



ASX Announcement

31 January 2020

Noxopharm Dec 2019 Appendix 4C For the period ending 31 December 2019

- **DARRT-1 program delivers impressive results with 48% of men with Stage 4 prostate-cancer showing durable anti-cancer response at 6 months**
 - **NOX now proceeding to multi-national placebo-controlled DARRT clinical trial**
 - **LuPIN program also continuing to deliver impressive results, with all-important overall survival data on the first 32 men to be released mid-February 2020**
 - **Veyonda® on track to become breakthrough immunotherapy for late-stage cancers**
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SYDNEY, January 31, 2020: Noxopharm (NOX:ASX) today releases its Appendix 4C for the quarter ending 31 December 2019, as well as providing an outline of its activities for the upcoming period.

Noxopharm took a major step forward this quarter in bringing its frontline drug candidate, Veyonda®, towards gaining marketing approval, following confirmation of anti-cancer results in the DARRT-1 Phase 1b Study that Noxopharm considers ground-breaking. On the basis of that data, combined with the positive data continuing to come from the LuPIN Study, Noxopharm is confident that Veyonda® has the potential to become a standard of care drug in the treatment of late-stage cancers, starting with prostate cancer, and then expanding into other forms of solid cancer including breast, ovarian and lung.

Veyonda® Clinical Research

DARRT- 1

During the quarter, the DARRT-1 study reported strong efficacy signals in patients with advanced prostate cancer, with approximately half of men (10/21) with the disease responding to DARRT therapy. Given that the cancers in these men had progressed on all available therapies, this outcome represents a potential major advance in the management of this disease. Noxopharm and its advisors believe that this data provides proof of concept for the significant potential of DARRT treatment in late-stage solid cancers in general.

Importantly, Veyonda® was very well tolerated with no noteworthy drug-related adverse safety signals. An excellent safety profile is extremely important for regulatory authorities, as well as for patients who after having undertaken multiple rounds of often damaging chemotherapy, now are considering a salvage treatment option.

Based on these strong results, Noxopharm has commenced the process of initiating a multi-national Phase 2b study. This involves determining study design, patient population, number of patients, and selection



of trial sites and countries. This planning, under the direction of Dr Gisela Mautner is being undertaken in conjunction with the Company's medical Advisory Boards and regulatory advisors and is expected to take much of the rest of 2020.

The proposed study is projected to be a placebo-controlled study involving men with castrate-resistant prostate cancer that has progressed on two lines of taxanes (docetaxel, cabazitaxel) and androgen deprivation therapy (abiraterone or enzalutamide) and have visceral and/or bone metastases.

LuPIN

In November 2019, results of the LuPIN Phase 1 Study were publicly presented by the St Vincent's Hospital, Sydney clinical team undertaking the trial. The LuPIN Study showed that, within the limits of comparing data sets from different studies, combination treatment of Veyonda® + ¹⁷⁷LuPSMA-617 was considerably superior to monotherapy treatment with ¹⁷⁷LuPSMA-617 alone, in terms of:

- patients able to undergo a 4th treatment cycle without relapsing (69% vs 21%)
- progression-free survival (PFS) based on PSA levels (7.8 vs 3.4 months)
- survival estimation for PFS based on PSA.

The LuPIN Study is close to fully enrolling its 56 patients. Further clinical data including overall survival results for the first 32 men are being presented at the ASCO Genitourinary Cancers Symposium being held on 13-15th February 2020 in San Francisco, California. The significance of this upcoming data lies in pointing to whether the increased time to disease progression (based on PSA) previously reported through the addition of Veyonda®, will translate into longer survival, the paramount measure of efficacy set by regulators such as the U.S. Food and Drug Administration (FDA) agency.

Other research

Noxopharm is continuing to conduct research on Veyonda® with the aim of expanding its ultimate market reach. This is focusing on:

- confirming the role of Veyonda® as an immuno-oncology agent through its first-in-class inhibition of sphingosine-1-phosphate (S1P), a key regulator of immune function in tissues, with over-activity of S1P thought to be a prime factor in tumours being rendered 'cold' through the elimination of immune cells. The ability to restore immune function to tumours currently is a major objective in oncology
- confirming the role of Veyonda® in the treatment of cancers other than prostate cancer, including sarcomas and nasopharyngeal carcinoma, a major cancer in China with substantial unmet need and the opportunity for strategic alliances in China.



