



Date: 26 October 2018

Sydney, Australia

ASX: NOX

Noxopharm Limited

ABN 50 608 966
123

**Registered Office
and**

Operational Office:

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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 – SEPTEMBER 2018 QUARTER

Sydney, 26 October 2018: Noxopharm (ASX: NOX) today releases its Appendix 4C for the quarter ended 30 September 2018, as well as providing guidance on the next 12-18 months.

This report is presented in the context of the Company's overriding objective which is to bring its lead pipeline drug, Veyonda[®], to market in 2022 as a standard companion drug to radiotherapy in the management of many forms of cancer.

Current clinical studies in men with progressive, late-stage prostate cancer point to a combination of Veyonda[®] and radiotherapy providing patients with improved outcomes over standard care. Accordingly, the Company believes that Veyonda[®] has the potential to transform the practice, not just of the treatment of prostate cancer, but of cancer therapy in general and in so doing become one of the most widely-used drugs in oncology.

The Company has put in place a strategy designed to realise that potential in the shortest possible timeframe and with the least amount of expenditure and shareholder dilution as possible. It also is pursuing a patent strategy expected to provide a commercially meaningful level of IP protection.

1. September Quarter 2018

The key areas of progress reported this quarter were:

- Release of interim clinical data from the DARRT-1 study reporting both on the tolerance of a combination of Veyonda[®] and radiotherapy, and the encouraging evidence of clinical signals of efficacy in patients
- Expansion of the LuPIN study from 16 to 32 patients at the request of the clinical investigators
- Pre-clinical evidence to support the potential benefit of using Veyonda[®] in combination with radiotherapy as a treatment in children with a form of brain cancer known as diffuse intrinsic pontine glioma (DIPG)
- Discovery in the NOX isoflavonoid drug program of a potentially new family of drugs targeting key signalling proteins involved in chronic inflammation and autoimmune diseases
- Progress with NYX-330, one of the non-oncology assets in the Company's subsidiary, Nyrada Inc. NYX-330 is being developed to treat high blood cholesterol levels.

2. Veyonda®

2.1 Veyonda® - approaching the registration stage

The Company is focusing its efforts on bringing Veyonda® to market as an enhancer of externally delivered radiotherapy using the DARRT regimen. DARRT is Direct and Abscopal Response to RadioTherapy. It involves adding Veyonda® to radiotherapy to treat late-stage, metastatic disease where the primary intention of radiotherapy is to be palliative, i.e. seeking to provide temporary relief of symptoms such as pain, with no real expectation of increasing survival times. Typically, palliative treatment involves irradiating between 1 or 2 larger tumours over 5 days. Adding Veyonda® to that treatment aims to shift the response from palliative (temporary, partial response of irradiated tumours) to more curative (complete response of irradiated tumours and partial/complete responses of non-irradiated tumours).

The current DARRT-1 study is a Phase 1b study in men with metastatic castrate-resistant prostate cancer. This means that they have secondary lesions that have stopped responding to standard anti-androgen (hormone) treatment. This study is designed to (i) provide the justification for conducting a final study in late-stage prostate cancer, (ii) confirm an acceptable level of safety of the treatment, and (iii) determine the appropriate therapeutic dosage of Veyonda®. The full complement of 24 men in DARRT-1 is expected to be fully recruited by the end of January 2019; interim data is expected to be reported in December 2018; 12- and 24-week data that will form the basis of a final protocol design is expected to be available by mid-2019.

As reported in the last quarter, dosages of 400 mg and 800 mg of Veyonda® in combination with 20-30 Gy of external beam radiotherapy have been well tolerated. Importantly, those combinations in men with progressive late-stage prostate cancer have produced evidence of a halt in disease progression, including abscopal responses. The study currently is using the highest dosage of 1200 mg, the dosage that we anticipate being the therapeutic dosage.

The Company sees the next and final trial of Veyonda® as having the following features:

- A double-blinded, controlled, adaptive trial design, starting with Phase 2 study that converts into Phase 3
- commencing H2 2019 and likely running until early-2021 and involving an anticipated 300-700 patients (depending on the strength of response seen in DARRT-1)
- being conducted in men with metastatic castrate-resistant prostate cancer
- using the 3-week DARRT treatment regimen of Veyonda® and palliative radiotherapy to 1-2 lesions
- seeking to boost the cancer-killing effect of radiotherapy and shift its outcome from a palliative treatment to a more curative outcome including the induction of abscopal responses in a high proportion of men
- with main end-points anticipated being Progression-Free Survival and Overall Survival
- a multi-national study to be conducted in Australasia, North America, EC and certain South-East Asian countries.

Planning for this final stage trial is underway with the recent appointment of an international CRO.

2.2 Veyonda® - IND

The Company has initiated the process of obtaining Investigational New Drug (IND) approval for Veyonda® from the US Food and Drug Administration (FDA). A key step in that approval process is to conduct a Phase 0 pharmacokinetic study in healthy subjects. A Phase 0 study is to be done in Australia in Q1 2019. Achieving IND status will mean that US clinics can participate in the proposed Phase 2/Phase 3 registration study.

