

# June 2023 Quarterly Activities Report and Appendix 4C

- Announcement of study results showing new Sofra<sup>™</sup> drug reduces inflammation
- Company selected by Austrade for US trade delegation
- Sofra research presented at prestigious European event

**Sydney 14 July 2023:** Australian drug development company **Noxopharm Limited (ASX:NOX)** provides its Quarterly Activities Report and Appendix 4C for the period ending 30 June 2023.

## Summary

The June 2023 quarter saw the company continue to make progress with its preclinical portfolio, announcing research from a product candidate in its Sofra<sup>™</sup> technology platform that has shown effectiveness against inflammatory skin disease in preclinical models. Related research was also presented to a prestigious European Molecular Biology Organization event by Associate Professor Michael Gantier of the Hudson Institute of Medical Research, Noxopharm's strategic partner.

Noxopharm was also invited to join Austrade's Advance Australia delegation to the US ahead of the BIO 2023 conference in Boston. The program brought together established Australian biotechnology companies and leaders in healthcare to highlight their respective capabilities and showcase the broader innovation capabilities of Australia. The delegation of senior leaders from a small select group of companies met with key US investors and innovation partners in a formal and structured program comprising site visits, information and pitch sessions, and networking opportunities.

Noxopharm CEO Dr Gisela Mautner took the opportunity to promote the company's capabilities and assets to various stakeholders both during the delegation and at the conference itself. BIO 2023 was the world's largest gathering of the biotechnology industry this year, attracting more than 14,000 biotechnology and pharma leaders for a week of networking designed to discover new opportunities and partnerships.

Also in the quarter, preliminary data from the IONIC investigator-initiated pilot Phase 1 trial of oncology drug candidate Veyonda<sup>®</sup> was published online in the form of an abstract at the American Society of Clinical Oncology (ASCO) annual meeting.

Reflecting on these activities, Dr Gisela Mautner said: "This quarter saw two presentations that highlighted the benefits of our Sofra platform to new audiences around the world. The results from the study we presented in South Korea showed that our SOF-XX drug reduces inflammation in an animal model, which is an important stepping-stone as we build our data package and leverage the work currently being undertaken in conjunction with the Hudson Institute. We also highlighted the Sofra technology, especially our SOF-VAC<sup>™</sup> mRNA vaccine enhancer, to various organisations during BIO 2023. This outreach will continue throughout the rest of the year as we build our profile in this field and raise awareness of the proprietary technology we have to offer in order to support long term value creation and growth."



# Sofra<sup>™</sup> and Chroma<sup>™</sup>

As part of the Sofra platform, Noxopharm announced that a new preclinical product candidate had shown effectiveness against inflammatory skin disease in preclinical models.

In research presented at the 15th International Congress on Systemic Lupus Erythematosus held in Seoul, Noxopharm reported its novel drug, preliminarily known as SOF-XX, represented a promising new class of therapeutics for the treatment of autoimmune diseases such as psoriasis and lupus. The results also act as preclinical proof of concept for the company's recently announced SOF-VAC mRNA vaccine enhancer, which shares the same underlying Sofra technology.

Some autoimmune diseases, including lupus and psoriasis, involve the overactivation of an immune sensor known as Toll-like receptor 7 (TLR7). When Noxopharm's SOF-XX was applied topically via a gel to a mouse model with skin inflammation, it blocked TLR7 activity and thereby significantly protected mice from the development of skin scaling and redness (see appendix for results). There are currently no approved therapeutic inhibitors of TLR7 on the market, making this a unique solution for an urgent unmet need. The global immunology market is projected to grow from USD 92 billion in 2021 to USD 158 billion in 2028.3

The Sofra technology platform is being developed in partnership with Melbourne's Hudson Institute via Noxopharm's Pharmorage subsidiary. During the quarter, Associate Professor Michael Gantier from the Hudson Institute presented research underlying the Sofra technology platform at the European Molecular Biology Organization (EMBO) Non-Coding RNA Medicine Workshop, held in Poland. His presentation focused on ultra-short nucleic acid sequences known as oligonucleotides that have a broad range of potential therapeutic applications due to their ability to target specific inflammatory receptors (eg Toll-like receptors 7 and 8) to block inflammation at its source. This is the core foundation of the company's proprietary Sofra platform, and the technology can be readily adapted to treat a variety of conditions.

