



**ASX Announcement | 16 March 2021**  
**Noxopharm Limited (ASX:NOX)**

## **ASX Small-Mid Cap Conference Corporate Presentation**

**Sydney 16 March 2021: Australian clinical-stage drug development company Noxopharm Limited (ASX:NOX)** announces that CEO and Founder, Dr Graham Kelly, has been invited to present at the virtual ASX Small-Mid Cap Conference on 16-17 March, 2021.

The Noxopharm presentation will focus on the Company's goal of establishing Veyonda (NOX66) as a highly sought-after, next generation immuno-oncology drug, to be used to boost the anti-cancer effectiveness of most standard anti-cancer therapies including radiotherapy, chemotherapy and immune checkpoint inhibitors.

This distinctive broad use across the spectrum of cancer treatments is based on a unique action of restoring immune function to tumours in a process referred as converting tumours from 'COLD' to 'HOT', restoring the ability of the body's immune system to take advantage of the anti-cancer action of the standard treatments.

Dr Kelly will review the Company's progress in generating the underlying proof-of-concept data towards its goal of raising both the potential commercial value and international profile of Veyonda.

Attendance at the virtual conference is complimentary.  
To register, please visit: [ASX Small-Mid Cap conference](#)

Dr Kelly's presentation titled, "ASX Small-Mid Cap Conference Presentation March 2021" is attached.

-ENDS-

*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.*

### **About Noxopharm**

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

Veyonda is the Company's first pipe-line drug candidate currently in Phase 2 clinical trialing. Veyonda has three main drug actions – highly selective inhibition of sphingosine kinase, STING signaling and autophagy. Sphingosine kinase inhibition contributes to its dual-acting oncotoxic and immuno-oncology functions designed to enhance the effectiveness and safety of standard oncology treatments, i.e., chemotherapies and immune checkpoint inhibitors;



STING signaling inhibition provides an anti-inflammatory effect, contributing to an anti-cancer action, but also potentially blocking sepsis; autophagy inhibition is believed to augment the immunotherapy effect of radiotherapy, in particular the triggering of an abscopal response.

Noxopharm also is the major shareholder of US biotechnology company Nyrada Inc (ASX:NYR), and wholly owns Pharmorage, a private drug development company focused on drug development in the areas of sepsis and autoimmunity.

To learn more visit: <https://www.noxopharm.com/>

**Investor & Corporate enquiries:**

Prue Kelly

M: 0459 022 445

E: [info@noxopharm.com](mailto:info@noxopharm.com)

**Company Secretary:**

David Franks

T: +61 2 8072 1400

E: [David.Franks@automicgroup.com.au](mailto:David.Franks@automicgroup.com.au)

**Media Enquiries**

Julia Maguire

The Capital Network

E: [julia@thecapitalnetwork.com.au](mailto:julia@thecapitalnetwork.com.au)

T: + 61 2 8999 3699

**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 (ASX:NOX)

ASX SMALL-MID CAP CONFERENCE PRESENTATION  
March 2021

Dr Graham Kelly  
CEO and Managing Director

Discover



Develop



Deliver



# Disclaimer



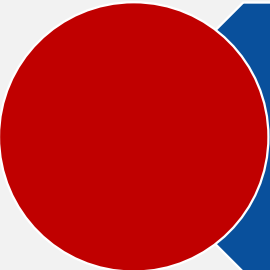
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Medical advances have helped delay the progression of many forms of cancer. However, once an aggressive cancer becomes metastatic (with secondary tumours), current treatment options generally are very limited in their effectiveness

