
**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: November 10, 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:

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.

Orogenics, Inc. ("Orogenics" or the "Company") expects to use the investor presentation (the "Investor Presentation") on November 11, 2021 in connection with presentations to potential investors, and thereafter from time to time to potential investors, industry analysts and others. A copy of the Investor Presentation is attached hereto as Exhibit 99.1 and is incorporated herein by reference. Additionally, the Investor Presentation will be available under the "Presentations" tab in the "News and Media" section of the Company's website, located at www.orogenics.com.

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 Investor Presentation is summary information that 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 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	<u>Investor Presentation</u>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 10th day of November, 2021.

ORAGENICS, INC.
(Registrant)

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



Developing Vaccines & Novel Antibiotics to Prevent & Treat Today's & Tomorrow's Infections

Corporate Presentation

NYSE American: **OGEN**

November 2021

Forward-Looking Statements

Certain statements made in this presentation include forward-looking actions that Oragenics, Inc. ("Oragenics," or the "Company") anticipates based on certain assumptions. These statements are indicated by words such as "expect", "anticipate", "should" and similar words indicating uncertainty in facts, figures and outcomes. Such statements are made pursuant to the Safe Harbor Provisions of the Private Securities Litigation Reform Act of 1995. While Oragenics believes that the expectations reflected in such forward-looking statements are reasonable, it can give no assurance that such statements will prove to be correct. The risks associated with the Company are detailed in the Company's various reports filed by the Company with the Securities and Exchange Commission.

Agenda

- **Introduction**
 - Dr. Fred Telling, Executive Chair
- **COVID-19 Vaccine Commercial Analysis & Terra CoV-2 Opportunity**
 - Dr. Timothy Cooke, Commercial Consultant
- **Terra CoV-2 Development Status**
 - Terrence Cochrane, CMC Consultant
- **Corporate Status Update**
 - Michael Sullivan, Interim Principal Executive Officer and Chief Financial Officer

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Corporate Overview

Oragenics is a development-stage company dedicated to fighting infectious diseases, including coronaviruses and multidrug-resistant organisms

Lead product is Terra CoV-2, a vaccine candidate to prevent COVID-19

- Gained access to multiple enabling technologies
- Focusing on intranasal vaccine due to medical need and potential for differentiation

Lantibiotics research program features a novel class of antibiotics to address infectious diseases that have developed resistance to commercial antibiotics

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Investment Highlights

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Terra CoV-2 Combines Multiple Technologies:

- De-risked antigen to SARS-CoV-2 spike protein vaccine technology from NIH
- Cell line that can rapidly respond to new variants from NRC Canada
- Intranasal adjuvant from Inspirevax

2

Potential for Highly Differentiated COVID-19 Vaccine:

- Intranasal vaccine could reduce transmission and is needle-free
- Limited number of competing intranasal vaccines (5 Phase 1/2 viral vaccines)
- Expect to file US IND in April 2022

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Lantibiotics platform features a novel class of peptide antibacterial compounds, with activity against a variety of multidrug-resistant infections



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COVID-19 Vaccine Commercial Analysis & Terra CoV-2 Opportunity

COVID-19 Vaccine Commercial Analysis

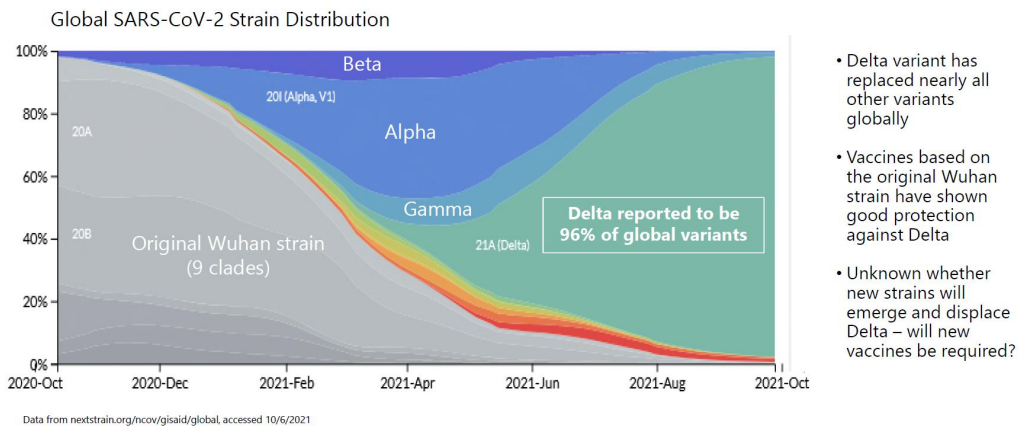
- **Market evolving rapidly across several dimensions**
 - Virus evolution with emergence & disappearance of variants
 - Target populations are increasingly “seropositive” (from vaccination or exposure)
 - Rapidly shifting competitive landscape
- **Terra CoV-2 commercial opportunity**
 - Assessed distinct formulations for intramuscular or intranasal administration
 - Intramuscular approach with Adjuvance TQL1055 adjuvant
 - Intranasal approach with Inspirevax BDX301 adjuvant

