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: January 20, 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** **Sarasota, FL** **(Address of principal executive offices)**	**34202** **(Zip Code)**

813-286-7900
(Registrant's telephone number, including area code)

1990 Main Street
Suite 750
Sarasota, FL 34236
(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 RD DISCLOSURE.

Oragenics, Inc. ("Oragenics" or the "Company") expects to use the presentation attached hereto as Exhibit 99.1, which is incorporated herein by reference (the "Presentation") on January 20. 2026 in connection with a presentation by the Company's CEO at the Sequire Investor Summit. 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 disclosure.

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	Presentation Dated, January 20, 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 January 20, 2026.

ORAGENICS, INC.
(Registrant)

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

Exhibit 99.1

ORAGENICS

Transforming Concussion Care with Innovative Intranasal Delivery

The first potential FDA-approved therapy for concussion.

NYSE AMERICAN: OGEN

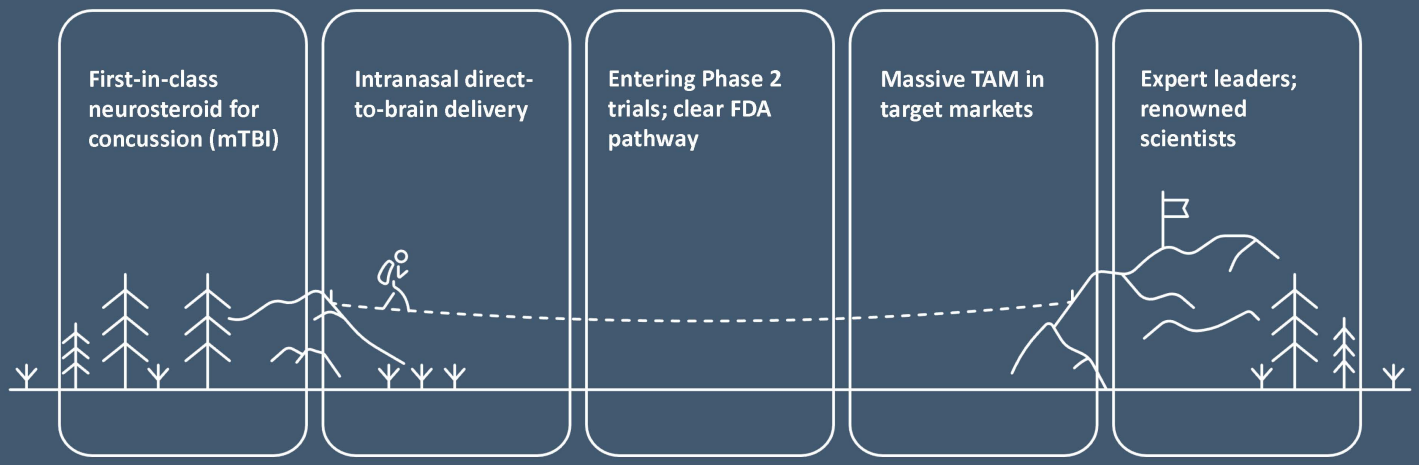
WINTER 2025/2026

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-ready lead asset with validated efficacy and strong safety profile

- Targets the biology of brain injury, not just symptoms

De-risked U.S. clinical and regulatory pathways following Phase 2a trial in Australia

- 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 dosing expected in Q1 '26; data readout expected by end of 2026

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*

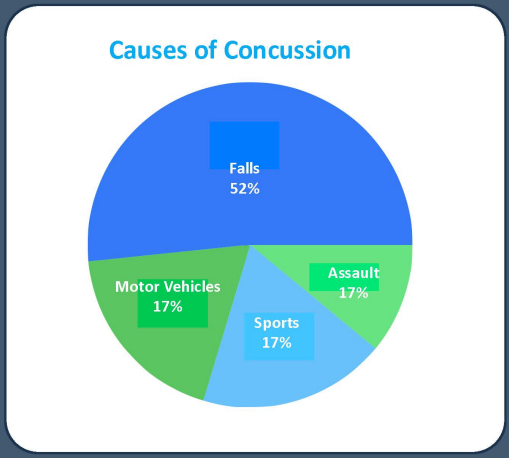
- ZERO FDA-approved pharmacological treatments for concussion
- Oragenics positioned to own category definition as first FDA-approved treatment

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."

