

Date: 31 January 2018 Sydney, Australia

**ASX: NOX** 

ASX Limited 20 Bridge Street SYDNEY NSW 2000

**Noxopharm Limited** 

ABN 50 608 966 123

# Registered Office and Operational Office: Suite 3, Level 4 828 Pacific Highway

828 Pacific Highway Gordon NSW 2072 Australia

## Board of Directors Mr Peter Marks

Chairman Non-Executive Director

### **Dr Graham Kelly**

Chief Executive Officer Managing Director

#### **Dr Ian Dixon**

Non-Executive Director

# **APPENDIX 4C - DEC 2017 QUARTER**

**Sydney, 31 January 2018:** Noxopharm Limited (NOX:ASX) is pleased to release its Appendix 4C for the quarter ended 31 December 2017, as well as providing guidance on the current quarter.

The key points of activity this quarter were as follows.

## 1. Securing a supply of NOX66

The Company is planning for a significant increase in its NOX66 clinical trial program in 2018, with up to several hundred patients expected to be treated. This means having a secure supply of GMP grade product available from about mid-2018. A Director of Manufacturing (Dr Lara Babich BSc, MSc, PhD) was appointed this quarter to oversee this important activity. Lara's responsibilities encompass the supply of active drug from overseas contract suppliers and the commissioning of a NOX66 formulation and packaging line in Melbourne with a projected capacity of up to 100,000 doses per day.

#### 2. Chemistry resources

The Company increased its investment this quarter into studying the chemistry behind the success of NOX66. The Company's intellectual property position with NOX66 lies not with the active drug idronoxil, which is generic, but with the formation in the body of a pro-drug form known as idronoxil-C. The Company is confident that it is this form that is enabling NOX66 to provide its clinical effect, including facilitating an abscopal response, as well as the important breakthrough step of crossing the blood-brain barrier. The Company has joined forces with the University of NSW (Sydney) and the University of South Australia to map the apparent novel drug features of idronoxil-C, with that knowledge underpinning the future registration of NOX66 and important patent lodgements.

## 3. Pre-Clinical Studies

Pre-clinical studies continued this quarter in two related areas, with the Company significantly increasing its funding commitments. The first is the potential therapeutic use of NOX66 in the treatment of brain cancer. These studies are underway at the University of Hong Kong, the Lowy Cancer Research Institute (Sydney) and the Sydney Children's Hospital into the use of NOX66 to treat adult and paediatric brain cancers. The second is understanding the mechanism by which NOX66 enhances the efficacy of radiotherapy in human cancer, and the possible application of this to the treatment of brain cancer. These laboratory studies are

underway at the Lowy Cancer Research Institute (Sydney) and the Olivia Newton John Cancer Research Institute (Melbourne).

#### 4. Clinical studies

Three clinical trials are current.

- (i) The **SCAN Study** (Sensitisation of Carboplatin by NOX66) is the Company's first-in-human clinical study of NOX66. It is fully recruited and continues to work towards its conclusion in April 2018 when the last patient completes 7 months of treatment. The Company reported the latest data to the ESMO Asia conference in Singapore on 18<sup>th</sup> November 2017. The data showed that for 11 patients who had completed 3 months of treatment with NOX66 and low-dose carboplatin, only 1/11 showed disease progression, 9 showed no progression, and 1 showed a partial response. The Company will be presenting the latest clinical data at a cancer conference in Paris on 5<sup>th</sup> March 2018. The rationale of this study is that a combination of NOX66 and low-dose carboplatin will provide a meaningful increase in progression-free survival in late-stage cancer without significant toxicity.
- (ii) The **LUPIN Study** (Lutetium-PSMA In combination with NOX66) at St Vincent's Hospital (Sydney) has its initial 4 patients under treatment. A condition of approval of this study was a review of the safety data from the first 4 patients after 6 weeks of treatment. That review is anticipated in late-February 2018, opening the study up then for full recruitment. The rationale behind this study is that NOX66 will enhance the cancer-killing effect of intravenous brachytherapy radiotherapy (177 lutetium-PSMA-617) in men with metastatic castrate-resistant prostate cancer.
- (iii) The first study in the Company's **DARRT program** (Direct and Abscopal Response to Radiotherapy) is the **PROSCART Study** (Prostate Cancer Radio-enhancing Study) and currently is recruiting patients. After experiencing initial slow recruitment, considerable effort was made this last quarter in opening up additional sites in Australia, New Zealand and Georgia, along with making oncologists and patients more aware of the study. The objective is to have this study fully recruited by the end of May 2018, and completed by August 2018. The rationale behind this study is that NOX66 will enhance the cancer-killing effect of external beam radiotherapy in men with metastatic castrate-resistant prostate cancer, with both irradiated lesions showing greater degree of shrinkage (direct radio-enhancement) and non-irradiated lesions also showing shrinkage (abscopal response).
- (iv) The Company continues to make NOX66 available on a compassionate use basis to patients who are not eligible for any current NOX66 clinical studies. The Company has begun the process of accessing that data in order to have it published as clinical reports.

