



Date: 30 October 2019

Sydney, Australia

ASX Limited
20 Bridge Street
SYDNEY NSW 2000

APPENDIX 4C - SEPTEMBER 2019 QUARTER

- Clinical data from DARRT-1 Study continues to support the Company's confidence in Veyonda® becoming a major new anti-cancer agent for prostate cancer
 - Company now planning final stage of development of Veyonda® to commence in 2020
 - Major opportunity to position Veyonda® as an important new immuno-oncology drug based on unique sphingosine-1-phosphate inhibitory/STING agonist actions
 - Executive team re-structured in preparation for anticipated significant corporate growth
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Sydney, 30 October 2019: Noxopharm (ASX: NOX) today releases its Appendix 4C for the quarter ending 30 September 2019, as well as providing guidance for the next 12 months.

1. Veyonda® Clinical Program

The Veyonda® clinical program strategy continues to be refined, with the treatment of prostate cancer in combination with radiotherapy the Company's primary focus.

This last quarter delivered positive 3-month post treatment data for all 22 men in the DARRT-1 study with evaluable disease, 'evaluable' meaning that we were able to measure all 3 primary indicators of an anti-cancer response - PSA response, pain response, and disease status by RECIST (radiographic measure of tumour dimensions and tumour numbers). We saw no disease progression in 73% men, and significant pain relief in at least half of the men. Given the late stage and progressive nature of disease in these men, that is a highly encouraging outcome that augurs well for a positive outcome in a larger clinical study.

The positive clinical signals and well-tolerated nature of the DARRT treatment regimen has given the Company the confidence to expedite the development of Veyonda® by seeking to move directly into a registration study. Noxopharm currently is planning the DARRT-2 study, a Phase 2/Phase 3 adaptive, two-arm, double-blind study capable of leading to marketing approval. The aim is to commence this study in H2 2020. Australian and U.S. medical advisory boards comprising eminent oncologists and radiation oncologists specializing in the treatment of



prostate cancer have been convened and met in the quarter, the necessary vendors are in the process of being appointed, and large-scale drug manufacture is being undertaken.

The second radiotherapy approach is the LuPIN study, where Veyonda® is being used in combination with radiopharmaceutical, ¹⁷⁷lutetium-PSMA-617, again in late-stage prostate cancer. The recruitment of the 1200 mg dose-expansion arm continued this quarter, with recruitment of all 56 men on-track to be completed before the end of 2019. Like DARRT-1, the LuPIN study continues to deliver highly encouraging data in terms of response rates and tolerability. The LuPIN study is distinguished from other studies looking at ¹⁷⁷lutetium-PSMA-617 therapy in that LuPIN is using men with more advanced disease and following more lines of chemotherapy. Each subsequent line of therapy leads to a more advanced disease state and a cancer likely to be less responsive to any form of treatment. Given this, the high response rates being seen in LuPIN are highly encouraging.

This puts the Company in the unique position of having potentially two transformative treatments for late-stage prostate cancer.

2. The science behind Veyonda®

Veyonda® potentiates low-dose radiation treatment to produce an apparent anti-cancer response in both irradiated and non-irradiated tumours. We have known for some years that Veyonda® works at least partly by blocking a vital pro-survival messenger in cells known as sphingosine-1-phosphate (S-1-P). S-1-P has long been recognized as a key tool that cancer cells use to stay alive, to spread, to grow into large tumours, and to develop resistance to chemotherapy and radiotherapy. Now recent research shows that S-1-P also plays an important role in how cancer cells switch off the patient's immune system to prevent the patient's immune system from clearing the cancer. As a result, the search for S-1-P inhibitors has become a major focus in the pharmaceutical industry.

3. Veyonda® and immuno-oncology drugs

Immuno-oncology drugs have attracted a lot of attention in recent years. Whilst some patients benefit from immuno-oncology drug treatment, a substantial portion do not.

There is the potential for Veyonda® to work as an inhibitor of S-1-P , selectively on cancer cells, to potentiate treatment with other immuno-oncology drugs such as immune checkpoint inhibitors.



One such application is our IONIC program, where we plan on using Veyonda® to see if patients with lung cancer will respond to one of the immune checkpoint inhibitors (a class of immunology drugs) where there is no response to those inhibitors alone.

The planning for IONIC-1 is underway with a start mid-2020 the objective.

The Company sees this is an exciting opportunity given the considerable current global effort to find ways of increasing the relatively poor response rates to checkpoint inhibitors in most cancers.

