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: October 3, 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") from time to time with 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

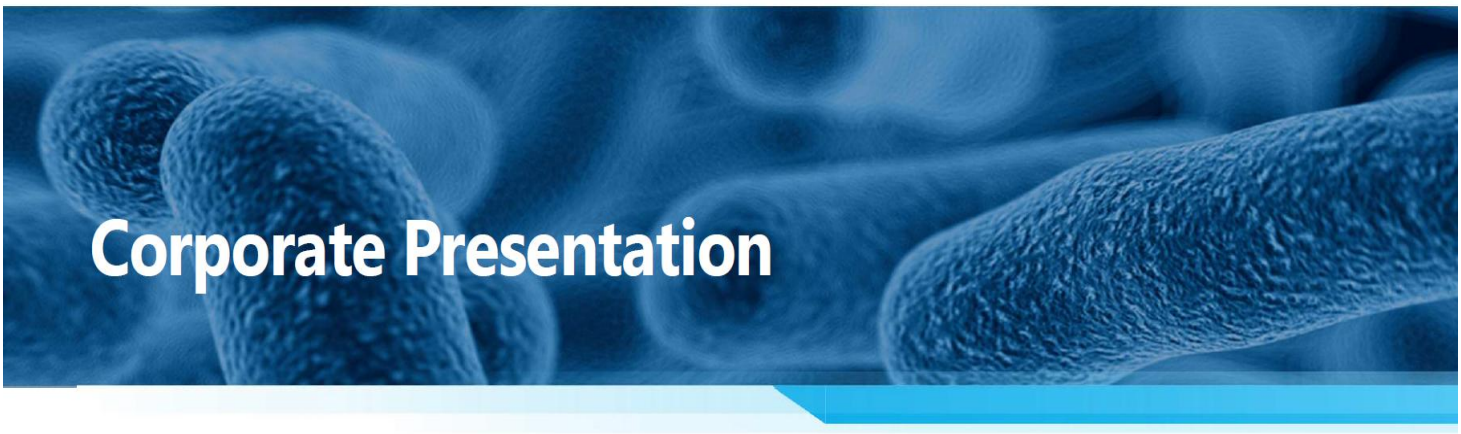
In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on this 3rd day of October, 2022.

ORAGENICS, INC.
(Registrant)

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

Exhibit 99.1

ORAGENICS



Corporate Presentation

October 2022
NYSE American: OGEN

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 its vaccine candidate and lantibiotics candidate 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 the vaccine and lantibiotic product candidates, 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 vaccines 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 our vaccine candidate to variants and 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 the outcome of preclinical studies, nasal administration, transmission, manufacturing, 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 and risks, as well as other uncertainties described in our filings with the U.S. Securities and Exchange Commission. All information set forth is as of the date hereof unless otherwise indicated. You should consider these factors in evaluating the forward-looking statements included 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.

Key Investment Highlights

Experienced Leadership

Kim Murphy, CEO, has more than 25 years' experience leading vaccine franchises at GSK, Merck and Novartis and executed multiple successful commercial launches

Differentiated Intranasal COVID Vaccine: NT-CoV2-1

Non-viral platform with adjuvant; rapid production for emerging variants

Large Market Opportunity

Potential multibillion dollar market, unmet need for intranasal delivery & reduction of transmission

Near-Term Milestones

Pivotal trial completion in 4Q22
Phase 1 data in 1H23

Opportunistic Business Model

New strategic initiatives to create value

Intranasal COVID-19 Vaccine Overview

- **Lead Asset: NT-CoV2-1**
  - Licensed from NIH – two-proline substitution of SARS-CoV-2 spike protein
  - Currently in pivotal toxicology study and expected to enter clinical studies in 1Q22
- **NT-CoV2-1 Non-Viral 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
  - 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 hamster nasal turbinates and lungs
  - Significant reduction in weight loss
  - Prevented cellular binding of viral Spike protein based on ancestral reference strain and certain variants of concern
- **National Research Council of Canada Collaboration**

