

Date: June 6, 2019 Sydney, Australia

**ASX: NOX** 

**Noxopharm Limited** 

ABN 50 608 966 123

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Chairman Non-Executive Director

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Chief Executive Officer
Managing Director

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Non-Executive Director

ASX Limited 20 Bridge Street SYDNEY NSW 2000

# NOXOPHARM CORPORATE PRESENTATION June 2019

**SYDNEY, June 6, 2019:** Noxopharm Ltd (ASX: NOX) (Noxopharm or 'Company') is pleased to provide the market with its updated corporate presentation for June 2019.

The presentation can also be found by visiting the Noxopharm website www.noxopharm.com and going to the Investors/ASX Announcements page.

#### About Veyonda®

Veyonda® (previously known as NOX66) is an innovative dosage formulation of the experimental anti-cancer drug, idronoxil. Idronoxil inhibits the oncogene, Ecto-NOX disulfide-thiol exchanger type 2, leading to inhibition of the key secondary pro-survival messenger, sphingosine-1-phosphate. This enhances the DNA-damaging effects of both radiotherapy and cytotoxic chemotherapy, in turn triggering up-regulation of the body's innate immune system.

#### About the DARRT program

The Company's DARRT (Direct and Abscopal Response to Radiotherapy) Program is testing the ability of Veyonda® to increase tumour response to palliative dosages of radiotherapy. The DARRT treatment regimen entails a 5-day course of radiotherapy (20-30 Gy) in 5 fractionated dosages targeting a single tumour, with Veyonda® administered daily for up to 3 weeks. The rationale of DARRT is to combine the radio-enhancing properties of Veyonda® that stem from its inhibition of sphingosine-1-phosphate pro-survival functions, combined with its ability to stimulate the body's first line immune defence cells against cancer. The clinical outcome being sought is greater shrinkage of irradiated tumours and shrinkage of non-irradiated tumours (abscopal response). The DARRT treatment regimen is being tested initially in prostate cancer, but in due course is to be extended into other forms of solid cancer that the Company believes will assist the Veyonda® marketing approval process.

#### **About LuPIN-1**

LuPIN-1 is a dose escalation and dose expansion trial of men with mCRPC progressing despite having received docetaxel, cabazitaxel and either abiraterone or enzalutamide. All men enrolled are being administered up to 6 cycles of  $^{177}$ Lu-PSMA-617 at six-weekly intervals. The first eight men received 400 mg of Veyonda® daily on days 1-10 of each cycle. Following a safety data review, the dose for patients 9-16 was escalated to 800 mg of Veyonda®. Once the next safety data review of these 8 patients treated with 800 mg was concluded, an additional 16 patients were recruited at this dose, bringing the total patients recruited to 32 (8 x 400 mg, 24 x 800 mg). The trial now will enroll 56 men.

#### **About CEP**

The Company's CEP Program (Chemotherapy Enhancement Program) is testing the ability of Veyonda® to restore sensitivity of cancer cells to carboplatin in patients whose late-stage cancers have stopped responding to chemotherapy, and to do that to the extent that the dosage of carboplatin can be lowered to a level unlikely to cause serious adverse side-effects. The clinical outcome being sought is the ability to offer a well-tolerated chemotherapy regimen to patients considered unsuitable for standard dosage due to age or illness.

#### **About Noxopharm**

Noxopharm is a clinical-stage Australian drug development company with offices in Sydney, New York and Hong Kong. The Company has a primary focus on the development of drugs based on a phenolic chemical structure, with Veyonda<sup>®</sup> the first pipeline product. The pipeline includes a number of other drug candidates for both oncology (within NOX) and non-oncology indications (in subsidiary company, Nyrada Inc).

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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. No representation, warranty or assurance (express or implied) is given or made by Noxopharm that the forward-looking statements contained in this announcement are accurate and undue reliance should not be placed upon such statements.



