May 18, 2026

ORAGENICS PROVIDES INVESTOR UPDATE

A MESSAGE FROM OUR CHIEF EXECUTIVE OFFICER

Sarasota, FL, May 18, 2026 (GLOBE NEWSWIRE) -- Oragenics, Inc. (NYSE American: OGEN)

Dear Fellow Shareholders,

Since our last investor update, Oragenics has continued to execute across all fronts — in the clinic, in the regulatory pipeline, on our balance sheet, and strategically. We have reached a pivotal moment: our Phase IIa clinical trial of ONP-002 is active in Australia, patients are being enrolled and dosed, and we have now signed a Letter of Intent to pursue a licensing agreement for a complementary CNS-related medical device. Our focus is sharper than ever — and the progress we are making reflects that.

Below is a full account of what has been accomplished and what is coming next.

PHASE IIa CLINICAL TRIAL — EXECUTION UNDERWAY

ONP-002 | First-in-Class Intranasal Neurosteroid for Concussion / mTBI

Our Phase IIa randomized, placebo-controlled feasibility study of ONP-002 in Australia is no longer a future event — it is happening now. Key clinical updates:

- Mackay Base Hospital — site formally activated March 31, 2026. Site staff trained, protocol in place, drug on site. Patient enrollment began immediately upon activation.
- First patient dosed at Mackay within days of activation — which we believe is a strong signal of clinical site readiness and real-world demand for the trial.

- Alfred Hospital (Melbourne) - site formally activated in April 2026. Site staff trained and drug on site. Patients are actively being screened for enrollment.
- Royal Adelaide Hospital — Site initiation visit and staff training completed in May 2026. Formal site activation is pending final Research Governance Office approval processes and is anticipated imminently.
- Southern Star Research continues to manage CRO operations across all sites.
- Zero serious adverse events have been recorded.

Trial design: 40-patient enrollment target | Randomized, placebo-controlled | First dose within 12 hours of concussion | 30-day follow-up with neurocognitive testing | Primary endpoints: safety, tolerability, and feasibility.

U.S. IND PROGRAM — ON CRITICAL PATH

In parallel with the Australian Phase IIa trial, Oragenics is actively advancing the regulatory program required to bring ONP-002 to U.S. clinical trials. Our scientific and regulatory team is progressing across all IND-enabling disciplines — including pharmacology, toxicology, chemistry and manufacturing controls, and clinical protocol design.

Two near-term milestones anchor our U.S. pathway. First, we are targeting submission of a Type C Meeting Request to the FDA in the second quarter of 2026 — a formal pre-IND interaction that allows the Company to receive FDA guidance on the U.S. clinical development path before committing to full study designs. Second, we are targeting submission of the full Investigational New Drug application by the end of 2026, which would position Oragenics to initiate U.S.-based clinical trials in 2027.

We believe both milestones are on track. Our regulatory consulting partners continue to drive the technical work, and the scientific team provides weekly progress updates. We remain confident in our ability to meet these timelines.

STRATEGIC PIPELINE EXPANSION — LOI SIGNED

Licensing Agreement LOI Executed — CNS Medical Device

Oragenics has signed a Letter of Intent (LOI) to pursue a licensing agreement for a complementary CNS-related medical device. We believe this transaction, if completed, could expand the Company's addressable indication set beyond ONP-002 while reinforcing Oragenics' strategic identity as a CNS platform company.

Key deal structure considerations:

- Licensing structure carves out TBI indication rights while allowing the licensor to pursue other indications independently.
- Additive to the CNS pipeline narrative: alongside ONP-002 and the CNS candidate molecules identified through our Receptor.AI collaboration, we believe this device will expand our addressable indication set and strengthen our platform.

FINANCIAL POSITION

Key Financial Metrics

Q1 2026 for the three months ended March 31, 2026:

- Cash balance: $6.1 million
- Research and development expenses were $0.6 million – increased 89% from the same period in 2025
- General and administrative expenses were $ 1.6 million – decreased 4% from the same period in 2025

Capital Markets Activity:

- ATM facility active: New S-3 filed January 2026; SEC review completed and the facility is available to the Company upon request.

- ATM activity generated proceeds in Q1 2026; the Company continues to evaluate optimal timing for future capital raises in connection with clinical and regulatory milestones.

CORPORATE & OPERATIONAL MILESTONES

Annual Shareholder Meeting

- Annual Meeting scheduled for June 29, 2026.

ANTICIPATED UPCOMING CATALYSTS

The following milestones represent near-term value inflection points for the Company and our shareholders:

- Additional Australian clinical trial site activations (Royal Adelaide Hospital — expected near-term)
- Multi-patient enrollment progress update
- Type C Meeting Request submitted to FDA
- Annual Shareholder Meeting (June 29, 2026)
- IND submission to FDA - 2026
- Phase IIa data readout - 2026

About Oragenics, Inc.

Oragenics, Inc. (NYSE American: OGEN) is a clinical-stage biopharmaceutical company focused on pioneering neurological therapeutics for patients with unmet medical needs. The Company's lead asset, ONP-002, is a first-in-class intranasal neurosteroid in Phase IIa clinical trials for the treatment of concussion and mild traumatic brain injury — a condition affecting an estimated 69 million people worldwide annually for which no FDA-approved pharmacological treatment currently exists. Delivered via a proprietary intranasal device, ONP-002 is designed to bypass the blood-brain barrier to directly reduce neuroinflammation and oxidative stress at the source of injury. 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. There can be no assurances that the transactions contemplated by the Letter of Intent will be consummated on the terms described therein or at all.

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