



ASX Announcement

30 April 2020

Quarterly Activities Report & Appendix 4C For the period ending 31 March 2020

- **Idronoxil confirmed as potent inhibitor of STING signaling pathway, extending potential clinical indications from cancer to septic shock**
 - **Company actively pursuing use of Veyonda® to treat septic shock deaths in COVID-19 patients**
 - **LuPIN Phase I/II clinical trial delivered impressive interim data including a Median Overall Survival of 17.1 months, an outstanding outcome for end-stage prostate cancer patients**
 - **Completion of recruitment for LuPIN with the final 24 patients now receiving treatment**
 - **DARRT clinical program advancing**
 - **Confirmation of abscopal responses in DARRT-1 patients**
 - **First IND granted for Veyonda® in sarcoma**
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SYDNEY, April 30, 2020: Noxopharm (ASX:NOX) today releases its Appendix 4C for the quarter ending 31 March 2020 as well as providing an outline of its activities for the period and guidance for the activities anticipated in the June quarter.

Dr Graham Kelly, Noxopharm CEO, said, "The March quarter was marked by three important developments. The first was the strong progress we made in our core business of developing Veyonda® as a new treatment for end-stage prostate cancer, including the recent announcement about seeing abscopal responses in 4 of 15 patients."

"The second was significant progress in the development of a drug pipeline, with the identification of a drug offering an exciting new approach to the treatment of brain cancer. As we strive to become a global player, a pipeline will become increasingly important."

"The third was a discovery by our research partner, the Hudson Institute of Medical Research, that one of the ways that idronoxil works as an anti-cancer agent is through blocking a tissue signalling pathway known as STING. But beyond contributing to our understanding of how idronoxil is working as an anti-cancer agent, blocking the STING signalling pathway also means it should be able to block the cytokine storm syndrome believed to be causing most deaths in COVID-19 patients. The Company has embraced this important opportunity and currently is seeking regulatory approval to use Veyonda® in a clinical trial in patients who are at-risk of multi-organ failure and acute respiratory distress syndrome associated with COVID-19 and other infections."



“We also terminated our convertible loan facility and reduced the convertible loan balance to zero. This marked an important transition as we enter a pre-commercial high-growth stage and adopt a strategy to access traditional equity funding arrangements.”

Dr Gisela Mautner, Noxopharm Chief Medical Officer, stated: “We are extremely pleased with our achievements in the March quarter. Our lead product candidate Veyonda[®] was granted Investigational New Drug (IND) approval by the U.S. Food and Drug Administration (FDA) for use in patients with soft tissue sarcomas. In addition, positive interim results and full recruitment were reported from the LuPIN Phase I/II clinical trial and we also made good progress on planning for our Phase 2b DARRT-2 study in 2021. We also are excited about formalising our clinical alliance with GenesisCare to offer Veyonda[®] under their compassionate care program which has already benefitted an increasing number of patients.”

Veyonda[®] Clinical Programs

DARRT Program

During the quarter, Noxopharm continued to advance its planning and preparations for the DAART-2 trial following the successful completion of the DARRT-1 trial in December 2019. Current planning includes finalising the design and size of the study, clinical endpoints, eligibility criteria and participating trial sites. The Company also has appointed a contract research organisation to advise on regulatory affairs.

The DARRT-2 trial is expected to commence in early 2021 and is designed to be a control-arm, multi-national, Phase 2 study that the Company sees as a basis for the commercialisation of Veyonda[®].

Furthermore, the Company’s clinical team is continuing to prepare the final report for DAART-1 which will examine whether further radiographic analysis of the measured lesions will provide further insights.

Looking ahead, Noxopharm will be presenting a DARRT-1 scientific poster presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting being held from 29 May to 2 June 2020. Last year’s meeting attracted 42,500 oncology professionals and while this year’s meeting will be conducted virtually, it continues to be one of the most prestigious oncology events in the world. A LuPIN poster presentation will also be presented by St Vincent’s Hospital, along with a Noxopharm study abstract relating to nasopharyngeal carcinoma.

