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# Oragenics Initiates a Pivotal IND-Enabling Toxicology Study on its Intranasal COVID-19 Vaccine Candidate, NT-CoV2-1

*Data to establish the safety profile and human dose of vaccine candidate*

TAMPA, Fla.--(BUSINESS WIRE)-- **Oragenics, Inc. (NYSE American: OGEN)** ("**Oragenics**" or the "**Company**") today announced the initiation of a Good Laboratory Practice (GLP) toxicology study to evaluate the safety profile and immunogenicity of its NT-CoV2-1 vaccine candidate in rabbits. The study is designed to provide Investigational New Drug (IND)-enabling data to help advance this candidate to human clinical studies. Oragenics has contracted with Frontage Laboratories (through its wholly owned subsidiary Experimur) to conduct the study, with top-line interim data expected in August.

Glenn Washer, Frontage's North American President and EVP of Global Safety & Toxicology commented, "We are delighted to support Oragenics on what could be the next generation of vaccines to combat COVID-19 infections. With the recent acquisition of Experimur, Frontage is well positioned to support Oragenics' development needs through the IND and beyond."

"We are thrilled to have begun this pivotal study with Frontage, a premier drug development contract research organization, and are thankful to the acceleration Frontage has offered our important IND-enabling study. We believe the results from this rabbit toxicology study will support our development strategy for our intranasal COVID-19 vaccine candidate, NT-CoV2-1. The intranasal delivery route is particularly relevant as it may further reduce transmission of the virus and provide a needle-free delivery option. The findings from this preclinical toxicology study will be a part of our Investigational New Drug filing to the U.S. Food and Drug Administration," said Frederick W. Telling, Ph.D., Executive Chairman of Oragenics.

Oragenics has previously demonstrated protection by NT-CoV2-1 in a hamster challenge study (<https://www.biorxiv.org/content/10.1101/2022.03.02.482651v1.full.pdf>).

## 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](http://www.oragenics.com).

### **About Frontage Laboratories**

Frontage Holdings Corp (1521.HK), together with its wholly owned subsidiary Frontage Laboratories, Inc., is a global Contract Research Organization (CRO) which provides integrated, science-driven, product development services from drug discovery to late phase clinical process to enable biopharmaceutical companies to achieve their development goals. Comprehensive services include drug metabolism and pharmacokinetics, analytical testing and formulation development, preclinical and clinical trial material manufacturing, bioanalysis, preclinical safety and toxicology assessment and early phase clinical studies. Frontage has enabled many biotechnology companies and leading pharmaceutical companies of varying sizes to advance a myriad of new molecules through development and to successfully file global regulatory submissions. For more details visit: [www.frontagelab.com](http://www.frontagelab.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 antibiotics 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 antibiotic 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 antibiotics, 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 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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