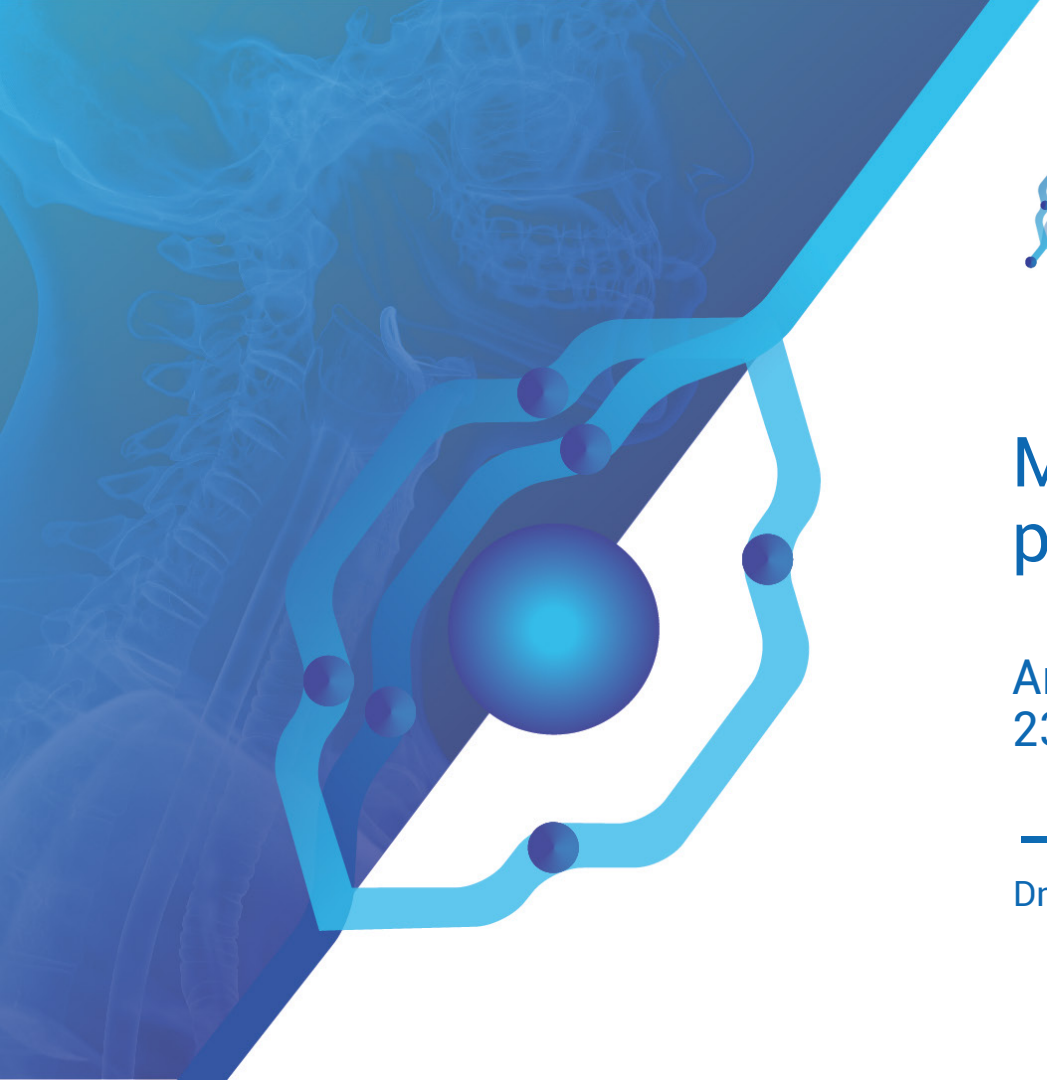

CLARITY
PHARMACEUTICALS

# Managing Director's presentation

## Annual General Meeting
## 23 November 2023

Dr Colin Biggin

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# Corporate Snapshot

**Proprietary SAR Technology: a true platform technology**

Three best-in-class products in clinical development protected by 24 patent families, offering high accuracy and precision for both diagnosing and treating disease

**Global leader in Targeted Copper Theranostics (TCTs)**

Employs copper-64 for diagnosis and imaging and copper-67 for therapy

**Significant supply, logistical, dependability and scalability benefits**

Mass production of isotopes on cyclotrons and e-accelerators with finished products having an ideal product shelf life

**Environmental advantages over current isotopes**

No reliance on nuclear fuel cycle; TCTs do not generate long-lived waste products

**Targeted clinical development strategy**

Commercialisation of diagnostic products first, generating revenue to fund late-stage therapeutic trials

**Highly experienced leadership team**

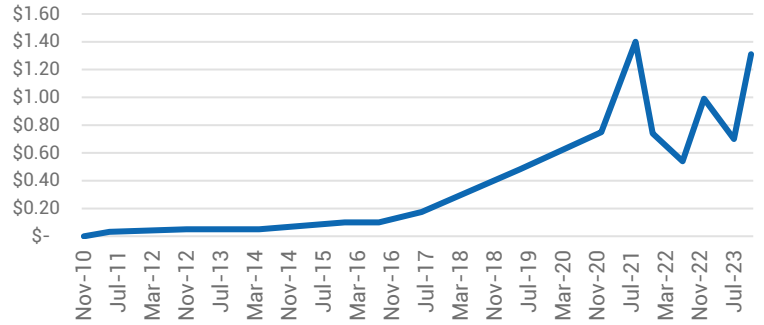
Diverse and in-depth expertise spanning corporate finance, operations, commercialisation & industry. Significant radiopharmaceutical experience across all functions

Clarity Pharmaceuticals is a clinical stage radiopharmaceutical company developing next-generation products to address the growing need for better diagnostics and treatments in oncology

| ASX code: | CU6 |
|---|---|
| Share Price[1] | A$1.31 |
| Cash at bank[2] | A$53.6M |
| Shares on issue | 262.8M |
| Options on issue | 26.2M |
| Market cap (undiluted)[2] | A$344.3M |

1. As at 22 November 2023
2. As at 30 September 2023

## Share price

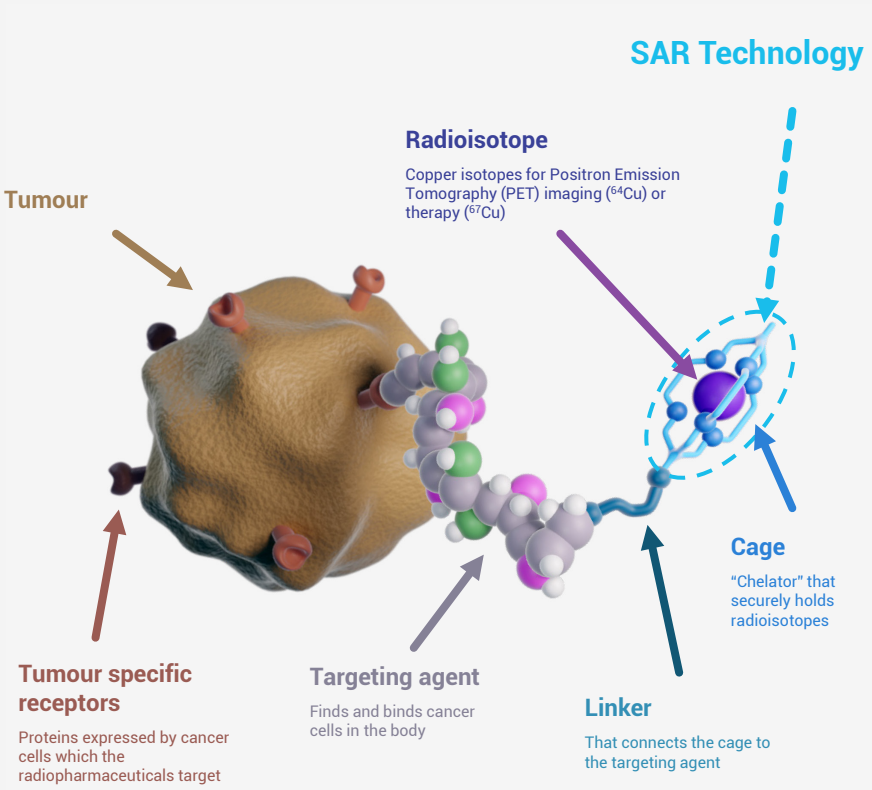


# Clarity – The Copper Theranostics Company

Targeted Copper Theranostics are the next-generation disruptive platform in radiopharmaceuticals that employ the “perfect pairing” of copper-64 ($^{64}$Cu) and copper-67 ($^{67}$Cu) for diagnosis and therapy

