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Oragenics, Inc. Provides Shareholder Update on Strategic Progress and Announces Janet Huffman as Interim CEO

SARASOTA, Fla., Jan. 21, 2025 (GLOBE NEWSWIRE) -- Oragenics, Inc. (NYSE American: OGEN), a biotechnology company advancing innovative treatments for brain-related health conditions, today provided an update on its strategic progress since its last capital raise in September 2024. The Company also announced the appointment of Janet Huffman as its new interim Chief Executive Officer.

Strategic Progress Since Capital Raise

Following the Company's \$4 million capital raise in September 2024, the Company has made significant advancements, including:

- **Formulation and Device Enhancements:** The Company has improved the formulation and intranasal delivery device for ONP-002 and in connection therewith has taken significant steps with the goal of securing its intellectual property for such formulations and devices.
- **Advancing Phase II Preparations:** The Company has vetted clinical research organizations (CROs) and hospital partners in Australia and is in the process of finalizing site agreements for its Phase II clinical trials in Australia. The goal remains to dose the first patient in Australia by the end of Q1 2025, or early Q2.
- **Supply Chain Preparedness:** Completion of the spray-dry campaign is expected to ensure sufficient drug-device units for the upcoming trials, with all units validated and prepared for shipment.
- **Prototyping for Enhanced Accessibility:** Prototyping for an automated intranasal device, designed for patients with altered states of consciousness, has been completed.
- **Regulatory Milestones:** Closure of the Phase I clinical trial and submission of data for investigational new drug (IND) and investigator's brochure (IB) approval remain on track.

Leadership Transition

The Company is also pleased to announce the appointment of Janet Huffman as interim Chief Executive Officer. Since joining Oragenics, Ms. Huffman has played a pivotal role in driving the Company's strategy, leveraging her extensive experience in capital raising, mergers and acquisitions, and financial planning.

Before her tenure at Oragenics, she served as Chief Financial Officer for TRxADE HEALTH, Inc. (NASDAQ:MEDS), a company focused on health services IT for retail pharmacies. In 2019, Ms. Huffman was a founding member of Banyan Pediatric Care Centers, where she served as CFO and played a critical role in its merger with Assisted 4 Living, Inc., later renamed Arboreta Healthcare Inc. She also held financial leadership roles at Signature HomeNow, Infinity Homecare, and Family Home Health Services.

“I am honored to take on this role, and am deeply committed to Oragenics’ mission of addressing unmet medical needs through innovation,” said Ms. Huffman. “As we work to advance ONP-002 and prepare for the next phase of clinical development, I look forward to collaborating with our dedicated team and stakeholders to build on the momentum we’ve created. Together, we are charting an exciting course that prioritizes both patient outcomes and shareholder value.”

The Oragenics Board of Directors expressed confidence in Ms. Huffman’s leadership during this pivotal time for the Company. “Janet’s proven track record as a strategic leader and her deep understanding of Oragenics’ operations make her an excellent choice to guide the Company during this transition,” said Charles Pope, Chairman of the Board of Directors at Oragenics. “Her expertise in financial stewardship and her commitment to advancing our development plans position Oragenics to maintain its momentum and continue creating value for patients and shareholders alike.”

Financial Overview

Since the September 2024 capital raise, the Company has strategically allocated resources with the goal of delivering operational efficiency:

- Additional investments were made in improved drug and device formulation, device prototyping, and clinical trial preparations for phase II.
- Additional investments were made to continue the Company’s efforts in protecting existing patents and securing new patents for the Company’s improved drug formulation and device prototype.

Next Steps and Upcoming Milestones

The Company remains focused on executing its clinical and regulatory plans, with the following goals:

- Submission of the IB package by Q1 2025 for Australia phase II clinical trials.
- Formalizing the Company’s strategic partnerships in Australia for clinical trial site selections and clinical research leadership to lead the Australia clinical trials.
- Dosing of the first patient in Australia in the Phase II clinical trial by the end of Q1 2025 or early Q2 2025.
- Submission of the IND package for phase IIb clinical trials in the US targeted for Q3 of 2025.

“I am thrilled about the opportunities ahead in 2025 as we position Oragenics for a transformative year,” said Ms. Huffman. “I am filled with optimism about what this year holds as we advance ONP-002 and lay the groundwork for future growth. With ONP-002 advancing into its next phase of development, we are at a critical juncture that holds tremendous promise for both patients and stakeholders. Leading the way is our innovative

science, strategic focus, and unwavering commitment to our mission, I believe this positions us well to continue to make meaningful progress that will shape our future and create lasting value.”

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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.oralgenics.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, 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