



Date: 27 November, 2017

Sydney, Australia

ASX Limited  
20 Bridge Street  
SYDNEY NSW 2000

## NOX AGM CORPORATE PRESENTATION

### ASX: NOX

### Noxopharm Limited

ABN 50 608 966 123

**Registered Office:**  
Suite 1 Level 6  
50 Queen St  
Melbourne VIC 3000  
Australia

**Operational Office:**  
Suite 3, Level 4  
828 Pacific Highway  
Gordon NSW 2072  
Australia

**Board of Directors**  
**Mr Peter Marks**  
Chairman  
Non-Executive  
Director

**Dr Graham Kelly**  
Chief Executive Officer  
Managing Director

**Dr Ian Dixon**  
Non-Executive  
Director

**Sydney, 27<sup>th</sup> November 2017:** Noxopharm Limited (ASX:NOX) is pleased to provide to the market and shareholders the Corporate Presentation for today's 2017 Annual General Meeting.

To be held at 2.00 pm at the Sydney Sofitel Wentworth Hotel, Adelaide Room, Level 4, 61-101 Phillip Street, Sydney.

#### About Noxopharm

Noxopharm is an Australian drug development company with offices in Sydney and Hong Kong. The Company has a primary focus on the development of drugs to address the problem of drug-resistance in cancer cells, the major hurdle facing improved survival prospects for cancer patients. NOX66 is the first pipeline product, with later generation drug candidates under development. The Company also has initiated a pipeline of non-oncology drugs.

#### Investor & Corporate Enquiries:

Prue Kelly  
M: 0459 022 445  
E: [info@noxopharm.com](mailto:info@noxopharm.com)

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

#### Company Secretary :

David Franks  
T: +61 2 9299 9690  
E: [dfranks@fa.com.au](mailto:dfranks@fa.com.au)

#### 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.



**CEO REVIEW**

**2017 AGM**

# *Our objectives*

## *For the doctor:*

- Drugs that boost the effectiveness of radiotherapy (and chemotherapy) .... with lower (better tolerated) treatment dosages

## *For the patient:*

- Better survival outcomes without fewer side-effects

## *For the investor:*

- A technology platform with the potential to become standard of care .... with an aim of generating revenue in 2022

# Radiotherapy ... the best anti-cancer treatment we have

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DNA before and after radiation





### RADIATION EFFECTS

Measurements in millisieverts (mSv). Exposure is cumulative.

■ **Potentially fatal radiation sickness. Much higher risk of cancer later in life.**

**10,000 mSv:** Fatal within days.

**5,000 mSv:** Would kill half of those exposed within one month.

**2,000 mSv:** Acute radiation sickness.

■ **No immediate symptoms. Increased risk of serious illness later in life.**

**1,000 mSv:** 5% higher chance of cancer.

**400 mSv:** Highest hourly radiation recorded at Fukushima. Four hour exposure would cause radiation sickness.

**100 mSv:** Level at which higher risk of cancer is first noticeable

■ **No symptoms. No detectable increased risk of cancer.**

**20 mSv:** Yearly limit for nuclear workers.

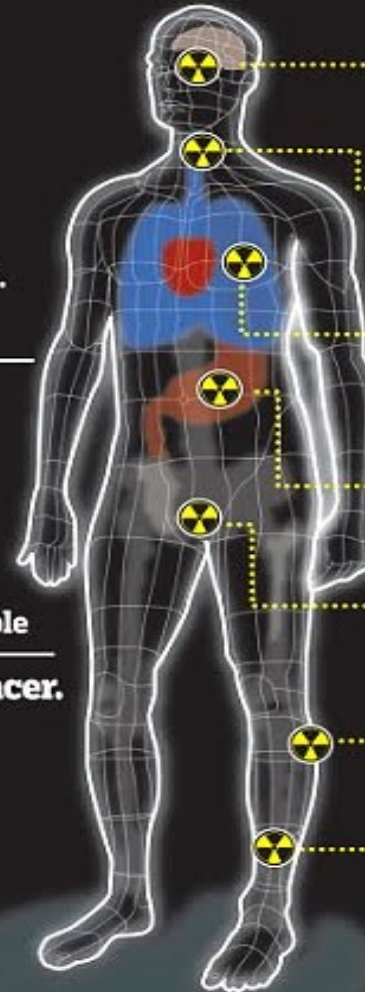
**10 mSv:** Average dose from a full body CT scan

