



**Date: 12 March 2018**

**Sydney, Australia**

**ASX: NOX**

**Noxopharm Limited**

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and**

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Chairman

Non-Executive

Director

**Dr Graham Kelly**

Chief Executive Officer

Managing Director

**Dr Ian Dixon**

Non-Executive

Director

ASX Limited  
20 Bridge Street  
SYDNEY NSW 2000

## **CORPORATE PRESENTATION: POST- INTERIM CLINICAL DATA RELEASE**

**Sydney, 12 March 2018:** Noxopharm (ASX: NOX) is pleased to release its latest corporate presentation following the release of an interim report on clinical data from the CEP-1 clinical study.

The Company currently is pursuing 3 distinct uses of its experimental drug, NOX66:

- enhancement of external beam radiotherapy (DARRT program) in late-stage prostate cancer
- enhancement of intravenous brachytherapy radiotherapy (LUPIN program) in late-stage prostate cancer
- combination with low-dose carboplatin chemotherapy (CEP program) in common solid cancers.

The CEP-1 clinical study is a sighting study concerned with evaluating the safety and evidence of clinical benefit in patients with progressive, late-stage breast, ovarian, lung or prostate cancer that have stopped responding to standard treatment options. The objective is to develop a drug treatment regimen capable of offering a meaningful survival benefit without significant toxicity. CEP-1 will conclude in April 2018.

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### **About NOX66**

NOX66 is an innovative dosage formulation of the experimental anti-cancer drug, idronoxil, developed specifically to preserve the anti-cancer activity of idronoxil in the body and to enhance its drug-like behaviour. Idronoxil is a kinase inhibitor that works by inhibiting a range of enzymes including sphingosine kinase and PI3 kinase that regulate cell pro-survival mechanisms and which are over-expressed in cancer cells, as well as inhibiting external NADH oxidase Type 2 (ENOX 2) which is responsible for maintaining the transmembrane electron potential (TMEP) in the plasma membrane of cancer cells and whose expression is limited to cancer cells. Inhibition of these enzymes results in disruption of key downstream pro-survival mechanisms including resistance mechanisms, sensitizing the cancer cell to the cytotoxic effects of chemotherapy drugs and radiotherapies.

**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 sensitise cancer cells to radiotherapy and chemotherapy. NOX66 is the first pipeline product, with later generation drug candidates under development.

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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.



**A CLINICAL ONCOLOGY COMPANY**

**March 2018**

# **Our aim. To bring to market:**

- **the first approved radio-enhancing drug**
- **that will increase the effectiveness of radiotherapy**
- **including the possibility of obtaining abscopal responses**
- **and become a standard-of-care in cancer therapy.**



Noxopharm



**NOX66**

Lipid-protected form of **idronoxil**

## ABOUT IDRONOXIL

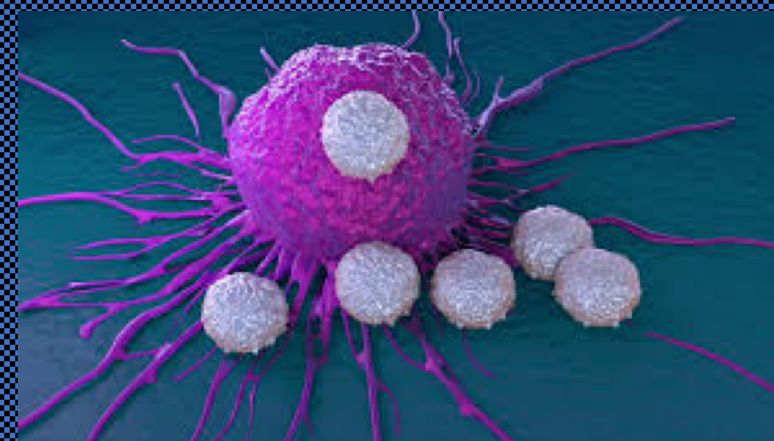
Multiple anti-cancer actions

### 1. Inhibits DNA repair

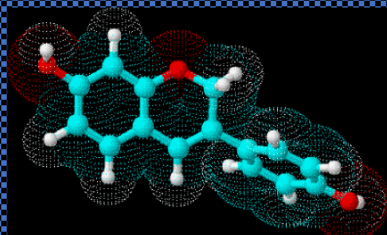
*inhibits PARP-1, topoisomerases 1 and 2*