# **Noxopharm Limited**

**Veyonda**®



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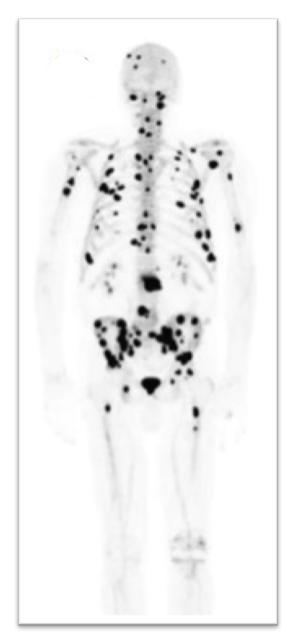
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This presentation may contain forward-looking statements which are identified by words such as 'may', 'could', 'believes', 'estimates', 'targets', 'expects', or 'intends' and other similar words that involve risks and uncertainties. These statements are based on an assessment of past and present economic and operating conditions, and on a number of assumptions regarding future events and actions that, as at the date of this presentation, are expected to take place. Such forward-looking statements are not guarantees of future performance and involve known and unknown risks, uncertainties, assumptions and other important factors many of which are beyond the control of the Company, its Directors and management.

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Metastatic prostate cancer

#### **Metastatic disease typically involves multiple tumors including**

- A primary tumor
- A number of visible (on scanning) secondary tumors, and
- Multiple less visible secondaries (micro-metastases)

#### The challenges in the treatment of metastatic disease are:

- Extensive tumor load
- Resistance to chemotherapy/radiotherapy due to prior treatment
- Presence of ultra-resistant cancer stem cells
- Different mutational profiles in different tumors within the 1 patient
- Creation by the cancer cells of a defensive shield against the immune system, and
- Elimination of immune cells from individual tumors.

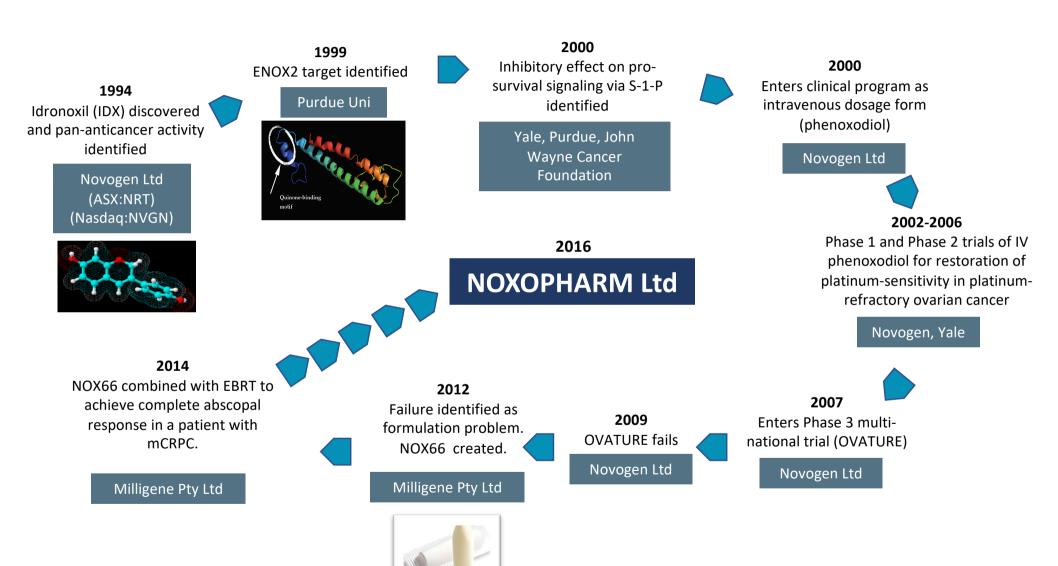
Metastatic disease rarely is curable once established

#### Veyonda®

is being developed as a universal treatment of metastatic disease



# History of Veyonda® and the active ingredient idronoxil (IDX)





### **Veyonda**®

#### **Active ingredient IDRONOXIL (IDX)**

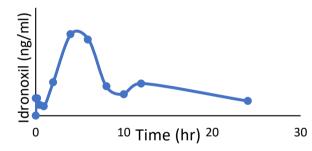
- Oral and IV formulations previously known as phenoxodiol
- Over 20 years of pre-clinical and clinical research
- 61 PubMed publications



