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# 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.--(BUSINESS WIRE)-- **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.kbibioharma.com](http://www.kbibioharma.com)

### **About Orogenics, Inc.**

Orogenics, 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 Orogenics, please visit [www.orogenics.com](http://www.orogenics.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-CoV2-1 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, 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-CoV2-1 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 NT-CoV2-1 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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