
**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, 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 7.01 Regulation FD Disclosure.

Oragenics, Inc. (“Oragenics” or the “Company”) will be using an investor presentation (the “Investor Presentation”) from time to time in connection with presentations 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.oragenics.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	Investor Presentation.

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, 2020.

ORAGENICS, INC.
(Registrant)

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

A blue-tinted microscopic image of cells, likely bacteria or viruses, serving as a background for the title text.

Developing Vaccines & Novel Antibiotics to Treat Tomorrow's Infections

Corporate Presentation

NYSE American: **OGEN**

November 10, 2020

Safe Harbor Statement

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.

Oragenics Company Description

Oragenics (NYSE American: OGEN) is a development stage company dedicated to fighting infectious diseases. It is focused on advancing its TerraCoV2 vaccine candidate to combat the novel coronavirus pandemic, leveraging coronavirus spike protein research licensed from the National Institutes of Health. It is also developing lantibiotics, a novel class of antibiotic, focused on combatting multidrug-resistant organisms.

Investment Highlights

1

Recent Acquisition of Noachis Terra provides access to NIH-created SARS-CoV-2 (COVID-19) Spike Protein Vaccine Technology
Expect to enter human clinical studies in mid 2021

2

Multi-billion market for COVID-19 vaccines likely to accommodate multiple players
Cash through early 2021

3

Lantibiotics Platform: A **novel class** of peptide antibacterial compounds, with activity against a variety of MDR infections
Lead lantibiotic OG716 addresses *C. difficile*



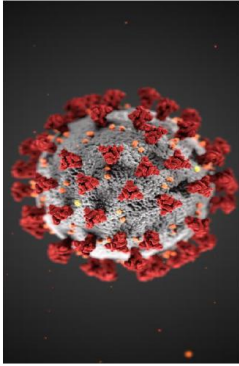


Lead Program:

NIH-created SARS-CoV2 S-2P (COVID 19) vaccine candidate focused on the stabilized "Spike Protein"



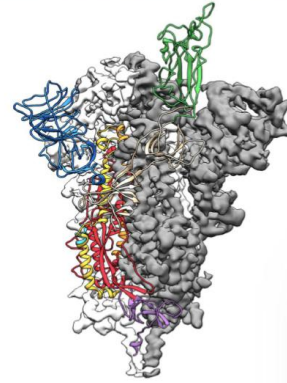
Overview



Objective: To develop and commercialize a vaccine providing long lasting immunity from SARS-CoV-2 infection focusing on the spike protein.

Benefits: Long lasting protection from SARS-CoV-2 virus, COVID-19 infection prevention, more rapid immune response, lower antigen concentration required.

Future: Potential cross protection against other coronaviruses.



The molecular structure of the spike protein.
Jason McLellan/Univ. of Texas at Austin

Corona Viruses Technology Overview – RSV F Protein: Spike Proteins Continually Changing Shape

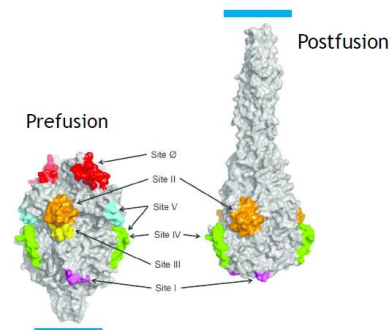
Accessible antigenic sites depend on protein conformation:

- Pre sites: O, V
- Post site¹: I
- Pre/post sites: II, III, IV

Absorption of human convalescent serum with postfusion F modestly reduces neutralizing antibodies

Absorption of human convalescent serum with prefusion F removes almost all neutralizing antibodies

1. MAbs to site 1 preferentially bind postfusion conformation

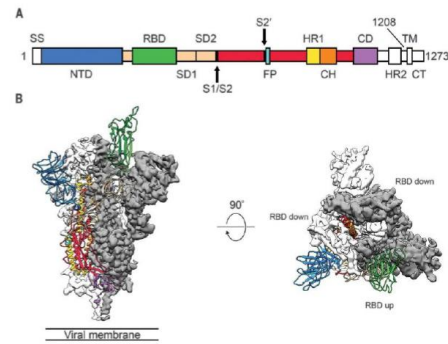


Flynn et al, PLOS ONE | DOI:10.1371/journal.pone.0164789 Oct. 20, 2016

Corona Virus Technology Overview – Enhanced Immune Response Utilizing Stabilized Spike Protein Antigen

