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: April 19, 2022
(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 7.01 Regulation FD Disclosure.

Oragenics, Inc. ("Oragenics" or the "Company") expects to use the investor presentation (the "Investor Presentation") on April 19, 2022 in connection with presentations at the World Vaccine Congress Washington, 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.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.
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 19th day of April, 2022.

ORAGENICS, INC.
(Registrant)

BY: */s/ Michael Sullivan*
Michael Sullivan
Interim Principal Executive Officer
and Chief Financial Officer

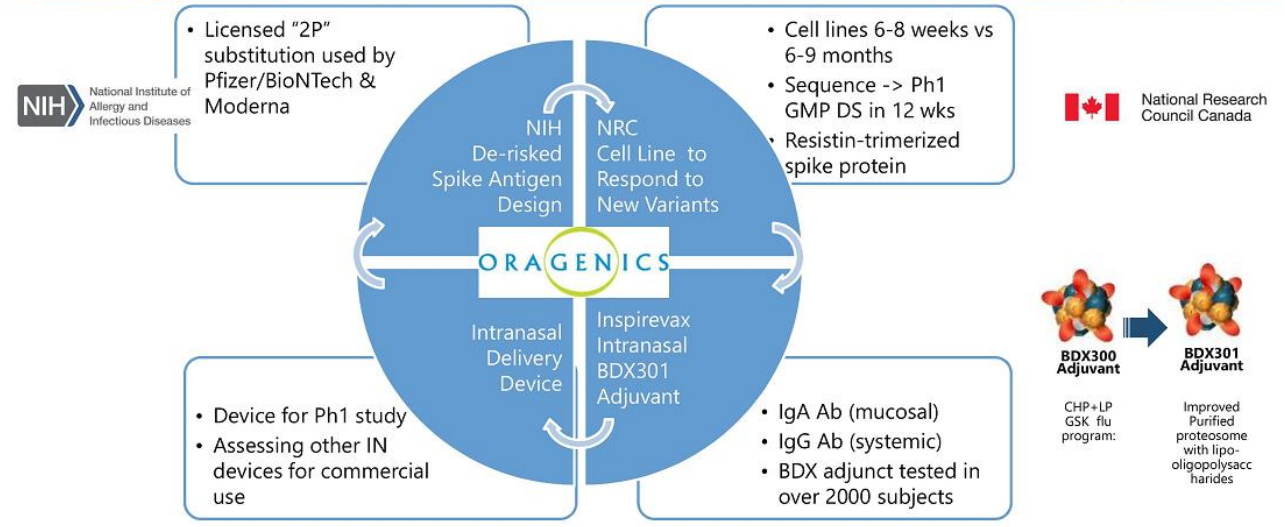
Exhibit 99.1

April 18-22, 2022
NYSE: OGEN

Oragenics Summary

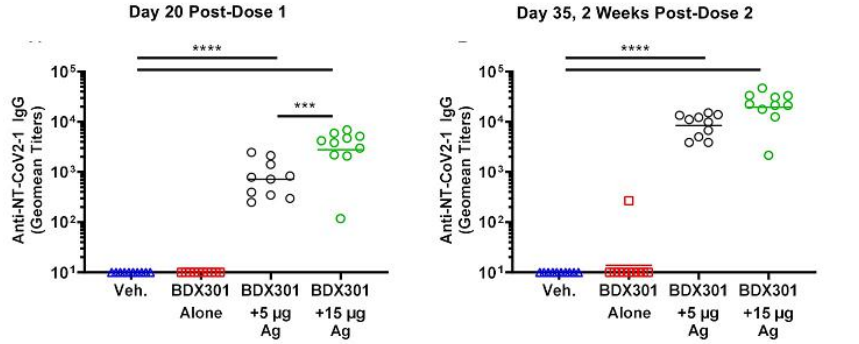
- **Lead Asset: NT-CoV2-1**
  - Licensed from NIH – two-proline substitution of SARS-CoV-2 spike protein
- **NT-CoV2-1 Intranasal Vaccine Differentiation and Advantages**
  - Patient-friendly, needle-free administration
  - May reduce virus transmission at source of infection (mucosal nasopharyngeal surfaces)
  - Protein subunit-based intranasal vaccine approach versus live viral intranasal vaccine
  - Small intranasal competitive landscape, others need to prove new vector safety
  - NRC Platform allows rapid production of cell lines in 6-8 weeks
- **Animal Studies Demonstrated High Immunogenicity & Strong Neutralizing Activity**
  - Intranasal formulation led to high IgG and IgA anti-spike protein titers in blood and lungs of mice
  - Undetectable viral loads in hamsters nasal turbinates and lungs; significant reduction of weight loss
  - Prevented the cellular binding of the viral Spike protein based on the ancestral reference strain
- **Ongoing IND-enabling GLP-Tox Study in Rabbits, Phase 1 expected this year**

