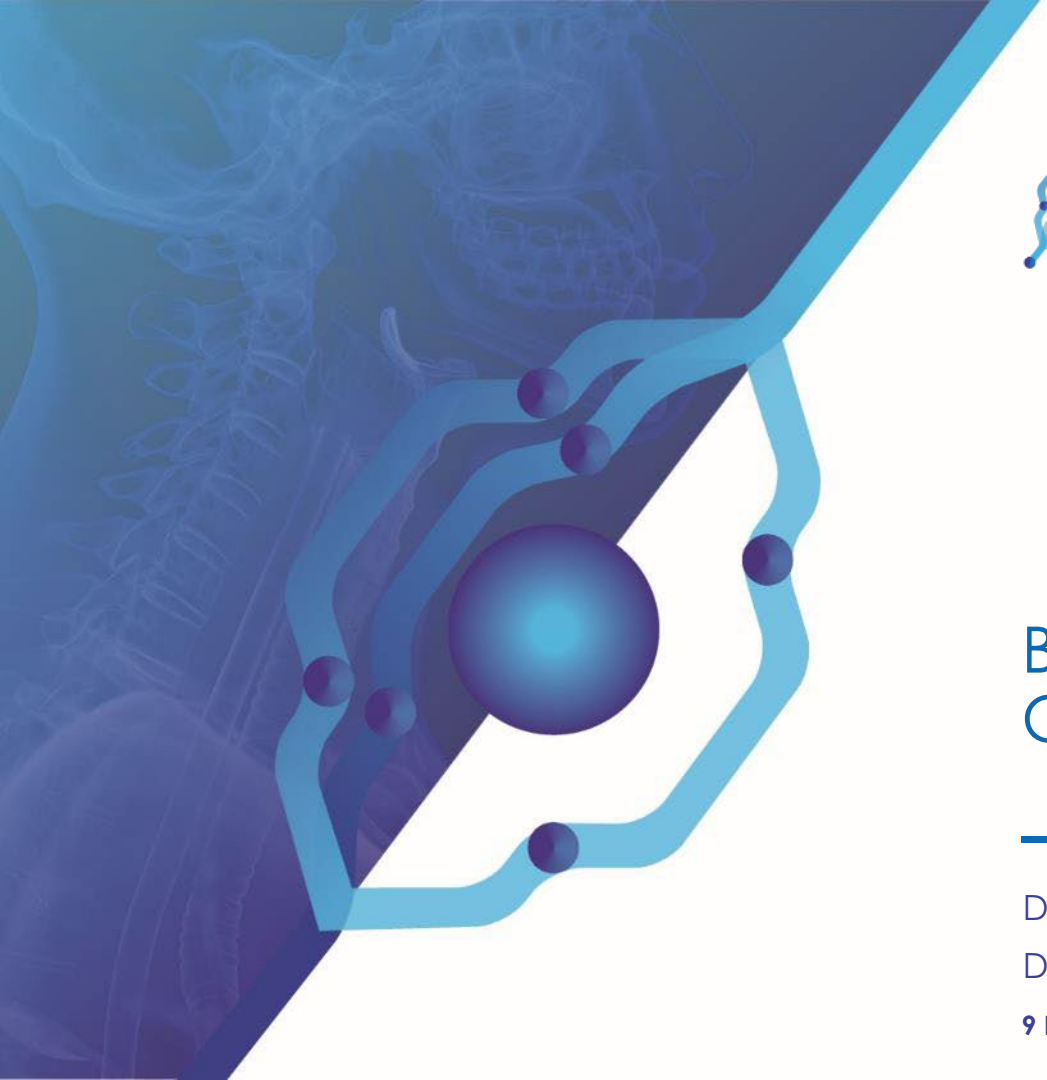

CLARITY
PHARMACEUTICALS

Developing the next-generation of radiopharmaceuticals to improve treatment outcomes for children and adults with cancer

Bell Potter Healthcare Conference 2022

Dr Alan Taylor, Executive Chairman
Dr Colin Biggin, Chief Executive Officer

9 November 2022

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Clarity in a nutshell (ASX:CU6)

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

Proprietary SAR Technology: a true platform technology

Three best-in-class products in clinical development 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 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

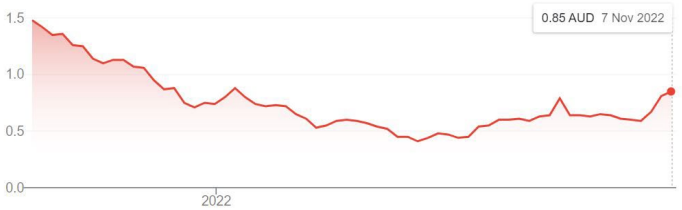
Diagnostic products will be the first to reach the market, generating revenue to fund late-stage therapeutic trials