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COVID-19 Vaccine Commercial Analysis

Rapid global evolution of variants



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COVID-19 Vaccine Commercial Analysis

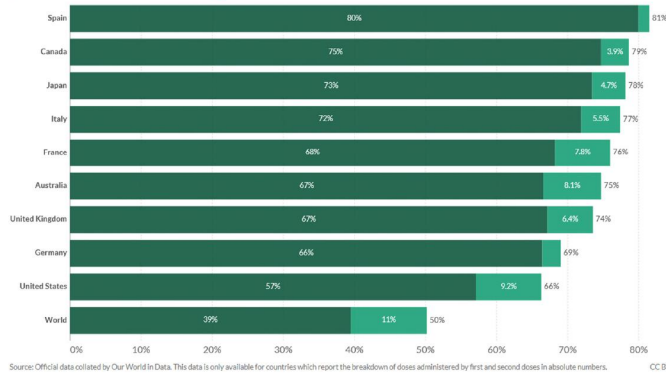
Target populations are increasingly vaccinated

Share of people vaccinated against COVID-19, Nov 5, 2021

Alternative definitions of a full vaccination, e.g. having been infected with SARS-CoV-2 and having 1 dose of a 2-dose protocol, are ignored to maximize comparability between countries.

Our World in Data

■ Share of people fully vaccinated against COVID-19 ■ Share of people only partly vaccinated against COVID-19



• Populations in target high-income countries are receiving "primary" immunization

• Opportunities for new vaccines are as booster doses or primary immunization of young children

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COVID-19 Vaccine Commercial Analysis

Competitive landscape

- **Most competitive vaccine market ever**
 - 129 Marketed/clinical-stage vaccines
 - 45 Clinical-stage protein subunit vaccine candidates (same type as Terra CoV-2)
 - 9 Clinical-stage intranasal vaccines
 - 194 Preclinical-stage vaccine candidates
- **Late market entrants need to differentiate their vaccine**
 - Improve reduction in transmission of virus
 - Provide needle-free administration options
 - Fit with future target markets
 - "Best booster" for seropositives
 - Routine childhood immunization schedule
 - Protect against dominant variant

Pipeline figures from WHO COVID-19 Vaccine Tracker: www.who.int/teams/blueprint/covid-19/covid-19-vaccine-tracker-and-landscape, dated 11/5/2021

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COVID-19 Vaccine Commercial Analysis

Intranasal vaccine pipeline is limited and earlier stage

Clinical-stage Intranasal Vaccine Candidates vs. Oragenics' Terra Cov-2

Organization	Organization Type	Vaccine Candidate	Vaccine Type	Clinical Stage	
Precision Viralogs/ Bharat Biotech	US private biotech/ Indian vaccine manufacturer	BBV154	Live chimpanzee adenovirus	Phase 2	<ul style="list-style-type: none"> • All competing intranasal vaccine candidates are based on live viruses • Live virus vaccines have more safety risks with immunocompromised, pregnant women and young children. • Indian manufacturers may have challenges obtaining approval in US & EU
Oxford University/ Astra Zeneca	UK university/ Big Pharma	Vaxzevria/AZD1222 (marketed for intramuscular injection)	Live chimpanzee adenovirus	Phase 1	
Codagenix / Serum Institute of India	US private biotech/ Indian vaccine manufacturer	COVI-VAC	Live attenuated SARS-Cov-2 virus	Phase 1	
Meissa Vaccines	US private biotech	MV-014-212	Live respiratory syncytial virus	Phase 1	
CyanVac	US private biotech	CVXGA1	Live parainfluenza-5 virus	Phase 1	
Oragenics	US public biotech	Terra CoV-2	Protein subunit + BDX-300/301 adjuvant	Preclinical	