LuPIN

In February 2020, Noxopharm announced positive interim results from the LuPIN phase I/II clinical trial which is being conducted in collaboration with St Vincent’s Hospital Sydney. The key efficacy findings were:

- Median Overall Survival for patients was 17.1 months, indicating a significantly longer survival duration than clinically expected
- 47% of patients (15/32) were well enough to receive all 6 cycles of therapy, indicating a durable response and enabling them to continue to receive treatment until the end of the study



- 87% of patients (28/32) had a fall in Prostate-Specific Antigen (PSA, an important marker for anti-cancer activity) and 62.5% (20/32) had a strong PSA response of over 50%
- Half (12/24) of the patients with severe pain at study start had a significant reduction of their pain due to the secondary tumours

Following the encouraging interim results, the LuPIN clinical trial reached an important milestone in March 2020, completing recruitment for the trial and bringing the total number of participating patients to 56.

Further LuPIN trial data will be presented in a poster presentation at the ASCO Annual Meeting with more data expected later this year.

US FDA Grants First IND for Veyonda

In February 2020, the FDA approved the first IND application for Veyonda® marking an important milestone for the Company. The IND approves a Phase 1b study involving a combination treatment of Veyonda® and doxorubicin in adults with soft tissue sarcomas and opens the opportunity for the use of Veyonda® in patients in the U.S. The company is seeking non-dilutive funding for this trial.

Compassionate use of Veyonda®

In February 2020, Noxopharm announced a clinical alliance with leading oncology services provider GenesisCare. The alliance formalises a program under which Noxopharm has been making Veyonda® available for compassionate use in combination with ¹⁷⁷Lu-PSMA therapy for patients with advanced, treatment-resistant, metastatic prostate cancer. This represents an important partnership for the Company as GenesisCare is one of the largest private providers of oncology services across Australia and Europe.

COVID-19 Program

Following the close of the quarter, Noxopharm announced its proposal to evaluate the use of idronoxil in patients at risk of multi-organ failure and acute respiratory distress syndrome (ARDS) associated with COVID-19 infection. This proposal was in response to the Hudson Institute of Medical Research showing that idronoxil exerted an anti-inflammatory action through potent inhibition of the STING (Stimulation of Interferon Genes) signalling pathway. STING plays a key role in detecting the presence of viruses in tissues, triggering the body's immune system to fight the virus and the body's inflammatory system to repair any tissue damage. In patients where the viral infection becomes overwhelming, the STING system can become hyper-active, triggering an excessive inflammatory reaction known as a 'cytokine storm' which leads to self-destruction of major organs in a process known as septic shock. Most deaths in patients with COVID-19 infection are believed to be due to septic shock.

In response to the evolving global pandemic, Noxopharm intends to test Veyonda® in a clinical trial as a potential cytokine storm inhibitor.



Intellectual Property Protection

During the quarter, Noxopharm announced that an Australian patent application for Veyonda® was allowed by the Australian Patent Office. The patent claims are directed to a suppository formulation including idronoxil and the allowed claims provide broad coverage for Veyonda® as a therapeutic.

The patent validates the Company's belief that Veyonda® has considerable potential commercial value and secures the Company's proprietary ownership.

More recently, Noxopharm lodged a provisional patent application to the Australian Patent Office for the use of idronoxil for early-stage organ damage associated with inflammation caused by viral or bacterial infection in order to prevent severe organ damage, ARDS and septic shock. This patent application relates to the use of idronoxil for the treatment of COVID-19.

Corporate & Financial

Board and Management Team

During Q3 FY20, the Company strengthened its Board by appointing Mr Boris Patkin as a Non-Executive Director. Mr Patkin replaced Dr Beata Niechoda who resigned from the Board of Directors in 2019 due to family reasons.

Corporate Finance

In February 2020, Noxopharm announced the termination of its convertible loan facility including the payment of \$4.085 m resulting in the reduction of the convertible loan balance to zero. In response to the buy back and termination notices issued by Noxopharm, The Lind Partners LLC and CST Investment Funds (the lenders) exercised their right under the convertible loan agreement to convert \$575,000 of convertible loan balance into shares. Noxopharm, in respect of this, issued 2.94m shares to the lenders.

As at 31 March 2020, Noxopharm had \$2.04m in cash. Net cash used for operating activities during the quarter amounted to \$3.1m, compared to \$4.1m in the quarter to December 2019. The company made payments for research and development of \$1.8m during the quarter.

