**ASX Announcement | 15 October 2020**
**Noxopharm Limited (ASX:NOX)**

# September Quarter Activities Report: Veyonda® Identified as Revolutionary Cancer Therapy

**Investment Highlights**

- **Pre-clinical studies confirm ability of Veyonda® to convert tumours from 'COLD' to 'HOT'**
- **Represents significant industry development marking Veyonda® as important and potentially highly valuable second generation immuno-oncology (I-O) drug candidate**
- **Specialty pharma industry US corporate advisory company appointed to help steer Veyonda® clinical and commercial strategies in light of its emerging I-O profile**
- **Veyonda® on track to commence multi-national Phase 2 trial (DARRT-2) as I-O drug in late-stage prostate cancer in Q1 2021**
- **Phase 1 pilot study (NOXCOVID-1) testing Veyonda® in patients with early-stage respiratory distress associated with SARS-CoV-2 infection (COVID-19) commences**
- **Noxopharm remains well funded (including its anticipated R&D Rebate in Q4) to underwrite the planning of its clinical trial program.**

**Sydney, 15 October 2020: Australian clinical-stage 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 September 2020.

During the quarter, Noxopharm remained focused on the following three priorities:

1. To conduct the necessary clinical trials towards establishing Veyonda® as an important new I-O drug candidate, capable of meeting major unmet needs in the oncology field
2. To build a data package that ascribes a $ value to Veyonda® and that is capable of attracting an industry partner
3. To build a drug pipeline that underwrites a future for the Company beyond Veyonda®.

## CLINICAL

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. All three programs have a goal of confirming the utility of Veyonda® as an important new therapeutic and of raising its profile both in the market and in the industry.

### ❖ DARRT program

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

Following on from the successful DARRT-1 study, the Company made important progress in the 3rd quarter towards conducting its Phase 2 DARRT-2 study with the development of a clinical protocol and the awarding of the research contract to conduct the DARRT-2 study to Parexel® International, a leading global Clinical Research Organisation with one of the most comprehensive drug development capabilities of any CRO worldwide.

The DARRT-2 study is the next major step in confirming the value of Veyonda® as an I-O therapeutic for use with radiotherapy in the treatment of advanced prostate cancer. DARRT-2 will be a multinational open label study involving up to about 200 men with Stage 4 metastatic castration-resistant prostate (mCRPC). The first patient is anticipated being enrolled in Q1 2021.

❖ **LuPIN program**

LuPIN treatment (combination Veyonda® and intravenously-administered radiotherapy in the form of $^{177}$Lutetium-PSMA-617) targets a similar patient group as in the DARRT program with end-stage prostate cancer.

The LuPIN trial reached another milestone in the 3rd quarter as the first set of data was published in a peer-reviewed journal – European Urology Oncology. This journal is the first official publication of the European Association of Urology that is fully devoted to the study of genitourinary cancer. The authors of the LuPIN publication are renowned medical experts from the Kinghorn Cancer Centre, St Vincent's Hospital Sydney, Garvan Institute of Medical Research, Monash University, Sir Peter MacCallum Dept of Oncology, and Princess Margaret Cancer Center, Toronto. The authors concluded that in heavily pre-treated late-stage prostate cancer patients, the combination treatment of $^{177}$LuPSMA-617 and Veyonda® is both safe and delivered promising efficacy outcomes, among them a median Overall Survival of 17.1 months. The authors noted that the median Overall Survival in a study conducted in a comparable heavily pre-treated patient population receiving standard chemotherapy was only 4.5 months.

❖ **NOXCOVID program**

Noxopharm took significant steps towards starting a Phase 1b pilot study (NOXCOVID-1) 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® is an anti-inflammatory function that comes from blocking STING signalling, an action that research suggest could block the cytokine storm and septic shock believed responsible for many COVID-19 deaths.

NOXCOVID-1 is to be conducted in up to 40 patients in a number of European hospitals.

**PRE-CLINICAL**

Pre-clinical activities focused on three areas.

❖ **COLD to HOT**

Noxopharm advanced its research effort in understanding the I-O effects of Veyonda® based on its sphingosine-1-phosphate inhibiting function leading to a capacity to repopulate tumours with activated immune cells (known as converting tumours from COLD to HOT). Collaborations with a number of research partners matured, further increasing the Company's understanding of the mechanisms involved and

generating robust proof-of-concept data with a view to publishing these novel findings in peer-reviewed international journals. As a result of the work conducted, the Company was able to file a patent application covering use of Veyonda® as an I-O agent. We are confident that the dataset currently being developed will allow Veyonda® to gain a prominent position in the current I-O landscape.

❖ **STING signalling**

Significant progress also was made toward better defining the effect of Veyonda® on the STING pathway through the Company's collaboration with the Hudson Institute of Medical Science. In addition to filing a provisional patent covering the potential application of Veyonda® toward the treatment of acute inflammation and sepsis, the data generated has allowed Noxopharm to initiate its ongoing NOXCOVID clinical trial. Moreover, as STING inhibition is increasingly being considered a potential favourable effect in patients with cancer, we are currently investigating how the impact of Veyonda® on the STING pathway could also contribute to enhancing its I-O properties.

❖ **Future pipeline**

Since the last quarter, the Company has made solid progress in its drug discovery program, with two programs getting closer to providing the Company with its next generation of anti-cancer drugs. One of these programs has already been announced and involves the development of a first-in-class drug to treat brain cancer based on blocking the cancer-promoting actions of the main brain neurotransmitter, glutamate. The second program will be announced once a patent has been lodged, but involves a novel chemotherapy against two of the most aggressive cancers in the community.

