



26 April 2023

Sydney, Australia

## Nyrada Quarterly Activities Report & Appendix 4C

---

### Highlights:

- **Cholesterol-Lowering Program:**
    - Preclinical dose formulation work finalised
    - Remaining safety and pharmacology studies to be completed end of April
    - Phase I/IIa first-in-human study to start early 2H CY2023
    - Mr Seth Gordon, former pivotal member of the Lipitor® marketing team at Pfizer, appointed as Principal Consultant to advise on program strategy and asset development
  - **Brain Injury Program:**
    - Preclinical *in vitro* safety and toxicology studies well advanced, *in vivo* studies to follow
    - Phase I first-in-human study to commence 1H CY2023
    - Results from preclinical stroke model study expected mid Q2-CY2023
    - International patent search confirms Nyrada's TRPC channel blocker is "novel and inventive", indicating that our PCT patent is likely to be granted
  - **Cash balance of \$6.6M, well-placed to pursue clinical development in CY2023**
- 

**Nyrada Inc** (ASX: NYR), a preclinical stage, drug development company specialising in novel small molecule drugs to treat cardiovascular and neurological diseases today provides its Quarterly Activities Report and Appendix 4C for the period ending 31 March 2023, including a summary of progress for its Cholesterol-Lowering and Brain Injury Programs.

**Commenting on the quarter, Nyrada CEO, James Bonnar said:** "Our key priority during the quarter has been the progression of the required preclinical studies for Nyrada's drug development programs. Pleasingly, these studies are now close to completion for the Cholesterol-Lowering Program, and we are looking forward to the start of the Phase I/IIa study.

"We were also excited to announce the appointment of Mr Seth Gordon as Principal Consultant to our Cholesterol-Lowering Program. Mr Gordon's experience in establishing the statin drug Lipitor® as one of the most successful pharma brands of all time will be a key advantage as we look to build on the value of our drug candidate beyond Phase I," Mr Bonnar added.



## Preclinical Programs Update

### **Cholesterol-Lowering Program – Small Molecule PCSK9 Inhibitor**

#### Preclinical Studies

During the quarter, we finalised the formulation development work necessary to ensure Nyrada's cholesterol-lowering drug candidate could be dosed to achieve sufficiently high exposures in preclinical studies. Additional time was needed to complete this work, which impacted the progress of a number of the preclinical Good Laboratory Practice (GLP) studies required by the regulators to assess the safety and tolerability of our drug candidate prior to starting a clinical trial. Pleasingly, the final of the eight studies required is on track to be completed by the end of April.

#### Phase I/IIa Study

Due to the additional time required to finalise the formulation development work, we anticipate starting the Phase I/IIa study early in the second half of the year. Conditional on receiving the draft reports for the GLP studies, the last of which is expected to be available mid-June, we envisage submitting an application to the Human Research Ethics Committee (HREC) in July for approval to commence the Phase I/IIa study. Typically, it can take 6 weeks for a response to be received from HREC. Subject to ethics approval, we plan to finalise the necessary arrangements to dose the first study patient shortly thereafter.

The Phase I/IIa study will assess Nyrada's drug candidate for safety and tolerability, as well as provide an early indication of the drug's efficacy in the target patient population. The inclusion of a small number of high-cholesterol patients in the study positions us well to bring forward the start of a Phase IIb study, a potential time saving of up to 12 months.

We have engaged Scientia Clinical Research (Scientia) to run the Phase I/IIa study. Scientia has world class clinical trial experience and state of the art facilities located in Sydney, NSW, where the study will be run. The Nyrada team has been working closely with Scientia as we move to finalise the details of the study protocol.

#### Phase IIb Study

Following completion of the Phase I/IIa study, Nyrada anticipates submitting an Investigational New Drug (IND) Application to the US Food and Drug Authority, for approval to run a Phase IIb study in high cholesterol patients in Australia and the US. The Phase IIb study will further evaluate the efficacy of Nyrada's Cholesterol-Lowering drug candidate in the target population.



## Principal Consultant Appointment

Nyrada also recently appointed Mr Seth Gordon as Principal Consultant to our Cholesterol-Lowering Program. Seth was a pivotal member of the Lipitor® Marketing team at Pfizer, helping the statin become one of the most successful pharma brands in history. Mr Gordon will be advising on strategy and asset development, as we look to grow the value of our cholesterol-lowering drug candidate beyond Phase I.

## **Brain Injury Program**

### Collaboration with Walter Reed Army Institute of Research (WRAIR) & UNSW Sydney

We continue to work closely with the teams at WRAIR and UNSW Sydney ahead of the TBI efficacy study which is expected to be run in 1H CY2023, with results anticipated in the second half of the year.

### Preclinical Studies

#### *Formulation Development*

The formulation development work necessary to ensure Nyrada can deliver an optimal dose form suitable for intravenous administration of our brain injury drug candidate is near completion. Finalisation of this work is imperative for the *in vivo* safety and toxicology studies, Phase I trial and stroke model study.

#### *Stroke Model Study*

The efficacy of Nyrada's brain injury drug candidate is being evaluated in a well-established preclinical stroke model. We expect the results to be available mid-Q2 CY2023. There has been a slight delay to the timing of the study due to a necessary modification to the study design to facilitate optimal dosing, compounded by international shipping delays.