## Proprietary SAR Technology enables Targeted Copper Theranostics

- Clarity's SAR technology is a proprietary, highly specific and highly stable bifunctional cage (chelator) with a superior ability to retain copper isotopes within it and prevent their leakage into the body
- TCT deliver a compelling combination of high accuracy and high precision in the treatment of a range of cancers, as well as providing supply and logistical advantages over current theranostics

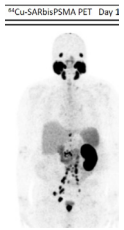


# Why Copper?

The physical properties of copper-64 and copper-67 have optimal characteristics for global commercialisation

## Diagnostic radionuclides

| | Copper-64 | Gallium-68 | Fluorine-18 |
|---|---|---|---|
| **Half life** | 12.7 hours | 1.1 hours | 1.83 hours |
| **Typical product shelf life** | Up to 48 hours | Up to 4 hours | Up to 10 hours |
| **Production** | Cyclotron | Mainly from Generators | Cyclotron |
| **Imaging window** | From 1 to >48 hours | ~60 mins | ~60 mins |
| **Ability to centrally manufacture** | Yes | No | No |

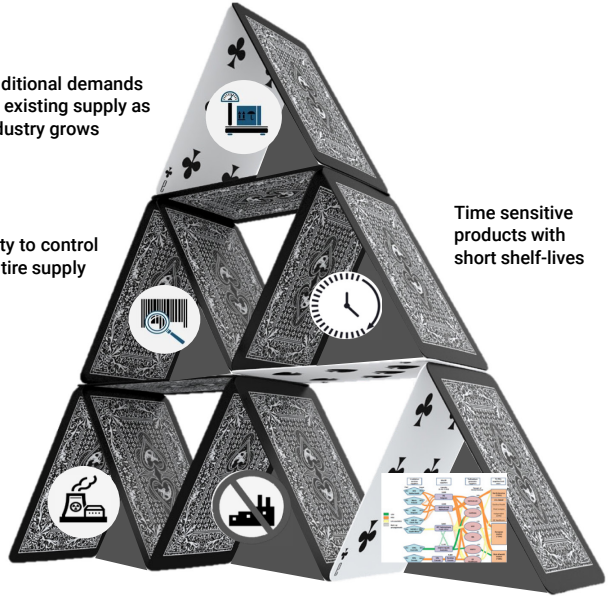



## Therapeutic radionuclides

| | Copper-67 | Lutetium-177 |
|---|---|---|
| **Half life** | 2.6 days | 6.7 days |
| **Decay mode** | Beta emitter | Beta emitter |
| **Range in tissue** | ~0.7mm | ~0.7 mm |
| **Production mode** | Electron accelerators | Nuclear reactors |
| **Cost to scale supply** | Low (~US$15M) | High (>US$1Bn) |
| **Time to scale supply** | Quick (<18 months) | Slow (>10 years) |

CLARITY PHARMACEUTICALS

# Current industry challenges




# Combined with a history of supply issues

nature › news › article

Published: 12 September 2016

**Reactor shutdown threatens world's medical-isotope supply**

SNMMI SOCIETY OF NUCLEAR MEDICINE AND MOLECULAR IMAGING

August 6, 2018

US Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Shortage of Germanium-68/Gallium-68 Generators for the Production of Gallium-68

NewScientist

SUBSCRIBE AND SAVE 60%

**Australia has a huge shortage of the medical isotope needed for scans**

MANUFACTURING

**Novartis halts US production of cancer radiotherapies, citing potential quality issues**

By Angus Liu • May 5, 2022 12:44pm

wnn world nuclear news
Celebrating 15 years

Energy & Environment | New Nuclear | Regulation & Safety | Nuclear Policies | Corporate | Uranium & Fu

**Medical isotope supply chain faces challenges from COVID-19**

21 April 2020

Bayer Suspends Production of Radium-223 Due to Manufacturing Problem

October 17, 2014
Beth Fand Incollingo

# Create challenges for prescribers

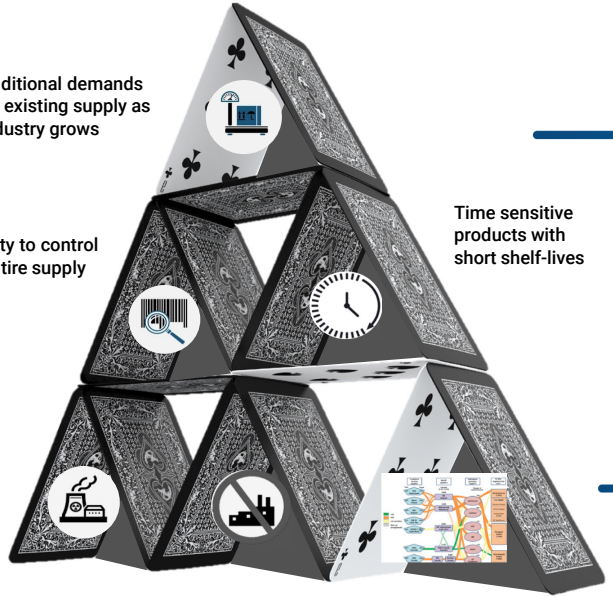
Oncologists need a safe, dependable and reliable source of radiopharmaceutical products

*"We have patients on months long waiting lists when this may be all the time they have, and so it's been really disheartening to have to deal with these things"*

*- Roby Thomas, MD, a medical oncologist and hematologist at UPMC Hillman Cancer Center*

CLARITY PHARMACEUTICALS

# Current industry challenges



Additional demands on existing supply as industry grows

Inability to control the entire supply chain

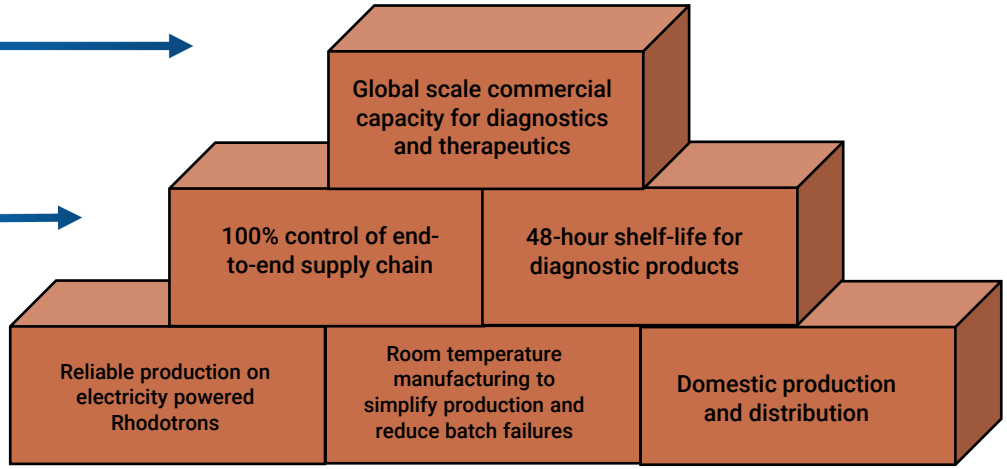
Time sensitive products with short shelf-lives

