ASX Announcement | 29 July 2020
Noxopharm Limited (ASX:NOX)

June Quarter 4C: Noxopharm advances Veyonda® into DARRT-2 and COVID-19 European study

Investment Highlights

- Lead drug candidate, Veyonda®, being progressed into multi-national Phase 2 trial (DARRT-2) in Stage 4 prostate cancer; on-schedule for commencement in Q1 2021
- Phase 1 pilot study (NOXCOVID) testing Veyonda in patients with early-stage respiratory distress associated with SARS-CoV-2 infection (COVID-19) on track to commence Q3 2020
- Idronoxil, the active ingredient in Veyonda, confirmed as achieving major goal of converting 'COLD' tumours to 'HOT' tumours, a significant industry development milestone
- Noxopharm remains well funded to continue progressing its clinical trials with A$7.1million cash at end of quarter

Clinical-stage Australian drug development company **Noxopharm Limited (ASX:NOX) ("Noxopharm"** or the **"Company")** is pleased to provide its Appendix 4C Quarterly Activities report for the period ending 30 June 2020.

During the quarter, Noxopharm remained focused on its priority of establishing its lead drug candidate, Veyonda, as an important new immuno-oncology drug. The Company also progressed to being on the verge of commencing a Phase 1 (pilot) study testing the ability of Veyonda to block or reduce cytokine storm development in patients with early-stage respiratory distress associated with SARS-CoV-2 infection (COVID-19).

Advancing the Veyonda commercial opportunity

Noxopharm has three active clinical programs underway, all based around the first-in-class dual action of Veyonda® (NOX66) as an inhibitor of both sphingosine-1-phosphate (S1P) and STING signalling.

1. **DARRT program**

DARRT is the Company's principal oncology program involving combination treatment of Veyonda® and externally-delivered radiotherapy.

The Phase 2 DARRT-2 study, following on from the successful DARRT-1 study, will be a multinational open label study involving about 200 men with Stage 4 metastatic castration-resistant prostate (mCRPC) who are receiving palliative therapy and are eligible for low-dose radiotherapy to help deal with pain and discomfort from 1 or 2 individual tumours.

The objectives of DARRT-2 will be to confirm:

- the optimal therapeutic dose of Veyonda;

- that the DARRT treatment regimen is well-tolerated;
- that the DARRT treatment regimen delivers a meaningful clinical benefit that is likely to lead to regulatory approval in a larger Phase 3 trial;

DARRT-2 is in the active planning stages, with the first patient anticipated being enrolled in Q1 2021. The Company regards DARRT-2 as its final goal, with a successful outcome leading to a partnership opportunity.

2. COVID-19 program

Noxopharm took significant steps towards starting a Phase 1b pilot study (NOXCOVID) testing Veyonda in patients with early-stage respiratory distress associated with COVID-19. This opportunity is based on evidence that one of the anti-cancer actions of Veyonda in blocking STING signalling potentially blocks or reduces the development of a cytokine storm and septic shock that occur in some COVID-19 patients.

The NOXCOVID study is to be conducted in up to 30 patients in several Eastern European hospitals.

The aim of this pilot study is to determine the safety of Veyonda in patients with moderate COVID-19 disease, and to determine the effect of Veyonda on a range of biomarkers including pro-inflammatory cytokines.

The Company hopes to recruit the first patient in September 2020, once it has received regulatory and ethics approvals, and to have concluded the treatment phase of the study before the end of the year.

The data from NOXCOVID will inform the Company's decision to potentially conduct a clinical trial of Veyonda in the U.S. in patients with SARS-CoV-2 (COVID-19) infection.

3. LuPIN program

The LuPIN treatment is targeting a similar patient group as in the DARRT program – end-stage mCRPC, but with distinctly different clinical characteristics. The LuPIN treatment regimen involves a combination of Veyonda and intravenously-administered radiotherapy in the form of ^{177}Lutetium-PSMA-617.

The LuPIN-1 study is a Phase 1b/2a investigator-initiated study in 56 men with end-stage mCRPC. The Company anticipates that ^{177}Lutetium-PSMA-617 (Novartis) in due course will receive marketing approval and become a standard form of therapy for metastatic prostate cancer. The objective of the LuPIN program is to see if Veyonda can improve the response rate to ^{177}Lutetium-PSMA-617, in particular, increasing the length of time men are able to remain on treatment with the intravenous radiotherapy.

This study is fully recruited with the last patient expected to finish the 9-month course of treatment in Q3 2020. The Company looks forward to seeing data updates progressively over the 12-month follow-up period.

Idronoxil achieves major goal

Post the quarter, pre-clinical data from two independent research groups confirmed that idronoxil, the active ingredient in Veyonda, achieved a major goal in restoring cancer-fighting immune function within 'COLD' micro-tumours by converting them to 'HOT'.

Other pre-clinical data held by the Company, together with new research data, indicates that Noxopharm may be close to claiming the first drug capable of converting 'COLD' tumours to 'HOT' tumours across multiple cancer types in a well-tolerated way.

