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 20, 2025
(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)**

1990 Main Street **Suite 750** **Sarasota, FL**	**34236**
(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 presentation attached hereto as Exhibit 99.1, which is incorporated herein by reference, regarding Neurotrauma Medicine (the "Presentation") on May 20, 2025 in connection with a webinar presented by the Company's Scientific Advisory Board. 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.
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 May 20, 2025.

ORAGENICS, INC.
(Registrant)

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

FORWARD LOOKING STATMENTS

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, including without limitation statements regarding the Company's future performance, prospects, outlook, and plans. 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, the following: availability of cash on hand, or another alternative source of cash; the Company's ability to raise capital and obtain funding, non-dilutive or otherwise; the Company's ability to advance the development of its product candidates; the regulatory application process, including any meetings, decisions by regulatory authorities, such as the FDA and investigational review boards; favorable or unfavorable findings that effect meeting milestones of the Company's product candidates; the Company's ability to obtain, maintain and enforce necessary patent and other intellectual property protection; the Company's expectations as to the outcome of preclinical studies and clinical trials, such as delays in regulatory review, interruptions to manufacturers and supply chains, adverse impacts on healthcare systems and disruption of the global economy; the potential benefits, effectiveness and safety of our product candidates; and general economic and market conditions and risks, as well as other uncertainties described in our filings with the U.S. Securities and Exchange Commission, which are available through EDGAR at WWW.SEC.GOV. All information set forth is as of the date hereof unless otherwise indicated. You should consider these factors in evaluating the forward-looking statements included and not place undue reliance on such statements. 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.

OVERVIEW - KEY OBJECTIVES FOR THE CALL

Leadership & Strategic Vision - Introduce the team guiding Oragenics through transformation and explain our focused mission in concussion care.

Investor Alignment & Market Opportunity - Discuss how our strategy aligns with unmet market needs—and why ONP-002 represents a significant commercial opportunity.

Clinical and Regulatory Progress - Provide a transparent update on ONP-002's development, including recent approvals, trial readiness, and next-phase planning.

Milestones & Execution Timeline - Walk through key upcoming catalysts across clinical, regulatory, and business development milestones.

Next Steps & Stakeholder Engagement - Outline how we plan to strengthen communication, pursue strategic partnerships, and deliver on near-term value drivers.

MANAGEMENT OVERVIEW

Janet Huffman, Chief Executive Officer:

Bio Highlights:

- Appointed CEO of Oragenics in April 2025 after joining the company in March 2023.
- Brings over 15 years of executive leadership experience across healthcare sectors, including home health, skilled nursing, rehab, pharmacy, and health IT.

Prior Roles Include:

- CFO, TRxADE HEALTH (NASDAQ: MEDS): Led finance for a digital health services company focused on retail pharmacies.
- Founding CFO, Banyan Pediatric Care Centers: Key architect of its merger with Assisted 4 Living, later renamed Arboreta Healthcare Inc.
- Held senior financial leadership roles at Signature HomeNow, Infinity Homecare, and Family Home Health Services, overseeing growth, M&A, and operational transformation.

ORAGENICS

Our Team Board and Scientific Team

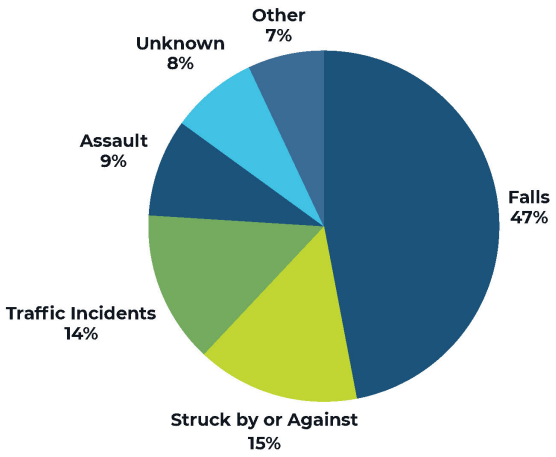
Board of Directors Highlights: Long-tenured leadership with biotech, finance, and regulatory experience