Reliance on ageing nuclear reactor fleet

Manufacturing outages

Complex international supply chains

# Clarity's TCTs Solution




MANUFACTURING

**Novartis halts US production of cancer radiotherapies, citing potential quality issues**

By **Angus Liu** • May 5, 2022 12:44pm

*"We have patients on months long waiting lists when this may be all the time they have, and so it's been really disheartening to have to deal with these things"*

*- Roby Thomas, MD, a medical oncologist and hematologist at UPMC Hillman Cancer Center*

# Key FY23 highlights

## CLINICAL

- Actively progressing seven clinical trials of Clarity's three key product areas
- 1st Phase III diagnostic trial commencing
- Initial therapy data with $^{67}$Cu-SAR-bisPSMA is very encouraging

## OPERATIONS

- Commercial scale Cu-67 now being routinely supplied exclusively to Clarity by NorthStar Medical Radioisotopes
- Supply agreement with PETNET for $^{64}$Cu-SAR-bisPSMA for Phase III clinical trials

## CORPORATE

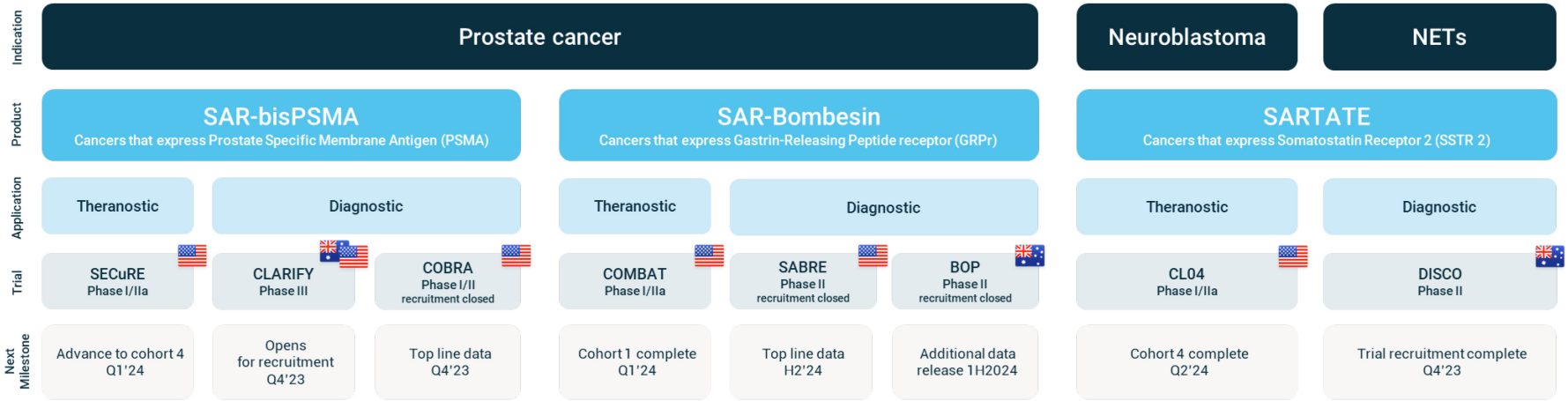
- Strengthened leadership team:
  - VP of Regulatory and Quality, Ms Kathryn Williams Day
  - Senior Medical Director, Dr Othon Gervasio
- Leading expert joined Advisory Board
  - Jon Stoner

## FINANCIAL

- Strong cash balance of $53.6 million as at 30 September 2023
- Anticipated R&D tax incentive for FY23: ~$9.5 million
- ~$63 million to fund the existing trial pipeline and provide cash runway deep into 2024

# Three core product areas in US clinical trials

Clarity has potential to address multiple oncology indications with unmet needs through a range of products and their applications. These include large indications, such as prostate and breast cancers, as well as small and orphan indications, such as neuroendocrine tumours (NETs) and neuroblastoma, an aggressive childhood cancer.




Each product class can be used as:

- A stand-alone $^{64}$Cu-based diagnostic
- Combined as a theranostic using $^{64}$Cu-labelled products to select patients for therapy with $^{67}$Cu-labelled products

# Clinical development in multiple cancers

Clarity's products are progressing through sponsored clinical trials in the US and Australia

## Clinical development pipeline as of 23 November 2023

| Indication | Product | Application | Current Trial | Discovery | Preclinical | Phase I | Phase 2 | Phase 3 | Next Milestone |
|---|---|---|---|---|---|---|---|---|---|
| Prostate Cancer | SAR-bisPSMA | Theranostic mCRPC | SECURE | | | | | | Advance to cohort 4 |
| | SAR-bisPSMA | Diagnostic in pre-radical prostatectomy | CLARIFY | | | | | | CLARIFY Phase III opens for recruitment |
| | SAR-bisPSMA | Diagnostic in BCR PCa | COBRA | | | | | | COBRA top line data |
| | SAR-BBN | Diagnostic in BCR PCa | SABRE | | | | | | SABRE topline data |
| | SAR-BBN | Theranostic mCRPC | COMBAT | | | | | | Cohort 1 complete |
| Neuroblastoma | SARTATE | Theranostic | CL04 | | | | | | Cohort 4 complete |
| NETs | SARTATE | Diagnostic | DISCO | | | | | | DISCO recruitment complete |
| SAR Discovery Platform | Undisclosed | Undisclosed | | | | | | | |
| | Undisclosed | Undisclosed | | | | | | | |

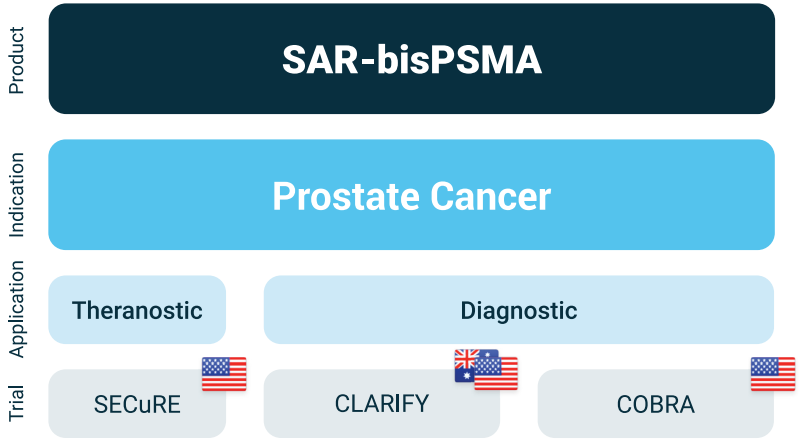
Current progress

Note clinical development pipeline is indicative only, subject to review.

All US studies are conducted under IND

# SAR-bisPSMA

Targets the Prostate Specific Membrane Antigen (PSMA), present in the majority of prostate cancers




**SECuRE - Phase I/IIa**

- Recruiting in 12GBq therapy cohort
- 100% of participants in cohort 2 (8GBq) had a PSA decrease of >80% from a single therapy cycle

**PROPELLER - Phase I**

- Results presented at ASCO, ASCO GU and SNMMI conferences
- SAR-bisPSMA demonstrated significantly higher uptake in tumours compared to SOC
- $^{64}$Cu-SAR-bisPSMA is safe and efficacious in the detection of prostate cancer

**COBRA - Phase I/II**

- 100% recruitment milestone in February 2023
- Initial data readout imminent

**CLARIFY - Phase III**

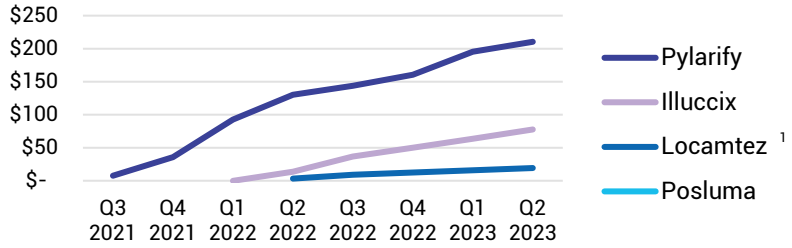
- Registrational Phase III PET imaging trial of participants with high-risk prostate cancer prior to radical prostatectomy using $^{64}$Cu-SAR-bisPSMA
- Start of recruitment imminent