NT-CoV2-1 Combines Four Technologies

National Institute of Allergy and Infectious Diseases

- Licensed "2P" spike protein design
- Highly de-risked (Pfizer/BioNTech, Moderna)

NIH De-risked Spike Antigen Design

NRC Cell Line to Respond to New Variants

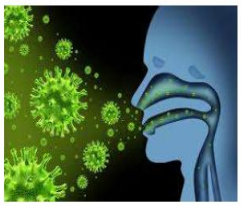
- Sequence -> Ph1 GMP DS in 12 wks
- Multiple VOC spike antigens produced

National Research Council Canada

ORAGENICS

Intranasal Delivery

Inspirevax Intranasal BDX301 Adjuvant

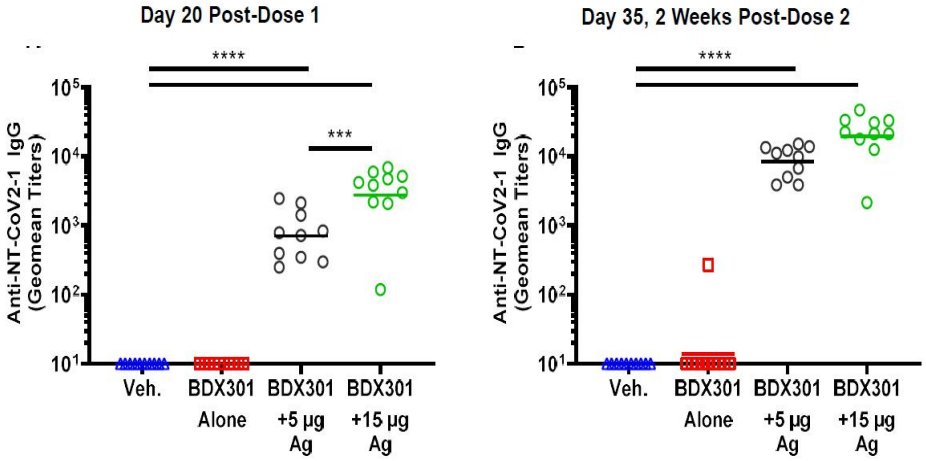


- Patient-friendly
- Potential to reduce infection and transmission

- IgA Ab (mucosal)
- IgG Ab (serum)
- BDX adjuvant family has clinical experience

INSPIREVAX

Hamster Study Results



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. SmT1v3 antigen is based on the original Wuhan sequence incorporating the NIH 2P substitution and the NRC resistin trimerization.

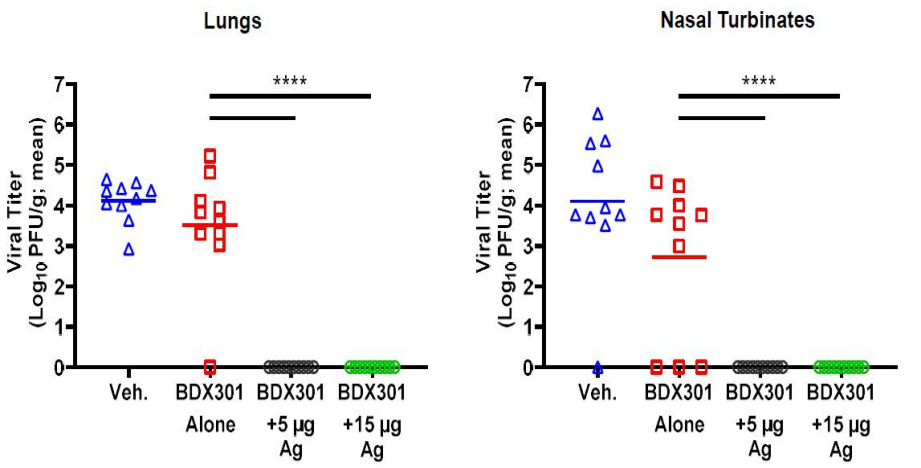
For statistical analysis, antibody titers were log-transformed and then analyzed by a one-way ANOVA with Tukey's multiple comparisons test. ***: $p<0.001$, ****: $p<0.0001$.

