



March 2022 Quarterly Activities Report and Appendix 4C

Highlights

- **Orphan Drug Designation granted by the United States FDA, bringing benefits to the ongoing clinical and commercial development of lead drug candidate Veyonda®**
- **Cohort 1 of DARRT-2 Phase 2 trial fully enrolled with first dose safe and well tolerated, Cohort 2 recruitment ongoing**
- **First patient enrolled in CEP-2 Phase 1 trial**
- **A series of specific preclinical drug candidates for pancreatic cancer have been identified for further screening and advancement**
- **Appointment of new CEO and Managing Director Dr Gisela Mautner brings international pharmaceutical industry experience to lead Noxopharm through the next stages of growth**
- **Solid cash position of ~A\$18.1M in line with planned clinical and preclinical work programs**

Sydney 28 April 2022: Australian clinical-stage drug development company **Noxopharm Limited (ASX:NOX)** provides its Quarterly Activities Report and Appendix 4C for the three month period ending 31 March 2022 (Q3 FY22).

Management

Dr Gisela Mautner was appointed Noxopharm CEO and Managing Director from February 2022 with the full support of the Board. Dr Mautner first joined the Company in 2019 in the leadership role of Chief Medical Officer and has made a seamless transition to the CEO role due to her strong understanding of its assets and science-driven strategy to advance new drugs from discovery through preclinical investigations and clinical trials. Dr Mautner has a career history in senior executive roles in a number of large multinational pharmaceutical companies including MSD, Bayer and Amgen based internationally as well as in Australia. Through this experience Dr Mautner is well positioned to lead Noxopharm through its key next stages of growth.

Dr Mautner leads a multidisciplinary senior management team with more than 100 years of scientific and pharma experience between them. This deep experience spans end-to-end drug development and commercialisation, including research, clinical and operational experience from global pharmaceutical organisations.

Commenting on her appointment, Dr Mautner stated, “This is an exciting time to step into the CEO role working with an accomplished and dedicated team who are experts at steering the path from molecule to clinic. Working together for a number of years now, we have leveraged our collective professional expertise and networks to establish clinical trials in world-leading hospitals in the US and Australia, institutions including the MD Anderson Cancer Center and City of Hope.

“We are currently working on a robust product pipeline stemming from our two technology platforms to deliver proprietary drug compounds for the treatment of cancer and inflammatory diseases, both substantial areas of unmet need,” she concluded.

Outgoing CEO Dr Graham Kelly has remained on the Board as a Non-Executive Director and Consultant to the Company.

Orphan Drug Designation

In March, Veyonda was granted Orphan Drug Designation (ODD) by the United States Food and Drug Administration (FDA) for its use in the treatment of soft tissue sarcoma. This is a valuable and rarely awarded designation; last year only four Australian companies achieved this status.

ODD status is only granted to drugs that show promise for safe and effective treatment of diseases affecting fewer than 200,000 people per year in the USA and confers the following benefits:

- Seven years of market exclusivity
- Waiver of New Drug Application fees (value of approximately USD 2.9 million in 2021)
- Opportunities for grant funding from the Office of Orphan Products Development
- Regulatory guidance and assistance from the FDA with the drug development process

These benefits will streamline the CEP program, the Noxopharm clinical trial program studying Veyonda in combination with chemotherapy and will provide regulatory and commercial benefits to Veyonda in the longer term. This improves our efficiency as we move Veyonda through the clinical trial process and increases the attractiveness of the drug to potential partners.

Clinical Program Focus

The **DARRT-2** Phase 2 clinical trial (Veyonda in combination with low-dose radiotherapy) saw Cohort 1 fully enrolled in Q3 FY22. The first dose tested was found to be safe and well tolerated and therefore the second dose cohort has been opened and patients are currently being treated. This study is being conducted at world-class cancer hospitals. Recruitment is underway at the MD Anderson Cancer Center which is consistently ranked in the top ten cancer treatment centres in the USA and at the prestigious Beverly Hills Cancer Center in California, as well as at Sydney's Macquarie Private Hospital. Further sites will be joining the study over coming months. The next safety results are expected in Q1 of FY23.

The first patient was enrolled in the **CEP-2** Phase 1 study (Veyonda and the chemotherapy drug, doxorubicin) at top-ranked U.S. cancer hospital, the City of Hope Cancer Center in Los Angeles. City of Hope is an influential study site as it is a founding member of the National Comprehensive Cancer Network, a non-profit alliance of 21 US cancer centres that publishes clinical practice guidelines for cancer treatment. Recruitment is ongoing and additional sites in the U.S. will be joining the study in the near-term.

