# Nyrada Inc

#### Improving Lives, Offering Hope

Developing New Therapies for Cardiovascular & Neurological Disorders





# Message from the CEO

I hope this newsletter finds you safe and well.

It is encouraging to see the significant progress the Nyrada team has made in our brain injury and cholesterol-lowering drug development programs since listing on the ASX on 16 January 2020.

I continue to be impressed with the team's enthusiasm and dedication, as we prepare to enter the clinic with our cholesterol-lowering program by the end of CY 2021 and in mid CY 2022 for the brain injury program. For both programs, we will be conducting a first-in-human Phase 1 study in Australia.

I am particularly excited about the <u>recently announced collaboration</u> <u>agreement</u> Nyrada signed with the Walter Reed Army Institute of Research (WRAIR) and UNSW Sydney (UNSW). WRAIR is part of the US Department of Defense and has a dedicated traumatic brain injury (TBI) research unit, The Brain Trauma Neuroprotection Branch (BTN). The primary mission of BTN is to develop ground-breaking solutions to mitigate the effects of TBI at the point of injury to reduce morbidity and mortality.

The goals of WRAIR and Nyrada are closely aligned. We are both looking to develop the first ever treatment of TBI, one of the key motivations behind the Collaboration. The other is it enables Nyrada to seek non-dilutive funding jointly with WRAIR, which has a long history of successfully partnering with organisations to secure grant funding. In the US alone, ~2.8m people every year suffer TBI. With no drug treatments currently available, it is an unmet clinical need with a very large market.

UNSW is an intrinsic part of the Collaboration and is where the proof-ofconcept work for the Nyrada brain injury program was originally conducted. Bringing WRAIR on board allows us to take that research onto the world stage and work with the leading researchers in brain injury.

Importantly, the intellectual property interests of each party to the Collaboration are protected within the terms of the underlying agreement.

We expect to be in a position to report on the findings of the preliminary study, which will evaluate Nyrada's neuroprotection molecule during the first half of CY 2021, with updates on the second study to follow in the later part of this year.

I look forward to keeping you informed of the progress of our drug development programs and on behalf of the Nyrada team, wish to thank you for your continued support.

James Bonnar Chief Executive Officer

# Corporate Information

ASX Code	NYR
Funds Raised at IPO	A\$8.5M
Share Price (at 1 Mar 2021)	A\$0.32
Market Cap (at 1 Mar 2021)	A\$36M
Cash-at-bank (at 31 Dec 2020)	A\$4.1M

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# Who is the Walter Reed Army Institute of Research (WRAIR)?

Since 1893, WRAIR (located in Maryland, US) has been a leader in solving the most significant threats to soldier readiness and lethality such as disease and battle injury. Around the world, WRAIR works alongside civilian researchers, medical professionals, and military personnel to develop and test products that will ultimately reduce the impact of some of the most dangerous and debilitating diseases.

Research in military psychiatry and neuroscience has been an integral part of WRAIR's portfolio for more than 70 years. WRAIR researchers are recognised leaders in operational medical research for the military in a number of fields, including brain trauma, blast exposure, deployment stressors, and sleep management.

#### WRAIR's Focus on TBI Research

TBI is a major threat to soldier readiness and currently lacks any FDA-approved drug treatment options. WRAIR is working to fill this capability gap by developing novel, ground-breaking solutions to mitigate TBI at the point-of-injury to reduce morbidity and mortality in a prolonged field care environment.

Fieldable diagnostic, preventive and treatment options are critical to soldiers operating in the multi-domain environment. In addition to physical damage, TBI can meaningfully degrade mental capacity, including learning ability, decision making, attention span, memory, and emotion. Without these and other abilities or ready access to evacuation, the Warfighter is at serious risk in all phases of conflict.

"The Collaboration with Nyrada is one of the key industry partnerships WRAIR has established as part of a wider initiative to develop a new treatment to mitigate the significant impact of TBI. WRAIR is excited about the opportunities the Collaboration creates for both organisations to further progress this work and achieve the end goal of creating the first ever treatment for TBI."