### 2. Promotes anti-tumour immunity

*Increases NK (natural killer) cell activity*



# Oral Idronoxil



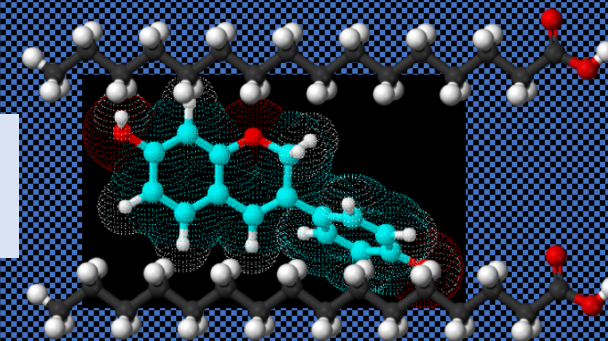
Subject to  
metabolism



95-100% of  
drug  
inactivated

# NOX66 suppository

LIPROSE  
Technology



Drug protected  
from  
metabolism



Protected drug  
remains active

# Three clinical NOX66 programs

## 1. Enhance external beam radiotherapy

**DARRT program**     *prostate cancer*     *rare cancers*

## 2. Enhance intravenous radiotherapy

**LUPIN program**     *prostate cancer*

## 3. Enhance chemotherapy

**CEP program**     *common cancers*

# DARRT program

## *Direct and Abscopal Response to Radiotherapy*

### Objectives:

- ▶ irradiated tumours to respond better  
***(direct response)***
- ▶ non-irradiated tumours to respond as well  
***(abscopal response)***



