ODYSSEY GROUP INTERNATIONAL

Novel Drug Development to Treat Concussion, An Unmet Medical Need

Overview

The mission of Odyssey Health, Inc. or "Odyssey" (OTC: ticker symbol ODYY) is to acquire unique medical products that have a clinical advantage and meet a critical unmet need. In September 2021 our unique neurosteroid compound, PRV-002, intended to treat mild traumatic brain injury, was approved for a phase 1 human trial. Odyssey is a fully reporting public company and timely on all SEC filings.

Drug Development for Concussion

Odyssey's primary drug candidate is being developed as the first treatment for mild Traumatic Brain Injury (mTBI) a.k.a. concussion. The drug candidate, PRV-002, is a novel neurosteroid that easily crosses the blood brain-barrier. The company has completed the GMP synthesis of PRV-002 and all pre-clinical efficacy studies needed to begin human trials. Preclinical animal studies reported that PRV-002 improves behavioral (working memory, motor performance, and anxiety levels) and molecular (inflammation, oxidative stress and swelling) outcomes following brain trauma through an amplified gene transcription mechanism internal to cells in the brain.

Odyssey's development team has completed toxicology studies in rat and dog. Studies show that PRV-002 has a safety margin over 200X it's predicted efficacious dose. PRV-002 to date has been shown to be stable up to 104-degrees for 6-months. The drug candidate has been spray-dry manufactured into a powder and filled into a novel; breath-propelled nasal device developed by Odyssey. The device is a light weight, one time use that is easy to use in the field. Odyssey's novel nasal device is breath-propelled causing the soft palate to close in the back of the nasopharynx. This mechanism traps PRV-002 in the nasal cavity allowing for a more abundant and faster drug availability in the traumatized brain. Safety studies have established a dosing regimen of 2X/day for14d. Odyssey has completed all IND-enabling studies including Safety Pharmacology, Genotoxicity, ADME and CMC activities. Clinical Trial Phase I has launched in Melbourne, Australia (CRO, Nucleus Network, Inc.). Australia provides a 20% currency exchange advantage and a 43.5% rebate at the end of the fiscal year from the Australian government on all R & D performed in Australia. The Phase I trial is a Single-Ascending and Multiple-Ascending Dose design.

Pre-clinical Data Reports

PRV-002 Efficacy:

(a) Molecular

Acute nasal treatment of PRV-002 in animals beginning at 15-min post-concussion followed by 1 and 6hr activates transcription of pro-survival genes, translating proteins that remove swelling, pro-oxidants and inflammatory mediators in the traumatized regions of the brain.

(b) Behavioral Treatment

Following treatments (PRV-002) at 1, 6 and 24hr of concussed animals' results show improved memory and righting reflexes compared to vehicle treatment alone. Further there was a complete prevention of thigmotaxic behavior which is indicative of depressive/anxiety-like behavior seen at 48hr when treating with PRV-002.

PRV-002 Brain Biodistribution:

Nasal administration of nano-PRV-002 in dog was measured following 3 doses (initial, 4hr and 8hr). Brains were removed and PRV-002 levels measured at 30-minutes after the final dose. Results in the table below show that within 30-minutes after the final dose all regions of the brain contained high levels of PRV-002 which were considerably greater than that found in blood plasma and cerebrospinal fluid (CSF).

Tissue	Subregion	Mean_PRV-002 concentration (ng/g brain) or (ng/ml CSF and plasma)	Fold difference tissue exposure/plasma exposure
Brain tissue section	Frontal lobe	2403	3.9
	Occipital lobe	2332	3.8
	Olfactory lobe	2049	3.4
	Parietal lobe	2386	3.9
	Temporal lobe	2368	3.9
	Whole brain	1888	3.1
CSF		33.2	0.05
Plasma		607	1

PRV-002 GLP-Toxicology:

The objective of this study was to evaluate the toxicity of PRV-002, when administered as three times a day doses, approximately 4 hours apart, for 14 days at concentrations of 0, 3, 10 or 23 mg/mL at a volume of 1 mL/nostril. Reversibility of toxicity was evaluated during a 14-day recovery period following the final dose of test article, and systemic exposure was evaluated.