Dr Deborah Shear, Director of the Brain Trauma Neuroprotection Branch of WRAIR

# Military TBI : by the numbers



ENVIRONMENTS

#### 383,947



## 80%

of non-fatal traumatic brain injuries are diagnosed as concussion. Concussions can cause cognitive, physical, and emotional effects that may not fade with time. Critically, Soldiers are at greater risk of sustaining repeated concussions, which can result in second concussion syndrome, where the brain swells rapidly, leading to more serious symptoms.

## \$16 billion

estimated total lifetime cost of severe TBIs sustained in Operation Iraqi Freedom and Operation Enduring Freedom through August 2005.

# \$32,760

average cost per concussion case; this can exceed \$400,000 with more severe traumatic brain injury.



# The Next Stage of Nyrada's Brain Injury Program

The Collaboration with WRAIR allows Nyrada to pursue non-dilutive funding jointly with WRAIR.

Through the Collaboration, Nyrada has greater access to funding opportunities (such as research grants) to advance our brain injury program that will not require additional Nyrada shares to be issued, thereby not diluting existing shareholder interests in the Company.

The Collaboration with WRAIR positions Nyrada to engage with groups such as the Medical Technology Enterprise Consortium (MTEC) and Transforming Research and Clinical Knowledge in TBI (TRACK-TBI) network (among others), which provide networking and grant funding structures in relation to TBI and other related neurological disorders.

#### Medical Technology Enterprise Consortium

MTEC is an international consortium with members from industry, academia and the non-profit sector. Its mission is to be the partner for private industry, academic institutions, government agencies, and other research organisations seeking to accelerate the development of medical solutions that prevent and treat injuries and restore America's military and veterans to full health.

#### Transforming Research & Clinical Knowledge in TBI (TRACK-TBI) network

TRACK-TBI is a National Institute of Neurological Disorders & Stroke (NINDS) funded multi-centre consortium, with the aim to streamline future Phase II clinical trials for TBI. It is well connected with the TBI research community including the US Department of Defense, academia, as well as public and private sector organisations, with 18 clinical enrolment/ study sites across the US available to conduct Phase II clinical trials.

## Industry News: The International Neuro Trauma Symposium

Nyrada was delighted to attend the 14<sup>th</sup> International Neurotrauma Symposium, held virtually between 7-11 February, 2021.

The conference program included presentations from leading experts in the field of neurotrauma, covering both clinical and basic aspects of brain and spinal cord injury.

Major themes explored during the Symposium included the importance of understanding the localisation of brain biomarkers, the critical role of neuroinflammation in injury and repair mechanisms, and advances in neuroimaging following TBI.

Biomarker screening and neuroimaging are critical in identifying the TBI severity and serve as endpoints for determining the efficacy of a therapeutic in a clinical trial. This meeting has provided an excellent platform for Nyrada to engage with experts in the TBI clinical field to assist in the program's future Phase II trial.



# Nyrada Profile

# Professor Gary Housley, Scientific Advisory Board Chair

Professor Gary Housley holds the Chair in Physiology at UNSW Sydney (UNSW), where he is the founding Director of the Translational Neuroscience Facility. He has thirty years of leadership experience delivering research programs in the Brain Sciences, spanning neuroscience discovery to clinical trials. He is the Chair of Nyrada's Scientific Advisory Board.

Gary completed M.Sc. and Ph.D. studies at the University of Auckland (New Zealand), and post-doctoral research in the US and UK in cellular and molecular neuroscience in sensori-motor circuits. In 2005 he was awarded the prestigious Royal Society of New Zealand James Cook Fellowship in Health Sciences to undertake international collaborative studies on the molecular physiology of auditory neuropathy.

He was recruited to UNSW in 2006 to establish the translational neuroscience initiative in the School of Medical Sciences. Brain injury models developed by his team at UNSW provided a platform for initial drug screening, which supported the identification of the novel target that is the focus of Nyrada's neuroprotection drug development program.

A focal ischaemic brain injury model recently published in the journal Translational Stroke Research, provided the platform for proof-of-concept studies on the rescue of brain injury by blocking the targeted calcium dysregulation in the days following stroke. He is a co-inventor of the Nyrada Inc. neuroprotection technology.



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*Authorised by Mr John Moore, Non-Executive Chairman, on behalf of the Board.*