Minimized C<sub>max</sub> peak while keeping a therapeutic concentration for >12 hours to allow for twice-daily dosing

#### Re-formulated as a suppository (NOX66)

- Using proprietary flavonoid delivery technology LIPROSE
- Protecting against Phase 2 metabolism
- Providing an optimal pharmacokinetic profile with extended half-life



Proprietary dose formulation that delivers idronoxil continuously over 12 hours to enable prolonged anti-cancer activity

Is a convenient-to-use, self-administered dosage form given twice daily to provide continuous 24-hour cover



# **Veyonda® - First in Class**



- Inhibitor of pro-survival mechanisms in cancer cells
- Activator of STING mechanisms

No known off-target activity in most body functions

Rarely mild anemia and GI toxicity

All cancer phenotypes responsive to IDX

Wide range of anticancer effects

Increased DNA fragmentation activates STING and innate immunity

#### TARGET: Ecto-NADH oxidase disulfide-thiol exchanger Type 2 (ENOX2)

Human genome has two genes (ENOX1 and ENOX2) controlling expression of externally-located enzyme (ENOX) that regulates the transmembrane proton pump.

- Human cells overwhelmingly express ENOX1
- Rapidly dividing cells express both ENOX1 and ENOX2
- Cancer cells only express ENOX2

Idronoxil inhibits ENOX2; has no effect on ENOX1

#### **EFFECT OF ENOX2 INHIBITION:**

Build-up of protons in plasma membrane inhibits **sphingosine kinase** which blocks production of **sphingosine-1-phosphate** a key secondary messenger driving critical pro-survival/growth signaling pathways:

RAS-RAF-MEK-ERK / Akt-PI3K-mTOR / CDK-regulated mitosis /

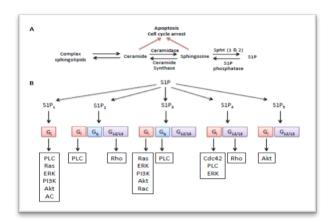
DNA repair



# **Veyonda® - First in Class**



- Inhibitor of pro-survival mechanisms in cancer cells
- Activator of STING mechanisms

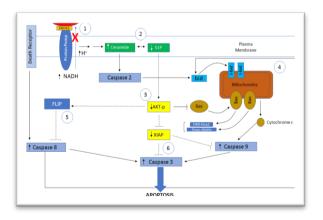


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DNA repair



# **Veyonda® - First in Class**



- Inhibitor of pro-survival mechanisms in cancer cells
- Activator of STING mechanisms

