

# 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.--(BUSINESS WIRE)-- **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 <a href="https://www.oragenics.com">www.oragenics.com</a>.

## **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 forwardlooking 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.

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Source: Oragenics, Inc.