ORAGENICS

Corporate Presentation

2024

NYSE American: **OGEN**

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, including without limitation statements regarding the ability of the Company to timely and successfully undertake clinical trials regarding its 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.

At Oragenics, Nasal Drug Delivery is our Future

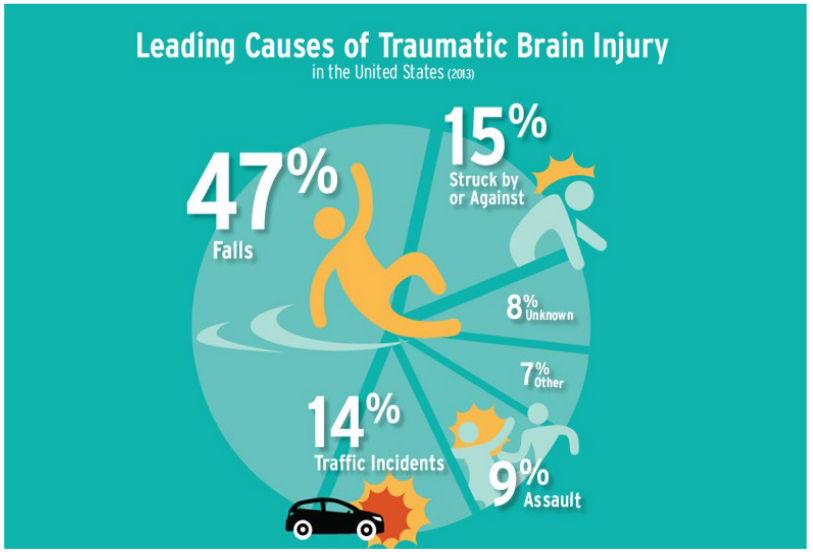
- We are investing in the future and have expanded our pipeline further into nasal drug delivery.
- ONP-002 is a first-in-class neurosteroid being developed for the treatment of moderate to severe concussion.
- Concussion is a significant unmet need – No therapeutic is currently available for the treatment of concussion.
- Phase IIa clinical studies are expected to start in 4Q-24.

- Systemic approaches often fail to efficiently supply the central nervous system with drugs for the treatment of neurological disorders, which presents an interesting opportunity for intranasal drug delivery.
- Nasal delivery offers many advantages over standard systemic delivery systems, such as:
  - Its non-invasive character.
  - A fast onset of action.
  - In many cases reduced side effects due to a more targeted delivery.[1]
- The global nasal drug delivery technology market is projected to grow to $112B by 2030.[2]

1. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7829061/
2. https://finance.yahoo.com/news/global-nasal-drug-delivery-technology-214500912.html

Concussion Landscape

- Concussion is a type of traumatic brain injury caused by a blow or bump to the head or violent shaking of the body and head.
- Common symptoms include nausea, headache, dizziness, fatigue, drowsiness, blurry vision, and ringing in the ears.
- Complications include post-concussion syndrome, vertigo, post-traumatic headaches, and second-impact syndrome.
- Protectthebrain.org reports that there are approximately 3.8 million concussions in the US annually that are sports-related alone. It is predicted that as high as 50% of all concussions go un-reported.[1]



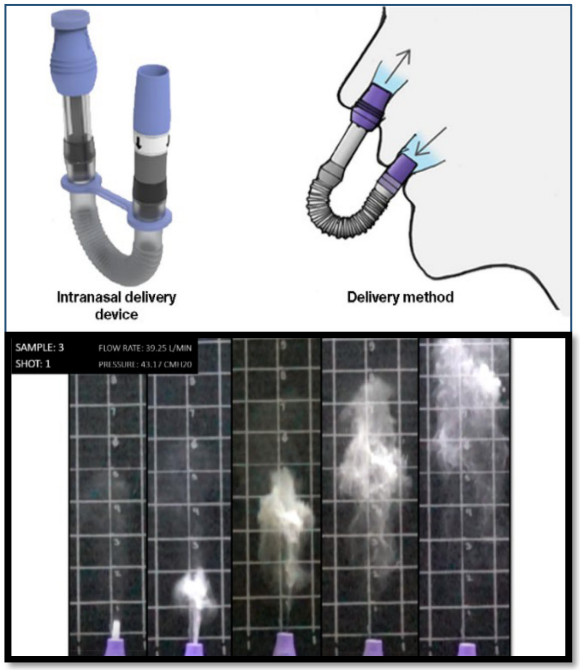
1. https://www.researchgate.net/publication/8928767_Unreported_Concussion_in_High_School_Football_Players

