UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

Date of Report: March 10, 2026
(Date of earliest event reported)

Oragenics, Inc.
(Exact name of registrant as specified in its charter)

FL	001-32188	59-3410522
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification Number)

9015 Town Center Parkway, Suite 143 Lakewood Ranch, Florida	34202
(Address of principal executive offices)	(Zip Code)

813-286-7900
(Registrant's telephone number, including area code)

(Former Name or Former Address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	OGEN	NYSE American

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

ITEM 8.01. OTHER INFORMATION.

On March 10, 2026, Oragenics, Inc. (the "Company") issued a press release announcing that it had received final Human Research Ethics Committee (HREC) approval in Australia to commence the Company's Phase IIa clinical trial evaluating the Company's lead drug candidate, ONP-002, for the treatment of concussion and mild traumatic brain injury (mTBI).

On March 11, 2026, the Company issued a press release announcing that the Company is exploring discussions with third parties regarding the potential acquisition of additional assets in the central nervous system (CNS) space.

On March 12, 2026, the Company intends to issue a press release announcing today announced it has completed the first site initiation visit (SIV) for its Phase IIa clinical trial of ONP-002 in Australia.

A copy of each of the Press Releases is attached hereto as Exhibits 99.1, 99.2 and 99.3, respectively, and is incorporated by reference herein.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated March 10, 2026.
99.2	Press Release dated March 11, 2026.
99.3	Press Release dated March 12, 2026.
104	Cover page Interactive Data File (embedded in the cover page formatted in Inline XBRL)

SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on this 11th day of March 2026.

ORAGENICS, INC.
(Registrant)

BY: */s/ Janet Huffman*
Janet Huffman
Chief Executive Officer

Exhibit 99.1

FOR IMMEDIATE RELEASE

Oragenics Receives HREC Approval for Phase IIa Clinical Trial of ONP-002 as a Treatment for Concussion and Mild Traumatic Brain Injury in Australia

All required regulatory approvals secured for trial site onboarding and patient enrollment at three Australian sites

Potential first and only pharmacological treatment for the most prominent neurological condition without an FDA-approved therapeutic

SARASOTA, Fla., March 10, 2026 (BUSINESS WIRE) — Oragenics, Inc. (NYSE American: OGEN), a clinical-stage biotechnology company developing brain-targeted therapeutics through proprietary intranasal delivery technology, today announced that it has received final Human Research Ethics Committee (HREC) approval in Australia to commence its Phase IIa clinical trial evaluating its lead drug candidate, ONP-002, for the treatment of concussion also known as mild traumatic brain injury (mTBI). Oragenics has now secured all necessary regulatory approvals and submitted all required filings to proceed with clinical site onboarding at three sites in Australia, with Bayside Health (Alfred Health) serving as the Lead Site.

Traumatic brain injury ranks as the most prominent neurological condition without an FDA-approved therapeutic. 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 exist — leaving patients, military personnel, athletes, and families without effective intervention 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]

ONP-002 is a first-in-class intranasal neurosteroid designed to address the underlying biology of mTBI — 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, potentially representing a paradigm shift from symptom management to active neurological intervention. It would also enter a nasal drug delivery market expected to reach nearly $93 billion by 2030.[3]

“Concussion and mTBI represent areas of enormous unmet medical need, and we have spent years building toward this moment responsibly and rigorously. With our Australian HREC and governance approvals now in place, we have everything we need to move forward expeditiously with clinical site onboarding and patient enrollment in Australia. We expect to dose our first patient before the end of March. This is a major milestone for Oragenics — but more importantly, it is a meaningful step toward bringing a potential breakthrough therapy to a patient population that has had no viable treatment options. For the millions of people who suffer from mTBI every year and are told there is nothing that can be done, we are here to change that,” said Janet Huffman Oragenics Chief Executive Officer.

“The HREC approval process is thorough by design — it exists to protect patients and ensure that only protocols with sound scientific rationale and rigorous safeguards move forward. We believe receiving this clearance confirms that our trial design, safety protocols, and investigator teams meet the highest standards. As a clinician who has worked with concussion patients for decades, I understand the significance of this moment. ONP-002 targets the injury itself, not just the symptoms. That is a fundamentally different approach to mTBI care, and we are now putting it to the test in patients. The Phase 1 safety profile gives us strong confidence as we advance into this next phase,” said Dr James Kelly Oragenics Chief Medical Officer.

Oragenics’ approved 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 are expected to receive first dosing within 12 hours of injury, 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.

The Phase IIa clinical data readout is projected before year-end 2026. Oragenics expects that findings will support its planned investigational new drug (IND) application submission to the FDA for further clinical trials in the U.S.

[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

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

Southern Star Research, a leading full-service Australian clinical research organization (CRO), is expected to manage all aspects of the Phase IIa trial from start to finish.

