

#### Noxopharm 2022 AGM Corporate Presentation

**Sydney, 17 November 2022:** Innovative biotech company **Noxopharm Limited (ASX:NOX)** is pleased to release its 2022 AGM Corporate Presentation.

Highlights:

- Progress in Veyonda<sup>®</sup> clinical trials
- Patient recruitment ongoing
- Safety milestones being met
- World-class clinical centres signed up
- Growing asset pipeline as part of multi-platform strategy
- New CRO-67 drug promising against pancreatic cancer
- Sofra<sup>™</sup> R&D progress
- Strong patent portfolio
- Expanding partnerships

-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 clinical 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: <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.

### **NOXOPHARM LIMITED**

Delivering Science. Transforming Lives. AGM 2022



NOXOPHARM (ASX:NOX)

**DELIVERING SCIENCE. TRANSFORMING LIVES.** 



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Veyonda® currently is not approved for use in Australia or any other country.



# Dr Gisela Mautner CEO & MD



### Noxopharm Overview

- Noxopharm is an innovative biotechnology company with a multi-platform strategy to advance the most promising life-saving therapies for patients with cancer or inflammatory diseases
- It has grown to have three separate drug development programs:
  - Lead clinical-stage drug candidate **Veyonda**®
  - Chroma<sup>™</sup> technology platform
  - Sofra<sup>™</sup> technology platform
- Multiple Phase 1 and 2 studies running in a range of cancer types including prostate, breast and lung cancer, as well as sarcoma
- Well-funded for current programs with \$9.9 million cash\* plus \$5 million federal R&D tax rebate received in November 2022
- Expert team, highly experienced at identifying and driving novel drugs from **molecule to marketplace** while **adding value** at each step



\* As at 30 September 2022

## Past 12 Months – Highlights

#### <u>Veyonda®</u>

- Clinical trials progressing:
  - Patient recruitment ongoing and safety milestones being met
  - World-class clinical trial sites
  - Implemented more stringent quality assurance processes
  - Manufacturing increased and streamlined
  - Stable supply of drug to achieve global delivery
- Orphan Drug Designation secured

#### <u>Chroma™</u>

• New CRO-67 drug promising against pancreatic cancer – dual-cell therapy approach targets tumour cells and protective barrier

#### <u>Sofra™</u>

· Preclinical studies ongoing, with in-licensed patents and new application filed

#### **IP Protection**

• Strong patent portfolio

#### **Expansion of Noxopharm Network**

• New partners brought on board







### The Noxopharm Network





### Three Separate Therapy Development Programs





# $Veyonda^{\mathbb{R}}$



# Veyonda<sup>®</sup> Combination Therapy Programs



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External Beam Radiation



Chemotherapy

Immuno-oncology Therapy

### Working with top ranked cancer centres in the USA

\* IIT – investigator initiated trial



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

\* IIT - Investigator-initiated trial

Program	Combination	Indication	Phase 1	Phase 2	Status
DARRT	+ Radiation Therapy	Prostate Cancer	DARRT-1 Completed	DARRT-2 Active	DARRT-1 manuscript in preparation; DARRT-2 recruiting
СЕР	+ Chemotherapy	Multiple Tumours	CEP-1 Completed		Results published in CTR 2021
CLF	- Chemomerapy	Sarcoma	CEP-2 Active		Recruitment ongoing / safety phase
IONIC (IIT)*	+ Immunotherapy (Opdivo®) †	Multiple Tumours	IONIC Active		Recruitment ongoing / safety phase
LuPIN (IIT)*	+ <sup>177</sup> LuPSMA-617 (Pluvicto®) ‡	Prostate Cancer	LuPIN Completed		Results published in JNM in 2022
NOXCOVID	Monotherapy	COVID-19	NOXCOVID Completed		Manuscript in preparation

† Bristol Myers Squibb

‡ Novartis

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## DARRT-2 Trial – End-Stage Metastatic Cancers

- DARRT is a Phase 1b/2a trial examining the combination of Veyonda with low-dose radiotherapy for the treatment of prostate, breast and lung cancer in the US, EU and Australia.
- Top-ranked US clinical sites include the Beverly Hills Cancer Center in Los Angeles, and the renowned MD Anderson Cancer Center in Houston.
- Healthcare systems remain under pressure, but conditions improving after COVID-related impacts.
- Prostate cancer is the most frequently diagnosed cancer in 112 countries, and the leading cause of cancer death in 48.