# Multiple anti-cancer biologies able to attack metastatic disease

#### **Monotherapy effect:**

- Cytostasis
- Cytotoxicity

#### **Chemo-enhancing effect:**

- ➤ Inhibit DNA repair
- > Inhibit MDR mechanisms

#### Radio-enhancing effect:

- ➤ Inhibit DNA repair
- > STING agonism



# Safety of Veyonda® and IDX in >400 Patients

Authors/Study/SAS	Formulation	Combination	Patients	Cancer type(s)	Safety related to Veyonda®/idronoxil/phenoxodiol
			(N)		
Howes, 2011	IV	M	6	Breast, prostate	No AEs
De Souza, 2006	IV	M	21	Various solid TUs	Lymphocytopenia (Gr3 n=9); hypersensitivity; Gr1-2 nausea, elevated ALP&ALT
Choueiri, 2006	IV	M	19	Various solid TUs	Gr3 emesis & fatigue (n=1); Gr 3 rash (n=1); <gr 3="" cough<="" diarrhoea,="" emesis,="" fatigue,="" nausea,="" td=""></gr>
Soukup, 2016 (review)	IV	M	21	Various solid TUs	No >Gr2 AEs; Gr1-2 fatigue, nausea, elevated ALP
Kelly, 2011	IV	C/Cisplatin or paclitaxel	32	Ovarian, fallopian tube, primary peritoneal CA	Gr 4: hospitalization, hypomagnesemia, neutropenia (n=1 each); 3 discontinuations; Gr 3: 14 haematological events, 12 non-haematological events
Fotpoulou, 2014	Oral	C/Carboplatin	142	Platinum-resistant ovarian CA	Neutropenia, thrombocytopenia, diarrhoea; 6 deaths due to PD
Gibney, 2010	Oral	M	24	Prostate CA	
Soukup, 2016 (review)	Oral	M	7	Haematological CA	No toxicities
Soukup, 2016 (review)	Oral	Cisplatin	25	Renal CA	DLT diarrhoea (n=2)
Soukup, 2016 (review)	Oral	M	25	CRPC	Vomiting, lethargy, fatigue (n=3)
Soukup, 2016 (review)	Oral	M	26	SCC/adeno CA cervix, vagina, vulva	Severe AE prolonged aPTT (n=1)
Soukup, 2016 (review	Oral	Docetaxel	30	Ovarian, fallopian, primary peritoneal CA	No data
CEP-1 (data on file)	Suppository	M& C/Carboplatin	18	Refractory solid TUs	Gr2 anaemia
DARRT-1 (data on file)	Suppository	C/Palliative Radiotherapy	24 (to date)	mCRPC	To date: mild fatigue, mild dry mouth, oral mucositis, stomatitis, moderate sinus arrhythmia
LuPIN-1 (investigator initiated study)	Suppository	C/ <sup>177</sup> Lutetium PSMA- 167	16 (to date)	mCRPC	Gr ≥2: haematologic, fatigue (n=3 each), pneumonitis (n=1)
SAS Cat. A (TGA) (data on file)	Suppository	C/Docetaxel C/Palliative RT	9 (to date)	Various solid TUs	Severe perianal rash (n=1)



### **Veyonda® - Clinical Program**



- Inhibitor of pro-survival mechanisms in cancer cells
- Activator of STING mechanisms

#### Multiple anti-cancer biologies able to offer 4 ways to attack metastatic disease



#### **CEP**

Chemo-Enhancement Program

#### **Chemo-enhancement effect:**

- Inhibit DNA repair - Inhibit MDR mechanisms



#### **DARRT**

Direct and Abscopal Response to Radiotherapy

#### Radio-enhancement effect:

- Inhibit DNA repair - STING agonism



#### **LuPIN**

Lutetium-PSMA in Combination with NOX66

#### Radio-enhancement effect:

- Inhibit DNA repair - STING agonism



#### **IONIC**

Immuno-Oncology with NOX66 in Combination

#### Immuno-oncology effect:

- STING agonism



### **CEP: Chemo-Enhancement Program**



Noxopharm is pursuing a combination of Veyonda® + cytotoxic chemotherapy as a treatment for late-stage metastatic disease burden because:

- Chemotherapy is the mainstay treatment of most forms of cancer<sup>1</sup>
- Off-target toxicity and development of tumour resistance make chemotherapy less practical in late-stage disease<sup>1,2</sup>
- ➤ **IDX** enhances the anti-cancer activity of many cytotoxics by up to 2,000x and reverses resistance to drugs including alkylating agents and anthracyclines<sup>3</sup>
- Noxopharm believes CEP offers an expedited means of obtaining a New Drug Approval and coming to market



1. Rumpold H & Wimder T. Magazine of Eur Med Oncol. 2017;10:119-120. 2. Gupta S, et al. Ann N Y Acad Sci. 2011;1215:150-60. 3. Brown D, et al. Drugs Fut. 2008;33(10):844-860.

