

# June 2022 Quarterly Activities Report and Appendix 4C

#### Highlights

- City of Hope Cancer Center completes enrolment of first dose cohort in CEP-2 trial
- IONIC and DARRT-2 trial patient enrolment progressing steadily
- Two new grants to support research and drug development program
- Cash position of \$14.0 million in line with planned clinical and preclinical work programs

**Sydney 27 July 2022:** Australian clinical-stage drug development company **Noxopharm Limited (ASX:NOX)** provides its Quarterly Activities Report and Appendix 4C for the period ending 30 June 2022.

## Corporate

Since her appointment as CEO in February of this year, Dr Gisela Mautner has been working with Noxopharm's management team to review the Company's assets and capabilities, and also develop the company's strategic direction, as communicated in the <u>Corporate Presentation</u> released this quarter.

Noxopharm is focused on developing life-saving therapies for patients with cancer and inflammatory diseases. The last quarter has seen progress made in its lead drug candidate Veyonda<sup>®</sup> clinical trials, as well as in the Chroma<sup>™</sup> and Sofra<sup>™</sup> technology platforms.

Noxopharm's recent achievements reflect its science-driven strategy that leverages valuable collaborations and partnerships with industry-leading organisations. This strategic focus has resulted in several announcements this quarter from both the clinical and pre-clinical programs.

The Veyonda clinical trials continue to increase their enrolment across three continents, and it is testament to Noxopharm's work that additional world-leading sites including the Mayo Clinic have come on board as trial sites.

Preclinical research and discovery continues in the Chroma<sup>™</sup> platform, where the Company is working with the University of NSW and its world-class pancreatic cancer model. It is expected preliminary results from this program will be shared in the third quarter of this calendar year.

Dr Mautner commented: "It has been extremely satisfying to work with the Noxopharm management team and our many leading collaborators to achieve these results this quarter. Our strategy is not only bringing our exciting technologies forward, but also attracting outstanding scientists, investigators and sites to participate in our trials.

"In this quarter, we have been focused on presenting our strategy and technologies to potential investors and collaborators both in Australia and overseas, and have had encouraging feedback. This



will put us in the best position to maximise the value of our technologies as they reach key inflection points and deliver that value to our shareholders."

## **Veyonda® Clinical Program Focus**

Enrolment of the second dose cohort of the **DARRT-2** Phase 2 clinical trial (Veyonda in combination with low-dose radiotherapy) continued during the quarter. The safety results for the 1200mg dose are expected in early August, and enrolment for the next dose level (1600mg) will commence immediately thereafter.

In line with Noxopharm's strategy, recruitment continues at high-ranking hospitals including at the MD Anderson Cancer Center, consistently ranked in the top 10 cancer treatment centres in the US, and at the prestigious Beverly Hills Cancer Center in California.

Top-ranked US cancer hospital City of Hope Cancer Center in Los Angeles has completed enrolment of the first dose cohort of the **CEP-2** Phase 1 study (Veyonda and chemotherapy drug doxorubicin). Recruitment is ongoing and additional prestigious sites in the US have recently joined the study. The Mayo Clinic, one of the world's best-known medical providers, is participating in the CEP-2 trial with two sites – the Mayo Clinic in Rochester, Minnesota, which is the original and largest Mayo Clinic campus, as well as the Mayo Clinic in Florida. Additionally, Washington University's School of Medicine in St. Louis, a leader in medical research, teaching and patient care, is also recruiting. The next safety results for the trial are expected in the next few weeks.

Regarding the **IONIC** trial, patient enrolment is progressing steadily. This trial is a Phase 1, proof-ofconcept trial combining Veyonda with Bristol Myers Squibb's checkpoint inhibitor nivolumab (Opdivo<sup>®</sup>), which is underway in a number of Australian hospitals. The final site is expected to be activated shortly.

Despite frequently reported global issues with supply chains, Noxopharm can report there have been no concerns with the ongoing manufacturing of Veyonda. It continues to be successfully shipped to warehouses in San Diego and Berlin, for subsequent distribution to US and European clinical study sites that are involved with the DARRT-2 and CEP-2 studies. Ongoing analytical work has allowed the company to increase the shelf life of Veyonda to two years, with the current data confirming good stability of both idronoxil and Veyonda. This allows greater latitude with manufacture, warehouse storage, shipping and supply, and consequently de-risks potential future supply chain concerns.

In wider news, the American Society of Clinical Oncology (ASCO) published a research abstract relating to idronoxil, the active ingredient in Veyonda, confirming its immunomodulatory properties. Importantly, Idronoxil in combination with the chemotherapy agent cisplatin was found to change the tumour environment from 'cold' to 'hot'. It was reported to be significantly more effective against nasopharyngeal carcinoma cells than the control, and the combination had improved anti-cancer activity compared to cisplatin alone.

