



18 February 2025

Sydney, Australia

## Nyrada Half Year FY2025 Results

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### Highlights:

- Development of lead drug candidate NYR-BI03 continues:
    - Preclinical efficacy study demonstrated 86% cardioprotective effect following myocardial ischemia-reperfusion injury.
    - Phase Ia first-in-human clinical trial approved to commence.
    - Composition of matter patent applications submitted.
  - Sound financial position:
    - Fully subscribed placement successfully raised AU\$3.29 million equity (before costs).
    - Securities Purchase Plan raised AU\$0.09 million (before costs)
    - R&D tax rebate of AU\$1.24 million received.
    - Cash balance of AU\$5.71 million at 31 December 2024.
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**Nyrada Inc (ASX:NYR)**, a drug discovery and development company focused on innovative Transient Receptor Potential Canonical (TRPC) ion channel blockers today released its Financial Report for the half year ended 31 December 2024 together with an update on its lead drug candidate development program.

**Commenting on Nyrada's 1HFY2025 performance, Nyrada CEO James Bonnar said:** "The first half of FY2025 was a pivotal one for Nyrada with foundations laid for the Company's transition from a preclinical to a clinical company. The second half of the financial year opening with a further securing of foundations with HREC approval received to commence a Phase Ia clinical trial for our lead drug candidate NYR-BI03.

"Our focus over the first six months of the FY2025 year was on completing the preparatory work for our Phase Ia first-in-human clinical trial. The second half of the financial year will be a focus on advancing our clinical trial with patient recruitment soon to commence and first dosing expected before the end of March 2025. We look forward to providing regular updates on our Phase Ia trial.

"We were also very excited by the results from our cardioprotection study which showed strong preclinical efficacy of NYR-BI03 in mitigating heart damage following ischemia reperfusion injury. The result presents the Company with additional and significant strategic options enabling us to advance our ambition of developing treatments for diseases where there is an unmet clinical need, or where current treatments are suboptimal.



“The Nyrada team remains committed and focused on the development of NYR-BI03. As we accumulate more compelling data to evidence of the potential for NYR-BI03 as a game-changing therapy.”

### **Lead Drug Asset – NYR-BI03**

#### ***Acute Myocardial Ischemia-Reperfusion Injury***

Early in the half-year ending December 2024, Nyrada announced the [results of a preclinical coronary heart disease study](#). This study demonstrated that NYR-BI03 conferred a statistically significant 86% cardioprotection effect following myocardial ischemia-reperfusion injury. Ischemia-reperfusion injury is a leading cause of tissue damage following the restoration of blood flow to the heart post-injury.

[Supplementary echocardiographic and biomarker studies](#) further demonstrated significant the cardioprotective benefits of NYR-BI03 following myocardial infarction.

NYR-BI03 has a unique potential to fill a significant treatment gap because there are no FDA-approved drugs targeting myocardial or cerebral ischemia-reperfusion injury.

#### ***Good Laboratory Practice Safety Studies***

During the half-year, Nyrada concluded Good Laboratory Practice (GLP) studies which confirmed a favourable safety profile for NYR-BI03. The completion of these GLP studies provided the Company with confidence that it will transition well into human studies.

A total of eight GLP studies were conducted and reported:

<b>GLP Study</b>	<b>Reported</b>
<a href="#">AMES</a>	16 July 2024
<a href="#">hERG</a>	16 July 2024
<a href="#">Rat CNS</a>	06 August 2024
<a href="#">Rat Respiratory</a>	20 August 2024
<a href="#">Dog cardiovascular safety</a>	09 September 2024
<a href="#">14-day Dog Toxicology</a>	27 September 2024
<a href="#">In vivo micronucleus</a>	07 October 2024
<a href="#">14-day Rat Toxicology</a>	16 October 2024



### ***Phase I Clinical Trial***

During the half year ending December 2024, Nyrada submitted to the Human Research Ethics Committee (HREC) a regulatory package to commence a first-in-human Phase Ia clinical trial of NYR-BI03 in healthy human volunteers. Soon after the conclusion of the half year, [approval was received](#).

A double-blind, randomised, placebo-controlled, dose-escalating study will be conducted, comprising five (5) cohorts of eight (8) healthy volunteers who will receive an intravenous dose over three hours of either NYR-BI03 or placebo. There will be six (6) active and two (2) placebo participants per cohort.