Highly experienced leadership team

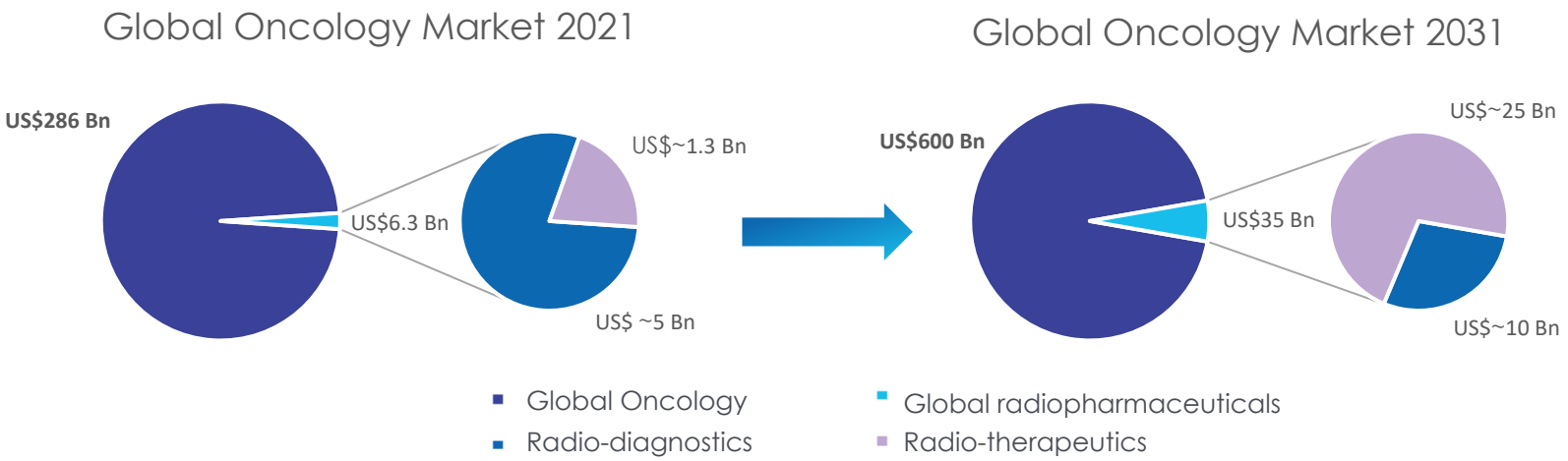
Diverse and in-depth expertise spanning corporate finance, operations, commercialisation & industry

ASX Code: CU6

- Share Price: **$0.85** as at 7 Nov 2022
- Cash at bank: **$84.7 million** as at 30 Sep 2022
- R&D tax incentive for FY22: **~$6 million**
- **~$90 million** to fund the existing trials and provide cash runway into 2024
- Shares on issue: 258.9 million
- Options on issue: 25.4 million
- Market capitalisation: **$220 million** as at 7 Nov 2022



Radiopharmaceuticals: Market overview



	2021		2031
Global oncology market	US$ 286 Billion	→	US$ >600 Billion
Global radiopharmaceuticals	US$ 6.3 Billion	→	US$ 35 Billion
Radio-diagnostics	US$ ~5 Billion	→	US$ ~10 Billion
Radio-therapeutics	US$ ~1.3 Billion	→	US$ ~25 Billion

Growth drivers

Radiopharmaceuticals have shown significant growth potential both diagnostically and therapeutically and companies, similar to Clarity, have proven to be very profitable

Positive changes

- Re-imbursement
- Pricing (Pluvicto >US$ 250k for 6 doses)
- Broader clinician uptake
- Positive Phase III results for Xofigo, Lutathera & Pluvicto

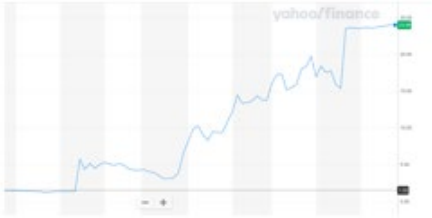
have driven Big Pharma interest in the space

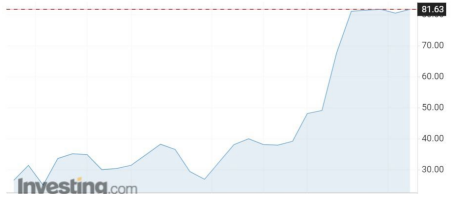
- Novartis
- Bayer

ALGETA

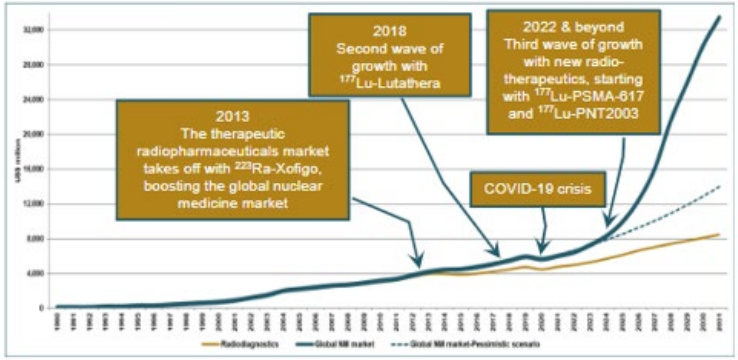
ENDOCYTE

Advanced Accelerator Applications





The Nuclear Medicine Market 1990-2031

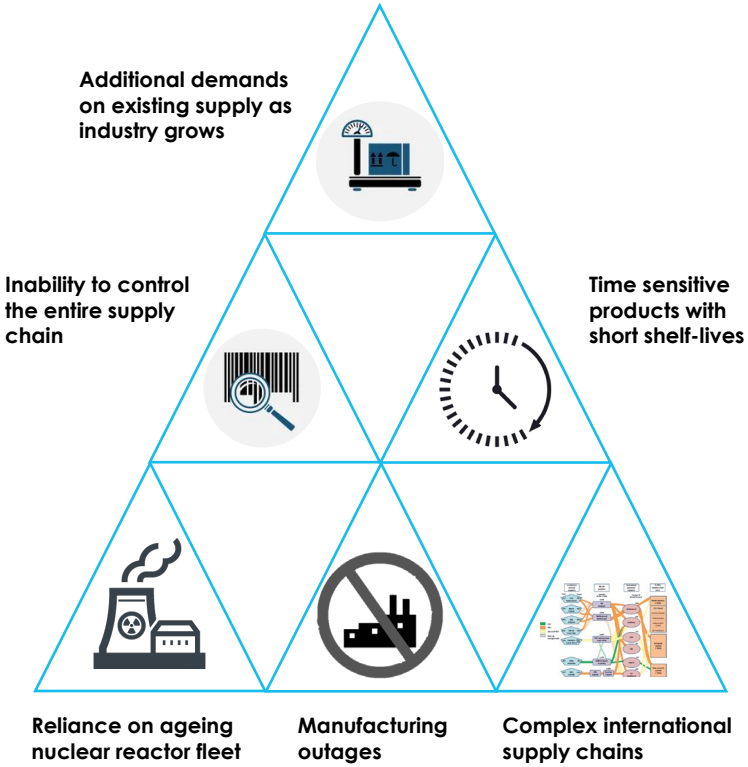


Recent approved diagnostics:
Pylarify: Q3 22 US sales ~USD144M

Recent approved therapy:
Pluvicto: Q3 22 US sales USD80M *

*1st full quarter of product launch

Current industry challenges



Combined with a history of supply issues

NUCLEAR MEDICINE EUROPE

COMMUNICATION FROM NMEU TO EU OBSERVATORY FOR THE SUPPLY OF MEDICAL RADIOISOTOPES

Global Mo-99 and I-131 Production Impacted by Delay of Two Reactors Restarting from Scheduled Maintenance