From WHO COVID-19 Vaccine Tracker: www.who.int/teams/blueprint/covid-19/covid-19-vaccine-tracker-and-landscape, dated 11/5/2021
List excludes 4 vaccine candidates from Cuba, Hong Kong University, Iran and Mexican veterinary vaccine company.

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COVID-19 Vaccine Commercial Analysis

Potential benefits of intranasal COVID vaccines are well-recognized

COVID-19 vaccines: could a squirt up the nose be just as good as a shot in the arm?

There are several COVID-19 vaccines being used around the world, but all need to be injected and some need ultra-cold refrigeration. Could next-generation intranasal vaccines be a quicker and easier way of protecting ourselves?

24 March 2021 - by Priya Jol



MEDPAGE TODAY*

Can Intranasal COVID Vaccines Help Stop the Spread?

— It's time for new approaches to fighting this virus

by David Tees, MD, and Martin A. Strosberg, PhD · September 1, 2021

pharmaceutics

Can the Nasal Cavity Help Tackle COVID-19?

Bissera Pilicheva^{1,2,*} and Radka Boyuklieva¹
Pharmaceutics 2021, 13, 1612. <https://doi.org/10.3390/pharmaceutics13101612>

3 October 2021

STAT

A snort or a jab? Scientists debate potential benefits of intranasal Covid-19 vaccines

By Helen Branswell^{1,2} Aug. 10, 2021

VIEWPOINT: COVID-19

Scent of a vaccine

Intranasal vaccination should block SARS-CoV-2 transmission at the source

By Frances E. Lund¹ and Troy D. Randall²

SCIENCE 23 JULY 2021

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COVID-19 Vaccine Commercial Analysis

Protein subunit vaccine pipeline

Late-stage Protein Subunit Vaccine Candidates vs. Orogenics' Terra Cov-2

Company	Company Type	Adjuvant	Route Admin.	Clinical Stage
Medigen	Taiwanese vaccine manufacturer	CpG 1018 (Dynavax)	Intramuscular (IM) injection	EUA (Taiwan)
Novavax	US public biotech	Matrix-M (Novavax)	IM injection	EUA (Indonesia)
Sanofi Pasteur	Big Pharma	AS03 (GSK)	IM injection	Phase 3
Clover	Chinese public biotech	CpG 1018 (Dynavax)	IM injection	Phase 3
SK Parma	Korean vaccine manufacturer	AS03 (GSK)	IM injection	Phase 3
Medicago	Canadian biotech	AS03 (GSK)	IM injection	Phase 3
Orogenics	US public biotech	TQL1055 (Adjuvance)	IM injection	Preclinical

EUA = Emergency Use Authorization

From WHO COVID-19 Vaccine Tracker: www.who.int/teams/blueprint/covid-19/covid-19-vaccine-tracker-and-landscape, dated 11/5/2021

- Six late-stage protein subunit candidates with adjuvants are progressing toward approval

- An additional 6 protein subunit candidates are in Phase 1 & 2 studies (from companies located in high-income countries)

- Given intense competition for protein subunit vaccines administered by intramuscular injection, Orogenics has decided to focus on its intranasal vaccine candidate

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COVID-19 Vaccine Commercial Summary