Pipeline

Noxopharm intends developing a pipeline of drug candidates as part of a strategy of expanding the profile of the Company in the global pharmaceutical industry.

The next drug beyond Veyonda® being sought is a potential ground-breaking project pursuing a novel agent to treat glioblastoma multiforme (GBM) through inhibition of glutamate-activated calcium ion channel activity, a process now believed to be a primary driver of the rapid growth of GBM.

Corporate & Financial

Board and Management Team

During the December quarter Noxopharm strengthened its executive management team with the following appointments:

- Dr Graham Kelly continued in the roles of Chief Executive Officer and Executive Chairman
- Mr Alex Hunter was appointed as Chief Commercial Officer
- Dr Gisela Mautner was promoted to Chief Medical Officer
- Mr Greg Ambra was appointed as Senior Vice-President North American Operations
- Dr Oliver Laczka was appointed as Director of Drug Discovery and Research

Jeanette Bell has resigned in order to establish a consultancy business and will continue to work with Noxopharm as a part-time contractor assisting the Company with project management of clinical workflow.

During the quarter, Dr Beata Edling resigned from the Board of Directors due to family reasons.

Corporate Finance

In December, Noxopharm secured an increase to its existing funding agreement with two New York institutional investors, Lind Global Macro Fund, LP and CST Investment Funds, comprising a A\$2.4m (face value) secured convertible security with a lock up period until end-March 2020.

This funding has allowed Noxopharm to continue its clinical and preclinical programs while it actively builds investor and banking relationships, secures Australian and U.S. research coverage and discusses with its corporate advisors the optimal funding option for its DARRT-2 Study.

As at 31 December 2019, Noxopharm had \$1.7M in cash and had a \$500K loan to subsidiary Nyrada Inc repaid on Feb 16 following that Company's successful IPO.



Net cash used in operating activities for the quarter amounted to \$4.1M, which is in line with previous quarters.

The Company is budgeting for a gradual increase in monthly expenditure as the business continues to work towards the commercialization of Veyonda® and responds to calls and opportunities for collaborations on clinical use of Veyonda®.

As announced previously, Noxopharm has secured access to a A\$26 million funding facility which it can avail itself of as required. However, to manage this rising need for development funding, Noxopharm has undertaken a strategic review of its future funding needs, past capital raising practices, and its relationships with investment banks, fund managers and other stakeholders in the US and Australia capital markets. In CY '20 Noxopharm plans to pursue more secure, longer-term relationships and sources of funds and is confident of securing those funds in the near future. Noxopharm will advise the market of these funding arrangements as soon as possible.

Nyrada Inc.

Noxopharm subsidiary Nyrada was listed on the ASX on 16th January 2020. Nyrada was established in 2017 to advance the non-oncology assets developed by Noxopharm, leaving Noxopharm free to concentrate on the development of Veyonda® and other oncology assets.

On a fully diluted basis, Noxopharm holds a 26.9% shareholding in Nyrada. Noxopharm is represented on the Nyrada board by Dr Graham Kelly and Mr Peter Marks in non-executive director roles.

Based on the Nyrada share price trading range at the date of this announcement, the implied market value of the Noxopharm shareholding in Nyrada is detailed in the table below.

Nyrada Share price trading range	Noxopharm shareholding*	Implied market value of NOX shareholding
\$0.215	45,373,845	\$9.8m
\$0.305		\$13.8m
<i>* Includes 33.4m CDI's and 12m performance shares</i>		

Corporate Outlook

Noxopharm has a priority in commercializing Veyonda® via the DARRT treatment regimen for metastatic castrate resistant prostate cancer (mCRPC) in men who are eligible for palliative radiotherapy. This is a major unmet need with a global market estimated to be approximately 300,000 patients p.a.

The objective is to offer a meaningful and durable anti-cancer effect in a high proportion of men who have no remaining standard treatment options and to do so in a convenient, well-tolerated and cost-effective way.