Key Takeaways

- Intranasal formulation led to high IgG anti-spike protein titers
- Correlation between increased dose of NT-CoV2-1 and immune response

Stark et al, June 2022, www.nature.com/scientificreports, https://rdcu.be/cPyZF

Hamster Challenge Study Results



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. SmT1v3 antigen is based on the original Wuhan sequence incorporating the NIH 2P substitution and the NRC resistin trimerization.

For statistical analysis, a one-way ANOVA with Tukey's multiple comparisons test was performed. ****: $p<0.0001$.

Key Takeaways

- Intranasal formulation led to undetectable viral loads
- Potential to reduce transmission by reducing viral titers (unlike current mRNA vaccines)
- Hamsters receiving NT-CoV2-1 maintained healthy body weight

Stark et al, June 2022, www.nature.com/scientificreports, https://rdcu.be/cPyZF

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 variants of concern (VOC)
  - 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

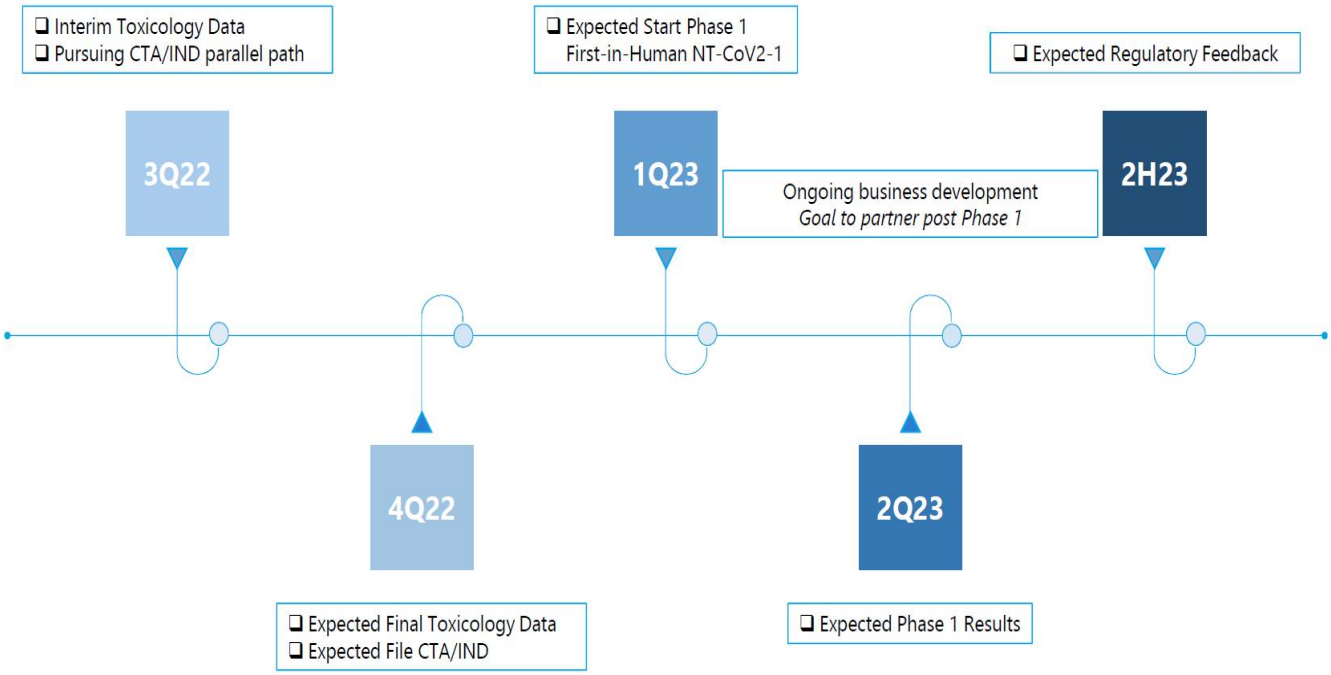
COVID-19 Vaccine Competition

Competitive landscape for intranasal COVID vaccines

Organization	Organization Type	Vaccine Type	Stage	Comments
Astra Zeneca	Global pharma	Live chimpanzee adenovirus vector	Phase 1	Known AEs (blood clots) may hinder approval & acceptance in US/EU
Codagenix	US private biotech	Live attenuated SARS-CoV-2 virus	Phase 1	Hard to establish safety of live, attenuated SARS-CoV-2 vaccine
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
CastleVax	US private biotech	Live Newcastle disease viral vector	Phase 1	Need to establish safety of new viral vector