About Our Lead Program, ONP-002

- New chemical entity: Proprietary neurosteroid that reduces inflammation, oxidative stress and swelling in the brain.
- Nasal administration with novel device allows for fast and efficient delivery to the brain with less systemic exposure.
- ONP-002 is spray-dry manufactured into a powder and filled into the lightweight intranasal device.
- ONP-002 to date has been shown to be stable up to 104 degrees and -20 degrees, preventing need for any environmental storage protocols in the field.
- Proven in-vivo and in vitro efficacy in animal and cell culture concussion models through molecular induction of anti-inflammatories, anti-oxidants, efflux fluid channels and cell debris transporters.
- Improvements post-concussion in animal behavior including memory, anxiety and sensory-motor performance.
- Phase I single and multiple ascending dose safety trials complete and well tolerated.
- Phase I studies show 90-fold safety margin compared to animal toxicology studies.

Proprietary Drug Delivery Method

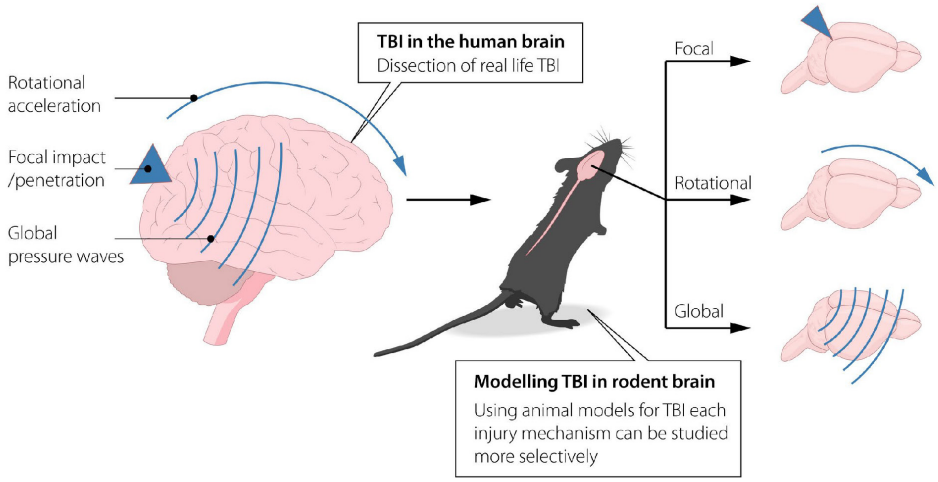
- Intranasal (IN) administration allows rapid and direct accessibility to the brain.
- Allows patients to blow into device which closes the soft palate eliminating the flow of drug to the lungs or esophagus.
- Minimizes systemic exposure and side effects.
- Enhances dispersion to the superior nasal roof for direct olfactory nerve brain delivery via a novel double tube airflow system.
- Compact, lightweight, and easy to use.
- Full application submitted covering device and method of delivery for treatment of brain injury, USPTO pending.



The powder begins to expand at 1" from the end of the nozzle and becomes fully aerated around 5"

ONP-002's Pre-Clinical Summary

- In cell culture, ONP-002 has a positive effect on neuronal survival and reconnectivity
- In animal models, ONP-002 has positive effects on oxidative stress, swelling, cell clean-up, blood brain-barrier integrity and inflammation following brain-injury. n=6/group, $p<0.05$
- In animals, ONP-002 significantly improves short-term memory, sensory-motor performance and reduces depression and anxiety-like behaviors. All within 48-hrs of brain-injury. n=10/group, $p<0.05$
- IND-enabling and toxicology studies have shown ONP-002 to have a large safety margin. Studies show that ONP-002 has a safety margin over 90X its predicted efficacious dose.



ONP-002's Phase I Summary

- Phase I was designed to determine the safety profile of the drug in healthy human subjects.
- It was double-blinded, randomized and placebo controlled (3:1, drug:placebo).
- Forty human subjects (31 males, 9 females) were successfully enrolled in Phase I.
- Phase I used a Single Ascending/Multiple Ascending (SAD/MAD) drug administration design.
- The SAD component was a 1X treatment (low, medium, or high dose) and the MAD component was a 1X/day treatment for five consecutive days (low and medium dose).
- Blood and urine samples were collected at multiple time points for safety pharmacokinetics. Standard safety monitoring (AEs/SAEs) was provided for each body system.
- The Safety Review Board, made up of medical doctors, has reviewed the trial data and has determined the drug is safe and well tolerated at all dosing levels.

ONP-002's Planned Phase II Program

A Phase II clinical trial is anticipated to be performed administering ONP-002 intranasally to concussed patients 2x a day for 10 days. The Phase IIa feasibility study is anticipated to be performed in AUS with a target initiation date in the 4th quarter of 2024 to be followed closely by a Phase IIb proof of concept study in the US following IND approval in the 1st quarter of 2025.

