September 2023 Quarterly Activities Report and Appendix 4C

- **Pancreatic cancer drug candidate receives US FDA Orphan Drug Designation**
- **Encouraging new CRO-67 data from Chroma™ platform**
- **Company presents RNA-related Sofra™ preclinical program to global audience**

Sydney, 13 October 2023: Australian drug development company **Noxopharm Limited (ASX:NOX)** provides its Quarterly Activities Report and Appendix 4C for the period ending 30 September 2023.

Summary

Just after the quarter ended, the company achieved a significant milestone with CRO-67 being granted Orphan Drug Designation (ODD) by the US Food and Drug Administration for the treatment of pancreatic cancer. The FDA grants ODDs for drugs designed to prevent, diagnose or treat rare diseases or conditions.

The designation comes with a range of benefits including tax credits, substantial fee exemptions and a potential seven years of market exclusivity after approval. CRO-67's designation as an orphan drug supports the company's development plan for the asset, and its future commercial value, as Noxopharm continues to build the data package that will be required for regulatory progression.

So far this year only two other Australian companies have received an ODD from the FDA, from a total of 260 issued.

The September 2023 quarter saw the company continue its focus on developing and accelerating its Chroma™ and Sofra™ preclinical platforms, as well as taking steps to promote its assets to international audiences.

This outreach included poster presentations at the RNA Leaders USA Congress, and the American Association of Cancer Research (AACR) Special Conference on Pancreatic Cancer. The latter included encouraging new data from the company's CRO-67 pancreatic cancer drug candidate. Both events were held in Boston, one of the world's leading centres of biotechnology and medical research, and showcased the company's portfolio, attracting interest from a wide variety of researchers and industry professionals.

Among extensive business development activities, the company was invited by Investment NSW to present its portfolio and strategy to a delegation of health industry investors and companies visiting Sydney from China as part of the 29th NSW-Guangdong Joint Economic Meeting. Dr Mautner and the team also continued forging relationships with industry, academia and government stakeholders, including briefing Australia's Chief Scientist, Dr Cathy Foley, on the company's latest research activities and corporate priorities.

Reflecting on these activities, Dr Gisela Mautner said: "The ODD for CRO-67 is a significant milestone, and it was granted shortly after we announced encouraging data that reinforces the approach we have

taken to develop our data package. Beyond the financial benefits, the ODD will also strengthen our commercial position in a market that has seen very few new treatments over recent decades.

"During the quarter we continued to develop our assets and highlight their qualities to an array of international audiences. We have also made excellent progress with our Sofra platform. Our poster's acceptance at a targeted global RNA congress generated solid interest and validated our belief that the platform has strong potential to deliver value and generate growth opportunities for Noxopharm."

Sofra™

Noxopharm continued to actively develop and promote its Sofra platform over the quarter, strategically focusing on the SOF-VAC™ mRNA vaccine enhancer. SOF-VAC is a proprietary asset designed to be combined with all types of RNA vaccines, such as the mRNA vaccines used against COVID, to reduce mRNA-induced inflammation.

SOF-VAC has a well-defined selective and novel mechanism of action and offers the industry the opportunity to enhance any type of mRNA vaccine and a broad range of RNA drugs currently in development globally.

The company presented an overview of both SOF-VAC™ and its SOF-XX asset at the RNA Leaders USA Congress in Boston in early September. The conference is a dedicated forum that brings together global experts across the entire RNA ecosystem and delivers access to business partnering opportunities, with sessions covering the scientific, clinical and commercial development of RNA therapeutics and vaccines.

The company, in conjunction with the Hudson Institute of Medical Research, will also attend and present novel scientific data at various international RNA conferences before the end of the year. These conferences are important events as they give Noxopharm the opportunity to highlight its data to the scientific community, and also engage in business development activities and have meetings with companies of commercial interest.

Regarding SOF-XX, the promising inflammation-reduction research presented by the company at the 15th International Congress on Systemic Lupus Erythematosus (LUPUS 2023), which was held in Seoul in May, has now been published as an abstract in *Lupus Science & Medicine*, a global peer-reviewed, open access online journal. Noxopharm's study showed that when SOF-XX was applied topically via a gel to a mouse model of Toll-like receptor 7 (TLR7)-induced skin inflammation, it significantly protected the skin from the development of scaling and redness by blocking TLR7 immune sensor activity.

There are currently no approved therapeutic inhibitors of TLR7 on the market, making this a unique solution with multiple opportunities that can be applied to numerous diseases in a global immunology market projected to grow from USD 92 billion in 2021 to USD 158 billion in 2028.

In other news, Noxopharm CEO Dr Mautner published an article in *Australasian BioTechnology*, the journal of the AusBiotech industry association, focusing on the importance and role of small biotech companies in Australia's nascent RNA industry. She was also interviewed by *Health Industry Hub* around the National Science Week theme of innovation and powering future industries.

Turning to partnerships, the Hudson Institute gave an internal $50,000 Science Innovation Seed Funding Award to senior researchers Associate Professor Michael Gantier, Noxopharm's principal scientific collaborator on the Sofra platform, and his colleague Dr Shayanti Mukherjee for Sofra-related research targeting inflammation in a women's health context. While this is an external initiative and not a Noxopharm project, the company will be monitoring this early research with interest. General background information can be found here.

Additionally, *Nature Communications*, a high-calibre peer-reviewed scientific journal, recently published a paper entitled *Pharmacological inhibition of TBK1/IKKε blunts immunopathology in a murine model of SARS-CoV-2 infection*. The paper was co-authored by scientists from Noxopharm, the Hudson Institute, Monash University, and the Centenary UTS Centre for Inflammation. The research was partially supported by the Victorian Government's Operational Infrastructure Support Program and COVID-19 Treatments Medical Research Fund.