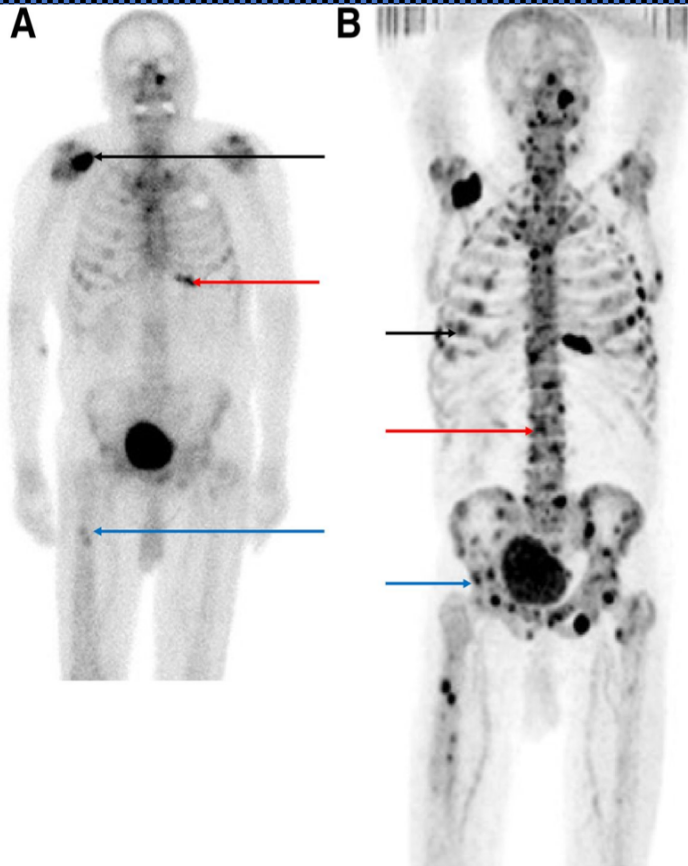
External beam radiotherapy

# DARRT program



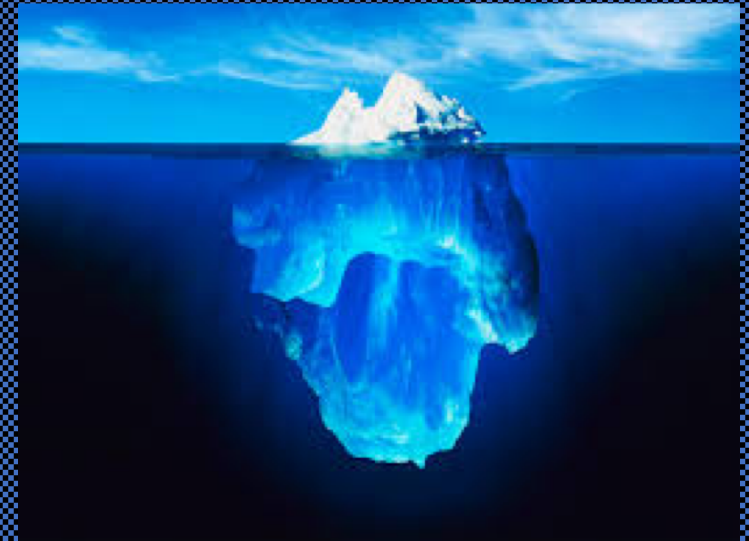
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## *Metastatic cancer too extensive for radiotherapy*



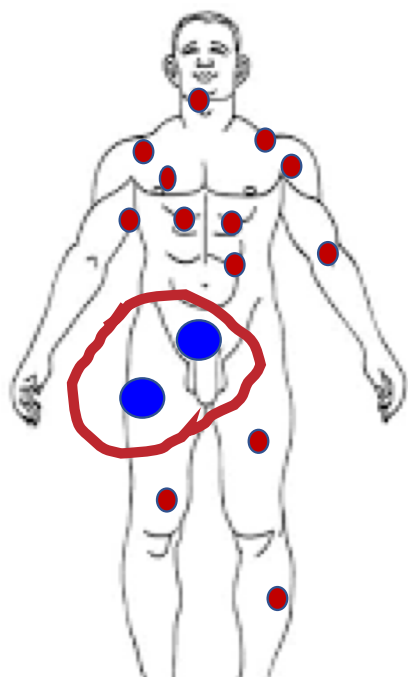
CT/MRI scans identifies tumours  $> 2\text{mm}$  diameter. (Fig. A). These can be irradiated.

But majority of secondary cancers generally much smaller than this and scattered throughout the body. (Fig. B). Whole of body irradiation not possible.

