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 27, 2025
(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)

1990 Main Street Suite 750 Sarasota, FL	34236
(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 27, 2025, Oragenics, Inc. (the "Company") issued a press release updating the Company's shareholders on recent Company developments that have occurred in the first quarter of 2025. A copy of the Press Release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release Dated, March 27, 2025.
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 27th day of March 2025.

ORAGENICS, INC.
(Registrant)

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

Exhibit 99.1

Oragenics, Inc. Provides Q1 2025 Shareholder Update on Strategic and Financial Progress

ONP-002 Advances Toward Phase IIa Concussion Trial with Strengthened Financial Foundation and Industry Momentum

SARASOTA, Fla., Mar. 27, 2025 (GLOBE NEWSWIRE) — Oragenics, Inc. (NYSE American: OGEN), a biotechnology company focused on developing novel intranasal therapies for brain-related conditions, today provided shareholders with an update on its strategic and financial progress for the first quarter of 2025. The Company has made meaningful advancements across regulatory, clinical, financial, and partnership initiatives, further positioning its lead therapeutic candidate, ONP-002, as a first-in-class solution for treating concussion.

"We believe ONP-002 is one of the most undervalued clinical assets in biotechnology today," said Janet Huffman, Interim CEO of Oragenics. "With strong preclinical validation and clinical safety data, a scalable ONP-002 intranasal delivery system, and no current FDA-approved treatments for concussion, ONP-002 could redefine the standard of concussion care. Our Q1 progress — from regulatory submissions to our landmark partnership with BRAINBox — reflects a sharpened strategic focus and operational momentum. We're energized by what's ahead and remain committed to delivering long-term value for our shareholders."

Key Accomplishments in Q1 2025

In the first quarter of 2025, Oragenics achieved several strategic and operational milestones:

- **Industry Engagement & Awareness**: Participated in the 12th Annual Brain Health Summit at Leigh Steinberg's Super Bowl Party 2025, helping raise visibility for traumatic brain injury (TBI) and ONP-002's potential therapeutic impact.
- **Strategic Partnership**: Established a collaboration with BRAINBox Solutions to combine diagnostic biomarkers with ONP-002's intranasal delivery system, aiming to transform concussion treatment by enabling faster, more targeted care.
- **Clinical Trial Advancements**: Submitted the Investigator's Brochure (IB) for the Phase IIa clinical trial in Australia, marking a key regulatory step. The trial is now publicly listed on ClinicalTrials.gov.
- **Strengthened Financial Position**: Raised approximately $5 million through a combination of dilutive and non-dilutive capital, including approximately $2.6 million via At-the-Market (ATM) equity financing and approximately $2.25 million through non-dilutive debt funding.
- **Shareholder Communications**: Announced that the 2025 Annual Shareholder Meeting will be held on May 2, 2025, with the preliminary proxy filed with the SEC on March 19, 2025.

ONP-002: An Undervalued Asset with First-Mover Advantage

Oragenics' lead drug candidate, ONP-002, is a neuroprotective, anti-inflammatory compound administered intranasally for the treatment of concussion, classified as a mild traumatic brain injury (mTBI). ONP-002 is an intranasal therapeutic being developed for concussion and is designed to interrupt key biological pathways involved in inflammation, oxidative stress, and swelling following head trauma.

Although still in clinical development, ONP-002 represents a "silent asset" that has been significantly de-risked through extensive preclinical studies. These include cardiotoxicity, genotoxicity, and dose-ranging evaluations. In addition ONP-002 successfully completed a Phase I human study that was well-tolerated with no serious adverse events. With a novel formulation and scalable ONP-002 intranasal delivery system already in place, ONP-002 is ready for rapid and cost-effective progression through clinical phases.

Clinical and Regulatory Milestones Build Momentum

In late 2024 and early 2025, Oragenics finalized drug production for the Phase IIa clinical trial and submitted the Investigator's Brochure to regulatory authorities in Australia. The trial has been officially listed on ClinicalTrials.gov, and the Company is now awaiting approval from the Human Research Ethics Committee (HREC), with first patient enrollment expected shortly thereafter.

"Reaching this stage of clinical preparation—especially with a commercial-ready delivery device and finalized drug product—positions us for rapid execution once regulatory clearance is received," added Huffman.