The selected lead candidates now are entering a new development phase with their efficacy currently being tested *in vivo*.

## CORPORATE & FINANCIAL

❖ **Appointment of corporate advisor**

U.S.-based Destum Partners was appointed to advise the Company on the commercial imperatives of its clinical programs. A series of reports have been commissioned for delivery by mid-November 2020.

❖ **Financials**

At 30 September 2020, the Company had $3.9M in cash, from $7.1M at the end of the June quarter. Net cash used for operating activities during the quarter amounted to $3.3M, compared to $2.9M in the June quarter. The Company made payments of $1.6M for R&D activities 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.

*Graham Kelly, CEO and Managing Director 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 the treatment of cancer and septic shock.

Veyonda® is the Company's first pipe-line drug candidate currently in Phase 2 clinical trialling. Veyonda® has two main drug actions – inhibition of sphingosine kinase and inhibition of STING signalling. Activity against the former target contributes to its dual-acting oncotoxic and immuno-oncology functions designed to enhance the effectiveness and safety of standard oncology treatments, i.e., chemotherapies, radiotherapy and immune checkpoint inhibitors. Activity against the latter target provides an anti-inflammatory effect, also contributing to an anti-cancer action, but also potentially blocking the development of septic shock.

Noxopharm also 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 September 2020 |

| **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 | (1,582) | (1,582) |
| | (b) product manufacturing and operating costs | - | - |
| | (c) advertising and marketing | (19) | (19) |
| | (d) leased assets | - | - |
| | (e) staff costs | (857) | (857) |
| | (f) administration and corporate costs | (907) | (907) |
| 1.3 | Dividends received (see note 3) | - | - |
| 1.4 | Interest received | - | - |
| 1.5 | Interest and other costs of finance paid | (3) | (3) |
| 1.6 | Income taxes paid | - | - |
| 1.7 | Government grants and tax incentives | 38 | 3,8 |
| 1.8 | Other (provide details if material) | - | - |
| **1.9** | **Net cash from / (used in) operating activities** | **(3,330)** | **(3,330)** |

| | | | |
|---|---|---|---|
| **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 (3 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 | - | - |
| 2.4 | Dividends received (see note 3) | - | - |
| 2.5 | Other (deconsolidation of Nyrada Inc.) | - | - |
| **2.6** | **Net cash from / (used in) investing activities** | **-** | **-** |

| | | | |
|---|---|---|---|
| **3.** | **Cash flows from financing activities** | | |
| 3.1 | Proceeds from issues of equity securities (excluding convertible debt securities) | 142 | 142 |
| 3.2 | Proceeds from issue of convertible debt securities | - | - |
| 3.3 | Proceeds from exercise of options | - | - |
| 3.4 | Transaction costs related to issues of equity securities or convertible debt securities | (14) | (14) |
| 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 – Proceeds/(repayment) of intercompany loans | - | - |
| **3.10** | **Net cash from / (used in) financing activities** | **128** | **128** |

| | | | |
|---|---|---|---|
| **4.** | **Net increase / (decrease) in cash and cash equivalents for the period** | | |
| 4.1 | Cash and cash equivalents at beginning of period | 7,094 | 7,094 |
| 4.2 | Net cash from / (used in) operating activities (item 1.9 above) | (3,330) | (3,330) |
| 4.3 | Net cash from / (used in) investing activities (item 2.6 above) | - | - |

| Consolidated statement of cash flows | | Current quarter $A'000 | Year to date (3 months) $A'000 |
|---|---|---|---|
| 4.4 | Net cash from / (used in) financing activities (item 3.10 above) | 128 | 128 |
| 4.5 | Effect of movement in exchange rates on cash held | (9) | (9) |
| **4.6** | **Cash and cash equivalents at end of period** | **3,884** | **3,884** |

| 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 | 3,861 | 7,035 |
| 5.2 | Call deposits | - | - |
| 5.3 | Bank overdrafts | - | - |
| 5.4 | Other (provide details)<br>- Business debt cards<br>- Bank balances held in trust | 23<br>- | 59<br>- |
| **5.5** | **Cash and cash equivalents at end of quarter (should equal item 4.6 above)** | **3,884** | **7,094** |

| 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 | 153 |
| 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 salaries (including superannuation) for executive director and related parties.

| 7. | **Financing facilities**<br>*Note: the term "facility' includes all forms of financing arrangements available to the entity.*<br>*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 | 4,200 | 4,200 |
| 7.2 | Credit standby arrangements | - | - |
| 7.3 | Other (please specify) | - | - |
| 7.4 | **Total financing facilities** | 4,200 | 4,200 |

| | | |
|---|---|---|
| 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.

Unsecured loan provided by Nora Goodridge Investments Pty Limited, at an annual interest rate of 10%, maturing 30 November 2020.

| 8. | **Estimated cash available for future operating activities** | **$A'000** |
|---|---|---|
| 8.1 | Net cash from / (used in) operating activities (Item 1.9) | (3,330) |
| 8.2 | Cash and cash equivalents at quarter end (Item 4.6) | 3,884 |
| 8.3 | Unused finance facilities available at quarter end (Item 7.5) | - |
| 8.4 | Total available funding (Item 8.2 + Item 8.3) | 3,884 |
| 8.5 | **Estimated quarters of funding available (Item 8.4 divided by Item 8.1)** | 1.17 |

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

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. In addition the 2020 Research and development grant refund for approximately $4.5M is expected to be received at the end of November.

## 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: 15 October 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.