# SAR-bisPSMA market opportunity

## PSMA based diagnostics

- Current US patient pool for PSMA-PET imaging is **~355k scans per year** between initial-staging, suspected recurrence and patient selection for targeted therapy
- At ~US$4.4k per patient dose this represents a US market potential of **~US$1.55Bn/year**
- By 2028 this is expected to grow to 600,000 scans per year, representing a US market potential of **>US$3Bn/year**

**Quarterly US Sales ($M USD) - PSMA PET Diagnostics**




SAR-bisPSMA aims to disrupt current diagnostic and therapeutic utilisation with a best-in-class agent for imaging and treating prostate cancer

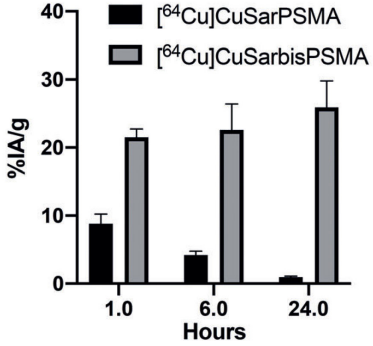
## PSMA based therapy (mCRPC)

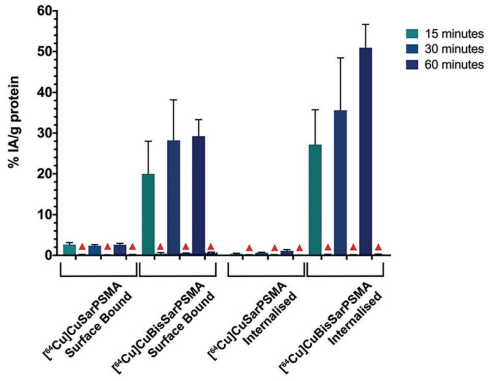
- Current US market opportunity (post chemo): **>US$5Bn**
- Future US market opportunity (including pre-chemo): **>US$10Bn**
- Novartis YTD CY23 Pluvicto sales were ~US$707M despite the significant supply challenges

[1]Locametz sales estimated at 25% of Illuccix sales

# Not all PSMA targeting agents are created equal

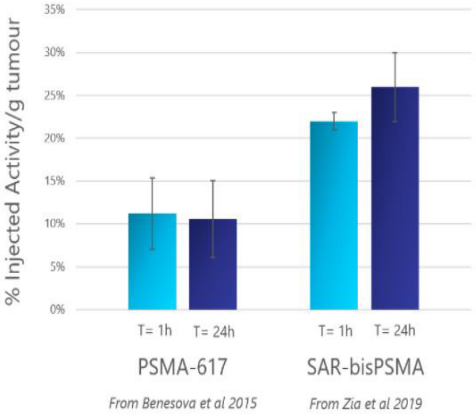
## Superior performance of SAR-bisPSMA compared to monomer SAR-PSMA

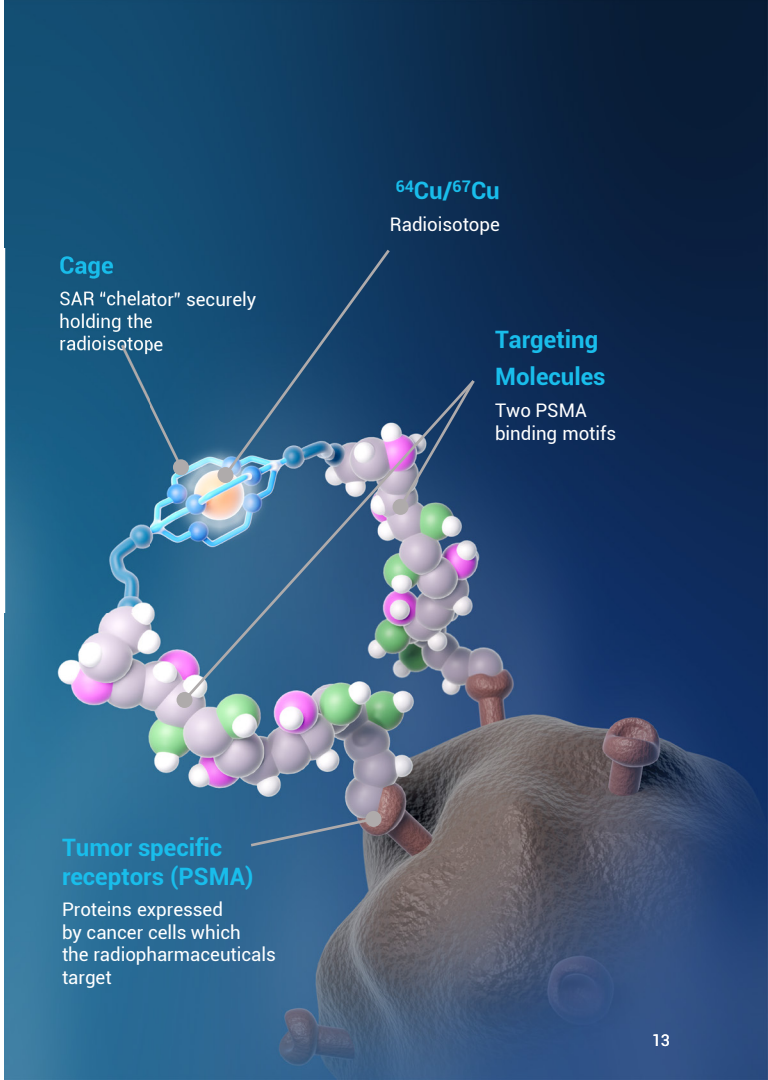



*Zia et al., 2019. Ang.Chem*

SAR-bisPSMA has higher uptake in tumours and strong retention compared to PSMA monomers



# Next-generation SAR-bisPSMA diagnostic is coming

Improved uptake of SAR-bisPSMA may support better diagnosis compared to first-generation PSMA PET agents.
Significant market opportunity to displace currently approved products, which are set to generate > US$1Bn in 2023.

Lantheus: PYLARIFY® ($^{18}$F DCFPyL) sales Q3 23: ~US$215M

Telix: Illuccix ® (generic PSMA-11 kit) sales Q3 23: ~ US$85M

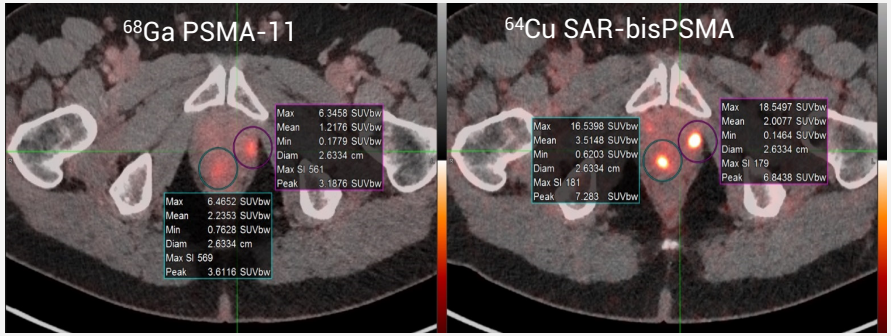
→

Specificity ~ 96% ✓

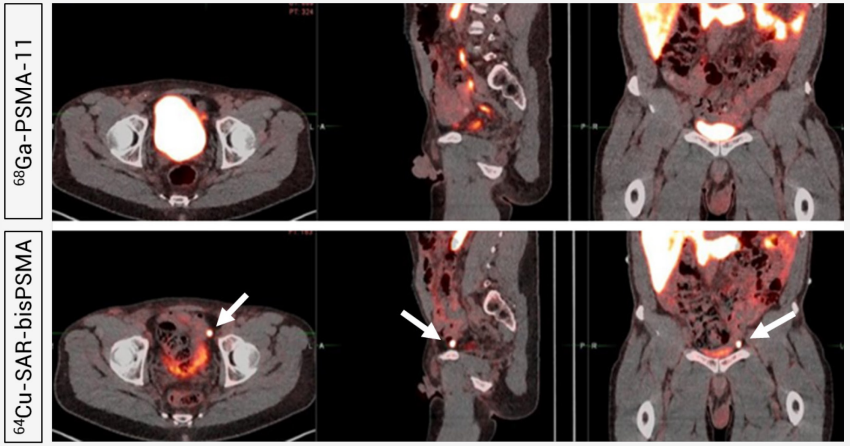
Sensitivity ~ 35% ✗

## Comparison with $^{68}$Ga PSMA-11 – PROPELLER study

Comparison of $^{68}$Ga PSMA-11 (image left) to Clarity's $^{64}$Cu SAR-bisPSMA (image right) in the same patient




