
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: March 9, 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") will be making an electronic investor presentation (the "Investor Presentation") on March 9, 2021. The Company also expects to use the Investor Presentation from time to time thereafter 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.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 8.01. Other Information.

On March 9, 2021, the Company issued a press release announcing that it had entered into material transfer agreement with Biodextris Inc. for mucosal adjuvant for intranasal COVID-19 vaccine.

A copy of the press release is attached as Exhibit 99.2 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	<u>Investor Presentation.</u>
99.2	<u>Press Release dated March 9, 2021.</u>

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 9th day of March, 2021.

ORAGENICS, INC.
(Registrant)

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



Developing Vaccines & Novel Antibiotics to Treat Tomorrow's Infections

Corporate Presentation

NYSE American: **OGEN**

March 2021

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, Covid-19, 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.

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Company Highlights

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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 3/4Q 2021

2

Multi-billion market for COVID-19 vaccines likely to accommodate multiple players
Cash runway for vaccine to begin Phase 2 studies in 1Q22

3

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

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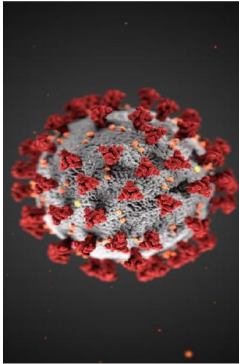
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Lead Program:

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

Overview



Objective: To develop and commercialize an intranasal 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, reduced viral spread, more rapid immune response, lower antigen concentration required.

Future: Potential cross protection against other coronaviruses and Covid-19 variants.



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

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

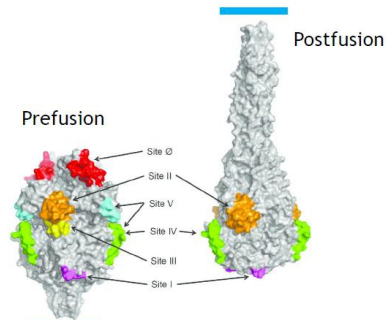
Accessible antigenic sites depend on protein conformation:

- 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

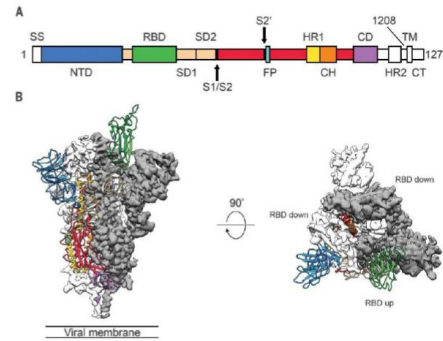
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Corona Virus Technology Overview – Enhanced Immune Response Utilizing Stabilized Spike Protein Antigen

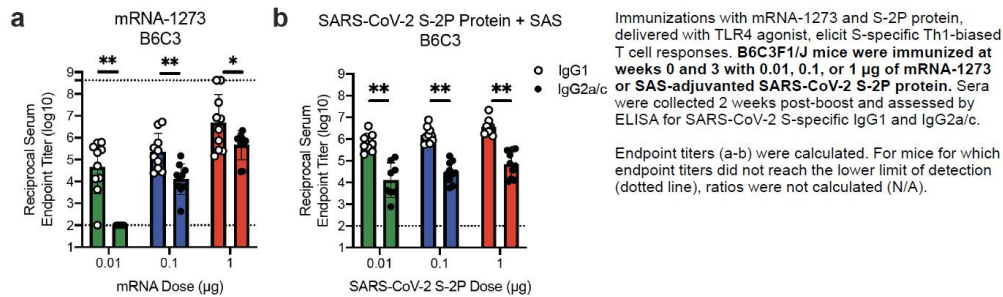
Stabilized Prefusion Spike Protein Ectodomain Trimer

- 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 Neutralization Titers

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

Mouse Serum Pool # ¹	Reciprocal IC ₅₀ Titer		Fold Difference 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)

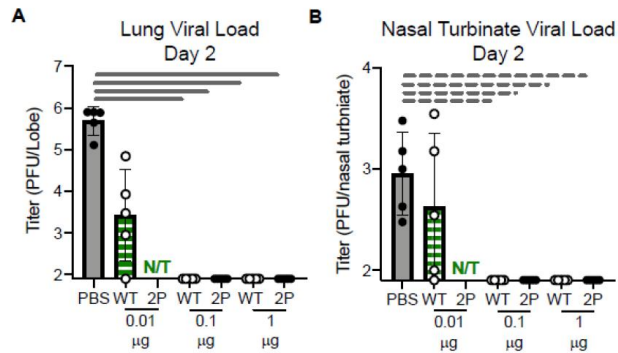
3. IC₅₀ titer from PRNT assay completed once.

