

**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: May 18, 2021
(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 Information.

On May 18, 2021, Orogenics, Inc. ("Orogenics" or the "Company") issued a letter to its shareholders updating the shareholders on the Company's execution of its business strategy.

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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Letter dated May 18, 2021 from Orogenics 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 18th day of May, 2021.

ORAGENICS, INC. (Registrant)

BY: */s/ Michael Sullivan*

Michael Sullivan
Chief Financial Officer



Oragenics Issues Letter to Shareholders

Executive Chairman Affirms Company Direction with Commitment to Speedy Execution of Business Strategy

Highlights Deep Bench Strength Among Management, Board and Advisors in Vaccine Development and in Life Sciences

TAMPA (May 18, 2021) – Oragenics, Inc. (NYSE American: OGEN) today issued the following letter to shareholders from its Executive Chairman, Frederick W. Telling, PhD:

To My Fellow Shareholders,

In light of the recent changes to the executive management team of Oragenics, I would like to affirm to our shareholders the overall direction of our company is unchanged and to express my deep commitment to a speedy yet prudent execution of our business strategy. Following the resignation of Alan Joslyn, PhD as Chief Executive Officer I have taken on a more active role in the day-to-day management of Oragenics under my new title of Executive Chairman.

On behalf of the Oragenics Board of Directors and my colleagues, I thank Dr. Joslyn for his service and dedication. He helped put in place several initiatives that management and outside advisors are now advancing in a meaningful way. In particular, we are working quickly to develop the Terra CoV-2 vaccine candidate to address SARS-CoV-2 and its variants, as well as a new class of lantibiotics to address the daunting problem of antibiotic resistance. Rest assured we are committed to the speedy execution of milestones and have the human capital to get it done.

Our Leadership Team

Let me share with you some more detail about our human capital, meaning the talented professionals who are working on behalf of our shareholders and the patients afflicted by infectious diseases around the world. Personally, I was honored to work for Pfizer for 30 years until retiring in June 2007. I was appointed as Corporate Vice President and Vice President of Corporate Strategic Planning and Policy in October of 1994. During my career, my focus was on product licensing, mergers and acquisitions, and global health policy. I joined the Oragenics Board of Directors in 2011, so I have been intimately involved with our programs and developments for a number of years. This tenure has given me insight into the capabilities of our team and the potential of our pipeline. I hold a PhD in Economics and Public Policy from Cornell University.

Rising to the occasion is Michael Sullivan, who has served as Chief Financial Officer of Oragenics since 2012. He has now assumed the additional title of Interim Principal Executive Officer. Michael's public and private company experience is extensive, having served as Chief Financial Officer for several companies in Florida over the course of his career. He holds the CPA designation and an MBA from Florida State University College of Business.

Martin (Marty) Handfield, PhD is a talented scientist leading the research and development activities at Oragenics. Serving as our Senior Vice President, Discovery Research, Dr. Handfield joined our company in 2009. Prior to Oragenics, he was a Tenured Associate Professor at the Center for Molecular Microbiology and the Department of Oral Biology at the University of Florida College of Dentistry, where he co-invented IVIAT and co-founded ivi Gene Corp. and Epicure Corp. to commercialize this and related technologies. He received his MS and PhD in Microbiology and Immunology from the Université Laval College of Medicine.

I want to highlight some of my Director colleagues with particularly notable experience in vaccine and drug development. We are fortunate to count among them Kimberly M. Murphy, who joined the Board in May 2020 when we acquired Noachis Terra. She is an accomplished leader and proven professional with substantial experience in vaccine development, including more than a decade at GlaxoSmithKline (GSK). At GSK she led the global influenza vaccine and pandemic preparedness businesses and was responsible for the strategic and prelaunch planning for multiple development-stage vaccines through to commercialization, including Shingrix. She managed a 2,000-person vaccine development, sales, manufacturing and distribution team, and was responsible for the integration planning of GSK's acquisition of Novartis AG's vaccine division. Earlier in her career, she worked in commercialization and marketing roles within Novartis Vaccines and Diagnostics Inc. and Merck & Co., Inc. Kim holds an MBA in Pharmaceutical Marketing from Saint Joseph's University.