4. Other clinical trials

Beyond, DARRT-2, LuPIN and IONIC-1 clinical trials, a further two trials will be conducted in 2020:

- The CEP-2 study (Veyonda® + doxorubicin) involving patients with soft tissue sarcomas is due to start once the FDA grants an Investigational New Drug (IND) approval for that use. The IND submission is expected to be lodged in November 2019
- A small Phase 1a pharmacokinetic study has been approved to be run in Australia early-2020. The data from this study will be crucial in supporting an IND application for DARRT-2.

The clinical program is under the supervision of Dr Gisela Mautner, Chief Medical Officer. Dr John Wilkinson, Chief Scientific Officer, and his team are providing the necessary logistical support in the task of conducting a large clinical trials program including a likely registration study across 3-4 continents.

5. Research Pipeline

Three R&D programs are current and under active research.

- (a) The development of an inhibitor of glutamate-activated ion channel activity in the treatment of glioblastoma multiforme (GBM). This is the most advanced of all three pipeline programs. This program has been triggered by recent research showing that GBM cancer growth is driven by glutamate, the main neurotransmitter in the brain. The Company is collaborating with its subsidiary, Nyrada, on this program. Several potential lead candidate compounds have been identified, and the process of selecting the lead is underway.
- (b) The development of a chemotherapy drug capable of killing cancer stem cells. The Company has a potential lead candidate compound and currently is looking to incorporate this compound into its LIPROSE drug delivery system.
- (c) The third program involves the development of chemotherapy drugs against IRAK4 and TPL2 molecular targets. Melanoma and leukemias are the likely clinical targets.



The drug pipeline program is being supervised by Director of Drug Development and Research, Dr Olivier Laczka.

6. Board

The Board recently lost non-executive director, Dr Beata Edling, due to family reasons. Beata had made a significant contribution to the Board and will be missed. The Board has elected not to replace Beata at this time. With a pending dual listing coming in 2020, there is likely to be a need to expand the Board with a number of independent U.S.-based directors.

7. Nyrada Inc

As the majority owner, Noxopharm has continued to support the development of its spin-off subsidiary in the last quarter, both financially and through access to resources. The potential IPO of Nyrada is progressing well and Perth-based Alto Capital has been appointed as Lead Manager.

The Company will continue to update Noxopharm shareholders as details become available.

8. Funding

The Company finished the quarter with \$4.673 million in cash. This, along with access to a funding facility up to the value A\$26 million, is expected to provide the Company with sufficient funds to continue with its planned business activities over the short-term.

The Board constantly monitors the cash position in relation to the budget and prevailing market conditions and will augment its cash reserves at an appropriate time.

About Noxopharm

Noxopharm is a clinical-stage Australian drug development company with offices in Sydney and New York. The Company has a primary focus on the development of Veyonda® and is the major shareholder in Nyrada Inc, a spin-off company developing a pipeline of non-oncology drugs.

www.noxopharm.com

Investor & Corporate Enquiries

Media Contact Australia

Prue Kelly

M: 0459 022 445

E: Prue.Kelly@noxopharm.com

Company Secretary:

David Franks

T: +61 2 9299 9690

E: David.Franks@automicgroup.com.au



Media Contact USA:

Frank de Maria

Purposeful Communications

T: +1 347 647 0284

E: frank.demaria@purposefulcommunications.com

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 2019

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	(2,036)	(2,036)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(42)	(42)
(d) leased assets	-	-
(e) staff costs	(1,284)	(1,284)
(f) administration and corporate costs	(1,261)	(1,261)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	1	1
1.5 Interest and other costs of finance paid	(5)	(5)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	3,762	3,762
1.8 Other (Listing process costs)	-	-
1.9 Net cash from / (used in) operating activities	(865)	(865)
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) property, plant and equipment	-	-
(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	-	-

3. Cash flows from financing activities		
3.1 Proceeds from issues of shares	600	600
3.2 Proceeds from issue of convertible notes	2,300	2,300
3.3 Proceeds from exercise of share options	-	-
3.4 Transaction costs related to issues of shares, convertible notes or options	(253)	(253)
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	2,647	2,647

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	2,910	2,910
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(865)	(865)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	-	-
4.4 Net cash from / (used in) financing activities (item 3.10 above)	2,647	2,647

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	(19)	(19)
4.6	Cash and cash equivalents at end of quarter	4,673	4,673

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	2,173	2,824
5.2	Call deposits	2,000	-
5.3	Bank overdrafts	-	-
5.4	Other	-	-
	- business debit cards	72	86
	- bank balances (held in trust)	428	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	4,673	2,910

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
287
-

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	1,100
9.2 Product manufacturing and operating costs	100
9.3 Advertising and marketing	40
9.4 Leased assets	-
9.5 Staff costs	1,200
9.6 Administration and corporate costs	500
9.7 Other (provide details if material)	-
9.8 Total estimated cash outflows	2,940

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)

30 October 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.