

**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: October 16, 2025
(Date of earliest event reported)

Oragenics, 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 1.01 Entry into a Material Definitive Agreement

On October 16, 2025, the Company entered into a Settlement Agreement (the “**Settlement Agreement**”) with Ladenburg Thalmann & Co., Inc. (“**Ladenburg**”), pursuant to which the Company and Ladenburg agreed to settle all claims between the parties, including those arising under the Investment Banking Agreement between the parties dated December 7, 2022 (the “**IB Agreement**”). As previously reported, Ladenburg claimed it was due \$2,500,000 in connection with the Company’s purchase of assets from Odyssey Health, Inc. In response, the Company initiated a confidential action for arbitration against Ladenburg with the Financial Industry Regulatory Authority on March 12, 2024, seeking, among other things, a declaratory judgment that no such fee was owed. Pursuant to the Settlement Agreement, the Company paid \$700,000 to Ladenburg in exchange for a mutual release of all claims, and the parties agreed to dismiss their respective claims.

Item 3.01 Notice of Delisting or Failure to Satisfy A Continued Listing Rule or Standard; Transfer of Listing.

On October 20, 2025, Oragenics, Inc. (the “**Company**”) received a letter from the NYSE American informing the Company it has regained compliance with the stockholder’s equity requirements of the NYSE American continued listing standards. As such, it is expected that at the opening of trading on October 21, 2025, the below compliance (“**BC**”) indicator will be removed and the Company will be removed from the list of NYSE American noncompliant issuers.

As previously disclosed, on April 16, 2024 and August 13, 2024, the Company received deficiency letters from the NYSE American indicating that it was not in compliance with the continued listing standards set forth in Sections 1003(a)(i), (ii) and (iii) of the NYSE American Company Guide (the “**Company Guide**”). Section 1003(a)(i) requires stockholders’ equity of no less than \$2,000,000 if the Company has sustained losses from continuing operations and/or net losses in two of its three most recent

fiscal years. Section 1003(a)(ii) requires a listed company to have stockholders’ equity of \$4 million or more if the listed company has reported losses from continuing operations and/or net losses in three of its four most recent fiscal years. Section 1003(a)(iii) requires a listed company to have stockholders’ equity of \$6 million or more if the listed company has reported losses from continuing operations and/or net losses in its five most recent fiscal years. On May 17, 2024, the Company submitted a plan of compliance (the “**Plan**”) to the NYSE American. If the Company had not regained compliance with the continued listing standards by October 18, 2025, the Company would have been subject to delisting procedures as set forth in the Company Guide.

On June 18, 2024, the NYSE American accepted the Company’s Plan and since that time the Company has been executing on its Plan by raising additional capital and reducing expenses. Most recently, as previously reported, on July 2, 2025, the Company successfully consummated a public offering of Series H Convertible Preferred Stock, initially convertible into up to 9,570,000 shares of Common Stock, inclusive of dividends payable on the Series H Preferred Stock and Warrants to purchase up to 660,000 additional shares of Series H Preferred Stock. The July 2025 offering resulted in gross proceeds to the Company of approximately \$16.5 million before deducting placement agent fees and other estimated offering expenses payable by the Company. Prior to that, as previously disclosed, on February 5, 2025, the Company sold 7.8 million shares of Common Stock pursuant to its ATM program, for gross proceeds of \$2.75 million before subtracting commission and legal expenses. Prior to that, as previously disclosed, on September 5, 2024, the Company successfully consummated a public offering of 3,078,378 shares of Common Stock and Pre-Funded Warrants to purchase 5,028,206 shares of Common Stock. The September 2024 Offering resulted in gross proceeds to the Company of approximately \$4.45 million before deducting placement agent fees and other estimated offering expenses payable by the Company.

As a result of foregoing efforts, the Company believes it is in compliance with 1003(a)(i), (ii) and (iii) of the NYSE American Company Guide as the Company’s stockholder’s equity exceeds \$6.0 million, as of October 18, 2025.

