ASX Announcement | 25 January 2021
Noxopharm Limited (ASX:NOX)

Clinical Progress and Business Development Features of December 2020 Quarter

Investment Highlights

- **Critical LuPIN study survival data submitted for February conference**
- **IONIC study nears start, testing COLD to HOT tumour ability of Veyonda® to boost effectiveness of major immuno-oncology drug, Opdivo® (Bristol Myers Squibb)**
- **NOXCOVID-1 study successfully advances to final dosage cohort**
- **DARRT-2 study planning accelerates**
- **Business development activities have NOX well-positioned for commercial negotiations**
- **Drug pipeline expands in order to increase value of proprietary technology platform**
- **Noxopharm establishes, Pharmorage Pty Ltd, a dedicated septic shock/autoimmune disease subsidiary**
- **Balance sheet and net cash position strengthened by A$23m capital raise**
- **Major non-dilutive boost to future funding delivered by Federal Government approval granted for future overseas R&D expenditure**

Sydney 25 January 2021: Australian clinical-stage drug development company Noxopharm Limited (ASX:NOX) is pleased to provide its Appendix 4C Quarterly Activities report for the period ending 31 December 2020 along with an operational update.

OVERVIEW

NOX CEO, Dr Graham Kelly, said, "Based on mounting clinical evidence, we now are even more confident that Veyonda® is on track to become a highly valuable, breakthrough drug in cancer treatment, and based on the progress in our NOXCOVID study, hopes also are building that it has the potential to become an effective treatment in the field of septic shock. This growing confidence has allowed us to set commercial targets along with an ambitious timetable to meet those targets based on quarterly objectives. I am pleased to report that we met all of our key objectives in the last quarter."

"The coming quarter will see the Company continue to progress. In February, we have an important update on the LuPIN study being presented to an international cancer conference; we also anticipate the IONIC study to begin patient recruitment. Both of these studies have the objective of boosting the effectiveness of drugs owned by two major pharmaceutical companies – Novartis and Bristol Myers Squibb - and are expected to be of key interest to those companies with the opportunity to boost drug sales."

"We also have an emerging and exciting drug discovery pipeline, which combined with our major investment in Nyrada Inc and our new subsidiary, Pharmorage Pty Ltd, is designed to create significant shareholder value and build a business around a proprietary drug development technology platform. Importantly, the Company's recent capital raising leaves it well-positioned to fund both clinical and pipeline development programs. We anticipate a busy and productive second half of the financial year accompanied by a strong news flow."

CLINICAL TRIAL PROGRAM ADVANCING ON MULTIPLE FRONTS

(i) LuPIN-1:

- Last (56th) patient treated Q4 2020
- New data on PSA response, pain response, and median overall survival from all 56 patients to be released early-February 2021 at a major international cancer conference
- *Objective is to show that Veyonda can boost the anti-cancer effect of the Novartis radiopharmaceutical drug, ^{177}Lu-PSMA-617, leading to more men with late-stage prostate cancer responding and living longer. This drug was the subject of a 2018 US$ 6 billion acquisition.*

(ii) IONIC-1:

- Study protocol confirmed and submitted for ethics approval with patient recruitment planned to start in February 2021
- *NOX hopes to show that Veyonda can overcome tumour resistance to the Bristol Myers Squibb anti-cancer drug, nivolumab (Opdivo®), expanding its use in more patients, a result that would add considerably to its current annual sales of US$8 billion.*

(iii) DARRT-2:

- Company acts on independent commissioned report received recommending significant strategic and commercial advantages in extending study into a range of cancer types
- Study protocol finalized involving prostate, breast and lung cancer patients
- Participating countries and hospital sites currently being identified and recruited
- *NOX hopes to show that Veyonda in combination with standard radiotherapy can lead to a high incidence of the rare and highly desirable phenomenon of abscopal responses in solid cancers, providing a revolutionary cost-effective and minimally invasive cancer treatment.*

(iv) NOXCOVID-1:

- This study is progressing well despite overwhelming pressure from the pandemic on facilities and staff at the three participating hospitals
- Cohorts 3 and 4 now fully enrolled

- Safety Steering Committee approved unanimously to advance to the next (5th Cohort) higher dose level (1800 mg) as per protocol
- *NOX objective is to show that Veyonda can block the hyperinflammatory condition known as cytokine release syndrome ('cytokine storm') that causes rapid progression of lung dysfunction in a proportion of COVID-19 patients, with attendant high rates of disability and death.*

NOVEL DRUG PIPELINE CONTINUES TO BUILD

- In the first program, a family of new compounds has been developed with improved drug-like features including a potent ability in the laboratory to kill pancreatic, bile duct, and colo-rectal cancer cells resistant to all standard drugs. Animal studies are being finalized and due to be reported on in February
- In the second drug program, NOX is developing an entirely new approach to the treatment of brain cancers such as glioblastoma multiforme (GBM). This program is based on a recent discovery that the aggressive growth of these cancers is due to the stimulatory action of the major brain neurotransmitter, glutamate. The Company has identified a family of novel compounds that blocks this stimulatory effect, thereby bringing fresh hope of an acceleration in the search for a treatment that offers a meaningful anti-cancer effect compared to the modest incremental effects currently on offer.

