

# March 2023 Quarterly Activities Report and Appendix 4C

- Strategic decision taken by Board to focus on Sofra™ and Chroma™ technology platforms
- Announcement of new proprietary SOF-VAC™ mRNA vaccine enhancement technology to reduce vaccine side effects
- Cash position of \$6.4 million to support development programs

**Sydney 24 April 2023:** Australian drug development company **Noxopharm Limited (ASX:NOX)** provides its Quarterly Activities Report and Appendix 4C for the period ending 31 March 2023.

# **Summary**

The March 2023 quarter saw the company make good progress with its preclinical platforms, and also make a significant strategic announcement related to the discontinuation of two Veyonda® clinical trials shortly after the three-month period ended.

During the quarter, Noxopharm announced a new proprietary mRNA vaccine enhancer based on Sofra™ technology called SOF-VAC™, which aims to make a broad range of mRNA vaccines, like COVID vaccines, safer by reducing inflammation. The mRNA market has significant potential and growth prospects, with increasing interest worldwide in the ability of mRNA technology to target various diseases.

The company also announced that research demonstrating proof-of-concept of the Sofra™ technology will be presented at the upcoming LUPUS 2023 conference, while at the same time Noxopharm has deepened its relationship with the Hudson Institute of Medical Research, its strategic partner for the Sofra™ platform.

Given the promising nature of Chroma™ and Sofra™ research, and to mitigate risk and prudently utilise the company's limited resources, the Board determined to prioritise the development of these two preclinical programs and limit further investment into Veyonda clinical trials by discontinuing DARRT-2 and CEP-2.

Reflecting on the quarter, Dr Gisela Mautner, CEO and Managing Director of Noxopharm, said: "We are naturally disappointed to have discontinued the DARRT-2 and CEP-2 trials, but slow patient recruitment due to the ongoing COVID impact on the US healthcare system, as well as challenges with patients accepting the drug's suppository delivery method, led to a projected unsustainable rise in costs and trial delays.

"The strategic pivot to our preclinical platforms has been made in the best interests of our shareholders as we believe it will put the company in a stronger position for long-term growth. The Chroma™ and Sofra™ platforms comprise innovative proprietary technologies in the cancer, inflammation, and mRNA vaccine space. These high-potential assets are backed by strong IP and demonstrate encouraging commercial opportunities in growth markets, which are critical elements to have in place in the drug development pathway.



"The recent announcement for the lead candidate in the Sofra™ platform, SOF-VAC™, represents a very significant outcome of our collaboration with the Hudson Institute, in one of today's most exciting and rapidly developing areas of medicine. Along with our work developing therapeutics for autoimmune diseases, it is a clear sign that our Sofra™ platform is a viable opportunity for long term value creation and growth."

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

As part of the Sofra™ platform, Noxopharm announced the development of a new proprietary product candidate based on mRNA technology. Under the ongoing collaboration with the Hudson Institute of Medical Research, the team has synthesised a novel 'vaccine enhancer' called SOF-VAC™. This preclinical technology aims to make a broad range of mRNA vaccines, like the COVID vaccines, safer by reducing inflammation associated with their administration. In addition, the technology has the potential to support more cost-effective mRNA vaccine manufacturing.

SOF-VAC™ is a short oligonucleotide (a nucleic-acid chain composed of building blocks of DNA and RNA) that has shown strong *in vitro* and *in vivo* activity against inflammation and represents a first-inclass achievement as the smallest known molecule of its type to have demonstrated this biological activity. The major advantage of such a small molecule is it reduces the risk of off-target effects compared to larger molecules of this type.

Noxopharm also announced that research from its Sofra™ preclinical program will be presented both orally and as a poster at the upcoming 15th International Congress on Systemic Lupus Erythematosus (LUPUS 2023). The event will be held in Seoul from 17-20 May and will feature a large audience of more than 2,000 international participants, including representatives from pharmaceutical companies and world-renowned experts in autoimmune diseases. The abstract will also be published in *Lupus Science & Medicine®*, the official journal of the Lupus Foundation of America.

During the quarter Noxopharm deepened its relationship with the Hudson Institute of Medical Research, its strategic partner on the Sofra™ platform, by renewing contracts related to ongoing collaborations. Further development of assets is continuing, as is work to strengthen the IP portfolio in this area.

As part of the company's Chroma™ platform, development has 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. UNSW Sydney has increased its headcount for staff working on Noxopharm's preclinical assets, and the projects are progressing according to the schedule mapped out for 2023.