An additional \$410,000 cash inflow was received from the conversion of collateral shares in April 2020. The company is planning a capital raising to be undertaken in the next 4 weeks, full details of this will be announced to the market when available.

Noxopharm continues discussions with stakeholders including investment banks and fund managers across Australia and the US to assess partnering and corporate finance options. The Company will continue to seek a range of funding options including non-dilutive funding for its Veyonda and COVID-19 programs.



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

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.

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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 cash flow report for entities subject to Listing Rule 4.7B

Name of entity

NOXOPHARM LIMITED

ABN

50 608 966 123

Quarter ended ("current quarter")

31 March 2020

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	(1,849)	(5,697)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(34)	(124)
(d) leased assets	-	-
(e) staff costs	(676)	(3,156)
(f) administration and corporate costs	(541)	(2,848)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	7
1.5 Interest and other costs of finance paid	(5)	(14)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	-	3,762
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(3,105)	(8,070)
2. Cash flows from investing activities		
2.1 Payments to acquire:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(d) investments	-	-
(e) intellectual property	-	-

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
(f) other non-current assets	-	-
2.2 Proceeds from disposal of:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	-	-
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-
2.3 Cash flows from loans to other entities	700	700
2.4 Dividends received (see note 3)	-	-
2.5 Other (deconsolidation of Nyrada Inc.)	(159)	(159)
2.6 Net cash from / (used in) investing activities	541	541

3. Cash flows from financing activities		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	3,087	3,787
3.2 Proceeds from issue of convertible debt securities	-	4,300
3.3 Proceeds from exercise of options	-	-
3.4 Transaction costs related to issues of equity securities or convertible debt securities	(202)	(946)
3.5 Proceeds from borrowings	4,200	4,200
3.6 Repayment of borrowings	(4,085)	(4,600)
3.7 Transaction costs related to loans and borrowings	(42)	(42)
3.8 Dividends paid	-	-
3.9 Other – Proceeds/(repayment) of intercompany loans	-	-
3.10 Net cash from / (used in) financing activities	2,958	6,699

4. Net increase / (decrease) in cash and cash equivalents for the period		
4.1 Cash and cash equivalents at beginning of period	1,651	2,910
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(3,105)	(8,070)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	541	541
4.4	Net cash from / (used in) financing activities (item 3.10 above)	2,958	6,699
4.5	Effect of movement in exchange rates on cash held	(7)	(42)
4.6	Cash and cash equivalents at end of period	2,038	2,038

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	2,038	485
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
	- Business debt cards	-	68
	- Bank balances held in trust	-	1,098
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	2,038	1,651

6. Payments to related parties of the entity and their associates

- 6.1 Aggregate amount of payments to related parties and their associates included in item 1
- 6.2 Aggregate amount of payments to related parties and their associates included in item 2

**Current quarter
\$A'000**

142

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Note: if any amounts are shown in items 6.1 or 6.2, your quarterly activity report must include a description of, and an explanation for, such payments

Director fees and salary for executive director and related parties.

7. Financing facilities

Note: the term "facility" includes all forms of financing arrangements available to the entity.

Add notes as necessary for an understanding of the sources of finance available to the entity.

	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 Total financing facilities	-	-

7.5 **Unused financing facilities available at quarter end** -

7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (Item 1.9)	(3,105)
8.2 Cash and cash equivalents at quarter end (Item 4.6)	2,038
8.3 Unused finance facilities available at quarter end (Item 7.5)	-
8.4 Total available funding (Item 8.2 + Item 8.3)	2,038
8.5 Estimated quarters of funding available (Item 8.4 divided by Item 8.1)	0.66

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

1. Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer: No - the operations have been significantly scaled back as a result of Covid 19 pandemic.

2. Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer: The company is planning a capital raising to be undertaken in the next 4 weeks, full details of this will be announced to the market when available. An additional \$410,000 cash inflow has been received from the conversion of collateral shares in April 2020.

3. Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

1. Answer: The company expects to be able to continue its operations and meet its business objectives through use of funding raised from the capital raising currently being planned.

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.

Date:30 April 2020.....

Authorised by:By the board.....
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow 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 cash flow 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.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.