**9 mSv:** Yearly dose for airline crews.

**3 mSv:** Single mammogram

**2 mSv:** Average yearly background radiation dose in UK

**0.1 mSv:** Single chest x-ray



**EYES** High doses can trigger cataracts months later.

**THYROID** Hormone glands vulnerable to cancer. Radioactive iodine builds up in thyroid. Children most at risk.

**LUNGS** Vulnerable to DNA damage when radioactive material is breathed in.

**STOMACH** Vulnerable if radioactive material is swallowed.

**REPRODUCTIVE ORGANS** High doses can cause sterility.

**SKIN** High doses cause redness and burning.

**BONE MARROW** Produces red and white blood cells. Radiation can lead to leukaemia and other immune system diseases.

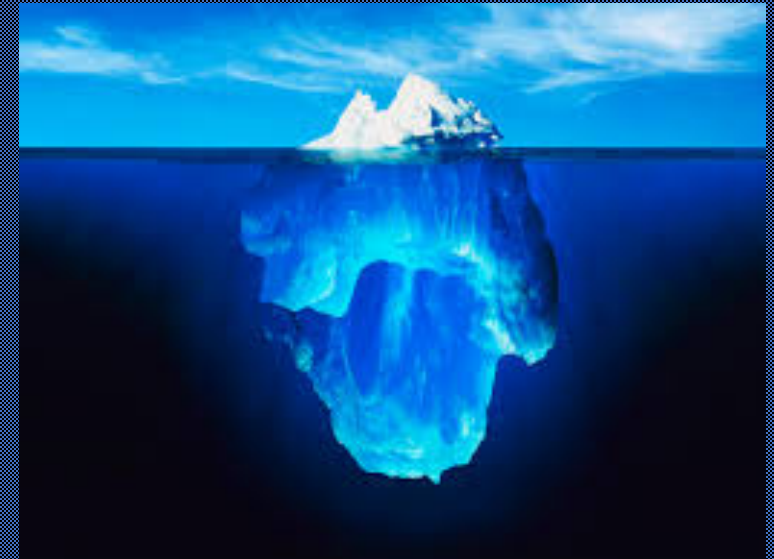
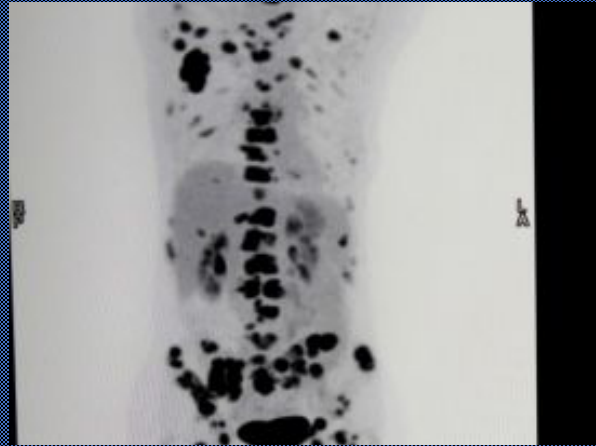
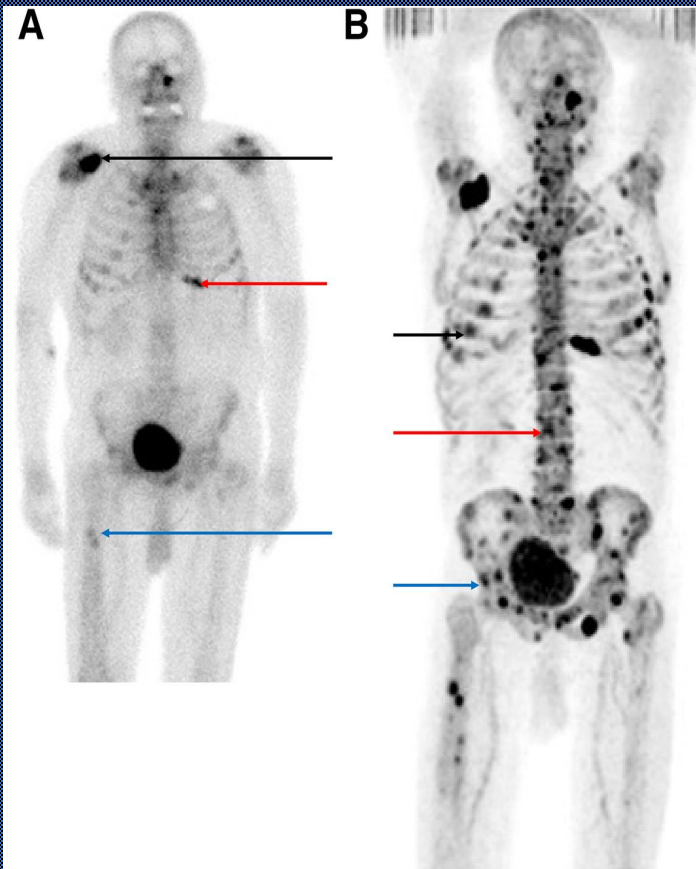
# Limitation of radiotherapy

