



Date: 27 April 2018

Sydney, Australia

**ASX: NOX**

**Noxopharm Limited**

ABN 50 608 966 123

**Registered Office**  
and

**Operational Office:**

Suite 3, Level 4

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

ASX Limited  
20 Bridge Street  
SYDNEY NSW 2000

## APPENDIX 4C – MARCH 2018 QUARTER

- **successful capital raise concluded - \$10.0M (net) raised**
- **3 clinical studies underway**
- **Next phases of clinical program well funded.**

**Sydney, 27 April 2018:** Noxopharm (ASX: NOX) is pleased to release its Appendix 4C for the quarter ended 31 March 2018, as well as providing guidance for the current quarter.

The key activities during this quarter were as follows.

### 1. Clinical program

Achieving marketing approval for NOX66 remains the Company's primary focus, and identifying the most certain, most economic and quickest route to achieving that goal is the basis of the current clinical development program.

Three separate programs are underway, titled DARRT, LUPIN and CEP. Each program has a Phase 1 study underway, and significant progress was made in this quarter across all 3 studies under the direction of Ian Minns, Director of Clinical Development and Medical Affairs.

#### (i) **DARRT Program (Direct and Abscopal Response to Radiotherapy).**

This program is using NOX66 to enhance the cancer-killing effect of externally delivered radiotherapy. The program involves patients with late-stage, metastatic cancer with no remaining treatment options, where radiotherapy is being used on a palliative (non-curative) basis to relieve pain from certain large tumours. Often these tumours are in sensitive areas such as in the spine or close to the heart, meaning that the dose of radiotherapy needs to be even more limited.

The rationale of DARRT is that adding NOX66 to this standard form of radiotherapy has two possible outcomes. The first outcome is that the 1 or 2

tumours receiving radiotherapy will show greater shrinkage (a direct response). The second is that all other tumours also will respond (an abscopal response).

The first study in this program (DARRT-1) is testing this concept in 24 late-stage prostate cancer patients. The study is being conducted in 11 clinical sites in Australia, New Zealand and Georgia. Treatment involves 5-10 days of radiotherapy combined with up to 15 days of NOX66 treatment.

The first 4 patients have completed their combination treatment, and the next 4 patients recruited. The study is on schedule to be fully recruited by the end of May 2018.

**(ii) LUPIN Program (Lutetium-PSMA In combination with NOX66).**

This program is using NOX66 to enhance the cancer-killing effect of internally administered radiotherapy in late-stage prostate cancer. <sup>177</sup>Lutetium-PSMA-617 brachytherapy is becoming increasingly used in men with late-stage prostate cancer who have failed to respond to standard forms of therapy. Details of this type of therapy are available at the following link: <http://endocyte.com/>

The study is being conducted at St Vincent's Hospital, Sydney, with 16 men who are to receive up to 6 injections of <sup>177</sup>Lutetium-PSMA-617 every 3-4 weeks in combination with NOX66 therapy. Scans to be conducted at 6, 12 and 52 weeks after commencement of treatment.

The first 4 have commenced therapy. A safety review of these 4 patients was conducted recently, and in the absence of any adverse events, cleared the study to continue with further recruitment. Complete enrolment of all 16 subjects is anticipated by August 2018.

**(iii) CEP Program (Chemo-Enhancement Program).**

This program is using NOX66 to enhance the anti-cancer effect of certain common chemotherapy drugs in order for those drugs to be used at dosages generally considered to be sub-optimal in terms of anti-cancer activity, but associated with fewer side-effects. Commonly-used chemotherapy drugs such as cisplatin, carboplatin, paclitaxel and vincristine are associated with significant side-effects. Some of those side-effects, such as nausea, vomiting and hair loss last only for the duration of treatment, while others such as bone marrow depression (low red and white blood cell levels) and nerve damage (peripheral neuropathy, ototoxicity) can persist for long periods post-treatment and be significantly debilitating. The CEP program is seeking to use NOX66 to minimise or even avoid the worst of these side-effects, without compromising the anti-cancer effect of the chemotherapy. Achieving this objective could represent a major step forward in the use of chemotherapy.

CEP-1 (also known as the SCAN Study) is nearing completion, with the last patient due to come off study at the end of April 2018.

## **2. Pre-clinical program**

The pre-clinical program, under the direction of Dr John Wilkinson, Chief Scientific Officer, has 3 major objectives:

- (i) The first is designed to support the current NOX66 clinical program, including generating data that will be required to conduct a Phase 3 clinical study and then to support marketing approval. As part of this process, the Company initiated contact in this quarter with the US FDA as part of its aim to obtain IND (Investigational New Drug) status ahead of conducting clinical studies in North America later this year. The required data has been identified and is being acted on.

- (ii) The second is to obtain proof of concept data for using NOX66 in combination with radiotherapy in the treatment of adult (GBM) and paediatric (DIPG) brain cancer. The Company is pursuing this important indication because of the ability of NOX66 to cross the blood-brain barrier. Those *in vitro* studies (being conducted in collaboration with the Lowy Cancer Research Institute and the Sydney Children's Hospital) are nearing completion and on the basis of successful data, are due shortly to progress into animal studies.
- (iii) The third is to investigate the basis of the nature of the radio-enhancing effect of NOX66. This information is considered vital in supporting the introduction of NOX66 into the market post-registration. This work is being conducted in collaboration with the Olivia Newton John Cancer Research Institute. These studies are progressing and continuing to deliver important insights.