Chroma™

Shortly after the end of the quarter, CRO-67 was granted Orphan Drug Designation by the US Food and Drug Administration. The FDA grants ODD status for drugs designed to prevent, diagnose or treat rare diseases or conditions, and the designation comes with various benefits that include:

- Tax credits for qualified clinical trials
- Exemption from user fees
    - (e.g. FDA application fees, potentially around US$3 million)
- Potential seven years of market exclusivity after approval

CRO-67's designation as an orphan drug supports the company's development plan for the asset, and its future commercial value, as Noxopharm continues to build the data package that will be required for regulatory progression.

During the quarter, 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.

The team at UNSW Sydney, Noxopharm's long-term collaborator, presented the latest CRO-67 preclinical *in vivo* results as a scientific poster and a talk at the American Association of Cancer Research (AACR) Special Conference on Pancreatic Cancer, which was held in Boston in late September.

The results arose from a study that involved human pancreatic cancer tumour cells being implanted under the skin into mice. The mice were then treated with CRO-67 for 21 days, with tumour volume measured over this dosing period. At the end of drug treatment, CRO-67 significantly reduced tumour volume *in vivo* by an average of 56.7% versus the untreated controls (p=0.0013). Additionally, CRO-67 slowed down the rate at which the tumours grew by 48%. The doubling time for the tumours treated with CRO-67 was 8.5 days, compared to 4.4 days for the untreated controls.

These results demonstrate that CRO-67 has now been shown to be bioavailable and biologically active in an animal model, and further supports the company's confidence in the asset as the development program continues.

In a related development, Noxopharm made a submission to the Australian Senate inquiry into equitable access to diagnosis and treatment for individuals with rare and less common cancers, including pancreatic cancer. The terms of reference invited input concerning funding for research into rare cancers, and as an active participant in this field, the company made a submission that it will share when publicly available.

Veyonda® Clinical Program

As part of the closing down of the CEP-2 and DARRT-2 company-sponsored trials, the company continued to work with the assigned Contract Research Organisation to ensure that close-out activities at sites were carried out according to regulatory and Good Clinical Practice (GCP) guidelines.

Operationally, over the course of the two trials, various safety and clinical metrics were accrued from the participating sites. After the trials were discontinued, the data was collated and Noxopharm sought expert advice, resulting in an assessment that the data was not strong enough to have met the stringent regulatory hurdles required to proceed with later-stage trials in the future.

Financially and from a risk management perspective, the discontinuation of the two trials at an early stage will significantly reduce the company's cash requirements through the coming quarters and reduce risks.

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® (nivolumab). The IONIC trial is taking place across six sites in the Sydney area and regional NSW.

As an investigator-initiated trial, Professor De Souza and the investigators are responsible for the conduct of the study including the screening and recruitment of patients, the administering of doses, and all decisions regarding patient cohorts and dose escalations. To date, just over half of the targeted number of study patients have been enrolled, and patient recruitment continues to be challenging.

Shortly after the end of the reporting period, a Safety Review Committee meeting evaluated the patients in Part 1 (dose escalation phase) of the trial who had been on an 1800mg dose of Veyonda. It was decided to conduct Part 2 (dose expansion phase) of the trial at the same 1800 mg dose level.

Financial Update

- As of 30 September 2023, Noxopharm had A$1.14m 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$1.83m, compared to operating outflows of A$3.45m in the quarter to 30 June. The company made payments for research and development of A$579k during the quarter, compared to A$1.96m in the June 2023 quarter.

- 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 $1.9m 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™ (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: noxopharm.com

Investor, Corporate & Media enquiries:
Julian Elliott
M: 0425 840 071
E: julian.elliott@noxopharm.com

Company Secretary:
David Franks
T: +61 2 8072 1400
E: David.Franks@automicgroup.com.au

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 September 2023

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	(579)	(579)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(27)	(27)
	(d) leased assets	-	-
	(e) staff costs	(875)	(875)
	(f) administration and corporate costs	(333)	(333)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	-
1.5	Interest and other costs of finance paid	(13)	(13)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)		
1.9	**Net cash from / (used in) operating activities**	**(1,827)**	**(1,827)**

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 (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 (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	2,974	2,974
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(1,827)	(1,827)
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)	-	-
4.5	Effect of movement in exchange rates on cash held	-3	-3
4.6	**Cash and cash equivalents at end of period**	**1,144**	**1,144**

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	1,149	2,991
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (business debit cards)	(5)	(17)
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**1,144**	**2,974**

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: 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	2,000	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	2,000	-

7.5	**Unused financing facilities available at quarter end**	2,000

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 currently waiting on the refund from the ATO for the 2023 R&D tax rebate. Interim financing is to be provided through 4F Investments Pty Ltd, a related party to Mr. Fred Bart. This loan is unsecured, and interest will be charged at 16%p.a. on the drawn down loan amount. The loan will mature on 31 December 2023 and be repaid from the proceeds of the ATO R&D rebate refund.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(1,827)
8.2	Cash and cash equivalents at quarter end (item 4.6)	1,144
8.3	Unused finance facilities available at quarter end (item 7.5)	2,000
8.4	Total available funding (item 8.2 + item 8.3)	3,144
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	1.72

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 expects that it will continue to have the current level of operating cashflows for the foreseeable future. It appears that the Company has less than two 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 of approximately $6M, and a forecast operating cash outflow of circa $1.9M 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 addition 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 $2M 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 endeavours to apply 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 revised business plans for the foreseeable future. Moreover, the Company is highly 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 its 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.

Date: 13 October 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".

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.