As part of the company's Chroma<sup>™</sup> platform, development continued on the new CRO-67 dual-cell therapy drug that is effective in killing both pancreatic cancer cells and their barrier cells to achieve a more profound anti-cancer treatment outcome. A number of preclinical studies are ongoing, and the company is deepening its partnership with Professor Phoebe Phillips and the team at UNSW as they progress through the research program and strengthen the data package.

# Veyonda<sup>®</sup> Clinical Program

Noxopharm is continuing to supply Veyonda to support currently enrolled and future patients in the investigator-initiated IONIC Phase 1 proof-of-concept trial led and sponsored by Professor Paul de Souza, combining Veyonda with Bristol Myers Squibb's checkpoint inhibitor Opdivo<sup>®</sup> (nivolumab). The IONIC trial is taking place across six sites in the Sydney area and regional NSW and, while no further doses of Veyonda are being manufactured, there is sufficient stock to support the trial.

As an investigator-initiated trial, Professor De Souza and his staff are responsible for every aspect of the study including the screening and recruitment of patients, the administering of doses, and all decisions regarding patient cohorts and dose escalations.



The trial is currently still in its Part 1 dose escalation phase and patients are being treated with a Veyonda dose of 1800 mg. Noxopharm will continue to receive regular updates from the trial, but the slow recruitment rate remains a challenge.

During the quarter, preliminary data reported by Professor De Souza from the IONIC trial was published online as part of the annual meeting of the American Society of Clinical Oncology (ASCO). The abstract was titled 'A Phase I/II trial of NOX66 in combination with nivolumab in patients (pts) with advanced cancer' and is available here: https://meetings.asco.org/abstracts-presentations/224651. As the data is preliminary and from a partial data set, no conclusive scientific results are available at this stage.

On the regulatory front, the company received a positive response to its orphan medicinal product application to the European Medicines Agency for Veyonda in regard to the treatment of soft tissue sarcoma.

As part of the closing down of the CEP-2 and DARRT-2 company-sponsored trials, the US FDA has been notified of the discontinuation, along with Australia's TGA for DARRT-2. The company is also working with the Contract Research Organisation to support current patients on treatment as close-out activities at sites continue according to regulatory and Good Clinical Practice (GCP) guidelines. Safety monitoring for patients treated with Veyonda is paramount and a safety follow-up period is in place. The compassionate use program has been closed for new patients.

Overall, the discontinuation of the two trials will significantly reduce the company's cash requirements through the coming quarters.

## **Financial Update**

- As of 30 June 2023, Noxopharm had A\$2.97m in cash.
- The current cash position meets the company's forecast funding needs.
- Net cash outflows for operating activities during the quarter amounted to A\$3.5m, compared to operating outflows of A\$4.7m in the quarter to 31 March. The company made payments for research and development of A\$2.0m during the quarter, compared to A\$3.5m in the March 2023 quarter.
- Due to one-off costs associated with discontinuing the clinical trials the closure of internal clinical operations, the current quarter's cash outflows are significantly higher than forecast for the upcoming quarters.
- Operationally, Noxopharm has approximately four quarters of operating cash flows remaining, based on current cash holdings plus the estimated 2023 R&D rebate proceeds and a forecast operating cash outflow of circa \$2.4m per quarter moving forward.

\*\* 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 non-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, including a pioneering technology to enhance mRNA vaccines.

The company utilises specialist in-house capabilities and strategic partnerships with leading researchers to build a growing pipeline of new proprietary drugs based on two technology platforms – Chroma<sup>™</sup> (oncology) and Sofra<sup>™</sup> (inflammation, autoimmunity, and mRNA vaccine enhancement).