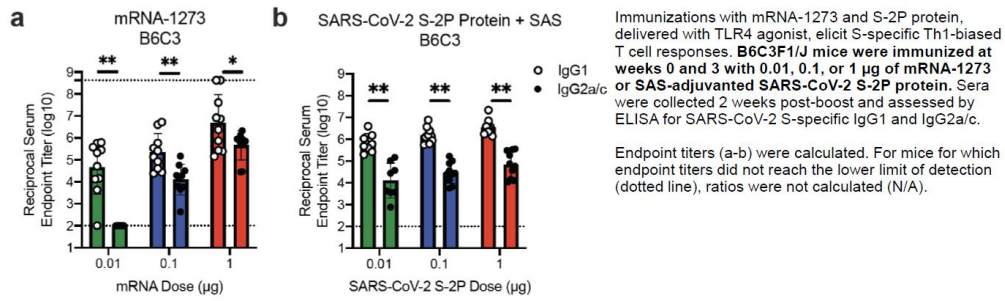
Stabilized Prefusion Spike Protein Ectodomain Trimer

- Class I fusion protein
- Two amino acid substitutions stabilize prefusion conformation
- T4 fibrin trimerization domain
- Expressed in mammalian cell line; Chinese Hamster Ovary (CHO) cells



Daniel Wrapp et al. Science 2020; 367:1260-1263

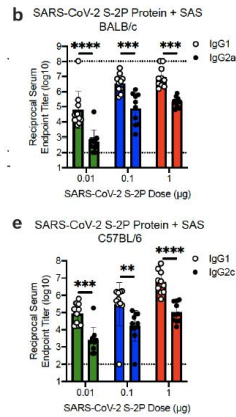
SARS-CoV-2 S-2P IgG subclass Results: B6C3 Mice



SARS-CoV-2 S-2P protein with SAS adjuvant produces significant and balanced IgG1 and IgG2_{a/c} levels at doses as low as 0.01 µg demonstrating level of immune response.

Corbett *et al*, BioRxiv. 2020. <https://www.biorxiv.org/content/10.1101/2020.06.11.145920v1>

SARS-CoV-2 S-2P IgG subclass Results: BALB/c and C57BL/6 Mice



SAS-adjuvanted S-2P protein elicit both IgG2a and IgG1 subclass S-binding antibodies. BALB/cJ (b) or C57BL/6J (e) mice were immunized at weeks 0 and 3 with 0.01 (green), 0.1 (blue), or 1 µg (red) of SARS-CoV-2 S-2P protein adjuvanted with SAS. Sera were collected 2 weeks post-boost and assessed by ELISA for SARS-CoV-2 S-specific IgG1 and IgG2a or IgG2c for BALB/cJ and C57BL/6J mice, respectively.

Similar significant and balanced IgG1 and IgG2_a or IgG2_c titers were also observed in BALB/c and C57BL/6 mice immunized with SARS-CoV-2 S-2P protein with SAS adjuvant indicating the immune response is robust and seen in a second strain of mouse.

SARS-CoV-2 S-2P Neutralization Titers

Extended Data Table 1. Concordance of Pseudovirus Neutralization Assay and PRNT.

Mouse Serum Pool # ¹	Reciprocal IC ₅₀ Titer		<i>Fold Difference</i> ⁴
	Pseudovirus Neutralization ²	PRNT ³	
1	893.5 +/- 1.4	933.5	1.0
2	211.6 +/- 1.5	314.5	0.7
3	159.8 +/- 1.3	397.1	0.5

1. BALB/cJ mice were immunized at weeks 0 and 3 with 1 µg SARS-CoV-2 S-2P protein, adjuvanted with SAS. Sera were collected 2 weeks post-boost and pooled (N = 3 mice/pool).

