



29 August 2022

Sydney, Australia

## FULL YEAR RESULTS FY22

### Highlights:

- Research and development costs of \$1.8M as Nyrada's lead preclinical programs advance (FY2021: \$2.2M).
- Robust cash position of \$10.8M as at 30 June 2022 providing the Company with sufficient cash reserves for Phase I studies for both programs.
- Cholesterol-Lowering Program progresses with patent grant and further exploratory analysis results, with preclinical safety and toxicology studies expected to commence in H2 CY2022.
- Nyrada's oral PCSK9 inhibitor was shown to block the early stages of atherosclerosis in a novel human tissue-engineered blood vessel model study run by researchers at Duke University (following financial year-end).
  - Optimised compound also demonstrated an improved pharmacokinetic profile and will be evaluated in Nyrada's Phase I study in the first half of CY2023.
- Brain Injury Program's NYR-BI02 was revealed as a potent, versatile TRPC ion channel blocker, limiting excitotoxicity with potential to pursue multiple additional indications.
- Preclinical stroke model study results anticipated during Q4 CY2022 with preclinical safety and toxicology studies in Q3 CY2022 and Phase I study in H1 CY2023.

**Sydney, 29 August 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 Annual Report for the 12 months ended 30 June 2022.

**Commenting on the Company's progress and outlook, CEO James Bonnar said,** "Despite a challenging backdrop with COVID-related impacts, the team has made significant headway and Nyrada remains focused on both our lead programs, completing the required preclinical studies before moving into the clinic in the first half of 2023.

"As part of our preclinical studies, further exploratory cholesterol efficacy analysis confirmed Nyrada's oral drug candidate has the potential to provide a valuable alternative to expensive and inconvenient injectable PCSK9 inhibitor drugs. This year we also explored new opportunities and future indications for our Cholesterol-Lowering Program.



“We were pleased with initial study results indicating our new lead Brain Injury Program drug candidate, NYR-BI02, is a potent blocker for three of the TRPC channels and offers significant potential to treat multiple additional diseases involving those channels. Additionally, we discovered NYR-BI02 could be developed as an oral drug to treat concussion, representing an exciting possibility for Nyrada to pursue concussion as an indication for Nyrada’s drug, in addition to TBI and stroke.

“We look forward to updating the market on results from preclinical safety and toxicology studies, as well as our preclinical stroke model study ahead of a Phase I first-in-human study in H1 CY2023,” Mr Bonnar added.

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

During the year, Nyrada progressed testing of the safety and efficacy of the Company’s Cholesterol-Lowering preclinical candidate, NYX-PCSK9i.

In the first half of the 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 in lowering cholesterol, with no adverse effects.

Extended COVID-related delays in Shanghai, which slowed drug manufacture, meant the required preclinical safety and toxicology studies were delayed, and are now expected to commence in H2 CY2022, with the Phase I first-in-human study expected to commence during the first half of CY2023.

Nyrada continued to focus on intellectual property and the European Patent Office formally granted the composition of matter patent for Nyrada’s novel compounds inhibiting PCSK9, providing protection for Nyrada’s intellectual property relating to its PCSK9 inhibitor technology. The Company now has patent protection for the compounds in both the US and the European Union.

Following the financial year-end, preclinical study results from a study run by researchers at Duke University found Nyrada’s PCSK9 inhibitor was able to block the early phases of atherosclerosis, the build-up of plaque in the inner lining of the arteries, representing a new disease indication for this asset. An optimised version of NYX-PCSK9i with superior pharmacokinetic parameters (improved absorption and distribution) was evaluated in this study. Accordingly, this compound will be assessed in Nyrada’s Phase I study in the first half of CY2023.



## Brain Injury Program Activity

Nyrada's Brain Injury Program made progress with its neuroprotectant drug designed to limit secondary brain injury. Exploratory pharmacokinetic studies indicated excellent oral bioavailability of Nyrada's drug candidate NYR-BI02, which will advance into Nyrada's Phase I first-in-human study.

The required preclinical studies are anticipated to commence in Q3 CY2022 and will evaluate the safety and tolerability of Nyrada's lead brain injury drug candidate in research models. Data from these studies will determine the safe starting dose for the Phase I study.

The manufacture of the batch of drug to be used in the preclinical and clinical studies has been completed and is now undergoing formulation development to deliver a dose form suitable for intravenous administration. The necessary formulation development work is being undertaken at a leading US based CRO from mid-September and is expected to take between 2 – 6 weeks to complete.

This formulation work does not impact the timing of the cell-based *in vitro* safety and toxicology studies, which are due to commence in Q3 CY2022. However, this formulation work must be completed prior to the commencement of the *in vivo* safety and toxicology studies to ensure optimal drug delivery. The ongoing COVID-19 pandemic has led to an industry-wide constraint on resources and complicated logistics, resulting in a lack of availability of GLP study slots and making scheduling preclinical work with CROs challenging.

Our expectation is that the Phase I study will commence in the first half of CY2023. Nyrada continues to work closely with our preclinical and clinical vendors to progress these studies in an expeditious manner.

The oral bioavailability of NYR-BI02 indicated it has the potential to be administered orally to patients who suffer a concussion, where intravenous infusion is not preferred, offering the potential to significantly improve patient outcomes. Nyrada is considering an additional program for NYR-BI02's development as an oral treatment for concussion.

As the Company has reported, the COVID lockdowns in Shanghai delayed the start of the preclinical stroke model study, with the study results now anticipated to be available in the fourth quarter. This work in stroke is outside of the studies being undertaken as part of Nyrada's 3-way collaboration with the Walter Reed Army Institute of Research (WRAIR) and UNSW Sydney (UNSW).

More recently, Nyrada revealed the biological target of its Brain Injury Program targets three Transient Receptor Potential Canonical (TRPC) ion channel subtypes, making it a versatile, potent blocker of the channel, and with indications it can reach therapeutic levels in the



injured brain. There are currently no FDA-approved small molecule blockers of TRPC 3, 6, 7 ion channels. Nyrada has filed a provisional patent covering a library of molecules, including NYR-BI02, that block these channels.

Nyrada continued its traumatic brain injury (TBI) efficacy study under the collaboration with UNSW and WRAIR. Initial pilot work was completed during the financial year and the design for the efficacy study was also finalised. Due to COVID-related delays, this study is expected to progress in the new year, and this will not impact the commencement of the Phase I first-in-human study as these studies can be run in parallel.

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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](http://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.