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: November 12, 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 November 12, 2025, Oragenics, Inc. (the "Company") issued a press release updating the Company's shareholders on recent Company developments that have occurred in the third quarter of 2025 and shortly thereafter. 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 November 12, 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 12th day of November 2025.

ORAGENICS, INC.
(Registrant)

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

Exhibit 99.1

Oragenics Q3 2025 Shareholder Update

Building on Solid Ground: From Vision to Execution

Restoring Compliance, Advancing Innovation, Preparing for Clinical Milestones

SARASOTA, Fla., November 12, 2025 — Oragenics, Inc. (NYSE American: OGEN), a clinical-stage biotechnology company developing brain-targeted therapeutics through proprietary intranasal delivery technology, today reported key operational, financial, and strategic achievements for the third quarter of 2025. These milestones reflect the Company's evolution from vision to execution as it advances toward critical clinical trial initiation in Q4 2025/Q1 2026.

OPERATIONAL EXCELLENCE: FOUNDATION RESTORED

NYSE American Compliance Regained

On October 20, 2025, Oragenics regained full compliance with NYSE American's continued listing standards, resolving the stockholder equity deficiency that had placed the Company on noncompliant status. The below-compliance indicator has been removed, and Oragenics has been removed from the NYSE American noncompliant issuers roster.

"Regaining compliance represents more than checking a regulatory box—it demonstrates our commitment to financial discipline, operational accountability, and transparent investor relations," said CEO Janet Huffman. *"We addressed the equity deficiency head-on, executed a strategic capital raise, and emerged with a balance sheet that supports our clinical objectives. That's the kind of execution investors should expect from this management team."*

Clinical Trial Infrastructure Secured

Oragenics has established the critical operational infrastructure required for successful Phase IIa trial execution in Australia:

- **Human Research Ethics Committee (HREC) approval** secured in Q2 2025
- **Southern Star Research** appointed as Clinical Research Organization (CRO)
- **Sterling Pharma Solutions** contracted for cGMP manufacturing at their Cary, North Carolina facility
- **HREC protocol amendments submitted** to update sponsor, principal investigator, and clinical protocol—currently under regulatory review

"Clinical trial execution requires meticulous attention to regulatory detail. We're working through HREC amendments methodically and properly—not cutting corners to meet arbitrary deadlines," said Huffman. *"Once these final amendments are approved, we anticipate that we will onboard clinical sites, enroll patients, and dose our first patient. We believe that milestone will represent the first drug Oragenics has ever advanced into clinical trials—a transformational moment for this company."*

STRATEGIC INNOVATION: BEYOND A SINGLE ASSET

Receptor.AI Partnership: Accelerating Pipeline Development

In Q3 2025, Oragenics formalized a strategic collaboration with Receptor.AI, an artificial intelligence-driven drug discovery platform, with the goal of accelerating the development of the Company's expanded molecule portfolio beyond ONP-002. We believe this partnership leverages advanced AI modeling to identify optimal receptor binding profiles for molecules Oragenics acquired in previous years, enabling more efficient laboratory validation and potential therapeutic applications across multiple neurological conditions.

"We're not building a one-drug company—we're building a neurological therapeutics platform," said Huffman. *"The Receptor.AI partnership demonstrates how we're thinking strategically about capital efficiency. Instead of blindly testing molecules in the lab, we're hoping to use AI to predict which candidates have the highest probability of success. That's smart science and smart business."*

We believe the Company's intranasal delivery platform has potential applications beyond concussion treatment, including Parkinson's disease, Alzheimer's disease, PTSD, anxiety disorders, and other acute and chronic neurological conditions. The AI-driven partnership positions Oragenics to systematically explore these opportunities while maintaining focus on ONP-002 clinical development.

Market Opportunity: Platform Technology Leadership

Oragenics' proprietary intranasal delivery technology positions the Company at the forefront of a rapidly expanding market:

- **Nasal drug delivery market** projected to exceed $40 billion by 2030
- **Concussion/mTBI market** estimated at $8.9 billion globally by 2027
- **No FDA-approved pharmacological treatments** currently exist for concussion
- **3.8 million concussions** occur annually in the United States alone

FINANCIAL DISCIPLINE: CAPITAL EFFICIENCY AND RUNWAY

Strengthened Balance Sheet

We believe the Company's July 2025 capital raise of $16.5 million (gross proceeds) through Series H Convertible Preferred Stock and Warrants provides meaningful runway to advance ONP-002 through Phase IIa clinical trials in Australia and prepare for U.S. Phase IIb trials. Post-capital raise:

- **Net proceeds:** ~$15.2 million after fees and expenses
- **Debt eliminated:** $3 million note payable paid in full
- **NYSE compliance:** Stockholder equity restored above $6 million threshold

Operational Efficiency Metrics

For the nine months ended September 30, 2025, Oragenics demonstrated continued operational discipline:

- **30% reduction** in research and development expenses (year-over-year)
- **5% decrease** in total operating expenses (year-over-year)

Note: As Oragenics advances toward Phase IIa initiation and subsequent U.S. Phase IIb trials, the Company anticipates strategic increases in R&D investment to support clinical excellence and accelerated development timelines. The current expense reductions reflect the transition period between asset acquisition, regulatory preparation, and active clinical trial execution.

ANTICIPATED UPCOMING CATALYSTS AND MILESTONES

Near-Term Value Drivers (Q4 2025/Q1 2026)

- **Final HREC amendment approval** enabling clinical site onboarding
- **Phase IIa clinical trial initiation** with first patient dosed in Australia
- **IND submission preparations** for U.S.-based Phase IIb clinical trials

Medium-Term Strategic Goals (2026)

- Phase IIa data readout from Australia trials
- IND submission to FDA for U.S. based clinical trials
- Continued AI-driven pipeline expansion research
- Strategic partnership development in concussion care ecosystem

A MESSAGE FROM OUR CEO

Building a Company Worth Believing In

The past quarter represents a turning point for Oragenics—not because we made grand pronouncements, but because we delivered on operational fundamentals that many biotech companies struggle to achieve.

We regained NYSE compliance. We eliminated debt. We secured manufacturing partnerships. We established clinical trial infrastructure. We formalized strategic collaborations that expand our platform beyond a single drug candidate. These aren't flashy milestones, but they're the foundation upon which successful pharmaceutical companies are built.

The regulatory process for clinical trials is complex, methodical, and sometimes frustrating. HREC amendments take time. Manufacturing agreements require thorough vetting. CRO relationships demand careful coordination. We're working through these processes properly—not cutting corners to meet arbitrary timelines that would compromise trial integrity or patient safety.

Our partnership with Receptor.AI demonstrates how we're thinking beyond ONP-002. While our lead program remains the immediate priority, we're attempting to strategically position Oragenics as a neurological therapeutics platform company—not a one-asset bet. The intranasal delivery technology we've developed has potential applications across multiple devastating brain conditions, and we're using cutting-edge AI to identify the most promising opportunities.

To our shareholders: You've supported us through capital raises, reverse splits, and operational pivots. The management team you're backing today is fundamentally different from years past—more experienced, more disciplined, more focused. We're striving to build a company capable of bringing breakthrough therapies to patients who desperately need them.

The first patient dosed in our Phase IIa trial will mark a historic milestone—the first drug Oragenics has ever advanced into clinical trials. But that milestone is just the beginning. We're building infrastructure, partnerships, and capabilities designed to sustain multiple programs through clinical development, regulatory approval, and commercialization.

This is what execution looks like. This is how you build a pharmaceutical company that lasts.

Janet Huffman

Chief Executive Officer

ABOUT ONP-002

ONP-002 is an investigational neuroprotective, anti-inflammatory intranasal drug candidate targeting mild traumatic brain injury (mTBI) or concussion. Designed to interrupt biological pathways involved in inflammation, oxidative stress, and swelling following head trauma, ONP-002 has demonstrated safety and tolerability in Phase I clinical trials. The drug candidate utilizes Oragenics' proprietary intranasal delivery platform to enable rapid 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. Phase IIb trials planned to follow pending FDA 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 concussion and mild traumatic brain injury. Oragenics is progressing ONP-002 through Phase IIa clinical trials in Australia, with U.S. Phase IIb trials planned to follow. The Company's 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, including, but not limited to, statements regarding our future performance, business prospects, events and product development plans. These forward-looking statements are not historical facts, but are based on current expectations, estimates and projections about our industry, our beliefs and our assumptions. These forward-looking statements include statements about our strategies, objectives and our goals. To the extent statements in this Quarterly Report involve, without limitation, our expectations for growth, estimates of future revenue, our sources and uses of cash, our liquidity needs, our current or planned clinical trials or research and development activities, product development timelines, our future products, regulatory matters, expense, profits, cash flow balance sheet items or any other guidance on future periods, these statements are forward-looking statements. 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 Form 10-K, Forms 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.

CONTACTS

Janet Huffman
Chief Executive Officer
IR@oragenics.com