2.3 Veyonda® - the broader DARRT program

While the Company sees Veyonda® coming to market in the first instance with approval for the treatment of late-stage prostate cancer, we obviously want to see it used broadly in combination with radiotherapy across many forms of cancer, including cancers where radiotherapy is not currently a first choice. To that end, the Company is running a strategy intended to provide evidence of utility across a broad spectrum of cancers. This strategy will involve a number of Phase 2 studies where the objective is to generate published data available for later marketing purposes, without necessarily taking each application through to a registration trial.

This broader program is targeting 3 cancer types: lung cancer, sarcomas, and primary brain cancer. Lung cancer because of its prevalence and therefore large need; sarcomas because of their rarity and therefore ability to lead to Orphan Drug status; brain cancer because Veyonda® crosses the blood-brain barrier and therefore is in a very small category of drug molecules capable of reaching brain cancer cells. Orphan Drug status carries important marketing and IP advantages.

DARRT-2 will be in patients with late-stage (non-small cell) lung cancer who have failed all standard treatment options including standard chemotherapy and immunotherapies. As with the DARRT-1 study, DARRT-2 patients will have metastatic disease with 1-2 tumours exposed to radiation in the presence of Veyonda®. The aim being to induce both complete remission of the irradiated tumours and partial to complete abscopal responses in the non-irradiated tumours. The Company is aiming to start this study in Q2 2019 and to run it in Australia and NZ.

DARRT-3 will be in sarcomas, a rare form of cancer involving the body's connective tissues (bone, fat, muscle, blood vessels, nerves) and comprising about 5% of all cancers in adults and 15% in children. Sarcomas in general are very poorly responsive to chemotherapy and radiotherapy. The Company is aiming to start this study in Q2 2019 and to run it in Australia and a number of South-East Asian countries.

The third program (currently pre-clinical) concerns primary brain cancer in both adults and children. Veyonda® has already been shown to enhance the cancer-killing effect of radiation both with glioblastoma multiforme (GBM) adult brain cancer cells and DIPG paediatric brain cancer cells in vitro. Current studies are seeking to repeat that effect in animals and, if successful, will lead into clinical studies in due course in GBM and DIPG.

Radiotherapy is a standard first-line treatment in many forms of brain cancer, but rarely is curative. By adding Veyonda® to radiotherapy, our aim is to achieve a greater response to radiotherapy without compromising brain function.

2.4 Veyonda® - the LuPIN program

The LuPIN program (Lutetium-PSMA In Combination With Veyonda®) involves the use of Veyonda® to enhance the cancer-killing effect of radiation injected intravenously, as opposed to the externally-delivered radiation in the DARRT program.

The radiation is in the form of a radioactive isotope (¹⁷⁷lutetium) attached to a peptide (PSMA- 617) that seeks out and attaches to prostate cancer cells. ¹⁷⁷lutetium-PSMA- 617 is an experimental drug that currently is the subject of a global Phase 3 registration study in 700 men with metastatic castrate-resistant prostate cancer. With only about 50% of men reportedly showing a response to this therapy, and with a response of only modest duration in most responders, the LuPIN study is testing the theory that adding Veyonda® will result in a higher response rate and a more durable response. That result potentially would add considerable weight and value to the use of ¹⁷⁷lutetium-PSMA- 617 therapy.

LuPIN is an Investigator-Initiated study being run at St Vincent's Hospital Sydney. It will enrol a total of 32 men, with enrolment expected to be completed by end of January 2019. Currently 18 patients

have been enrolled. Cohort 1 (8 patients) received 400 mg Veyonda[®]; Cohort 2 (24 patients) is receiving 800 mg Veyonda[®].

2.5 Veyonda[®] - chemo-enhancing program (CEP)

As already stated, the Company's current focus is on bringing Veyonda[®] to market as a radio-enhancer. However, we also have looked at its ability to enhance the anti-cancer activity of chemotherapy by conducting a Phase 1b study (CEP-1) of Veyonda[®] in combination with carboplatin in late-stage cancer patients. The purpose of that study was to see if Veyonda[®] could boost the anti-cancer activity of carboplatin enough to allow the dosage of carboplatin to be lowered to a less toxic level. Interim data has already been released suggesting that that has been achieved. The final data is expected to be released in November and the Company believes that the final data will support a possible role of Veyonda[®] as an enhancer of chemotherapy, particularly in patients where life-threatening side-effects of chemotherapy are a barrier to its use.

2.6 Veyonda[®] - manufacture and IP

An important clinical support development has been the successful commissioning of a GMP-quality manufacturing facility to support the final stage of clinical development and a commercial launch.

An important commercial development has been the issuance of a report by the International Patent Examiner clearing the way for progression of a family of patents relating to Veyonda[®] into the national phase in a wide variety of countries.

