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: February 23, 2023
(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 1.01 ENTRY INTO A MATERIAL DEFINITVE AGREEMENT.

On February 23, 2023, the Company entered into a Commercial License Agreement (the "License Agreement") with Inspirevax Inc. ("Inspirevax") pursuant to which Inspirevax granted the Company an exclusive worldwide license to use Inspirevax's inventions, patents, trade secrets, know-how, copyright, biological material, designs, and/or technical information created by or on behalf of Inspirevax (the "Inspirevax Technologies") relating to its novel lipid-protein based intranasal adjuvants, to make, research, and develop an intra-nasal vaccine in combination with an antigen ("Combination Product") to be used in an intranasal vaccine for use against diseases caused by coronaviruses and any genetic variants thereof to be sold by us.

As consideration for the grant of the license, the Company will pay an upfront signing fee of $50,000. The Company will be subject to certain milestone payments as follows: (a) $75,000 upon the Company's decision on an appropriate nasal spray device, (b) $100,000 upon a first patient being dosed in a phase 2a clinical trial, (c) $200,000 upon a first patient being dosed in a Phase 2b/3 clinical trial, (d) $800,000 upon a biologics License Application being submitted to the FDA, (e) $400,000 upon first filing of marketing authorization outside of the United States, and $200,000 for each such additional filing up to five filings, (f) $2,000,000 upon first commercial sale in the United States, (g) $1,000,000 upon first commercial sale in Europe, (h) $500,000 upon first commercial sale outside of United States and Europe and $250,000 for each other country or region up to five. Additionally, during the term the Company will pay to Inspirevax a 7% royalty on net sales subject to certain gross revenue limitations at which time the

royalty will decrease to 4%.

The Company will be required to use its best efforts to develop a product using the Inspirevax technology including the following: (a) first subject enrollment in first clinical study by December 31, 2023, (b) the first subject enrolled in a Phase 2a study by September 30, 2024, (c) first subject enrolled in a phase 3 registration trial by December 31, 2026, and (d) first marketing approval application submitted by June 30, 2028.

Pursuant to the License Agreement, Inspirevax is required to bear the responsibility and pay the costs to obtain and maintain patents related to the Inspirevax Technologies.

Pursuant to the License Agreement, any and all intellectual property rights in any invention conceived, reduced to practice, or developed during the Term of the License Agreement solely arising from or solely related to the Combination Product or the antigen will be owned by the Company, and the Company will bear the responsibility and pay the costs to obtain and maintain patents related to these inventions.

Pursuant to the License Agreement, the Company is required to indemnify and hold Inspirevax and its employees and agents harmless from and against all liability and damages in connection with or arising out of all claims, demands, losses, damages, costs including solicitor and client costs, actions, suits or proceedings brought by any third party that are in any manner based upon, arising out of, related to, occasioned by, or attributable to the manufacturing, distribution, shipment, offering for sale, sale, or use of Products, services based on the Inspirevax Technologies and product liability and infringement of intellectual property rights other than copyright, if any, licensed under the License Agreement.

Unless terminated earlier, the License Agreement will terminate the later of (i) twenty (20) years from the first commercial sale of a product, (ii) the last date a product is covered by a valid patent claim, or (iii) the expiration of regulatory exclusivity. The Company may terminate the License Agreement, by giving thirty (30) days written notice to Inspirevax. Either party may terminate, if the other party defaults or is in breach of the License Agreement, provided that if the defaulting party cures the breach within sixty (60) days after the notice is given, the License Agreement shall continue in full force and effect. The License Agreement contains customary confidentiality obligations.

The companies will form a Joint Development Committee (JDC) comprising representatives of both companies to oversee the development efforts collaboratively. Additionally, the agreement provides a certain period of time for the companies to expand their collaboration to pursue the development of additional intranasal vaccine candidates using Inspirevax's adjuvants.

On March 1, 2023, Oragenics, Inc. issued a press release announcing an exclusive Global License Agreement with Inspirevax to Develop Intranasal Covid Vaccine Candidate. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release dated March 1, 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 1st day of March, 2023.

ORAGENICS, INC. (Registrant)

BY: */s/ Kimberly Murphy*
Kimberly Murphy
President and Chief Executive Officer

Exhibit 99.1

Oragenics Enters into an Exclusive Global License Agreement with Inspirevax to Develop Intranasal Covid Vaccine Candidate

Licensing milestones provides opportunity to expand vaccine program

TAMPA, Fla. (March 1, 2023) Oragenics, Inc. (NYSE American: OGEN) ("Oragenics" or the "Company"), a biotech company dedicated to fighting infectious diseases including COVID-19, today announced that the Company has entered into an exclusive global license agreement with Inspirevax Inc. for its novel intranasal mucosal adjuvant, BDX301, for the development of NT-CoV2-1, Oragenics' lead intranasal COVID-19 vaccine candidate.

Under the exclusive licensing agreement, Oragenics will pursue the development of NT-CoV2-1 with Inspirevax's novel BDX301 intranasal mucosal adjuvant. The companies will form a Joint Development Committee (JDC) comprising representatives of both companies to oversee the development efforts collaboratively. Oragenics will make clinical, regulatory and commercial milestone payments, as well as tiered royalty payments. Additionally, the agreement provides a certain period of time for the companies to expand their collaboration to pursue the development of additional intranasal vaccine candidates using Inspirevax's adjuvants.

"This agreement represents a major milestone for Oragenics and our corporate strategy initiatives to expand our development opportunities. We are excited to collaborate with the experts at Inspirevax to pursue the development of novel intranasal vaccine candidates," explains Kimberly Murphy, President and Chief Executive Officer of Oragenics. "There is an unmet medical need for an intranasal COVID-19 vaccine. We are currently evaluating formulation options for NT-CoV2-1 and assessing various regulatory pathways to advance this program efficiently and thoughtfully. We are working diligently to advance the program and intend to provide an update in mid-2023."

"Intranasally delivered vaccines with our BDX301 adjuvant have shown encouraging results in preclinical models for COVID-19 infections. We welcome the opportunity to partner with Oragenics' in the development of a potential novel intranasal vaccine candidate in the global fight against COVID-19 and infectious disease," stated Joseph Zimmermann, President and Chief Executive Officer of Inspirevax.

In December 2022, Oragenics reported results indicating no toxicity signals or adverse events from its Good Laboratory Practices toxicology study in rabbits evaluating the safety and immunogenicity of NT-CoV2-1 plus BDX301, including a full histopathology evaluation. Oragenics believes these findings confirm a safety and immunogenicity profile that supports its plan to advance the program further toward clinical study. NT-CoV2-1 vaccine candidate demonstrated a robust antigen-specific IgG and IgA titers in preclinical models and a reduction in viral load is made possible by two complementary technologies, the spike protein licensed from the National Institutes of Health and Inspirevax's intranasal mucosal adjuvant, BDX301. This enables several potential benefits compared with injectable vaccines, including targeting mucosal immunity, reducing transmission, and offering a needle-free alternative for patients.

About Inspirevax Inc.

Inspirevax (formerly Biodextris) 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.

About Oragenics, Inc.

Oragenics, 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 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 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; the ability to sustain compliance with our 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.
Kimberly Murphy, Chief Executive Officer
Tel: 813-286-7900
kmurphy@oragenics.com

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

# # #