Neurological Team: Experts in TBI, emergency medicine, neurosteroids (Dr. Peacock, Dr. Kelly)

THE PROBLEM – CONCUSSION IS A PUBLIC HEALTH CRISIS

Concussions Are a Subset of Traumatic Brain Injury (TBI)

- A concussion is classified as a mild traumatic brain injury (mTBI)—the most common form of TBI.
- While considered "mild," concussions can cause serious neurological symptoms that may last weeks, months, or longer.
- All concussions are TBIs, but not all TBIs are concussions. TBI severity ranges from mild (concussion) to severe (bleeding, coma, permanent impairment).
- Concussions often go undiagnosed because they may not appear on standard imaging, yet they disrupt brain function in real and lasting ways.
- Understanding concussion as part of the broader TBI spectrum highlights the critical need for early, targeted intervention.



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OUR SOLUTION - ONP-002 INTRANASAL THERAPY

ONP-002: First-in-class intranasal drug for moderate-to-severe concussion

- Rapid brain biodistribution
- Reduces swelling, inflammation, and oxidative stress
- Completed Phase 1 clinical trial: Safe and well-tolerated

Strategic Impact

- Expanded Oragenics' pipeline into neurology and intranasal drug delivery.
- Targets high-growth markets, including a concussion treatment market projected to reach $8.9 billion by 2027.
- Addresses a significant unmet need: An estimated 5 million concussions occur annually in the U.S., including 3.8 million from sports-related injuries—up to 50% of which go unreported.

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RECENT CLINICAL ACCOMPLISHMENTS

Clinical Progress:
Significant progress, with patient enrollment expected to begin in Q2 2025 in Level 1 trauma emergency departments in Australasia.

Phase 1:
Clinical trial reports and data have been finalized and delivered. The regulatory team is organizing the data for submission in an IB and IND package.

Phase 2:

- **HREC Approval** – Australia (April 2025): Received Human Research Ethics Committee (HREC) clearance to initiate Phase II clinical trial of ONP-002.

- **HDEC Submission** – New Zealand (April 2025): Health and Disability Ethics Committee (HDEC) allowing trial to be conducted at Christchurch Hospital, a leading emergency and research institution serving over 83,000 patients annually.

RECENT STRATEGIC ACCOMPLISHMENTS

Department of Defense (DoD):
Submitted a grant application to support ONP-002 development for concussion care.

Strategic partnership with BRAINBox Solutions:
Entered into a partnership with BRIANBox to create a first-of-its-kind test-to-treat platform for concussion. Combines ONP-002 with BRAINBox's blood biomarker diagnostic tools.

- **Leader in multi-modality diagnostics for TBI**, to co-develop the first comprehensive "trigger-to-treat" platform for concussion. This collaboration represents a transformative growth step.
- **Enhancing patient selection and precision enrollment** for the upcoming Phase IIa trial—improving data quality, reducing variability, and enabling a potentially faster path to clinical proof-of-concept.
- **Establishing a differentiated commercial model** that positions Oragenics not just as a drug developer, but as part of a next-generation care pathway for mTBI—delivering both the diagnosis and the treatment.

DR. JIM KELLY
CHIEF MEDICAL OFFICER

ONE OF THE NATION'S FOREMOST AUTHORITIES ON CONCUSSION AND TRAUMATIC BRAIN INJURY, LEADING CLINICAL STRATEGY FOR ONP-002.

- Former Director, NICoE at Walter Reed, advancing military TBI care
- Longtime neurological consultant to the NFL; helped shape modern concussion protocols
- Co-author of the American Academy of Neurology's concussion guidelines
- Former Professor of Neurology, University of Colorado School of Medicine
- Renowned for bridging clinical research, neurorehabilitation, and real-world sports medicine

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WHAT HAPPENS IN THE BRAIN AFTER A CONCUSSION?

