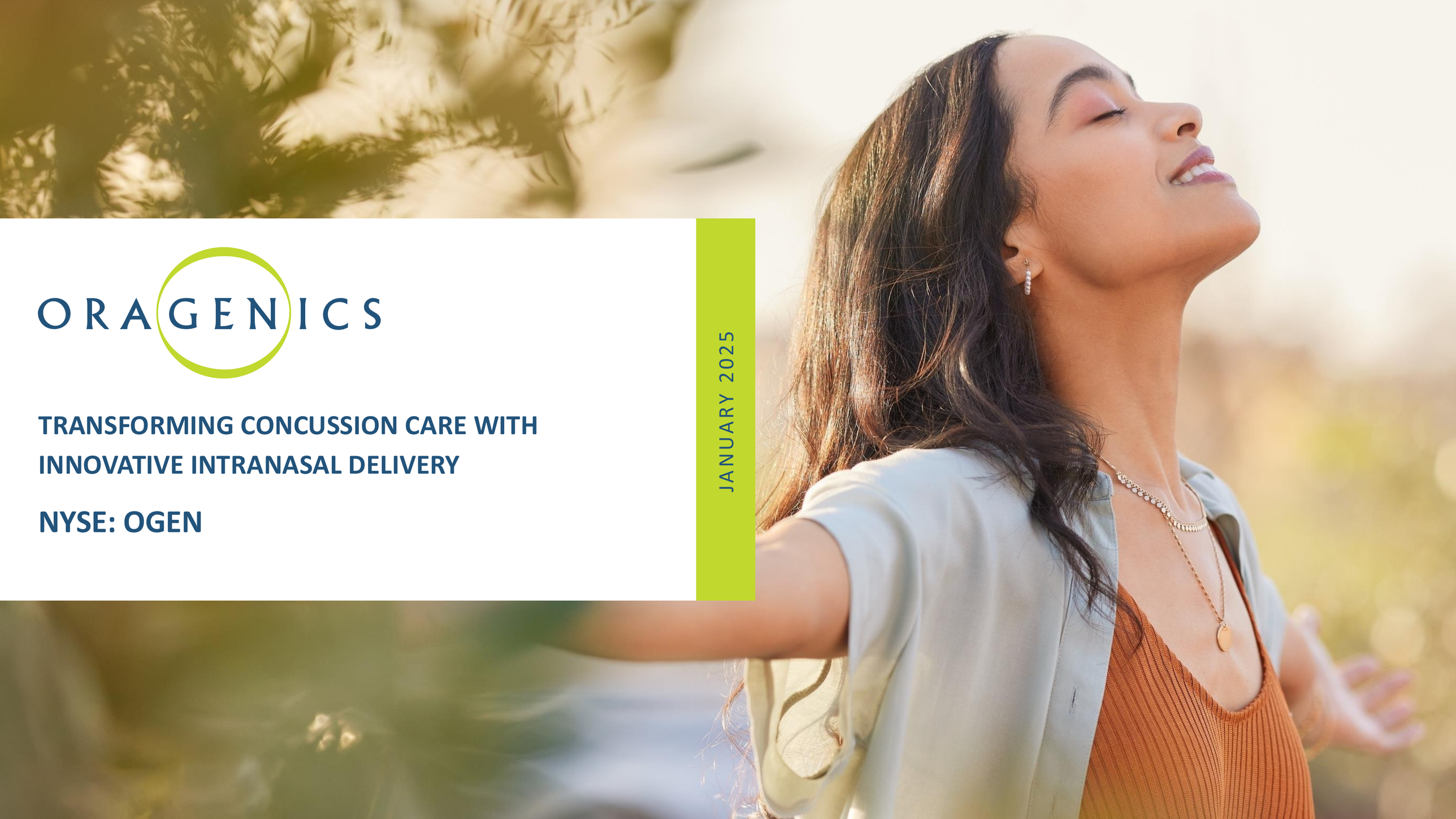
ORAGENICS

TRANSFORMING CONCUSSION CARE WITH INNOVATIVE INTRANASAL DELIVERY

NYSE: OGEN

JANUARY 2025



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 ability of the Company to timely and successfully achieve the anticipated benefits of acquiring neurology assets from Odyssey Health, Inc. and the Company’s future performance, business prospects, events and product development 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 our 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. 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.