### 5. Nyrada

In November 2017, Noxopharm shareholders approved the establishment of subsidiary, Nyrada Inc (Nyrada). Noxopharm transferred two drug assets into Nyrada, and Nyrada also acquired a third drug asset through acquisition of another entity, Cardio Therapeutics Pty Ltd. Nyrada then conducted a capital raise through the issue of convertible notes (Raise), with the Raise to close by 31 January 2018. The outcome of that Raise will be announced shortly. Noxopharm owns 66.7% (pre-Raise) of Nyrada and will continue to play a major role in its function. Noxopharm believes that Nyrada represents significant value to NOX shareholders, providing an opportunity to add value to non-oncology assets that otherwise would have likely been marginalised in the task of developing NOX66.

#### 6. Kazia Therapeutics Ltd

In December 2017, Noxopharm entered into mediation with Kazia Therapeutics Ltd (KZA) in relation to claims of ownership of certain intellectual property. Both parties agreed to settle the claims on a permanent basis by the Company issuing a certain number of shares and options to KZA. The Company

took this commercial decision in order to provide both it and the market with the certainty both needed as NOX66 moves into its final stages of development.

#### 7. Funding

The Company finished the calendar year with approximately \$4.0 million in cash, excluding any funds held in under the abovementioned Nyrada Raise.

Since 31 December 2017, as announced on 17 January 2018, the Company received \$855,518 through the Federal Government's R&D Rebate Scheme.

In addition to the inflow noted above from the R&D Rebate Scheme, the Company holds approximately \$3.0 million from the Nyrada Raise. Until the Raise is closed and the convertible notes allotted, the funds are held in trust.

The progression of the Company this year towards its planned Phase 2/Phase 3 clinical program for NOX66 means that additional funds will be required, with the timing of this following on the release of clinical data that would justify ongoing development.

The Company shortly will be formalising with Nyrada the sharing of resources (such as office premises costs and personnel) under a general services agreement, providing cost-savings for both companies.

### 8. Guidance for the current quarter

The Company's primary objectives for the March 2018 quarter are:

- to be well advanced in the recruitment of patients into the LUPIN and PROSCART studies, with early clinical data available for review and release in April/May 2018
- to have completed planning and site recruitment for an enlarged SCAN Study in Australia and Europe, and for Phase 2 studies in the DARRT Program in patients with lung cancer and rare cancers in Australasia, Europe and the US
- to be well advanced in commissioning the NOX66 GMP manufacturing line.

#### **About NOX66**

NOX66 is an innovative dosage formulation of the experimental anti-cancer drug, idronoxil, developed specifically to preserve the anti-cancer activity of idronoxil in the body and to enhance its drug-like behaviour. Idronoxil is a kinase inhibitor that works by inhibiting a range of enzymes including sphingosine kinase and PI3 kinase that regulate cell pro-survival mechanisms and which are over-expressed in cancer cells, as well as inhibiting external NADH oxidase Type 2 (ENOX 2) which is responsible for maintaining the transmembrane electron potential (TMEP) in the plasma membrane of cancer cells and whose expression is limited to cancer cells. Inhibition of these enzymes results in disruption of key downstream prosurvival mechanisms including resistance mechanisms, sensitizing the cancer cell to the cytotoxic effects of chemotherapy drugs and radiotherapies.

## **About Noxopharm**

Noxopharm is an Australian drug development company with offices in Sydney and Hong Kong. The Company has a primary focus on the development of drugs to sensitise cancer cells to radiotherapy. NOX66 is the first pipeline product, with later generation drug candidates under development.

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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 Noxopharm about circumstances and events that have not yet taken place. Although Noxopharm 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. No representation, warranty or assurance (express or implied) is given or made by Noxopharm that the forward-looking statements contained in this announcement are accurate and undue reliance should not be placed upon such statements.