NT-CoV2-1 Combines Four Technologies



Hamster Study Results – NRC/Oragenics

Intranasal formulation led to high IgG anti-spike protein titers

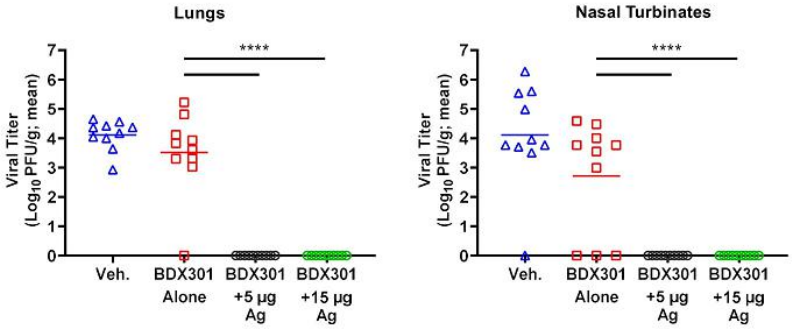


Anti-Spike IgG titers induced by SmT1v3 antigen and BDX301 adjuvant formulations in hamsters. Syrian Golden hamsters (n=10/group) were immunized twice on Days 0 and 21 with PBS (vehicle control, Veh.) with BDX301 (5 µg) with or without SmT1v3 (5 µg or 15 µg) via the intranasal route. Serum collected on Day 20 and Day 35 were analyzed by ELISA to determine the levels of antigen-specific IgG titers. Antibody titers are expressed as a reciprocal value of the serum dilution calculated to generate an OD450 = 0.2. For statistical analysis, antibody titers were log-transformed and then analyzed by a one-way ANOVA with Tukey's multiple comparisons test. ***: $p<0.001$, ****: $p<0.0001$. SmT1v3 antigen is based on the original Wuhan sequence incorporating the NIH 2P substitution and the NRC resistin trimerization.

Stark et al., bioRxiv, March 2, 2022, https://doi.org/10.1101/2022.03.02.482651

Hamster Study Results – NRC/Oragenics

Intranasal formulation led to undetectable viral loads



Efficacy of SmT1v3 and BDX301 formulations against SARS-CoV-2 viral challenge in hamsters. Syrian Golden hamsters were immunized twice on Days 0 and 21 with PBS (vehicle control, Veh.) delivered intramuscularly or BDX301 (5 µg) with or without SmT1v3 (5 or 15 µg) via the intranasal route. On Day 42 all hamsters were challenged with 1 x 10^5 PFU of SARS-CoV-2. On Day 47, hamsters were euthanized, and viral titers were quantified in lung and nasal turbinates by plaque assay. For statistical analysis, a one-way ANOVA with Tukey's multiple comparisons test was performed. ****: p<0.0001. SmT1v3 antigen is based on the original Wuhan sequence incorporating the NIH 2P substitution and the NRC resistin trimerization.

Stark et al., bioRxiv, March 2, 2022, https://doi.org/10.1101/2022.03.02.482651

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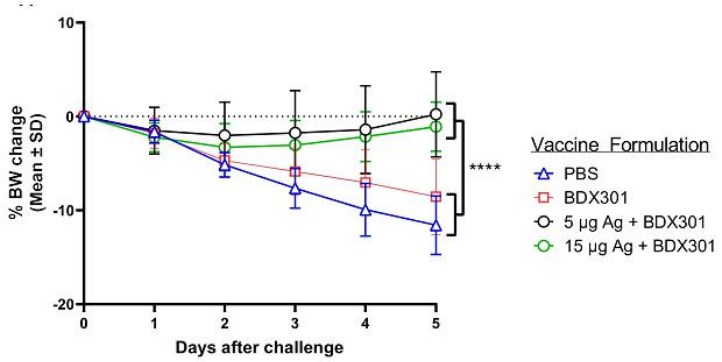
Hamster Study Results – NRC/Oragenics

Intranasal formulation decreased body weight loss



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Stark et al., bioRxiv, March 2, 2022, https://doi.org/10.1101/2022.03.02.482651

Intranasal COVID-19 Vaccines

Potential benefits of intranasal COVID vaccines

- **Intranasal vaccines may address limitations of current vaccines**
  - Waning efficacy requiring third (and fourth) doses for new VOCs
  - Transmission remains a concern due to high nasopharyngeal viral loads
    - Recent study in healthcare workers in Israel during Omicron VOC shows limitations of mRNA vaccines[1]
    - 4th dose efficacy against any infection was 30% Pfizer/BioNTech vaccine (95% CI -9% to 55%) and 11% for the Moderna vaccine (95% CI -43% to 44%)
    - Authors conclusion: "next generation vaccines may be needed to provide better protection against infection with highly transmissible future variants"[2]
  - Intranasal vaccines could reduce nasopharyngeal viral loads vs. IM vaccines
- **Intranasal vaccines offer needle-free option**
  - 1 in 4 adults and 2 out of 3 children have strong needle fears[3]
  - 10% of people may delay COVID-19 vaccine due to fear of needles[3]

1. Regev-Yochay et al., NEJM, March 16 2022, https://doi.org/10.1056/NEJMc2202542
2. Regev-Yochay et al., medRxiv, posted Feb 15 2022, https://doi.org/10.1101/2022.02.15.22270948
3. www.cdc.gov/childrensmentalhealth/features/needle-fears-and-phobia.html