ORAGENICS:

PIONEERING NEUROLOGICAL HEALTH SOLUTIONS

Developing cutting-edge intranasal technology and powdered formulations to address significant unmet medical needs, with a particular focus on concussions

HOW ORAGENICS ACQUIRED NEUROLOGICAL ASSETS

Acquisition Overview
Completed acquisition of Odyssey Health's neurological drug therapies and technologies on January 2, 2024.

Key Acquired Assets

ONP-002:
- First-in-class intranasal drug for moderate-to-severe concussion.
- Broad brain biodistribution; reduces swelling, inflammation, and oxidative stress.
- Completed Phase 1 clinical trial: Safe and well-tolerated.

ONP-001:
- Neurosteroid for Niemann Pick Type-C Disease (NPC).
- Proprietary Intranasal Delivery Device: Enhances drug delivery efficiency.

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: 5 million annual concussions in the U.S., with up to 50% unreported.

WHAT IS A CONCUSSION?

A concussion is a type of **mild traumatic brain injury (mTBI)** that occurs when a blow or jolt to the head causes the brain to move within the skull rapidly. This sudden movement can disrupt normal brain function, leading to a variety of physical, cognitive, and emotional symptoms. Concussions are often caused by falls, sports injuries, car accidents, or impacts in combat situations.