2. IC50 titers were averaged from pseudovirus neutralization assays completed in 5 experimental replicates. (GMT +/- geometric SD)

3. IC50 titer from PRNT assay completed once.

4. Fold difference calculated as average pseudovirus neutralization IC50 titer relative to PRNT IC50 Titer

SARS-CoV-2 S-2P protein with SAS adjuvant produces significant Nab titers in BALB/c mice.

Well Established Production Process for Terra Cov-2 Vaccine Creation

Creation of Antigen Producing cell line (CHO) (Aragen)



Production of Antigen under GMP (Avid)



Addition of FDA approved Adjuvant



Completion of Fill/Finish (Catalent)

Examples of recombinant protein + Adjuvant
Hepatitis B
HPV

Key Vaccine Attributes

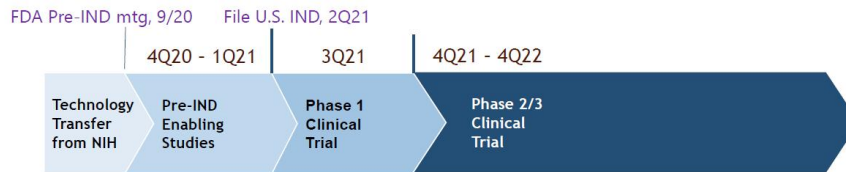
- Well established vaccine product characteristics: recombinant protein + adjuvant (Hep B, HPV, Influenza vaccines)
- Potential for single dose efficacy (based on Phase 1 results)
- Provided in pre-filled syringes – ease of use.....
- Storage and transport at refrigerated (5°C) temperatures: not -50° to -80°C
- Advantage for remote locations, particularly in 2nd and 3rd tier countries
- Designed for availability and use post-pandemic distribution

Technology Overview – Current Status

- NIH/NIAID license secured with acquisition of Noachis Terra
- Non-dilutive grants, primarily DoD, under development
- Contracts in place for:
 - Cell bank manufacture
 - Vaccine manufacture
 - Clinical Research Organization & Regulatory Consultants
- **Creation of cell line complete**
- **Development of analytical methods and transfer to manufacturing facility underway**
- **FDA pre-IND meeting complete**

Regulatory Strategy: Aggressive Fast Track Approach

Proposed Clinical Trial Pathway and Timeline



Assumptions:

1. RCB used as GMP cell line
2. Pilot batch acceptable for IND and Phase 1
3. Toxicology study report initially filed with clinical only

Why Invest Now? Vaccine News Flow

- 1Q21:
 - Release of NIH confidential viral load data
 - Completion of mouse immunogenicity study
 - Completion of hamster challenge study
 - Announcement of adjuvant access deal
- 2Q21:
 - Complete creation of Master Cell Bank for GMP production
 - File IND and initiate Phase 1 clinical study activities
- 3Q21
 - Non-dilutive funding or partnership?

A blue-tinted microscopic image of bacteria, showing several rod-shaped cells with textured surfaces. The text "Novel Lantibiotic Platform for Multidrug Resistant Bacterial Infections" is overlaid in white.

Novel Lantibiotic Platform for Multidrug Resistant Bacterial Infections

2019 CDC List of Antibiotic Resistant Bacteria and Fungi

Urgent Threats

- [Carbapenem-resistant *Acinetobacter*](#)
- [Candida auris](#)
- [Clostridioides difficile](#)
- [Carbapenem-resistant Enterobacteriaceae](#)
- [Drug-resistant *Neisseria gonorrhoeae*](#)

Serious Threats

- [Drug-resistant *Campylobacter*](#)
- [Drug-resistant *Candida*](#)
- [ESBL-producing Enterobacteriaceae](#)
- [Vancomycin-resistant Enterococci \(VRE\)](#)
- [Multidrug-resistant *Pseudomonas aeruginosa*](#)
- [Drug-resistant nontyphoidal *Salmonella*](#)
- [Drug-resistant *Salmonella* serotype Typhi](#)
- [Drug-resistant *Shigella*](#)
- [Methicillin-resistant *Staphylococcus aureus* \(MRSA\)](#)
- [Drug-resistant *Streptococcus pneumoniae*](#)
- [Drug-resistant Tuberculosis](#)

