

# Date 30 October 2017

•

•

Sydney, Australia

# ASX: NOX

Noxopharm Limited

## ABN 50 608 966 123

#### **Registered Office:**

Suite 1 Level 6 50 Queen St Melbourne VIC 3000 Australia

#### **Operations 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 - SEPT 2017 QUARTER**

Noxopharm Ltd is pleased to release its Appendix 4C for the quarter ended 30 September 2017, as well as providing a brief guidance on the current quarter.

The Company's focus in the last quarter was on 4 key areas:

- Adoption and initiation of a clinical trial program strategy known as DARRT
  - Completion of enrolment in the Phase1b *first-in-human* study of NOX66 in combination with carboplatin in patients with late-stage solid cancer
- Establishment of US subsidiary, Nyrada Inc
  - Ensuring that the Company continues to operate on a sound financial footing.

# DARRT Program

The thrust of the DARRT program (Direct and Abscopal Responses to RadioTherapy) is the use of NOX66 to increase the effectiveness of radiotherapy. The adoption of this strategy followed a review of pre-clinical and clinical data.

DARRT is a novel approach to cancer therapy embracing 3 distinct uses of radiotherapy.

The first approach is *direct radio-sensitisation*. The setting for this is where an external source of radiotherapy is used to shrink a small number of tumours. Typically, the purpose of this is to reduce tumour load ahead of receiving other therapies, or to provide temporary relief from symptoms such as pain. In this setting, the purpose of NOX66 is to achieve a more complete and a more durable response in the irradiated tumours.

The second approach is called an *abscopal response*. This is an extension of direct radiosensitisation, where the aim is to result in remission, not just of the few irradiated tumours, but of all those other tumours not exposed to radiation. The objective is to achieve complete and permanent eradication of all cancer cells in the body.

The third approach is in *brachytherapy*. Here, NOX66 is being used to enhance the local cancer-killing effect of a radiation source placed inside the body.

The first two effects (direct radio-sensitisation and abscopal response) are being tested simultaneously in the same patient. Patients with late-stage cancer will have multiple

tumours, at least 3 of which are measurable by scanning. Between 1-3 measurable tumours will receive low-dose radiotherapy, along with NOX66 therapy, over a 2-3 week treatment period. The fate of both irradiated (direct radio-sensitisation) and non-irradiated (abscopal response) tumours then will be studied by follow-up scans at 6, 12 and 24 weeks.

The first 2 such studies are being conducted in Australia and involve men with metastatic castrateresistant prostate cancer. The main study is known as the **PROSCART (Prostate Cancer Radiosensitising Therapy) Study.** This is a company-sponsored study being conducted at 5 Australian sites (3 QLD, 2 NSW). Fully enrolled, it will have 24 patients.

Two other studies to be undertaken in 2018 will seek to extend the direct sensitising and abscopal effects beyond prostate cancer, into patients with a range of common and rare forms of cancer.

The brachytherapy approach is being undertaken in patients with metastatic castrate-resistant prostate cancer involving combination therapy of NOX66 + intravenous <sup>177</sup>lutetium-PMSA-617 (**LUPIN Study**) being conducted at St Vincent's Hospital, Sydney. This study also is recruiting currently.

#### First-in-human study

The **SCAN Study** (Sensitisation of Carboplatin by NOX66) is being conducted in Georgia in patients with late-stage solid cancers. Using a combination of NOX66 and carboplatin, it is intended to provide data on the safety and efficacy of this combination therapy. The SCAN Study fits within the DARRT program because of the possible need to provide additional therapy to patients who might experience a positive direct radio-sensitising effect, but not an abscopal effect.

Data from a preliminary analysis was presented to the ESMO Conference in Madrid on Sept 11. We reported on a high degree of tolerance of low-dose NOX66 + low-dose carboplatin after 3 months of treatment. Most patients (4/5) eligible for scanning after 3 months also showed a stabilisation of their disease.

This study now is fully recruited (18 patients).

#### Nyrada, Inc

Noxopharm finalised all legal, regulatory, taxation and accounting matters in relation to the establishment of its US subsidiary, Nyrada. A Notice of Meeting was sent to shareholders in relation to a General Meeting to consider the matter to be held on 6 November 2017. If both resolutions are approved by shareholders, then Nyrada proposes to conduct a modest capital raising that will fund the establishment of a core team of scientists and executives, with the aim of bringing each of the Company's 3 drug assets to proof-of-principle status and with a determinable market value. It is proposed to co-locate Nyrada within the Noxopharm offices for the next 12 months for cost-mitigation purposes.