The **IONIC** Phase 1, proof-of-concept trial (Veyonda combined with the Bristol Myers Squibb checkpoint inhibitor, nivolumab (Opdivo®)) is underway, and initial patients have been treated. Recruitment in this investigator-initiated study has been slower than initially anticipated due to

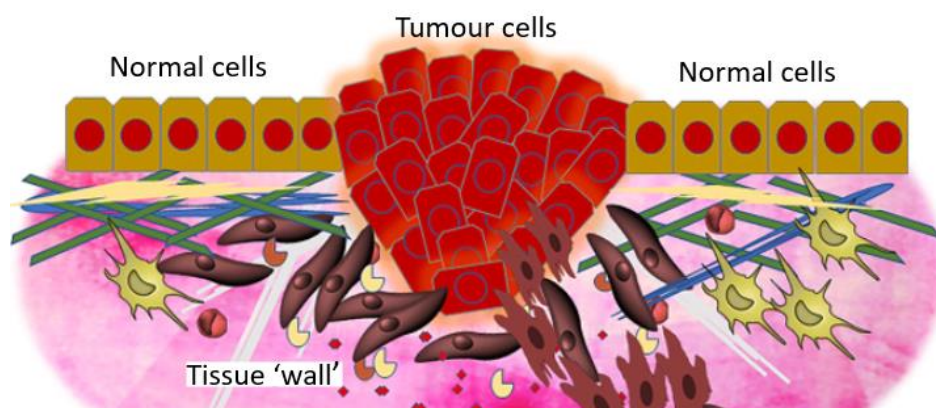
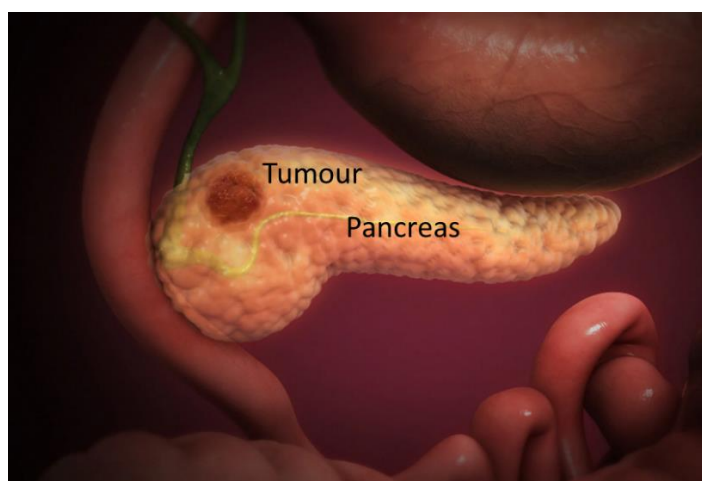
extended administrative times to open additional study sites, however the activation of additional sites is expected to occur shortly.

Preclinical Program Focus

To ensure ongoing extension to its pipeline, Noxopharm continues to work on the development of novel proprietary drug compounds to address targets for the treatment of cancer and inflammatory diseases.

Oncology - Pancreatic Cancer:

A number of novel and proprietary drug candidates Noxopharm is studying are looking very promising against pancreatic cancer, with strong efficacy signals that warrant further investigation. In collaboration with our partners at UNSW, the testing of our drug candidates is being performed using an innovative, state-of-the-art human explant model that uses cancer tissues taken from pancreatic cancer patients. This model is the first of its kind and creates a unique new perspective in the fight against pancreatic cancer, as described in a recent paper in *Nature*¹. The researchers were able to not only grow the tumour itself but also the surrounding tissue, which represents a much closer real-life situation than any other model.



A tumour in the pancreas is characterised by growth of tumour cells but also by surrounding tissue which builds a strong network of cells. These supply the tumour cells with nutrients but also act like

a 'wall' to keep drugs out. The challenge therefore is to develop a drug that affects the tumour cells and at the same time weakens the 'wall'.

Pancreatic cancer is high on the agenda of health authorities in Australia, with a five-year survival rate of only 10.7 per cent. It is expected to become Australia's second leading cause of cancer mortality by 2025. There is undoubtedly a major unmet need for an effective treatment.

Inflammation

TBK1: Following the filing of its NCE provisional patent in December, a series of specific TBK1 inhibition candidates have been identified. These lead molecules are now being further screened and several of the selected compounds will be tested for *in vivo* efficacy signals in chronic and acute inflammation models. Noxopharm is working in collaboration with Hudson Medical Research Institute (HMRI) for this program.