Alan W. Dunton, MD is a long-serving Director, having joined our Board in 2011. Alan is the principal and founder of Danerius, LLC, which since 2006 has provided specialized consulting services to public and private pharmaceutical and biotechnology companies. While his more recent affiliations have been with smaller public biotechnology companies, and he currently serves on the boards of directors of Palatin, Inc., CorMedix and Recce, Ltd., he has extensive large pharmaceutical experience as well. From 1994 to 2001, Dr. Dunton was a senior executive in various capacities in the Pharmaceuticals Group of Johnson & Johnson, and also held leadership roles at the Janssen Research Foundation, a Johnson & Johnson Company. Dr. Dunton holds an MD degree from New York University School of Medicine.

Support from Esteemed Advisors

While these executives and Directors bring to Oragenics tremendous pharmaceutical and vaccine experience, we also have engaged various advisors to help us navigate the research and development, manufacturing and regulatory pathways.

We engaged David Zarley, PhD, who has more than 30 years in vaccine research and development in the private sector, including as a consultant to Noachis Terra. He was Vice President of Program Management for Vaccine Research and Development at Pfizer and Senior Director / Medicines Team Leader for Pfizer Primary Care Business Unit. He was also a Senior Director for Wyeth Research Project Management Business Unit and Senior Director for Technical Operations and Product Supply at Wyeth Vaccines. His experience includes Senior Research Biochemist and Project Leader for Viral Vaccine Research and Development at Lederle-Praxis Biologicals. Dr. Zarley received his PhD in Molecular, Cellular and Development - Biology from Indiana University.

Terrence (Terry) Cochrane is President at BrevisRefero Corporation in Ontario, Canada, and brings to Oragenics two decades of life sciences industry experience with 20+ years of progressive management experience in biopharmaceutical development and GMP manufacturing industry for biologics therapies and vaccines. BrevisRefero provides biopharma outsourcing assistance in the identifying and selecting service providers and follow-on technical program management to realize delivery of products to clinic and market. It supports complex clinical-stage programs by handling technology transfer, development, scale-up and GMP manufacturing along with CMC regulatory strategy and support Terry holds a BSc degree from the University of Winnipeg in Biochemistry and Biology.

We have also engaged a third independent advisor with more than 30 years of vaccine development experience in early- to late-stage research and development programs, including technology transfer of projects along the continuum from academic labs to industry research labs, to development labs and on to manufacturing and quality control settings. This advisor spent nearly 20 years at Merck, helping to develop several blockbuster vaccines, and has been a vaccine development consultant to MNCs, small biotechs and NGOs around the world for more than 10 years.

I am proud to call all of these talented individuals my colleagues, and collectively our skills and experiences are tremendous. The key takeaway for you, our shareholders, is that Orogenics' scientific expertise is exceptional and broad. These individuals will be redoubling their efforts to bring a solution to the most pressing needs of the planet as quickly as possible.

Our Terra CoV-2 Program

Our Terra CoV-2 COVID-19 vaccine program is investigating two different modes of administration, namely intramuscular and intranasal. Animal work is ongoing, as are discussions with potential partners. That said, we are committed to accelerating the advancement of this program. As a reminder, the Terra CoV-2 vaccine is based on a nonexclusive intellectual property license from the National Institutes of Health (NIH) to the prefusion stabilized spike protein vaccine candidate. Our 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 generation, resulting in improved immunogenic responses.

Recently released information indicates that pretreatment of mice with the NIH-created COVID-19 spike protein in combination with an adjuvant (TLR-4 agonist Sigma Adjuvant System) completely inhibited viral growth in the nasal cavities and lungs of infected animals, compared with unvaccinated control animals. In October 2020, we received feedback to our Type B Pre-IND Meeting Request from the FDA. The response indicated that the FDA broadly supported our planned approach to the preclinical program that will ultimately support our clinical development of the Terra CoV-2 vaccine. As a result, we anticipate filing the IND application in the fourth quarter of 2021 and immediately upon the receipt of approval from the FDA, commencing the Phase 1 clinical study, the protocol for which is currently under development.

