



Date: 26 April 2019

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

Dr Graham Kelly
Executive Chairman

Mr Peter Marks
Deputy Chairman
Non-Executive Director

Dr Ian Dixon
Non-Executive Director

Mr John Moore
Non-Executive Director

**Mr Shawn van
Boheemen**
Chief Financial Officer

ASX Limited
20 Bridge Street
SYDNEY NSW 2000

APPENDIX 4C – MARCH 2019 QUARTER

- **Veyonda[®] clinical program continuing on plan**
- **CEP and DARRT programs to be expanded and expedited on basis of positive clinical data**
- **Pending release of DARRT-1 and LuPIN-1 interim clinical data**
- **Board changes ahead of planned growth and anticipated U.S. listing**
- **Continuing emphasis on value creation via expanded IP portfolio.**

Sydney, 26 April 2019: Noxopharm (ASX: NOX) (**'Noxopharm'** or the **'Company'**) today releases its Appendix 4C for the quarter ended 31 March 2019, as well as providing guidance for the remainder of 2019. This report is for the Noxopharm group covering both NOX and its majority-owned subsidiary, Nyrada Inc.

The Company's primary focus remains Veyonda[®] and running a clinical program designed to confirm its benefit in enhancing the anti-cancer activities of chemotherapy and radiotherapy and as an immuno-oncology drug. The objective is long-term patient survival in a well-tolerated way.

The Company believes that Veyonda[®] has the potential to become a transformative drug in the treatment of most forms of cancer. In light of that, the Company undertook in the March quarter a strategic review of its clinical study and commercial plans, directed at raising the profile of the Company, and Veyonda[®], in both global capital markets and in the global pharmaceutical industry.

The key decisions of that strategic review are being acted on and are as follows:

1. **Veyonda[®] Program**

The Company currently is deploying Veyonda[®] in 3 different clinical programs – as an enhancer of:

- I. cytotoxic chemotherapy (**CEP Program**)
- II. external beam radiotherapy (**DARRT Program**)
- III. intravenous radiopharmaceuticals (**LuPIN Program**).

All 3 usages are based on the same underlying mechanism of action which is (i) deactivating pro-survival mechanisms in cancer cells such as DNA repair, and (ii) reactivating the body's primary line of defence, the innate immune system. The objective is a new approach designed to harness and boost

the body's own defence systems to fight the cancer, rather than the 60-year old approach of seeking to inflict as much damage as possible on the cancer, and in so doing, damage the body's defence mechanisms. The rationale in the use of Veyonda[®] is to work with the body's existing anti-cancer mechanisms, not against them.

1.1 Chemotherapy Enhancing Program (CEP): Veyonda[®] + cytotoxic chemotherapy.

The Company last quarter released the headline data from the Final Report on the CEP-1 Phase 1b clinical study. This study involved patients with heavily pre-treated, Stage 4, metastatic, progressive disease (breast, lung, ovarian, prostate cancers) that had stopped responding to standard therapies. The Company was pleased to note that of the 9 patients in this study given the higher dosage (800 mg) of Veyonda[®], 5/9 showed stable disease or better over the 8-month term of the study, an outcome regarded by the Company and its medical advisors as highly significant clinically given the advanced nature of disease in these patients. Just as importantly, this outcome was achieved with a low, better-tolerated dose of chemotherapy (carboplatin) designed to be less damaging to the body's immune system.

The Company now intends to take the CEP approach to the next level by testing a combination of Veyonda[®] and doxorubicin in sarcomas. Pre-clinical studies have confirmed that Veyonda[®] is as effective in combination with doxorubicin as it is with carboplatin; also, that Veyonda[®] is cytotoxic to sarcomas on its own, but even more so with additional doxorubicin.

This study is to be run in the U.S., with a start date of Q4 2019. The necessary Medical Advisory Board of sarcoma specialists has been assembled, and the Company is in discussion with the FDA.

