

March 12, 2026



ORAGENICS INITIATES PHASE IIA CLINICAL TRIAL SITE ACTIVATION

FIRST SITE INITIATION VISIT COMPLETED IN AUSTRALIA

SARASOTA, Fla., March 12, 2026 (GLOBE NEWSWIRE) -- Oragenics, Inc. (NYSE American: OGEN), a clinical-stage biotechnology company pioneering brain-targeted therapeutics through proprietary intranasal delivery technology, today announced it has completed the first site initiation visit (SIV) for its Phase IIA clinical trial of ONP-002 in Australia. The visit marks the formal launch of clinical trial operations at the first of three planned trial sites in Australia, including completion of site staff training, protocol orientation, and site regulatory documentation.

The remaining two clinical trial sites are currently completing their Research Governance Office (RGO) reviews — the final administrative step required following Human Research Ethics Committee (HREC) approval before each site can activate to begin patient enrollment and dosing. The Company expects these reviews to be completed in the near term, at which point all three sites will be positioned to enroll patients.

The Phase IIA trial initiation follows the Company's receipt of HREC approval earlier this year, which represented the final regulatory clearance required to commence clinical site contract finalization, activation, and onboarding.

PHASE IIA CLINICAL TRIAL OVERVIEW

The Phase IIA trial is a randomized, placebo-controlled study evaluating the safety, tolerability, and preliminary clinical signals of ONP-002 in patients presenting with acute concussion and mild traumatic brain injury. Key design parameters include:

- Enrollment target: 40 patients across three Australian clinical sites
- Dosing window: First dose administered within 12 hours of concussion onset
- Primary endpoints: Safety (adverse events, nasal examinations), neurocognitive follow-up assessments, and participant compliance/tolerability
- Trial status: First SIV complete; two remaining sites in RGO final review prior to activation

"We said we would advance ONP-002 into patients in Australia — and that process is now underway. Our first site is trained, operational, and ready to enroll. The remaining sites are completing their final governance reviews, and we expect them to follow shortly. This is the kind of measured, disciplined execution that clinical development demands, and our team is delivering. Patient dosing is the next step, and we are ready." — Chief Executive Officer, Janet Huffman.

"Site initiation marks the transition from regulatory preparation to active clinical operations. Our investigators are trained on the protocol, safety procedures are in place, and our CRO is coordinating operations across all three sites. The RGO review process at the remaining sites is proceeding as expected. We anticipate completing site activation across all three locations in the near term and beginning patient enrollment shortly thereafter."

— Chief Medical Officer, Dr James Kelly M.D.

ABOUT ONP-002

ONP-002 is a first-in-class intranasal neurosteroid in Phase IIa clinical development for the treatment of concussion and mild traumatic brain injury. Unlike current approaches limited to symptom management and rest, ONP-002 is designed to interrupt the neuroinflammatory cascade triggered by brain trauma — reducing neuroinflammation, oxidative stress, and cerebral edema at the source. Phase 1 clinical trials in 40 patients demonstrated ONP-002 was safe and well-tolerated across all dose levels with zero serious adverse events (SAEs). There are currently no FDA-approved pharmacological treatments for concussion or mTBI.

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 our 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; the timing, conduct, interim results announcements and outcomes of our clinical trials for our product candidates, including ONP-002 for the treatment of concussion and mTBI; our acquisition strategy and prospects; and our ability to finance our operations. 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, circumstances should change, except as otherwise required by law.

ABOUT ORAGENICS

Oragenics, Inc. (NYSE American: OGEN) is a clinical-stage biotechnology company pioneering brain-targeted therapeutics through proprietary intranasal drug delivery technology. The Company's lead candidate, ONP-002, is a first-in-class intranasal neurosteroid in Phase IIa clinical development for the treatment of concussion and mild traumatic brain injury (mTBI) — conditions affecting an estimated 69 million people globally each year with no approved pharmacological treatment. Oragenics' intranasal delivery platform is designed to enable rapid, non-invasive delivery of therapeutics directly to the brain by bypassing the blood-brain barrier. The Company is exploring broadening its CNS pipeline strategy through both internal development and strategic business development. For more information, visit www.Oragenics.com.

Investor Contact:

800-383-4880

ir@oragenics.com



Source: Oragenics, Inc.