April 13, 2026

Oragenics Doses First Patient in Phase IIa Clinical Trial of ONP-002 for Mild Traumatic Brain Injury

- *Mackay Base Hospital activated March 31, 2026 as first clinical trial site; first patient dosed within days of activation — a signal of strong enrollment velocity and significant unmet medical need*

SARASOTA, Fla., April 13, 2026 (GLOBE NEWSWIRE) -- Oragenics, Inc. (NYSE American: OGEN), a clinical-stage biotechnology company developing brain-targeted therapeutics through proprietary intranasal delivery technology, today announced that the first patient has been dosed in its ongoing Phase IIa clinical trial evaluating ONP-002, the Company's lead candidate for the treatment of concussion and mild traumatic brain injury (mTBI). The milestone was achieved at Mackay Hospital in Australia — the first site to be activated in the trial — within days of site activation on March 31, 2026.

Concussion, aka, mild traumatic brain injury, represents the most prominent neurological conditions without an FDA-approved pharmacological treatment. According to the CDC, an estimated 1.7 to 3.8 million people in the U.S. experience traumatic brain injuries annually, with sports and recreational activities among the leading causes.[1] Globally, an estimated 69 million individuals sustain traumatic brain injuries each year. Despite this scale, no pharmacological treatments have been approved — leaving patients, military personnel, athletes, and families with few effective options beyond rest and symptom management. If approved by the FDA, ONP-002 would be the first and only pharmacological standard of care for a global concussion market projected to reach over $9 billion by 2030.[2]

The commencement of patient dosing follows the receipt of Human Research Ethics Committee (HREC) approval in Australia and the activation of Mackay Hospital as the first clinical site. The rapid presentation of an eligible patient immediately upon site activation underscores the breadth and urgency of unmet clinical need in this population. Two additional Australian sites — Alfred Hospital (Melbourne) and Royal Adelaide Hospital (Adelaide) — are progressing through site governance approvals, with activation expected in the second quarter of 2026.

ONP-002 is a first-in-class intranasal novel neurosteroid designed to address the underlying biology of brain injury — reducing neuroinflammation, oxidative stress, and cerebral edema — rather than simply managing symptoms. As an investigational neuroprotective intranasal drug, ONP-002 targets the biological cascade triggered by trauma, with the potential to represent a paradigm shift from symptom management to active neurological intervention. ONP-002 is delivered via Oragenics' proprietary intranasal spray-dry powder device. The

drug candidate serves a nasal drug delivery market expected to reach nearly $93 billion by 2030.[3]

Oragenics' Chief Executive Officer, Janet Huffman stated, "We said we would dose our first patient in Australia — and we have. Mackay Hospital was active for only a matter of days before an eligible patient presented, and that immediacy is not a coincidence. It reflects the reality of what we have always said: there is no pharmacological treatment for concussion, and patients and clinicians are ready for something new. Site activation was swift and now the trial is underway. We are executing, and we intend to keep executing. For the millions of people who suffer concussions every year and are told there is nothing that can be done — we are here to change that."

Dr. James Kelly, Oragenics' Chief Medical Officer, added, "The Phase 1 safety profile gave us strong scientific confidence entering this next phase. The HREC process is rigorous by design — it exists to protect patients, and receiving that clearance confirmed that our trial design, safety protocols, and investigator teams meet the highest standards. As a clinician who has worked with concussion patients for decades, this moment is deeply meaningful. ONP-002 targets the injury itself, not just the symptoms. That is a fundamentally different approach to concussion care, and we are now putting it to the test in patients."

PHASE IIA TRIAL DESIGN

Oragenics' Phase IIa clinical trial is a randomized, placebo-controlled study designed to evaluate 40 patients who meet enrollment criteria based on CT scan findings, presenting symptoms, and emergency room or hospital admission. Patients will receive first dosing within 12 hours of concussion, followed by continued treatment for up to 30 days. The trial will assess safety and tolerability parameters through follow-up visits for nasal examinations, physical assessments, and neurocognitive testing. Feasibility will be determined according to tolerability and participant compliance.