#### Status Update

- Currently in Part 1 Dose-escalation; three dose cohorts have been tested with doses being escalated as part of safety phase of trial. Safety Steering Committee determined Cohort 1 and 2 dose safe and well tolerated.
- Cohort 3 Safety Steering Committee Meeting is expected in Q1 2023.
- Current safety phase will either be finished in Q1 2023 or continue with the last dose cohort into either late Q1 or early Q2 2023, after which efficacy phase commences.
- All sites are active enrolment rate has increased.
- Company actively exploring ways to reduce patient numbers and costs while bringing forward efficacy data.
- When results are meaningful, Noxopharm will target data releases via high-profile conferences / publications to maximise commercial potential.



### CEP-2 Trial – Sarcoma

- Phase 1, open-label, dose-escalation and dose-expansion study of Veyonda administered to cohorts of patients being treated with doxorubicin for metastatic soft tissue sarcoma.
- Approximately 30 patients with a range of soft tissue sarcomas are being enrolled to be treated with the Veyonda / doxorubicin combination as a first-line treatment.
- Top-ranked US sites participating include the City of Hope Cancer Center in Los Angeles, the Mayo Clinic in Minnesota and Florida, plus Northwestern University, Washington University in St. Louis and Medical College of Wisconsin.
- Similar COVID-related impacts.
- Soft tissue sarcomas are rare and generally very aggressive cancers.

#### Status Update

- CEP-2 started in February 2022.
- First safety milestone passed in August 2022.
- Second dose cohort finished, with Safety Steering Committee meeting held 15 Nov – decision made to escalate dose to 1800 mg. This will be the last dose cohort.
- Current safety phase will continue until approximately Q1 2023, after which efficacy phase commences.
- When results are meaningful, Noxopharm will target data releases via high-profile conferences / publications to maximise commercial potential.

## **IONIC** Trial – Checkpoint Inhibitors



- Investigator-initiated trial.
- IONIC is a pilot Phase 1 trial exploring the safety and efficacy signals of Veyonda® combined with the Bristol Myers Squibb checkpoint inhibitor Opdivo® (nivolumab) for the treatment of a range of solid tumour types.
- First time Veyonda investigated with an Immuno-Oncology (IO) drug.
- Aim is to investigate whether Veyonda can overcome drug resistance to immune checkpoint inhibitors such as Opdivo®.

#### Status Update

- All sites now activated, and enrolment gaining momentum.
- 11 patients have been enrolled more than one third of planned total.
- Part 1 nearing completion.
- Safety Steering Committee meeting scheduled for 1 December 2022.
- Depending on decision, if no further dose escalation, Part 2 will begin immediately to explore efficacy.
- When results are meaningful, Noxopharm and the Investigator will target data releases via high-profile conferences / publications to maximise commercial potential.



# Regulatory Engagement for Veyonda®

#### **Orphan Drug Designation (ODD)**

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- US Food and Drug Administration (FDA) granted ODD to Veyonda for soft tissue sarcoma early 2022.
  - Supports Veyonda's development in sarcoma via the CEP-2 trial.
- Only four Australian companies received ODD approval in 2021.

#### **Regulatory trial approvals**

- US FDA Investigational New Drug (IND) granted for Veyonda in combination with doxorubicin for the treatment of sarcoma CEP-2 trial.
- US FDA IND granted for investigation of Veyonda in prostate cancer DARRT-2 trial.
- Approvals followed regulatory evaluation of significant Veyonda data packages.
- Enabled CEP-2 and DARRT-2 trials to take place in these important commercial territories.
- Trial sites in Australia, the United States and Europe.

#### **Highly Valuable ODD Benefits**

ODD encourages the development of safe and effective treatments of rare diseases affecting fewer than 200,000 people in the U.S. annually.