Appendix

COVID-19 Vaccine Commercial Analysis

Intranasal vaccine pipeline is limited

Intranasal Vaccine Candidates vs. Oragenics' NT-CoV2-1

Organization	Organization Type	Vaccine Type	Stage	Comments
Precision Viralogics/ Bharat Biotech	US biotech/Indian manufacturer	Live chimpanzee adenovirus vector	Phase 2	Indian-made vaccines unlikely to be approved in US/EU
Codagenix/Serum Institute of India	US biotech/Indian manufacturer	Live attenuated SARS-CoV-2 virus	Phase 1	Hard to establish safety of live, attenuated SARS-CoV-2 vaccine
Oxford University/ Astra Zeneca	UK university/ Big Pharma	Live chimpanzee adenovirus vector	Phase 1	Known AEs (blood clots) may hinder approval & acceptance in US/EU
Meissa Vaccines	US private biotech	Live respiratory syncytial virus vector	Phase 1	Need to establish safety of new viral vector
CyanVac	US private biotech	Live parainfluenza-5 virus vector	Phase 1	Need to establish safety of new viral vector
Mt. Sinai, NY	US academic medical center	Live Newcastle disease viral vector	Phase 1	Need to establish safety of new viral vector
Oragenics	*US public biotech*	*Protein subunit + BDX-301 adjuvant*	*Late preclinical*	*Non-viral intranasal vaccine candidate*
Intravacc	*Netherlands private CDMO*	*Protein subunit + OMV adjuvant*	*Late preclinical*	*Non-viral intranasal vaccine candidate*

From WHO COVID-19 Vaccine Tracker: www.who.int/teams/blueprint/covid-19/covid-19-vaccine-tracker-and-landscape, dated March 8, 2022
List excludes 4 vaccine candidates from Cuba, Hong Kong University, Iran and Mexican veterinary vaccine company.

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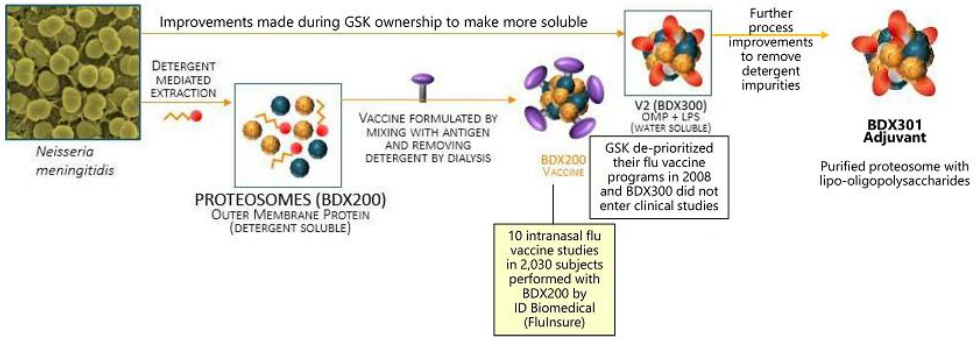
BDX301 Intranasal Adjuvant

Positive clinical data for adjuvant family & improved processes



WRAIR Walter Reed Army Institute of Research → Intellivax Spin-out based on George Lowell's work at WRAIR → Acquired 2001 → ID BIOMEDICAL → Acquired 2005 → gsk → Spun out 2015 → biodextris BRINGING INNOVATION TO LIFE → Spun out 2021 → Inspirevax Owner of BDX301 adjuvant

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Oragenics Team

- **Terry Cochrane – CMC**
  >20 years biopharmaceutical development and GMP manufacturing experience
- **Tim Cooke PhD, MBA – Commercial**
  >30 years vaccine industry experience at Merck, CEO NovaDigm & Mojave Therapeutics, COO AVANT Immunotherapeutics, National Vaccine Advisory Committee 2015-2023, CARB-X Advisory Board, WHO Tech Advisory Group for AMR Vaccines
- **Marty Handfield PhD – Preclinical/Tox**
  13 years as SVP Research, Oragenics & Associate Professor, U. Florida
- **Consultant – CMC**
  >30 years vaccine industry experience at Merck, CSO NovaDigm Therapeutics, extensive experience in global health vaccine projects with Gates Foundation and PATH
- **Robert House PhD – USG Contracts**
  >30 years industry experience, President DynPort Vaccines, SVP Ology Bioservices, Covance, IITRI
- **Florian Schödel MD – Clinical/Regulatory**
  >30 years academic, government & vaccine industry experience, including Max Planck, WRAIR, INSERM and Merck, provides clinical/regulatory support for multiple vaccine companies, including COVID-19 vaccine programs
- **David Zarley PhD– Preclinical/Tox & Clinical Assays**
  >30 years vaccine industry experience at Lederle/Wyeth/Pfizer, including development of the intranasal FluMist vaccine, consulted for Noachis Terra on their COVID-19 vaccine