#### *Safety Toxicology and Pharmacology Studies*

The *in vitro* safety and toxicology studies have made good progress during the quarter and the *in vivo* studies are planned to follow.

### Phase I Study

Structured as a randomised, double-blind, placebo controlled, single ascending dose escalating study, the Phase I first-in human study will evaluate the safety and pharmacokinetics of Nyrada's brain injury drug candidate.



We plan to commence the study in the first half of the year in Australia, with approximately 40 healthy human volunteers participating.

### Phase IIa Study

Following the Phase I study, Nyrada plans to open an Investigational New Drug (IND) in the United States with the intention to conduct the Phase IIa study in the United States leveraging the existing US DoD infrastructure around TBI clinical studies. These clinical studies are performed under guidance from the [TRACK-TBI network](#), which specialises in large multi-centre trials to assess the efficacy of novel TBI therapeutics.

### Patent Update

In June 2022, Nyrada submitted a provisional patent in respect of its TRPC channel blocking brain injury drug candidate.

The results of a recent international patent search confirmed our small molecule drug is 'novel and inventive', a strong indication that the patent is likely to be granted in due course. Once granted, it is expected that the patent will have coverage across the US, Europe, and Australia.

## **Corporate and Financial Summary**

### **Cash Flow & Cash Position**

Total cash operating outflows for the March 2023 quarter were approximately A\$2.8 million (A\$1.5 million in the prior quarter). Research & Development (R&D) related expenses accounted for 81% of total expenditure during the quarter with the balance comprised of administrative, corporate and staff costs.

Nyrada is eligible for a cash rebate of up to 43.5% in relation to expenditure incurred on eligible R&D activities conducted during the fiscal year pursuant to the Australian Federal Government's R&D tax incentive program. The Company anticipates cash outflows in future quarters will increase as both Programs progress toward and enter Phase I clinical trials.

Nyrada has a cash position of A\$6.6 million as at 31 March 2023 (A\$9.3 million as at 31 December 2022), positioning the Company well to pursue Phase I clinical development in CY2023 for its Brain Injury and Cholesterol-Lowering programs.

In accordance with Listing Rule 4.7C, payments made to related parties and their associates included in item 6.1 of the Appendix 4C was approximately A\$145,000 and included Director fees.

-ENDS-



## 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 Mr. John Moore, Non-Executive Chairman, on behalf of the Board.*

### Investor & Corporate Enquiries:

Laura Vize

Investor Relations Manager

T: 02 9498 3390

E: [info@nyrada.com](mailto:info@nyrada.com)

### Company Secretary:

David Franks

T: 02 8072 1400

E: [David.Franks@automicgroup.com.au](mailto:David.Franks@automicgroup.com.au)

### Media Enquiries:

Catherine Strong

Citadel-MAGNUS

T: 02 8234 0111

E: [cstrong@citadelmagnus.com](mailto:cstrong@citadelmagnus.com)

## 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.

## Appendix 4C

### Quarterly cash flow report for entities subject to Listing Rule 4.7B

**Name of entity**

Nyrada Inc.

**ABN**

54 625 401 818

**Quarter ended ("current quarter")**

31 March 2023

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(2,279)	(3,755)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(260)	(745)
(f) administration and corporate costs	(272)	(1,119)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	43	107
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	1,169
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(2,768)</b>	<b>(4,343)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>-</b>	<b>-</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>-</b>	<b>-</b>

<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	9,344	10,816
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,768)	(4,343)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	-
4.5	Effect of movement in exchange rates on cash held	(9)	94
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>6,567</b>	<b>6,567</b>

<b>5.</b>	<b>Reconciliation of cash and cash equivalents</b> at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	<b>Current quarter \$A'000</b>	<b>Previous quarter \$A'000</b>
5.1	Bank balances	6,567	9,344
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>6,567</b>	<b>9,344</b>

<b>6.</b>	<b>Payments to related parties of the entity and their associates</b>	<b>Current quarter \$A'000</b>
6.1	Aggregate amount of payments to related parties and their associates included in item 1	145
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments.</i>		

The amount at 6.1 includes Director fees and salary (including superannuation) and consulting fees for directors and related parties.

<b>7. Financing facilities</b>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
<i>Note: the term "facility" includes all forms of financing arrangements available to the entity. Add notes as necessary for an understanding of the sources of finance available to the entity.</i>		
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
<b>7.4 Total financing facilities</b>	<b>-</b>	<b>-</b>
<b>7.5 Unused financing facilities available at quarter end</b>		<b>-</b>
7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.		

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	(2,768)
8.2 Cash and cash equivalents at quarter end (item 4.6)	6,567
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	6,567
<b>8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	<b>2.4</b>
<i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i>	
8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?	
Answer: N/A	
8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?	
Answer: N/A	
8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?	
Answer: N/A	
<i>Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.</i>	

**Compliance statement**

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

26 April 2023

Date: .....

By Order of the Board

Authorised by: .....  
 (Name of body or officer authorising release – see note 4)

**Notes**

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.