# 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 18, 2026**
**(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)** |

| | |
|---|---|
| **9015 Town Center Parkway, Suite 143 Lakewood Ranch, Florida** | **34202** |
| **(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 7.01 Regulation FD Disclosure.**

Oragenics, Inc. ("**Oragenics**" or the "**Company**") expects to use the attached presentation (the "**Presentation**") from time to time with potential investors, and will host one-on-one meetings with investors at Sidoti's Micro-Cap Virtual Investor Conference, taking place on May 20-21, 2026. A copy of the Presentation is attached hereto as Exhibit 99.1 and is incorporated herein by reference. Additionally, the Presentation will be available under the "Presentations" tab in the "News and Media" section of the Company's website, located at www.oragenics.com.

By filing this Current Report on Form 8-K and furnishing the information contained herein, the Company makes no admission as to the materiality of any information in this report that is required to be disclosed solely by reason of Regulation FD.

The information contained in the Presentation is summary information that is intended to be considered in the context of the Company's Securities and Exchange Commission ("**SEC**") filings and other public announcements that the Company may make, by press release or otherwise, from time to time. The Company undertakes no duty or obligation to publicly update or revise the information contained in this report, although it may do so from time to time as its management believes is warranted. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosures.

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 8.01. OTHER EVENTS.**

On May 18, 2026, issued a press release providing an update to its Shareholders. On May 19, 2026, the Company issued a press release announcing that it was making a presentation and meeting with investors at Sidoti's Micro-Cap Virtual Investor Conference.

A copy of the Press Releases are attached hereto as Exhibit 99.2 and 99.3, respectively and are incorporated by reference herein.

**ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Presentation. |
| 99.2 | Press Release dated May 18, 2026. |
| 99.3 | Press Release dated May 19, 2026. |
| 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 19th day of May 2026.

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

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

Exhibit 99.1

ORAGENICS

# *Transforming Concussion Care with Innovative Intranasal Delivery*

The first potential FDA-approved therapy for concussion.

NYSE AMERICAN: OGEN

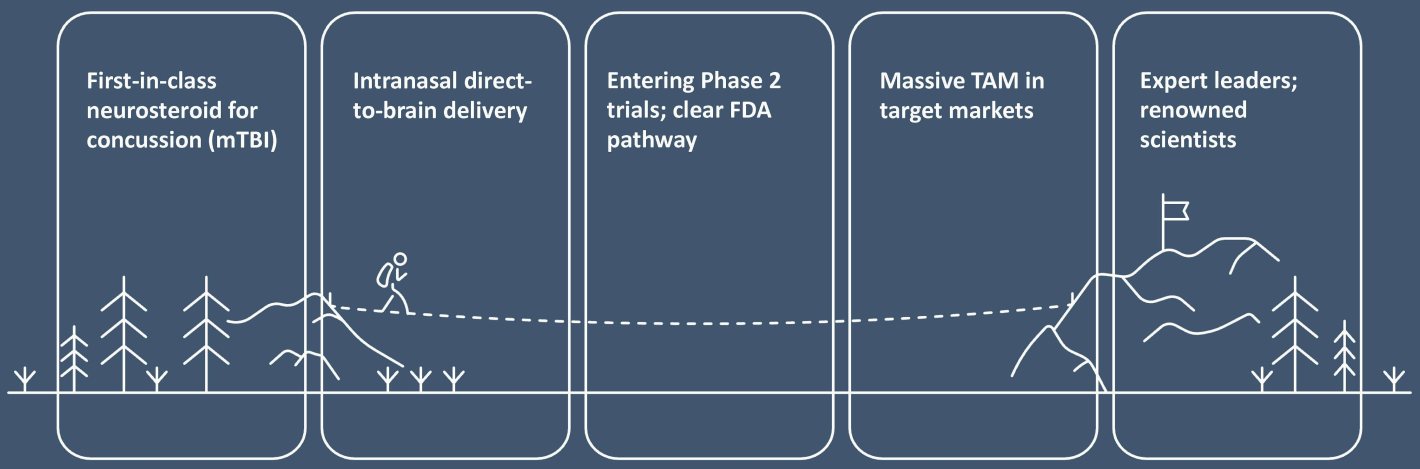
SPRING 2026

# 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," "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.

# Brain-First Neurotherapeutics

## Pioneering a New Standard of Care for Concussion



# Investment Highlights

## Multiple Levers for Value Creation

**First & only neurotherapeutic for most prominent neurological condition without an FDA-approved solution**

- Expanding IP Portfolio and new chemical entity (NCE) designation

**Zero competition in massive markets for concussion and mild traumatic brain injury (mTBI)**

- 69M concussions annually worldwide; many develop post-concussion symptoms

  *(Journal of Neurosurgery, Estimating the global incidence of traumatic brain injury (PubMed)*