Brussels, 20 October 2022

NewScientist

SUBSCRIBE AND SAVE 60%

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

HEALTH 21 September 2019

Bayer Suspends Production of Radium-223 Due to Manufacturing Problem

October 17, 2014
Beth Fand Incollingo

nature › news › article

Published: 12 September 2016

Reactor shutdown threatens world's medical-isotope supply

MANUFACTURING

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

By Angus Liu • May 5, 2022 12:44pm

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

Dear Dr. Marzella and Dr. Zadecky,

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

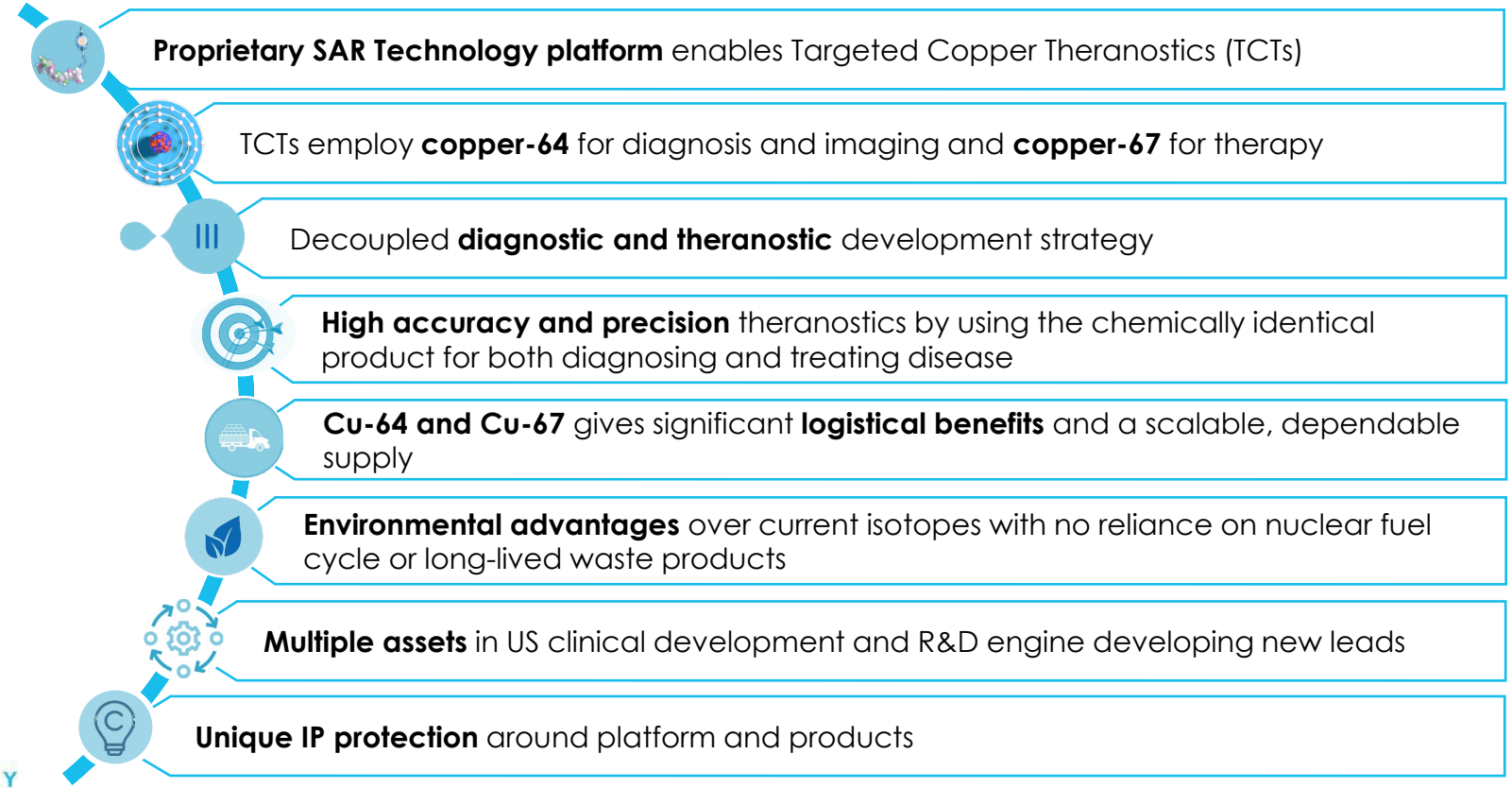
Creates challenges for prescribers

Work to be done to convince oncologists that there is a safe, dependable and reliable source of radiopharmaceutical products.

Without this supply chain, radiopharma may struggle to become a pillar of oncology when its competing with long shelf life oral oncolytics.