PRV-002 did not affect ophthalmology, body weights or food consumption.

Increased salivation was observed in all combined male and female PRV-002 treated groups, with incidence increased with concentration and is considered PRV-002-related, but not an adverse effect.

At Day 15, there were no alterations in hematology, clinical chemistry, coagulation, respiration or urinalysis parameters attributable to the administration of PRV-002. Similarly, there were no changes in organ weights and no macroscopic observations related to administration of PRV-002 at the Day 15 time point.

PRV-002 Chemistry, Manufacturing and Controls (CMC) Activities:

GMP-Synthetic chemistry and HPLC analytical methods completed

GMP-manufacturing completed/scaled to 100-gram production for Phase 1 clinical trials

GMP-stability testing for 18-months at room temperature and 6-months at 104-degress completed with no change in chemical structure

PRV-002 IND-enabling studies:
Safety Pharmacology performed on off target receptors including hERG cardio-receptor showed no concern

Absorption, Distribution, Metabolism and Excretion (ADME) standard studies completed including plasma protein binding, CYP inhibition/induction testing, transporter inhibition/substrate testing, Metabolic stability and identification and Liver microsomal testing (PRV-002 plasma clearance rate).

Genotoxicity studies including AMES test and in-vitro micronucleus testing were negative. In-vivo micronucleus testing will be completed Q1, 2022.

Patent Portfolio

Filed/Issued	In-Development
Composition of Matter	Nanoparticle Formulation
Synthetic Steps	Drug in Device
Use for Brain Injury	Dosing and Pharmacokinetics
Intranasal Device	Improved synthetic steps

Formulation and Manufacturing

PRV-002 is formulated in Hydroxy-Propyl Beta Cyclodextrin and dissolved in an aqueous solution. The aqueous solution is then spray-dried and tested for final percentage of PRV-002 by GMP-HPLC analytical methods. The spray-dried powder is then analyzed for particle density and filled into the reservoir of the breath-propelled device, labeled and shipped to clinical trial sites. Efforts are underway to further reduce the number of synthetic steps needed to produce the API. This work will improve future scalability while reducing cost.

Leadership

Michael Redmond, CEO

Mr. Redmond has served as our Chief Executive Officer, President and Chairman of the Board since 2017. Mr. Redmond has over 30 years commercial experience in medical device companies. Prior to joining Odyssey, Mr. Redmond served as CEO of Parallax Health Sciences, Inc., a healthcare related company, from 2010 to 2017 where he acquired two businesses and three different patented technologies. Prior to this, Mr. Redmond was V.P. of Business Development for DxTech, Inc., a start-up company developing a unique point of care diagnostic testing platform, from 2007 to 2009 when the company was sold. Prior to this, Mr. Redmond served as the V.P. of Sales and Marketing for Bioject Medical Technologies, Inc. ("Bioject"), a medical device company specializing in unique drug delivery technologies, from 1996 to 2007. While at Bioject, Mr. Redmond helped raise over $15 million in capital, entered into several licensing and distribution deals with major biotech and pharmaceutical companies and grew the market cap of the company from under $10 million to over $400 million. Prior to this, Mr. Redmond held various sales and marketing positions at Abbott Laboratories a multi-billion dollar healthcare company and helped start KMC Systems Inc., now a leading private label developer and manufacturer of medical devices and instrumentation. Mr. Redmond was in charge of Sales and Marketing and grew the company from start-up to over $50 million in revenue. Mr. Redmond has a B.A. degree from Denison University.

Jacob VanLandingham, Ph.D.