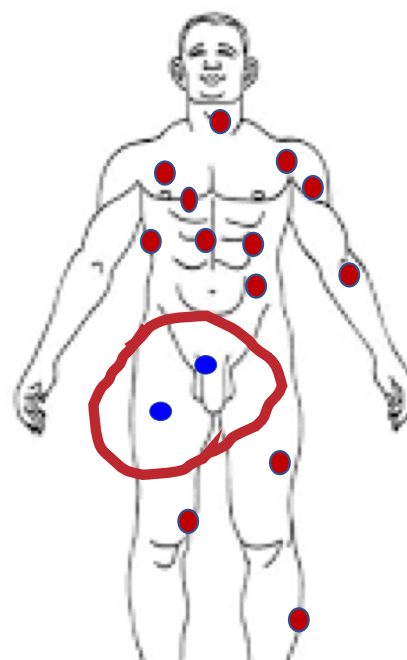


# DARRT program

## DIRECT Response to Radio-Therapy



Radiotherapy applied to large tumours for pain relief

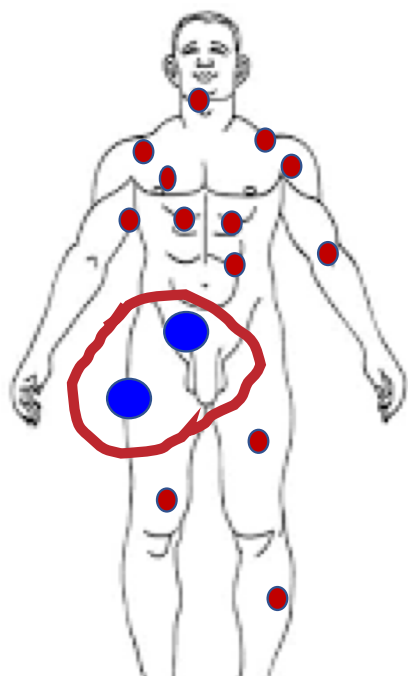


Shrinkage of irradiated tumours

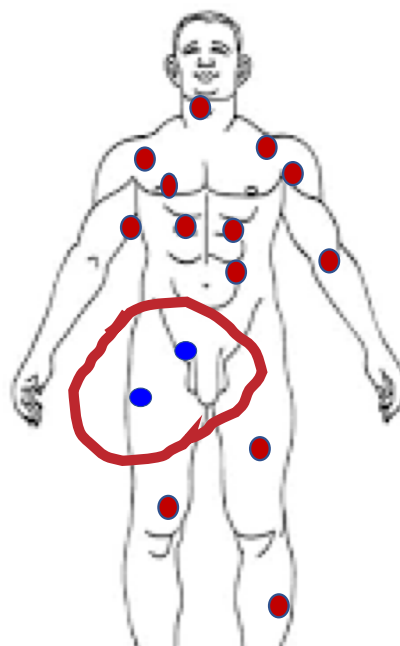


# DARRT program

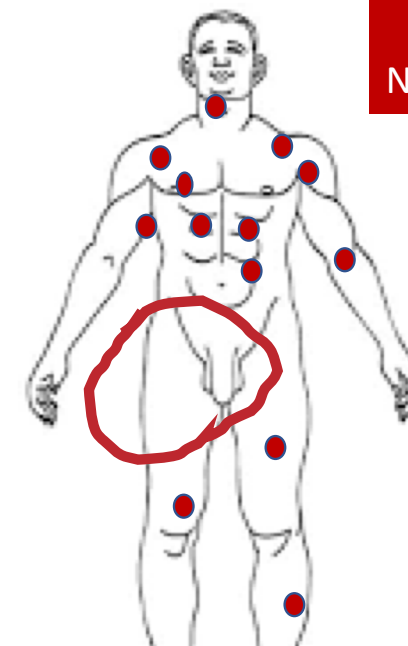
## DIRECT Response to Radio-Therapy



Radiotherapy applied to large tumours for pain relief



Shrinkage of irradiated tumours



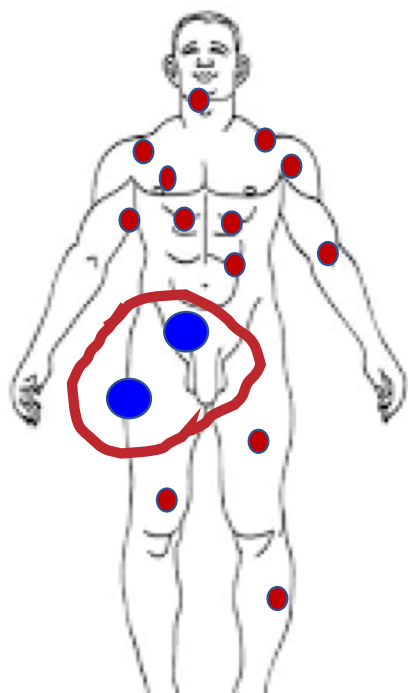
Seeking **complete remission** of irradiated tumours