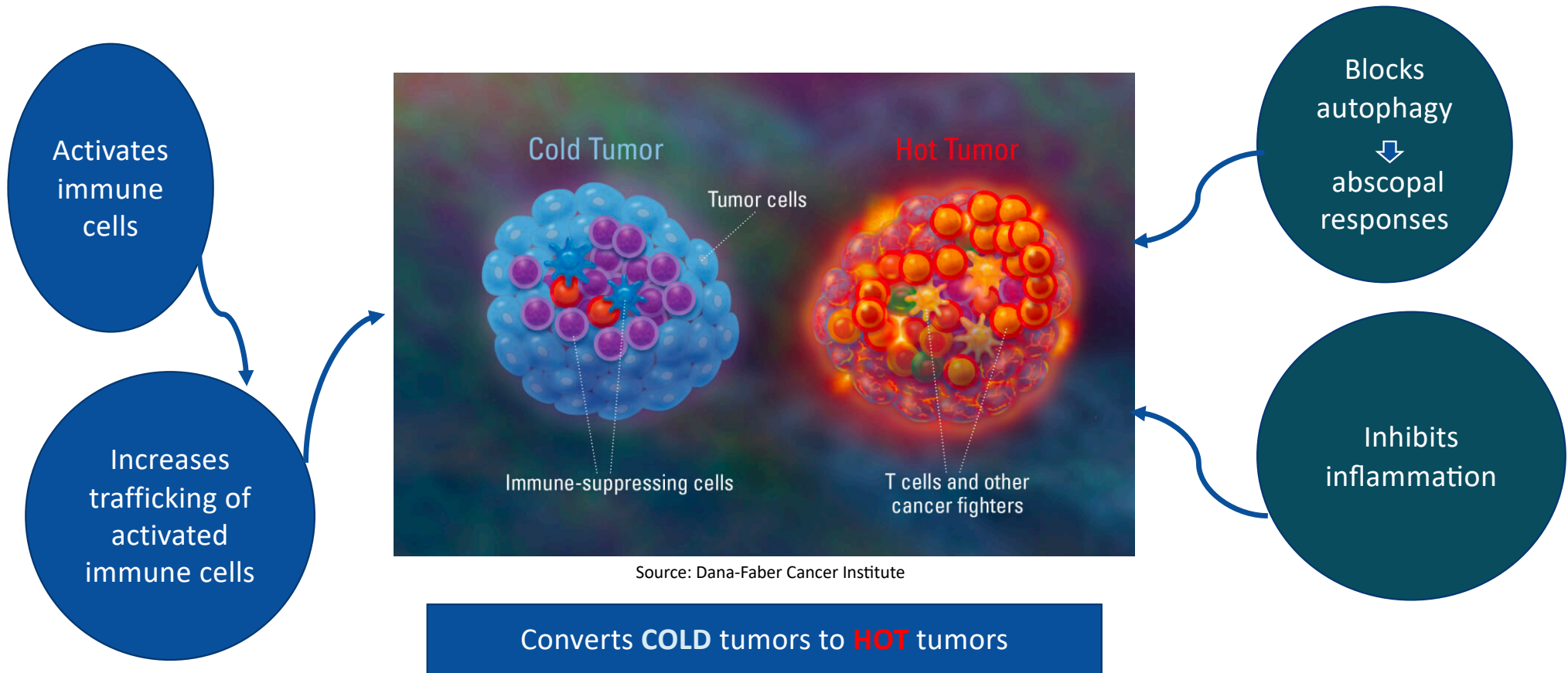
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**Our aim is simple. To boost the effectiveness of most current forms of cancer treatment, delivering long-term remission in most patients, by restoring the cancer-fighting capacity of the body's immune system**

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**We believe that Veyonda<sup>®</sup> is about to achieve that goal and in so doing revolutionise the treatment of cancer**

