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Oragenics, Inc. Announces Partnership with BRAINBox Solutions to Revolutionize Concussion Diagnosis and Treatment

Collaboration Aims to Develop First Intranasal Therapy for Mild Traumatic Brain Injury Aka Concussion, Establishing a Comprehensive Test-to-Treat Platform

SARASOTA, Fla. and RICHMOND, Va., Feb. 11, 2025 (GLOBE NEWSWIRE) -- Oragenics, Inc. (NYSE American: OGEN), a biotechnology company advancing innovative treatments for concussion and brain-related health conditions, today announced a strategic partnership with BRAINBox Solutions, a leader in multi-modality diagnostics for traumatic brain injury (TBI). This collaboration seeks to develop the first intranasal therapy for mild traumatic brain injury (mTBI) aka concussion, creating a comprehensive trigger-to-treat platform by combining BRAINBox's advanced multimarker/ multimodality diagnostic capabilities with Oragenics' novel therapeutic development.

The partnership intends to integrate BRAINBox's proprietary diagnostic product platform—which utilizes a combination of neurological biomarkers, neuropsychological assessments, and AI-driven analytics to provide early and accurate TBI assessments—with Oragenics' intranasal therapeutic candidate, ONP-002. ONP-002 is designed to mitigate the effects of brain injury and promote recovery. Together, these technologies aim to transform the standard of care for concussion patients by providing rapid diagnosis, predictive prognosis, and timely, targeted treatment.

"This collaboration represents a significant step forward in concussion care," said Janet Huffman, Interim Chief Executive Officer of Oragenics. "By combining our innovative intranasal therapeutic with BRAINBox's state-of-the-art diagnostic product platform, we hope to offer a comprehensive solution that addresses both the identification and treatment of mTBI, ultimately improving patient outcomes. We believe BRAINBox's diagnostic tools will be instrumental in our upcoming Phase IIa trials, enabling precise patient selection and real-time monitoring of therapeutic efficacy."

BRAINBox's testing platform offers both diagnostic and prognostic insights, identifying patients at higher risk for long-term symptoms and guiding personalized treatment strategies. Oragenics' ONP-002, an intranasal neurosteroid therapeutic, has demonstrated significant potential in preclinical studies to reduce brain injury effects and support recovery. A Phase I clinical trial showed ONP-002 to be well-tolerated and Oragenics' novel intranasal device to be easily operated. The integration of these technologies could lead to a seamless trigger-

to-treat ecosystem, facilitating early intervention and improving outcomes for millions affected by TBI annually.

Donna Edmonds, Chief Executive Officer of BRAINBox Solutions, added, “Partnering with Oragenics allows us to enhance the impact of our diagnostic technology by linking it directly to a promising therapeutic option. Together, we aim to set a new standard in the management of brain injuries, providing clinicians with the tools they need to deliver timely and effective care.”

With over 5 million concussions occurring annually in the U.S. alone, there is a significant unmet need for effective diagnostic and therapeutic solutions. This partnership positions Oragenics and BRAINBox at the forefront of innovation in TBI care, offering a compelling opportunity for advancing healthcare solutions in neurology.

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About Oragenics, Inc.

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 (mTBI), also known as concussion, and for treating Niemann Pick Disease Type C (NPC), as well as proprietary powder formulation and an intranasal delivery device. For more information, please visit www.oragenics.com.

About BRAINBox Solutions

BRAINBox Solutions is developing the first AI-enabled, multi-modality approach for the diagnosis and prognosis of Mild Traumatic Brain Injury, commonly referred to as a concussion. The company seeks to establish a clinical best-practice standard for the diagnosis and prognosis of concussion. The product incorporates a panel of proprietary, patented blood biomarkers that can be read in a few moments on a point-of-care instrument or using standard laboratory systems, as well as neurocognitive testing, to provide a single-system score that measures the severity of the injury and post-concussive symptoms. The company is led by key physician and scientific thought leaders in the field and an experienced, clinically focused management team.

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, those described in our Form 10-K and other 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, circumstances should change, except as otherwise required by law.



Source: Oragenics