Terra CoV-2 commercial opportunity

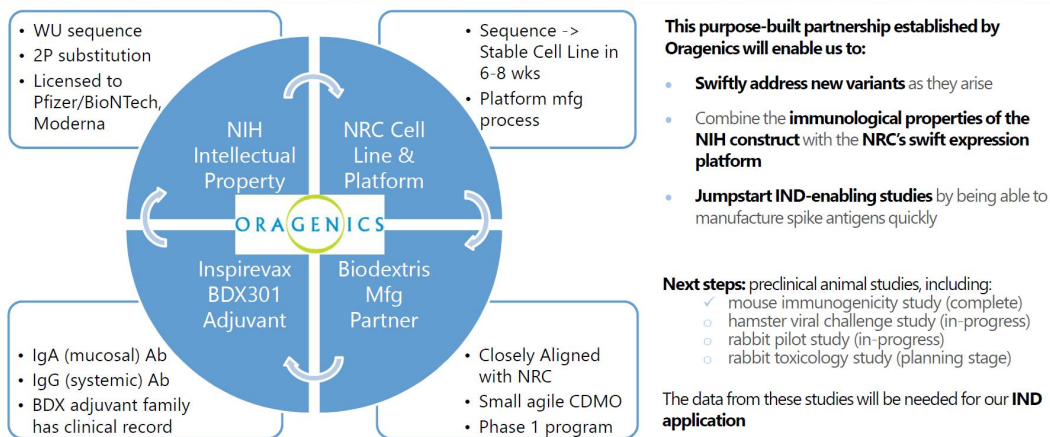
- **Focus on intranasal Terra CoV-2 candidate**
 - Less competition and more opportunities to differentiate
- **Establish first as preferred booster dose**
 - Reduce virus transmission at source of infection (mucosal surfaces)
 - Needle-free
 - Advantages of protein subunit intranasal vaccine versus live viral vaccines
- **Develop for routine childhood immunization**
 - Longer-term objective
 - Needle-free option appreciated by kids and parents
 - Easier to fit needle-free into crowded immunization schedule

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Terra CoV-2 Development Status

Differentiation & Rapid Response Through Multi-Partner Collaboration



Vaccine Program CMC Updates

Activity	Status
National Research Council of Canada (Licensor of Cell Line & Platform)	
• Important partner to Orogenics/Biodeltrix	Supporting R&D activities to de-risk development and critical path activities
• Areas of program support	Process -> Methods -> Characterization -> Cell Line Development -> R&D
• Clonal cell line development program	In-progress for Wuhan (WU) antigen; planned for Delta antigen
• Hamster Challenge Study	In-life completed; data anticipated Nov. 30 th
• Journal publication opportunity:	Orogenics-NRC-Inspirevax collaboration (NRC lead)
• GLP-Tox Enabling Pilot Rabbit Study	In-life on-going; data anticipated Dec. 30 th
Biodeltrix (Antigen Manufacturer)	
• 3 Stable Cell GMP Banks produced (WU+Beta+Delta)	In-Progress; Being Released
• Process & Methods tech transfer from NRC/Orogenics to Biodeltrix	Complete (process), In-Process (Methods)
• Materials Procurement	De-risked & largely complete
• Current focus of CMC activities; timing of IND submission	WU+IN administration; est. April 2022 (Delta available if needed)
Inspirevax (Adjuvant Technology)	
• GMP BDX301 availability	Available
• Nasal delivery device selection	In-Progress
• Final clinical kit fill/finish	Planning Stage

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Corporate Status Update

Capitalization

	<u>Common Stock Equivalents</u>		
Common Stock Outstanding	116,394,806	Cash	\$30.0M
Series A and Series B Convertible Preferred (As Converted)	2,261,703		
Warrants (WAEP \$1.42)	18,040,572		
Reserved for issuance under stock incentive plan	8,009,250		
Total	<u>144,706,331</u>		

The Information is as of September 30, 2021. The Series A and B Preferred stock have no price based down-round protection for the conversion price and carry no accrued dividend.

Company Summary

- SARS-CoV-2 spike protein vaccine technology licensed from NIH expected to enter human clinical studies in 2022; potential long-lasting protection against SARS-CoV-2, new variants and perhaps other coronaviruses
- NRC's swift expression platform in combination with NIH constructs accelerates high-yield production of spike protein antigens to combat existing and emerging variants
- Potentially improved vaccine access through development of intranasal delivery technology and adjuvant
- Multibillion-dollar market for COVID-19 vaccines likely to accommodate multiple players, particularly in the post-pandemic period
- Cash through 3Q22
- Novel class of peptide antibacterial compounds called lantibiotics
 - Activity against a variety of multidrug-resistant infections, believed to be the next human health crisis

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November 2021