Concerning Threats

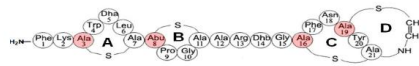
- [Erythromycin-Resistant Group A *Streptococcus*](#)
- [Clindamycin-resistant Group B *Streptococcus*](#)

Watch List

- [Azole-resistant *Aspergillus fumigatus*](#)
- [Drug-resistant *Mycoplasma genitalium*](#)
- [Drug-resistant *Bordetella pertussis*](#)

Lantibiotics: Novel Platform of Antibiotics to Treat Serious Life-Threatening Infections

- 19



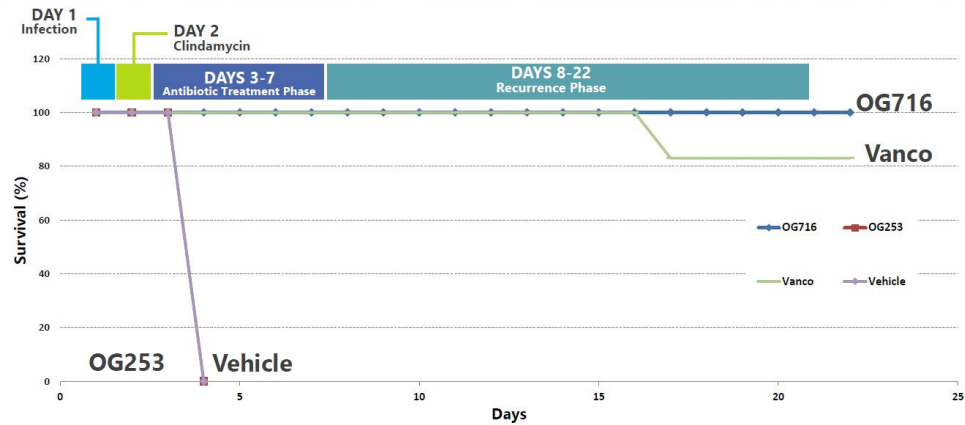
Mutacin 1140: a lantibiotic produced by *Streptococcus mutans*

C. difficile and *C. difficile* Infection (CDI): Epidemiology

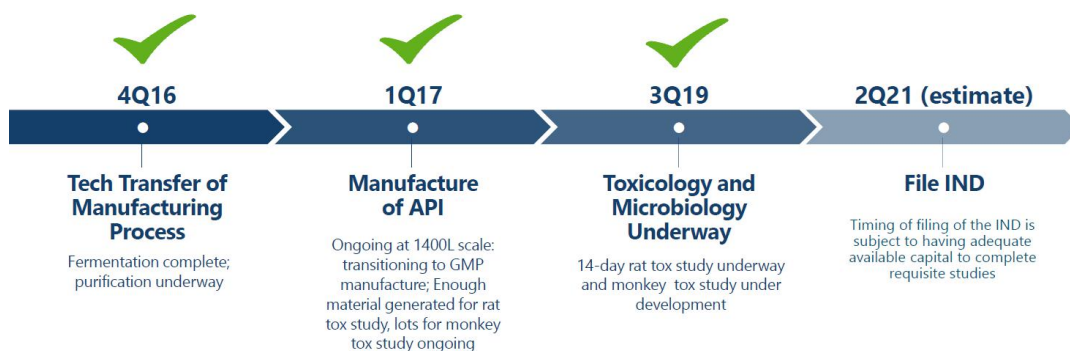
- *C. difficile* is an infection of the colon causing colitis by producing toxins that damage lining of the colon
- 223,900 infections annually resulting in 12,800 deaths
- 83,000 will experience at least one recurrence
- Healthcare-associated infections occur: 37% hospital onset, 36% nursing home onset, and 27% community onset
- *C. difficile* associated diarrhea is associated with a 1-2 week hospital stay at a cost of \$1BN/year
- **Emerging problem:** 8% of CDI associated with onset of concomitant Vancomycin Resistant Enterococci (VRE) infection