Head Trauma → Ionic Shift → Inflammation → Oxidative Stress → Brain Swelling → Synaptic Dysfunction

- There are approximately 5M documented concussions in the US a year which exceeds the combined incidence of Stroke, Alzheimer's Disease, Parkinson's Disease, Multiple Sclerosis, and ALS aka Lou Gehrig's Disease.
- Annual worldwide cost for managing TBI to healthcare system is over $400B
- Core groups driving the need for a concussion treatment are athletics, military, pediatrics and the rapidly increasing elderly population at risk for falls.
- Repetitive concussions may be linked to other chronic neurodegenerative conditions.

Concussions initiate a chain reaction of biological damage.

Secondary effects worsen over hours or days if untreated.

Synaptic disruption leads to memory, mood, and motor deficits.

The first 24 hours post-injury are the key therapeutic window.

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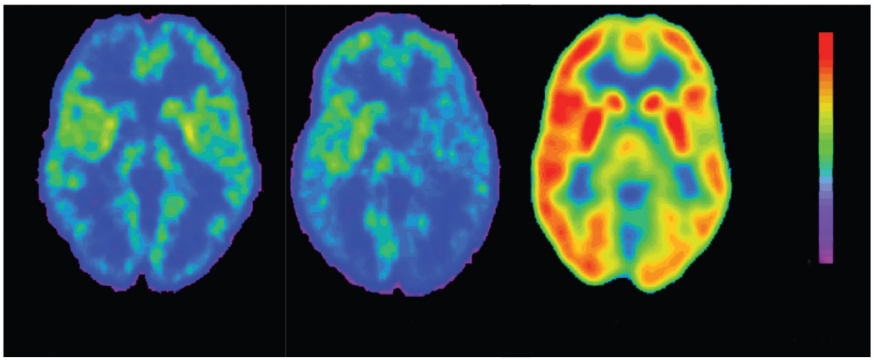
MILD VS SEVERE TBI
ACUTE BRAIN RESPONSE

Mild GCS 15 **Severe GCS 5** **Normal**



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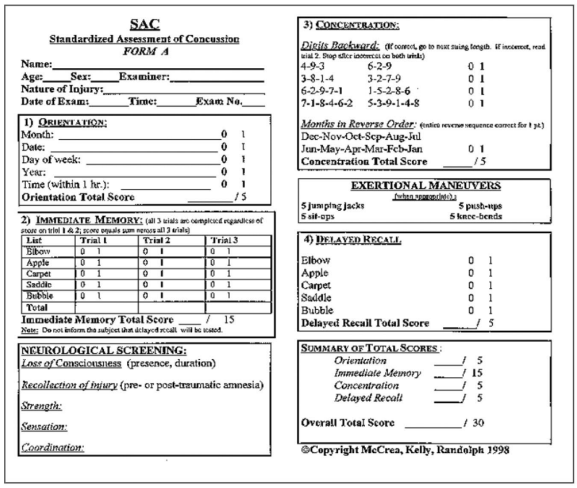
CONCUSSION CLINICAL ASSESSMENT



SAC
Standardized Assessment of Concussion
FORM A

Name:
Age: Sex: Examiner:
Nature of Injury:
Date of Exam: Time: Exam No.

1) ORIENTATION:

Month:	0	1
Date:	0	1
Day of week:	0	1
Year:	0	1
Time (within 1 hr.):	0	1

Orientation Total Score ____ / 5

2) IMMEDIATE MEMORY: (all 3 trials are completed regardless of score on trial 1 & 2; score equals sum across all 3 trials)

List	Trial 1	Trial 2	Trial 3
Elbow	0 1	0 1	0 1
Apple	0 1	0 1	0 1
Carpet	0 1	0 1	0 1
Saddle	0 1	0 1	0 1
Bubble	0 1	0 1	0 1
Total			

Immediate Memory Total Score ____ / 15

Note: Do not inform the subject that delayed recall will be tested.