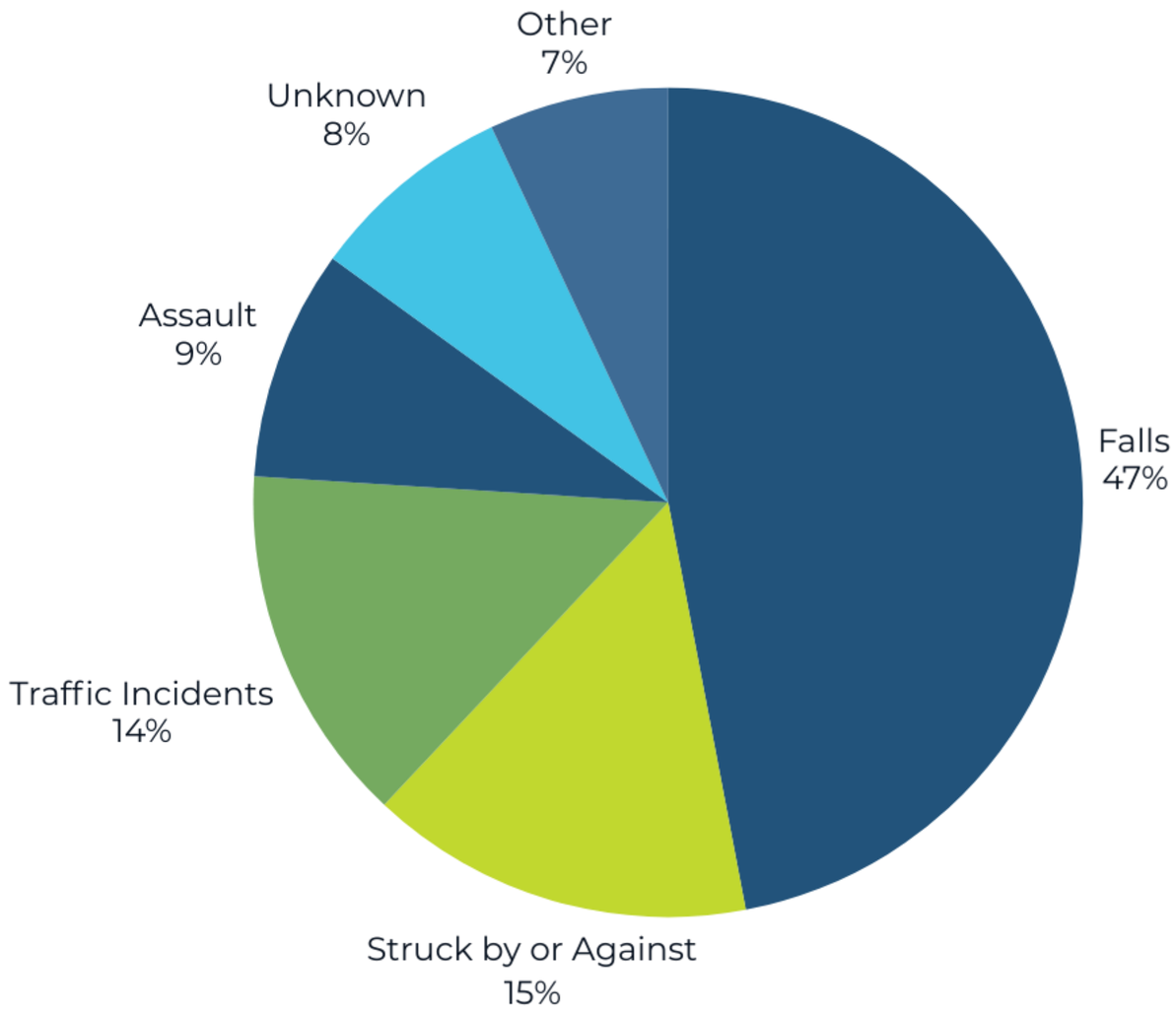
MARKET OPPORTUNITY: UNMET NEED IN CONCUSSION TREATMENT

The Global Concussion Market is projected to reach $8.9 billion by 2027 with CAGR of 3.7%

Nasal drug delivery market is projected to exceed $40 billion by 2030, highlighting a rising interest in non-invasive solutions

Global Concussion Market, 2016-2027 (US$M)

https://www.grandviewresearch.com/horizon/outlook/nasal-drug-delivery-technology-market/united-states
https://www.grandviewresearch.com/horizon/outlook/concussion-market-size/global



ADDRESSING A MAJOR PUBLIC HEALTH CRISIS

Approximately **3.8 million concussions** reported in the U.S. annually

Undiagnosed cases driving concussions even higher - 50%

High incidence in contact sports, military-related cases and traffic incidents

Leading cause of death from falls in elderly populations

Neurodegenerative Diseases: Significant long-term health implications for untreated concussions

HTTPS://PMC.NCBI.NLM.NIH.GOV/ARTICLES/PMC9987206/#:~:TEXT=ESTIMATES%20SUGGEST%20THAT%203.8%20MILLION,50%25%20OF%20CONCUSSIONS%20GOING%20UNREPORTED.

ORAGENICS

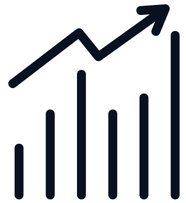
OVERVIEW OF EXISTING TREATMENTS

Symptom Management Focus

Current therapies for concussions primarily focus on symptom management rather than addressing the underlying neuroinflammation and other biological processes. This gap highlights the need for innovative solutions.

Inadequate Treatment Options

Existing options do not adequately address the underlying biological mechanisms and therefore do not prevent long-term health impairment and functional outcomes.



Market Demand

Lack of effective treatments leads to reliance on symptom management. There are currently no FDA-approved treatments for concussions, positioning our therapy as a potential first-in-class solution to address this unmet medical need.

INTRODUCING ONP-002: ADVANCED INTRANASAL Technology

ONP-002 is a proprietary neurosteroid targeting inflammation, swelling, and oxidative stress. Our innovative intranasal delivery system is designed for rapid and effective brain access, enhancing therapeutic potential.