# **Veyonda® Clinical Program**

Shortly after the quarter ended, following a review of the corporate risk position the Board determined to limit further investment into clinical trials by discontinuing **DARRT-2** and **CEP-2**.

Reduced hospital staff capacity due to COVID, coupled with insufficient numbers of patients accepting suppositories given the alternative trial options available, meant the DARRT-2 and CEP-2 company-



sponsored trials continued to experience protracted recruitment delays. This would have resulted in considerably longer projected readout timelines and associated cost increases, which made these trials unsustainable.

The Board also took the difficult decision to disband Noxopharm's clinical trials team and reduce its overall headcount, with those affected leaving the company by early May. Ongoing expenditure will be further reduced through the winding down of Veyonda production, with the last doses having now been manufactured.

The process of discontinuing the two trials has commenced, with trial sites notified and final dosing dates for patients being determined. A safety follow-up period will occur after the last treatment as per regulatory requirements, and the company will continue to offer existing trial patients and their doctors the opportunity to access Veyonda via a tailored compassionate use program, pending FDA approval.

Various tasks and regulatory interactions will have to occur as part of the winding down process, including the closing-out arrangements with the company's contract research organisation. This will significantly reduce the company's cash requirements through the remainder of CY 2023.

Noxopharm will continue 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® (nivolumab). While no further doses are being manufactured, there is a sufficient stockpile of Veyonda to support the trial.

The IONIC trial is taking place across six sites in the Sydney area and regional NSW. The current patient cohort is being treated with a Veyonda dose of 1800mg, however the slow recruitment rate remains a challenge. Due to Noxopharm downsizing its clinical team, various administrative activities are being transferred to Professor De Souza's staff.

Preliminary data from the IONIC trial will be published online in conjunction with the upcoming American Society of Clinical Oncology (ASCO) annual meeting taking place from 2-6 June 2023.

Additionally, a manuscript detailing some of the immunomodulatory properties of idronoxil, the active ingredient of Veyonda, has now been <u>published</u>. The extensive research leading to this scientific publication was conducted at the University of Hong Kong and focused on nasopharyngeal carcinoma.

In terms of intellectual property, the last quarter saw Noxopharm granted a patent by the Australian Patent Office regarding Veyonda's use in combination with chemotherapy (patent number: 2021266308).

# **Financial Update**

- As of 31 March 2023, Noxopharm had A\$6.4m in cash.
- The current cash position of ~A\$6.4m meets the company's forecast funding needs.
- Net cash outflows for operating activities during the quarter amounted to A\$4.7m, compared
  to operating inflows of A\$1.2m in the quarter to 31 December. The positive cash inflows in
  the December quarter were due to the company receiving the 2022 R&D rebate from the ATO.



The company made payments for research and development of A\$3.5m during the quarter, compared to A\$2.5m in the December 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 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™ (oncology) and Sofra™ (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: <u>noxopharm.com</u>

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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

31 March 2023

Con	solidated 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	-	-
1.2	Payments for		
	(a) research and development	(3,465)	(8,389)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(68)	(160)
	(d) leased assets	-	-
	(e) staff costs	(1,026)	(3,062)
	(f) administration and corporate costs	(154)	(1,089)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	22	86
1.5	Interest and other costs of finance paid	(1)	(15)
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	(4,692)	(7,590)

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 (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	-
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	11,111	14,011
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,692)	(7,590)
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 (9 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	9	7
4.6	Cash and cash equivalents at end of period	6,428	6,428

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	6,435	7,122
5.2	Call deposits	-	4,000
5.3	Bank overdrafts	-	-
5.4	Other (business debit cards)	(7)	(11)
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	6,428	11,111

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: F	Note: Payments in 6.1 include payments of \$38k to Directors for non-executive directors fees.		

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 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.		

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(4,692)
8.2	Cash and cash equivalents at quarter end (item 4.6)	6,428
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	6,428
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	1.37

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 closure of its two clinical trial programs, a 40% reduction in staffing levels and a review of all expenditure, which will significantly reduce the level of net operating cash outflows on an ongoing basis.
  - 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 a very focused R&D program that it believes represents an appropriate use of shareholder funds as well as adding 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. It will also be subject to market conditions prevailing at the time of any proposed capital campaign. In additional to external funding, the Company expects to receive funding through its R & D rebate later in 2023.

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. Nevertheless, the Company remains diligent in its oversight of its ongoing cash reserves and will take the necessary steps to ensure that it remains a viable business. The Company maintains an ongoing review 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**

- 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:	24 April 2023

Authorised by: By Order of 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".
- 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.