This 'COLD' to 'HOT function is a major industry objective. The Company believes that commercialising a drug with such action would create a market arguably in excess of US$200bn per annum. The Company now is working to position Veyonda as a key component of that market.

Building a strong drug pipeline

Noxopharm is working to build a pipeline of drugs, with the purpose of growing the Company into a traditional biopharma company with multiple drug opportunities.

Two drug discovery programs are underway with important progress made this last quarter. The Company anticipates revealing details about these two programs in the coming quarter.

Corporate and Financial

The principal corporate activity this quarter was the successful conclusion of an entitlement issue that raised A$7,919,876. The issue was fully underwritten by Canaccord Genuity (Australia). The net proceeds to the Company after costs was A$7.33M. Apart from general running costs, the funds will be applied to the logistics of planning and setting up the DARRT-2 and running the NOXCOVID study.

As at 30 June 2020, Noxopharm had A$7.1m in cash. Net cash used for operational activities during the quarter amounted to A$2.7m, compared to A$3.1m in the quarter to March 2020. The company made payments for research and development of A$1.5m during the quarter.

In accordance with Listing Rule 4.7C, payments made to related parties and their associates included in items 6.1 of the Appendix 4C includes Director fees and salary (including superannuation) for executive directors and related parties.

Noxopharm CEO and Executive Chairman, Dr Graham Kelly said: "During the June quarter, we took some significant steps towards obtaining a return on our investment in Veyonda. We saw solid progress on three main fronts. First, following a review of the clinical data of the DARRT-1 study which showed clear evidence of Veyonda safely delivering clinical benefit, we immediately committed to planning for a Phase

2 DARRT-2 study. Second, after receiving independent advice that indicated Veyonda worked in a way that potentially could help COVID-19 patients avoid progressing from moderate disease into severe and potentially lethal disease, we committed to planning the Phase 1 NOXCOVID clinical study. Third, we obtained laboratory evidence confirming that Veyonda was stimulating the immune system in a way that is increasingly being recognised as a major goal in optimising the effectiveness of immuno-oncology drugs. On the corporate side of things, we also took the opportunity to replenish our cash position with a successful non-renounceable rights issue that raised A$7.9M before costs."

Graham Kelly, CEO and Chairman of Noxopharm, has approved the release of this document to the market on behalf of the Board of Directors.

-ENDS-

About Noxopharm
Noxopharm Limited (ASX:NOX) is an Australian clinical-stage drug development company focused on treating cancer with Veyonda®, its first drug candidate.

Veyonda® is a dual-acting oncotoxic and immuno-oncology drug designed to enhance the effectiveness and safety of standard oncology treatments, i.e. chemotherapy, radiotherapy and immuno-oncology drugs. The drug acts by harnessing the body's immune system to inflict damage on cancer cells throughout the body and has shown promise in treating a broad spectrum of cancers.

Noxopharm also has an active research and development program for additional drug candidates and is the major shareholder of US biotechnology company Nyrada Inc. (ASX:NYR).

To learn more, please visit: 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.

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity	
NOXOPHARM LIMITED	
ABN	**Quarter ended ("current quarter")**
50 608 966 123	30 June 2020

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(1,478)	(7,178)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(34)	(157)
	(d) leased assets	-	-
	(e) staff costs	(696)	(3,852)
	(f) administration and corporate costs	(543)	(3,391)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	7
1.5	Interest and other costs of finance paid	(6)	(19)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	72	3,834
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(2,685)**	**(10,756)**

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	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
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
2.4	Dividends received (see note 3)	-	-
2.5	Other (deconsolidation of Nyrada Inc.)	-	(159)
2.6	**Net cash from / (used in) investing activities**	**-**	**541**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	8,328	12,116
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	(606)	(1,553)
3.5	Proceeds from borrowings	-	4,200
3.6	Repayment of borrowings	-	(4,600)
3.7	Transaction costs related to loans and borrowings	-	(42)
3.8	Dividends paid	-	-
3.9	Other – Proceeds/(repayment) of intercompany loans	-	-
3.10	**Net cash from / (used in) financing activities**	**7,722**	**14,421**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	2,038	2,910
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,685)	(10,756)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	541

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	7,722	14,421
4.5	Effect of movement in exchange rates on cash held	19	(23)
4.6	**Cash and cash equivalents at end of period**	**7,094**	**7,094**

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	7,035	2,038
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details) - Business debt cards - Bank balances held in trust	59 -	- -
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**7,094**	**2,038**

6.	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	129
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

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)	(2,685)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	7,094
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	7,094
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	**2.64**

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: Yes, the Company has sufficient funding to run the business until early-2021

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 has put in place an R&D program that it believes represents appropriate use of shareholder funds and appropriate exploitation of the Company's opportunities. However, to sustain the anticipated growth in R&D activities, additional funding will be required within the next 6 months, and the timing, method and quantum of the next capital raise is the subject of ongoing discussions between the Board and potential funders

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

Answer: The Company believes it has sufficient working capital to meet its obligations and proposed business plans for the foreseeable future. Nevertheless, the Company will remain diligent in its oversight of its cash position and will take the necessary steps to ensure that it remains a viable business

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: 29 July 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.