PHARMORAGE, A DEDICATED SEPTIC SHOCK/AUTOIMMUNE DISEASE SUBSIDIARY

In November, Noxopharm announced a partnership with Hudson Institute of Medical Research ('Hudson Institute') and a collaboration with The Australian National University ('ANU') had led to the formation of Pharmorage Pty Ltd ('Pharmorage'), a new Australian drug development company.

- NOX, through its collaboration with the Hudson Institute, has generated an extensive dataset confirming the potential of Veyonda and Veyonda derivatives to mitigate the onset of cytokine storms via a novel mechanism. This opens up significant opportunities in the field of septic shock, responsible for an estimated 11 million deaths globally per annum[1], as well as the approximate 2 million deaths attributed to date to the SARS-CoV-2 pandemic
- A collaboration with an internationally-renowned research team at the Australian National University made a solid start in studying the ability of the same family of compounds to block the processes that lead to the development of a number of autoimmune diseases, including motor neurone disease.

CORPORATE

During the quarter the Company received $21.4m (net) from the issue of shares and a further $201k from shareholders exercising options.

- As a result, the Company had cash reserves of $22.9M at the end of the December quarter
- Net cash used in operating activities during the December quarter amounted to $2.6m, compared to $3.3m in the September quarter

- The Company made payments of $1.4m for R&D activities during the quarter, down from $1.6m in the September quarter
- The Company anticipates receiving a cash rebate in excess of $4m in the coming quarter by way of the Federal Government's R&D Tax Incentive Rebate scheme for the 2019/2020 FY
- The Company received confirmation from the Federal Government that future overseas R&D expenditure would qualify for the 43% Rebate scheme, thereby providing an annualized source of significant non-dilutive funding
- 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.

1. *Rudd KE et al (2020). Global, regional, and national sepsis incidence and mortality, 1990-2017: analysis for the Global Burden of Disease Study. Lancet 395:200-211*

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

-ENDS-

About Noxopharm
Noxopharm Limited (ASX:NOX) is an Australian clinical-stage drug development company focused on the treatment of cancer and septic shock.

Veyonda® is the Company's first pipe-line drug candidate currently in Phase 2 clinical trialling. Veyonda® has two main drug actions – inhibition of sphingosine kinase and inhibition of STING signalling. Activity against the former target contributes to its dual-acting oncotoxic and immuno-oncology functions designed to enhance the effectiveness and safety of standard oncology treatments, i.e., chemotherapies, radiotherapy and immune checkpoint inhibitors. Activity against the latter target provides an anti-inflammatory effect, also contributing to an anti-cancer action, but also potentially blocking sepsis.

Noxopharm also is the major shareholder of US biotechnology company Nyrada Inc (ASX:NYR).

To learn more, please visit: noxopharm.com

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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 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 December 2020

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	2	2
1.2	Payments for		
	(a) research and development	(1,397)	(2,980)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(29)	(48)
	(d) leased assets	-	-
	(e) staff costs	(728)	(1,585)
	(f) administration and corporate costs	(430)	(1,337)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	-	-
1.5	Interest and other costs of finance paid	(4)	(7)
1.6	Income taxes paid	-	-
1.7	Government grants and tax incentives	13	50
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(2,574)**	**(5,905)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire:		
	(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 (6 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 (deconsolidation of Nyrada Inc.)	-	-
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)	23,000	23.116
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	201	213
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(1,600)	(1,600)
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 – Proceeds/(repayment) of intercompany loans	-	-
3.10	**Net cash from / (used in) financing activities**	**21,600**	**21,728**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	3,884	7,094
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,574)	(5,905)
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 (6 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	21,600	21,728
4.5	Effect of movement in exchange rates on cash held	(22)	(28)
4.6	**Cash and cash equivalents at end of period**	**22,889**	**22,889**

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	22,833	3,861
5.2	Call deposits	-	-
5.3	Bank overdrafts	-	-
5.4	Other (provide details) - Business debt cards - Bank balances held in trust	56 -	23 -
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**22,889**	**3,884**

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	143
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

Director fees and salaries (including superannuation) for executive director and related parties.

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	4,200	4,200
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	4,200	4,200

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.

Unsecured loan provided by Nora Goodridge Investments Pty Limited, Link Traders (Aust) Pty Limited and Bart Superannuation Pty Limited at an annual interest rate of 10%, maturing 30 May 2021.

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (Item 1.9)	(2,574)
8.2	Cash and cash equivalents at quarter end (Item 4.6)	22,889
8.3	Unused finance facilities available at quarter end (Item 7.5)	-
8.4	Total available funding (Item 8.2 + Item 8.3)	22,889
8.5	**Estimated quarters of funding available (Item 8.4 divided by Item 8.1)**	8.89

8.6 If Item 8.5 is less than 2 quarters, please provide answers to the following questions:

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:

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:

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:

Yes – and additionally the 2020 Research and development grant refund for approximately $4.6M is expected to be received in the next quarter from the ATO.

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: 25 January 2021

Authorised by: By 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.