On October 20, 2025, the Company received a notice from the NYSE American that it is in compliance with Section 1003(a) of the Company Guide.

Item 7.01 Regulation FD Disclosure.

On October 21, 2025, the Company issued a press release announcing that it had regained compliance with the NYSE American listing standards. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information presented in Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “**Exchange Act**”), or otherwise subject to the liabilities of that section, unless the Company specifically states that the information is to be considered “filed” under the Exchange Act or specifically incorporates it by reference into a filing under the Securities Act of 1933, as amended, or the Exchange Act.

Item 9.01 Financial Statements And Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated October 21, 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 21st day of October 2025.

ORAGENICS, INC.
(Registrant)

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

**Orogenics Regains Full NYSE American Compliance,
Company Resolves Stockholder Equity Deficiency**

SARASOTA, Fla., October 21, 2025 (GLOBE NEWSWIRE) — Orogenics, Inc. (NYSE American: OGEN), a clinical-stage biotechnology company developing brain-targeted therapeutics through proprietary intranasal delivery technology, announced today that it has regained full compliance with NYSE American's continued listing standards and is positioning the Company to focus exclusively on advancing its lead clinical program.

NYSE Compliance Regained

Effective October 20, 2025, the NYSE American notified Orogenics that the Company has regained compliance with Section 1003(a)(iii) of the NYSE American Company Guide, which requires listed companies to maintain stockholders' equity of at least \$6 million. The below-compliance ("BC") indicator will be removed, and Orogenics will be removed from the NYSE American noncompliant issuers roster.

"Regaining compliance represents more than a regulatory milestone—it reflects our commitment to transparency, financial discipline, and restoring investor confidence," said CEO Janet Huffman. "We acknowledged the equity deficiency directly, took decisive action to address it, and emerged with a strengthened balance sheet that supports our clinical objectives."

Strategic Capital Raise Provides Clinical Runway

The compliance restoration follows the successful July 2, 2025 closing of a \$16.5 million public offering of Series H Convertible Preferred Stock. This capital infusion not only restored stockholder equity to compliant levels but also provides meaningful runway to advance ONP-002 through critical Phase II clinical milestones in Australia and prepare for U.S. Phase IIb trials.

Refocused on Clinical Execution

With compliance restored, and capital in place, Orogenics is now singularly focused on advancing ONP-002, its lead candidate for concussion and mild traumatic brain injury. The Company is progressing Phase IIa clinical trials in Australia, with potential U.S. Phase IIb trials planned to follow. ONP-002 represents a potential first-in-class treatment leveraging Orogenics' proprietary intranasal delivery platform, which has potential broad applications across acute and chronic neurological conditions.

"We've cleaned house financially and operationally," said Huffman. "Our team is fully aligned on one objective: delivering clinical data that validates ONP-002's potential to transform care for patients suffering from traumatic brain injuries. That's where our energy and capital are now directed."

About Orogenics

Orogenics is a clinical-stage biotechnology company pioneering brain-targeted therapeutics through proprietary intranasal delivery technology. The Company's lead candidate, ONP-002, is being developed as a potential first-in-class treatment for concussion and mild traumatic brain injury. Orogenics is advancing ONP-002 into Phase IIa clinical trials in Australia, with U.S. Phase IIb trials planned to follow. The Company's intranasal delivery platform has broad potential applications across acute and chronic neurological conditions. For more information, visit www.Orogenics.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Statements 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. These statements include, but are not limited to, statements regarding the Company's ability to maintain compliance with NYSE American listing standards, the expected timing and outcomes of clinical trials, the potential applications of Orogenics' technology platform, the sufficiency of capital to fund operations, and the Company's strategic plans. These forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could cause actual results to differ materially, including risks related to the clinical development process, regulatory approval processes, the Company's ability to secure adequate funding for operations, and those risks set forth in Orogenics' most recent Forms 10-K, 10-Q, and other SEC filings, which are available through EDGAR at www.sec.gov. Orogenics undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, after the date of this press release, except as may be required by law.

Investor Contact

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