



13 October 2020

Sydney, Australia

## Nyrada Quarterly Activities Report & Appendix 4C

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### Highlights:

- **Brain Injury Program progress:**
    - Durable therapeutic levels achieved by lead candidates following continuous intravenous administration, plus safe and well-tolerated
    - Pharmacokinetic study expected to report further safety and tolerability data from higher dose levels over longer duration in the coming weeks
  - **Cholesterol-Lowering Program advances:**
    - Lead compound NYX-PCSK9i selected and demonstrated efficacy equivalency to the two FDA approved monoclonal PCSK9 antibody drugs
    - Interim results from an ongoing *in vivo* efficacy study of NYX-PCSK9i by the end of 2020 with final results expected in early 2021
  - Nyrada founder and seasoned biotech entrepreneur, **Dr Ian Dixon joins the Board** as Non-Executive Director
  - **Strong cash position**, with A\$5.2 million in cash as at 30 September 2020, providing cash runway until the end of 2021
  - Received R&D Tax Incentive refund of \$1.075 million for 2018/2019 financial year
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**Sydney, 13 October 2020:** Nyrada Inc (ASX: NYR), a preclinical stage, drug development company specialising in novel small molecule drugs to treat cardiovascular, neurological, and chronic inflammatory diseases is pleased to provide its Appendix 4C and Quarterly Activities Report for the period ending 30 September 2020. The Company also provides an update on the ongoing development of its lead programs in Brain Injury and Cholesterol-Lowering.

**Commenting on the Company's progress and outlook, Nyrada CEO James Bonnar said:** "We are extremely encouraged by the progress made in our lead programs this quarter and are pleased to continue to have only minimal impacts from COVID-19 on our operations. Preclinical results in the Brain Injury Program showed that our drug candidates were well-tolerated at dose levels we anticipate will be therapeutic when administered via the preferred route for stroke and moderate-severe TBI. This gives us confidence as we continue preclinical efficacy studies and move towards selecting the clinical candidate in the first half of 2021.

"Our Cholesterol-Lowering Program is also advancing well. Preclinical results demonstrated equivalency between our lead compound and the two FDA approved monoclonal PCSK9 antibody drugs, while offering the convenience of a pill and being lower cost. Looking ahead,



we expect further preclinical results from a current efficacy study by early 2021 and are on track to reach clinical trials in late 2021.”

## **Preclinical Program Update**

### **Brain Injury Program**

In July, Nyrada reported encouraging results from a preclinical pharmacokinetic study of two Brain Injury drug candidates, NYX-242 and NYX-1010. The study was designed to assess optimal dosing and drug levels in the brain via a 6-hour continuous intravenous infusion, the preferred route for patients suffering from moderate-severe traumatic brain injury and stroke. The study showed that both candidates achieved durable therapeutic levels and were safe and well-tolerated with no adverse effects observed in the animal models.

Nyrada is currently conducting a further pharmacokinetic study to evaluate the safety and tolerability of lead candidate NYX-1010 when administered at higher dose levels for a longer duration period. The Company expects to report the results of this study in the coming weeks.

In addition, data from Nyrada’s Brain Injury Program was published by the United States’ Military Health System Research Symposium (MHSRS), which is the most prominent scientific meeting held by the US Department of Defense for presenting scientific knowledge from military research and development. The published data related to preclinical work which showed that Nyrada’s small molecule blocks sustained  $\text{Ca}^{2+}$  build up in cells, which is a key driver of secondary brain injury.

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

During the quarter, Nyrada reported encouraging preclinical results which demonstrated equivalency between Nyrada’s PCSK9 inhibitor, NYX-PCSK9i, and the two FDA approved monoclonal PCSK9 antibody drugs evolocumab (Repatha™, Amgen) and alirocumab (Praluent™, Sanofi/Regeneron). The study which used healthy donor human white blood cells (lymphocytes), confirmed these results with and without the addition of a statin (Mevastatin) indicating the potential for NYX-PCSK9i to be used alone or combined with a statin in a single-pill oral treatment for hypercholesterolemia.

These encouraging results have led to the selection of NYX-PCSK9i as Nyrada’s lead preclinical compound to be taken forward for optimisation studies prior to clinical trials. As part of its optimisation, the Company completed a pharmacokinetic study of NYX-PCSK9i during the quarter which demonstrated that the compound is well-tolerated and can be dosed orally at levels believed to be therapeutically optimal.

During the quarter, Nyrada also commenced an efficacy study of NYX-PCSK9i in an *in vivo* animal model. Nyrada has chosen to use a specialised mouse model which has been created to possess human-like characteristics with respect to cardiovascular health and is well



regarded in the pharmaceutical industry, having been used for over 170 drug intervention studies over the last 15 years. The study will measure lipid profile, plasma PCSK9 levels, and liver function at regular intervals throughout a 3-week treatment period to assess the overall effectiveness of NYX-PCSK9i to improve hypercholesterolemia.