Dr. VanLandingham is the Executive VP of Drug Development for Odyssey Group International. Dr. VanLandingham was the Founder and President of Prevacus, Inc. which was acquired by Odyssey Group International in March 2021. He has a B.S. in Physical Therapy and spent 3-years working with neurologically impaired children with brain injuries in and around the time of birth. His Ph.D. is in Neuroscience from Florida State University with a molecular biology focus on brain disorders including, Traumatic Brain Injury, Chronic Depression, Parkinsons, Alzheimers and Wilsons disease. His Post-doctoral work was in translational research and neurobehavioral aspects of diseases at Emory University. At Emory he also oversaw the clinical biomarker study for the ProTECT clinical trial using progesterone for acute treatment of severe to moderate TBI as the Assistant Director of the Brain Research Laboratory the largest laboratory in the Emergency Medicine Department. Dr. VanLandingham was an Assistant Professor in Biomedical Sciences at the Florida State University College of Medicine for 8-years where while overseeing his research laboratory he taught molecular aspects of disease in the following courses: Microanatomy, Human Anatomy and Physiology, Medical Biochemistry and Pathology. Dr. VanLandingham has been on many board and grant committees that focus on finding solutions and funding for neurological disorders. He currently consults for concussion and non-opioid pain relief clinics.

Michael 'Mike' Lewandowski

Mr. Lewandowski is the Chief Scientific Officer of Odyssey Group International, Inc. He brings over 40-years of experience in drug development and over 25 drugs approved by the FDA. As a member of Genentech, Inc. Mr. Lewandowski helped develop tPA (Genentech, Inc.) the leading clot-buster still on the market for stroke and coronary disease. He is also very proud to have been the identifier and primary developer of Natrecor (Scios, Inc. Bought by J and J) a leading drug for acute Congestive Heart Disease. He is a toxicologist by trade and has run his on drug development company for over 15-years, Global Bio-development, LLC. M. Lewandowski has over 20 years of experience working on drugs in Australia including pre-clinical animal efficacy studies, toxicology and clinical trials.

Key Medical and Sports Advisory Board Members

Dallas Hack, M.D.

Dr. Hack is the former head of the Combat Casualty Care and Neurotrauma Division of Research for the Department of Defense. Dr. Hack was the lead consultant for the NCAA and its CARE Consortium Program for analyzing concussion in college athletes at over 21 major universities including all three military academies. He is assisting Odyssey is the Phase 2/3 clinical trial design and Odyssey will be using validated outcome measures that are part of the NCAA CARE Consortium protocol to sjow drug efficacy.

James Kelly, M.D.

Dr. Kelly is the former Director of the US National Intrepid Center of Excellence (NiCOE). Dr. Kelly a neurologist was the original Director of NiCOE which is the foremost treatment center for brain-injured warriors in the United States. Dr. Kelly is currently practicing in Colorado and a member of the medical school team at the University of Colorado. He is also the Director of the Marcus Foundation for Brain Injury and is developing multiple centers across the country for treating Military Veteran's with brain injury. Dr. Kelly is assisting Odyssey in the development of the Phase 2/3 Clinical Trials.

Brett Favre

Brett is a former NFL Quarterback primarily with the Green Bay Packers. He was recently inducted into the Pro Football Hall of Fame. Brett has had trouble the past few years with short term memory loss which could possibly be from concussions he sustained during his playing days. Brett has been a member of the Prevacus team for the past 5 -years and was instrumental in helping us raise over 3.5M USD in his home state of Mississippi. Brett has done interviews with Dr. VanLandingham supporting the need for a drug to treat concussion. Brett has aided in outreach to recruit other advisory members and is in contact with NFL leadership.

Steve 'Mooch' Mariucci

Mooch is the former Head Coach for in the NFL with both the San Francisco 49ers and Detroit Lions. He was also Brett Favre's Quarterback coach when he arrived in Green Bay. Mooch just joined our team and he is on the NFL Safety and Rules Advisory Board. He has arranged meetings between Dr. VanLandingham and the lead of independent neurologists that oversee each NFL game to spot and remove concussed players.

Abby Wambach

Abby is an American retired soccer player, coach, two-time Olympic gold medalist and FIFA Women's World Cup champion. She is also a six-time winner of the U.S. Soccer Athlete of the Year award. Abby has scored more goals using her head than any other soccer player. She has personally experienced the effects of concussion and has legally donated her brain to science upon her death. Abby is a great international ambassador for Odysseyand the mission to treat concussion.