$^{64}$Cu SAR-bisPSMA detected a pelvic lymph node that was not detected with $^{68}$Ga-PSMA-11 in the same patient

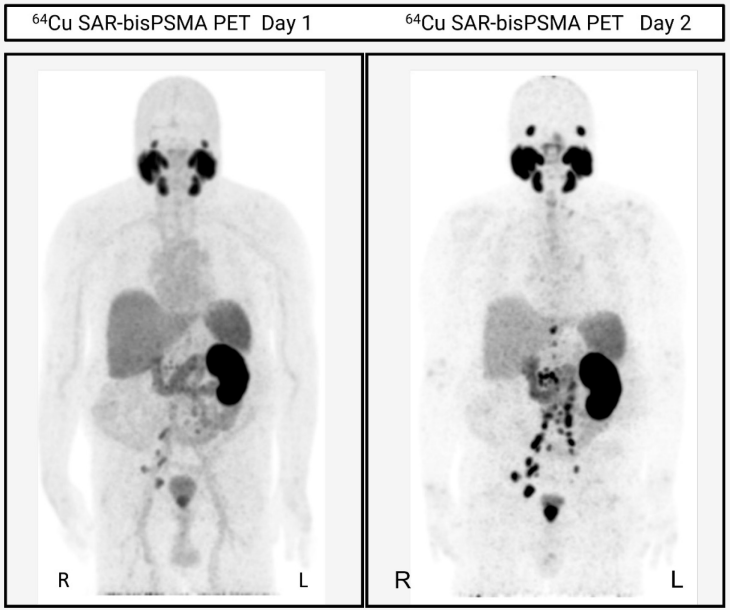


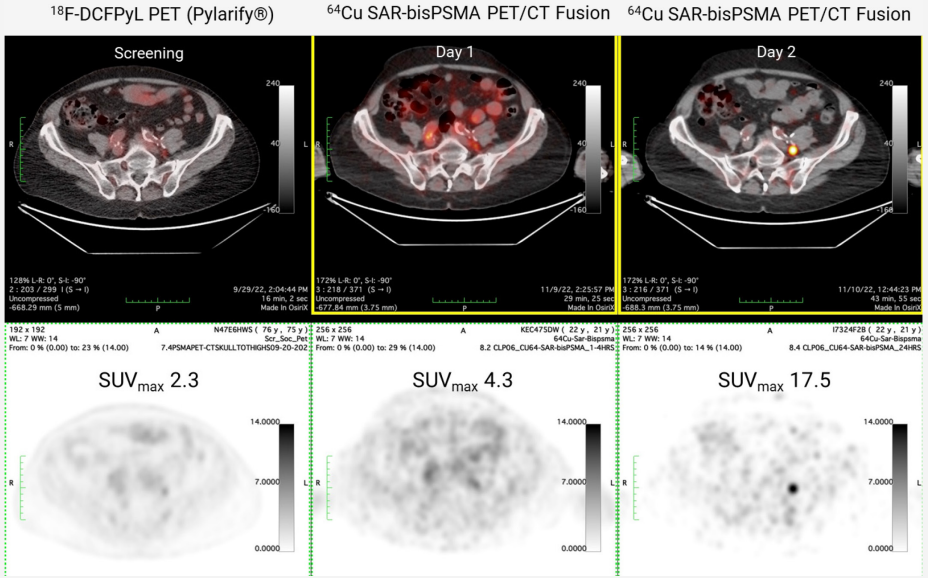
# Copper brings significant additional advantages

Beyond the supply chain advantages of a 12.7 hour half-life PET imaging agent, SAR-bisPSMA allows patients to be imaged from 1 hour to >24 hours post administration

**$^{64}$Cu-SAR-bisPSMA PET has the ability to image both on the day of administration and at later timepoints, potentially providing clinicians with better insight into the disease**

## Images from Clarity's COBRA study



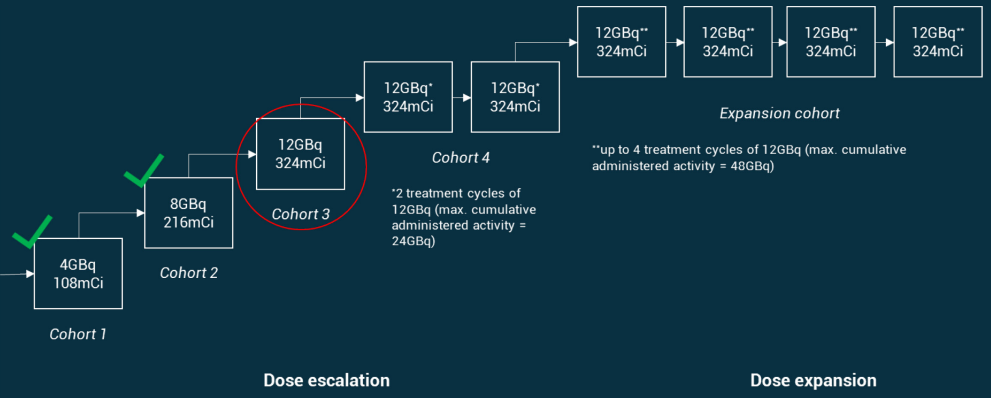



# Therapy program with $^{67}$Cu-SAR-bisPSMA

Currently recruiting into cohort 3 in the US-based study

## Trial overview

- Phase I/II study in mCRPC
- Participants do not need to have received chemotherapy
- Dose escalation followed by cohort expansion with up to 4 cycles of therapy

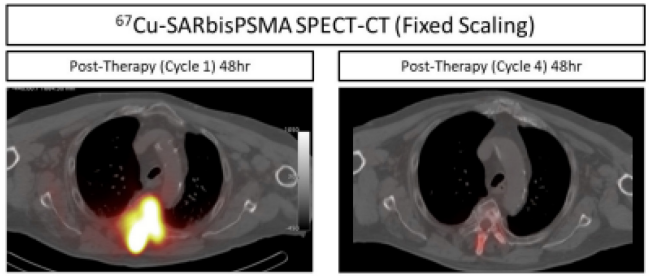



SECuRE

## Trial highlights to date

- Now recruiting in cohort 3 at 12GBq dosing (Pluvicto dose capped at 7.4GBq)
- One third of patients in cohort 1 had a PSA decline greater than 50% from a single cycle
- 100% of patients in cohort 2 had a PSA decline greater than 80% from a single cycle
- No DLTs have been observed to date
- Additional therapy cycles have been administered in cohorts 1 and 2 under FDA EAP