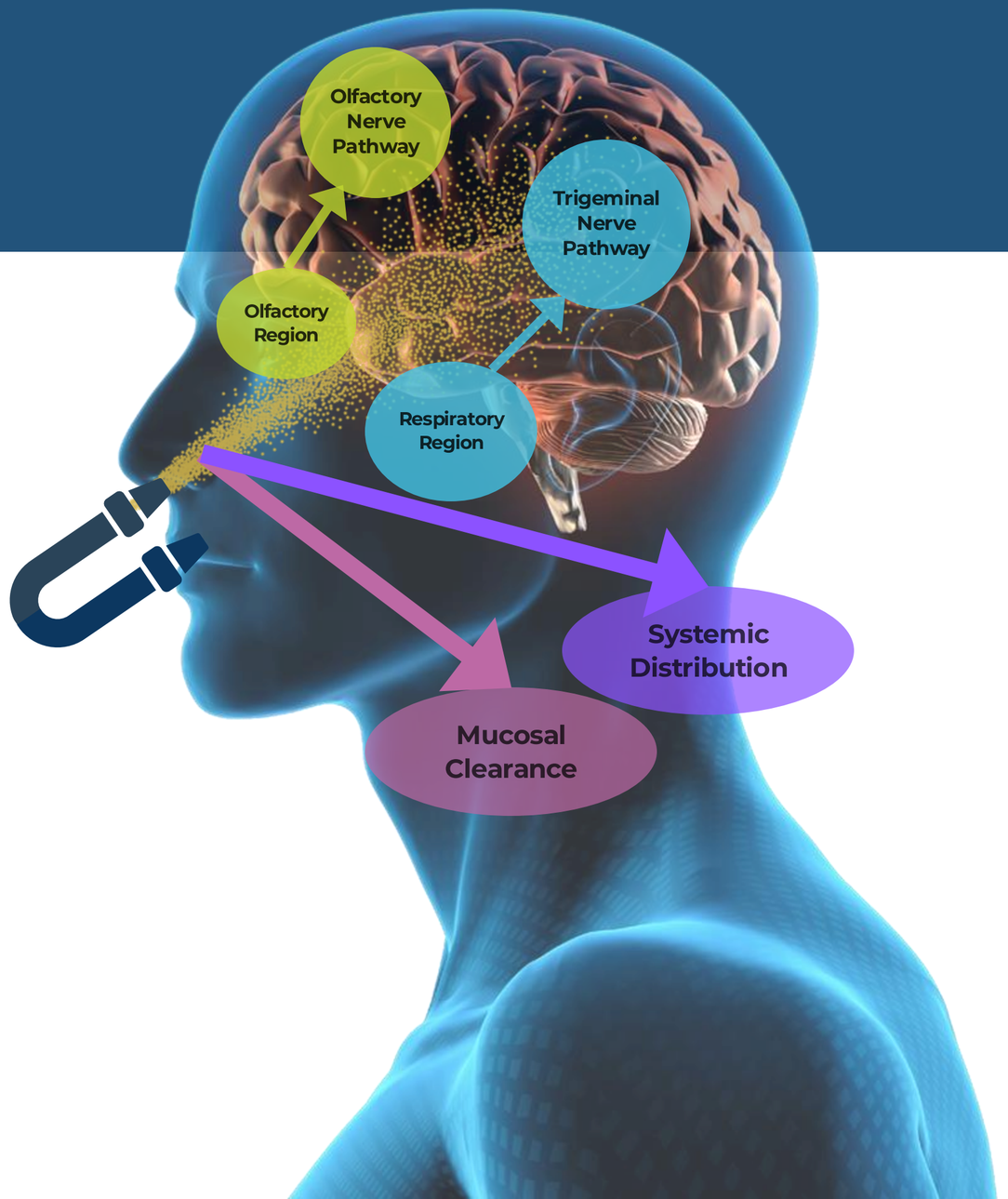
ONP-002: MECHANISM OF ACTION

Reduces Inflammation and Stress
ONP-002 works by reducing inflammation, oxidative stress, and brain swelling.

Enhances Cellular Cleanup
It intends to enhance removal of cell debris and stabilizes the Blood Brain-Barrier.

Targets Key Pathways
ONP-002 targets key pathways involved in concussion-related damage.

Promotes Recovery
The drug intends to provide neuroprotection and promotes cellular recovery.



