Sydney, Australia



30 August 2021

# FULL YEAR RESULTS FY21

### Highlights:

- Research and development costs of \$2.2M as Nyrada's lead preclinical programs advance (FY2020: \$1.4M)
- Capital raising program completed raising \$11.5M to fund Phase I clinical trials in both Nyrada's lead drug development programs
- Robust cash position of \$13.8M as at 30 June 2021 and expects to receive FY2021 R&D tax incentive refund of \$1.3M in the fourth quarter of CY2021, further boosting capital resources
- Cholesterol-Lowering Program advances with encouraging preclinical results, first patent granted by US Patent and Trademark Office and Phase I expected to commence mid-CY2022
- New lead drug candidate selected for Brain Injury Program efficacy studies in collaboration with the Walter Reed Army Institute of Research (WRAIR) and University of NSW Sydney (UNSW), preliminary tests in Q1 FY2022, with initial results expected before the end of CY2021

**Sydney, 30 August 2021:** Nyrada Inc (ASX: NYR), a preclinical stage, drug development company specialising in novel small molecule drugs to treat cardiovascular and neurological diseases, today released its Annual Report for the 12 months ended 30 June 2021.

**Commenting on the Company's progress and outlook, CEO James Bonnar said**, "We have delivered some exceptional results this year and are pleased with the advancement in both our programs. Nyrada is focused on completing the remaining studies ahead of a first-in-human trial for our Cholesterol-Lowering Program in mid-2022. As part of these preparations, we will be conducting safety pharmacology and toxicology studies later this year.

"In addition, this year we formed a new collaboration with the Walter Reed Institute of Army Research and UNSW Sydney for our Brain Injury Program, validating the potential of our drug candidates. Our newly improved and highly potent drug candidate, NYR-BI01, crossed the blood-brain-barrier at above therapeutic levels which means it can reach the area of the brain damaged by traumatic brain injury. We anticipate testing of NYR-BI01 in WRAIR's TBI animal model later in 2021, with results expected before the end of the year," Mr Bonnar added.



#### **Cholesterol-Lowering Program Activity**

During the year, Nyrada continued to test the safety and efficacy of the Company's cholesterol-lowering preclinical candidate, NYX-PCSK9i.

Nyrada reported results from an *in vivo* efficacy study in a specialised transgenic mouse model (APOE\*3-Leiden.CETP) to evaluate NYX-PCSK9i in combination with a statin. Over the study period, NYX-PCSK9i reduced total cholesterol by 65% when dosed in combination with the statin drug Lipitor<sup>®</sup> (atorvastatin, Pfizer) and by 46% as a monotherapy. This compares favourably to the reduction achieved using Lipitor<sup>®</sup> alone of 27%. NYX-PCSK9i was well-tolerated with no significant changes in food intake, body weight, or liver function observed.

Nyrada has selected NYX-PCSK9i as the preferred compound for safety pharmacology and toxicology studies to commence in the second half of CY2021 at an internationally recognised Contract Research Organisation, with a Phase I first-in-human study anticipated to commence in mid-CY2022.

#### Brain Injury Program Activity

Nyrada's Brain Injury Program reported significant progress with its neuroprotectant drug designed to limit secondary brain injury.

During the year, Nyrada announced a new collaboration with WRAIR and UNSW. The collaboration studies aim to examine the efficacy of a lead preclinical neuroprotection compound to interrupt and minimise the excitotoxicity process responsible for secondary damage to the brain in TBI.

Nyrada announced the selection of a new analogue of its brain injury candidate, NYR-BI01, to be taken forward into its collaboration studies with WRAIR. NYR-BI01 is a more potent and improved version of its predecessor, NYX-1010. This follows a pharmacokinetic study in which NYR-BI01 showed impressive drug-like characteristics and was able to cross the blood-brain-barrier at above therapeutic levels.

Pilot work has commenced with WRAIR and UNSW to determine the baseline injury signal of NYR-BI01 in TBI animal models that are expected to be used in the studies. Following this pilot work, Nyrada anticipates testing of NYR-BI01 in the TBI models at WRAIR will commence in the third quarter of CY2021, with the initial results expected before the end of the year. The Company anticipates commencing the first-in-human Phase I study in the second half of CY2022.

- ENDs -



Nyrada is a preclinical stage, drug discovery and development company, specialising in novel small molecule drugs to treat cardiovascular and neurological diseases. The Company has two main programs, each targeting market sectors of significant size and considerable unmet clinical need. These are a cholesterol lowering drug and a drug to treat brain injury, specifically traumatic brain injury and stroke. Nyrada Inc. ARBN 625 401 818 is a company incorporated in the state of Delaware, US, and the liability of its stockholders is limited.

www.nyrada.com

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

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## **Forward-Looking Statements**

This announcement may contain forward-looking statements. You can identify these statements by the fact they use words such as "aim", "anticipate", "assume", "believe", "continue", "could", "estimate", "expect", "intend", "may", "plan", "predict", "project", "plan", "should", "target", "will" or "would" or the negative of such terms or other similar expressions. Forward-looking statements are based on estimates, projections, and assumptions made by Nyrada about circumstances and events that have not yet taken place. Although Nyrada believes the forward-looking statements to be reasonable, they are not certain. Forward-looking statements involve known and unknown risks, uncertainties and other factors that are in some cases beyond the Company's control (including but not limited to the COVID-19 pandemic) that could cause the actual results, performance, or achievements to differ materially from those expressed or implied by the forward-looking statement.