Planned Phase IIa Feasibility study – 30-days

- n (40) – 20 patients per arm.
- Two arms – ONP-002 dose or placebo (1:1)
- Primary evaluation of enrollment methods, safety, pharmacokinetics, and symptom improvements in concussed patients
- Early analysis of visual motor and neurocognitive effects of ONP-002 in concussed patients

Planned Phase IIb Proof of concept (POC) with Early Efficacy - 90 days

- n (120) – 60 patients per arm.
- Two arms – ONP-002 dose or placebo (1:1)
- POC measurements; blood biomarkers, neurocognitive and visual-vestibular measures, symptom severity and incidence of developing Post-Concussion Syndrome (PCS), time to return to normal function, and disability ratings

Regulatory–Possible Scenarios for ONP-002

ONP-002 Regulatory Opportunities as an Unmet Medical Need

1. **Fast-Track -** Fast track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an **unmet medical need (concussion)**. The purpose is to get important new drugs to the patient earlier. Fast Track addresses a broad range of serious conditions.

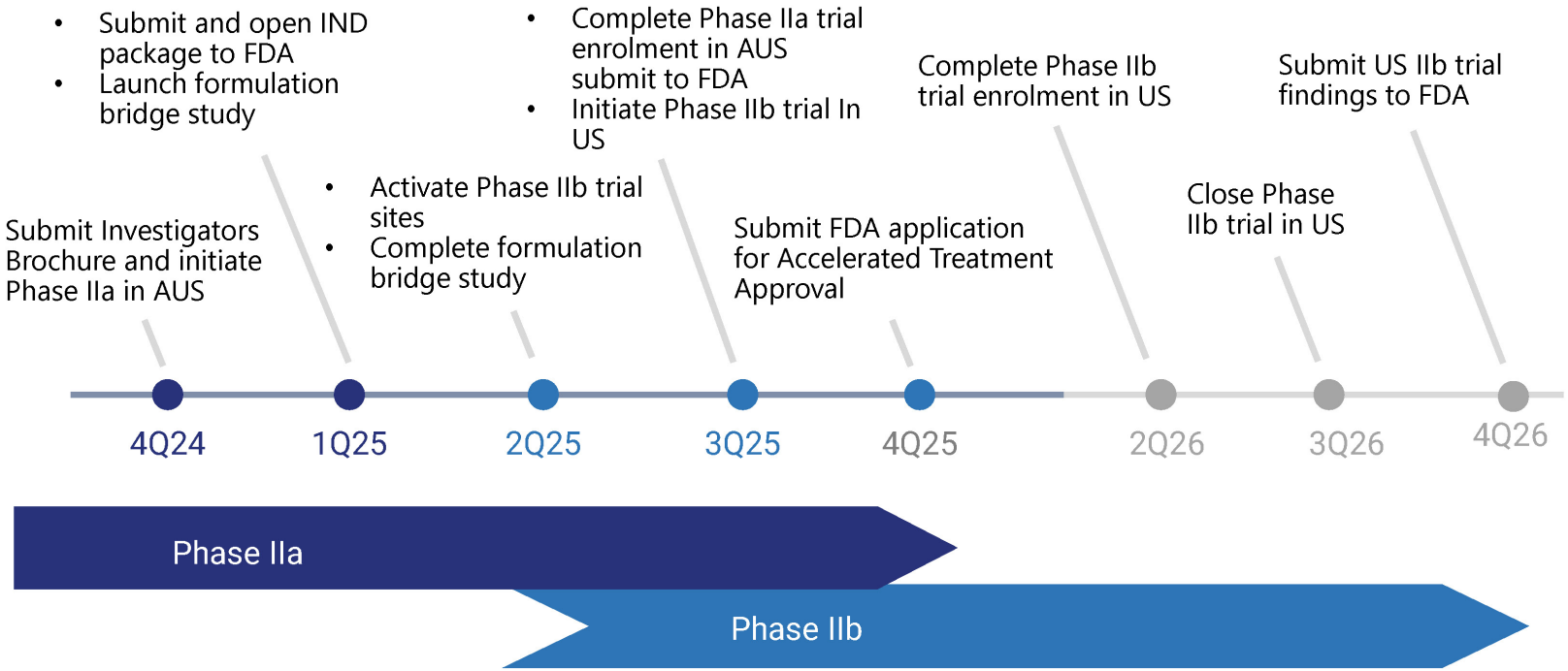
2. **Breakthrough Therapy Designation** – an FDA process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy (**none for concussion**) on a clinically significant endpoint.