## 2. *Metastatic cancer too extensive for radiation*



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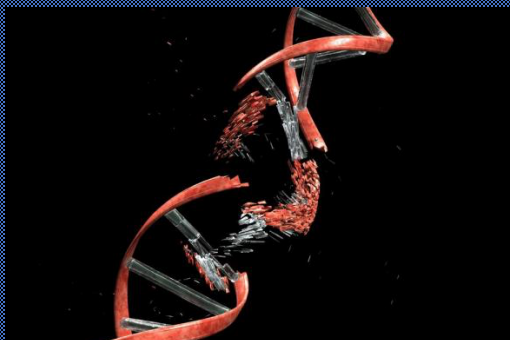


# DARRT

## Direct and Abscopal Response to Radio-Therapy

# DIRECT Sensitisation of Radio-Therapy

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- ☠ DNA damaged. Cell attempts to repair the damage.
- ☠ Extensive damage .. beyond repair.....cell dies.  
Modest damage ... repairable .... cell lives.
- ☠ Most dosages of radiotherapy not high enough to deliver extensive damage to all cancer cells .... tumour survives.

## NOX66

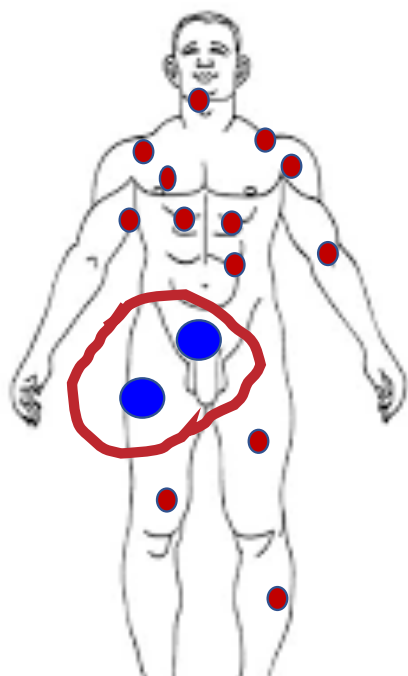
- ❖ Blocks ability of cancer cell to repair damage .... even modest damage becomes un-repairable .... cell dies
- ❖ Does NOT increase extent of damage
- ❖ No effect on healthy cells