4GBq $^{67}$Cu SAR-bisPSMA over 4 cycles



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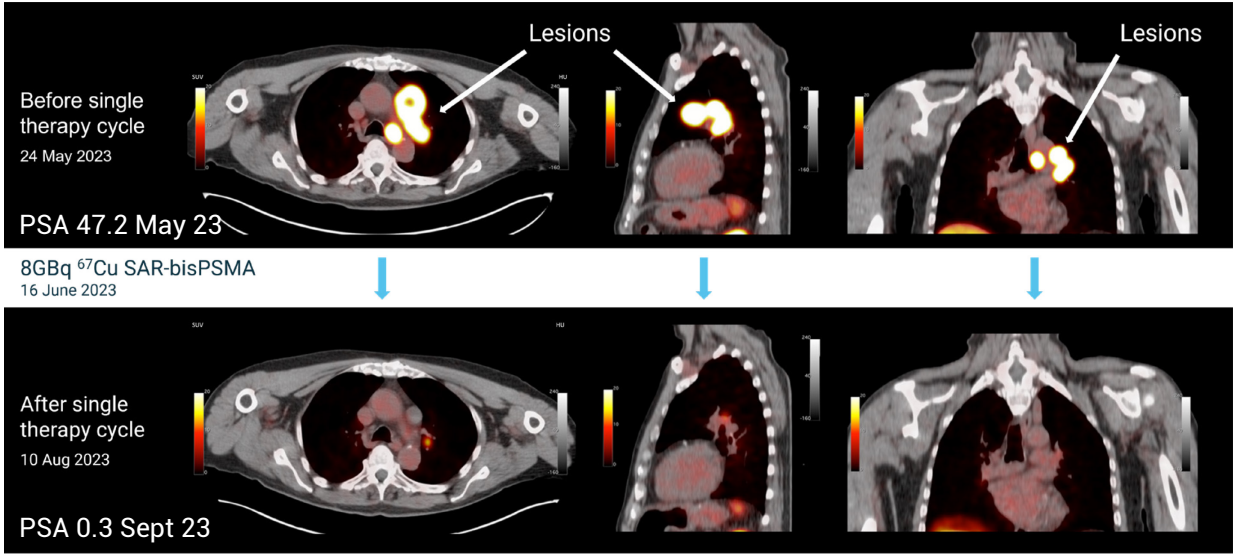
# $^{67}$Cu-SAR-bisPSMA therapy
# Phase I/II SECURE trial in mCRPC :

## $^{64}$Cu-SAR-bisPSMA PET/CT imaging before and after a single cycle of 8GBq $^{67}$Cu-SAR-bisPSMA



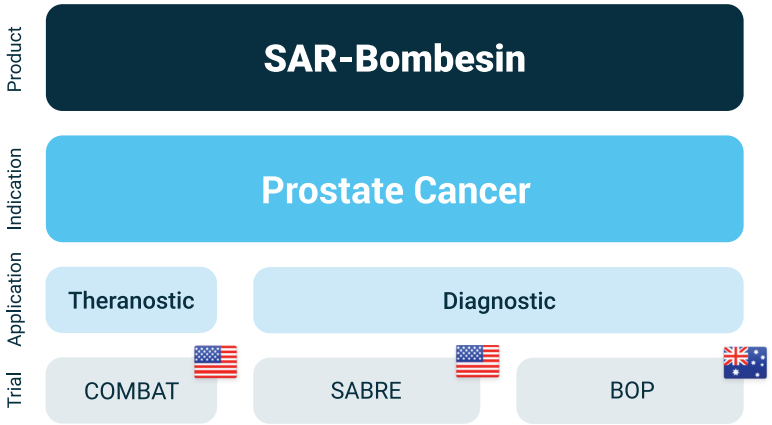

| Cohort 2 (n=3) | PSA decrease following single therapy cycle |
|---|---|
| 1 | >95% |
| 2 | >99% |
| 3 | >80% |

Considerable reduction in uptake of $^{64}$Cu-SAR-bisPSMA on imaging following administration of $^{67}$Cu-SAR-bisPSMA

Next updates
- Dosing of first three patients in cohort 3 (12GBq) completed; Safety Review Committee meeting planned for end of November
- Second group of three patients in cohort 3 expected to be recruited this year
- Cohort 4 expected to commence recruitment in Q1 24

# SAR-Bombesin

Targets the Gastrin Releasing Peptide receptor (GRPr), which is present in a number of cancers, including breast and prostate cancers




**COMBAT – Phase I/IIa therapy**

- 1st therapy patient treated in October 2023

**SABRE – Phase II**

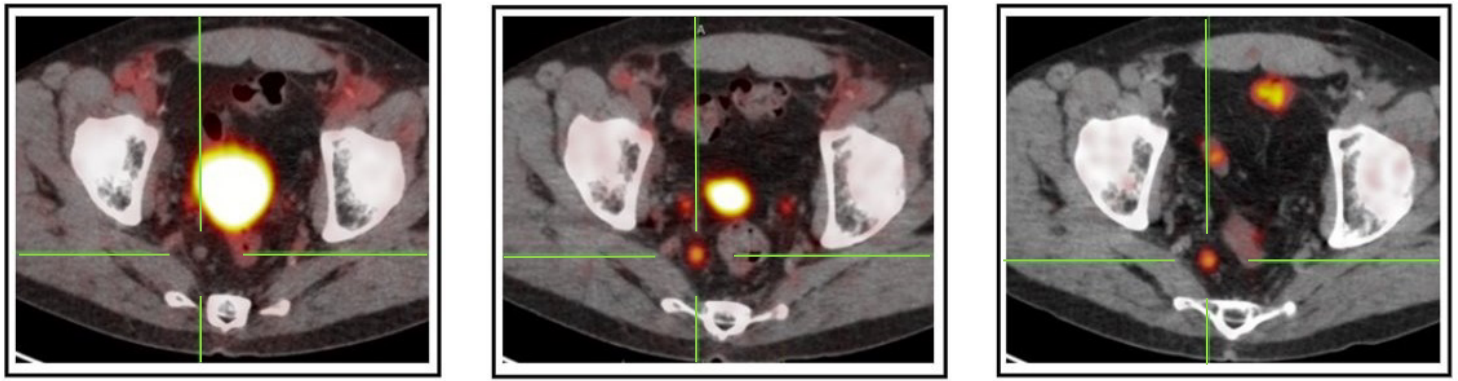
- 50% recruitment milestone in July 23
- 100% recruitment milestone reached in November 2023

**BOP – Phase II**

- Investigator initiated trial led by Prof Louise Emmett at St Vincent's Hospital Sydney
- 100% recruitment milestone reached in June 23
- Initial results presented at EANM 2023

# Lesion detection by $^{64}$Cu-SAR-BBN in PSMA-negative/equivocal biochemical recurrent PC

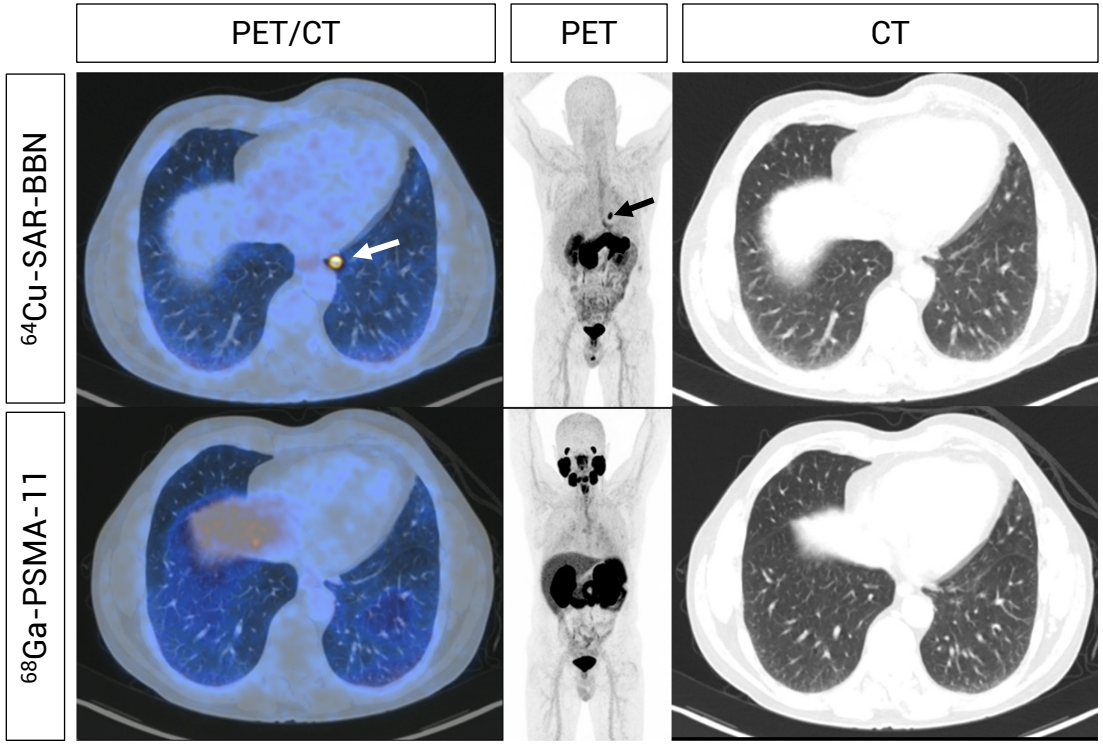
| $^{18}$F-DCFPyl PET/CT (Pylarify) | $^{64}$Cu-SAR-BBN PET/CT Day 1 | $^{64}$Cu-SAR-BBN PET/CT Day 2 |
|---|---|---|