A WINNING COMBINATION: ONP-002 + INTRANASAL DELIVERY

Intranasal Delivery Advantages

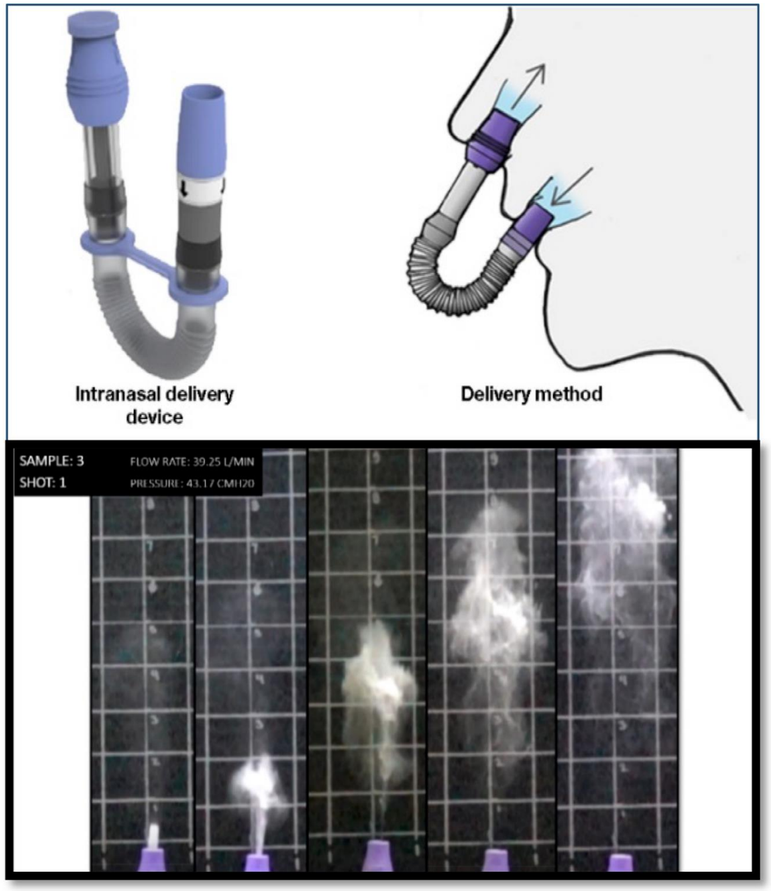
- Rapid and direct access to the brain
- Swift therapeutic effects
- Quicker onset compared to oral medications