Seven-year period of market exclusivity Waiver of new drug application fees, valued at approximately \$2.9 million in 2021

Regulatory guidance and assistance from the FDA for drug development



## Chroma™









- ✓ Shared specific and novel bioactive properties
- ✓ Growing number of drug assets
- Deepening knowledge of structural /activity relationships
- ✓ Composition of Matter patents
- ✓ Promising early results in pancreatic cancer

#### Pancreatic ductal adenocarcinoma (PDAC)

- PDAC is the **fourth leading cause of cancer**related deaths in developed countries
- 5-year survival rate of 8% from diagnosis<sup>1</sup>, minimal improvements in the past four decades
- In 2018, approximately 458,918 people were diagnosed with pancreatic cancer, while 432,242 died<sup>2</sup>
- Chemotherapy treatments only extend life by 8-16 weeks<sup>3</sup>
- Pancreatic cancer is eligible for Orphan Drug Designation

### Urgent need to develop more effective treatments

<sup>1</sup> Siegel RL. 2018. doi:10.3322/caac.21442.
<sup>2</sup> Bray F, Ferlay J, Soerjomataram I, Siegel RL, Torre LA, Jemal A. Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin. 2018;68(6):394–424. doi: 10.3322/caac.21492. \.
<sup>3</sup> Kleeff J. 2016. doi:10.1038/nrdp.2016.22



### Pancreatic Cancer Dual-Cell Therapy CRO-67

- Preclinical research in unique pancreatic cancer UNSW explant model.
- CRO-67 attacks both pancreatic tumour cells **and** barrier cells surrounding the tumour.
- Reducing the barrier exposes tumour to immune cells and to anticancer treatments.
- The number of tumour cells decreased by 85% (p < 0.0002)
- The number of barrier cells decreased by 87% (p < 0.0001)
- Tumour cell multiplication decreased by 73% (p < 0.0001)
- Overall cell death increased by 6.2-fold (p < 0.0001)



Statistical significance p < 0.05



Sofra™





- ✓ Noxopharm has in-licensed a technology from Hudson Institute of Medical Research to create the Sofra™ technology platform, which is housed in Noxopharm's subsidiary Pharmorage.
- This technology platform is based upon short nucleic acid sequences, the building blocks of DNA or RNA, known as oligonucleotides.
- ✓ These oligonucleotides provide a novel treatment approach, acting on specific cells to modulate inflammation at its source.
- They have potential applications in the treatment of excessive inflammatory responses like those sometimes seen after viral or bacterial infections and in autoimmune diseases.
- ✓ Noxopharm is also exploring the potential for oligonucleotides to limit the potential inflammatory side effects associated with mRNA therapeutics and vaccines.
- ✓ The Hudson Institute has received \$1.5 million in government grants in 2022, for work that benefits the Noxopharm preclinical pipeline.

### Stimulate Inflammatory Response

### **Reduce Inflammation**

Infectious Inflammatory Diseases

Cancer



- Parkinson's
- Alzheimer's
- Huntington's
- Multiple Sclerosis

#### Cardiovascular Diseases

- Hypertension
- Atherosclerosis
- Stroke

#### SOFRA™ TECH PLATFORM

Including Pharmorage Oligonucleotides targeting inflammatory sensors

#### mRNA

- Vaccines
- Other therapeutics

#### Pulmonary Diseases

- Asthma
- COPD
- Bronchitis
- Hay fever

#### Metabolic Disorders

- Type 2 diabetes
- Fatty liver disease

#### Autoimmune Diseases

- Lupus
- Psoriasis
- Type 1 diabetes
- Rheumatoid arthritis
- Inflammatory bowel disease
- Multiple Sclerosis

#### Genetic Inflammatory Diseases

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### Sofra<sup>™</sup> – Market Opportunities



- Two main markets:
  - Chronic inflammatory conditions, including autoimmune diseases.
  - mRNA therapeutics, including vaccines.
- Global immunology market is projected to grow from USD 92 billion in 2021 to USD 158 billion in 2028.
- COVID-19 vaccines are projected to make up most of the mRNA market until 2025.
- Other prophylactic vaccines, therapeutic vaccines, and therapeutics will then become larger shares.
- The mRNA market is forecast to be USD 23 billion by 2035.





## **Financials and Business Outlook**



## Financial Summary (ASX:NOX)

Capital Structure*		
Share price	\$0.15	
Shares on issue	292M	
Market Capitalisation	\$42M	
Net capital raised <sup>1</sup>	\$63.8M	
Govt grants/rebates received <sup>2</sup>	\$23.5M	

#### Cash Position\*\*

Current Cash Holdings	\$9.9M
Curreni Casir Holdings	\$7.7IVI
R&D rebate for 2021/22	\$5M
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\* As at 11 Nov 2022 \*\* As at 30 Sep 2022 <sup>1</sup>

<sup>1</sup> Includes IPO monies raised

<sup>2</sup> Since IPO



### 2023 Catalysts





# **Closing Remarks**

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### **Delivering Science. Transforming Lives.**

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