# DARRT program

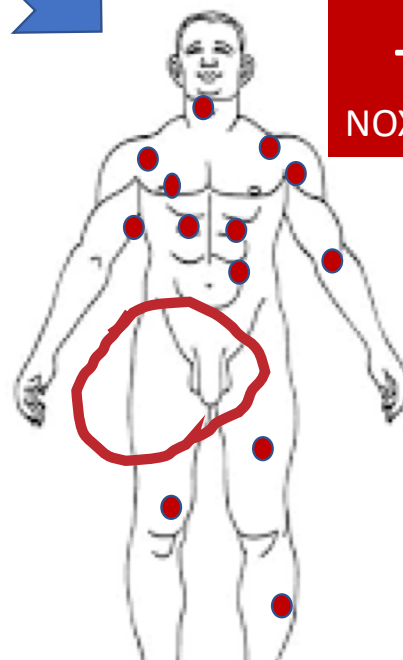
## ABSCOPAL Response

Exposed tumours respond

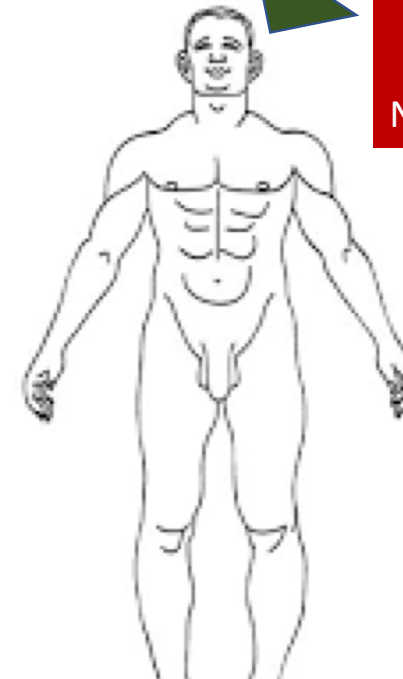
+ Non-exposed tumours also respond



Low-dose radiotherapy



Seeking **complete remission** of irradiated tumours



Abscopal response

# DARRT program

## ABSCOPAL Response

<b><i>Rare</i></b>	– very rare phenomenon
<b><i>Complete</i></b>	– primary AND secondary tumours respond
<b><i>Durable</i></b>	– potentially permanent
<b><i>Unrestricted</i></b>	– range of cancers reportedly involved
<b><i>Short treatment</i></b>	– single course of treatment (7-14 days)
<b><i>Low toxicity</i></b>	– none known
<b><i>Mechanism</i></b>	– unknown and likely multifactorial, but activation of NK cells believed involved

# DARRT program

## DARRT-1

**Phase 1b study.** Open, actively recruiting.

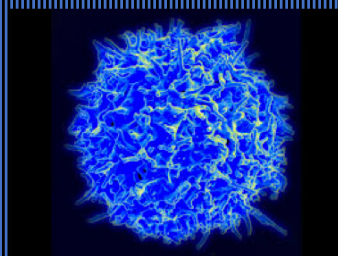
24 patients.

9 sites: NZ (1); Georgia (3); Australia (5)

- Prostate cancer (metastatic castrate-resistant)
- Patients with multiple (>3) tumours
- Low dose radiotherapy to 1-2 tumours (5 days)
- + NOX66 14 days
- Scan at + 2 months and + 4 months
- End-points = RECIST response in both irradiated and non- irradiated tumours

# LUPIN program

## Enhancing intravenous radiotherapy (brachytherapy)



Prostate cancer cells express high levels of **prostate-specific membrane antigen (PSMA)**



Antibody made to PSMA. When injected IV, locates and attaches to prostate cancer cells



1 of 2 radioisotopes attached to antibody:

- **Diagnostic.** Gallium-68 to identify presence of cancer cells;
- **Therapeutic.** Lutetium-177 to kill the cancer cells

# LUPIN program

## LUPIN-1

**Phase 1b study.** Open, recruiting.  
24-30 patients (4 currently being treated)  
St Vincent's Hospital, Sydney

- Prostate cancer (metastatic castrate-resistant)
- 6x monthly injections of  $^{177}\text{Lu}$ -PSMA-617
- + NOX66 10 days
- End-points: safety; monthly PSA levels; 3-monthly scans; pain scores; progression-free survival

# CEP program

**Aim 1:** to develop a **well-tolerated chemotherapy** regimen that can be used in conjunction with NOX66 + radiotherapy to provide a **whole-of-body anti-cancer effect** in those patients who do not experience an abscopal response.

