

**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: May 7, 2026  
(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)

9015 Town Center Parkway,  
Suite 143  
Lakewood Ranch, Florida

(Address of principal executive offices)

34202

(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 May 7, 2026, Oragenics, Inc. (the "Company") issued a press release announcing that it has signed a Letter of Intent ("LOI") with Sigyn Therapeutics, Inc. ("Sigyn") to license CardioDialysis™, an extracorporeal blood purification technology designed to enable broad-spectrum clearance of inflammatory and pathogenic molecules from the bloodstream.

A copy of the Press Releases 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	<a href="#">Press Release dated May 7, 2026.</a>
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 7<sup>th</sup> day of May 2026.

**ORAGENICS, INC.**  
**(Registrant)**

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

## Orogenics Signs Letter of Intent to License CardioDialysis™ Technology from Sigyn Therapeutics to Target TBI-Induced Systemic Inflammation

*The Expected License Agreement Would Position Orogenics as the Only Company with Therapeutic Strategies Targeting TBI-Induced Inflammation on Both Sides of the Blood-Brain Barrier*

**Sarasota, FL and San Diego, CA — May 7, 2026** — Orogenics, Inc. (NYSE American: OGEN) (“Orogenics” or the “Company”), a clinical-stage biopharmaceutical company pioneering neurological therapeutics, and Sigyn Therapeutics, Inc. (OTCQB: SIGY) (“Sigyn”), a developer of extracorporeal therapies, today announced the signing of a Letter of Intent (“LOI”) under which Orogenics expects to license from Sigyn, certain disease indications of CardioDialysis™, a blood purification technology that enables the broad-spectrum clearance of inflammatory and pathogenic molecules from the bloodstream.

Under the terms of the proposed license agreement, Orogenics would receive an exclusive license from Sigyn to develop and commercialize CardioDialysis™ for the treatment of Traumatic Brain Injury (TBI) and other chronic neurodegenerative diseases.

### Strategic Rationale: Targeting TBI Inflammation on Both Sides of the Blood-Brain Barrier

Orogenics is currently advancing ONP-002, a first-in-class intranasal neurosteroid in Phase IIa clinical trials for concussion and mild traumatic brain injury (mTBI). ONP-002 is designed to cross the blood-brain barrier and directly address the neuroinflammation and oxidative stress that drive TBI-related damage within the brain.

CardioDialysis™ addresses TBI-induced inflammation from a complementary direction — outside the brain — by purifying the bloodstream of inflammatory and pathogenic molecules that accumulate systemically following a TBI event. Together, the two therapeutic approaches would represent a dual-modality strategy designed to attack the inflammatory cascade of TBI at both the central and peripheral levels simultaneously.

There are currently no FDA-approved pharmacological treatments for concussion or mTBI. Orogenics believes this multi-pronged approach could represent a significant advancement in the standard of care for the estimated 69 million individuals worldwide who suffer a brain injury each year.

*“This letter of intent reflects our commitment to building a comprehensive TBI platform — one that addresses the full biology of brain injury, not just symptoms. While ONP-002 targets neuroinflammation directly within the brain, CardioDialysis™ offers a powerful complementary approach to clearing the systemic inflammatory burden that follows a TBI event. We believe combining these two strategies has the potential to redefine recovery outcomes for millions of patients who currently have no approved treatment options.” stated Orogenics’ Chief Executive Officer, Janet Huffman*

*“Beyond the benefit offered to our shareholders, we believe the proposed transaction will position Orogenics as the only Company with therapeutic strategies to directly target TBI-induced inflammation on both sides of the blood-brain barrier,” stated Sigyn Therapeutics CEO, Jim Joyce.*

*“In the future, we envision the possibility of ONP-002 and CardioDialysis™ being synergistically combined to accelerate TBI recovery and reduce long-term adverse events,” concluded Joyce.*

### Summary of LOI Terms

The proposed transaction is structured as an exclusive, assignable license of the CardioDialysis™ technology for use in the agreed Target Markets. Key terms of the LOI include:

**Consideration:** Orogenics expects to issue 3,250,000 shares of a new class of restricted preferred stock to Sigyn, convertible into Orogenics common stock on a one-to-one basis, subject to NYSE American rules and shareholder approval conditions.