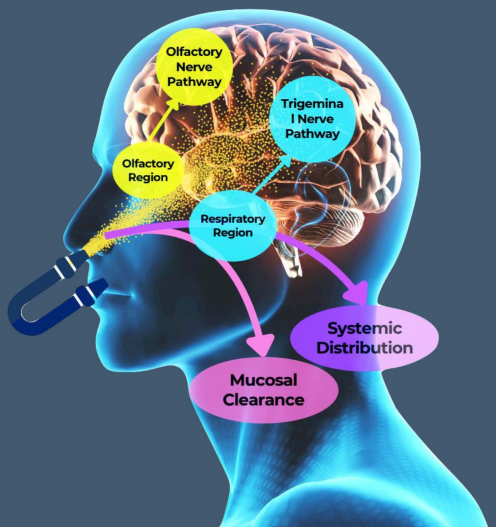
Intranasal Mechanism of Action

Delivery Pathway:

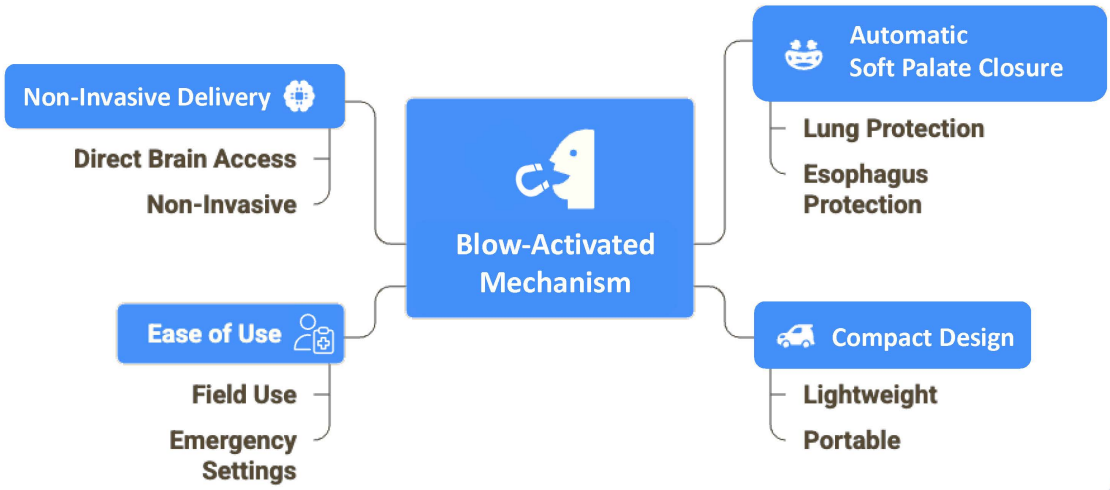
- Delivered via custom intranasal device
- Travels through olfactory pathway directly to brain
- Fast-acting with low systemic exposure

Biological Action:

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



The Direct-to-Brain Intranasal Advantage



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

Functional Recovery	Reduced Symptoms
• Improved memory function • Improved sensory-motor function • Reduced anxiety behaviors	• Reduced inflammation • Reduced oxidative stress • Reduced cerebral edema

Strategic Phase 2 Trial Design

Study Design	Enrollment Criteria	Primary Endpoints
• Location: Australia • Enrollment: 40 patients • First dose within 12 hours of concussion • Randomized, placebo-controlled	• CT scan negative for structural brain injury • Presenting symptoms: headache, loss of consciousness, amnesia, or altered mental status • Emergency room or hospital admission	• Safety: Adverse events, nasal examinations • Clinical: Follow-up visits with physical checks and neurocognitive testing • 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 pending approval (Q1 2026)
- Clinical trial protocol optimized through iterative regulatory dialogue
- CRO selected and contracted
- US Manufacturing partner secured (SPS-cGMP production)

Near Term Milestones

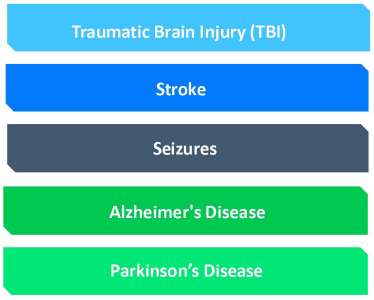
- Final HREC approvals – Q1 2026
- 20+ sites evaluated, 3 premier sites with contracts pending final HREC approval – Q1 2026
- First patient dosing imminent – Q1 2026
- Phase 2a data readout (Q4 2026)
- Continued pipeline development powered by AI

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:



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

Comparable Measures of Value

ORAGENICS	Alpha Cognition	NASUS PHARMA	tiziana LIFE SCIENCES	anavex LIFE SCIENCES Corp.
NYSE American: OGEN	Nasdaq: ACOG	NYSE American: NSRX	Nasdaq: TLSA	Nasdaq: AVXL
$3.8M market cap	$132M	$63M	$215M	$334M
$0.91 share price	$6.06	$7.35	$1.81	$3.75
Concussion/mTBI	Intranasal formulation for cognitive impairment with mTBI	Intranasal technology for emergency medical conditions	Nasal immunotherapy for MS, MSA, AD	Treatments for CNS disorder
Phase 2 ready	Preclinical; approved drug for AD	Phase 2	Phase 2	Phase 3

Data as of 12.02.2025

Value-Creating Near-Term Clinical Catalysts

Near-Term Value Drivers: (Q1 2026)

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

Medium-Term Strategic Goals: (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

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