20 February 2024

Sydney, Australia

# Nyrada Half Year FY2024 Results

## Highlights:

- Brain Injury Program:
  - Stroke model study underway with drug well tolerated to date. Efficacy results imminent.
  - Walter Reed brain injury study scheduled to commence in 3QFY2024.
  - GLP safety and toxicity studies scheduled to commence in 3QFY2024.
  - On track for Phase I Clinical trial in 1HFY2025.
- Cholesterol-Lowering Program:
  - Ongoing low-cost background works to identify alternative pathways for the Cholesterol Lowering program continuing.
- Sound financial position:
  - Cash position of \$4.65 million as at 31 December 2023 equivalent to 2.98 cents per share.
  - Research and development costs of \$0.90 million.
  - Sufficient funding for GLP and Brain Injury program Phase I study preparatory works currently scheduled to commence in 1HFY2025.

**Nyrada Inc (ASX: NYR),** a drug development company specialising in novel small molecule drugs today released its Financial Report for the half year ended 31 December 2023 together with an update on its Brain Injury and Cholesterol Lowering Programs.

**Commenting on the first half of FY2024, Nyrada CEO, James Bonnar said:** "The Nyrada team remains committed to our strategic ambition of developing treatments for diseases where there is an unmet clinical need, or where current treatments are suboptimal.

"Our main focus over the first six months of the FY2024 year has been on advancing our Brain Injury program candidate towards Good Laboratory Practice (GLP) safety and toxicity testing. Satisfactory outcomes in these tests are a necessary precondition for a Phase I clinical trial which are on track to commence in 1HFY2025.



"The efficacy of our lead Brain Injury candidate, NYX-BIO3, has also been tested in an ischemic stroke model. The early results indicate the drug is well tolerated when administered at two doses, and the final analysed results of this study are expected to be disclosed this quarter. Importantly too, our penetrative traumatic brain injury study, to be undertaken jointly with the Walter Reed Army Institute of Research and the University of NSW is also expected to commence this quarter.

"The team has also been undertaking low-cost background works to identify alternative options for our Cholesterol Lowering program while remaining guided by our strategic goal of delivering risk managed economic value for shareholders."

### Program Update

#### **Brain Injury Program**

During the half year to 31 December 2023, important progress was made to advance the Company's Brain Injury program.

Nyrada's lead Brain Injury program candidate NYX-BIO3 was tested for efficacy in a stroke model. Preliminary results indicate the drug is well tolerated when administered at two doses. This model is based on inducing an ischemic stroke with samples being assessed for lesion volume at the University of NSW, Sydney using magnetic resonance imaging (MRI). Levels of the biomarker neurofilament light (NF-L) are also being analysed as a study endpoint. The Company expects to announce the results of this stroke study in 3QFY2024.

The Company also continued to advance the formulation and planning work necessary to progress NYX-BI03 to Good Laboratory Practice (GLP) safety and toxicology studies which remain scheduled for commencement in 3QFY2024. Production of NYX-BI03 at scale has been completed for utilisation in both the GLP preclinical and Phase I clinical studies. Subject to satisfactory completion of GLP studies, the Company estimates a Phase I clinical trial for NYX-BI03 will commence in 1HFY2025. A Contract Research Organisation (CRO) has been engaged for this purpose.

Planning and preparation work for the Walter Reed Army Institute of Research TBI study were also undertaken during the half with a view to commencement this quarter (3QFY2024). The study is expected to continue for approximately six months.



During the half, a peer-reviewed research paper was published in the Translational Stroke Research journal. Nyrada's neuroscientist Dr. Jasneet Parmar was a lead author and Scientific Advisory Board Chair and UNSW Scientia Professor Gary Housley was a co-author. This paper described the work validating the pathophysiological role of TRPC ion channels in brain injury progression, showing animals lacking the target TRPC ion channels were protected against expansion of a photothrombotic-induced stroke infarct in the days following injury.

Dr. Parmar also presented on Nyrada's brain injury program at the US Military Health System Research Symposium during the half year.

# **Cholesterol Lowering Program**

In July 2023, Nyrada announced that its lead Cholesterol Lowering program candidate NYX-1492 would not be advanced into clinical development for cholesterol management. Subsequently, the Company identified an alternative PCSK9 inhibitor candidate. The compound was manufactured, and preliminary assessments were undertaken. However, it was determined that the commercial risk/reward profile of this alternative candidate did not warrant further investigation.

## Corporate Update

For the six months concluding 31 December 2023, the Nyrada Inc consolidated entity recorded a nominal operating profit of \$0.14 million (31 December 2022: \$2.67 million loss). This profit is principally attributed the receipt of the Research and Development (R&D) rebate offset for the Company's research and development activities. The Company expects to return to loss making as it continues to invest in R&D in future periods.

As at 31 December 2023, Nyrada had a cash position of A\$4.65 million (31 December 2022: \$3.71 million). This cash balance is equivalent to approximately \$0.0298 per share. The Company's cash balance was enhanced by the receipt of \$3.54 million for its R&D Tax Incentive refund received in December 2023.

### Outlook

Nyrada will continue to pursue its strategic ambition to developing treatments for diseases where there is an unmet clinical need, or where current treatments are suboptimal.

The Company expects to commence GLP studies for its lead Brain Injury program candidate NYX-BI03 in 3Q FY24, which subject to satisfactory completion, will enable the commencement of a Phase I clinical trial (estimated 1HFY2025).

The Walter Reed Army Institute of Research traumatic brain injury efficacy study and stroke model study will also commence this quarter (3QFY2024).

Ongoing low-cost background works to identify alternative pathways for the Cholesterol Lowering program are continuing.



-ENDS-

## About Nyrada Inc

Nyrada is a drug discovery and development company specialising in novel small molecule drugs to treat neurological and cardiovascular diseases. The Company has two main programs, each targeting market sectors of significant size and considerable unmet clinical need. These are a drug to treat brain injury, specifically traumatic brain injury and stroke, and a cholesterol lowering drug. 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 Mr. John Moore, Non-Executive Chair 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 that could cause the actual results, performance, or achievements to differ materially from those expressed or implied by the forward-looking statement.