The Phase Ia study aims to demonstrate the safety and tolerability of NYR-BI03 in healthy human subjects when dosed over 3-hours. Should it be required, a subsequent Phase Ib study will aim to demonstrate the safety and tolerability of NYR-BI03 when volunteers are dosed for extended periods of up to 72 hours.

Scientia Clinical Research will be the trial site and Southern Star Research will provide Contract Research Organisation services to support the trial.

### ***Walter Reed Traumatic Brain Injury (TBI) Study***

Nyrada's collaborative traumatic brain injury (TBI) study with the [Walter Reed Army Institute of Research](#) (WRAIR) and UNSW Sydney commenced late in the 2024 financial year and continued through the half year. This study is to assess the efficacy of NYR-BI03 in a rodent model of penetrating TBI. This model is proprietary to WRAIR and seeks to mimic the serious head injuries suffered by military service members.

As part of this study, the degree to which NYR-BI03 provides neuroprotection following a penetrating TBI is being assessed and measured.

Nyrada is expecting the results of the joint with WRAIR and UNSW Sydney penetrating TBI study within the coming weeks.

### ***Biomolecular Horizons 2024 Conference***

During the half year, Dr Georg Von Jonquieres, molecular and cell biologist at UNSW Sydney presented on Nyrada's preclinical stroke study at the Biomolecular Horizons conference, a globally recognised bioscience and biotechnology conference. Dr Von Jonquieres was the lead biologist on Nyrada's stroke study, including in reviewing and measuring MRI images.

A research paper on Nyrada's stroke study will be published in due course.



## **Corporate and Financial Update**

### ***Patent Submission***

During the half year, Nyrada submitted patent applications to protect its TRPC channel blocking intellectual property assets.

Nyrada's intellectual property applications are 'Composition of Matter' patents across several geographies including (but not limited to) Australia, Europe and North America. These patents will provide intellectual property protection for the chemical structure of Nyrada's TRPC drug assets.

Although these patents are pending subject to formal examination and assessment, Nyrada's intellectual property remains protected in the interim through final examination and assessment. Subject to the granting of these patents, Nyrada will retain exclusivity over its TRPC assets for at least 20 years from submission (November 2024).

### ***Cash and Financial***

For the six months concluding 31 December 2024, the Nyrada Inc consolidated entity recorded a nominal operating loss of \$2.46 million (31 December 2023: \$0.14 million profit). This loss is principally attributed to continuing investments in research and development.

As at 31 December 2024, Nyrada had a cash position of AU\$5.71 million (31 December 2023: AU\$4.77). The Company's cash balance was enhanced by the receipt of AU\$1.24 million for its R&D Tax Incentive refund received in December 2024, and AU\$3.38 million (before costs) from capital raising activities undertaken during the half.

An additional AU\$0.07 million (before costs) is expected to be received in March 2025 following the Company's Extraordinary General Meeting on 28 February 2025 where CDI holder approval will be sought for the issue of CDIs to Nyrada Non-Executive Directors. These CDIs are proposed to be issued on the same terms as those in the October 2024 placement and December Securities Purchase Plan (SPP) capital raises (A\$0.120 per CDI).

### **Outlook**

Nyrada remains committed to pursuing its strategic ambition of developing treatments for diseases where there is an unmet clinical need, or where current treatments are suboptimal.

During the coming period, Nyrada will be commencing its Phase Ia first-in-human clinical trial to assess the safety and tolerability of its lead drug candidate NYR-BI03. Nyrada expects final Phase Ia trial readouts in 3QCY2025. Regular updates will be provided throughout.



Given its broad therapeutic potential, low-cost background works will be undertaken to identify additional potential applications for NYR-BI03.

-ENDS-

### **About Nyrada Inc.**

Nyrada Inc. is a biotechnology company focused on the discovery and development of innovative small-molecule therapies, specifically targeting Transient Receptor Potential Canonical (TRPC) ion channels. The company's lead candidate, NYR-BI03, has shown efficacy in both neuroprotection and cardioprotection, positioning it for a first-in-human Phase I clinical trial. Nyrada Inc. (ARBN 625 401 818) is incorporated in Delaware, USA, with limited liability for its stockholders.

[www.nyrada.com](http://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.