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: July 26, 2021
(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 Definitive Agreement/

On July 26, 2021, Oragenics, Inc. ("Oragenics" or the "Company") entered into a non-exclusive Technology License Agreement (the "License Agreement") with the National Research Council of Canada ("NRC") pursuant to which the NRC grants to the Company a license to use NRC's inventions, patents, trade secrets, know-how, copyright, biological material, designs, and/or technical information created by or on behalf of the NRC (the "NRC Technologies") relating to the derivatives of CHO 2353 TM Cell Line listed in the License Agreement (the "Stable Cells") to: (i) make, research, and develop SARS-CoV-2 spike protein manufactured by a Stable Cell (the "Drug Substance*")* within Canada, Australia, the United Kingdom, the European Union and the United States (U.S.) (collectively the "Territory"); (ii) file regulatory approval, export and sell the final formulation of the Drug Substance ("Products") and (iii) engage contractors to use the Stable Cells to make Drug Substance or Products on behalf of the Company to be used and sold, worldwide, by the Company.

As consideration for the grant of the license, the Company will pay to the NRC an annual license fee, with the initial portion of the fee covering the first three years of the license. Additionally, the Company will pay certain milestone payments (a) upon transfer of each Stable Cell listed in the Agreement and (b) with regard to each of the first three Products, (i) upon submission of the Investigational New Drug application (IND) related thereto, (ii) upon dosing the first patient in a Phase 1 or Phase 2 clinical trial, (iii) upon dosing the first patient in a Phase 3 clinical trial and (iv) upon first regulatory approval. In addition, Oragenics will pay a low single-digit royalty to the NRC for the sale of

Products, based on sales revenue, commencing after the first commercial sale.

Pursuant to the License Agreement, the NRC is required to bear the responsibility and pay the costs to obtain and maintain patents related to the NRC Technologies in the U.S., Canada, Brazil, European Union, Japan, South Korea, Singapore, Australia, China, and India, and the NRC shall use reasonable efforts to obtain and maintain those patents. Additional countries may be requested by the Company, in which event, the NRC will file and maintain such patents, at the Company's expense.

Pursuant to the License Agreement, the Company is required to indemnify and hold the NRC 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 NRC 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 twenty (20) years from the effective date of the License Agreement. Either party may terminate the License Agreement, by giving written notice to the other party, if the other party defaults or is in breach of the License Agreement, provided that if the defaulting party cures the breach within 60 days after the notice is given, the License Agreement shall continue in full force and effect. The NRC may terminate the License Agreement if the Company becomes bankrupt, or insolvent, or has a receiver appointed to continue its operations, or passes a resolution for winding up. The License Agreement contains customary confidentiality obligations.

In addition, in connection with the initiative to develop its vaccine, the Company also previously entered into a material transfer agreement with the NRC for SARS-CoV-2 trimeric spike protein Wuhan variant and SARS-CoV-2 trimeric spike protein South African variant to move forward with pre-clinical testing.

Item 8.01 Other Information

As a result of the NRC License Agreement and shift in focus to a vaccine to address evolving variants, the Company now expects to file an IND application with the FDA in the first quarter of 2022 and immediately upon receipt of approval from the FDA to commence a Phase 1 clinical study.

On July 27, 2021, the Company issued a press release announcing it had entered into the License Agreement with the NRC. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated July 27, 2021.

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 27th day of July, 2021.

ORAGENICS, INC.
(Registrant)

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

Exhibit 99.1

Oragenics Enters into Licensing Agreement with the National Research Council of Canada, to Pursue the Rapid Development of Next-Generation SARS-CoV-2 Vaccines

- **Agreement provides Oragenics with antigen expression cell line technology capable of producing spike proteins within six to eight weeks of gene sequence definition**
- **Technology includes the ability to engineer vaccine antigens against SARS-CoV-2 including Wuhan, South African (beta) and other emerging variants of concern**

TAMPA, Fla. (July 27, 2021) – Oragenics, Inc. (NYSE American: OGEN) today announced it has entered into a licensing agreement with the National Research Council of Canada (NRC) that will enable Oragenics to pursue the rapid development of next-generation vaccines against the SARS-CoV-2 virus and its variants. The NRC technologies, in combination with the U.S. National Institutes of Health (NIH) elements found in the Company's Terra CoV-2 vaccine, provide Oragenics with a platform that can generate cell lines for high-yield production of spike protein antigens for existing and emerging variants of concern. This platform should allow production of cell lines within six to eight weeks of spike gene sequence availability, compared with six to nine months for traditional production of such cell lines. The NRC technologies, developed with support from the NRC's Pandemic Response Challenge Program, will expedite the evaluation of SARS-CoV-2 antigen candidates in preclinical and clinical studies.

"Entering into this licensing agreement as well as a separate material transfer agreement with the NRC are expected to have a profound, positive impact on our company's strategic direction and we look forward to pursuing the development of next-generation vaccines against SARS-CoV-2," said Frederick W. Telling, Ph.D., Oragenics' Executive Chairman. "We believe the combination of our previously licensed NIH technology with the NRC's swift expression platform will accelerate design of new vaccine candidates that benefit from the hybrid NIH/NRC constructs. This license enables us to jumpstart IND-enabling animal studies with supplies of spike proteins to address the wild-type Wuhan virus as well as the Beta (B.1.351 or "South African") variant that is currently of global concern among public health professionals. Preclinical studies started in June through our collaboration with the NRC. We initiated an immunogenicity study in mice to evaluate several adjuvant candidates. This study will allow for down-selection of the adjuvant candidates, with the best being advanced into a hamster challenge study to assess inhibition of viral replication and an IND-enabling GLP toxicology study."

Dr. Telling added, "With respect to our potential future competitive positioning against currently available SARS-CoV-2 vaccines, we believe the licensed technologies will improve development speed, while the ability to rapidly engineer new vaccine antigens will permit us to quickly address new variants as they arise. In addition, our agreement with Biodextris for an intranasal adjuvant is expected to complement our intramuscular administration options and should position Oragenics with several antigen-adjuvant options in the event that SARS-CoV-2 become a seasonal flu-like disease, as many experts anticipate will be the case."

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 Terra CoV-2, a vaccine candidate to prevent COVID-19 and variants of the SARS-CoV-2 virus. The Terra CoV-2 program leverages coronavirus spike protein research licensed from the NIH and the NRC with a focus on addressing supply-chain challenges, and offering more patient-friendly administration, such as intranasal. Its lantibiotics program features a novel class of antibiotics against infectious diseases that have developed resistance to commercial antibiotics.

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 Terra CoV-2 and 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, Terra CoV-2 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 Terra CoV-2 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 Terra CoV-2 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 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.

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