### **CEP-1: Chemo-Enhancement Program**



#### **CEP-1 Phase 1b Study** (Completed)

- Open label study; 19 patients with end-stage solid cancers (breast, lung, prostate, ovarian)
- Dose-finding (400 mg/800 mg Veyonda®) with low-dose carboplatin

Dose cohort	Assessment time point*	Count n	Partial response	Stable disease	Progressive disease
Cohort 1 Veyonda® 400mg, n (%)	Cycle 3	5	0 (0.0)	4 (80.0)	1 (20.0)
	Cycle 6	2	0 (0.0)	1 (50.0)	1 (50.0)
Cohort 2 Veyonda® 800mg, n (%)	Cycle 3	9	0 (0.0)	7 (77.8)	2 (22.2)
	Cycle 6	6	1 (16.7)	4 (66.7)	1 (16.7)

RECIST 1.1 Data for evaluable patients after 3 and 6 cycles

- Of the 9 patients allocated to the higher dosage (800 mg) of Veyonda®, 5/9 (56%) showed stable disease (no tumour growth and no new tumours) or a partial response after 6 cycles
- Veyonda® generally well tolerated with only one serious adverse event (anaemia) considered possibly related to Veyonda®

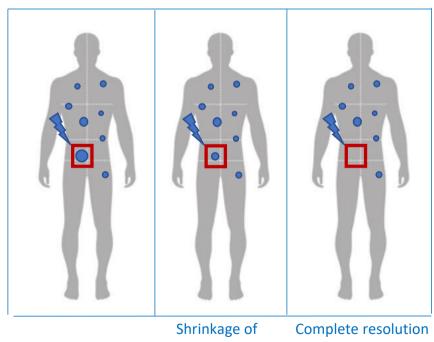


### **DARRT: Radio-Enhancement Program**

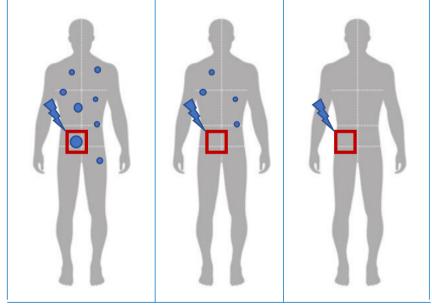


#### Rationale: Single course of Veyonda® + palliative external beam RT to a single lesion

- DNA repair inhibition boosts effect of RT on irradiated lesion
- STING agonist effect produces anti-cancer effect in non-irradiated lesions (abscopal effect)



Irradiated tumor of Irradiated tumor



Partial abscopal response

Complete abscopal response



### **DARRT: Radio-enhancement Program**



#### **DARRT-1 Phase 1b Study** (Current)

- Open label study; 24 patients with mCRPC post-taxane and abiraterone/enzalutamide
- Treatment regimen = 10 days Veyonda®: palliative EBRT (20-25 Gy) in 5 fractionated doses to a single lesion
  - Dose escalation arm: 12 patients: 400 mg/800 mg/1200 mg Veyonda®
  - Dose expansion arm: 12 patients: 1200 mg Veyonda®

At 24 weeks of follow up of 12 patients in the Dose Escalation Arm:

- > Safety and tolerability: All three doses continued to be well tolerated and no serious side-effects were reported as being related to Veyonda®
- Tumour size: Disease control (stabilization of tumour volume) was highly durable with 50% of patients remaining progression-free at 6 months<sup>1</sup>
- Pain: 5 of 7 patients maintained pain responses (≥ 30% falls) at 6 months as compared to 3 months, with two of these patients being completely pain-free at 6 months
- PSA: 5/14 patients (36%) experienced a clinically meaningful PSA response (≥ 50% fall) during the follow up period

Note: PSA responses in trials of palliative external beam radiotherapy alone range from 5-9% 2,3

1. Noxopharm Ltd. (2019). DARRT treatment has lasting disease control at six months. https://www.noxopharm.com. 2. Din OS, et al. Radiother Oncol. 2009;93:192-6. 3. Kwon ED, et al. Lancet Oncol. 2015;15:700-12.

### **LuPIN: Radio-enhancement Program**



# Rationale: To boost effectiveness of most radiopharmaceuticals which is limited by degree of expression of target receptor on cancer cells via

- > DNA repair inhibition to boost DNA-damaging effect of isotope on cancer cell
- >STING agonist effect to stimulate innate immune cell function in all lesions.