Nyrada expects to update the market with interim results of the *in vivo* efficacy study by the end of 2020 with final results expected in early 2021.

## **Corporate and Financial Summary**

### **Board Changes**

In August, the Company announced the appointment of Nyrada founder and seasoned biotech entrepreneur, Dr Ian Dixon as Non-Executive Director to the Board. Dr Dixon's appointment brings more than 20 years' Australian biotech experience to the Board. Nyrada also announced Dr Graham Kelly stepped down from the Nyrada Board as Non-Executive Director to focus on his role as Noxopharm CEO and Managing Director but remains involved in Nyrada as a consultant.

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

In July 2020, Nyrada received a A\$1.075 million cash rebate from the Australian Federal Government's Research & Development (R&D) tax incentive program. The rebate predominately related to expenditure incurred on eligible R&D activities conducted in relation to the Company's preclinical work on its two lead programs during the 2018/2019 financial year. Nyrada expects to receive a further R&D rebate for the 2020 financial year during the quarter ending 31 March 2021.

Total cash operating outflows (excluding R&D tax incentive refund and COVID related government stimulus) for the September 2020 quarter were approximately A\$1.0 million, broadly in line with operating outflows in the prior quarter. Looking ahead, the Company expects cash outflows in future quarters to increase as a result of further efficacy and safety testing of the NYX-PCSK9i Cholesterol-Lowering drug candidate, and testing the Brain Injury drug candidate NYX-1010 in a model of traumatic brain injury (TBI).

Nyrada's cash position was A\$5.2 million as at 30 September 2020. Based on current forecasts, Nyrada expects this to sustain R&D activities and operations until the end of 2021.

In accordance with Listing Rule 4.7C, payments made to related parties and their associates included in items 6.1 of the Appendix 4C includes Director fees and salary (including superannuation) for Executive Directors and related parties.



A summary of the expenditure for nine months ending 30 September 2020 compared with the proposed use of funds in Year 1 of Nyrada's Prospectus dated 26 November 2019 and Supplementary Prospectus dated 9 December 2019 is outlined below:

	Per Prospectus (A\$)	Period ending 30 September 2020 (A\$)
Research & Development (R&D) - Salaries	1,300,000	884,000
R&D – Brain Injury program	600,000	361,000
R&D – Cholesterol-lowering program	500,000	644,000
Other R&D	400,000	111,000
Repayment of part of the Noxopharm Loan	500,000	478,000
Working Capital	600,000	1,224,000
Costs of the Offer	800,000	869,000
<b>Total</b>	<b>4,700,000</b>	<b>4,571,000</b>

During the nine-month period ending 30 September 2020 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 requirements for a small ASX listed biotech company. As communicated, the Company has sufficient cash reserves to fund its operations until the end of 2021 as outlined in the Prospectus and Supplementary Prospectus.

-ENDS-

#### **About Nyrada Inc**

Nyrada is a preclinical stage, drug discovery and development company, specialising in novel small molecule drugs to treat cardiovascular, neurological, and inflammatory 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, USA, and the liability of its stockholders is limited.

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

*Authorised by John Moore, Non-Executive Chairman*

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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.

## 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 2020

<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	(434)	(434)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	-	-
(d) leased assets	-	-
(e) staff costs	(242)	(242)
(f) administration and corporate costs	(361)	(361)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	-
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	1,126	1,126
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>89</b>	<b>89</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
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 – Proceeds/(repayment) of intercompany loans	-	-
<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	5,146	5,146
4.2	Net cash from / (used in) operating activities (item 1.9 above)	89	89
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)	-	-
4.5	Effect of movement in exchange rates on cash held	(11)	(11)
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>5,224</b>	<b>5,224</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	5,224	5,146
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>5,224</b>	<b>5,146</b>

**6. Payments to related parties of the entity and their associates**

- 6.1 Aggregate amount of payments to related parties and their associates included in item 1
- 6.2 Aggregate amount of payments to related parties and their associates included in item 2

**Current quarter  
\$A'000**

120

-

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

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



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

**7. Financing facilities**

*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.*

	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
<b>7.4 Total financing facilities</b>	-	-

7.5 **Unused financing facilities available at quarter end** -

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)	89
8.2 Cash and cash equivalents at quarter end (Item 4.6)	5,224
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	5,224
<b>8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)</b>	<b>N/A</b>

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

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:

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:

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:

## 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.

Date: 13 October 2020  
 .....

Authorised by: By the Board  
 .....  
 (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.