# breakthrough COLD to HOT immunotherapy drug





# Treatment options for metastatic cancer

Used in most cancers

Radiotherapy

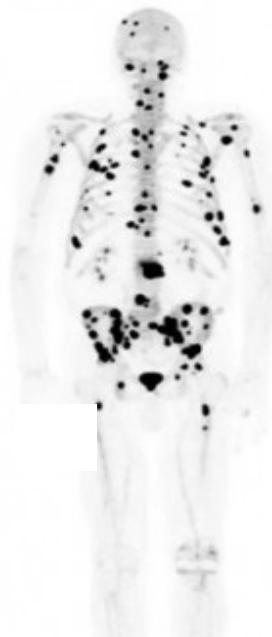
Chemotherapy

Limited to certain cancer types

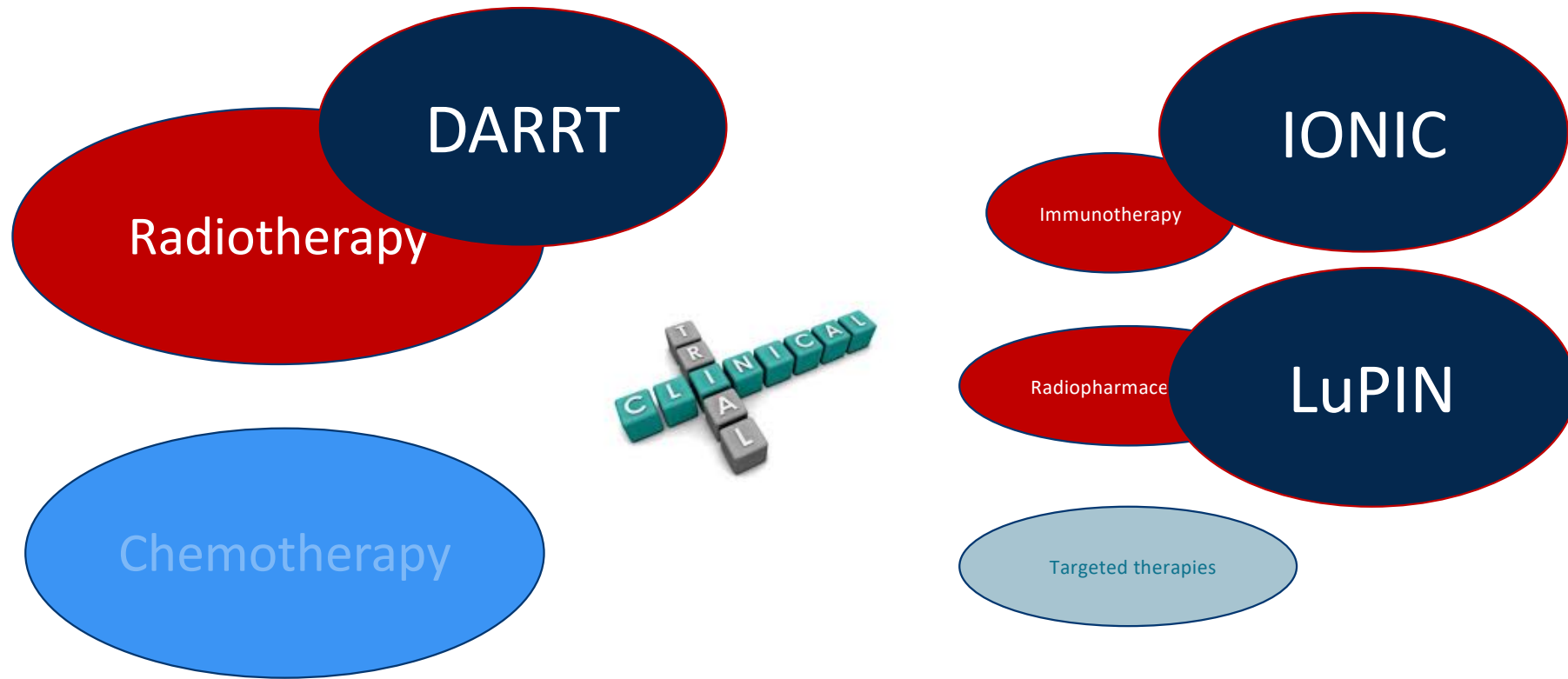
Immunotherapy

Radiopharmaceuticals

Targeted therapies



# Proof-of-concept being sought by NOX in 3 different cancer treatments





**DARRT**



**Veyonda<sup>®</sup> + Low Dose Radiotherapy**

**A revolutionary new treatment for solid cancer**

## Veyonda<sup>®</sup> + Low-Dose Radiotherapy



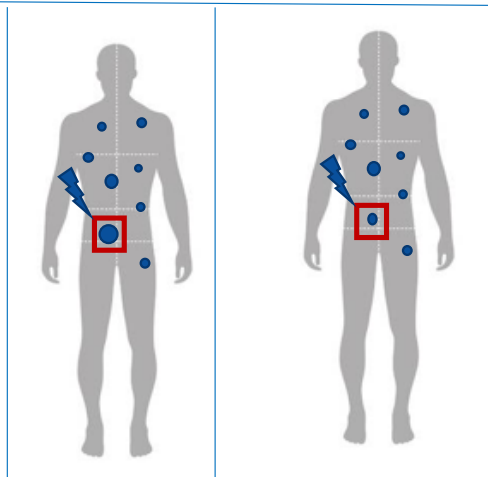
- In metastatic cancer, radiotherapy (RT) generally applied to 1 or 2 individual tumours
- Mainly used for relief of symptoms (eg pain, loss of function)
- No meaningful effect on patient survival or disease progression expected with low-dose RT alone

# DARRT Program

Direct and Abscopal Response to Radiotherapy

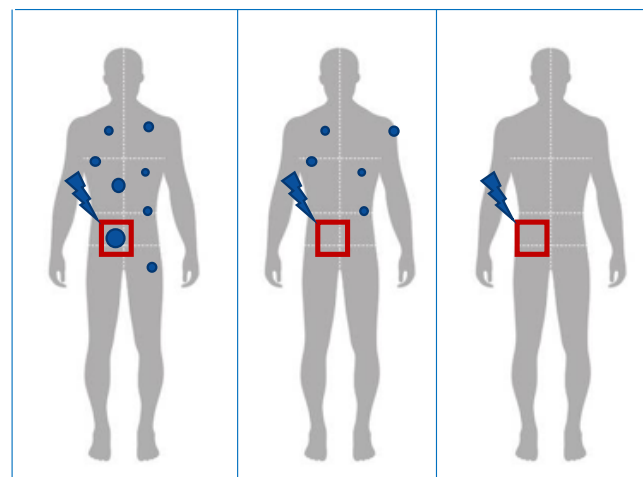


- Aim is to deliver a dose of radiation to a single tumour and to shrink or eradicate that tumour
- In the overwhelming majority of cases, the effect of the radiation is restricted to the irradiated tumour
- In extremely rare cases, tumours outside of the field of radiation also shrink. This is an immune response known as an **ABSCOPAL RESPONSE**



Shrinkage of irradiated tumour