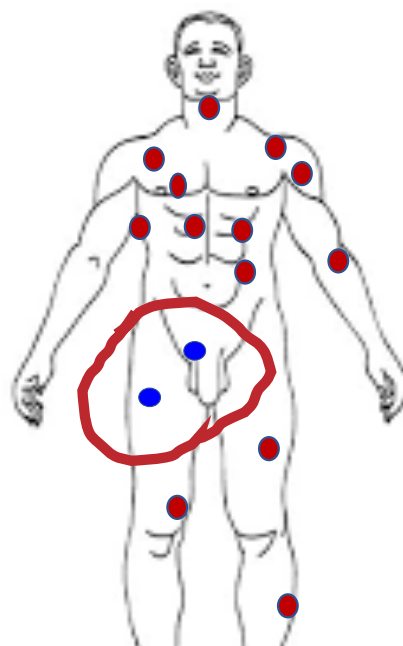
# DIRECT Response to Radio-Therapy

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Radiotherapy applied to large tumours for pain relief

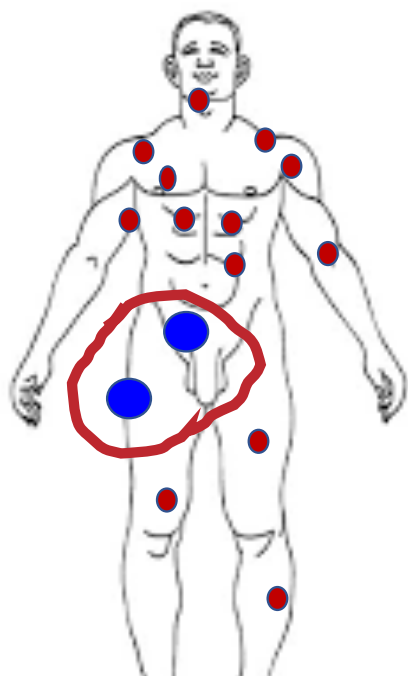


Shrinkage of irradiated tumours

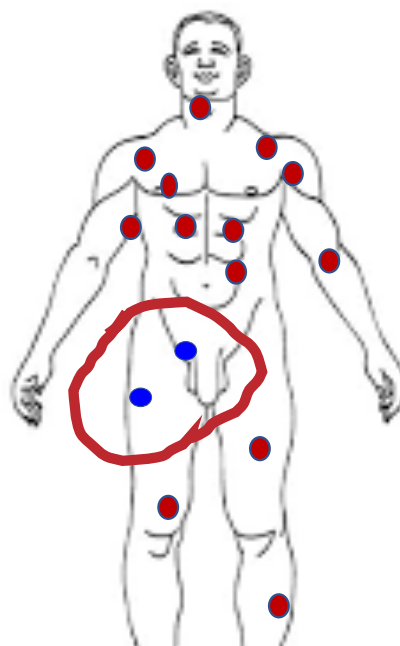
# DIRECT Response to Radio-Therapy

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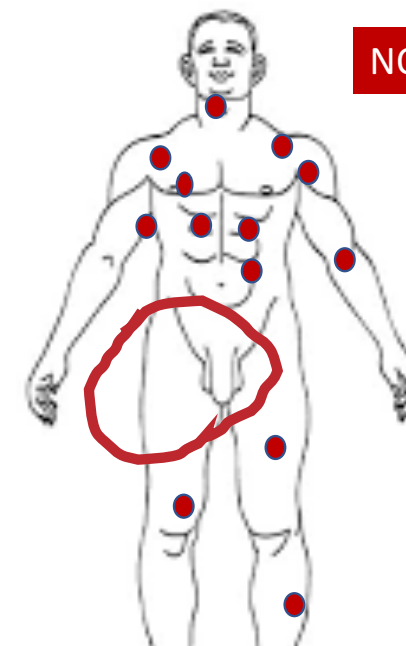
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Radiotherapy applied to large tumours for pain relief