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.

SARS-CoV-2 Spike Protein Demonstrates Protective Immunity in Mice

Completely inhibited virus growth in the nasal cavities and lungs of mice



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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 Adjuvant (TQL1055 or Intranasal BDX100, BDX 300, BDX 301)

Completion of Fill/Finish (BSM/Sharp)

Examples of recombinant protein + Adjuvant
Hepatitis B
HPV

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Key Vaccine Attributes

- Well established vaccine product characteristics: recombinant protein + adjuvant (Hep B, HPV, Influenza vaccines)
- **Intranasal Delivery – ideal for children and self administration**
- Potential for **single dose** efficacy (based on Phase 1 results)
- **Low COGs** based on production scheme
- Storage and transport at **refrigerated (5°C) temperatures**: not -50° to -80°C
- Access to **novel rationally designed adjuvant**
- Advantage for remote locations, particularly in 2nd and 3rd tier countries – allows for self administration
- Designed for availability and use post-pandemic distribution

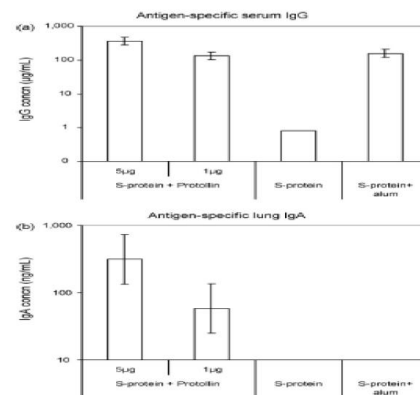
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Intranasal Vaccine Attributes

- BDx100 (Protollin), BDx 300 & BDx 301 developed by Biodextris
- Intranasal delivery of adjuvant stimulates production of IgA in the nasal cavity
 → Reduces spread of virus
- Systemic IgG production reduces severity of Covid-19 infection
- Ease of use ideal for children and populations adverse to needles
- Ease of transport and storage at refrigerated (5°C) temperatures and advantage in Tier 2 & 3 countries through self-administration
- Adjuvant technology originally developed at Walter Reed Army Research Hospital and licensed through GSK

Serum IgG & Lung IgA levels in Mice following S-protein SARS-COV-1



M.C. Hu et al. / Vaccine 25 (2007) 6334–6340

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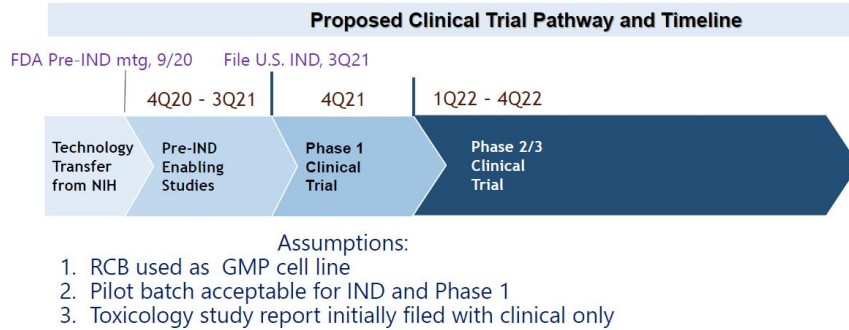
Technology Overview – Current Status

- 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
 - Formulation & fill/finish
 - Adjuvant agreement for preclinical studies, including hamster challenge
- **Creation of cell line complete**
- **Development of analytical methods ongoing**
- **Recombinant protein production at manufacturing facility ongoing**
- **FDA pre-IND meeting complete**

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Regulatory Strategy: Aggressive Fast Track Approach



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Vaccine News Flow

- 1/2Q21:
 - ✓ Release of NIH viral load data
 - ✓ Announcement of adjuvant access deal, including intranasal adjuvant delivery through Biodextris
 - Initiation of mouse immunogenicity study
 - Initiation of hamster challenge study
- 3/4Q21:
 - Complete creation of Master Cell Bank for GMP production
 - File IND and initiate Phase 1 clinical study activities
- 3/4Q21
 - Non-dilutive funding or partnership?