Clarity's TCTs address the current industry challenges

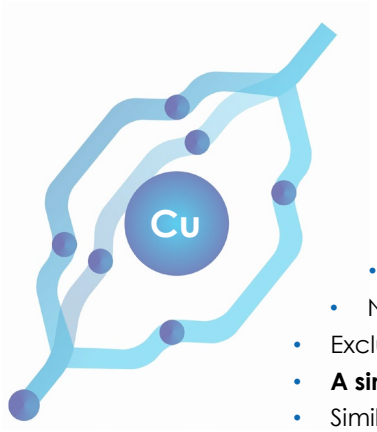
Clarity Pharmaceuticals is a clinical stage radiopharmaceutical company with a mission to develop next-generation products that improve treatment outcomes for children and adults with cancer



Clarity - the perfect pairing to address current challenges

Copper-64 (half-life = 12.7 hours)

- Mass produced on cyclotrons
- Every US zip code covered from 1 location
- Patient flexibility with product shelf-life of up to 48 hours
- Operational flexibility with imaging timepoints from 1 to 72 hours
- Delivered as a ready-to-use cGMP product
- 9-22 times lower exposure than commonly used ^{18}F products
- The ability to centralise capital investments and supply entire continents
- Similar half-life to iodine-123 which is routinely produced centrally



Copper-67 (half life = 2.6 days)

- Optimal half-life for peptide-based therapy
- Commercially available high powered rhodotron for mass production with a small footprint
- Scalable with relatively small investments
- Purpose-built supply in the markets of focus, including a US domestic supply
- Only inputs are electricity and Zinc
- No long-lived impurities
- Exclusive supply agreement with NorthStar Medical Isotopes
- **A single rhodotron can produce commercial quantities of ^{67}Cu**
- Similar half-life to yttrium-90, used in SIR-spheres.

Clarity's solution to radiopharmaceutical supply threats

- No time sensitive international supply chains
- No local production requirements (reduced costs and patient safety risk; universal availability)
- Economies of scale from the same manufacturing process
- Ability to quickly integrate new products

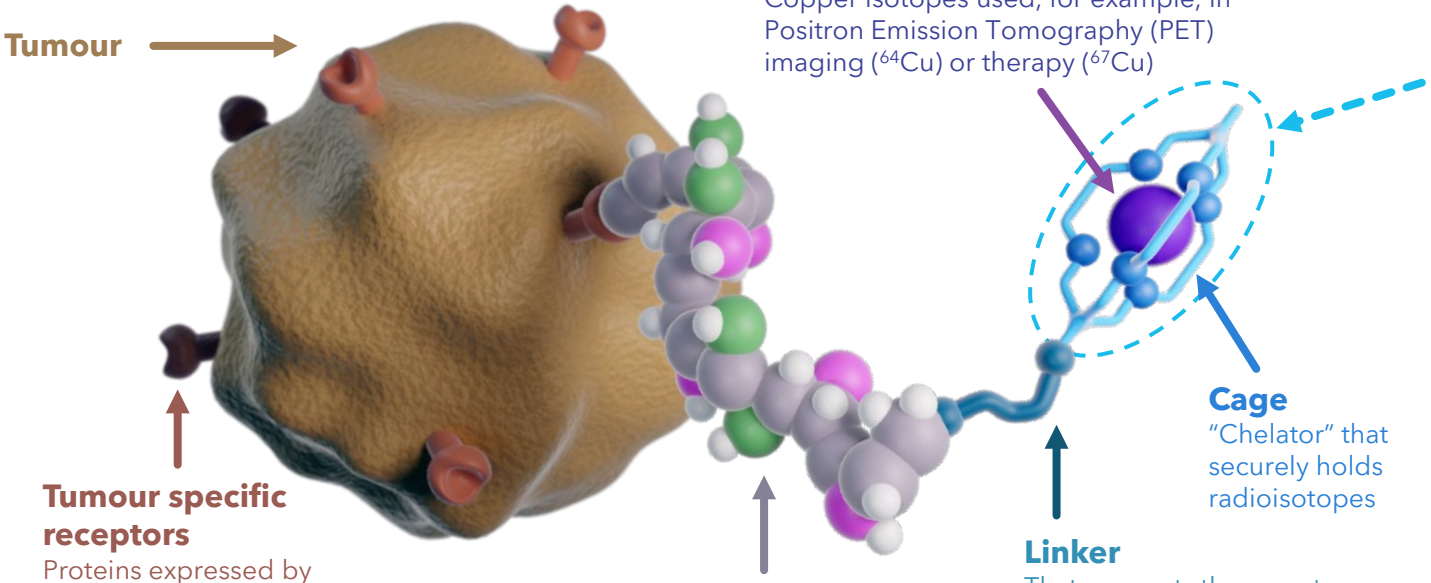
The environmental considerations*

- As the number of patient treatments increases, environmental factors will impact the selection of theranostic radiopharmaceuticals
- Production of ^{64}Cu and ^{67}Cu has favorable environmental characteristics, significantly reducing the environmental impact compared to the current generation theranostics based on ^{68}Ga or ^{177}Lu
- This is highly relevant considering the forecasted growth of theranostics over the next decade

*Norenberg J et al. Environmental Considerations Resulting from the Increased Use of Theranostics: Advantages of Targeted Copper Theranostics. Journal of Nuclear Medicine June 2022, 63 (supplement 2) 2655.19. https://jnm.snmjournals.org/ content/63/supplement_2/2655

Proprietary SAR Technology platform

Theranostic radiopharmaceuticals have four main elements: a radioisotope, cage, linker and targeting ligand and are administered intravenously



CLARITY PHARMACEUTICALS

SAR Technology platform

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

Unlike the current generation of radiopharmaceuticals, SAR products do not require heating in order to bind copper to the cage

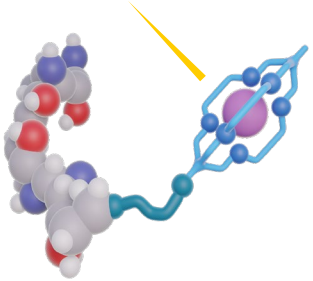
Global leader in Targeted Copper Theranostics

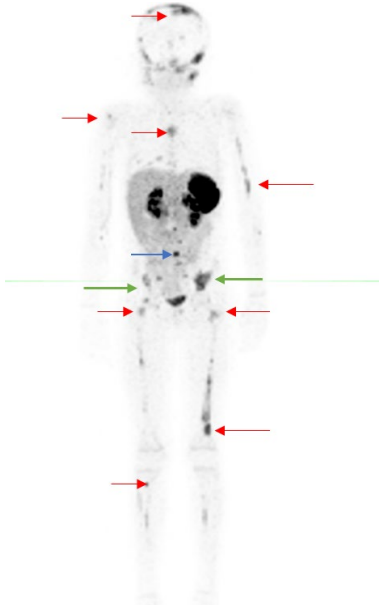
Clarity's SAR Technology is used to develop the next generation of radiopharmaceuticals that employ the "perfect pairing" of copper-64 (^{64}Cu) for diagnosis and copper-67 (^{67}Cu) for therapy

