

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: August 11, 2025
(Date of earliest event reported)

Orogenics, Inc.

(Exact name of registrant as specified in its charter)

FL
(State or other jurisdiction
of incorporation)

001-32188
(Commission
File Number)

59-3410522
(IRS Employer
Identification Number)

1990 Main Street
Suite 750
Sarasota, FL
(Address of principal executive offices)

34236
(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 August 11 2025, Orogenics, Inc. (the "Company") issued a press release updating the Company's shareholders on recent Company developments that have occurred in the second 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, August 11, 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 11th day of August 2025.

ORAGENICS, INC.
(Registrant)

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

Oragenics Q2 2025 Shareholder Update
Advancing Brain-First Recovery Platform Toward Clinical Milestones
Pioneering Intranasal Therapeutics for Concussion

SARASOTA, Fla., August 11, 2025 — Oragenics, Inc. (NYSE American: OGEN), a pioneering biotechnology company striving to develop **brain-targeted therapeutics through proprietary intranasal delivery technology**, today shared key strategic and financial milestones achieved during the second quarter of 2025 and shortly thereafter.

These successes underscore the company's momentum as it strives to transform neurotrauma care and advance its lead candidate, ONP-002, toward becoming **the first FDA-approved pharmacological treatment for concussion**.

"We're not just developing another drug, we're striving to pioneer a new era of brain-first recovery that could transform how we treat neurological trauma," said Janet Huffman, Chief Executive Officer of Oragenics. "We believe that our proprietary nasal delivery platform and our lead candidate ONP-002 for concussion, the Company's current cash position, combined with strategic partnerships, position us to lead a paradigm shift in neurotrauma care. We believe that early treatment could prevent chronic brain disorders as a result of mTBI."

CLINICAL LEADERSHIP AND COMPETITIVE ADVANTAGE

Strategic Evolution and Focus

Oragenics' acquisition of ONP-002 in 2024 represents a strategic transformation, focusing the company's extensive R&D capabilities on high-impact neurological therapeutics with clear commercial pathways. We anticipate this focused approach may position Oragenics to achieve a successful drug development milestone.

We anticipate Phase IIa trials will launch in Q3 2025, which we believe will allow Oragenics to maintain a significant clinical advantage in the intranasal neurotrauma space, potentially advancing toward becoming **the first company to bring an FDA-approved pharmacological treatment for concussion to market**.

Key Clinical Milestones Achieved in Q2:

- Human Research Ethics Committee (HREC) approval secured in Australia
- Southern Star Research appointed as Clinical Research Organization (CRO)
- US based cGMP manufacturing agreement finalized with Sterling Pharma Solutions

TRANSFORMATIONAL PLATFORM OPPORTUNITY

We believe Oragenics' proprietary intranasal delivery system positions the company at the forefront of the rapidly expanding nasal drug delivery market, projected to exceed \$40 billion by 2030. We anticipate this technology may enable targeted, non-invasive delivery of therapeutics directly to the brain. Although the Company is focused on the treatment of concussion with its lead candidate ONP-002, the applications for its novel intranasal device may extend beyond concussion treatment to acute neurological emergencies and chronic neurodegenerative diseases.

Our Anticipated Technology Advantages:

- Rapid onset and targeted brain biodistribution
- Bypasses systemic circulation, reducing side effects
- Non-invasive, patient and caretaker-friendly administration
- Scalable manufacturing and delivery system
- Potentially broad therapeutic applications across CNS conditions

BUILDING THE CONCUSSION CARE ECOSYSTEM

Industry Engagement and Strategic Partnerships

Oragenics' increased industry presence reflects our commitment to building comprehensive partnerships across the concussion care continuum. Our strategic engagements position us to participate in an integrated treatment ecosystem that aspires to address the full spectrum of brain injury care.

Q2 Industry Leadership:

- **2025 BIO International Convention** (Boston, MA) — Delivered corporate presentation on transforming concussion treatment paradigms
- **42nd Annual National Neurotrauma Society Symposium** (Philadelphia, PA) — Strengthened relationships with leading researchers and clinicians
- **3rd Nasal Formulation & Delivery Summit** (Boston, MA) — CMO shared insights on ONP-002's potentially revolutionary mechanism
- **NATO Blast Meeting** (Canadian Forces College - Toronto, Canada) — CMO attended NATO Blast meeting and strengthened relationships with leading international researchers and clinicians
- **The 15th Annual Traumatic Brain Injury Conference** (Boston, MA) — CMO and CCO attended and delivered corporate presentation on ONP-002, clinical blood biomarkers and the need for a trigger to treat model

STRATEGIC CAPITAL POSITION

Strengthened Financial Foundation

Our recent \$16.5 million capital raise through Series H Convertible Preferred Stock and Warrants reflects growing investor confidence in our transformational approach to neurotrauma treatment. These funds strategically position us to accelerate our lead program while advancing our nasal delivery platform.

Strategic Capital Deployment — We anticipate our recent capital raise may allow us to:

- Accelerate ONP-002 clinical development and Phase IIa and Phase IIb clinical trial execution
- Advance platform technology for future therapeutic applications
- Strengthen manufacturing and regulatory capabilities
- Support operational excellence and working capital needs

"We continue to explore non-dilutive funding opportunities, including government grants and strategic partnerships, to maximize shareholder value while maintaining our focus

on therapeutic development,” added Huffman.