### **3. Funding**

The Company had cash of \$11.88M at 31 March 2018. This followed a successful capital raising that closed on 23 March 2018, raising \$10.8M (before costs). The Raise was conducted in 2 tranches: Tranche 1 placement of 7,264,966 shares at 90 cents (\$6.53M) and Tranche 2 placement, subject to shareholder approval on 15 May 2018, of 4,735,034 shares at 90 cents (\$4.27M).

The funds are earmarked principally for the clinical and pre-clinical programs, and particularly to allow the Company to identify and plan a multi-national Phase 3 registration clinical study that will form the basis of an application for marketing approval.

### **4. Guidance for the current quarter**

The primary objectives for the June 2018 quarter are:

- Complete the CEP-1 study; lock, clean and review data
- Present near-complete data from CEP-1 at ASCO Conference, Chicago, June 2018
- Complete planning in conjunction with Medical Advisory Board on nature of CEP-2 study
- Complete enrolment in DARRT-1 study
- Complete planning and site selection for DARRT-2 study (in broader cancer types)
- Have enrolled 12 patients in the LUPIN study (75% enrolment)
- Commission NOX66 medium-scale GMP production facility.

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#### **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. Idronoxil also is an immuno-enhancing drug, stimulating the body's natural killer (NK) cells to attack cancer cells.

#### **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 and chemotherapy. 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.

## 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**

50 608 966 123

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

31 MARCH 2018

<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	(1,982)	(3,820)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(4)	(49)
(d) leased assets	-	-
(e) staff costs	(721)	(1,890)
(f) administration and corporate costs	(290)	(1,158)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	15	51
1.5 Interest and other costs of finance paid		(3)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	883	883
1.8 Other (Listing process costs)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(2,099)</b>	<b>(5,986)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire:		
(a) property, plant and equipment	(134)	(300)
(b) businesses (see item 10)	-	-
(c) investments	-	-

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
(d) intellectual property	-	-
(e) other non-current assets	-	-
<b>2.2 Proceeds from disposal of:</b>		
(a) property, plant and equipment	-	-
(b) businesses (see item 10)	-	-
(c) investments	-	-
(d) intellectual property	-	-
(e) other non-current assets	-	-
<b>2.3 Cash flows from loans to other entities</b>	-	-
<b>2.4 Dividends received (see note 3)</b>	-	-
<b>2.5 Other (provide details if material)</b>	-	-
<b>2.6 Net cash from / (used in) investing activities</b>	<b>(134)</b>	<b>(300)</b>

<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of shares	6,325	12,232
3.2 Proceeds from issue of convertible notes	3,990	3,990
3.3 Proceeds from exercise of share options	-	-
3.4 Transaction costs related to issues of shares, convertible notes or options	(195)	(609)
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 Net cash from / (used in) financing activities</b>	<b>10,120</b>	<b>15,613</b>

<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash and cash equivalents at beginning of quarter/year to date	3,993	2,553
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(2,099)	(5,986)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(134)	(300)
4.4 Net cash from / (used in) financing activities (item 3.10 above)	10,120	15,613

<b>Consolidated statement of cash flows</b>		<b>Current quarter \$A'000</b>	<b>Year to date (9 months) \$A'000</b>
4.5	Effect of movement in exchange rates on cash held		
<b>4.6</b>	<b>Cash and cash equivalents at end of quarter</b>	<b>11,880</b>	<b>11,880</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	8,141	439
5.2	Call deposits	3,700	3,500
5.3	Bank overdrafts		
5.4	Other		
	- business debit cards	39	54
	- bank balances (held in trust)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>11,880</b>	<b>3,993</b>

**6. Payments to directors of the entity and their associates**

<b>Current quarter \$A'000</b>
185
-

6.1 Aggregate amount of payments to these parties included in item 1.2

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**

<b>Current quarter \$A'000</b>
-
-

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

8. <b>Financing facilities available</b> <i>Add notes as necessary for an understanding of the position</i>	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.		

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9. <b>Estimated cash outflows for next quarter</b>	\$A'000
9.1 Research and development	(1,456)
9.2 Product manufacturing and operating costs	-
9.3 Advertising and marketing	(20)
9.4 Leased assets	-
9.5 Staff costs	(730)
9.6 Administration and corporate costs	(329)
9.7 Other (provide details if material)	-
<b>9.8 Total estimated cash outflows</b>	<b>(2,535)</b>

10. <b>Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)</b>	Acquisitions	Disposals
10.1 Name of entity	N/A	N/A
10.2 Place of incorporation or registration	-	-
10.3 Consideration for acquisition or disposal	-	-
10.4 Total net assets	-	-
10.5 Nature of business	N/A	N/A



**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)

**27 APRIL 2018**  
Date: .....

**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.
2. 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.