Innovative Design

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

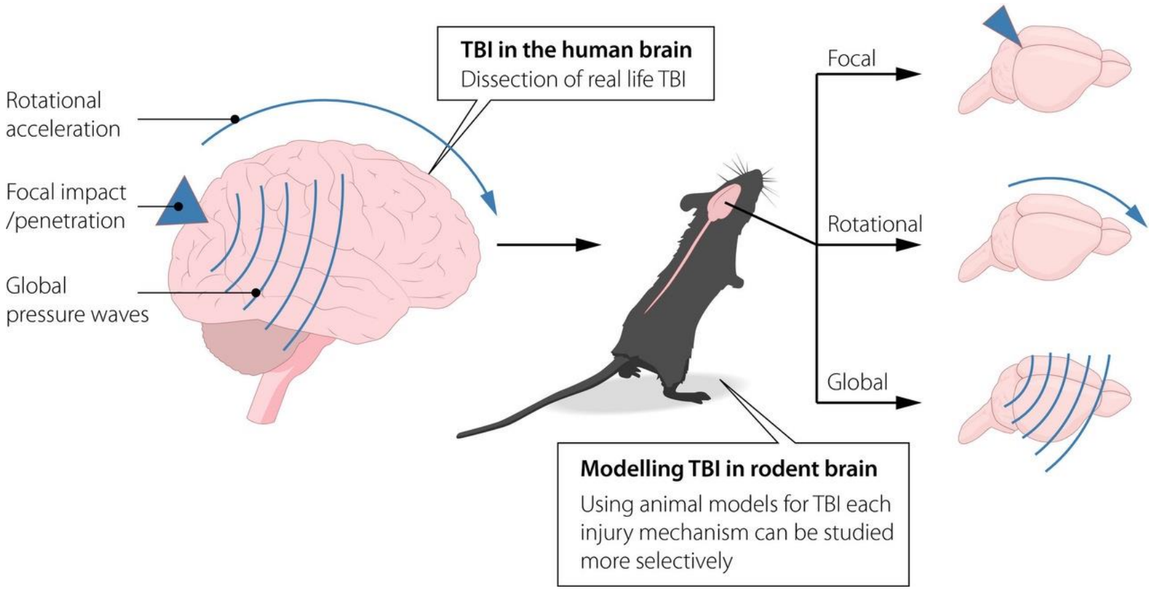
User-Friendly and Portable

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



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

ONP-002: PRECLINICAL EVIDENCE



Supporting Evidence from Animal Models

- Demonstrated behavioral improvements in memory, anxiety, and sensory-motor performance.
- Strong efficacy observed in various preclinical models of concussion.
- Neuro-protective molecular profiles established.
- A significant therapeutic window, 90 fold, seen in toxicology testing.
- Showed no cancer-causing DNA damage or genotoxicity.

In animal models, ONP-002 exhibits significant positive effects on multiple pathological parameters:

Oxidative Stress: Reduces oxidative damage, protecting neurons.

Blood-Brain Barrier Integrity: Supports the maintenance of blood-brain barrier function, preventing further neuronal injury.

Swelling and Cell Clean-Up: Mitigates cellular swelling and promotes the clearance of dead or damaged cells.

Inflammation: Effectively reduces inflammation associated with brain injury.

ONP-002:
PHASE I CLINICAL TRIALS RESULTS

Safety and Tolerability of ONP-002

Double-blinded, randomized, placebo-controlled study with 40 participants.

Drug Administration Designs

Dose escalation studies performed using intranasal delivery, with no reported serious adverse events.

Safety Review Board Confirmation

Safety Review Board confirmed drug is safe and well tolerated at all dosing levels.

ONP-002:
REGULATORY OPPORTUNITIES

ONP-002 Regulatory Opportunities as an Unmet Medical Need

Fast-Track Designation: Accelerates development and review for serious conditions with unmet needs, with submission planned alongside the upcoming IND.

Breakthrough Therapy Designation: Positioned as a breakthrough therapy, our treatment addresses a critical unmet need in a space with no existing approved drugs, offering hope for patients lacking viable options.

Accelerated Approval: Allows for earlier market entry based on biomarker surrogate endpoints, tailored for special populations (i.e., military, athletes, and the elderly population).

ONP-002:
CLINICAL DEVELOPMENT PLAN

1 **Phase IIa Clinical Studies**
Feasibility and early efficacy beginning Q4 2024

2 **Ongoing Development**
Formulation, drug synthesis and device improvements

3 **Phase IIb in the US**
Proof of concept to begin in 2025 with an open IND approved by the FDA

4 **Regulatory Interactions**
Planned to support accelerated pathways

ACCOMPLISHMENTS SINCE THE ACQUISITION

ONP-002: Advancing Concussion Treatment

Spray Dry Fill and Finish: Completed production of drug material for Phase 2a clinical trials.
New Formulation and Device Prototyping: Developed and tested optimized intranasal delivery systems.
Phase 1 Clinical Study Reports: Finalized for Investigational New Drug (IND) package submission.

Phase 2a Preparation:

- IND package submission on track for end of Q1 2024.
- Finalized clinical trial site selection in Australia.
- First patient dosing expected by late Q1 or early Q2 2024.

R&D Integration

- Seamless integration of Odyssey's clinical and R&D teams, ensuring continuity and expertise in advancing ONP-002.

Next Steps

- Launching Phase 2a trial for ONP-002 to evaluate safety and efficacy in moderate-to-severe concussion.
- Laying groundwork for future Phase 2b trials, including site coordination and FDA submission planning.

Key Takeaway: Significant progress has been achieved in a short time, positioning Oragenics for clinical milestones in 2025.