DARRT involves a combination of Veyonda® and a low (palliative) dose of external beam radiotherapy to provide dual effects of a strong radio-enhancing effect in the irradiated tumours and an immuno-oncology effect in non-irradiated tumours. The combination of these two properties aims at achieving an abscopal response, a treatment strategy now identified by the U.S. Government's National Cancer Institute as a major new direction in cancer therapy, with Noxopharm a major player in this emerging field.

<https://www.cancer.gov/news-events/cancer-currents-blog/2020/cancer-abscopal-effect-radiation-immunotherapy>

Noxopharm is confident that Veyonda® has the potential to deliver an abscopal response in a high proportion of patients with solid cancers, based on its ability to inhibit S1P, a key secondary messenger believed responsible for excluding immune cells from tumours.

While the initial focus is on prostate cancer, Noxopharm sees the current clinical program in mCRPC as providing proof-of-concept for future applications into other forms of solid cancer including breast, ovarian and lung. Noxopharm believes that Veyonda® has the potential to become standard of care for many forms of late-stage cancer, the largest sector of the oncology field, given that the bulk of patients with metastatic disease eventually develop end-stage disease despite ongoing improvements in survival.

In parallel, Noxopharm will continue with its LuPIN program, providing a complementary treatment option to DARRT for late-stage mCRPC. The LuPIN-1 Phase 2a clinical trial will continue for an estimated further 15-18 months and is designed to show if Veyonda® can increase both the response rate and the duration of the response to ¹⁷⁷lutetium-PSMA-617 therapy, an experimental drug owned by Endocyte Inc (Wholly-owned subsidiary of Novartis).

Dr Louise Emmett of St Vincent's Hospital Sydney will be delivering new interim LuPIN-1 data at the ASCO Genitourinary Symposium in San Francisco on the 13th February 2020.

In addition to these formal clinical trials, Noxopharm continues to make Veyonda® available on a compassionate basis for use with external beam radiotherapy or ¹⁷⁷lutetium-PSMA therapy. The Company is prepared to do this in part to help raise the profile of Veyonda® within the medical profession and in part to provide a treatment option where none currently exists.

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.

www.noxopharm.com

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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.

Authorisation: This release was authorised by Graham Kelly on behalf of the Board of Directors.

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 December 2019

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (6 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers		
1.2 Payments for		
(a) research and development	(1,811)	(3,847)
(b) product manufacturing and operating costs		
(c) advertising and marketing	(47)	(89)
(d) leased assets		
(e) staff costs	(1,196)	(2,480)
(f) administration and corporate costs	(1,046)	(2,307)
1.3 Dividends received (see note 3)		
1.4 Interest received	6	7
1.5 Interest and other costs of finance paid	(6)	(11)
1.6 Income taxes paid		
1.7 Government grants and tax incentives		3,762
1.8 Other (Listing process costs)		
1.9 Net cash from / (used in) operating activities	(4,100)	(4,965)
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 (6 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	100	700
3.2 Proceeds from issue of convertible notes	2,000	4,300
3.3 Proceeds from exercise of share options		
3.4 Transaction costs related to issues of shares, convertible notes or options	(491)	(744)
3.5 Proceeds from borrowings		
3.6 Repayment of borrowings	(515)	(515)
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	1,094	3,741

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	4,673	2,910
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(4,100)	(4,965)
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)	1,094	3,741

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
4.5	Effect of movement in exchange rates on cash held	(16)	(35)
4.6	Cash and cash equivalents at end of quarter	1,651	1,651

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	485	2,173
5.2	Call deposits		2,000
5.3	Bank overdrafts		
5.4	Other		
	- business debit cards	68	72
	- bank balances (held in trust)	1,098	428
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	1,651	4,673

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**

247

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	1,350
9.2 Product manufacturing and operating costs	
9.3 Advertising and marketing	30
9.4 Leased assets	
9.5 Staff costs	930
9.6 Administration and corporate costs	640
9.7 Other (provide details if material)	
9.8 Total estimated cash outflows	2,950

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:  Date: **31 January 2020**

(Company secretary)

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.