Kurt Warner

Kurt is a Hall of Fame Quarterback and NFL Super Bowl Champion. He has been passionate about findings solutions for care of brain injured victims for decades. Kurt's son lives with the effects of severe brain trauma. Kurt represents the highest of character and morals and is a true philanthropist. Currently, he is a commentator for the NFL Network working side by side with another Odyssey member, Coach Steve Mariucci. Kurt has created the Treasure House in Arizona providing state-of-the-art care for adult brain-injured survivors.

David Ross

David played 18 years of in Major League Baseball. He sustained multiple concussions as a catcher. Having lived with Post-Concussion Syndrome he is passionate about finding a solution. David is supported by his agents at Sports-1. Currently, David is the manager for the Chicago Cubs. David and Dr. VanLandingham have been friends since high school in Tallahassee, Fl.

Clinical Trial Design

- Phase 1- Safety in non-concussed subjects (n=48)
- Phase 2A- Efficacy in concussed athletes, double-blind placebo-controlled (n=250, Adaptive Design). In partnership with the NCAA and Department of Defense through previous CARE Consortium sites
- Phase 2B- Efficacy in concussed patients presenting to emergency room, double-blind placebo-controlled (n=250, Adaptive Design).

Primary Endpoints

- Patient reported symptoms (Post-Concussion Screening Scale)
- Short-term memory and processing speed (SCAT-5)
- Vestibulo-ocular system function (VOMS, King-Devick Testing for Balance and Visual Motor Performance)
- Aerobic exercise tolerance testing (Buffalo Concussion Treadmill Test)
- Percent diagnosis of post-concussion syndrome at 30 days, 3- and 6-months post-injury
- Psychiatric scales of anxiety as Hospital Anxiety Disorder Scale and Beck Depression Self Inventory
- Sleep analysis (Pittsburgh Sleep Quality Index)

Secondary Endpoints

- Blood biomarker analysis (UCH-L1 and GFAP)
- EEG testing for a quantitative demonstration of electrical brain activity
- Brain Imaging

Timeline

PRV-002	1Q22	2Q22	3Q22	4Q22

Complete IND-enabling studies				
Complete final nanoparticle drug formulation				
Complete SAD portion of Phase I trial				
Initiate MAD portion of Phase I trial				
Initiate Phase 2 drug manufacturing				
Pre-IND meeting with FDA				
Complete MAD portion of Phase I				
Submit Phase II Investigators Brochure				
Complete Phase II drug manufacturing				
Launch Phase II				

Summary

Currently, there is no FDA-approved pharmaceutical treatment for concussions. There is a worldwide annual estimate of 69M concussions with a healthcare burden over $450B. The number one cause of trauma-induced mortality in the world is brain injury. Recent published reports show that 1 in 3 youth who sustain a concussion are diagnosed with a mental health disorder. One concussion reduces the threshold for sustaining future concussions. There is an exponential increase in long-term health consequences associated with repetitive concussions. These consequences include early-stage dementia, chronic depression and suicidal ideation to name a few.

Odyssey is developing PRV-002 as a new chemical entity eligible for 7-year data exclusivity and patent term extension. The drug easily passes the blood brain-barrier and enters the brain within minutes. The nasal application allows for more drug in the brain faster and provides for an inexpensive, portable, field deliverable application. The Phase 1 clinical trial sites are established, and the trial has begun subject enrollment in Australia where there is a 43.5% rebate and currency exchange benefit (20%) for R and D work. Odysseys' Scientific Advisors are well versed in clinical aspects of brain injury, drug development and grantsmanship as well as medical monitoring of clinical trials. The Odyssey Sports Advisory Board is committed to finding solutions for the concussion epidemic and personally deal with the consequences of multiple concussions they sustained during their playing years.

It's time to find a treatment for concussion that expedites the return to work, play, school, and military duty. A treatment that can reduce the likelihood of long-term brain disease. Better helmets and rule changes can assist but will not prevent concussions. However, if the Odyssey drug candidate can reduce the pathological cascade of molecular events that occur in the acute phase of the injury a substantial improvement in patient outcomes can be achieved in athletic and other commonplace occurrences for concussion.