**Phase 2 asset in active clinical trial with validated efficacy and strong safety profile**

- Targets the biology of brain injury, not just symptoms

**Phase 2a trial in Australia expected to de-risk U.S. clinical and regulatory pathways**

- Positioned for IND submission to FDA for U.S. based clinical trials

**Demonstrated financial discipline and transparency supporting clinical development**

- Strong balance sheet with zero debt; proven capital efficiency

**Value-creating milestones and near-term clinical catalysts**

- Phase 2a first patient dosed at Mackay Base Hospital within days of site activation; multiple participants enrolled with follow-up visits underway; data readout targeted Q4 2026

**Active pipeline expansion beyond ONP-002**

- AI-driven CNS pipeline development (Receptor.AI collaboration) plus evaluation of complementary CNS licensing opportunities

# Proven Leadership, Scientific Expertise

**Janet Huffman | Chief Executive Officer & Chief Financial Officer**
CFO for Nasdaq-listed TRxADE HEALTH (Scienture Holdings); founding member, CFO for Banyan Pediatric Care Centers, leading merger with Assisted 4 Living (Arboreta Healthcare Inc.); CFO for Signature HomeNow.

**James P. Kelly, MA, MD, FAAN, FANA | Chief Medical Officer & Scientific Advisor**
Current Executive Director for Marcus Institute for Brain Health (MIBH), Professor of Neurology at University of Colorado's Anschutz Medical Campus, and National Director of Gary Sinise Foundation Avalon Network TBI Medical Programs; former Director of National Intrepid Center of Excellence (NICoE) at Walter Reed National Military Medical Center.

**William "Frank" Peacock MD | Chief Clinical Officer**
Current Vice Chair for Emergency Medicine Research at Baylor College of Medicine; past Professor at Cleveland Clinic Lerner College of Medicine; world-renowned speaker and researcher on biomarkers of traumatic brain injury.

**Charles L. Pope | Chairman of the Board**
CFO for five companies in various industries including TRxADE HEALTH (Scienture Holdings); Partner in in Audit and Financial Advisory Consulting Divisions and Accounting and SEC Directorate at PricewaterhouseCoopers.

**Mark Gandolfo | Project Manager**
Project Manager at Odyssey Health; Oakland Spine and Physical Therapy.

# Massive Markets, Zero Competition

**$8.9B**

**Concussion Market by 2027***

- 69 million concussions annually worldwide
- 75-90% of ER visits for head injury involved concussion worldwide*

**TAM = $49B+**

**$125B+**

**Nasal drug delivery market by 2030***

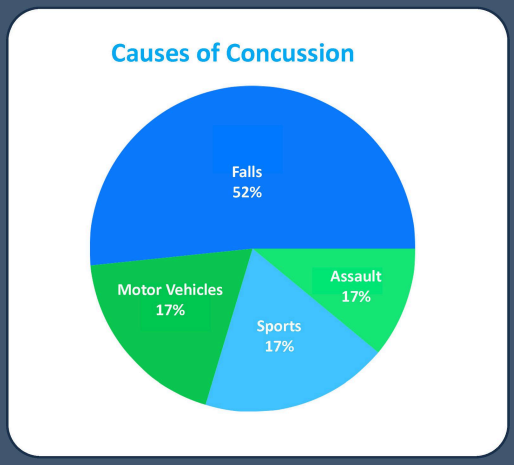
- ZERO FDA-approved pharmacological treatments for concussion
- Oragenics positioned to own category definition as first FDA-approved treatment

**First and Only Treatment**

*Read more on the data:*

**Grand View Research, Concussion Market Size Worth $8.9 Billion By 2027 | CAGR: 3.6%:*
**Premier Health, Concussion and Mild Traumatic Brain Injuries*
**Grand View Research, Nasal Drug Delivery Technology Market (2024 - 2030)*

# Unmet Medical Need for Concussion & Mild TBI




## What is a Concussion?

- Mild traumatic brain injury (mTBI) affecting 69M annually worldwide
- Symptoms: Headache, confusion, dizziness, memory problems, nausea
- Risk: 30-80% develop post-concussion syndrome; increased dementia risk

## Current Standard of Care

- "Rest, observe, wait" = symptom management only
- No approved pharmacological intervention
- Patients risk chronic complications
- Current treatment: Rest and hope

# ONP-002: Phase 2 Lead Asset

## Overview

- ONLY pharmacological treatment in clinical development with FDA pathway for acute concussion
- First-in-class intranasal neurosteroid
- Intellectual property protection through 2040+

## Mechanism

- Reduces swelling, inflammation, oxidative stress
- Targets the biology of brain injury, not just symptoms
- Phase I Results:
  - Safe and well tolerated in 40 patients
  - Zero serious adverse events (SAEs)
- "Treating the injury, not just the symptoms."