Single pelvic lymph node uptake seen on $^{64}$Cu SAR-BBN on both Day 1 and Day 2. A subsequent biopsy has confirmed prostate cancer.

# Metastasis detection of biochemical recurrent PC by $^{64}$Cu-SAR-BBN

$^{68}$Ga-PSMA-11-negative or equivocal

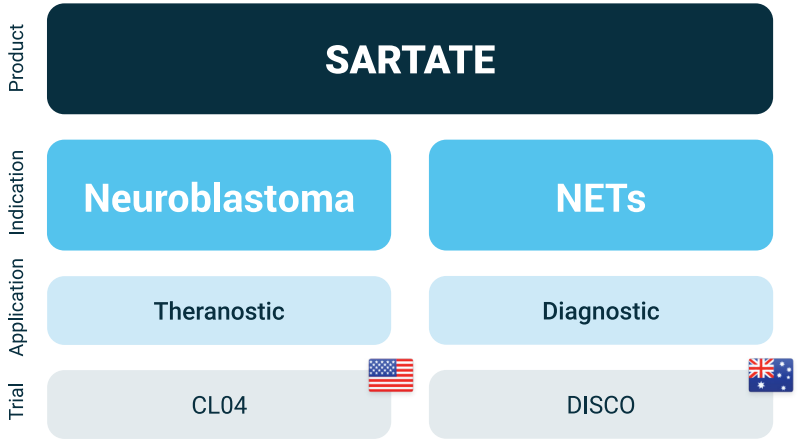



Fused, MIP and CT (left to right) images from $^{64}$Cu-SAR-BBN (top) and PSMA (bottom) PET, of a patient demonstrating a left subpleural lesion with $^{64}$Cu-SAR-BBN uptake without PSMA uptake. This patient underwent a lobectomy, with histopathology demonstrating metastatic prostate cancer.

Reproduced with permission from Prof Louise Emmett (St Vincent's Hospital, Sydney – Australia). BOP clinical trial. NCT05613842. EANM, 2023.

# SARTATE

Targets the Somatostatin Receptor 2 (SSTR2), which is present in an aggressive childhood cancer, neuroblastoma, as well as Neuroendocrine Tumours (NETs), among other cancers




**CL04 – Phase I/IIa**

- Cohort 3 was completed in July 2023
- Safety Review Committee recommendation to continue dose escalation phase, opening cohort 4
- No dose limiting toxicities to date

**DISCO – Phase II**

- 50% recruitment milestone in Feb 23

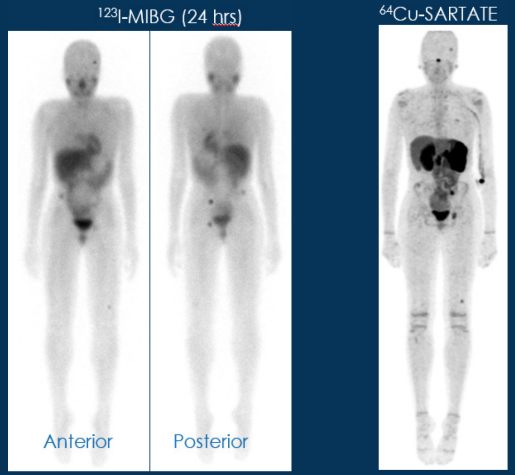
# Neuroblastoma therapy with $^{67}$Cu SARTATE

## CL04: $^{64}$Cu/$^{67}$Cu SARTATE Phase I/IIa trial in high-risk neuroblastoma in the US with up to 34 patients

### Trial Design

Multi-centre, dose-escalation/dose-expansion, open label, non-randomised, theranostic clinical trial

**CL04 patient dosed with 12.4GBq Cu-67 SARTATE in Feb 23**

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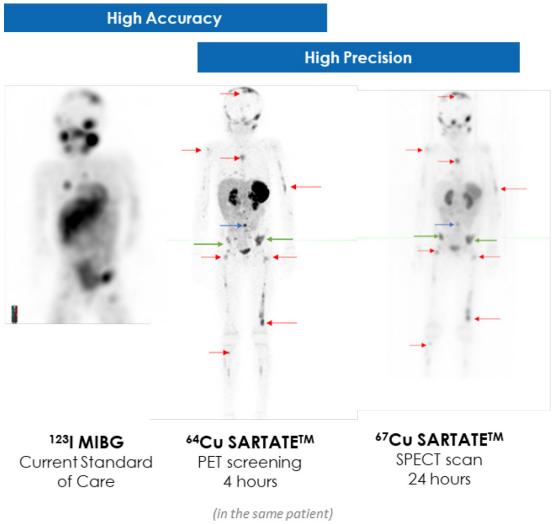
# CL04

CL04 trial is a $^{67}$Cu-SARTATE peptide receptor radionuclide therapy administered to paediatric patients with high-risk, relapsed, refractory neuroblastoma

### Status

- Cohort 1 complete, no safety issues (3 patients) 75MBq/kg b.w.
- Cohort 2 complete, no safety issues (3 patients) 175MBq/kg b.w.
- Cohort 3 complete, no safety issues (3 patients) 275MBq/kg b.w.
- **Cohort 4 recruiting (6 patients) 375MBq/kg b.w**
- Recruiting at multiple sites in the US




*CL04 ClinicalTrials.gov identifier: NCT04023331*

# Manufacturing

Scaling manufacturing for commercial launch

## Significant milestones

SIEMENS Healthineers

PETNET Solutions Inc, a Siemens Healthineers Company

The leading PET manufacturer in the United States will be producing $^{64}$Cu-SAR-bisPSMA for Clarity's Phase III clinical trials

NorthStar MEDICAL RADIOISOTOPES, LLC

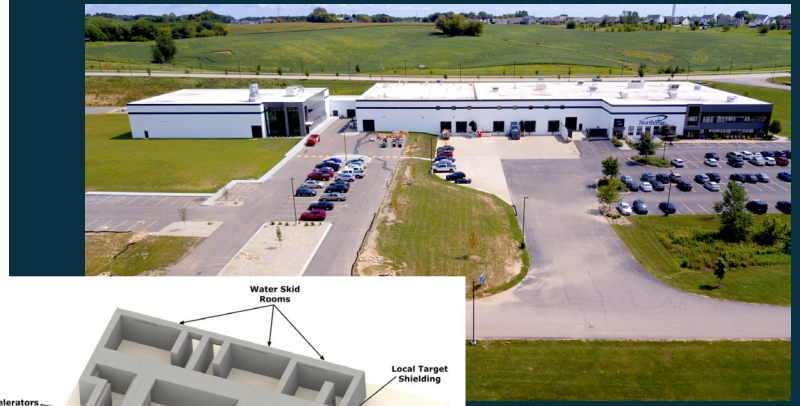
Large-scale rhodotron production of $^{67}$Cu now being used exclusively in Clarity's clinical programs