**Royalty:** Orogenics expects to pay a 3% royalty on revenue from sales of the licensed technology following FDA market clearance, for a period of six years from the date of first commercial sale per approved indication and country.

**Target Closing:** 90 days or sooner from the effective date of the LOI, subject to completion of due diligence, board approvals, an independent third-party valuation, and other customary closing conditions.

**Exclusivity:** Sigyn has agreed not to license the CardioDialysis™ technology to third parties for the proposed Target Markets during the exclusivity period.

The LOI is non-binding except for certain provisions including exclusivity, confidentiality, and governing law. The completion of a definitive agreement remains subject to due diligence satisfactory to Orogenics, board approvals by both companies, NYSE American continued listing compliance, and other customary closing conditions.

### About CardioDialysis™

CardioDialysis™, developed by Sigyn Therapeutics, is an extracorporeal blood purification technology engineered to enable broad-spectrum clearance of inflammatory cytokines, endotoxins, and other pathogenic molecules from the bloodstream. The technology is designed to leverage naturally occurring pressure dynamics to filter and purify blood plasma through a proprietary cartridge system, with a potential profile that distinguishes it from conventional large-scale plasmapheresis approaches. Sigyn Therapeutics is developing CardioDialysis™ for a range of serious inflammatory conditions.

### About Orogenics, Inc.

Orogenics, Inc. (NYSE American: OGEN) is a clinical-stage biopharmaceutical company focused on pioneering neurological therapeutics for patients with unmet medical needs. The Company’s lead asset, ONP-002, is a first-in-class intranasal neurosteroid in Phase IIa clinical trials for the treatment of concussion and mild traumatic brain injury — a condition affecting an estimated 69 million people worldwide annually for which no FDA-approved pharmacological treatment currently exists. Delivered via a proprietary intranasal device, ONP-002 is designed to bypass the blood-brain barrier to directly reduce neuroinflammation and oxidative stress at the source of injury. For more information, visit [www.rogenics.com](http://www.rogenics.com).

### About Sigyn Therapeutics™

Sigyn Therapeutics is the developer of CardioDialysis, a next-generation blood purification technology that enables continuous broad-spectrum clearance of inflammatory and pathogenic molecules from the bloodstream. Within the emerging field of subtractive medicine, CardioDialysis is the first therapy to integrate plasma separation and therapeutic adsorption within a single device. Therapeutic opportunities for CardioDialysis include sepsis, life-threatening viral infections, neuroinflammatory disorders, and cardiovascular disease. The Company’s development pipeline is comprised of ImmunePrep™ to optimize the delivery of therapeutic antibodies to treat cancer; ChemoPrep™ to enhance the targeted delivery of chemotherapy; and ChemoPure™ to reduce the toxicity of chemotherapy. To learn more about Sigyn Therapeutics, visit: [www.SigynTherapeutics.com](http://www.SigynTherapeutics.com)

---

## **Forward-Looking Statements**

This press release contains “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements include, but are not limited to, statements regarding the Company’s expectations regarding the proposed transaction with Sigyn Therapeutics, including the execution of a definitive license agreement, the therapeutic potential of CardioDialysis™, the potential clinical benefits of combining ONP-002 and CardioDialysis™, and the Company’s broader CNS platform strategy. The words “believe,” “expect,” “anticipate,” “intend,” “estimate,” “project,” “potential,” “may,” “will,” “could,” “should,” and similar expressions identify forward-looking statements. These statements are subject to a variety of risks, uncertainties, and other factors that could cause actual results to differ materially, including the risk that a definitive agreement may not be executed, that due diligence may reveal unfavorable results, that required approvals may not be obtained, and other risks described in the Company’s most recent Form 10-K, Form 10-Q, and other filings with the U.S. Securities and Exchange Commission. The Company does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future developments, or otherwise, except as required by law.

Although the letter of intent provides that certain provisions are binding on the parties, it does not obligate the parties to consummate the proposed transaction. The consummation of the proposed transaction remains subject to the negotiation, execution and delivery of a definitive license agreement and the satisfaction or waiver of applicable closing conditions. There can be no assurance that any definitive agreements will be entered into or that the proposed transaction will be consummated on the terms described herein or at all. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof and are not guarantees of future performance or outcomes.

## **Investor & Media Relations**

irth Communications  
800-383-4880  
ir@oragenics.com

---