



HALF YEAR RESULTS FY2022

Highlights:

- Research and development costs of \$1.13M as Nyrada's lead preclinical programs advance (1H FY2021: \$1.05M)
- Robust cash position of \$11.1M as at 31 December 2021, plus R&D tax rebate of \$1.3M received in January 2022, further boosting available capital resources
- Cholesterol-Lowering Program advances with preclinical studies in 1H CY2022 ahead of a Phase I first-in-human trial in Australia during 2H CY2022
- Efficacy of Nyrada's Brain Injury Program drug candidate to be evaluated via Walter Reed & UNSW collaboration and in a well-established preclinical model of stroke
- Brain Injury Program to commence Phase I first-in-human study in 2H CY2022

Sydney, 25th February 2022: 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 Financial Report for the half year ended 31 December 2021, along with an update on the Company's two lead drug development programs.

Commenting on the first half, CEO James Bonnar said, "We are extremely pleased with the advancements in both our Programs during the half. Nyrada is focused on completing the remaining preclinical studies ahead of a Phase I first-in-human trial for our Cholesterol-Lowering drug candidate, NYX-PCSK9i. Results from our efficacy study showed NYX-PCSK9i significantly increased plasma PCSK9 levels with no adverse effects, reaffirming our view that it is the best drug candidate to take into human trials.

"In addition, we are encouraged by the progress made in evaluating the efficacy of our highly potent Brain Injury drug candidate, NYR-BIO1, ahead of a Phase I first-in-human study later this year. NYR-BIO1 has crossed the blood-brain-barrier at above therapeutic levels which means it can reach the area of the brain damaged by traumatic brain injury (TBI), which affects 2.8 million people in the US alone each year. Importantly, the efficacy of NYR-BIO1 will also be evaluated in a well-established preclinical model of stroke, with the planned Phase I trial supporting the development of our drug in two indications, stroke and TBI," Mr Bonnar added.



Cholesterol-Lowering Program

During the half year, exploratory analysis results from an *in vivo* cholesterol efficacy study showed NYX-PCSK9i significantly increased plasma PCSK9 levels, supporting the mechanism of action of Nyrada's compound. No adverse effects of NYX-PCSK9i were identified during the 35-day study.

NYX-PCSK9i also significantly increased the number of LDL receptors responsible for removing cholesterol from the bloodstream, with further analysis revealing Nyrada's compound also enhances cholesterol clearance from the body.

Charles River Laboratories, Inc. has been appointed to conduct the Company's preclinical studies in the US in the first half of this year, ahead of a Phase I cholesterol-lowering trial in Australia during the second half of CY2022. The required preclinical studies will be used to evaluate the safety and tolerability of Nyrada's drug in research models. Data from these studies will determine the safe starting dose for the Phase I first-in-human study.

The Phase I study will be a first-in-human, double-blind, randomised, dose escalation study evaluating the safety, tolerability and pharmacokinetics of Nyrada's leading drug candidate in approximately 56 healthy volunteers, aged 18 to 50 years. The Company will also evaluate efficacy by measuring changes in LDL cholesterol levels in the blood.

Pending scale-up manufacturing of the drug and ethics committee approval of the trial protocol, recruitment and dosing of the first participant is expected in the second half of this year.

Brain Injury Program

The efficacy of Nyrada's brain injury drug candidate, NYR-BI01, will be evaluated in a study to be run as part of the three-way collaboration the Company has with UNSW Sydney and the Walter Reed Army Institute of Research (WRAIR). A pilot study is currently being conducted to optimise the design of the efficacy study, specifically to refine the location and extent of injury in each brain injury model and select optimal timepoints to assess a therapeutic effect of Nyrada's drug in preventing secondary brain injury.

The data from the pilot study will allow Nyrada to ascertain the number of animals that will be required to provide a meaningful assessment of the therapeutic effect of the drug.

In addition, the efficacy of Nyrada's Brain Injury drug candidate will be evaluated in a well-established preclinical model of stroke during the first quarter of CY2022. This work in stroke is outside of the studies being undertaken as part of Nyrada's collaboration with WRAIR and UNSW.



Nyrada expects to commence a Phase I first-in-human study to evaluate the safety and tolerability of the Company's Brain Injury drug candidate in Australia in the second half of CY2022. The Phase I clinical trial for the Brain Injury Program will support the development of Nyrada's drug in both TBI and stroke indications, significantly expanding the commercial opportunities available to the Company.

Nyrada will provide an update on the preclinical studies with WRAIR and UNSW, as well selection of the contract research organisation and study design for the Phase I study in the first half of this year.

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About Nyrada Inc

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

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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.