#### Funding

Noxopharm successfully completed a capital raise by way of a private placement of stock to a small number of sophisticated investors in Australia and Asia. \$5.5M was raised at a share price of \$0.33, a 15% discount to the 5-day VWAP.

#### Guidance for the current quarter

The PROCART and LUPIN studies are scheduled to commence treatment in November and to be well advanced in their enrolment targets by the end of the year. The Company anticipates that both of these studies will be pivotal in determining the nature of the clinical indication to be pursued for the Phase 3 registration study.

The Company expects also to make progress in the following areas:

- Establishment of a large-scale GMP manufacturing program for NOX66
- Determination of the utility of NOX66 as a radio-sensitiser in the treatment of primary brain cancers of adults and children
- Development of intravenous and pessary dosage forms of idronoxil-C.

The recent capital raise (\$5.5M), when added to the carry-over cash position and the anticipated 43% R&D rebate from the 2016-2017 FY, gives the Company a cash position that it believes will allow it to pass a number of key upcoming inflection points in its NOX66 clinical development program, each capable of acting as a catalyst to re-rate the Company ahead of any further capital needs. While the Company has no immediate plans to raise further capital, it needs to be recognised that success in any of the Company's drug development programs inevitably means an increased requirement for funds. The Company therefore remains alert both to need and opportunity to raise additional funds, although ever mindful of the need to balance the responsibility of creating shareholder value with minimising shareholder dilution.

#### Anticipated reporting schedule

Noxopharm is presenting clinical and pre-clinical data at a number of conferences in November, including an update (oral presentation) on the SCAN Study at ESMO Asia in Singapore.

The Company anticipates having interim data from both PROSCART and LUPON studies before the end of this year. The timing of the release of that data to the market will be a function of balancing the market sensitivity of the news with the opportunity of lodging the data with regulators in support of various forms of interim regulatory approval.

••••••

#### 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 pro-survival mechanisms including resistance mechanisms, sensitizing the cancer cell to the cytotoxic effects of chemotherapy drugs and radiotherapy.

#### 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 address the problem of radiation- and drug-resistance in cancer cells, the major hurdle facing improved survival prospects for cancer patients. NOX66 is the first pipeline product, with later generation drug candidates under development. The Company also has initiated a pipeline of non-oncology drugs.

Investor & Corporate Enquiries: Prue Kelly M: 0459 022 445 E: info@noxopharm.com Company Secretary: David Franks T: +61 2 9299 9690 E: dfranks@fa.com.au

www.noxopharm.com

+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

50 608 966 123

Quarter ended ("current quarter")

966 123

30 SEPTEMBER 2017

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers		
1.2	Payments for		
	(a) research and development	(708)	(708)
	<ul> <li>(b) product manufacturing and operating costs</li> </ul>	-	-
	(c) advertising and marketing	(37)	(37)
	(d) leased assets	-	-
	(e) staff costs	(447)	(447)
	(f) administration and corporate costs	(499)	(499)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	11	11
1.5	Interest and other costs of finance paid	(1)	(1)
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	(1,681)	(1,681)

2.	Cash flows from investing activities		
2.1	Payments to acquire:		
	(a) property, plant and equipment	(138)	(138)
	(b) businesses (see item 10)	-	-
	(c) investments	-	-

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (3 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	(138)	(138)

3.	Cash flows from financing activities		
3.1	Proceeds from issues of shares	5,500	5,500
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	(402)	(402)
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	5,098	5,098

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	2,553	2,553
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,681)	(1,681)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(138)	(138)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	5,098	5,098

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
4.5	Effect of movement in exchange rates on cash held		
4.6	Cash and cash equivalents at end of quarter	5,832	5,832

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	689	258
5.2	Call deposits	5,080	2,200
5.3	Bank overdrafts		
5.4	Other (business debit cards)	63	95
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	5,832	2,553

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	111
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 transactio items 7.1 and 7.2	ns included in

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)	-	-
0.4	la shuda balavu a daa su'atian af aa sh faali		

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	(1,649)
9.2	Product manufacturing and operating costs	(150)
9.3	Advertising and marketing	(23)
9.4	Leased assets	-
9.5	Staff costs	(415)
9.6	Administration and corporate costs	(251)
9.7	Other (provide details if material)	(100)
9.8	Total estimated cash outflows	(2,588)

10.	Acquisitions and disposals of business entities (items 2.1(b) and 2.2(b) above)	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)

30 October 2017

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.