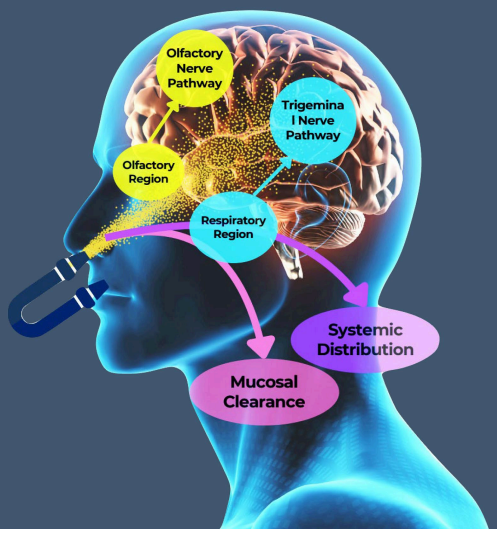
# Intranasal Mechanism of Action

### Delivery Pathway:

- Delivered via custom intranasal device
- Travels through olfactory pathway directly to brain
- Fast-acting with low systemic exposure

### Biological Action:

- Preserves blood-brain barrier integrity
- Promotes cell survival and neuroprotection
- Reduces inflammation and oxidative stress



# ONP-002:

## Phase 1 Safety Validation, Phase 2 Progression

*Phase I Single and Multiple Ascending Dose (SAD/MAD) safety study of ONP-002:*

- Neuroprotective molecular and behavioral effects within hours
- Pharmacokinetic profile confirms minimal systemic exposure
- Excellent safety profile with zero severe adverse events; well-tolerated across all dose levels
- Intranasal administration: quick and significant distribution to all regions of the brain

| Anticipated Functional Recovery | Anticipated Reduced Symptoms |
|---|---|
| • Improved memory function<br>• Improved sensory-motor function<br>• Reduced anxiety behaviors | • Reduced inflammation<br>• Reduced oxidative stress<br>• Reduced cerebral edema |

# Strategic Phase 2 Trial Design

| Study Design | Enrollment Criteria | Primary Endpoints |
| --- | --- | --- |
| • Location: Australia<br>• Enrollment: 40 patients<br>• First dose within 12 hours of concussion<br>• Randomized, placebo-controlled | • CT scan negative for structural brain injury<br>• Presenting symptoms: headache, loss of consciousness, amnesia, or altered mental status<br>• Emergency room or hospital admission | • Safety: Adverse events, nasal examinations<br>• Clinical: Follow-up visits with physical checks and neurocognitive testing<br>• Feasibility: Tolerability, participant compliance |

# Clear Regulatory Pathway to Market

A thorough regulatory process ensures trial integrity, while diligent preparation de-risks the U.S. pathway and positions positive Phase 2a results to provide a strong rationale for an IND submission.

## Phase 2 Regulatory Foundation Built

- HREC approval obtained (Q1 2025)
- 3 HREC amendments processed and approved
- Clinical trial protocol optimized through iterative regulatory dialogue
- CRO selected and contracted
- US Manufacturing partner secured (SPS-cGMP production)

## Near Term Milestones

- ✓ First patient dosed at Mackay Base Hospital within days of site activation (March 2026)
- Mackay Base Hospital activated — first patients dosed and enrolled
- ✓ Multiple participants enrolled; follow-up visits underway
- Phase 2a data readout targeted Q4 2026 ⚑ [CEO/CSO confirm]
- Alfred Hospital (Melbourne) formally screened for enrollment
- ✓ Royal Adelaide Hospital — site initiation visit and staff training completed May 2026; formal activation

## 2026: Data & U.S. Expansion

- U.S. IND submission for continued clinical trials in the US
- U.S. clinical trial preparation and launch
- Continuous enrollment momentum in Australia

# Scalable Platform
## for Pipeline Expansion

**Possible Future CNS Therapeutic Applications:**

- Traumatic Brain Injury (TBI)
- Stroke
- Seizures
- Alzheimer's Disease
- Parkinson's Disease