Strategic Partnership with BRAINBox Solutions

In February, Oragenics formed a pivotal collaboration with BRAINBox Solutions, a diagnostics company pioneering biomarker-based concussion testing. This partnership pairs Oragenics' intranasal therapeutic with BRAINBox's diagnostic tools to create a smarter, faster, and more personalized approach to concussion care.

"This collaboration unites two emerging leaders in brain health—Oragenics in therapeutic innovation and BRAINBox in diagnostic excellence," said Huffman. *"Together, we are designing a smarter, faster approach to treating concussion that could set a new benchmark for the field."*

Increased Visibility and Market Awareness

Beyond industry events, Oragenics has made a concerted effort in recent months to engage investors, clinicians, and thought leaders through media, podcasts, and speaking opportunities. The Company's outreach has focused on raising awareness around the scale of untreated concussion, the science behind ONP-002, and the lack of approved pharmacological options.

"We've worked diligently to educate the market—both the investment community and clinical stakeholders—about the game-changing potential of ONP-002," said Huffman. *"The response has been highly encouraging. It's clear there is an unmet need, and the concept of a fast-acting, intranasal treatment resonates with physicians, patients, and investors alike."*

Financial Foundation and Capital Structure Improvements

In Q1 2025, Oragenics raised approximately $5 million in new funding through a balanced mix of equity and debt capital. This included approximately $2.6 million via ATM equity sales and approximately $2.25 million in non-dilutive debt financing. In addition, the Company submitted a grant request to the Department of Defense to secure non-dilutive capital in support of its concussion program. In Q4 2024, Oragenics also converted all outstanding Series A and B preferred shares to common stock, simplifying its capital structure and enhancing transparency for shareholders.

"This funding underscores our ability to secure capital through multiple channels and at critical moments," Huffman stated. *"It reflects growing confidence in our strategy and allows us to continue executing with discipline and focus."*

Operational Efficiencies and Governance Updates

As part of its disciplined approach to resource management, Oragenics implemented executive leadership changes in late 2024 that have meaningfully reduced fixed overhead costs. These moves ensure that capital is directed toward value-driving programs like ONP-002. The Company also confirmed that its 2025 Annual Shareholder Meeting will be held on May 2, 2025, with preliminary proxy materials filed in March.

Key Milestones Ahead

With strong positioning across clinical, operational, and financial fronts, Oragenics is preparing to advance ONP-002 through the next stage of development. The Company's upcoming projected milestones include:

Milestone	Expected Timing
HREC approval in Australia	Q2 2025
First patient enrolled in Phase IIa trial	Q2 2025
Completion of Phase IIa enrollment	Q4 2025
Interim safety and biomarker readout	Q4 2025 – Q1 2026
Initiation of Phase IIb (Part B)	Q1 2026
Topline Phase IIb results	Q2 2026
FDA End-of-Phase 2 Meeting	Q3 2026
FDA Accelerated Approval Filing (if eligible)	Q3 2026
First revenues from licensing or early access	2027 (projected)

Our Commitment to Long-Term Value Creation

As Oragenics enters a pivotal execution phase, the Company remains committed to advancing ONP-002 with urgency and precision. Its goal is to deliver a meaningful clinical breakthrough in concussion care and to generate long-term value for its shareholders.

"We are committed to seeing ONP-002 through to its full potential," said Huffman. *"With each milestone we reach, our conviction only grows stronger. This is more than a drug program—it's an opportunity to change the standard of care for millions of patients. Our team is fully aligned, fully engaged, and determined to deliver results that matter for shareholders and society alike."*

Investor Contact

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About Oragenics, Inc.

Oragenics is a biotechnology company focused on developing intranasal therapeutics for neurological disorders, including its lead candidate, ONP-002, for the treatment of mild traumatic brain injury (mTBI) or concussion. The Company is also advancing proprietary powder formulations and intranasal delivery technology to enhance drug administration. 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. These forward-looking statements are based on management's beliefs and assumptions and information currently available. The words "believe," "expect," "anticipate," "intend," "estimate," "project" 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 Form 10-K and other filings with the U.S. Securities and Exchange Commission. All information set forth in this press release is as of the date hereof. You should consider these factors in evaluating the forward-looking statements included in this press release and not place undue reliance on such statements. 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.