Standard response



Partial abscopal response

Complete abscopal response

Very rare abscopal response

Aim of DARRT therapy is to convert an abscopal response from extremely rare to commonplace

# DARRT Program



## Low-dose radiotherapy

- ▮ to a single lesion
- ▮ external beam radiotherapy
- ▮ 8-30 Gy
- ▮ 1-10 fractionated doses
- ▮ single cycle of radiotherapy

## Veyonda® (NOX66)

- ▮ 21-day cycle: daily dosing for 14 days (7 days rest)
- ▮ starting Day -1
- ▮ repeat monthly cycles (in DARRT-2) until disease progression

## RATIONALE

- ▮ standard dose of radiation designed to **kill** cancer cells
- ▮ low dose of radiation designed to **damage** cancer cells to trigger an immune response
- ▮ Veyonda used to tip that immune response over into an **ABSCOPAL RESPONSE**

## Features:

- Highly accessible. External radiotherapy readily available
- Cost-effective treatment
- Very well tolerated
- Potential for all solid cancer types

## DARRT-1 Phase 1 trial



26 men with end-stage prostate cancer

- had stopped responding to treatment
- had metastatic and progressive disease
- were considered to have limited life-spans
- were treated with Veyonda + low-dose RT

- In 10/15\* men, tumours stopped growing or reduced in size
- 10/16\*\* had meaningful pain reduction
- Treatment well tolerated
- Abscopal responses confirmed in 4 men#

