October 9, 2024

Oragenics, Inc. Updates Shareholders on Concussion Drug Progress and Phase II Trial Preparation

SARASOTA, Fla., Oct. 09, 2024 (GLOBE NEWSWIRE) -- Oragenics, Inc. (NYSE American: OGEN), a biopharmaceutical company committed to developing novel therapies for neurological disorders, today provided a corporate update reflecting on the company's progress throughout 2024, including key milestones in the development of ONP-002, its lead candidate for the treatment of concussions.

Company Overview: A Vision for Innovation in Neurology
Oragenics is focused on revolutionizing drug delivery for neurological disorders using innovative intranasal technology. The company's lead program, ONP-002, is a first-in-class neurosteroid being developed to treat moderate to severe concussions. Intranasal delivery provides numerous advantages over traditional systemic methods, including faster brain delivery, reduced systemic exposure, and a non-invasive approach.

"Our mission is to address significant unmet medical needs by developing cutting-edge therapies," stated Michael Redmond, President of Oragenics. "There are over 3 million annual concussion occurrences in the U.S. and an estimated 69 million globally, however it is believed that a substantial number, up to 50%, of cases go unreported. Given that there is still no FDA approval, and patients in need continue to face limited treatment options, the urgency to advance our efforts is greater than ever.

Key Milestones in Concussion Drug Development
Oragenics has made significant advancements in the development of ONP-002 during 2024, including:

Strengthened Clinical Leadership: In 2024, the company appointed two renowned experts —Dr. James "Jim" Kelly as Chief Medical Officer and Dr. William "Frank" Peacock as Chief Clinical Officer—bringing deep expertise in brain health and emergency medicine to oversee the clinical development of ONP-002.

Phase II Clinical Trial Preparation: Building on successful Phase I trials, which demonstrated the safety and tolerability of ONP-002, the company is preparing to initiate Phase II clinical trials, which will evaluate the drug's efficacy based on patient outcomes.

Successful Cardiotoxicity Testing: In July 2024, ONP-002 demonstrated a strong cardiac safety margin, clearing FDA-required cardiotoxicity tests. These results suggest that the treatment is unlikely to cause cardiac arrhythmias, a crucial milestone that derisks the

program as it moves forward into the Phase II clinical trial.

FDA-Required Genotoxicity Studies: In August 2024, ONP-002 successfully completed the necessary studies regarding FDA-required genotoxicity testing, confirming that the drug does not cause DNA damage, further strengthening its safety profile as it advances towards Phase II.

Partnership with Avance Clinical: In May 2024, the company entered into a partnership with Avance Clinical, a leading CRO, strengthening the company's ability to execute its Phase II trial for ONP-002 and leveraging Avance's expertise in clinical trial management and regulatory pathways.

Temperature Stability Achieved: ONP-002 demonstrated stability across a wide temperature range, eliminating the need for cold-chain storage. This milestone is especially important for field delivery, where concussions frequently occur, such as in sports or military environments.

Spray-Dry Manufacturing and Device Completion: The company completed the spray-dry formulation of ONP-002 and filled intranasal delivery devices needed for upcoming Phase II trial. These ready-to-use devices should enable fast, targeted treatment to patients following a concussion.

Improved Drug Percentage in Final Formulation: A novel nanoparticle spray dried powder formulation was created that should enhance intranasal absorption and increase the amount of ONP-002 per dose by 4-fold. This new formulation is expected to allow for more drug to enter the brain at each treatment increasing the chance for reaching therapeutic levels and patient improvement.

Completion of FDA-Recognized Study for Concussion Drug, ONP-002: Intranasal casting studies are critical for FDA approval of pharmaceuticals delivered via the nasal passage. The study results demonstrated the drug successfully targets the interior nose that is made from cast metal (AINI), making it more likely to reach and treat the brain after a concussion. This model is standard for intranasal drug delivery and is accepted by the FDA as a surrogate for the actual nasal.

Recent Financing and Strategic Growth
In September 2024, Oragenics closed a public offering, raising approximately $4.45 million, contributing to a total of over $6 million raised throughout the year, including previous financing efforts. These funds will support the continued development of ONP-002, allowing the company to advance toward Phase II clinical trials and further address the unmet medical need for concussion treatments.

"We are grateful for the confidence that our investors have placed in our vision," added Redmond. "This financing allows us to continue advancing ONP-002, which we believe has the potential to be the first approved drug for concussion treatment."

Looking Ahead: Key Milestones
Oragenics anticipates several key milestones in the coming months, including:

Initiation of Phase II Clinical Trials: The company plans to begin Phase II trials later this

year, initially in Australia, followed by U.S. trials. These trials will evaluate safety and efficacy - evaluating the effects of ONP-002 on concussion patient symptom reduction and functional recovery.

Clinical Site Selection The company is currently working with Avance Clinical, a clinical CRO along with major neurotrauma centers in Australia on Phase II clinical protocols. A key feature of the Phase II trial is to develop emergency department protocols for patient inclusion/exclusion with the goal of having the first dose occur within 8 hours of the injury. Efficacy evaluations during this 10-day trial include testing of visual-motor and neurocognitive functional performance while also assessing patient symptoms relative to drug treatment.

Australian Regulatory Submission Brochure

In preparation for its upcoming Phase II clinical trials, Oragenics plans to submit the Australian Regulatory Submission Brochure during the fourth quarter of 2024. This submission is a critical component for the regulatory approval of the trial in Australia and outlines the clinical trial safety and efficacy protocols, informed consent protocols, and data collection methods.

Continued Development of Intranasal Delivery System: Oragenics' intranasal system is a breakthrough in brain injury drug delivery, designed to provide rapid, targeted brain delivery with minimal side effects. This system will continue to be a key focus as the company advances ONP-002. This includes the breath-propelled and automated device technologies.

Commitment to Shareholders
Oragenics remains committed to maintaining transparency and open communication with its shareholders. The company will continue to provide updates on its progress as it advances toward key milestones and works to commercialize ONP-002.

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.

Investor Relations:
Rich Cockrell
404.736.3838
achv@cg.capital

Source: Oragenics