### Technology Platform

- Proprietary intranasal delivery system with broad applications
- Same technology applicable across multiple neurological conditions

### Market Context

- Nasal delivery market projected to exceed $125B by 2030
  - *Grand View Research, Nasal Drug Delivery Technology Market (2024- 2030)*
- Platform value extends beyond single indication

# Value-Creating Near-Term Clinical Catalysts

**Milestones Achieved + Q2 2026 Momentum**

- Final HREC amendment approval enabling clinical site onboarding
- Phase 2a clinical trial initiation with first patient dosed in Australia

**2026 Value Catalysts**(2026)

- Phase 2a data readout from Australia trials
- IND submission to FDA for U.S. based Phase 2 clinical trials
- Continued AI-driven pipeline expansion research
- Strategic partnership development in concussion care ecosystem
- Active evaluation of complementary CNS pipeline expansion opportunities

ORAGENICS

# Brain-First Recovery™

## *Unlocking the Brain's Capacity for Healing- One Breakthrough at a Time*

Oragenics | NYSE American: OGEN

Investor contact: ir@oragenics.com

**Exhibit 99.2**

**ORAGENICS PROVIDES INVESTOR UPDATE**
**A MESSAGE FROM OUR CHIEF EXECUTIVE OFFICER**

**Sarasota, FL — May 18, 2026 —** Oragenics, Inc. (NYSE American: OGEN)

Dear Fellow Shareholders,

Since our last investor update, Oragenics has continued to execute across all fronts — in the clinic, in the regulatory pipeline, on our balance sheet, and strategically. We have reached a pivotal moment: our Phase IIa clinical trial of ONP-002 is active in Australia, patients are being enrolled and dosed, and we have now signed a Letter of Intent to pursue a licensing agreement for a complementary CNS-related medical device. Our focus is sharper than ever — and the progress we are making reflects that.

Below is a full account of what has been accomplished and what is coming next.

## PHASE IIa CLINICAL TRIAL — EXECUTION UNDERWAY

**ONP-002 | First-in-Class Intranasal Neurosteroid for Concussion / mTBI**
Our Phase IIa randomized, placebo-controlled feasibility study of ONP-002 in Australia is no longer a future event — it is happening now. Key clinical updates:

- Mackay Base Hospital — site formally activated March 31, 2026. Site staff trained, protocol in place, drug on site. Patient enrollment began immediately upon activation.
- First patient dosed at Mackay within days of activation — which we believe is a strong signal of clinical site readiness and real-world demand for the trial.
- Alfred Hospital (Melbourne) - site formally activated in April 2026. Site staff trained and drug on site. Patients are actively being screened for enrollment.
- Royal Adelaide Hospital — Site initiation visit and staff training completed in May 2026. Formal site activation is pending final Research Governance Office approval processes and is anticipated imminently.
- Southern Star Research continues to manage CRO operations across all sites.
- Zero serious adverse events have been recorded.

*Trial design: 40-patient enrollment target | Randomized, placebo-controlled | First dose within 12 hours of concussion | 30-day follow-up with neurocognitive testing | Primary endpoints: safety, tolerability, and feasibility.*

## U.S. IND PROGRAM — ON CRITICAL PATH

In parallel with the Australian Phase IIa trial, Oragenics is actively advancing the regulatory program required to bring ONP-002 to U.S. clinical trials. Our scientific and regulatory team is progressing across all IND-enabling disciplines — including pharmacology, toxicology, chemistry and manufacturing controls, and clinical protocol design.

Two near-term milestones anchor our U.S. pathway. First, we are targeting submission of a Type C Meeting Request to the FDA in the second quarter of 2026 — a formal pre-IND interaction that allows the Company to receive FDA guidance on the U.S. clinical development path before committing to full study designs. Second, we are targeting submission of the full Investigational New Drug application by the end of 2026, which would position Oragenics to initiate U.S.-based clinical trials in 2027.

We believe both milestones are on track. Our regulatory consulting partners continue to drive the technical work, and the scientific team provides weekly progress updates. We remain confident in our ability to meet these timelines.

## STRATEGIC PIPELINE EXPANSION — LOI SIGNED

### Licensing Agreement LOI Executed — CNS Medical Device

Oragenics has signed a Letter of Intent (LOI) to pursue a licensing agreement for a complementary CNS-related medical device. We believe this transaction, if completed, could expand the Company's addressable indication set beyond ONP-002 while reinforcing Oragenics' strategic identity as a CNS platform company.