About ONP-002

ONP-002 is an investigational neuroprotective, anti-inflammatory intranasal drug candidate targeting mild traumatic brain injury (mTBI). Designed to potentially interrupt biological pathways involved in inflammation, oxidative stress, and 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. clinical 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 mild traumatic brain injury. Oragenics is progressing ONP-002 through Phase IIa clinical trials in Australia, with U.S. clinical trials planned to follow pending FDA investigational new drug application (IND) approval. The Company believes its intranasal delivery platform has potential applications across multiple neurological conditions, including Parkinson’s disease, Alzheimer’s disease, PTSD, and anxiety 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 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; and 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. 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.

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Exhibit 99.2

FOR IMMEDIATE RELEASE

ORAGENICS EXPLORES EXPANSION OF CNS PLATFORM
PURSUING ACQUISTION OF ASSETS IN BRAIN HEALTH, RECOVERY, AND NEUROPROTECTION

SARASOTA, Fla., March 11, 2026 (BUSINESS WIRE) — Oragenics, Inc. (NYSE American: OGEN), a clinical-stage biotechnology company pioneering brain-targeted therapeutics through proprietary intranasal delivery technology, today announced that it is exploring discussions with third parties regarding the potential acquisition of additional assets in the central nervous system (CNS) space, with a specific focus on brain health and brain recovery indications that demonstrate strategic synergies with the Company's lead candidate ONP-002 and its proprietary intranasal drug delivery platform.

The Company's portfolio expansion initiative is being pursued independently of its existing partnership with Receptor.AI, which focuses on artificial intelligence-enabled CNS drug discovery. Together, these two parallel strategies — traditional asset acquisition and AI-driven discovery — reflect Oragenics desire to build a diversified, platform-anchored CNS portfolio.

No definitive agreements have been reached, and there can be no assurance that any transaction will be completed on terms acceptable to the Company, or at all. The Company will disclose any material transaction in accordance with applicable securities laws and regulations.

STRATEGIC RATIONALE

Oragenics' CNS portfolio expansion strategy is grounded in the Company's belief that its proprietary intranasal delivery platform represents a broadly applicable technology with potential across multiple brain health and brain recovery indications. The Company is evaluating acquisition candidates on the following criteria:

- Brain Health and Brain Recovery Focus: Candidates targeting neurological conditions involving brain injury, neuroinflammation, cognitive impairment, or recovery of brain function
- Platform Synergy: Assets that are well-suited for intranasal delivery or that would benefit from the Company's existing CNS regulatory and clinical development capabilities
- Clinical Stage and Data: Candidates with meaningful preclinical or early clinical evidence that can be efficiently advanced through development
- Strategic Fit: Opportunities that complement — without displacing — the Company's commitment to advancing ONP-002 through Phase IIa in Australia and into U.S.-based Phase IIb trials

ONP-002 PROVIDES THE FOUNDATION

Oragenics' decision to actively pursue CNS portfolio expansion is grounded in the progress of its lead program. The Phase IIa clinical trial of ONP-002 is now in active site initiation, with the first site initiation visit completed in Australia and two additional sites in Australia completing final Research Governance reviews prior to patient enrollment.

ONP-002 is the only pharmacological candidate in clinical development targeting the underlying biology of concussion and mild traumatic brain injury — reducing neuroinflammation, oxidative stress, and cerebral edema at the source. Phase 1 demonstrated safety and tolerability in 40 patients with zero serious adverse events. There are currently no FDA-approved pharmacological treatments for concussion or mTBI.

Following Phase IIa in Australia, the Company plans to submit an IND application to the FDA for continued US based clinical trials in 2027 to advance the development of ONP-002.

"ONP-002 is advancing in human trials right now – and that progress is exactly what gives us the confidence to continue to look forward. We believe our intranasal delivery platform is not a single-drug asset. It is a technology designed to get therapeutics into the brain rapidly, non-invasively, and effectively. We believe there are real opportunities in the brain health and brain recovery space that could benefit from this platform – some of which we have begun to explore. Our goal isintend to build a CNS company that makes a meaningful impact on how the work treats diseases of the brain. That starts with ONP-002, and it should not stop there." – Janet Huffman, Chief Executive Officer, Oragenics, Inc.

ABOUT THE INTRANASAL DELIVERY PLATFORM

Oragenics' proprietary intranasal drug delivery system is designed to enable rapid, non-invasive delivery of therapeutic compounds directly to the brain via the olfactory and trigeminal nerve pathways, bypassing the blood-brain barrier. We believe the platform has the potential to address a fundamental challenge in CNS drug development: delivering therapeutics to the brain with efficiency, speed, and tolerability. Oragenics believes the platform has broad applicability across multiple brain health indications, positioning the Company to build a pipeline anchored in a differentiated and defensible delivery technology.

FORWARD-LOOKING STATEMENTS

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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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Exhibit 99.3

ORAGENICS INITIATES PHASE IIA CLINICAL TRIAL SITE ACTIVATION
FIRST SITE INITIATION VISIT COMPLETED IN AUSTRALIA

SARASOTA, Fla., March 12, 2026 (BUSINESS WIRE) — 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

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