3. **Accelerated Approval -** The FDA instituted its Accelerated Approval Program to allow for earlier approval of drugs that treat serious conditions, and that fill an **unmet medical need (concussion)** based on a **surrogate endpoint**. A surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit.

ONP-002's Intellectual Property

1. New chemical entity IP filing– USPTO pending, approved Europe and Canada
    - C-20 steroid compounds, composition and uses thereof to treat traumatic brain injury (TBI), including concussion.
    - The invention relates to ONP-002 composition and methods of use thereof to treat, minimize and/or prevent traumatic brain injury (TBI), including severe TBI, moderate TBI, and mild TBI, including concussions.
    - Patent expiration with max patent term extension – 9/17/2040
    - Patent expiration with no patent term extension – 9/17/2035
2. Method of intranasal delivery and device components – USPTO pending

Anticipated Timelines



The Executive Team

J. Michael Redmond (President)
Mr. Redmond has over 35 years experience in various commercial leadership positions with likes of, Abbott Laboratories KMC Medical Systems and Bioject Medical Technologies Inc. Mr. Redmond is currently the CEO of Odyssey Health, Inc. Mr. Redmond has joined the executive team at Oragenics as the President.

Janet Huffman (CFO)
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.

Christine M. Farrell (VP of Finance)
Ms. Farrell joined Odyssey in April 2019 and became Chief Financial Officer and Secretary in January 2021. Ms. Farrell was Vice President of Finance for Bioject Medical Technologies Inc., for over 15 years. Prior to joining Bioject, Ms. Farrell held multiple senior level accounting and financial management positions. Ms. Farrell has joined the Oragenics executive finance team.

The Scientific Team

James P. Kelly, MA, MD, FAAN, (Chief Medical Officer)

Dr. Kelly is the Executive Director of the Marcus Institute for Brain Health (MIBH) and Professor of Neurology at the University of Colorado Anschutz Medical Campus in Aurora, CO. He is National Director of the Gary Sinise Foundation Avalon Network TBI Medical Programs for which the MIBH serves as the clinical coordinating center. His immediate past position was Director of the National Intrepid Center of Excellence (NICoE) at Walter Reed National Military Medical Center in Bethesda, MD.

William Frank Peacock, IV, MD, FACEP, FACC, FESC (Chief Clinical Officer)

Dr. Peacock is the Vice Chair for Emergency Medicine Research at Baylor College of Medicine, Principal Investigator of the HEAD Injury Serum Markers and Multi-Modalities for Assessing Response to Head Trauma (HeadSMART II) Study, CEO of Comprehensive Research Associates – CRO involved in clinical trials for emergency care products, and Founder of Emergencies in Medicine, LLC

Greg Gironda

Mr. Gironda has over 30 years of pharmaceutical and biotechnology experience. Greg has held various strategic planning and business development roles at companies like King Pharmaceuticals, Labopharm, EMD Serono, Neura Therapeutik, and Genentech. Greg has built commercial infrastructures and processes for various biopharma companies and has overseen the advancement of multiple pharmaceutical products from conception to commercialization.

Summary Cap Table & Balance Sheet Data

Pre-Offering Cap Table	As of October 9, 2024
Common Shares	10,535,873
Preferred Shares [1]	7,511,220
Options (WAEP: $4.67)	1,022,053
Warrants (WAEP: $61.52)	293,827
Pre-funded warrants [2]	2,901,404

Balance Sheet Data	As of June 30, 2024
Total assets	$2,709,705
Total liabilities	$1,383.309
Total shareholders' equity	$1,326,396

Pre-Offering Cap Table

1. The preferred shares do not have voting rights and are shown as converted to common basis. This includes 5,417,000 shares of Series A Convertible Preferred Stock, convertible into approximately 9,028 shares of Common Stock; 4,050,000 shares of Series B Convertible Preferred Stock, convertible into approximately 13,500 shares of Common Stock; and 7,488,692 shares of Series F Convertible Preferred Stock, convertible 1:1 to shares of Common Stock.
2. Exercise price of the pre-funded warrants is $0.001

Investment Highlights

- Over 5mm annual concussion occurrences in the US territory alone, 69M worldwide.[1]
- Positive animal and cell culture model efficacy results.
- Sound safety data in animal and Phase 1 human studies.
- Phase IIa clinical studies are expected to start in 4Q-24.
- Phase IIb IND expected to open first clinical site in 3Q-25.
- No currently approved or advanced development competition.
- Strong patent position with delivery device, method of use, method of preparation composition of matter and synthetic steps.

1. (Dewan et al., 2018)