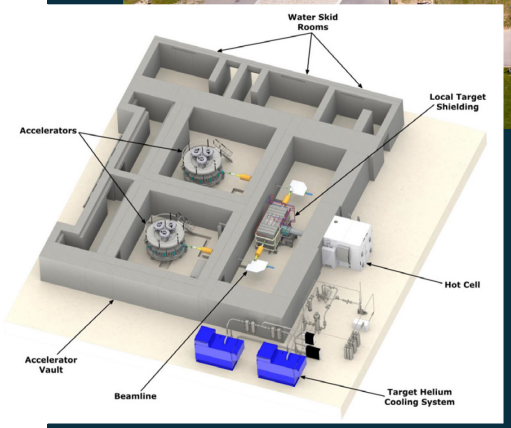
Current Rhodotrons now fully dedicated to $^{67}$Cu production for Clarity

## Patient doses in numbers

In the last 12 months:

- 200 diagnostic doses
- 34 therapy doses





# Robust IP driving the Discovery program

Clarity's proprietary SAR Technology platform can be used in conjunction with any number of targeting ligands to create new products and new IP

## Broad Patent Portfolio

### Platform Protection

- Granted and new chelator patents used in further developing lead and back-up products

### Product Protection

- Maintenance of pending applications for potential continuation or divisional filings on existing important patents
- New patents filed on lead and back-up compounds

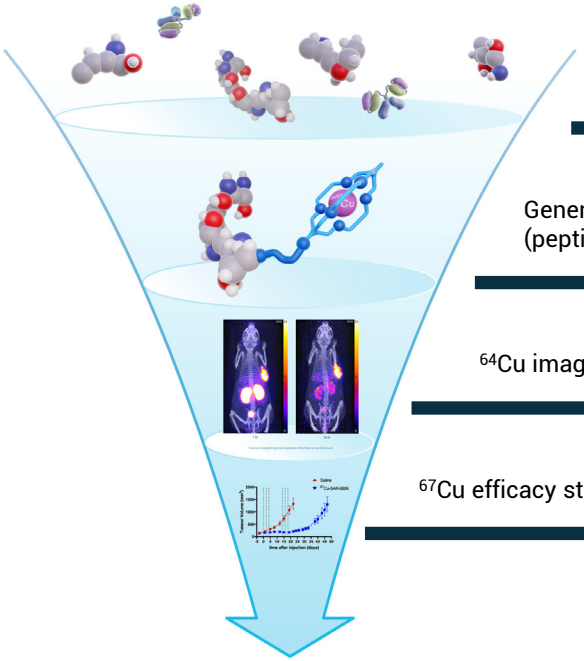
### Pipeline Protection

- New chelator patents used in future discovery products
- New patents filed on novel treatment regimes for radiopharmaceutical applications

### Manufacturing & Process Protection

- Manufacturing and formulation patents
- New patents filed on manufacturing processes

## Discovery Engine



Select high value cancer targets

Generate and radiolabel compounds (peptides and/or antibodies)

$^{64}$Cu imaging in tumour models

$^{67}$Cu efficacy studies in tumour models

SAR Technology platform

High value clinical candidates: SARTATE, SAR-bisPSMA, SAR-Bombesin, etc.

# Highly experienced team

Dr Alan Taylor
Executive Chairman

Dr Colin Biggin
CEO

Michelle Parker
EVP – Global Clinical Operations

Shaemus Gleason
EVP - Operations

Kathryn Williams-Day
VP of Regulatory Affairs and Quality

Dr Matt Harris
Chief Technology Officer

Dr Othon Gervasio
Senior Medical Director

Robert Vickery
Company Secretary

David Green
Chief Financial Officer

**Clarity's management team has a diverse and in-depth level of expertise spanning corporate finance, management, operations, commercialisation and industry**

- Development, approval and launch of 1st approved radiopharmaceutical therapy product for prostate cancer (Xofigo)
- Decades of experience spanning across science, nuclear medicine/PET, and pharmaceutical industries
- Investment banking experience focused on the life sciences sector

ALGETA NOVARTIS CardinalHealth™ BAYER sanofi Viralytics SANDOZ MERCK

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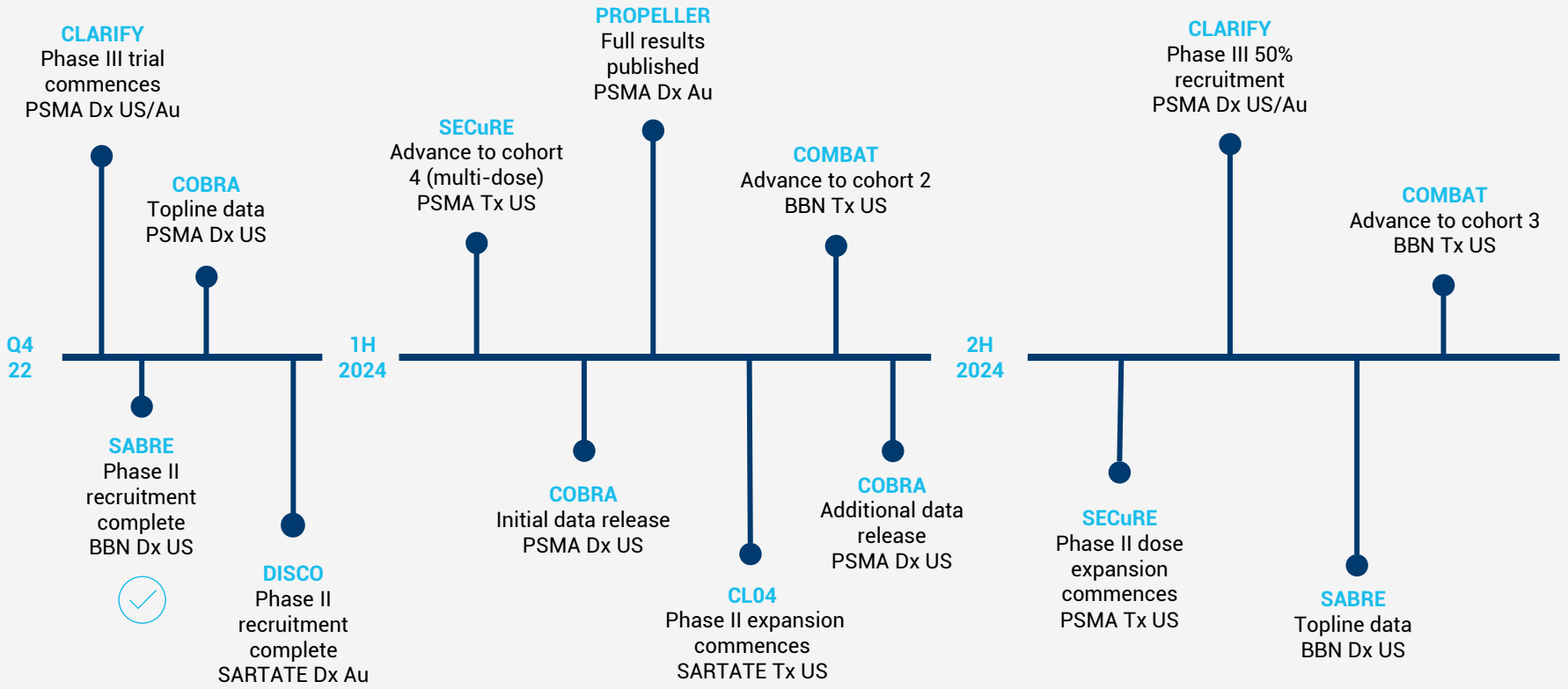
# Accelerating clinical progress



# Thank you

## Contact details

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**Dr Colin Biggin**
Managing Director
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