#### **LuPIN-1 Phase 1b Study (Current)**

- Open label study; 56 patients with mCRPC post-taxane and abiraterone/enzalutamide
- ightharpoonup Treatment regimen = 6 cycles of 10 days Veyonda® + single intravenous <sup>177</sup>lutetium-PSMA-617
  - Dose escalation: 8 patients 400 mg Veyonda®; 24 patient 800 mg; 24 patients 1200 mg
     Veyonda®

#### **Objectives:**

- To achieve higher response rates, with more patients able to complete the 6-course Lu-PSMA treatment without relapsing
- To achieve greater depth of response as measured by PSA levels
- To achieve more durable responses as measured by improved time to progression and overall survival.



### **LuPIN: Radio-enhancement Program**

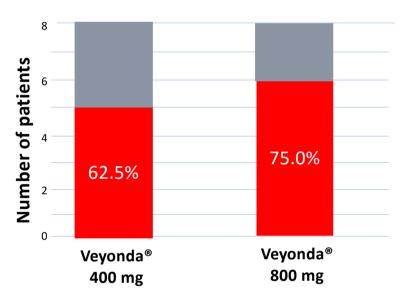


#### Interim data

#### First 16 subjects:

- All of whom have received ≥ 2 doses of 177Lu-PSMA-617
- 4/16 have already completed the planned 6 cycles
- Patients 1-8 received 400 mg of Veyonda®
- Patients 9-16 received 800 mg of Veyonda®

#### **PSA** response by Veyonda® dose



Adapted from Emmett L, et al. 2019<sup>1</sup>

69% overall PSA response rate (≥ 50% PSA fall) compares favourably with PSA response rates of <sup>177</sup>Lu-PSMA-617 alone, ranging between 31 - 61%<sup>2-5</sup>

1. Emmett LE, et al. Abstract submitted to SNMMI 2019. 2. Hofman MS, et al. Lancet Oncol. 2018;19(6):825-33. 3. Kratochwil C, et al. Journal Nuc Med. 2016;57(8):1170-6. 4. Emmett L, et al. J Med Rad Sci. 2017;64(1):52-60. 5. Emmett L, et al. Clin Genitourin Cancer. 2019;17:15-22.



### **Clinical Strategy**



#### CEP

Chemo-Enhancement Program



#### **DARRT**

Direct and Abscopal Response to Radiotherapy



#### **LuPIN**

Lutetium-PSMA in Combination with NOX66



#### IONIC

Immuno-Oncology with NOX66 in Combination

- > Considered likely quickest way to achieve NDA
- ➤ Select cancer type with poor therapeutic options (e.g. sarcomas)
- Opportunity for Accelerated Approval, Orphan Drug designation, Pediatric Review Voucher
- ➤ Timetable: Commence Phase 1b study Q4 2019; Phase 2 adaptive trial 2021; NDA grant 2023
- High priority given prevalence of mCRPC and unmet need
- Complete DARRT-1
- Q3 2020 commence DARRT-2 Phase 2 adaptive trial in latestage mCRPC
- Investigate use of Veyonda® + low-dose EBRT in earlier-stage prostate cancer (e.g., pre-castration Rx; non-mCRPC)
- Continue with LuPIN-1; anticipated completion end-2020
- Future development to be subject of discussion with owner of Lu-PSMA drug candidate
- Explore benefit of Veyonda® with other radiopharmaceuticals in cancers other than prostate cancer
- Veyonda® + checkpoint inhibitor (PD-1 or PD-L1) with or without low-dose EBRT considered likely preferred regimen
- Pre-clinical studies current
- Timetable: Commence Phase 1b study Q2 2020