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Novel Lantibiotic Platform for Multidrug Resistant Bacterial Infections

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*

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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

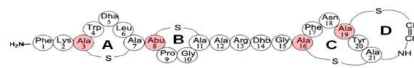


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Lantibiotics: Novel Platform of Antibiotics to Treat Serious Life-Threatening Infections

- Lantibiotics are a novel class of peptide antibacterial compounds naturally produced by a variety of Gram-positive bacterial strains to attack competing bacterial strains
- Platform: >700 lantibiotic structures created, potentially generating a pipeline of new compounds
- Platform provides potential for development in multidrug resistant infections:
 - Methicillin Resistant *Staphylococcus aureus* (MRSA)
 - Vancomycin Resistant Enterococci (VRE)
 - Virulent *Clostridium difficile*
 - Gram(-) infections

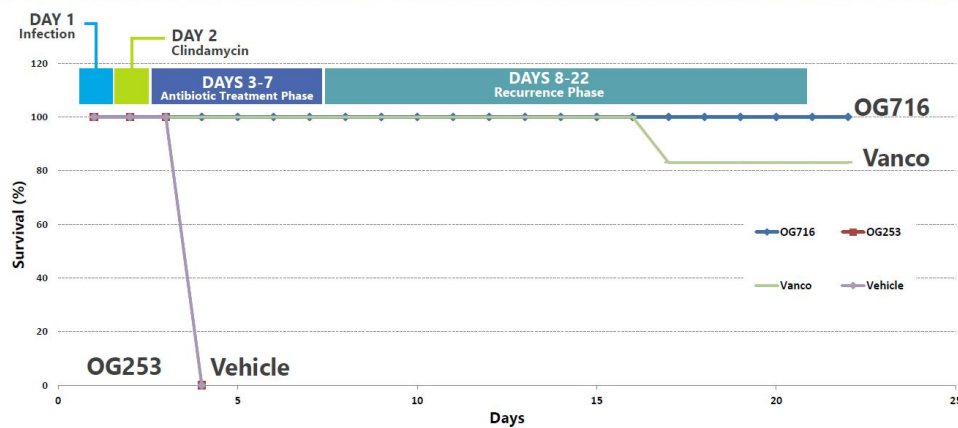


Mutacin 1140: a lantibiotic produced by *Streptococcus mutans*

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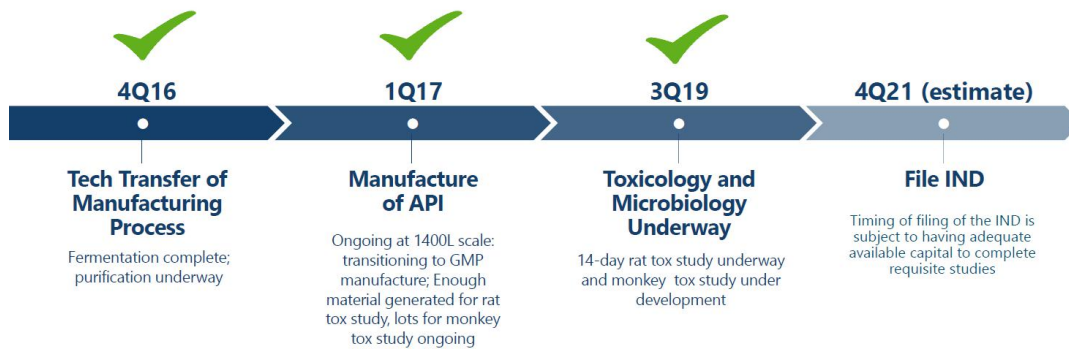
Oral OG716 Superior at Preventing *C. difficile* Deaths in Hamster Model



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Lantibiotics: OG716 *C. difficile* Program Milestones



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Corporate Status Update

Capitalization

	Common Stock Equivalents		
Common Stock Outstanding	109,646,119	Cash	\$33.5M
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	137,957,644		

The Information is as of February 25, 2021 and includes 15,406,618 shares of common stock issued in February as a result of the ATM offering (providing net proceeds of approximately \$19.2 million) and 2,472,573 shares of common stock issued in February as a result of warrant exercises (providing proceeds of approximately \$2.2 Million) and reflects the notice of redemption of all outstanding shares of Series C Preferred Stock for cash of approximately \$5.6 million. The Series A and B Preferred stock have no price based down-round protection for the conversion price and carry no accrued dividend.