Shrinkage of irradiated tumours



NOX66

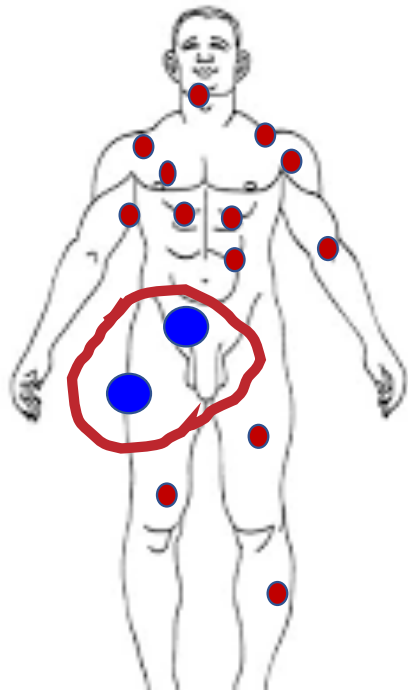
Complete remission of irradiated tumours

# ABSCOPAL Response to Radio-Therapy

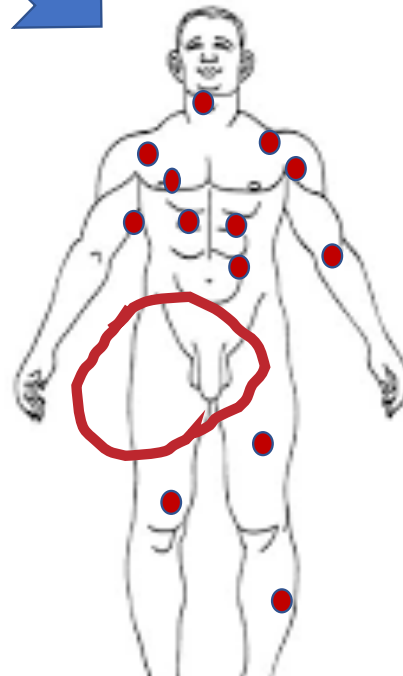
Noxopharm

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Exposed tumours respond

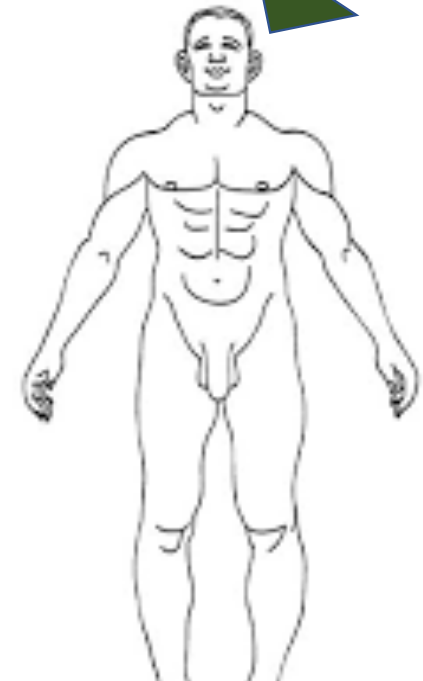


Low-dose radiotherapy



Remission of irradiated tumours

Non-exposed tumours respond

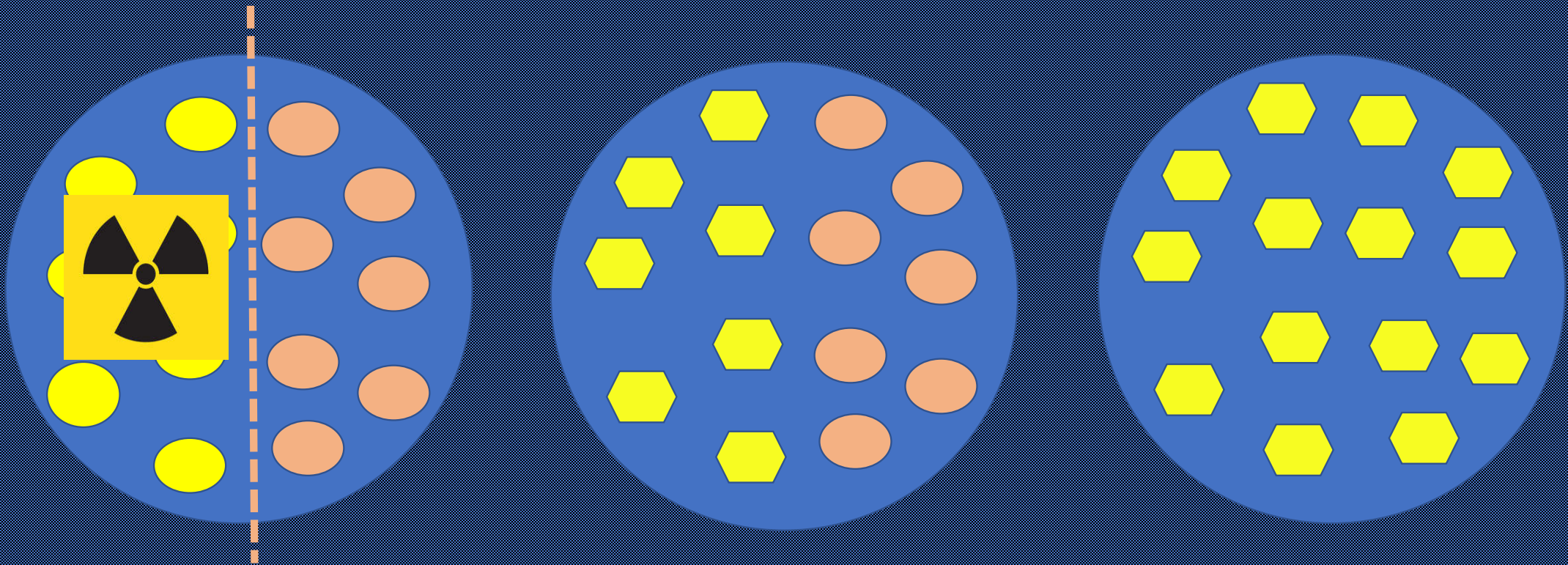


Abscopal response

# Features of an abscopal response

- Rare*** – very rare phenomenon
- Complete*** – primary AND secondary tumours disappear
- Durable*** – potentially permanent
- Unrestricted*** – range of cancers reportedly involved
- Short treatment*** – single course of treatment (7-14 days)
- Low toxicity*** – low-grade radiation sickness