ACCOMPLISHMENTS SINCE THE SEPTEMBER CAPITAL RAISE

New Formulation & Device: The Company has made significant progress improving its formulation and device prototyping/testing. IP work is underway.

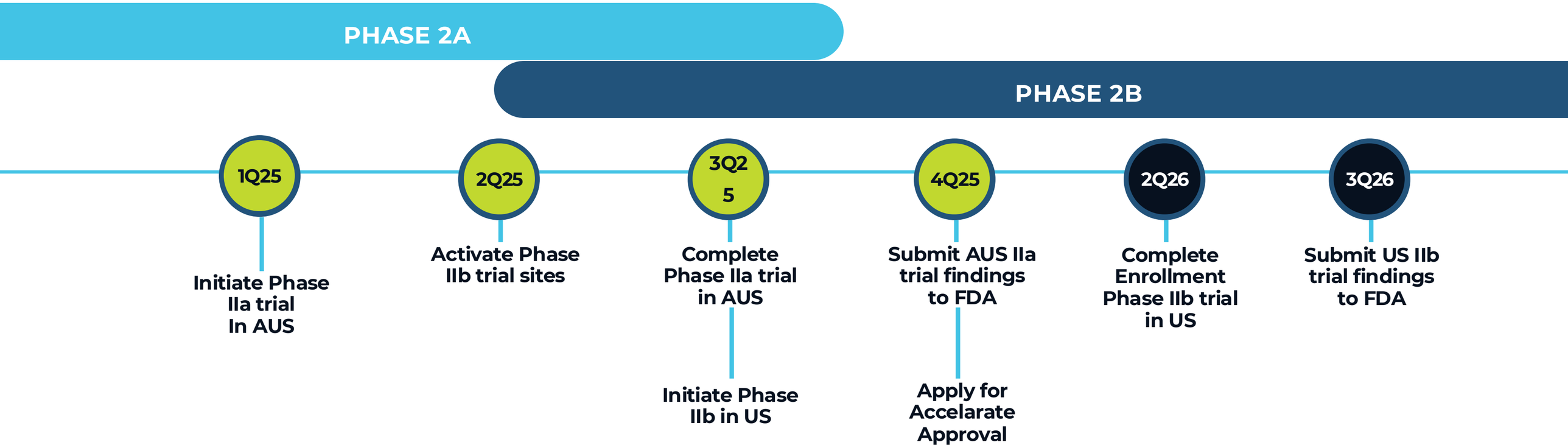
Clinical Progress: The Company has made significant progress in Australia, with clinical site partnerships close to finalization. Positive news includes the expected signing of a major hospital for Phase 2 trials, with the goal of dosing the first patient by the end of Q1 2025.

a. **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.
b. **Phase 2 Australia Clinical Trials:** Prepared materials, drafts of the investigator's brochure, and clinical protocol for the phase 2a trial. Clinical protocols are under hospital review and projected to receive final approval in January or February 2025.

Spray Dry Campaign: The spray-dried drug and device are ready for Phase 2a AU clinical trials, confirmed to be safe and ready for shipping to trial sites.

DoD Grant Submission: The team wrote and submitted a Department of Defense (DoD) grant application.