Diagnostic

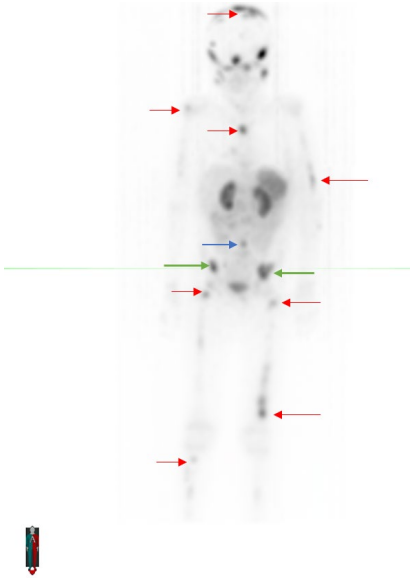
Positron emission from ^{64}Cu at the tumour site enables better diagnosis through PET imaging

^{64}Cu SARTATE™





^{64}Cu SARTATE™
PET screening
4 hours

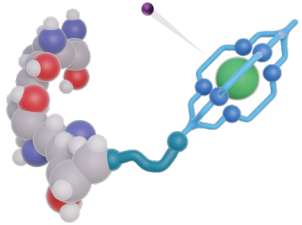


^{67}Cu SARTATE™
SPECT scan
24 hours

Therapeutic

Beta particle (β-) emission from ^{67}Cu delivers radiation directly to the cancer cells in order to kill them

^{67}Cu SARTATE™



Both diagnostics and therapeutics target the same cancer sites with high accuracy and precision, delivering a key platform advantage

Dual development strategy

SAR Technology enables a synergistic development of stand-alone diagnostics as well as paired theranostics

Diagnostics based on ^{64}Cu

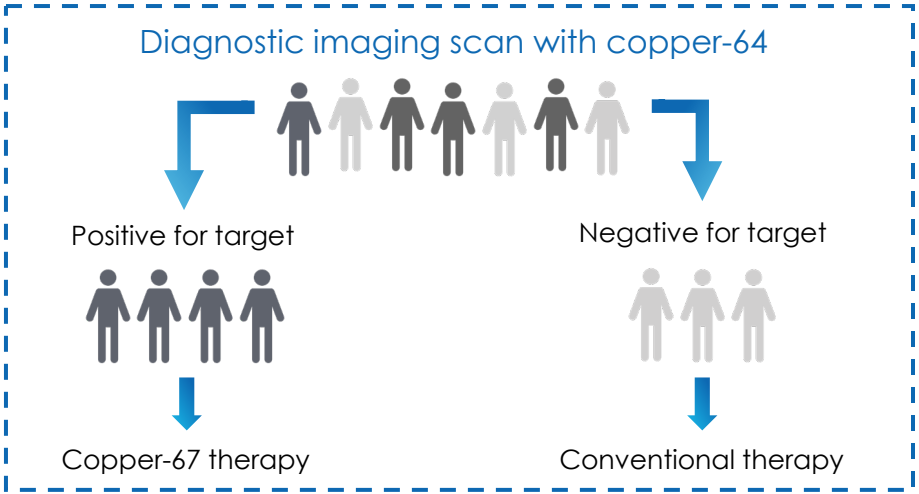
- Broad market opportunities
- Address the current supply and logistical constraints on the industry
- Provide universal access to diagnostic agents
- Short time to market, provides revenue for later stage therapy development
- Low production and distribution costs shield potential revenues from lost of pass-through-status after 3 years in the US