Oral OG716 Superior at Preventing *C. difficile* Deaths in Hamster Model



Lantibiotics: OG716 *C. difficile* Program Milestones





Corporate Status Update

Capitalization

	<u>Common Stock Equivalents</u>		
Common Stock Outstanding ⁽¹⁾	61,004,917	Cash	\$10.0M ⁽³⁾
Series A and Series B Convertible Preferred (As Converted)	2,261,703		
Series C Non-Convertible Perpetual Preferred ⁽²⁾ (113,941 shares outstanding)	-		
Warrants (WAEP \$1.36) ⁽¹⁾	20,513,145		
Reserved for issuance under stock incentive plan	8,009,250		
Total	91,789,015		

(1) Information is as of September 30, 2020.

(2) As of September 30, 2020, the Non-Voting, Non-Convertible Series C Preferred Shares have a stated value of \$33,847 per share and have an accruing dividend of 20% per year. The Series C Preferred Shares resulted from the conversion of approximately \$3.3 million in debt obligations previously owed to Precigen (fka: Intrexon). The Series A, B, and C Preferred stock have no price based downround protection for the conversion price.

(3) Information is as of September 30, 2020.

Near Term Milestones



3Q20

- Complete CHO cell line Vaccine Development
- Initiate Vaccine CDMO work
- Complete FDA pre-IND meeting for Vaccine Candidate

4Q20

- Initiate pre-clinical studies for Vaccine Candidate
- Advance Vaccine GMP manufacture at CDMO
- Initiate building of CHO MCB for the Vaccine

2Q21

- File IND for Vaccine
- Initiate Phase 1 Clinical Study

2Q21

- File IND for OG716

Investment Summary

- License to NIH-created SARS-CoV-2 Spike Protein Vaccine Technology set to enter human clinical studies in early 2021; potential for long lasting protection for SARS-CoV-2 and other coronaviruses
- \$Multi-billion market for COVID-19 vaccines likely to accommodate multiple players
- Cash through early 2021; Federal Grants for COVID-19 under review
- Novel class of peptide antibacterial compounds called Lantibiotics
 - Activity against a variety of MDR infections, believed to be the next human health crisis
 - Lead lantibiotic OG716 addresses *C. difficile* – a significant infection identified by the CDC.

Experienced Management Team

Dr. Alan F. Joslyn

Director, President and Chief Executive Officer

- Assumed CEO position at Oragenics in June 2016
- Held CEO positions at several private biotechnology companies including Sentinella Pharmaceuticals, Edusa Pharmaceuticals and Mt. Cook Pharma
- Over 25 years of drug development experience at Glaxo, Johnson & Johnson and Perwest

Mike Sullivan

Chief Financial Officer

- Held senior-level financial positions for both publicly and privately held businesses
- Significant experience in product licensing and IP issues with strong background in both domestic and international retail operations

Dr. Martin Handfield

Senior Vice President, Discovery Research

- Molecular Microbiologist and former Tenured Associate Professor, College of Dentistry at The University of Florida
- Prolific researcher focusing on infectious diseases, host-pathogen interactions and non-invasive diagnostics

Experienced Management Team

Dr. David Zarley

Consultant

- More than 30 years in vaccine research and development in the private sector
- Vice-President of Program Management for Vaccine Research and Development at Pfizer
- Senior Director /Medicines Team Leader for Pfizer Primary Care Business Unit
- Senior Director for Wyeth Research Project Management Business Unit
- Senior Director for Technical Operations and Product Supply (TOPS) at Wyeth Vaccines
- Senior Research Biochemist / Project Leader for Viral Vaccine Research and Development at Lederle-Praxis Biologicals

Oragenics, Inc.
4902 Eisenhower Blvd., Suite 125
Tampa, FL 33634
www.oragenics.com



For More Information

Corporate
Alan F. Joslyn PH.D.
President & CEO
813 286 7900 ext 232
ajoslyn@oragenics.com

Investors:
John Marco
Managing Director
CORE IR
516-222-2560
johnm@coreir.com

Media:
Jules Abraham
CORE IR
917-885-7378
julesa@coreir.com

NYSE American: **OGEN**

November 10, 2020