ONP-002:
CLINICAL MILESTONES

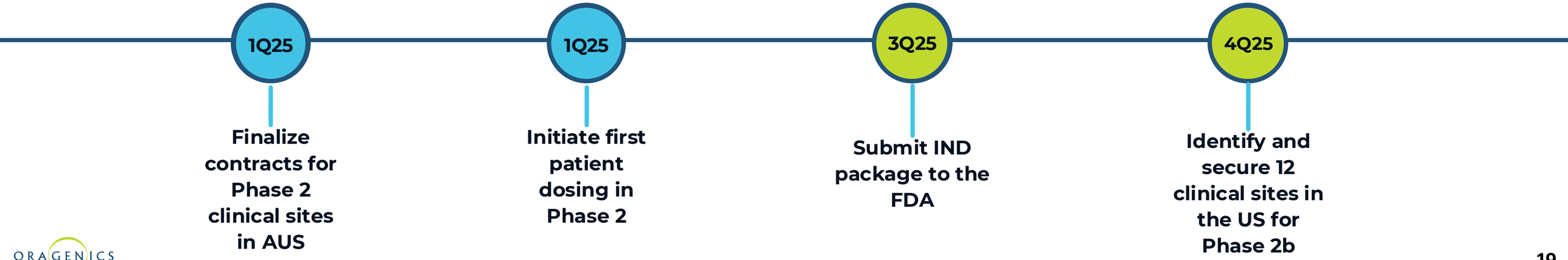


KEY EXPECTED UPCOMING MILESTONES

- Receive final hospital site approval for Australia site 1 and submit the IB for final approval.
- Finalize second site for Australia 2a clinical trials
- Begin dosing the first patient in the Phase 2 by the end of Q1, or early Q2.
- Start manufacturing of additional drug necessary for phase 2b clinical trials in the US.

Additional Milestones:

- Conduct meetings with potential clinical trial sites in the US.
- Conduct meetings to identify and secure a CRO for US clinical trials for phase 2b
- Complete the IND and submit to the FDA



ONP-002:
PROTECTING OUR INNOVATIONS

Patent Status	Pending USPTO and PCT filings for ONP-002 and its delivery device
Protection Duration	Until 2040, supporting long-term market exclusivity
Strategy Impact	Comprehensive IP strategy ensures competitive advantage
Upcoming Submissions	Drug-device PK from Phase I and automated device applications
Updates	Casting data for breath-propelled device, spray dried formulation improvements

EXPERIENCED MANAGEMENT

Janet Huffman
Chief Executive Officer

Ms. Huffman joined Oragenics in March of 2023. Prior to joining Oragenics Ms. Huffman held other CFO, Executive Leadership, and Board Director positions with private and public market companies in the health care industry, her career in the health care industry spans over 15 years. She was appointed interim CEO of Oragenics in January of 2025.

Charles Pope
Chairman & Executive Director

Mr. Pope joined Oragenics in 2022 as the Chairman of the Board of Directors. Prior, Mr. Pope was a Senior Partner at PricewaterhouseCoopers LLP, where he specialized in healthcare, audit, financial advisory, and SEC compliance. He was also CFO at several companies, including Palm Bancorp, Inc. (2009-2012) and Aerosonic Inc. (2007-2009). He brings broad expertise in finance, governance, and strategic planning to effectively guide Oragenics in achieving its long-term objectives.

James P. Kelly, MD
Chief Medical Officer

Dr. Kelly previously served as Executive Director of the Marcus Institute for Brain Health (MIBH) and Professor of Neurology and Rehabilitation at the University of Colorado Anschutz Medical Campus. MIBH, funded by the Marcus Foundation, provides specialized TBI care for U.S. veterans and first responders. He also led the Avalon Network TBI Medical Programs, with MIBH as the clinical coordinating center.

William F. Peacock, MD
Chief Clinical Officer

Dr. Peacock is the Vice Chair for Emergency Medicine Research at Baylor College of Medicine and a former Professor at the Cleveland Clinic. He is Principal Investigator of a trial on blood biomarkers to detect concussions and predict their severity in the emergency department. A prominent researcher, he helped advance high-sensitivity blood troponins for acute coronary syndrome, featured in JAMA Cardiology. He also edited the book Biomarkers of Traumatic Brain Injury.

INVESTMENT HIGHLIGHTS

Unmet Medical Need

First therapeutic specifically targeting concussion treatment, addressing a significant public health issue.

Regulatory Advantages

Potential for Fast-Track and Accelerated Approval designations, expediting development and market entry.

Innovative Technology

ONP-002's unique non-invasive intranasal delivery system provides direct brain targeted therapy and improved patient compliance.

Intellectual Property Protection

Patent protection until 2040 ensures market exclusivity and competitive advantage.

Growth Potential

Access to a multi-billion-dollar market with increasing demand for effective concussion treatments.

Upcoming Catalysts

Phase IIa trial initiation, new patent applications and regulatory submissions expected to drive value.

ORAGENICS

THANK YOU

NYSE: OGEN

JANUARY 2025