Dx revenue pays for late-stage Tx clinical development

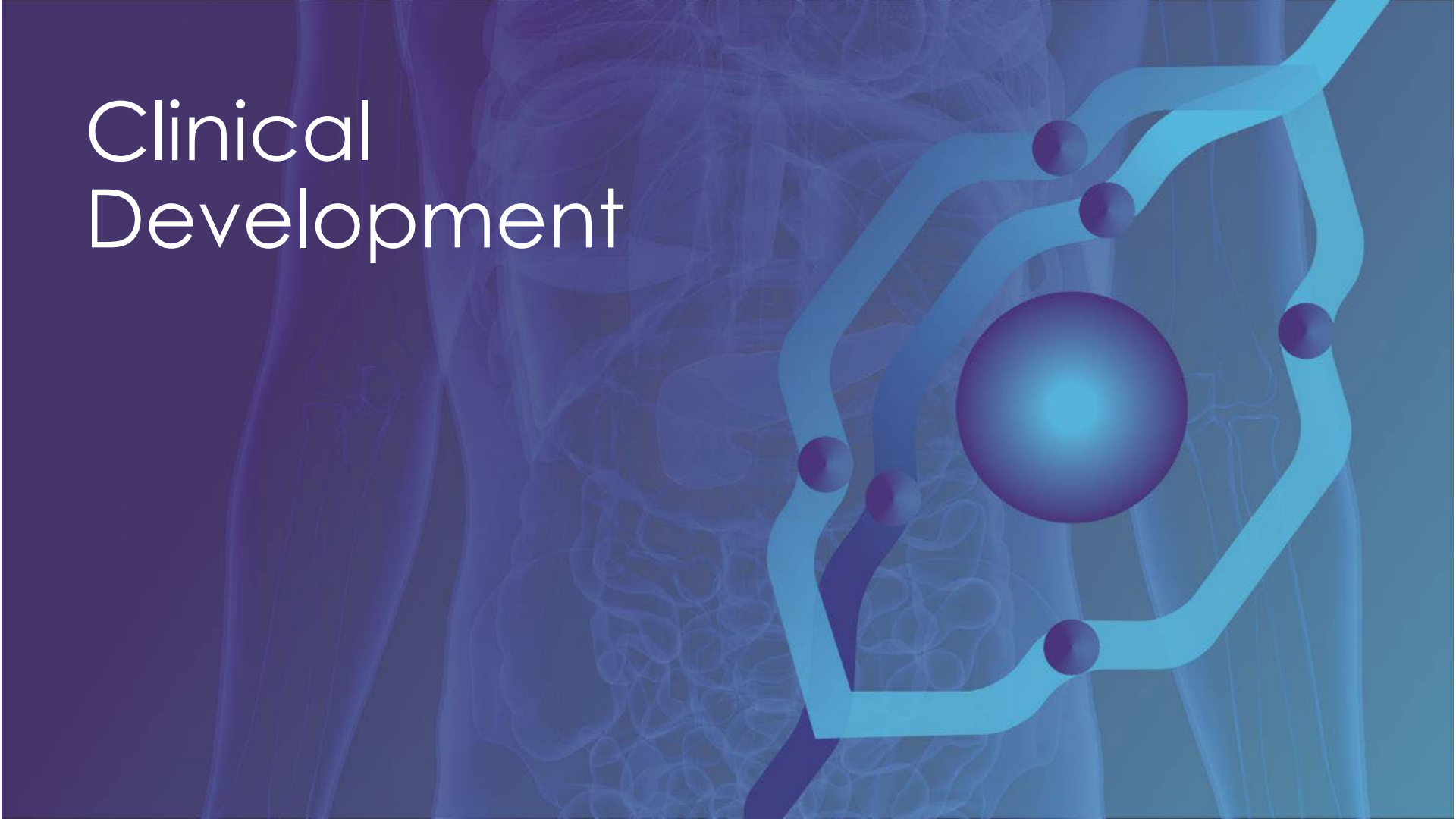
Theranostics based on $^{64}Cu/^{67}Cu$

- High precision, high accuracy
- Blockbuster potential for a range of assets
- Easy to scale up
- Domestic US supply
- No reliance on aging nuclear reactors

Marketed Dx re-enforces Tx position



Clinical Development



Three core product areas in clinical trials

Clarity has an active clinical development program in multiple oncology indications with unmet needs through a range of products and their applications. The SAR platform is also used in our SAR-DISCOVERY program which has significant synergies with the existing clinical program.

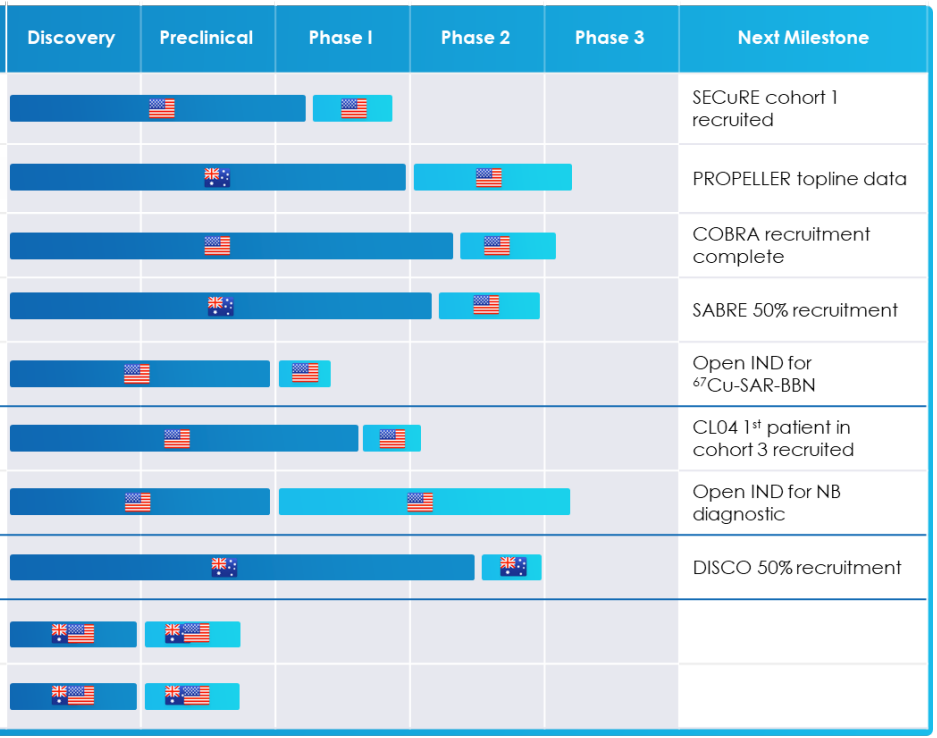
Product	SAR-bisPSMA Cancers that express Prostate Specific Membrane Antigen (PSMA)	SAR-Bombesin Cancers that express Gastrin Releasing Peptide receptor (GRPr)			SARTATE™ Cancers that express Somatostatin Receptor 2 (SSTR2)	DISCOVERY Developing new products based on Cu-64/Cu-67
Indication	Prostate Cancer				Breast Cancer	Neuro-blastoma	NETs
Current trials	Theranostic	Diagnostic	Theranostic	Diagnostic	Diagnostic	Theranostic	Diagnostic
Trial name/phase	SECURE Phase I/IIa	COBRA Phase I/II PROPELLER Phase I XCALIBUR IIT	IND expected Q4 Phase I/IIa	SABRE Phase II BOP Phase II IIT	C-BOBCAT Phase I IIT	CL04 Phase I/IIa	DISC Phase II

Clinical development in multiple cancers

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

Clinical development pipeline as of 9 November 2022

Indication	Product	Application	Current Trial	Next Milestone
Prostate Cancer	SAR-bisPSMA	Theranostic mCRPC	SECuRE	SECuRE cohort 1 recruited
	SAR-bisPSMA	Diagnostic in pre-radical prostatectomy	PROPELLER	PROPELLER topline data
	SAR-bisPSMA	Diagnostic in BCR PCa	COBRA	COBRA recruitment complete
	SAR-BBN	Diagnostic in BCR PCa	SABRE	SABRE 50% recruitment
	SAR-BBN	Theranostic		Open IND for ^{67}Cu-SAR-BBN
Neuroblastoma	SARTATE™	Theranostic	CL04	CL04 1st patient in cohort 3 recruited
	SARTATE™	Diagnostic		Open IND for NB diagnostic
NETs	SARTATE™	Diagnostic	DISCO	DISCO 50% recruitment
SAR Discovery Platform	Undisclosed	Undisclosed		
	Undisclosed	Undisclosed		



