



26 October 2021

Sydney, Australia

## Nyrada Quarterly Activities Report & Appendix 4C

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### Highlights:

- **Cholesterol-Lowering Program advances:**
    - New data from *in vivo* cholesterol study showed NYX-PCSK9i significantly increased plasma PCSK9 levels, supporting the mechanism of action of Nyrada's compound
    - Treatment with NYX-PCSK9i also significantly increased the number of receptors responsible for removing cholesterol from the bloodstream, enhancing cholesterol clearance from the body
    - Composition of matter patent granted for PCSK9 inhibitor technology by the United States Patent and Trademark Office (USPTO)
    - Preclinical studies expected to be completed by mid-CY2022 ahead of Phase I first-in-human study
  - **Brain Injury Program progress:**
    - Testing of NYR-BI01 in WRAIR's Traumatic Brain Injury (TBI) animal model is underway, with initial results expected before the end of the year
    - Phase I first-in-human study anticipated to commence second half of CY2022
  - **Robust cash position of A\$12.4 million**
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**Nyrada Inc** (ASX: NYR), a preclinical stage, drug development company specialising in novel small molecule drugs to treat cardiovascular and neurological diseases is pleased to provide its Quarterly Activities Report and Appendix 4C for the period ending 30 September 2021, and a summary of progress for its Cholesterol-Lowering and Brain Injury Programs.

**Commenting on the quarter, Nyrada CEO, James Bonnar said:** "I am pleased with the progress we have made in the Cholesterol-Lowering Program. Our lead drug candidate has delivered impressive results in our recently completed preclinical studies. Equally, the PCSK9 inhibitor technology patent, granted by the USPTO, is a valuable asset that adds to the commercial value of the Program.

"The Nyrada team, together with WRAIR and UNSW have been working diligently behind the scenes, as testing of our Brain Injury Program lead drug candidate, NYR-BI01, gets underway in WRAIR's TBI animal model. We are looking forward to the results of these studies, which are expected before the end of the year," Mr Bonnar added.



## **Preclinical Program Update**

### **Cholesterol-Lowering Program – PCSK9 inhibitor**

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. During this 35-day study in a specialised mouse model, NYX-PCSK9i was dosed at 50mg/kg as a monotherapy and in combination with the statin drug Lipitor® (atorvastatin, Pfizer) with no adverse effects identified.

Additionally, NYX-PCSK9i treatment significantly increased the number of LDL receptors responsible for removing cholesterol from the bloodstream. Further analysis also revealed Nyrada's compound enhances cholesterol clearance from the body.

The Company expects to complete safety pharmacology and toxicology studies by mid-CY2022, ahead of a Phase I first-in-human study anticipated to commence shortly thereafter. The timing of the Phase I study is dependent on CRO scheduling and availability. An announcement with further details on the timing and location of these studies will be made in the coming weeks.

### **Brain Injury Program**

Pilot work is well progressed with WRAIR and UNSW to determine the baseline injury signal of NYR-BI01 in the TBI animal models to be used in the planned efficacy studies. Testing of NYR-BI01 in the TBI models at WRAIR has commenced, with the initial results expected before the end of the year. The Company anticipates commencing the first-in-human Phase I study in the second half of CY2022.

## **US Patent Update**

In July, Nyrada was granted a new patent entitled, "Heterocyclic Inhibitors of PCSK9" by the USPTO, marking the first patent for the Company's Cholesterol-Lowering Program. The composition of matter patent provides protection for Nyrada's intellectual property (IP) relating to its PCSK9 inhibitor technology in the US and forms part of the Company's active IP strategy.

## **Corporate and Financial Summary**

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

Total cash operating outflows for the September 2021 quarter were approximately A\$1.2 million (A\$1.6 million in the prior quarter). Looking ahead, the Company expects cash outflows in future quarters to increase as both Programs progress towards Phase I clinical trials.



Nyrada's cash position was A\$12.4 million as at 30 September 2021. The Company also expects to receive a FY2021 R&D tax incentive refund of \$1.3M in the fourth quarter of CY2021, further boosting capital resources.

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\$134,000 and included Director fees.

A summary of the operating cashflows for the nine months ending 30 September 2021, compared with the proposed use of funds in Year 2 of Nyrada's Prospectus dated 26 November 2019 and Supplementary Prospectus dated 9 December 2019 is outlined below:

	Year 2 12-month period Per Prospectus (A\$)	9-month period ending 30 Sept 2021 (A\$)
Research & Development (R&D) - Salaries	1,500,000	692,000
R&D – Brain Injury program	1,000,000	520,000
R&D – Cholesterol-Lowering program	700,000	1,398,000
Other R&D	500,000	13,000
Repayment of part of the Noxopharm Loan	-	342,000
Working Capital	700,000	1,271,000
Government grants and tax incentives	-	(976,000)
<b>Total</b>	<b>4,400,000</b>	<b>3,260,000</b>

During the nine-month period ending 30 September 2021, overall R&D spend remains broadly in line with the estimated use of funds as set out in the Prospectus and Supplementary Prospectus.

The estimated R&D Tax incentive inflows for FY2019, FY2020 and FY2021 were not included in the use of funds statement and are partially funding the working capital requirements along with the Company's R&D programs.

Nyrada believes the working capital outflows are consistent with the requirements for an ASX listed biotech company of its size. As a result of the recent capital raise, the Company has sufficient cash reserves to complete Phase I studies in both its Brain Injury and Cholesterol-Lowering programs.

-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.

**ARBN**

625 401 818

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

30 September 2021

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (3 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	(502)	(502)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(228)	(228)
(f) administration and corporate costs	(465)	(465)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	2	2
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	-
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(1,193)</b>	<b>(1,193)</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 (3 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	(224)	(224)
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)	(45)	(45)
<b>3.10</b>	<b>Net cash from / (used in) financing activities</b>	<b>(269)</b>	<b>(269)</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	13,751	13,751
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,193)	(1,193)
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 (3 months) \$A'000</b>
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(269)	(269)
4.5	Effect of movement in exchange rates on cash held	156	156
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>12,445</b>	<b>12,445</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	12,445	13,751
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>12,445</b>	<b>13,751</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	134
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) 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)	(1,193)
8.2 Cash and cash equivalents at quarter end (item 4.6)	12,445
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	12,445
<b>8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	<b>10.4</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 October 2021

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.