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 10, 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 8.01 Other Information

On March 10, 2022, Oragenics issued a press release announcing it has entered into an agreement with KBI Biopharma, Inc. ("KBI") for the process transfer, process optimization and cGMP manufacturing of the Company's intranasal vaccine candidate NT-CoV2-1, which is expressed in a proprietary CHO cell line. 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 issued on March 10, 2022.
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 10th day of March, 2022.

ORAGENICS, INC.
(Registrant)

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

Exhibit 99.1

Oragenics Engages KBI Biopharma to Support Development of Intranasal COVID-19 Vaccine Candidate NT-CoV2-1

KBI to produce material for use in future expected Phase 2 clinical trial of Oragenics' intranasal vaccine candidate

TAMPA, Fla. (March 10, 2022) – Oragenics, Inc. (NYSE American: OGEN) ("Oragenics" or the "Company") today announced it has entered into an agreement with KBI Biopharma, Inc. ("KBI") for the process transfer, process optimization and cGMP manufacturing of the Company's intranasal vaccine candidate NT-CoV2-1, which is expressed in a proprietary CHO cell line. The agreement covers, among other things, both a 200L demonstration run and a 500L cGMP run.

"We are delighted to enter into a development collaboration for our SARS-CoV-2 intranasal vaccine candidate with an outstanding commercial partner. Successful completion of work under this agreement will enable Oragenics to secure material for a future expected Phase 2 clinical trial. Intranasally delivered SARS-CoV-2 vaccines could provide increased protection in the nose and throat where viral entry occurs. This could lead to lower transmission of the virus compared to the currently available intramuscularly delivered vaccines as well as offering a needle-free delivery option," stated Frederick W. Telling, Ph.D., Executive Chairman of Oragenics.

"As a contract manufacturer accelerating the development of innovative discoveries into life-changing biological products, KBI is perfectly positioned for first manufacturing for Oragenics," said Brandon Vail, Senior Vice President, KBI Business Development. "KBI is proud of the important role in the continued fight against SARS-CoV-2 through our partnership with Oragenics."

Oragenics previously demonstrated robust immune response and reduction of SARS-CoV-2 viral loads to undetectable levels in the nasal passages and lungs five days following a viral challenge in preclinical models. The company intends to file an IND in 2022 to conduct a first-in-human clinical study with NT-CoV2-1.

About KBI Biopharma, Inc.

KBI Biopharma, a JSR Life Sciences company, is a global contract development and manufacturing organization (CDMO) providing fully integrated, accelerated drug development and biologics manufacturing services and expertise to life science companies. With each of its 500+ client partners, KBI works closely to personalize and rapidly accelerate drug development programs. Built upon a foundation of world-class analytics capabilities and extensive scientific and technical expertise, KBI delivers robust process development and clinical and commercial cGMP manufacturing services for mammalian, microbial, and cell therapy programs. Recognized for quality manufacturing, KBI helps partners advance drug candidates into the clinic and beyond. KBI serves its global partners with multiple locations in Europe and the USA. www.kbibiopharma.com

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About Oragenics, Inc.

Oragenics, Inc. is a development-stage company dedicated to fighting infectious diseases including 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 NIH and the 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 NT-CoV2-1and lantibiotics 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 product candidate, NT-CoV2-1 and our lantibiotics, 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 NT-CoV2-1and lantibiotics, including any meetings, decisions by regulatory authorities, such as the FDA and investigational review boards, whether favorable or unfavorable; the potential application of NT-CoV2-1to 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 administration, 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 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.

Oragenics, Inc.

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