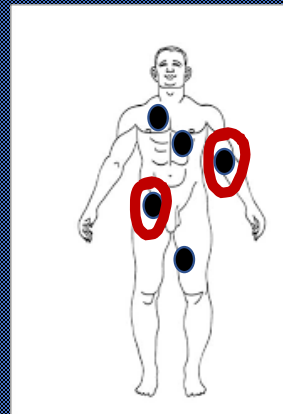
*How might an abscopal response/bystander effect work?*



## Direct Effect

## Abscopal Effect

- Patients with multiple (>3) tumours
- Irradiate 1-2 tumours (5 days)
- NOX66 14 days
- Scan + 2 months and 4 months



External Beam RT

## Direct Effect

## Abscopal Effect

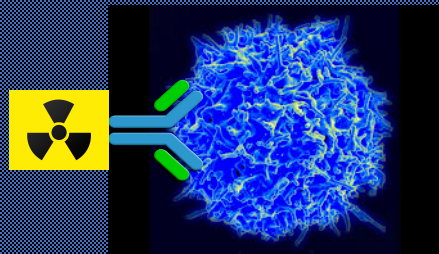
- Prostate cancer (metastatic castrate-resistant)
- Solid common cancers (eg. lung, breast, melanoma)
- Rare cancers (eg. sarcomas)



External Beam RT

## Direct Effect

## Abscopal Effect



Brachytherapy

- $^{177}$  Lutetium-PSMA-617
- 4 x monthly intravenous injections of LuPSMA/10 days NOX66
- Prostate cancer (metastatic castrate-resistant)
- ? Kidney cancer



# DARRT

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Where NOX66 + Radiotherapy needs a boost .....