Key deal structure considerations:

- Licensing structure carves out TBI indication rights while allowing the licensor to pursue other indications independently.
- Additive to the CNS pipeline narrative: alongside ONP-002 and the CNS candidate molecules identified through our Receptor.AI collaboration, we believe this device will expand our addressable indication set and strengthen our platform.

## FINANCIAL POSITION

### Key Financial Metrics

Q1 2026 for the three months ended March 31, 2026:

- Cash balance: $6.1 million
- Research and development expenses were $0.6 million – increased 89% from the same period in 2025
- General and administrative expenses were $ 1.6 million – decreased 4% from the same period in 2025

Capital Markets Activity:

- ATM facility active: New S-3 filed January 2026; SEC review completed and the facility is available to the Company upon request.
- ATM activity generated proceeds in Q1 2026; the Company continues to evaluate optimal timing for future capital raises in connection with clinical and regulatory milestones.

## CORPORATE & OPERATIONAL MILESTONES

### Annual Shareholder Meeting

- Annual Meeting scheduled for June 29, 2026..

**ANTICIPATED UPCOMING CATALYSTS**

The following milestones represent near-term value inflection points for the Company and our shareholders:

- Additional Australian clinical trial site activations (Royal Adelaide Hospital — expected near-term)
- Multi-patient enrollment progress update
- Type C Meeting Request submitted to FDA
- Annual Shareholder Meeting (June 29, 2026)
- IND submission to FDA - 2026
- Phase IIa data readout - 2026

**About Oragenics, Inc.**

Oragenics, 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.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. Statements in this news release 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." Forward-looking statements include statements regarding the Company's intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: our research, development and regulatory activities and expectations relating to product candidates, including without limitation ONP-002 and our proprietary nasal device; the effectiveness of these programs or the possible range of application and potential curative effects and safety in the treatment of diseases; and the timing, conduct, interim results announcements and outcomes of our clinical trials of our product candidates, including ONP-002 for the treatment of concussion and mTBI. 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 most recent Form 10-K, Form 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, should circumstances change, except as otherwise required by law. There can be no assurances that the transactions contemplated by the Letter of Intent will be consummated on the terms described therein or at all.

**CONTACT INFORMATION**

Investor Relations:
irth Communications
ir@oragenics.com

**Exhibit 99.3**

**Oragenics to Present at Sidoti's Micro-Cap Virtual Investor Conference May 20-21**

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**Sarasota, FL — May 19, 2026 —** Oragenics, Inc. (NYSE American: OGEN) ("Oragenics" or the "Company"), a clinical-stage biopharmaceutical company pioneering neurological therapeutics, will present and host one-on-one meetings with investors at Sidoti's Micro-Cap Virtual Investor Conference, taking place on May 20-21, 2026.

The presentation will begin at 3:15 ET on May 21, 2026 and can be accessed live here: https://sidoti.zoom.us/webinar/register/WN_4MxVYrk0Sl2JK5ByzTN6Pg. Oragenics will also host virtual one-on-ones with investors on Wednesday and Thursday, May 20-21, 2026. To register for the presentation or one-on-ones, visit www.sidoti.com/events. Registration is free and you don't need to be a Sidoti client.

**About Sidoti Events, LLC ("Events") and Sidoti & Company, LLC ("Sidoti")**

In 2023, Sidoti & Company, LLC , Sidoti & Company, LLC formed an affiliate company, Sidoti Events, LLC in order to focus exclusively on its rapidly growing conference business and to more directly serve the needs of presenters and attendees. The relationship allows Sidoti Events to draw on the over 25 years of experience Sidoti has as a premier provider of independent securities research focused specifically on small and microcap companies and the institutions that invest in their securities, with most of its coverage in the $200 million-$5 billion market cap range. Sidoti's coverage universe comprises approximately 150 equities, of which almost 70 percent participate in the firm's rapidly growing Company Sponsored Research ("CSR") and Sidoti Lighthouse Equity Research ("Lighthouse") programs. Sidoti Events is a leading provider of corporate access through the many investor conferences it hosts each year. By virtue of its direct ties to Sidoti, Sidoti Events benefits from Sidoti's small- and microcap-focused nationwide sales force, which has connections with over 2,500 institutional relationships in North America. This enables Sidoti Events to provide multiple forums for meaningful interaction for small and microcap issuers and investors specifically interested in companies in the sector.

**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 believes its intranasal delivery platform has potential applications across multiple neurological conditions. Oragenics is committed to developing innovative therapies that address significant unmet medical needs in neurological care. For more information, visit www.oragenics.com.

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**FORWARD-LOOKING STATEMENTS**

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**INVESTOR & MEDIA CONTACT**

**Investor & Media Relations**

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