1.2 Direct and Abscopal Response to Radiotherapy Program (DARRT): Veyonda[®] + external beam radiotherapy.

The Company last quarter released interim data from the first 12 patients enrolled in the DARRT-1 Phase 1b study. This study has enrolled men with end-stage prostate cancer that is castrate-resistant, metastatic, progressive and without any remaining standard treatment options. These men are eligible for palliative (low dose) radiotherapy intended to shrink individual lesions causing pain or compression. Multiple studies have shown that palliative radiotherapy has no meaningful effect on the course of the disease or on survival outcomes.

In this study, the radiotherapy is applied to a single lesion, with the objective of using the immuno-oncology functions of Veyonda[®] to drive a local immune response within the irradiated lesion, triggering a more general immune response that results in shrinkage of both the irradiated lesion and the non-irradiated lesions in the body. The latter is known as an *abscopal effect*, and can be partial (some lesions responding) or complete (all lesions responding).

The interim data came from the initial dose-finding arm of the Study involving 3 cohorts of 4 men receiving different dosages of Veyonda[®] - 400, 800 and 1200 mg daily. This study, in addition to the CEP-1 study, lead the Company to the view that the 400 mg dose is sub-therapeutic. Of the 8 patients in the 800 and 1200 mg cohorts, at 3 months only 1 patient had progressed (RECIST 1.1 criteria), while 7/8 had achieved disease control¹ (1 partial responder and 6 stable disease). Four of the 7 patients with disease control showed falls in PSA levels >50% (51-78%) and 5/7 reported falls in pain levels >30% (52-92%). As with the CEP data, the Company believes that this data is significant, given the advanced stage of disease in these patients.

The **6-month data** from these same 12 patients is due to be reported on in **early-May 2019**.

The ultimate goal of the DARRT treatment regimen in prostate cancer is to provide a material symptom-free survival benefit to men with progressive Stage 4 cancer who normally would have a limited life-span characterized by growing pain and disability. In DARRT-1, the Company is testing a very short and non-intrusive course of treatment (10-days Veyonda[®] + 5-days low-dose radiotherapy to a single lesion) for its ability to stop disease progression, particularly

progression of the boney lesions that form the bulk of the disease in end-stage prostate cancer. The Company is looking particularly for evidence of significant falls in PSA levels (> 50% decline) and pain scores (> 30%) at 3 and 6 months as surrogate markers of likely extension of progression-free survival.

This program remains the Company's signature program and an anticipated eventual approved clinical indication. The follow-up study is proposed for 2020. Planning also is underway to take the DARRT regimen into earlier stage prostate cancer in the hope of delaying or even avoiding the need for therapies such as chemical castration with its attendant side-effects.

1.3 Lutetium-PSMA and Veyonda® Program (LuPIN): Veyonda® + ¹⁷⁷Lutetium-PSMA-617.

The LuPIN study is a 32-man Phase 1b study testing whether Veyonda® can increase the response rate to the radiopharmaceutical, ¹⁷⁷Lutetium-PSMA-617 (Novartis), in subjects with the same end-stage prostate cancer as being enrolled in the DARRT-1 study. This study is fully enrolled, with interim data from the first 16 patients to be presented to the Annual Meeting of the Society of Nuclear Medicine and Molecular Imaging in Anaheim, CA, in **late-June 2019**.

¹ *Disease control = complete responses + partial responses + stable disease*

2. Pre-Clinical Programs

The Company's two key pre-clinical programs are:

- a) studies to better define the immuno-oncology functions of Veyonda® and its ability to induce an abscopal response; and
- b) a drug discovery program centered on drugs targeting interleukin-1 receptor associated kinase 4 (IRAK4) and tumour progression locus 2 (TPL2).

3. Nyrada Inc

Nyrada Inc is the U.S.-registered, majority-owned (67%) subsidiary of Noxopharm that holds the Group's non-oncology assets. Nyrada has four early-stage R&D programs. Nyrada currently is engaged in strategic discussions that the Company hopes to be able to announce shortly.

