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Oragenics Develops Automated Intranasal Device for Treating Concussed Patients

The device is intended for initial treatment in the acute setting

SARASOTA, Fla., June 27, 2024 (GLOBE NEWSWIRE) -- Oragenics, Inc. (NYSE American: OGEN), a company focused on developing unique, intranasal pharmaceuticals for the treatment of neurological disorders, today announced it has completed a prototype of its automated intranasal device for use in concussed patients who are initially confused, dazed or unconscious in the acute phase of injury. Oragenics' lead drug candidate, ONP-002, is a new chemical entity (NCE) designed to target the brain through delivery into the nasal cavity and onward to the brain. A Phase II study is being designed to analyze the effectiveness of ONP-002 on blood biomarkers and patient-reported outcomes of concussed patients.

Loss of consciousness along with acute memory impairment are linked to prolonged post-concussion symptoms and poor clinical outcomes. Oragenics' breath-propelled device requires the patient to administer ONP-002 into the nose. Concussed patients with an acute altered mental state may not be capable of following these instructions. Oragenics intends to use its breath-propelled device in the planned Phase II trial, which calls for multiple days of treatment. However, for those patients who have a loss of consciousness or altered mental status early on, the current automated prototype is being developed for their initial treatment by medical staff during the period in which they may struggle to follow directions for blowing.

"We are excited about this new automated technology as it allows us to treat the full range of concussive injuries. Both devices offer advantages and can deliver our nanoparticle powder. Given the early mental alterations many concussed patients experience, we aim to provide them the best drug delivery route to improve their clinical outcomes," stated Michael Redmond, President at Oragenics.

Approximately 10% of concussed patients lose consciousness, while many others experience an immediate altered mental state, with short-term memory loss and confusion. Both loss of consciousness and acute memory impairment are linked to prolonged post-concussion symptoms and poor clinical outcomes.

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
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.

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