ACM Biolabs	Singapore & Swiss private biotech	Protein subunit + polymer vesicles	Phase 1	Non-viral vaccine candidate
Oragenics	US public biotech	Protein subunit + BDX-301 adjuvant	Late preclinical	Non-viral vaccine candidate
Xanadu Bio	US public biotech	Protein subunit + polymer vesicles	Late preclinical	Non-viral vaccine candidate
Intravacc	Netherlands private CDMO	Protein subunit + OMV adjuvant	Late preclinical	Non-viral vaccine candidate

From WHO COVID-19 Vaccine Tracker: www.who.int/teams/blueprint/covid-19/covid-19-vaccine-tracker-and-landscape, dated Sept 2, 2022, company websites, clinicaltrials.gov and Waltz, Nature, vol 609, 9/8/2022.

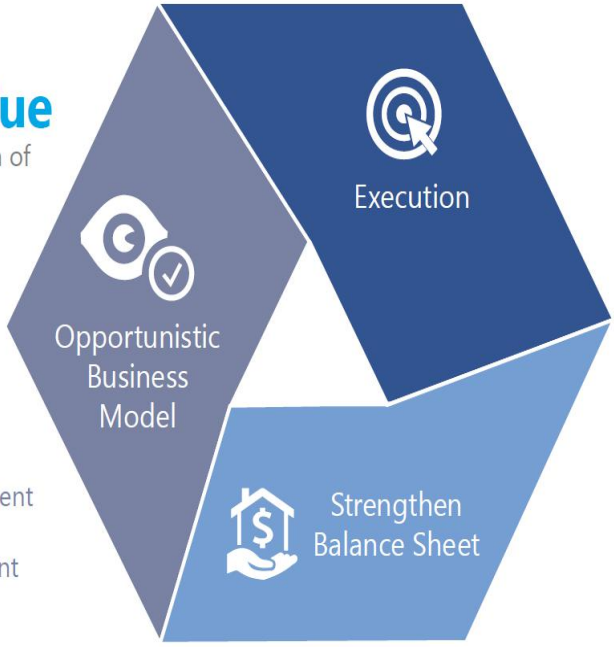
Milestone Timeline



New Management Objectives

Building Stakeholder Value

Through the synergistic execution of new management objectives



1. Capital Markets
2. Business Development
3. Clinical Development Pathways

1. Communicating and Achieving Milestone Timelines
2. Secure Capitalization for Sustained Operations
3. Building Visibility & Credibility

1. Secure Capital for Future Development Milestones
2. Pursue Non-dilutive Capital
3. Implement Streamlining Initiatives

Capitalization

Cash: $17.9M
As of June 30, 2022

Common Stock and Equivalents*	
Common Stock Outstanding	117,304,809
Series A and Series B Convertible Preferred (As Converted)	1,351,700
Warrants (WAEP $1.42)	18,040,572
Reserved for issuance under stock incentive plan	17,252,710
Total	**153,949,791**

*The Information is as of August 26, 2022 and reflects the voluntary conversion by a holder of Preferred A and B Stock into common stock. 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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