\* 15 patients had measurable disease as per RECIST v1.1 at 24 weeks

\*\* 16 patients were evaluable for pain assessments at 24 weeks

# First known demonstration of abscopal responses in prostate cancer in more than isolated cases

### DARRT-2 Study Design

- Phase 1b/2a study
- Differs from DARRT-1 in higher Veyonda dose and repeat cycles
- Multi-national
- Prostate, breast, lung cancers
- 100-150 patients
- Abscopal responses + range of other anti-tumour responses
- Commencing H2 2021

**LuPIN**



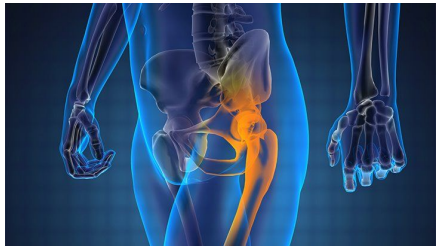
**Veyonda<sup>®</sup> + <sup>177</sup>lutetium-PSMA-617**



**An exciting new treatment for prostate cancer**



# LuPIN Program



**Lu-PSMA-617** is a radioactive drug injected IV and designed to deliver radiation to every prostate cancer cell throughout the body

Acquired by Novartis in 2018 for **US\$6 billion**

**Proposed new treatment** for prostate cancer once the cancer has spread widely

**But .....**

1/3<sup>rd</sup> men have little or no response; response in responders not long-lasting

**Aim .....**

Use Veyonda to boost the effectiveness of the Novartis drug ➡ more men responding as well as achieving significantly longer survival times

Phase I/II study. St Vincent's Hospital Sydney. 56 men. End-stage cancer. No remaining standard treatments. Anticipated median survival approximately 4.5 months

# LuPIN: Interim Data Reporting



American Society of Clinical Oncology Genitourinary Cancers Symposium Feb 11-13 2021

**ANSWER:** Yes, the combination of Veyonda and Lu-PSMA-617 looks to be considerably more effective than Lu-PSMA-617 on its own (*based on published Phase 2 data*<sup>1</sup>)

**56 men**

400 + 800 mg + 1200 mg Veyonda

Median Overall Survival:

**19.7 months**

a remarkable result for this late stage of the disease

**Combination was well tolerated**

**Noxopharm believes this to be a potential major breakthrough in the treatment of Stage 4 prostate cancer**

1. [https://ascopubs.org/doi/abs/10.1200/JCO.2019.37.7\\_suppl.228](https://ascopubs.org/doi/abs/10.1200/JCO.2019.37.7_suppl.228)

# LuPIN: Interim Survival Data



**Median overall survival = time when half the patients have died and half still alive**

Three standard lines of drug therapy once prostate cancer becomes metastatic



Historical data<sup>1</sup> → ~ 4.5 months

<sup>177</sup>Lu-PSMA-617 alone<sup>2</sup> → 13.3 months

<sup>177</sup>Lu-PSMA-617 + Veyonda (56 patients)<sup>3</sup> → 19.7 months

1. Buonerba C, et al. (2014) Future Oncol 10:1353–60. 2. Hofman M, et al. (2018) Lancet Oncol 19, 825. 3. Noxopharm ASX announcement 15 Feb 2021

**IONIC**



**Veyonda<sup>®</sup> + nivolumab (Opdivo<sup>®</sup>)**



**Overcoming resistance to checkpoint inhibitors**

# IONIC Study

Phase I/II proof-of-concept study



**15 patients pre-treated with Opdivo but tumours not responsive**

**15 patients not pre-treated with Opdivo because cancers considered to be unresponsive**

- Melanoma
- Lung
- Kidney
- Bladder
- Head & neck

Typically 10-30% response rate

All other cancer types

Typically 0-3% response rate

**Veyonda + Opdivo**

**Opdivo sales (2019) US\$8 billion**

**Increasing response rate to checkpoint inhibitors projected to increase sales >US\$50 billion**

# SUMMARY



## Both DARRT and LuPIN have provided clear evidence of proof-of-concept

**DARRT:** Adding **Veyonda** to a low dose of radiotherapy not expected to do anything more than shrink a single tumour, led in men with end-stage prostate cancer to:

- A halt to disease progression or better in 10/15 men
- Confirmed ABSCOPAL RESPONSES in 4 (25%) men, where few reports in prostate cancer exist

**LuPIN:** Adding **Veyonda** to Lu-PSMA-617 in men with end-stage prostate cancer:

- Resulted in a median overall survival of **19.7** m versus **13.3** m with the Novartis drug on its own

## IONIC trial

Veyonda has first-in-class action in the lab in converting COLD tumours to HOT, an action considered vital in overcoming resistance to drugs such as Opdivo (Bristol Myers Squibb)

## Veyonda is well tolerated as a combination treatment

# Our commercial end-point for Veyonda



**A number of important blockbuster (>US\$1 B annual sales) drugs are losing their exclusivity over coming years. This is putting pressure on big pharma to refresh revenue streams through M&A activity**



**Programs focusing on immuno-oncology and cell therapy remain the most attractive targets for partnering**

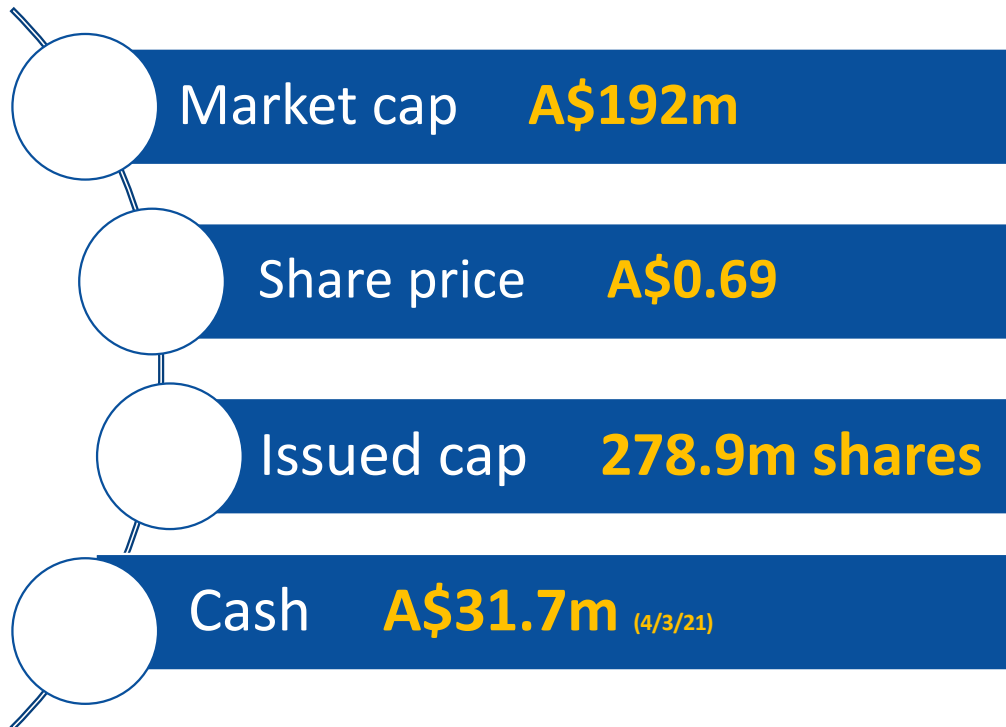


**In 2020, 52 deals >US\$1 billion were transacted, 31 of these were for immuno-oncology and cell therapy assets and platforms**



# Key metrics

as at 12 March 2021



## News Flow (next 6 months)

- IONIC-1 and DARRT-2 start patient recruitment
- COVID-19 clinical trial completion
- Growing first-in-class drug pipeline
- Pharmorage (subsidiary) progressing novel drug development for sepsis and autoimmunity



## *For further information*

email: [info@noxopharm.com](mailto:info@noxopharm.com)

web: [www.noxopharm.com](http://www.noxopharm.com)

twitter: [@noxopharm](https://twitter.com/noxopharm)

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Develop



Deliver