NEUROLOGICAL SCREENING:

Loss of Consciousness (presence, duration)

Recollection of injury (pre- or post-traumatic amnesia)

Strength:

Sensation:

Coordination:

3) CONCENTRATION:

Digits Backward: (If correct, go to next string length. If incorrect, read trial 2. Stop after incorrect on both trials)

4-9-3	6-2-9	0 1
3-8-1-4	3-2-7-9	0 1
6-2-9-7-1	1-5-2-8-6	0 1
7-1-8-4-6-2	5-3-9-1-4-8	0 1

Months in Reverse Order: (entire reverse sequence correct for 1 pt.)
Dec-Nov-Oct-Sep-Aug-Jul
Jun-May-Apr-Mar-Feb-Jan 0 1

Concentration Total Score ____ / 5

EXERTIONAL MANEUVERS
(when appropriate)

5 jumping jacks 5 push-ups
5 sit-ups 5 knee-bends

4) DELAYED RECALL

Elbow	0	1
Apple	0	1
Carpet	0	1
Saddle	0	1
Bubble	0	1

Delayed Recall Total Score ____ / 5

SUMMARY OF TOTAL SCORES:

Orientation	____ / 5
Immediate Memory	____ / 15
Concentration	____ / 5
Delayed Recall	____ / 5

Overall Total Score ____ / 30

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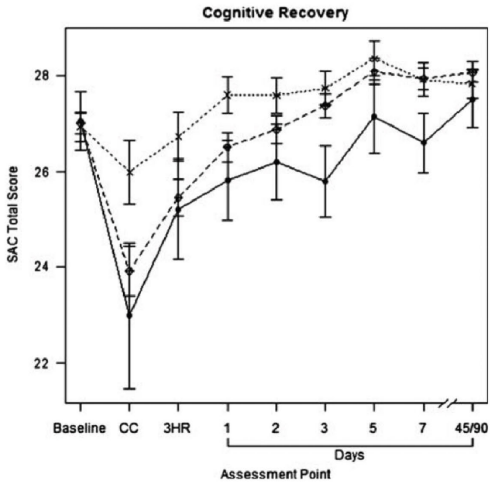

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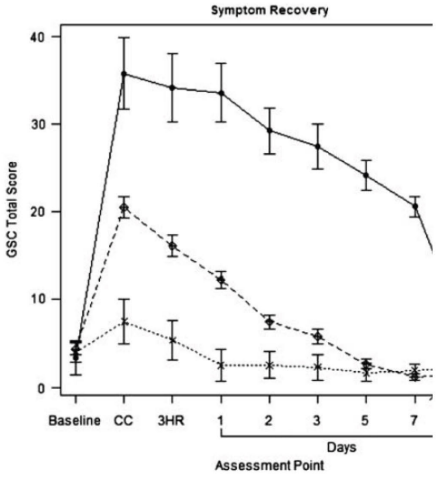
CONCUSSION CLINICAL SYMPTOMS

Score According to Severity		None 0	1	2	Moderate Severe 3 4 5		6
Symptom	Preseason Baseline	Time of Injury	24 Hours Post-Injury	Day 3 Post-Injury	Day 4 Post-Injury	Day 5 Post-Injury
Blurred Vision						
Dizziness						
Drowsiness						
Sleeping More than Usual						
Easily Distracted						
Fatigue						
Feeling "In a Fog"						
Feeling "Slowed Down"						
Headache						
Unusually Emotional						
Irritability						
Loss of Consciousness						
Loss of Orientation						
Memory Problems						
Nauseous						
Nervousness						
Personality Changes						
Poor Balance/Coordination						
Ringing in the Ears						
Sadness						
Seeing Stars						
Sensitivity to Light						
Sensitivity to Noise						
Sleep Disturbances						
Vacant Stares/Glassy Eyes						
Vomiting						
TOTAL SYMPTOM SCORE:						



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ONP-002 - PRECLINICAL EFFICACY

ONP-002 – Molecular Studies:

- Rodent - Reduces inflammation, oxidative stress and swelling in the injured brain
- Neuronal Culture - Enhances brain cell survival and growth when challenged with low oxygen and glucose
- ONP-002 – Behavioral Studies
  - Rodent - Improves sensory and motor performance, anxiety and depression-like behaviors, and short-term memory following brain injury