**Aim 2:** to develop a well-tolerated chemotherapy regimen that on its own (without radiotherapy) will provide a meaningful clinical benefit in those cancer types where **immuno-oncology drugs are proving to have minimal benefit**

## Enhancing chemotherapy





# CEP program

## CEP-1

**Phase 1b study.** Closed. Fully recruited  
18 patients  
3 Georgian sites

- Late-stage cancers (breast, ovarian, lung, prostate)
- 6x monthly treatment cycles
- NOX66 10 days/carboplatin IV injection
- End-points: safety; tumour response (RECIST/ECOG Score) at 3 and 6 months; Quality of Life score

# CEP program

## CEP-1

**Objective:** development of a drug regimen capable of providing clinical benefit in patients with late-stage cancer, without being associated with serious toxicity

Carboplatin normally given either weekly or every 2, 3 or 4 weeks over a 5-6 month period. Total amount of drug given over that period remains approximately the same regardless of frequency of dosing. Dosage at each injection expressed as AUC (Area Under the Curve).

AUC 2 every week  
or AUC 6 every 3 weeks  
or AUC 8 every 4 weeks

### CEP-1

NOX66 + **AUC 4 every 4 weeks for 3 months (50% of standard dose)**  
*followed by*

NOX66 + **AUC 6 every 4 weeks for 3 months (75% of standard dose)**

# CEP program

## CEP-1 STUDY

Interim report 5 March 2018

**14 patients underwent NOX66 + carboplatin (AUC 4) treatment/3 months**

**After 3 months:**

- **1 patient showed partial response (RECIST)**
- **11 patients showed no disease progression (RECIST)**
- **2 patients showed disease progression (RECIST, symptoms)**

**All non-progressing 12 patients then graduated to NOX66 + carboplatin (AUC 6) for further 3 months.**

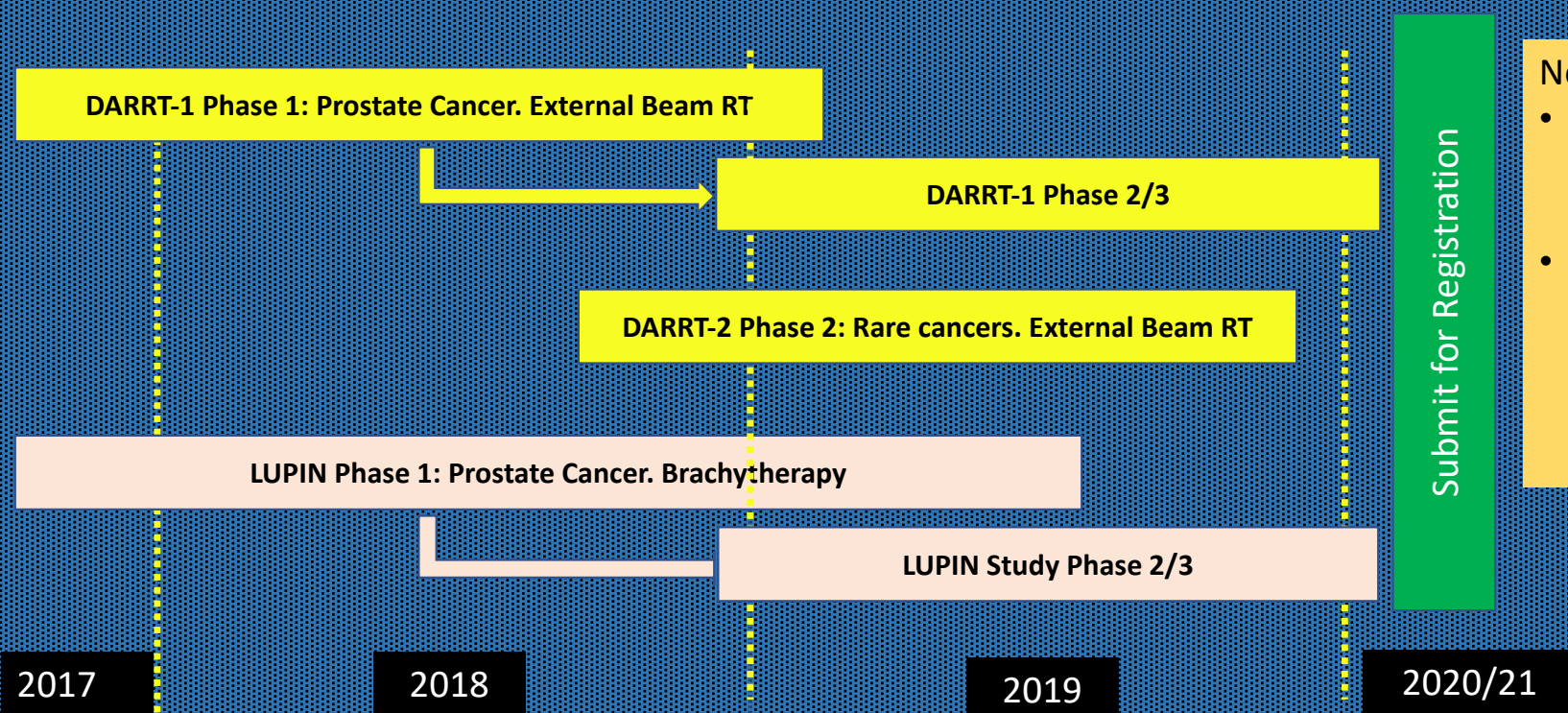
# Comparison of CEP-1 data with immunology drug data