3. Non-Oncology Program

The Company aims to grow into a traditional biopharmaceutical company with a pipeline of drugs across a range of therapeutic indications. It hopes to achieve this in large part through its isoflavonoid drug technology platform where it sees itself having a world-leading position. Isoflavonoids have long held promise as potential therapeutic agents, but their development has been hindered by a number of chemical features that challenge their drugability. Noxopharm believes that it has proprietary know-how and patentable IP able to overcome those hindrances.

Currently it has 3 identified drug candidates, with a fourth discovery program underway that it anticipates generating 2-3 further drug candidates. The 3 identified assets are NYX-104, NYX-205 and NYX-330.

- **NYX-104.** This first-in-class isoflavonoid molecule is being developed as a neuroprotectant to protect the brain from glutamate-induced excitotoxicity (secondary brain damage) following stroke or concussion. This program is in *lead optimisation* phase, meaning that we have identified the final compound and now are seeking to optimise its activity.
- **NYX-205.** This is another first-in-class isoflavonoid molecule being developed as an anti-inflammatory drug capable of crossing the blood-nerve barrier to treat peripheral neuropathies associated with diabetes and cancer chemotherapy. This program has identified the final drug candidate which is about to go into animal studies.
- **NYX-330.** This first-in-class small molecule (not an isoflavonoid) that inhibits binding between the plasma protein, PCSK9, and the LDL-cholesterol receptor. It is being developed to be used in combination with the statin family of drugs to achieve target LDL cholesterol levels in individuals with high cholesterol levels. It is intended to be taken orally. This program also is in *lead optimisation* phase.

4. Funding

The Company finished the September quarter with Group consolidated a cash reserve of **AUD\$9.63 million** which, in combination with the anticipated Federal Government R&D Rebate Scheme funds, is expected to provide the Company with sufficient funds to continue with its current planned business activities in the medium-term. In addition, and importantly, the Company also intends seeking non-dilutive funding for DARRT-3 and the 3 current non-oncology drug programs, each of which are in

areas of significant unmet need and open to funding by government departments and publicly-funded foundations. It should be noted that at this stage, no commitment has been made by the Company to raise additional capital. It will however consider the various options open to it over the next 9 months and put in place a capital raising strategy that the Board believes balances the best interests of all shareholders with the Company's ability to fund all key programs with minimal dilution.

5. Infrastructure

The Company expects to be making a number of key executive appointments over the next 12-18 months as it transits into a pre-commercial phase with the need to have an experienced team preparing for commercialisation. The first of these was made recently with the appointment of a Chief Medical Officer, a key position in light of the expanding clinical trial program.

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About Noxopharm

Noxopharm is a Group comprising Noxopharm Ltd, Nyrada Inc, and NoxAsia Ltd with offices in Sydney, New York and Hong Kong. The Group's drug pipeline contains 4 drug candidates: Veyonda[®], NYX-104, NYX-205, NYX-330. Veyonda[®] is being developed as an enhancer of radiotherapy across a range of cancers being treated with both standard external beam radiotherapy and intravenous radionuclide (¹⁷⁷lutetium-PSMA-617) therapy; NYX-104 is a neuroprotectant being developed to limit secondary brain damage (glutamate-induced excitotoxicity) following ischaemic stroke and concussion; NYX-205 is an anti-inflammatory being developed for the treatment of peripheral neuropathy associated with diabetes and chemotherapy; NYX-330 is a PCSK9 inhibitor being developed for the treatment of high blood LDL cholesterol levels that fail to respond adequately to statin therapy alone.

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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")

30 September 2018

Consolidated 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	(1,491)	(1,491)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(21)	(21)
(d) leased assets	-	-
(e) staff costs	(929)	(929)
(f) administration and corporate costs	(617)	(617)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	24	24
1.5 Interest and other costs of finance paid	(4)	(4)
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	(3,039)	(3,039)
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) property, plant and equipment	(4)	(4)
(b) businesses (see item 10)	-	-
(c) investments	-	-

Consolidated 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	(4)	(4)

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	75
3.4 Transaction costs related to issues of shares, convertible notes or options	-	-
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	75	75

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	12,612	12,612
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(3,039)	(3,039)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(4)	(4)
4.4 Net cash from / (used in) financing activities (item 3.10 above)	75	75

Consolidated 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	(13)	(13)
4.6	Cash and cash equivalents at end of quarter	9,631	9,631

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	3,031	2,521
5.2	Call deposits	6,500	10,001
5.3	Bank overdrafts		
5.4	Other		
	- business debit cards	100	90
	- bank balances (held in trust)		-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	9,631	12,612

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
281
-

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	(1,930)
9.2 Product manufacturing and operating costs	-
9.3 Advertising and marketing	(130)
9.4 Leased assets	-
9.5 Staff costs	(970)
9.6 Administration and corporate costs	(420)
9.7 Other (provide details if material)	-
9.8 Total estimated cash outflows	(3,450)

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: 
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(Company secretary)

26 Oct 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.