Current progress | 12 month progress

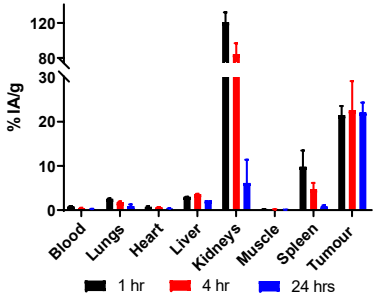
Note clinical development pipeline is indicative only, subject to review.

All US studies are conducted under IND

SAR-bisPSMA: Pre-clinical data

SAR-bisPSMA is ideally suited for a theranostic radiopharmaceutical

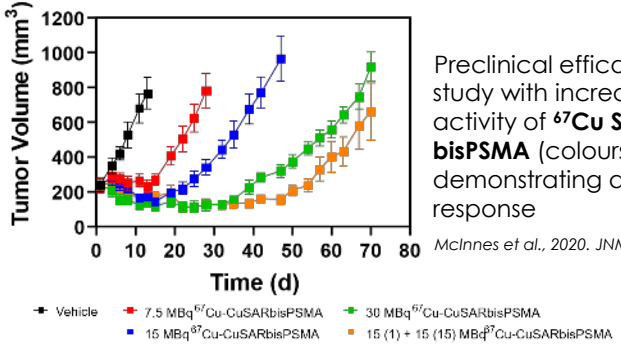
High uptake and retention in tumour



Preclinical biodistribution study demonstrating high uptake and retention of **^{64}Cu SAR-bisPSMA** in tumours with rapid clearance from non-target organs

Zia et al., 2019. Ang.Chem

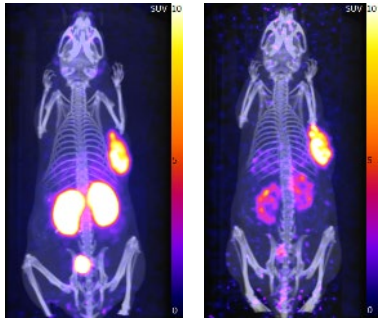
Significant anti-tumour effect



Preclinical efficacy study with increasing activity of **^{67}Cu SAR-bisPSMA** (colours) demonstrating dose response

McInnes et al., 2020. JNM

Rapid kidney clearance of non-bound activity



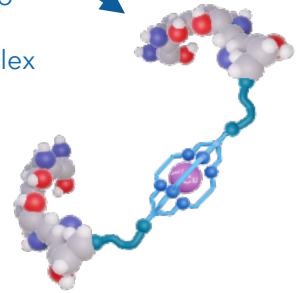
1 hr 24 hr

Tumour targeting and superior retention over 24 hours

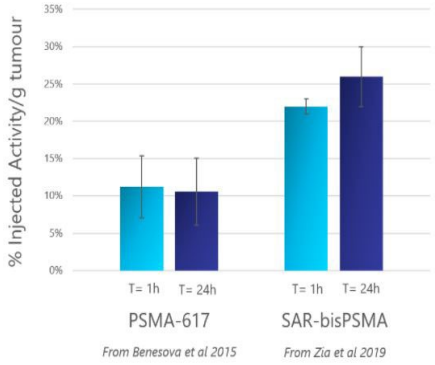
PET images showing **^{64}Cu SAR-bisPSMA** targeting to tumours over time and rapid kidney clearance

'bisPSMA'

The term "bis" is used to denote the presence of two identical but separate complex groups in one molecule



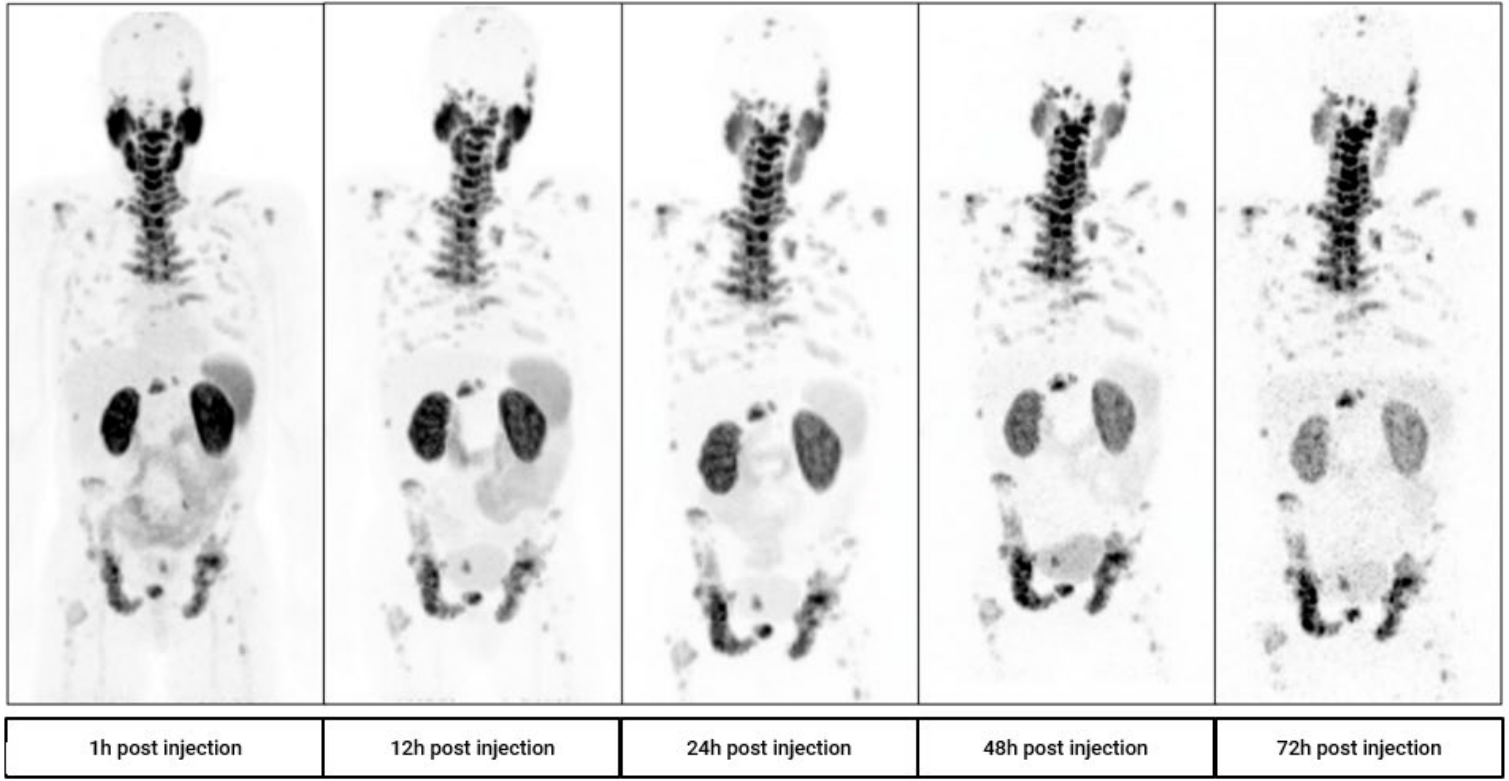
High uptake and retention in tumour compared to Pluvicto™ (PSMA-617)



