

March 17, 2026



ORAGENICS FILES ANNUAL REPORT ON FORM 10-K

REPORTS YEAR OF STRATEGIC TRANSFORMATION AND CLINICAL ADVANCEMENT

SARASOTA, Fla., March 17, 2026 (GLOBE NEWSWIRE) -- Oragenics, Inc. (NYSE American: OGEN), a clinical-stage biotechnology company pioneering brain-targeted therapeutics through proprietary intranasal delivery technology, today announced the filing of its Annual Report on Form 10-K for the fiscal year ended December 31, 2025, with the U.S. Securities and Exchange Commission. In conjunction with this filing, the Company is providing a shareholder update on key operational and clinical milestones achieved during 2025 and progress made in the first quarter of 2026.

The Annual Report on Form 10-K, including audited financial statements for the fiscal year ended December 31, 2025, is available on the SEC's EDGAR system at www.sec.gov and on the Company's investor relations website at www.ir.oragenics.com.

2025: A YEAR OF DECISIVE TRANSFORMATION

Fiscal year 2025 represented a pivotal year in Oragenics evolution — from a company managing legacy challenges to a focused, execution-oriented clinical-stage biotechnology company with a clear path forward. Key operational milestones achieved in 2025 include:

- **NYSE American Compliance Restored:** Regained full listing compliance, reflecting improved governance and shareholder alignment
- **CRO Engaged:** Contracted a qualified clinical research organization to lead Phase IIa trial operations across three Australian sites
- **US based Drug Manufacturing:** Moved drug manufacturing out of China and to the United States, contracting Sterling Pharma Solutions for FDA cGMP (Current Good Manufacturing Practice) manufacturing in Cary, North Carolina.
- **Receptor.AI Partnership Established:** Formalized a strategic partnership with Receptor.AI to leverage artificial intelligence in central nervous system (CNS) drug discovery, expanding the Company's pipeline development capability beyond ONP-002

Key financial milestones achieved in 2025 include:

- **\$16.5 Million Capital Raise:** Completed a successful financing that strengthened the Company's balance sheet and funded advancement of ONP-002 through Phase IIa clinical trials in Australia
- **No Debt:** Repaid in full the \$3.0 million promissory note
- **Financial Stewardship:** Reduced operating expenses by 11% year over year with

R&D expenses and overhead salaries and wages as the largest drivers of this expense reduction.

- **Cash Position:** Net cash used in operations was approximately \$ 9 million and net cash from financing was approximately \$16.8 million.

2026 PROGRESS — FIRST QUARTER

Building on 2025 momentum, the Company made the following material advances in early 2026:

- **HREC Ethics Approval Received:** Obtained Human Research Ethics Committee (HREC) approval in Australia — the final regulatory clearance required to begin patient dosing in the Phase IIa trial of ONP-002 in Australia
- **Phase IIa Site Initiation Underway:** Completed the first site initiation visit (SIV) at the initial Australian clinical trial site; two additional sites advancing through final Research Governance Office reviews
- **Patient Enrollment Positioning:** All three sites in Australia expected to complete RGO review in the near term, at which point patient enrollment and dosing will commence
- **CNS Portfolio Strategy Activated:** The Company is actively pursuing discussions with potential partners regarding the acquisition of additional CNS assets synergistic with ONP-002 and the Company's intranasal delivery platform
- **US Clinical Trial Strategy:** Engaged DUCK FLATS Pharma as its U.S. IND readiness and regulatory execution partner to support FDA-facing preparation and clinical trial design
- **Annual Report Filed:** Form 10-K filed for fiscal year ended December 31, 2025

2026 STRATEGIC PRIORITIES

- Enroll and dose patients in the Phase IIa clinical trial of ONP-002 in Australia
- File an IND with the FDA to enable a U.S.-based clinical trials
- Advance CNS portfolio expansion strategy by evaluating and pursuing synergistic asset acquisition opportunities

"2025 was the year we reset this company — financially, operationally, and strategically," reported Janet Huffman, the Company's Chief Executive Officer. "We raised capital, restored compliance, resolved a material legacy liability, and built the partnerships and infrastructure to compete at a higher level. None of that was easy, and none of it was accidental. It was the result of disciplined execution by a team that believes deeply in what ONP-002 can do for the 69 million people worldwide who suffer concussions every year with no approved pharmacological treatment available to them. 2026 is not about resetting. It is about executing. We are in the clinic. Patients will be dosed. And we are actively exploring the expansion of our CNS platform."

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 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.

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Source: Orogenics, Inc.