In-licensed technology platform from HMRI: During the quarter, the Company continued working very closely with HMRI to strengthen its intellectual property position around the in-licensed assets. The additional data generated allowed the filing of a final PCT patent covering a large number of lead drug candidates for the inhibition of a range of cellular RNA and DNA inflammatory receptors. Among these candidates, two are already being considered for subsequent *in vivo* testing. The models have been identified and will allow the establishment of the *in vivo* proof-of-concept for the use of this entirely new class of therapeutic agents, while also aiming to generate efficacy signals against specific acute and chronic inflammatory conditions, including relevant autoimmune diseases, like rheumatoid arthritis, and systemic lupus erythematosus.

Financial Update

- As at 31 March 2022, Noxopharm had A\$18.1m in cash, giving it a cash runway to early calendar year 2023.
- The 2021 ATO Research and Development Rebate for A\$5.86m was received on 7 January 2022.
- The current cash position of: ~A\$18.1M meets the Company's forecast funding needs for the next 9 months as in line with our budgeted position.
- Net cash from operating activities during the quarter amounted to A\$1.5m, compared to operating outflows of A\$6.9m in the quarter to 31 December 2021 (the March quarter saw positive cash from operations due to the R&D rebate being received). The company made payments for research and development of A\$2.6m during the quarter, compared to A\$5.5m in the December 2021 quarter. This decrease in R&D expenditure was due to some significant milestones being met in the current clinical trials during the December 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.

-ENDS-



About Noxopharm

Noxopharm Limited (ASX:NOX) is an innovative Australian biotech company discovering and developing novel treatments for cancer and inflammation.

It has three active drug development programs: its lead clinical-stage drug candidate Veyonda[®], plus two innovative technology platforms, which provide the basis for active development of a growing pipeline of new proprietary drugs.

Noxopharm also has a major shareholding in the US biotech company Nyrada Inc (ASX:NYR), which is active in the areas of drug development for cardiovascular and neurological diseases.

To learn more, please visit: noxopharm.com

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Dr Gisela Mautner, CEO and Managing Director of Noxopharm, has approved the release of this document to the market on behalf of the Board of Directors.

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 (including but not limited to the COVID-19 pandemic) 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

50 608 966 123

Quarter ended ("current quarter")

31 March 2022

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	2	18
1.2 Payments for		
(a) research and development	(2,610)	(10,934)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(11)	(73)
(d) leased assets	-	-
(e) staff costs	(1,140)	(3,067)
(f) administration and corporate costs	(675)	(1,687)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	-	50
1.5 Interest and other costs of finance paid	(2)	(20)
1.6 Income taxes paid	-	-
1.7 Government grants and tax incentives	5,893	5,893
1.8 Other (provide details if material)		
1.9 Net cash from / (used in) operating activities	1,457	(9,821)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(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 (9 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 (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 equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	-	1,205
3.4	Transaction costs related to issues of equity securities or convertible debt securities	-	-
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	-	1,205
4. Net increase / (decrease) in cash and cash equivalents for the period			
4.1	Cash and cash equivalents at beginning of period	16,691	26,796
4.2	Net cash from / (used in) operating activities (item 1.9 above)	1,457	(9,821)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

Appendix 4C
Quarterly cash flow report for entities subject to Listing Rule 4.7B

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	-	1,205
4.5	Effect of movement in exchange rates on cash held	(15)	(47)
4.6	Cash and cash equivalents at end of period	18,133	18,133

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	5,102	3,649
5.2	Call deposits	13,000	13,000
5.3	Bank overdrafts	-	-
5.4	Other (business debit cards)	31	42
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	18,133	16,691

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	282
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
<i>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.</i>		

7. Financing facilities	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
<i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i>		
<i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>		
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)	1,457
8.2 Cash and cash equivalents at quarter end (item 4.6)	18,133
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	18,133
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	N/A
<i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i>	
8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1 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: It should be noted that the figure above of 12.4 quarters is inflated by the receipt of the R & D rebate during the quarter.	
8.6.2 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 in place an extensive R&D and clinical program that it believes represents appropriate use of shareholder funds and together with significant value in in adding to the Company's IP portfolio. In order to sustain the anticipated growth in R&D and clinical activities, additional funding will be required within the next 12 months. The precise timing, method and quantum of the next capital raising program is subject to ongoing review and discussions between the Board as well as its advisers and potential funders, as well as being subject to prevailing market conditions.	

8.6.3 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.

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

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.

28 April 2022

Date:

The Board of Directors

Authorised by:
(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.