### **CEP-2: Chemo-enhancement Program**





# Phase 1b, open label; Veyonda® + doxorubicin; metastatic soft tissue sarcomas

- Design: Dose escalation and dose expansion study
  - Dose escalation: 400, 600, 800, 1200, 1800 mg Veyonda® (up to 30 patients)
  - Dose expansion: MTD Veyonda® dose (16 patients)
- > Sites: U.S.; multiple
- ➤ **Title:** A dose escalation and dose expansion study of Veyonda® (idronoxil suppository) plus doxorubicin in anthracycline-naïve, adult patients with soft tissue sarcoma
- ➤ **Eligibility:** Anthracycline naïve adult patients with metastatic soft tissue sarcoma for whom treatment with doxorubicin is considered to be appropriate.
- Objectives: MTD, safety, PK, QoL, efficacy (RECIST, PERCIST, PFS, OS)



### **Intellectual Property**



- Family of 5 PCT patents; final specifications lodged with USPO in 2017
- Based on LIPROSE drug delivery technology involving proprietary suppository formulation
- Key claims relate to protection of IDX from Phase 2 metabolism and sustained half-life
- Other claims relate to use (chemo-enhancement, radio-enhancement, etc)
- Patents currently in national phase in 80 countries
- Patent Attorneys: Freehills Patent Attorneys (Australia); ParkerHighlander (USA)



# Multiple anticipated milestones



	TIMING	STUDY	MILESTONE
СЕР	3Q 19	CEP-2	File IND
CLP	4Q 19	CEP-2	Initiate study
	3Q19	DARRT-1	Data: Interim results
DARRT	4Q 19	DARRT-1	Data: Interim results
	1Q 20	DARRT-1	Data: Interim results
LuPIN	3Q 19	LuPIN-1	Data: Interim results
LUPIIN	2Q 20	LuPIN-1	Data: Interim results
IONIC	2Q 20	IONIC-1	File IND



### **Senior Management**





Graham Kelly Executive Chairman BSc, BVSc, PhD

Graham has 25 years' experience in founding and leading biotech companies. He founded Novogen Ltd (ASX:NRT. NASDAQ: NVGN)(now Kazia Therapeutics, KZA) in 1994; Marshall Edwards Inc (NASDAQ:MEI) (now MEI Pharma, MEIP) in 2001; Noxopharm (ASX:NOX) in 2016. He oversaw NVGN from A\$12M market cap in 1994 to A\$900M in 2003.



#### **Greg van Wyk CEO**

MBBCh, BBA, MEc

Greg is a medical doctor who prior to joining NOX had a 11-year career as a Medical Director in Eli Lilly, leading medical teams in Australasia and North-Western Europe across a range of therapeutic areas including oncology. Greg also has post-graduate degrees in management and economics.



#### Gisela Mautner Global Medical Director

MD-PhD (TU-LMU Munich) MPH (Harvard) MBA (Kellogg) FACPE (Australia)

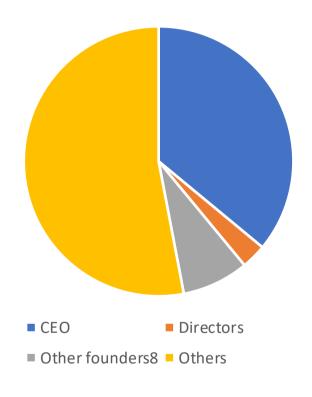
Gisela is a medical doctor with over 20 years' experience in the pharma/biotech industry in Europe, USA and Australasia. In her early career Gisela was a research scientist at NIH, Bethesda, MD. Since then she has focused on bringing new drugs and therapies to market in senior roles in Medical Affairs at Merck, Bayer and Amgen.



### **Key Metrics**



Number of Shares	121,902,310 shares outstanding  Free float 66.8%  25,282,956 options (expiring 2020-22)		
Market Cap (13 March 2019)	AU\$74M		
IPO price	20 cents		
12 month high/low	\$1.64/0.36		
Cash position	<ul> <li>AU\$ 6.2M (31 March 2019)</li> <li>AU\$4M anticipated July 2019 (Aust Govt R&amp;D Rebate)</li> </ul>		







# **Noxopharm Limited**

**Veyonda**®

