
**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: June 5, 2023
(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 8.01. OTHER EVENTS.

On June 5, 2023, Orogenics, Inc. (the “Company”) announced the award of a grant from CQDM, a Canadian bioresearch consortium, for the collaborative development of a variant-agnostic COVID-19 protein subunit vaccine candidate. The project is a collaboration with the National Research Council of Canada and Inspirevax.

A copy of the Company’s press release announcing these events is attached as Exhibit 99.1 to this Current Report on Form 8-K and is hereby incorporated by reference herein.

Item 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release Dated June 5, 2023
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 5th day of June 2023.

ORAGENICS, INC.
(Registrant)

BY: /s/ Janet Huffman
Janet Huffman
Chief Financial Officer



Oragenics Project to Develop a Variant-Agnostic Protein Antigen for Use in its COVID-19 Intranasal Vaccine Receives Funding from CQDM

TAMPA, Fla. (June 5, 2023) – **Oragenics, Inc. (NYSE American: OGEN) (“Oragenics” or the “Company”)**, a biotechnology company dedicated to fighting infectious diseases, announces the award of a grant from CQDM, a Canadian bioresearch consortium, for the collaborative development of a variant-agnostic COVID-19 protein subunit vaccine candidate. The project, which aims to build upon Oragenics’ current lead intranasal vaccine candidate NT-CoV2-1, is a collaboration with the National Research Council of Canada (NRC) and Inspirevax.

“By collaborating with our longstanding partners, we are better able to address the evolving SARS-CoV-2 virus by working to develop broadly protective antigens designed to protect against current and future variants. Our pan-coronavirus vaccine candidate presents a potential universal solution to the evolving nature of SARS-CoV-2 and potentially future coronaviruses by targeting mucosal immunity at the source, being readily deployable through faster manufacturing and exhibiting lower barriers for storage and transportation,” said Kim Murphy, President and Chief Executive Officer of Oragenics. “We are grateful for this new source of non-dilutive funding to advance our scientific work.”

“We are delighted to support the work of Oragenics and Inspirevax on the continued development of their intranasal vaccine, which offers a novel solution to reducing SARS-CoV-2 transmission by targeting mucosal immunity, among other benefits. Collaborative efforts such as this accelerate technological advancement by combining the most innovative R&D from each organization,” said Diane Gosselin, President and CEO of CQDM.

In March 2023, Oragenics entered into an exclusive global license agreement with Inspirevax for its novel intranasal mucosal adjuvant, BDx301, and also formed a Joint Development Committee to oversee development efforts collaboratively. The grant awarded by CQDM is expected to help Oragenics fund the development of two to four well-characterized stable CHO pools expressing new, cross-protective vaccine antigens with well-established preclinical efficacy using intranasal immunization. These antigens are expected to be rapidly deployable in next-generation vaccine formulations by leveraging the NRC’s advanced manufacturing platform currently utilized by Oragenics and previously developed for the reference strain SARS-CoV-2 spike antigen.

The grant funding is awarded through SynergiQC, a Quebec-based funding program for biopharmaceutical research created by CQDM. SynergiQC is designed to promote academic-based industrial research in the biopharmaceutical field that will generate economic benefits across Quebec. CQDM extends its funding capacity to the development of biopharmaceutical products with high industrial and commercial value, such as more competitive molecules and other technologies.

About CQDM

CQDM is a biopharmaceutical research consortium whose mission is to fund the development of innovative tools and technologies that will accelerate the discovery and development of safer and more effective drugs. We bring together world-leading pharmaceutical organizations, Canadian biotech companies, the best researchers from the public and private sectors, as well as the Canadian and Quebec governments. CQDM's collaborative approach bridges the funding gap needed to drive innovation across the academic and private sectors, especially where early-stage research is concerned. For more information please visit: www.cqdm.org, and the CQDM's pages on LinkedIn et Twitter.

About Inspirevax Inc.

Inspirevax Inc. (Montreal) is dedicated to the betterment of all people through the responsible use of advanced medical technology. Inspirevax is developing the Proteosome Intranasal Technology platform as a mucosal adjuvant system for use in nasal vaccines and immunotherapies. For more information about Inspirevax, please visit www.inspirevax.com.

About Orogenics, Inc.

Orogenics, Inc. is a development-stage company dedicated to fighting infectious diseases, including those caused by coronaviruses and multidrug-resistant organisms. Its lead product is NT-CoV2-1, an intranasal vaccine candidate to prevent COVID-19 and variants of the SARS-CoV-2 virus. The NT-CoV2-1 program leverages coronavirus spike protein research licensed from the National Institutes of Health (NIH) and the National Research Council of Canada (NRC) with a focus on reducing viral transmission and offering a more patient-friendly intranasal administration. Its lantibiotics program features a novel class of antibiotics against bacteria that have developed resistance to commercial antibiotics. For more information about Orogenics, please visit www.rogenics.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 obtain necessary funding, non-dilutive or otherwise, for the development of the vaccine and lantibiotic product candidates; 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 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 Canadian regulatory authorities 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 and license agreements; 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 such as delays in regulatory review, manufacturing delays and supply chain issues, adverse impacts on healthcare systems and disruption of the global economy; the ability to sustain compliance with our exchange listing requirements; 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 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.

Contacts

Oragenics, Inc.

Janet Huffman, Chief Financial Officer
813-286-7900
jhuffman@oragenics.com

LHA Investor Relations

Tirth T. Patel
212-201-6614
tpatel@lhai.com

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