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 2022 our unique neurosteroid compound, ONP-002, intended to treat mild traumatic brain injury, successfully completed a well-tolerated Phase I 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, ONP-002, is a novel neurosteroid that easily crosses the blood brain-barrier. The company first completed the GMP synthesis of the ONP-002 API along with a nanoparticle formulation using Hydroxy-Propyl β Cyclodextrin as the vehicle. All the needed pre-clinical efficacy studies (animal and cell) were completed to begin clinical trials. Preclinical animal studies reported that ONP-002 improves behavioral (working memory, motor performance, and anxiety levels) and molecular (inflammation, oxidative stress and swelling) outcomes following brain trauma through an amplified molecular mechanism internal to cells in the brain. Brain biodistribution was performed and concluded that intranasal administration of ONP-002 ensures it reaches the brain at significant levels and in a timely manner. Odyssey's development team completed toxicology studies in rat and dog. Studies showed that ONP-002 has a safety margin over 90X it's predicted efficacious dose. ONP-002 to date has been shown to be stable up to 104℃ for 18-mths.

The drug candidate has been spray-dried manufactured into a powder and filled into a novel device developed by Odyssey. The device is a light weight, one time use that is easy to use in the field. Odyssey's intranasal device is breath-propelled causing the soft palate to close in the back of the nasopharynx which occurs when an individual performs a blow. This mechanism traps ONP-002 in the nasal cavity allowing for a greater absorption and faster drug availability in the traumatized brain through peri axonal flow along the olfactory nerve. Currently, the device is also being designed for assistive use with an air dispensing bulb in the case that the individual is unconscious or cannot follow instructions to blow due to confusion. Safety studies have established a dosing regimen of 2X/day for 14-days. Odyssey has completed IND-enabling studies including Safety Pharmacology, Genotoxicity, ADME and CMC activities. Clinical Trial Phase I is complete and was well-tolerated. The trial was conducted 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 clinical trial used a Single-Ascending and Multiple-Ascending Dose design.

ODYSSEY HEALTH

Pre-clinical Data Reports

ONP-002 Efficacy:

(a) Molecular

Acute nasal treatment of ONP-002 in animals within 1hr and again at 6hr activates transcription of pro-survival genes, translating proteins that remove excess fluid and toxins, pro-oxidants, and inflammatory mediators from the traumatized regions of the brain. Specifically, ONP-002 induces the Pregnane X Receptor (PXR) leading to increased levels of Glutathione s-transferase and P-Glycoprotein (PGP) producing its neuroprotective effects by reducing oxidative stress and improving removal of fluid and cell debris. Concomitantly, the inflammatory marker, TNF-α is reduced. Cell culture treatments following a toxic challenge showed improved neuronal cell survival and synaptogenesis when treated with ONP-002.

(b) Behavioral Treatment

Following treatments (ONP-002) at 1 and 6hr after concussion our animal results show improved working memory and motor performance compared to vehicle treatment alone in the first 48hrs. Further there was a complete prevention of thigmotaxic behavior which is indicative of depressive/anxiety-like behavior when treating with ONP-002.

ONP-002 Brain Biodistribution:

Nasal administration of nano-formulated ONP-002 in dog was measured following 3 doses (initial, 4hr and 8hr). Brains were removed and ONP-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 ONP-002 which were considerably greater than that found in blood plasma and cerebrospinal fluid (CSF).

Tissue	Subregion	Mean-ONP-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

ONP-002 GLP-Toxicology:

The objective of this study was to evaluate the toxicity of ONP-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.

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

Increased salivation was observed in all combined male and female ONP-002 treated groups, with incidence increased with concentration and is considered ONP-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 ONP-002. Similarly, there were no changes in organ weights and no macroscopic observations related to administration of ONP-002 at the Day 15 time point.

ONP-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 I clinical trials

GMP-stability testing for 18-months at room temperature and 104℃ has been completed with no change in chemical structure

GMP-stability testing for 9-months at room temperature of drug formulation in device has been completed with no change in chemical structure. All bioburden testing of drug formulation in device has been negative to date.

ONP-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 (ONP-002 plasma clearance rate).

Genotoxicity studies including AMES test and in-vitro micronucleus testing were negative. In-vivo micronucleus testing will be completed Q1, 2023.