- Lung Cancer trial (**582 patients** evaluated)
- Opdivo vs standard of care chemotherapy (Taxotere)
  - Time to disease progression – **2.3 months (Opdivo) v 4.2 months (Taxotere)**
  - Overall Response Rate – **19% (Opdivo) v 12% (Taxotere)**
  - Survival of 50% of patients - **12.2 months (Opdivo) v 9.4 months (Taxotere)**
  - Adverse Reactions (**>20% of patients**) - fatigue, musculoskeletal pain, cough, breathing difficulty, decreased appetite

- US\$150,000 treatment cost
- Sales for first 6 months 2016 = US\$1.6 billion

# Moving towards first registration

**Likely registration indication:** NOX66 in combination with palliative external beam radiotherapy for the treatment of patients with metastatic cancer (prostate and others)



## Notes:

- ORPHAN DRUG approval to be sought where appropriate
- Registration studies to be conducted in US, UK, EC, Eastern Europe, Australia, Hong Kong, Singapore, China

# Where we hope to be in 2018

## Mid-2018

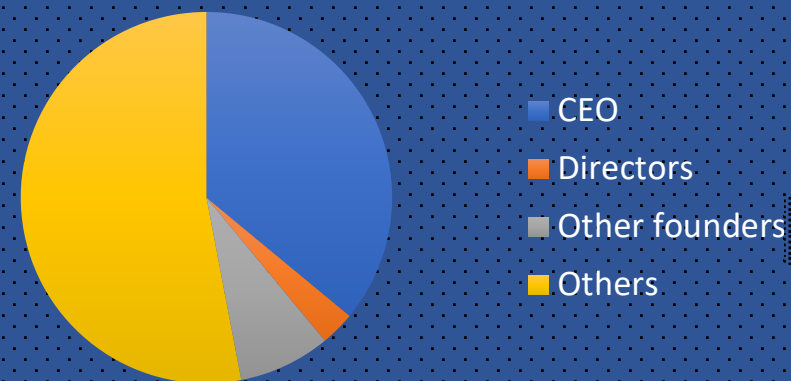
- Preliminary indication of most likely Phase 3 (registration) clinical indication/trial design

## End-2018

- Confirmation of Phase 3 registration study/studies
- Selection of sites (multi-national)
- Investigator meeting held. Protocol agreed
- IND obtained

# Key metrics .....

Shares outstanding	57M free; 52M escrowed (July 2018)
Other	25.3M options
Market Cap	\$130M
IPO price	\$0.20
Last traded	\$1.20
Cash position	\$4M (approx.)





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