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ONP-002 - PRECLINICAL SAFETY AND BIODISTRIBUTION

ONP-002 – Toxicology Studies:

- Rodent, Canine, and Monkey – Well-tolerated 2X-daily/14-days intranasally
- High safety margin (>20X) between animal dose and human dose (Phase I and upcoming Phase II trial) ONP-002 Brain Biodistribution
- Canine – Intranasal delivery provides for a 4X higher level of drug in brain compared to plasma
- Similar levels are seen throughout brain regions within 30 min of administration

All IND-enabling studies have been completed for cardiac and genotoxicity, and drug: drug interactions

ONP-002 – CLINICAL PRODUCT MANUFACTURING

- ONP-002 is a novel, neuro-steroid created through a synthetic process that results in a pure, well defined compound.
- ONP-002 is formulated as a intranasal powder formulation manufactured into a nanoparticle size improving uptake from nose to brain.
- ONP-002 has been shown to be stable up to 104 degrees for 18-months and -20 degrees for 30-days, preventing need for temperature-chain protocols in the field.

A WINNING COMBINATION: ONP-002 + INTRANASAL DELIVERY

Intranasal Delivery Advantages

- Rapid and direct access to the brain
- Swift therapeutic effects
- Quicker onset compared to oral medications

Innovative Design

- Patients blow into the device, elevating the soft palate
- Minimizes systemic exposure and side effects

User-Friendly and Portable

Compact and lightweight design ensures ease of use, making it accessible for patients in acute brain injury scenarios

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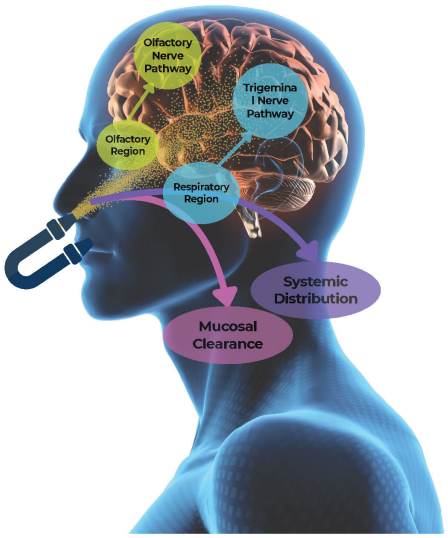

- Innovative Double-Tube Airflow System: Optimizes drug dispersion to the nasal roof.
- Direct Delivery: Targets the olfactory nerve for brain delivery which should improve clinical outcomes.

DR. FRANK PEACOCK
CHIEF CLINICAL OFFICER

A NATIONALLY RECOGNIZED EXPERT IN EMERGENCY MEDICINE AND BRAIN INJURY DIAGNOSTICS, LEADING REAL-WORLD CLINICAL IMPLEMENTATION FOR ONP-002.

- Vice Chair of Emergency Medicine Research, Baylor College of Medicine
- Former Professor at the Cleveland Clinic
- Principal Investigator on concussion biomarker trials in emergency settings
- Advanced the use of high-sensitivity blood troponins for cardiac diagnostics (featured in JAMA Cardiology)
- Editor of Biomarkers of Traumatic Brain Injury, a leading clinical reference in TBI research

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ONP-002 – CLINICAL R&D

PHASE I CLINICAL STUDY REPORT (CSR) AND TRIAL MASTER FILE (TMF) COMPLETED – ONP-002 WAS SAFE AND WELL TOLERATED IN 40 HEALTHY HUMAN VOLUNTEERS

Lead site for Phase IIa – Christchurch Hospital, New Zealand (NZ)
-CRO- Comprehensive Research Associates
-Clinical Protocol Submitted to HDEC in NZ

The drug is loaded in intranasal devices for 40 patient Phase IIa trial (safety and feasibility) – 9-month stability complete