Noxopharm also has a major shareholding in US biotech company Nyrada Inc (ASX:NYR), which focuses on 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 2023

Con	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	-	-
1.2	Payments for		
	(a) research and development	(1,957)	(10,346)
	<ul> <li>(b) product manufacturing and operating costs</li> </ul>	-	-
	(c) advertising and marketing	(44)	(204)
	(d) leased assets	-	-
	(e) staff costs	(1,187)	(4,250)
	(f) administration and corporate costs	(258)	(1,346)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	86
1.5	Interest and other costs of finance paid	(3)	(18)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	5,039
1.8	Other (provide details if material)		
1.9	Net cash from / (used in) operating activities	(3,450)	(11,039)

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	-

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	-	-

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	-	-
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	-	-

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	6,428	14,011
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,450)	(11,039)
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)	-	-
4.5	Effect of movement in exchange rates on cash held	-5	2
4.6	Cash and cash equivalents at end of period	2,974	2,974

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	2,991	6,435
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (business debit cards)	(17)	(7)
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	2,974	6,428

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	37.5
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-
Note: I	Payments in 6.1 include payments of \$38k to Directors for non-executive directors fees	5.

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, 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. The Company is in the process of finalising the advanced financing application for the 2023 R&D tax rebate. The financing is to be provided through Radium Capital who provide finance for up to 80% of the estimated full R&D rebate amount. This loan will be secured by a 'featherweight' security agreement and interest will be charged at 16%p.a. on the drawn down loan amount. The loan will mature on 31 December 2023.		itional financing

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(3,450)
8.2	Cash and cash equivalents at quarter end (item 4.6)	2,974
8.3	Unused finance facilities available at quarter end (item 7.5)	0
8.4	Total available funding (item 8.2 + item 8.3)	2,974
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	0.86

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: The Company announced a major organisational restructure on 7 April 2023, including the discontinuation of its two clinical trial programs, a 40% reduction in staffing levels and a review of all expenditure, which has significantly reduced the level of net operating cash outflows on an ongoing basis. Due to the one-off costs associated with discontinuing the clinical trials and the closure of the internal clinical operations, the current quarter's cash outflows are significantly higher than forecast for the remaining quarters of the financial year or beyond. Without regard to the above, it would appear that the Company has less than one quarter's cash flow remaining. However, operationally it has approximately four quarters of operating cash flows remaining. This is based on current cash holdings plus the estimated 2023 R&D rebate proceeds and a forecast operating cash outflow of circa \$2.4M per quarter moving forward.

- 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: Following the completion of the recent strategic review, the Company has in place a very focused R&D program that it believes represents an appropriate use of shareholder funds as well having the potential to add significant value to the Company's long term IP portfolio. In order to sustain the anticipated level of R&D activities, additional funding will be required within the next 12 months. The precise timing, method and quantum of the additional funding to be secured remains subject to ongoing review and discussions between the Board as well as its advisers and potential funders. The timing of securing additional funds will also be subject to market conditions prevailing at the time. In additional to external funding, the Company expects to receive funding through its R&D rebate later in 2023.The Company has arranged to advance finance the FY 2023 R&D rebate to provide an additional \$3M in cash to fund the operations until the final receipt of the 2023 R&D rebate from the Australia Taxation Office. In addition, the Company continually applies for non-dilutive funding through government and other grants programs.
- 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 continue with the implementation of its latest business plans for the foreseeable future. Moreover, the Company is diligent in managing its ongoing cash reserves and will take the necessary steps to ensure that it remains a viable business. The Company has embarked on a program of ongoing review of all of its activities to identify where any additional cost savings can be made in order to extend the cash runway.

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.

### 14 July 2023

Date:

## By order of the Board

Authorised by:

(Name of body or officer authorising release - see note 4)

#### Notes

- 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.