+Rule 4.7B

# **Appendix 4C**

# Quarterly report for entities subject to Listing Rule 4.7B

Introduced 31/03/00 Amended 30/09/01, 24/10/05, 17/12/10, 01/09/16

## Name of entity

NOXOPHARM LIMITED	
ABN	Quarter ended ("current quarter")
50 608 966 123	31 DECEMBER 2017

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers		
1.2	Payments for		
	(a) research and development	(1,130)	(1,838)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(8)	(45)
	(d) leased assets	-	-
	(e) staff costs	(722)	(1,169)
	(f) administration and corporate costs	(369)	(868)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	25	36
1.5	Interest and other costs of finance paid	(2)	(3)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (Listing process costs)	-	-
1.9	Net cash from / (used in) operating activities	(2,206)	(3,887)

2.	Ca	sh flows from investing activities		
2.1	Pay	ments to acquire:		
	(a)	property, plant and equipment	(28)	(166)
	(b)	businesses (see item 10)	-	-
	(c)	investments	-	-

<sup>+</sup> See chapter 19 for defined terms

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Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
	(d) intellectual property	-	-
	(e) other non-current assets	-	-
2.2	Proceeds from disposal of:		
	(a) property, plant and equipment	-	-
	(b) businesses (see item 10)	-	-
	(c) investments	-	-
	(d) intellectual property	-	-
	(e) 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)	-	-
2.6	Net cash from / (used in) investing activities	(28)	(166)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of shares	407	5,907
3.2	Proceeds from issue of convertible notes	-	-
3.3	Proceeds from exercise of share options	-	-
3.4	Transaction costs related to issues of shares, convertible notes or options	(12)	(414)
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)	-	-
3.10	Net cash from / (used in) financing activities	395	5,493

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of quarter/year to date	5,832	2,553
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,206)	(3,887)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(28)	(166)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	395	5,493

<sup>+</sup> See chapter 19 for defined terms 1 September 2016

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
4.5	Effect of movement in exchange rates on cash held		
4.6	Cash and cash equivalents at end of quarter	3,993	3,993

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter \$A'000	Previous quarter \$A'000
5.1	Bank balances	439	689
5.2	Call deposits	3,500	5,080
5.3	Bank overdrafts		
5.4	Other		
	- business debit cards	54	63
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	3,993	5,832

Section 4 and 5 cash balances <u>exclude</u> cash held in trust relating to Nyrada Inc raising via the issue of convertible notes, announced on 1 December 2017. The balance of cash held in trust as at 31 December 2017 was approximately \$760,000 and as at 31 January 2018 was approximately \$2,930,000. The convertible note raising is expected to be finalised imminently.

6.	Payments to directors of the entity and their associates	Current quarter \$A'000
6.1	Aggregate amount of payments to these parties included in item 1.2	244
6.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	-

6.3 Include below any explanation necessary to understand the transactions included in items 6.1 and 6.2

Director fees and salary for executive director and related parties.

7.	Payments to related entities of the entity and their associates	Current quarter \$A'000
7.1	Aggregate amount of payments to these parties included in item 1.2	-
7.2	Aggregate amount of cash flow from loans to these parties included in item 2.3	-

7.3 Include below any explanation necessary to understand the transactions included in items 7.1 and 7.2

1 September 2016

<sup>+</sup> See chapter 19 for defined terms

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8.	Financing facilities available Add notes as necessary for an understanding of the position	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
8.1	Loan facilities	-	-
8.2	Credit standby arrangements	-	-
8.3	Other (please specify)	-	-

8.4 Include below a description of each facility above, including the lender, interest rate and whether it is secured or unsecured. If any additional facilities have been entered into or are proposed to be entered into after quarter end, include details of those facilities as well.

9.	Estimated cash outflows for next quarter	\$A'000
9.1	Research and development	(1,300)
9.2	Product manufacturing and operating costs	(150)
9.3	Advertising and marketing	(25)
9.4	Leased assets	-
9.5	Staff costs	(415)
9.6	Administration and corporate costs	(250)
9.7	Other (provide details if material)	(100)
9.8	Total estimated cash outflows	(2,240)

10.	Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)	Acquisitions	Disposals
10.1	Name of entity	Cardio Therapeutics Pty Ltd	N/A
10.2	Place of incorporation or registration	Victoria, Australia	-
10.3	Consideration for acquisition or disposal	Shares in Nyrada Inc (33.3%)	-
10.4	Total net assets	\$37,000	-
10.5	Nature of business	Medical research in the field of non-oncology	N/A

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<sup>+</sup> See chapter 19 for defined terms

## **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.

Sign here:	(Company secretary)	Date:	31 JAN 2018
	DAVID FRANKS		
Print name:			

#### **Notes**

- 1. The quarterly report provides a basis for informing the market how the entity's activities have been financed for the past quarter and the effect on its cash position. An entity that wishes to disclose additional information is encouraged to do so, in a note or notes included in or attached to this report.
- If this quarterly 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 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.

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<sup>+</sup> See chapter 19 for defined terms