FDA-IND application submission planned for Q3 – Drug: Device Combination to CDER

Phase IIb plan for initiation - 2026 in the US – 12 initial sites

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PHASE IIA - ENROLLMENT CRITERIA

Enrolment criteria designed to identify most at risk for developing Persistent Concussion Symptoms beyond 30-days of injury

First treatment within 12-hrs of injury

- Glasgow Coma Score of 13-15
- Negative CT Scan
- Positive GFAP score
- Report of Headache
- History of one or more of the following: Loss of Consciousness, short-term amnesia, Altered Mental Status

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PHASE IIA TRIAL - OUTCOME AND SAFETY MEASURES

Safety

- Monitoring for AEs/SAEs – Patient reported and Physical Examination
- EKG
- Drug PK levels
- Intranasal evaluation for irritation

Clinical Outcomes

- Patient reported symptoms – Rivermead
- Neurocognitive performance – DANA and Braincheck
- Visual-Vestibular analysis – King-Devick Testing
- Blood Biomarkers levels – 1st clinical analysis for surrogacy of recovery
- Patient reported function – GOS-E
- Incidence of Persistent Concussive Symptoms at 30-days post injury

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BRAINBOX PARTNERSHIP PHASE IIA

Trigger to Treat Model

Kit provisions for blood draws, strips for blood biomarker analysis, and tabletop readers

Blood draw timepoints, per-dose (within 12 hours of injury), 24 hours, 72 hours, 5-days, 10-days, and 30-days

GFAP – elevation required for study admission with continued monitoring ST2

GFAP elevation required for study inclusion to assist in identifying the most severe concussions with poorer outcomes

Neurogranin

A brief neurocognitive test will be administered at the time of each blood biomarker analysis for correlation

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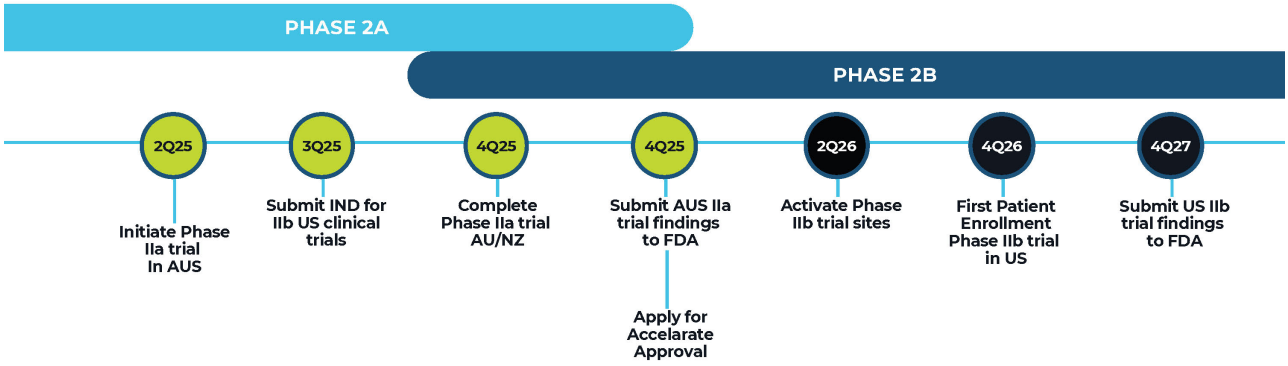
ONP-002: CLINICAL MILESTONES



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WHY ONP-002?
WHY ORAGENICS?
WHY NOW?

The Opportunity Is Clear

- **Large Market Opportunity:** Concussions affect 5M+ Americans annually
- **First of its kind:** No FDA-approved treatment
- **ONP-002 targets the root causes of concussion damage:** inflammation, oxidative stress, and brain swelling
- **Intranasal delivery platform:** enables fast, non-invasive, field-ready use
- **Strong Phase I safety data** and Phase IIa trial launching now in real-world trauma settings
- **Strategic partnerships and regulatory momentum** position us for value inflection
- **Led by a team of clinical and operational experts** in TBI, neurology, and emergency medicine

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