Patent Portfolio

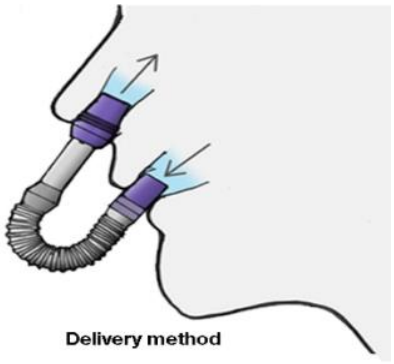
Filed/Issued	In-Development
Composition of Matter	Nanoparticle Formulation
Synthetic Steps	Drug in Device
Use for Brain Injury	Dosing and Pharmacokinetics
Intranasal Device	Improved synthetic steps

Formulation and Manufacturing

ONP-002 is formulated in Hydroxy-Propyl β Cyclodextrin and dissolved in an aqueous solution. The aqueous solution is then spray-dried and tested for final percentage of ONP-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 our clinical trial sites. Particle dispersion size is greater than 10 microns to prevent drug inhalation into the lungs. Currently, formulation improvements are being designed to gain a 32% API in the final treatment payload compared to the current 8%. This work is designed around the use of ethanol as the drug solvent prior to spray drying. 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.

Phase I clinical trial, SAD/MAD design


Intranasal delivery device



A total of 40 healthy human volunteers were treated with either ONP-002 or placebo at a ratio of 3: 1. ONP-002 treatments were given at a low (.14mg/kg), medium (.26 mg/kg) or high (.52 mg/kg) intranasal dose of the ONP-002 formulation. The Single-Ascending Dose (SAD), regimen included 24 volunteers at 8 per group (low, medium or high dose). The Multi-Ascending Dose (MAD) regimen included 16 volunteers at 8 per group (low or medium dose). MAD treatments were carried out once a day for 5-days. All EKG, spirometry and vital signs were within normal limits for SAD/MAD. Blood labs were all normal. Blood pharmacokinetics (PK) of the high dose showed a Cmax that was 4-fold less that seen in the high dose used in the dog and rat toxicology studies. No drug accumulation was seen through the 10-day follow-up period. PK findings throughout the evaluation period showed low blood levels of ONP-002 suggesting the intranasal route of administration pushed the majority of the drug into the brain where it was subsequently metabolized.

Phase II Clinical Trial Design and Implementation – All studies components will be randomized, double-blinded and placebo-controlled (1: 1) - Feasibility, Proof of Concept and Early Efficacy measures in concussed patients.

i. The development of "Clinical Strategies" and subsequent determination of "Feasibility" to enroll and provide initial treatment of ONP-002 to concussed patients within the acute window of 8hr. This study will include safety and pharmacokinetic testing. A total of 40 patients will be enrolled

ii. The conduction of a "Proof of Concept and Early Efficacy Measures" study in concussed patients treated within 8hrs of injury and subsequently daily for 14-days

Key Inclusion/Exclusion criteria -

1. Patients positive for blood biomarkers representing cellular damage in the brain
2. A SAC screening score of no more than 17 on a 30 scale
3. A PCSS score from borderline and extremely high

These criteria meet the standard of moderate to severe concussion that often develops into Post-Concussion Syndrome (PCS). Effectively these criteria eliminate mild concussion enrollment that often resolves on its own.

Primary Endpoints

- Patient concussion severity score
- Percent diagnosis of PCS at 30 days, 3- and 6-months post-injury
- Short-term memory and processing speed
- Visuo-vestibular system function
- Aerobic exercise tolerance
- Presence and degree of Anxiety and Depression
- Sleep function – too much or too little

Secondary Endpoints

- EEG testing
- Brain Imaging
- CSF analysis

Leadership

Corporate and Research and Development

Michael 'Mike' Redmond

Mr. Redmond has served as our Chief Executive Officer, President and Chairman of the Board of Odyssey Health, Inc. 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 'Jake' VanLandingham, Ph.D.

Dr. VanLandingham is the Lead Manager of Drug Development for Odyssey Health. 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, Parkinson's, Alzheimer's 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 a Scientific Consultant for Odyssey Health. 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.

Greg Gironda

Mr. Gironda is the Chief Operating Officer of Odyssey Health. He 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.

Erik Emerson

Mr. Emerson is the Chief Commercial Officer of Odyssey Health. He has over 20 years of experience in commercial pharmaceutical leadership. Mr. Emerson has worked in sales, marketing, commercial and business development for organizations that include Mezzion Pharmaceuticals, Adhera therapeutics, XOMA ltd, Gilead Sciences and King Pharmaceuticals.