NOX66-001 Phase 1b Study Georgia

+ Low-dose carboplatin (AUC4 – monthly)

400 mg NOX66

5 patients: 1 progressive; 4 non-progressive

800 mg NOX66

6 patients: 5 non-progressive; 1 partial response

# Clinical pipeline

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## **NOX66**

- + external beam radiotherapy**
- + brachytherapy**
- + chemotherapy (carboplatin)**

## **Idronoxil**

- + intravenous dosage form**
- + pessary dosage form**

# NOX66 Clinical Development Strategy

Ian Minns

Director, Clinical Development and Medical Affairs



# NOX66 Clinical Development

- Review of 2017 – Where are we now?
- Looking forward to 2018 – Where are we heading?
  - Moving NOX66 towards first registration - Radiotherapy
  - Chemotherapy and other research with NOX66
- Sharing our progress
- Communicating data in 2018 and beyond

## Review of 2017 – Where are we now?

### Mid-Year update

#### Studies planned:

1. Chemotherapy (Carboplatin): Study Commenced (Georgia)
2. Radiotherapy: External Beam RT in prostate cancer (Australia)
3. Radiotherapy: Stereotactic RT in prostate cancer (Investigator)
4. Radiotherapy: Brachytherapy in prostate cancer (Investigator)
5. Radiotherapy: External Beam RT in solid cancers (Hong Kong)
6. Rare Cancers: collect evidence in rare cancer population
7. Chemo-radiotherapy: in solid cancers (ANZ, Georgia)

# Review of 2017 – Where are we now?

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## Mid Year update → 6 months later

### Studies planned:

1. Chemotherapy (Carboplatin): Study Commenced

Recruitment completed, interim data presented

2. Radiotherapy: External Beam RT in prostate cancer

Open for Recruitment

3. Radiotherapy: Stereotactic RT in prostate cancer

Open for Recruitment

4. Radiotherapy: Brachytherapy in prostate cancer

Open for Recruitment

5. Radiotherapy: External Beam RT in solid cancers

6. Rare Cancers: collect evidence in rare cancers

Studies combined: multinational study in radiotherapy (all tumours) - Ethics submission (Aust) planned December

7. Chemo-radiotherapy: in solid cancers

De-prioritised, following discussions with oncologists

# Review of 2017 – Where are we now?

22

Mid Year update → 6 months later → Moving to first registration

Studies planned:

1. Chemotherapy (Carboplatin): Study Commenced

2. Radiotherapy: External Beam RT in prostate cancer

**Open for Recruitment**

3. Radiotherapy: Stereotactic RT in prostate cancer

4. Radiotherapy: Brachytherapy in prostate cancer

**Open for Recruitment**

5. Radiotherapy: External Beam RT in solid cancers

6. Rare Cancers: collect evidence in rare cancers

**Studies combined: Multinational study in Radiotherapy (all tumours) - Ethics submission (Aus) in December**

7. Chemo-radiotherapy: in solid cancers

# Moving towards first registration study

Target Indication: NOX66 in combination with Radiotherapy for the treatment of patients with metastatic cancer

## Studies:

NOX66-002A: Determine Dose of NOX66 (Prostate Cancer)

NOX66-006: Open Label, all tumours. safety and efficacy

NOX66-007: Randomised, common tumours. Efficacy in comparison to standard care

LuPIN Study:  $^{177}\text{Lu}$ -PSMA and NOX66 (Prostate Cancer)

Expansion of  $^{177}\text{Lu}$ -PSMA research

Other Radiotherapy Research (supportive data, for expanded indication in future) – e.g. brain, paediatrics, stereotactic, brachytherapy etc.

Submit for Registration

## Notes:

- Different Global Regulators may modify indication for specific tumour types
- Indication may also list when treatment can be used
- Indication will discuss how to use Radiotherapy with NOX66
- Rare cancers may not be included in indication, however evidence is important
- Reimbursement is as important as Registration



# Moving towards first registration

Target Indication: NOX66 in combination with Radiotherapy for the treatment of patients with metastatic cancer

## Studies:

NOX66-002A: Determine Dose of NOX66 (Prostate Cancer)

NOX66-006: Open Label, all tumours. Safety and efficacy

NOX66-007: Randomised, 2-3 tumours. Efficacy in comparison to standard care

LuPIN Study:  $^{177}\text{Lu}$ -PSMA and NOX66 (Prostate Cancer): Supporting registration

Expansion of  $^{177}\text{Lu}$ -PSMA research

Other Radiotherapy Research (supportive data, for expanded indication in future) – e.g. brain, paediatrics, stereotactic, brachytherapy etc.

