



Transforming Concussion Care with Innovative Intranasal Delivery

The first potential FDA-approved therapy
for concussion.



NYSE AMERICAN: OGEN

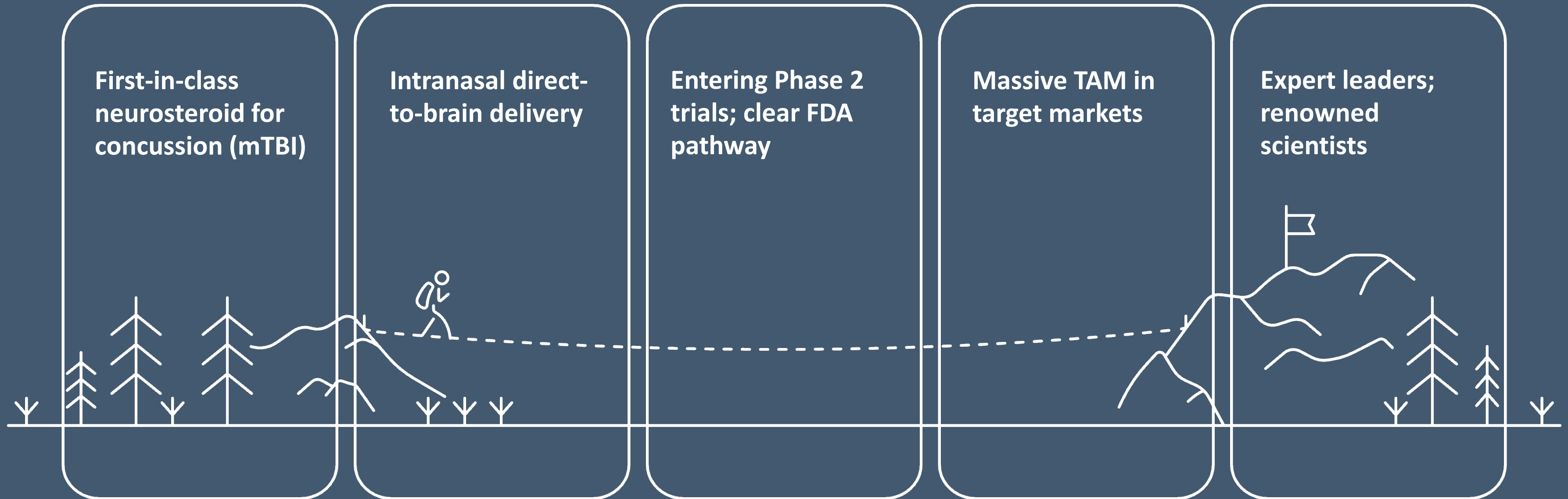
SPRING 2026

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 (Arborea 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 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*

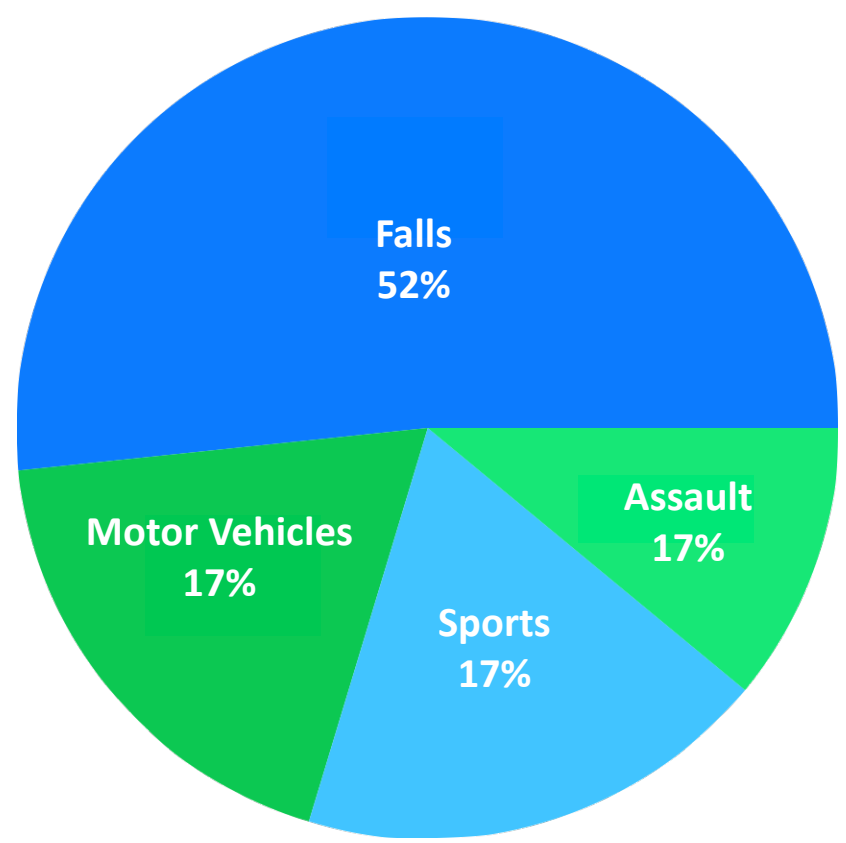
- ZERO FDA-approved pharmacological treatments for concussion
- Oragenics positioned to own category definition as first FDA-approved treatment