Christine M. Farrell

Ms. Farrell is the Chief Financial Officer for Odyssey Health. Previously, she was the Vice President of Finance for Bioject Medical Technologies Inc., for over 15 years. Prior to joining Bioject, Ms. Farrell held senior level accounting and financial management positions with Spar-Tek Industries, a manufacturer of cutting-edge technology for the plywood industry and Action Machinery, a manufacturer of robotic equipment.

Key Medical and Military Advisory Board Members

Medical

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 and Gary Sinise Foundations 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.

Military

James 'Jim' Linder

Jim is a recognized leader in the world of Special Operations and Intelligence organizations as a high performing and skilled strategist. A US General Officer with over three decades of direct command leadership around the globe. As a General Officer, he created new cutting-edge capabilities and accelerated the growth of highly skilled Afghan Special Forces. He also led and directed all US special operations across the African continent, while interacting with US interagency and African leaders to achieve US national security goals. He adeptly applied new ideas as commandant of the Army's premier Center of Excellence for selecting and training Special

Operations Forces and was the commander of all US and NATO special operations forces in combat in Afghanistan during a critical period of transition. Most recently, he achieved value-driven results managing a complex and agile organization of 80k persons with a $13.4B government operating budget as the Chief of Staff for US Special Operations Command.

Paul Toolan

Lieutenant Colonel (LTC) Paul Toolan joined the Army as a Private in 1986. Over the course of more than three decades in uniform, he has risen through the ranks and completed every elite school in the US Army. He is a Special Forces Airborne Ranger and started his Special Forces career as a Detachment Commander in 3rd Special Forces Group at Fort Bragg. He has held nearly a dozen leadership positions in multiple Special Forces Groups, including Detachment Commander, Company Executive Officer, Battalion Operations Officer, Support Company Commander, Company Commander, Group Operations Officer, Group Executive Officer, Battalion Commander, Chief of the Special Forces Training Division, and the Director of Operations at 1st Special Forces Command. He has worked at the National Counter-Terrorism Center as a Special Forces advisor and worked as a Special Forces consultant in the United States Army Special Operations Commander's Initiatives Group. He last duty assignment was the Deputy Commander of the 1st Special Warfare Training Group at Fort Bragg, North Carolina, where Green Berets are assessed, selected and trained. Since retiring from military service, Paul has dedicated himself to helping Special Operators address the effects of life in Special Operations such as post-traumatic stress (PTS), traumatic brain injury (TBI) and Operator Syndrome (overstimulated sympathetic nervous system) by facilitating access to treatment innovations.

Timothy 'Tim' Szymanski

Vice Admiral (r) Szymanski has led and served in many Navy and Joint Special Operations assignments as a Navy Special Warfare Officer (SEAL) for over 36 years. He most recently served as the Deputy Commander for United States Special Operations Command (USSOCOM) after serving as the Commander of Naval Special Warfare (NSW). In both roles he was responsible for the manning, equipping, and training, and employment of Navy SEAL and joint special operations forces, of 11,000 and 73,000 uniformed and civilian personnel, respectively.

He has commanded a SEAL Team, Special Boat Team, a Squadron at a Special Mission Unit, and a Special Operations Joint Task Force. His recent assignments as a flag officer were Deputy Commander USSOCOM, Commander Naval Special Warfare Command, Assistant Commanding General Joint Special Operations Command and Deputy Commander of NATO Special Operations Component Command – Afghanistan. Szymanski attended the U.S. Naval Academy Preparatory School and graduated from the United States Naval Academy in 1985.

Keenly aware of the detrimental effects of invisible wounds on Force and Family Readiness, he established policy to cognitively baseline the entire Special Operations community as well as created initiatives to prevent, protect, recover, and enhance cognitive performance and brain health.

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 ONP-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 powder-formulated drug in the brain faster and provides for an inexpensive, portable, field deliverable application that is stable at elevated temperatures. The Phase I clinical trial showed ONP-002 was well-tolerated. Odysseys' Scientific Advisors are well versed in clinical aspects of brain injury, drug development and grantsmanship as well as medical monitoring of clinical trials. Phase II clinical sites are being established and an initial trial design has been created. The Odyssey Military Board is represented by leaders who have been working for years on solutions to protect the mental health of soldiers during and after their service to this great country.

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 Health's 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 military settings as well as other commonplace occurrences for concussion most notably falls and car accidents.