Submit for Registration

2017

2018



2019

2020/21

## Notes:

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- Indication may also list when treatment can be used
- Indication will discuss how to use Radiotherapy with NOX66
- Rare cancers may not be included in indication, however evidence is important
- Reimbursement is as important as Registration

# Beyond the trials to reach registration

- **Manufacturing and formulation:** Optimise NOX66 formulation; GMP Manufacturing
- **Pre-clinical / non-clinical:** *in vitro* and animal studies to meet regulatory and other requirements for registration and marketing
- **Medical Affairs:** Liaison with oncologists, advisory boards, congress attendance and presentation 
- **Marketing:** Develop Noxopharm presence, brand-naming, commercialization (including pricing) strategy 



# Chemotherapy with NOX66

- Radiotherapy prioritised for pathway to registration
  - Duration of therapy and of trials
  - Clarity of treatment (i.e. combination with RT) across all tumours
- Chemotherapy remains important to development
  - NOX66-001 study to complete in Q2 2018
  - Next study, to be a randomised trial  $\pm$  NOX66, planned for H2 2018
    - Cancer type(s) and chemo to follow from advisory meetings with doctors
  - Further studies
    - Other tumour types, chemotherapy regimen and dosing
    - Led by medical need, in discussion with doctors
    - NOX66 alone (monotherapy) to be investigated

# Communicating Trials Progress 2018

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- Progress – based on Data Safety Monitoring Committee Review
  - Independent body – researchers and statisticians
  - Regular meetings during trials – expect ~6 across trials in 2018
  - Review overall progress → decisions on continuation
  - Findings of DSMBs will be communicated
- Trial Data at conferences
  - Contingent on significant milestones in trials (end of study, all patients through a pre-defined time point) – expect ~4 in 2018
  - Requires considerable planning (e.g. ASCO – meeting June, submit presentation in February)
  - Requirement that data are embargoed until presented
  - Where significant outcomes, top line result may be released as per ASX requirements prior to conference

## *What will 'good response' look like ???*

- Looking at a new breakthrough cancer treatment:
  - In Non-Small Cell Lung Cancer trial (582 patients evaluated)
  - Compared with a standard Chemotherapy
    - Median (50% of patients) overall Survival - 12.2 months compared with 9.4 months
    - Median Progression Free Survival (time before disease worsened) – 2.3 months v 4.2 months (not statistically significant)
    - Overall Response Rate (patients who had at least partial response) – 19% v 12%
      - Four Complete Responses v One
      - Mean (average) duration of Response 17 months v 6 months
    - Common Adverse Reactions (>20% of patients) - fatigue, musculoskeletal pain, cough, dyspnea, and decreased appetite



**NOXASIA**

诺素亚洲

- NOX66 clinical studies in Asian-centric cancers
  - *Hepatocellular carcinoma (liver cancer)*
  - *Gastric carcinoma*
- Identify KOLs and form collaborations
- Identify potential partners.



NYX-104

- Stroke
- Concussion
- Head trauma
- Hearing loss

NYX-205

- Peripheral neuropathy
- Ulcerative colitis
- Sclerosing cholangitis

NYX-330

- High cholesterol



# Key Messages

WE EXPECT TO KNOW BY END OF 2017 OF THE SUCCESS OF OUR MISSION

WE AIM TO BE IN A REGISTRATION STUDY BY END OF 2018

WE AIM TO HAVE MARKETING APPROVAL BY 2022

A SUCCESSFUL OUTCOME IS A MAJOR SHARE OF THE \$100 BILLION ONCOLOGY DRUG MARKET

REALISTIC POTENTIAL TO BECOME STANDARD OF CARE DRUG IN MANY CANCERS

- ✓ Lean operation
- ✓ Experienced team

- ✓ A number of key inflection points anticipated within next 12 months

- ✓ Several potential blockbuster drugs candidates

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