period will only be possible if multiple vaccines become available. Each will likely have its own particular efficacy characteristics, and each may have differences in manufacturing and distribution. We believe our Terra CoV-2 vaccine holds exceptional promise to play an important role in solving this crisis. We thank our stockholders, employees, partners and research scientists for their continued support, and look to the future with optimism and hope.

Sincerely,

Alan Joslyn
President and Chief Executive Officer
January 14, 2021

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 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; 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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