ANTICIPATED UPCOMING CATALYSTS AND MILESTONES

- Phase IIa clinical trial initiation (Q3 2025)
- IND submission to FDA for Phase IIb clinical trial (Q3-Q4 2025)

Anticipated Future Value Drivers (2026):

- Phase IIa data readout (Q3 2026)
- Phase IIb trial initiation in US (Q4 2026)

OPERATIONAL EXCELLENCE AND MARKET READINESS

Manufacturing and Regulatory Progress

Oragenics has secured critical infrastructure to support successful clinical execution and future commercial readiness:

- **Manufacturing Partnership:** Agreement with Sterling Pharma Solutions, a leading CDMO, should provide reliable, scalable cGMP production at their Cary, North Carolina facility
- **Clinical Operations:** Southern Star Research provides globally recognized CRO expertise with proven track record in Australia and Asia-Pacific region
- **Regulatory Strategy:** HREC approval achieved; IND submission preparations underway for U.S. Phase IIb trials

FINANCIAL STRENGTH AND OPERATIONAL EFFICIENCY

Key Financial Highlights for Six Months Ended June 30, 2025:

Operational Discipline: Year-over-year improvements demonstrate our commitment to efficient capital deployment:

- 50% reduction in research and development expenses
- 8% decrease in general and administrative costs
- 6% decline in net losses for the six-month period

Post-Capital Raise Strength:

- Gross proceeds: \$16.5 million from Series H Preferred Stock and Warrants
- Net proceeds: ~\$15.2 million after fees and expenses

As we advance toward Phase IIa initiation, we anticipate strategic increases in R&D investment to support clinical excellence and accelerated development timelines.

MARKET OPPORTUNITY AND COMPETITIVE LANDSCAPE

Massive Unmet Medical Need

With no current FDA-approved treatments for concussion or mild traumatic brain injury (mTBI), the market for effective therapies represents a substantial and completely unmet opportunity. Our proprietary intranasal delivery platform we believe has the potential to offer significant advantages that have the potential to transform concussion management and recovery.

Market Dynamics:

- **No FDA-approved pharmacological treatments** for concussion currently exist
- **Millions of cases annually** across sports, military, and civilian sectors
- **Growing recognition** of long-term effects and need for acute intervention
- **\$8.9 billion global concussion market** opportunity by 2027
- **\$40+ billion nasal delivery technology market** opportunity by 2030

Strategic Positioning: We believe that our first-mover advantage in intranasal neurotrauma therapeutics, combined with our platform technology’s potential for broader applications, may position Oragenics as the category leader in brain-first recovery solutions.

A MESSAGE FROM OUR CEO

Our mission extends beyond developing treatments—we’re attempting to revolutionize how the world approaches brain injury and neurological trauma. With a steadfast commitment to improving patient outcomes through breakthrough science, Oragenics is making strategic strides that position us to lead the transformation of neurotrauma care. Oragenics is positioning itself as more than a pharmaceutical company—we’re building a movement around brain-first recovery; we’re working to shift the conversation from symptom management to true neurological healing.

Our Strategic Focus:

- **Clinical Excellence:** Advancing ONP-002 toward becoming the first FDA-approved concussion treatment
- **Platform Leadership:** Exploring expanding our proprietary nasal delivery technology across multiple therapeutic areas
- **Movement Building:** Working towards creating comprehensive partnerships and advocacy programs that could shift the standard of care

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- **Operational Discipline:** Maintaining efficient capital deployment while accelerating development timelines

The convergence of our clinical leadership, platform technology, strategic partnerships, and strengthened financial position we believe is poised to seize an unprecedented opportunity to transform brain injury treatment while delivering exceptional value to our shareholders.

We're not just treating concussions—we're pioneering the future of brain-first recovery.

Janet Huffman
Chief Executive Officer

ABOUT ONP-002

ONP-002 is a revolutionary 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 post-head trauma, ONP-002 has the potential, we believe, to represent a paradigm shift from symptom management to true neurological healing.

Key Anticipated Differentiators:

- **First-in-class approach** to concussion treatment
- **Rapid brain delivery** through proprietary nasal delivery system
- **Strong preclinical efficacy** and Phase I safety data
- **Precision medicine approach** using biomarker guidance
- **Potential to prevent long-term neurological effects**

ABOUT ORAGENICS, INC.

Oragenics is striving to revolutionize neurological care through proprietary intranasal delivery technology that has the potential to enable targeted, non-invasive therapeutics for brain-related conditions. Our lead candidate, ONP-002, is advancing with the goal of becoming the first FDA-approved treatment for concussion, while our platform technology has the potential, we believe, to open pathways to address neurodegenerative diseases, CNS disorders, and other neurological conditions.

We're building more than a pharmaceutical company—we're creating a movement around brain-first recovery that transforms how patients, clinicians, and healthcare systems approach neurological trauma.

This press release does not constitute an offer to sell, or a solicitation of an offer to purchase, any securities and shall not form the basis of any contract.

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, 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.

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