### **Chroma™ and Sofra™**

The Noxopharm Chroma<sup>™</sup> technology platform is evaluating multiple candidates in preclinical studies. These drugs share specific and novel bioactive properties, which Noxopharm has expertise in developing to address multiple important targets, primarily for anticancer treatments.



Noxopharm has identified from its proprietary drug library a lead drug candidate for further development as a treatment for pancreatic cancer. This lead drug candidate in the Chroma<sup>™</sup> platform is currently being studied in the University of NSW's state-of-the-art pancreatic tumour model. Results from this important study are anticipated to be released in the third quarter of calendar year 2022.

The Sofra<sup>™</sup> technology platform is Noxopharm's pipeline of new proprietary drugs for inflammation and autoimmunity based on oligonucleotides (short nucleic acid sequences; the building blocks of DNA or RNA). During the quarter, the Company announced two grants that directly support its research and drug development program relating to the Sofra<sup>™</sup> platform.

The first grant saw Noxopharm collaborator Hudson Institute of Medical Research receive a Victorian Government A\$1.45 million grant to fund the joint development program of research aiming to identify novel drug compounds that dampen harmful excessive inflammation associated with COVID-19 infection. Noxopharm's wholly owned subsidiary, Victoria-registered Pharmorage Pty Ltd, is named on the grant as the collaborator that will design and synthetise the compounds with the view of commercialising any promising drug candidates generated by the research, in COVID-19 or in broader inflammatory indications, under the Sofra<sup>™</sup> technology platform.

The second grant was a A\$100,000 award from the mRNA Victoria Research Acceleration Fund, again to Hudson Institute, for a study into RNA-based therapeutics for the treatment of autoimmune disease. Noxopharm will match this funding, making an investment of A\$100,000 with a view to progressing promising drug candidates. Pharmorage is collaborating with Hudson Institute and the Australian National University on this project to explore TLR7-driven autoimmune disease. Autoimmune and auto-inflammatory disorders affect as many as 5% of Australians, with uncontrolled inflammation contributing to many chronic health issues. The focus of the research funded by this grant is lupus, an autoimmune disease that causes a range of debilitating conditions, severely impacting quality of life and life expectancy.

Both grants reflect Noxopharm's collaborative approach to R&D, and its strategy of partnering with specialised and highly respected organisations that can deliver critical expertise to the drug discovery process.

# **Financial Update**

- As at 30 June 2022, Noxopharm had A\$14m in cash.
- The current cash position of ~A\$14m meets the Company's forecast funding needs.
- We expect to receive a significant R&D rebate towards the end of the year.
- Net cash from operating activities during the quarter amounted to A\$4.1m, compared to operating inflows of A\$1.5m in the quarter to 31 March 2022 (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\$2.3m during the quarter, compared to A\$2.6m in the March 2022 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<sup>®</sup>, plus two innovative technology platforms Chroma<sup>™</sup> (oncology) and Sofra<sup>™</sup> (inflammation and autoimmunity), 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	Quarter ended ("current quarter")
50 608 966 123	30 June 2022

Cor	solidated 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	26	44
1.2	Payments for		
	(a) research and development	(2,263)	(13,197)
	<ul> <li>(b) product manufacturing and operating costs</li> </ul>	-	-
	(c) advertising and marketing	(43)	(116)
	(d) leased assets	-	-
	(e) staff costs	(1,108)	(4,175)
	(f) administration and corporate costs	(747)	(2,434)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	10	60
1.5	Interest and other costs of finance paid	(16)	(36)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	5,893
1.8	Other (provide details if material)		
1.9	Net cash from / (used in) operating activities	(4,141)	(13,961)

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

ASX Listing Rules Appendix 4C (17/07/20) + See chapter 19 of the ASX Listing Rules for defined terms.

Con	solidated 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	-	
2.4	Dividends received (see note 3)	-	
2.5	Other (provide details if material)	-	
2.6	Net cash from / (used in) investing activities	-	
2	Cash flows from financing 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	18,133	26,796
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,141)	(13,961)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	-

Con	solidated 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)	-	1,205
4.5	Effect of movement in exchange rates on cash held	19	(29)
4.6	Cash and cash equivalents at end of period	14,011	14,011

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	5,981	5,102
5.2	Call deposits	8,000	13,000
5.3	Bank overdrafts	-	-
5.4	Other (business debit cards)	29	31
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	14,011	18,133

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	272
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.		

7.	<b>Financing facilities</b> 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 qu	arter end	-
7.6	Include in the box below a description of each facility above, including the lender, interes 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.		itional financing

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(4,141)
8.2	Cash and cash equivalents at quarter end (item 4.6)	14,011
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	14,011
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	3.38

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.

- 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: Yes.

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. A further R&D rebate is expected later this year which will boost the cash reserves, and the Company continues to review its activities to identify where additional cost savings can be made to extend the cash pipeline.

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.

Date: 27 July 2022

Authorised by: <u>The Board of Directors</u> (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.