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Oragenics Inc. Shows Concussion Drug, ONP-002, Designed for Acute Field-Delivery Stable Across a Wide Temperature Range

• ONP-002 stability eliminates need for cumbersome cold storage
• No FDA-approved pharmaceutical treatment available for concussion

SARASOTA, Fla., Aug. 14, 2024 (GLOBE NEWSWIRE) -- Oragenics, Inc. (NYSE American: OGEN), a company focused on developing unique, intranasal pharmaceuticals for the treatment of neurological disorders, today announced its lead candidate for treating concussion, ONP-002, is stable across a wide temperature range, eliminating the need for cumbersome cold storage for the drug device combination. ONP-002 is a new chemical entity (NCE) designed to target the brain through a breath propelled delivery system into the nasal cavity to treat concussions.

Oragenics recently completed the synthesis of its ONP-002 drug batch for the planned Phase II clinical trial. The company reports 3-month stability with over 99% purity at temperatures ranging from -20°C to 104°C. Oragenics is confident in its belief that ONP-002 will not require cumbersome cold chain protocols during transport and storage, maintaining its chemical structure and function even in extreme temperatures.

Field conditions for contact sports and military operations involve a wide range of temperatures that may affect the stability and effectiveness of drugs intended for acute concussion treatment. ONP-002 has been formulated as a spray-dried powder to improve stability in extreme temperatures. In contrast, narrow temperature storage protocols can be cumbersome and pose greater risk for non-compliance during shipping and field operations.

“We understand the importance of getting ONP-002 into the brain quickly after concussive injury to squelch the pathological cascade of inflammation and oxidative stress. As an emergency medicine physician, I am especially excited to find out that Oragenics’ drug is expected to maintain its function out in the field where we plan to administer the initial dose. While there is currently no drug treatment for concussion, we believe strongly that targeting the brain intranasally during the acute field-phase will improve treatment efficacy,” commented Frank Peacock, MD and Chief Clinical Officer for Oragenics.

Concussion is an unmet medical need. There are an estimated 69 million concussions annually reported worldwide. Common causes of concussion include falls, motor vehicle accidents, and contact sports. Other neurological disorders, including Alzheimer’s Disease,

Parkinson's Disease, and Chronic Traumatic Encephalopathy (CTE), have been linked to concussion. Post-concussion symptomology is linked to long-term disability and occurs in as high as 20% of concussed patients.

About Oragenics
Oragenics is a development-stage biotechnology company focused on nasal delivery of pharmaceutical medications in neurology and fighting infectious diseases, including drug candidates for treating mild traumatic brain injury, also known as concussion, and for treating Niemann Pick Disease Type C, as well as proprietary powder formulation and an intranasal delivery device. For more information, 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, including without limitation statements regarding the ability of the Company to timely and successfully undertake Phase II clinical trial using its novel drug-device combination for the treatment of mild traumatic brain injury. 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 Company's ability to advance the development of its product candidates, including the neurology assets, under the timelines and in accord with the milestones it projects; the Company's ability to raise capital and obtain funding, non-dilutive or otherwise, for the development of its product candidates; the regulatory application process, research and development stages, and future clinical data and analysis relating to its product candidates, including any meetings, decisions by regulatory authorities, such as the FDA and investigational review boards, whether favorable or unfavorable; the Company's ability to obtain, maintain and enforce necessary patent and other intellectual property protection; the nature of competition and development relating to concussion treatments; the Company's expectations as to the outcome of preclinical studies and clinical trials and the potential benefits, activity, effectiveness and safety of its product candidates including as to administration, transmission, manufacturing, storage and distribution; 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 is as of the date hereof unless otherwise indicated. You should consider these factors in evaluating the forward-looking statements included 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.
Janet Huffman, Chief Financial Officer
813-286-7900
jhuffman@oragenics.com

Investor Relations:

Rich Cockrell
CG Capital
404-736-3838
ogen@cg.capital

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