4. Management

Greg van Wyk MB BCH, BBA, MEd assumes the joint roles of Chief Executive Officer and Chief Medical Officer and is building a clinical team of experienced ex-major pharmaceutical company executives ahead of the increase in the clinical program commencing late-2019:

- Gisela Mautner MD PhD MPH MBA FACPE has been appointed Global Medical Director
- Beata Niechoda MB BS, MBA, PhD joins the Board as a Special Advisor on the pharmaceutical industry.

Ms. Jeanette Bell BMedSc MScM has been appointed as Chief Operating Officer with particular responsibility for the logistics associated with the expanding clinical program.

The executive team also contains John Wilkinson PhD, Chief Scientific Officer, and Mr Shawn van Boheemen, Chief Financial Officer.

5. Board

Graham Kelly moves from Group CEO to Executive Chairman, with Peter Marks moving from Non-Executive Chairman to Non-Executive Deputy Chairman. This change was triggered by the Company's decision to seek a listing on the Nasdaq exchange later in 2019, a key plank in the aim of raising the Company's profile in the U.S. and to shift most of its clinical program to the U.S. As Executive Chairman, Graham will be devoting more time to overseeing the potential U.S. listing process ('**Potential Secondary Listing**') and the resulting interaction with the U.S. capital markets.

6. Funding

The Company ended the March quarter with a Group consolidated cash reserve of AUD\$6.2 million. This cash position is expected to provide the Company with sufficient funds to continue with its current planned research, clinical and business activities over the short-term. At the same time, the

Board constantly monitors the cash position in relation to the budget as well as prevailing market conditions and will select a time and means which it considers most appropriate and beneficial for all shareholders in relation to the securing of additional funding.

The Company has a total of 122,601,393 shares on issue at 31 March 2019.

About Noxopharm

Noxopharm is a clinical-stage Australian drug development company with offices in Sydney, New York and Hong Kong. The Company has a primary focus on the development of drugs based on a flavonoid chemical structure, with Veyonda® the first pipeline product. Non-oncology indications are under development in subsidiary company, Nyrada Inc.

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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 2019

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers		
1.2 Payments for		
(a) research and development	(1,491)	(4,608)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(22)	(65)
(d) leased assets	-	-
(e) staff costs	(1,165)	(3,098)
(f) administration and corporate costs	(676)	(1,974)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	24	90
1.5 Interest and other costs of finance paid	(3)	(11)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	3,264
1.8 Other (Listing process costs)	-	-
1.9 Net cash from / (used in) operating activities	(3,333)	(6,402)
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) property, plant and equipment	-	(7)
(b) businesses (see item 10)	-	-
(c) investments	-	-

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 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	-	(7)

3. Cash flows from financing activities		
3.1 Proceeds from issues of shares	-	-
3.2 Proceeds from issue of convertible notes	-	-
3.3 Proceeds from exercise of share options	-	75
3.4 Transaction costs related to issues of shares, convertible notes or options	(17)	(17)
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	(17)	58

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	9,589	12,612
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(3,333)	(6,402)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	-	(7)
4.4 Net cash from / (used in) financing activities (item 3.10 above)	(17)	58

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
4.5	Effect of movement in exchange rates on cash held	(14)	(36)
4.6	Cash and cash equivalents at end of quarter	6,225	6,225

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	1,147	2,990
5.2	Call deposits	5,001	6,501
5.3	Bank overdrafts		
5.4	Other		
	- business debit cards	77	98
	- bank balances (held in trust)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	6,225	9,589

6. Payments to directors of the entity and their associates

- 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

Current quarter \$A'000
308
-

Director fees and salary for executive director and related parties.

7. Payments to related entities of the entity and their associates

- 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

Current quarter \$A'000
-
-

8. Financing facilities available <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. Estimated cash outflows for next quarter	\$A'000
9.1 Research and development	950
9.2 Product manufacturing and operating costs	150
9.3 Advertising and marketing	45
9.4 Leased assets	-
9.5 Staff costs	1,250
9.6 Administration and corporate costs	500
9.7 Other (provide details if material)	-
9.8 Total estimated cash outflows	2,895

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)

26 April 2019
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.