

## Treating Concussion, PRV-002

### 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, aka concussion, 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 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 neuroprotective gene response 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 18-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 which occurs when an individual performs a blow. This mechanism traps PRV-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 ongoing in Melbourne, Australia (CRO, Nucleus Network, Inc.). The Phase I trial is a Single-Ascending (SAD) and Multiple-Ascending Dose (MAD) design. SAD has been completed and PRV-002 was well-tolerated.

### 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

## Leadership

### 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 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, 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.

## **Key Medical, Sports and Military Advisory Board Members**

### Medical

#### 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 in 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 show drug efficacy. Dr. Hack is a Board member for the Geneva Foundation, a CRO assisting Odyssey in its' military-based Phase II clinical trials.

#### 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.

#### Francis 'Fran' Beaudette

Over the course of his 32-year career in Army and Joint assignments, the majority of it as a Green Beret, Francis "Fran" M. Beaudette served with high performing organizations at varying levels, from a 12-man Special Forces 'A-team' to the 36,000-Soldier and Civilian US Army Special Operations Command. His recent assignments were Deputy Commanding General of the 1st Armored Division, Assistant Commanding General of JSOC, CG of 1st Special Forces Command and Commanding General of the US Army Special Operations Command. His operational assignments, totaling six years of deployed time, include the first Gulf War; comprehensive Africa

experience to include noncombatant evacuation operations in Sierra Leone and the Congo; multiple peacekeeping operations in Kosovo; numerous deployments in Iraq, Afghanistan, the Philippines and Jordan, all during eras of war, turmoil or crisis.

#### 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.

## Sports

### 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 Odyssey and the mission to treat concussion.

### Kurt Warner

Kurt is a Hall of Fame Quarterback and NFL Super Bowl Champion. He has been passionate about finding 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.

## Mark Rypien

Mark is a 2x Super Bowl Champion and MVP. He was the 1st Canadian quarterback to start in the NFL. Mark has been dealing for years with the cognitive and emotional side effects of multiple concussions. He is an advocate for finding treatment solutions and providing concussion awareness in youth sports as well as our military. Mark has been instrumental in connecting the Odyssey team with key members of NASCAR and brain care Foundations.

### Clinical Trials

- Phase 1- Safety in non-concussed subjects (n=40), ongoing and is so far well tolerated with an expected completion in August of this year
- Phase 2- Efficacy in concussed athletes and military personnel, double-blind placebo-controlled (n=250, Adaptive Design). In partnership with the NCAA and Department of Defense through previous CARE Consortium sites as well as Ft. Bragg, Camp Shelby, and the Geneva Foundation for Special Operations Command inclusion





### 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
- EEG testing for a quantitative demonstration of electrical brain activity
- Brain Imaging

### Timeline

PRV-002	2Q22	3Q22	4Q22
Complete SAD portion of Phase I trial			
Meeting with FDA			
Complete MAD portion of Phase I			
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 that is stable at temperature extremes. The Phase 1 clinical trial is currently underway and PRV-002 has been well-tolerated to date. 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. 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 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.