In March 2021, we entered into a material transfer agreement with Biodextris Inc. for the use of three intranasal mucosal adjuvants in our Terra CoV-2 vaccine against COVID-19. The three adjuvants – BDX100, BDX300 and BDX301 – are proteosome-based adjuvants comprised of proteins and lipopolysaccharides with improved attributes including enhanced immune response, manufacturing efficiency and the benefits of intranasal vaccine administration. As a reminder, this initial agreement calls for the three intranasal adjuvants to be used in combination with our antigen vaccine candidate as part of the preclinical immunological evaluation of Terra CoV-2, for the prevention of coronavirus disease caused by infection with SARS-CoV-2 virus.

Our next steps will be to study Terra CoV-2 plus Biodextris' intranasal mucosal adjuvants in preclinical animal studies, including hamster viral challenge studies, mouse immunogenicity studies and the rodent toxicology study. The information generated from the studies employing the new intranasal vaccine candidate may support our IND application and an application to Health Canada to initiate clinical trials. Importantly, our advisors have deep knowledge of research approaches that we may use to speed up the process.

While President Biden's stated goal is to vaccinate 70% of the U.S. population with at least one dose of the currently emergency use authorized vaccines by July 4th, and COVID-19 cases are dropping in the U.S., the pandemic continues to rage unabated elsewhere in the world, most notably in India. We believe our Terra CoV-2 vaccine will play an important role not only in addressing the current COVID-19 pandemic, but also in addressing new variants of concern and other coronaviruses that may come our way.

Our Lantibiotics Program

Orogenics is more than a COVID-19 vaccine company. Our foundation is lantibiotics, and we continue our preclinical work with this novel class of antibiotics to address multidrug-resistant organisms. While the world is currently focused on eradicating COVID-19, it is worth a reminder that according to the Centers for Disease Control and Prevention, more than 2.8 million antibiotic resistant infections occur in the U.S. each year, and more than 35,000 people die as a result. Our long-term goal is to become an important provider of preventions and cures for infectious diseases. Sadly, the pharmaceutical industry's pipeline of novel antibiotic product candidates is very, very thin.

Our Balance Sheet

In parallel with our product-development work, we recently took important steps to strengthen our balance sheet. In February we raised nearly \$22 million through the sale of common stock through an "at the market" facility, the exercise of common stock warrants and the redemption of our \$5.6 million in Series C Preferred Stock. That redemption eliminated the accruing annual 20% preferred dividend payment. We believe our existing cash and cash equivalents will fund our operating plan into the third quarter of 2022, and thus through our Phase 1 study of Terra CoV-2.

Looking Ahead

In closing, I am very excited to be undertaking a more active role in advancing the compelling intellectual property we have at Orogenics. We believe our Terra CoV-2 vaccine holds exceptional promise to play an important role in solving what many experts expect will be a continuing, yearly problem as SARS CoV-2 traverses the globe and mutates. In a similar vein, we hope our work with lantibiotics will address the mutations of bacterial organisms as they develop resistance to current drugs.

We have a bright future in front of us, and we are rolling up our sleeves to achieve these important goals. We thank our shareholders, employees, consultants, business partners and research scientists for their hard work and their continued support.

Sincerely,

Frederick W. Telling
Executive Chairman
May 18, 2021

About Orogenics, Inc.

Orogenics, Inc. is a development stage company dedicated to fighting infectious diseases including coronaviruses and multi-drug resistant organisms. Its lead product is Terra CoV-2, a vaccine candidate to prevent COVID-19, and variants of the SARS-CoV-2 virus. The Terra CoV-2 program leverages coronavirus spike protein research licensed from the National Institutes of Health, with a focus on addressing supply-chain challenges, and offering more patient-friendly administration, such as intra-nasal. Its lantibiotics program features a novel class of antibiotics against infectious diseases including Gram-negative and Gram-positive bacteria that have developed resistance to commercial antibiotics.

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 and lantibiotics 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 and our lantibiotics, 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 and lantibiotics, 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 and antibiotics; 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.

CONTACTS

Oragenics, Inc.

Michael Sullivan, Chief Financial Officer
813-286-7900
msullivan@oragenics.com

or

LHA Investor Relations

Kim Golodetz
212-838-3777
kgolodetz@lhai.com

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