Oragenics expects that findings will support its planned investigational new drug (IND) application submission to the FDA, targeting Q4 2026, for the next phase of clinical trials to be conducted in the U.S.

CLINICAL FOUNDATION & OPERATIONAL PARTNERS

The Phase 1 clinical trial of ONP-002 delivered a strong safety profile, with zero serious adverse events reported across all dose levels in 40 patients, supporting advancement to Phase 2. Preclinical data demonstrated reductions in swelling, inflammation, and oxidative stress in the brain, along with improvements in functional recovery.

Southern Star Research, a full-service Australian clinical research organization (CRO), is managing Phase IIa trial operations. Sterling Pharma Solutions is providing cGMP drug manufacturing services from its facility in Cary, North Carolina.

ABOUT ONP-002

ONP-002 is an investigational neuroprotective, anti-inflammatory intranasal drug candidate targeting mild traumatic brain injury (mTBI) and concussion. Designed to interrupt biological pathways involved in inflammation, oxidative stress, and brain swelling following head

trauma, ONP-002 has demonstrated safety and tolerability in Phase 1 clinical trials with zero serious adverse events across all dose levels. The drug candidate utilizes Oragenics' proprietary intranasal delivery platform to enable rapid, targeted brain delivery — potentially representing a paradigm shift from symptom management to active neurological intervention. Oragenics is advancing ONP-002 through Phase IIa clinical trials in Australia, with U.S. Phase IIb trials planned to follow pending FDA investigational new drug application (IND) approval.

ABOUT ORAGENICS, INC.

Oragenics, Inc. is a clinical-stage biotechnology company developing brain-targeted therapeutics through proprietary intranasal delivery technology. The Company's lead candidate, ONP-002, is being advanced as a potential first-in-class treatment for concussion, aka mild traumatic brain injury. Oragenics is progressing ONP-002 through Phase IIa clinical trials in Australia, with U.S. clinical trials planned to follow. The Company believes its intranasal delivery platform has potential applications across multiple neurological conditions, including Parkinson's disease, Alzheimer's disease, and other neurological disorders. Oragenics is committed to developing innovative therapies that address significant unmet medical needs in neurological care. For more information, 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. Statements in this news release concerning the Company's expectations, plans, business outlook or future performance, and any other statements concerning assumptions made or expectations as to any future events, conditions, performance or other matters, are "forward-looking statements." Forward-looking statements include statements regarding the Company's intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: our research, development and regulatory activities and expectations relating to product candidates, including without limitation ONP-002 and our proprietary nasal device; the effectiveness of these programs or the possible range of application and potential curative effects and safety in the treatment of diseases; and the timing, conduct, interim results announcements and outcomes of our clinical trials of our product candidates, including ONP-002 for the treatment of concussion and mTBI. These forward-looking statements are based on management's beliefs and assumptions and information currently available. The words "believe," "expect," "anticipate," "intend," "estimate," "project," "potential," "may," "will," "could," "should," 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 most recent Form 10-K, Form 10-Q and other filings we make with the U.S. Securities and Exchange Commission. You should consider these factors in evaluating the forward-looking statements included in this press release and not place undue reliance on such statements. All information we set forth in this press release is as of the date hereof. 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.

INVESTOR & MEDIA CONTACT
Investor & Media Relations
irth Communications
800-383-4880
ir@oragenics.com

FOOTNOTES

[1] American Association of Neurological Surgeons; Sports Related Head Injury / CDC TBI Data

[2] Grand Market Research; Concussion Market (2025–2030)

[3] Research and Markets; $92.91 Bn Nasal Drug Delivery Market Trends, Opportunities, and Forecasts, 2020–2024 & 2025–2030F

Source: Oragenics, Inc.