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Near Term Milestones



1/2Q21

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

3/4Q21

- File IND for Vaccine
- Initiate Phase 1 Clinical Study

4Q21

- File IND for OG716 (tentative)

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Company Summary

- License to NIH-created SARS-CoV-2 Spike Protein Vaccine Technology set to enter human clinical studies in 2021; potential for long lasting protection for SARS-CoV-2 and new variants and potentially other coronaviruses
- Improved vaccine access through development of Intranasal delivery technology and adjuvant
- Multi-billion market for COVID-19 vaccines likely to accommodate multiple players, particularly in the post-pandemic period
- Cash through 1Q22; 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.

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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 Penwest

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

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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

Terrence Cochrane Consultant

- More than 20 years experience life science industry; Founder of consulting firm, BrevisRefero
- Extensive experience in Quality Assurance, Quality Control, Validation, Manufacturing Operations, Process Development, Project Management and Business Development
- Contributed to CMC portfolios of 5 commercial products and 30 biopharmaceutical clinical trial programs

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Tampa, FL 33634
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For More Information

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NYSE American: **OGEN**

March 2021



Oragenics Enters into Material Transfer Agreement with Biodextris for Mucosal Adjuvant for Intranasal COVID-19 Vaccine

TAMPA, Fla. (March 9, 2021) – Oragenics, Inc. (NYSE American: OGEN) (“Oragenics” or the “Company”) announced it has entered into a material transfer agreement with Biodextris Inc. for the use of three intranasal mucosal adjuvants in the Company’s Terra CoV-2 vaccine against COVID-19. Adjuvants are added to vaccines to enhance their immunogenicity. 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.

The initial agreement calls for the three intranasal adjuvants to be used in combination with the Oragenics’ 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. The information generated from the studies employing the new intranasal vaccine candidate would potentially support the U.S. Food and Drug Administration (“FDA”) Investigational New Drug (“IND”) application and an application to Health Canada to initiate clinical trials. The agreement allows for the future collaboration regarding the intranasal delivery of vaccine during clinical development with the opportunity to enter into a commercial agreement upon regulatory approval of the intranasal vaccine.

The Terra CoV-2 vaccine plus Biodextris’ intranasal mucosal adjuvants will be studied in the preclinical animal studies, including hamster viral challenge studies, mouse immunogenicity studies and the rodent toxicology study required for regulatory approval prior to the initiation human testing.

“This material transfer agreement both expands and advances the development of our Terra CoV-2 vaccine with a novel delivery option,” said Alan Joslyn, Ph.D., President and Chief Executive Officer of Oragenics. “The Biodextris intranasal mucosal adjuvants in combination with the Oragenics antigen open up new possibilities for a vaccine that could potentially be a more effective and convenient option than those currently available. Given the benefits of intranasal administration along with Terra CoV-2’s other advantages, including the potential to be stored and distributed at refrigerated temperatures, we believe there is significant opportunity to help address the worldwide COVID-19 pandemic, particularly in the post-near term immunization phase where booster shots and potential effectiveness against a variety of Covid-19 variant strains may continue to be required.”

Joseph Zimmermann, President of Biodextris, added, “We are delighted to partner with Oragenics on exploring the potential of their Terra CoV-2 vaccine. Our proteosome-based compounds can be powerful adjuvants and offer several advantages, including the ability to elicit both mucosal and serum antibodies while offering innate and adaptive immunity.”

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 announced that its spike protein had been successfully inserted into Chinese Hamster Ovary (“CHO”) cells production and analytical development are underway. CHO cells are used to produce a number of FDA-approved recombinant proteins.

About Biodextris Inc.

Based in Laval, Québec, Biodextris is a contract research organization providing a suite of analytical, process development and CMC consulting services for vaccines and biologics in the clinical stages of development. The company’s expertise, facilities and quality systems support clients to confidently navigate a path from R&D to early-phase clinical trials. For more information, visit: www.biodextris.com.

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 diseases. 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 Institutes of Health. In addition, Oragenics has an exclusive worldwide channel collaboration with Eleszto Genetika, Inc. relating to the development of novel lantibiotics.

For more information about Oragenics, please visit www.oragenics.com.

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 including in potential combination with a nasal mucosal adjuvant; the Company’s ability to obtain funding, non-dilutive or otherwise, for the development of Noachis Terra’s Terra CoV-2 vaccine and adjuvant products, 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 including adjuvants; the Company’s expectations as to storage, administration and distribution, potential market and impact of other vaccines being administered; 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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