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

Causes of Concussion



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



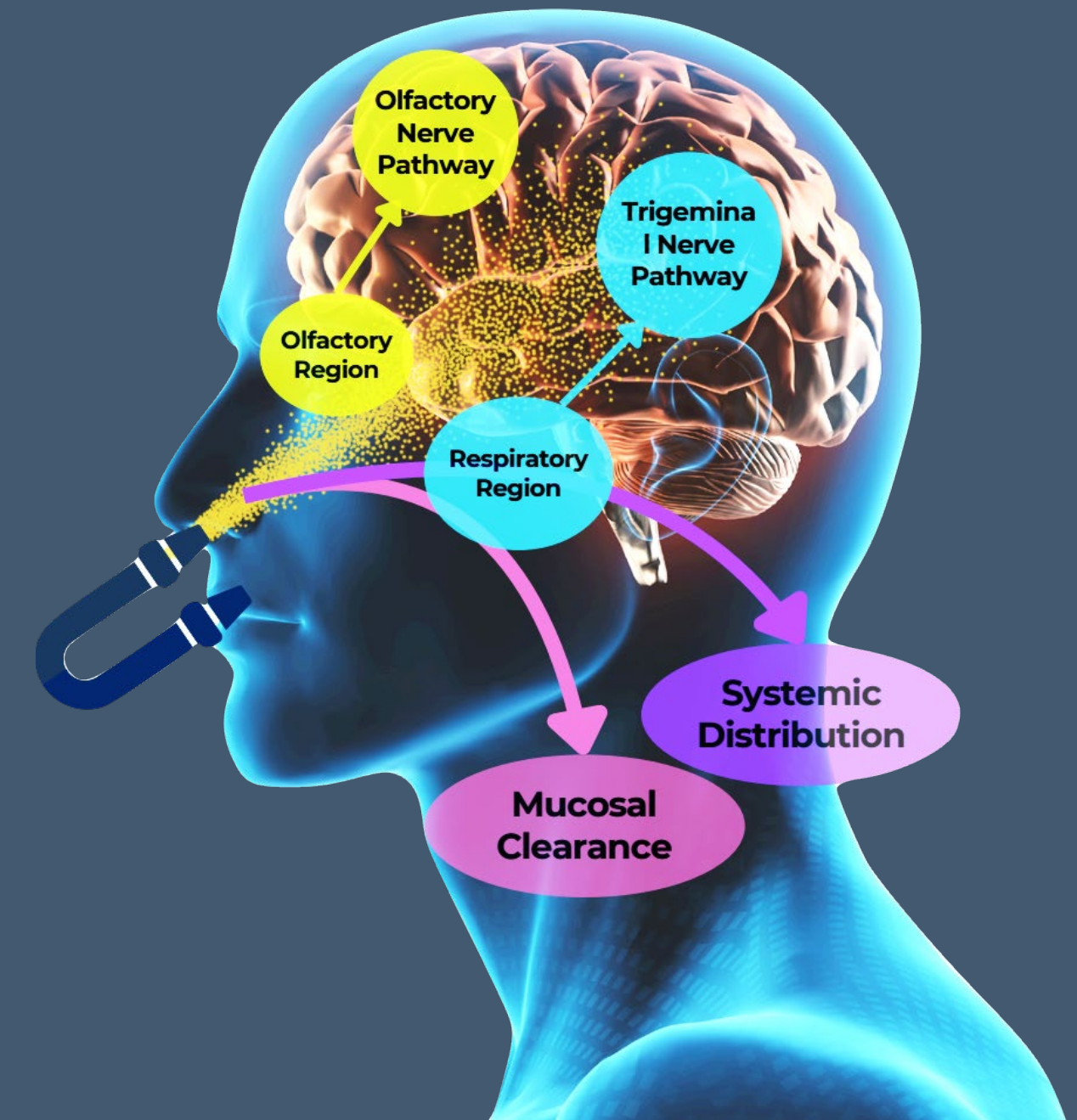
Delivery Pathway:

- 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

- Improved memory function
- Improved sensory-motor function
- Reduced anxiety behaviors

Anticipated Reduced Symptoms

- Reduced inflammation
- Reduced oxidative stress
- Reduced cerebral edema

Strategic Phase 2 Trial Design

Study Design

- Location: Australia
- Enrollment: 40 patients
- First dose within 12 hours of concussion
- Randomized, placebo-controlled

Enrollment Criteria

- CT scan negative for structural brain injury
- Presenting symptoms: headache, loss of consciousness, amnesia, or altered mental status
- Emergency room or hospital admission

Primary Endpoints

- 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 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

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

screened for enrollment

- ✓ Royal Adelaide Hospital — site initiation visit and staff training completed May 2026; formal activation

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



Brain-First Recovery™

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

Oragenics | NYSE American: OGEN

Investor contact: ir@oragenics.com