From Benesova et al 2015 *From Zia et al 2019*

SAR-bisPSMA therapy in prostate cancer

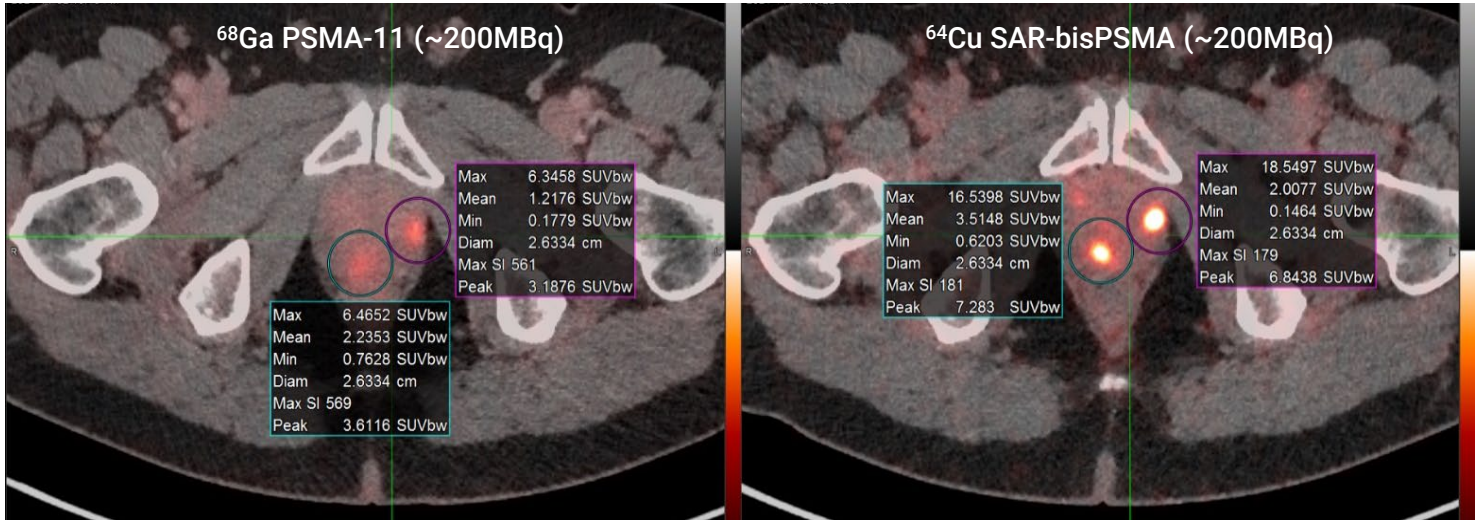
PET scans in a patient with metastatic castrate-resistant prostate cancer imaged over multiple timepoints between 1 and 72 hours post administration of ^{64}Cu SAR-bisPSMA (Normalised Voxel Intensity)



SAR-bisPSMA diagnostic in untreated, confirmed prostate cancer

PROPELLER

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



^{68}Ga PSMA-11 (~200MBq, left) vs. ^{64}Cu SAR-bisPSMA (~200MBq, right) in the same patient; time between serial imaging was 8 days. Standardised Uptake Value (SUVmax)* of the lesions were 6.5 and 6.3 for ^{68}Ga PSMA-11 and 16.5 and 18.5 for ^{64}Cu SAR-bisPSMA.

**SUV is a measurement of product uptake in tissue normalised to a distribution volume*

SAR-bisPSMA therapy in prostate cancer

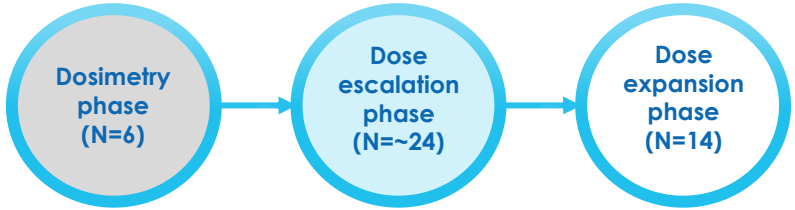
SECuRE

SECuRE: Systemic Copper theranostics in prostate cancer

- Phase I/IIa study of ^{64}Cu/^{67}Cu SAR-bisPSMA for identification and treatment of PSMA-expressing metastatic castrate resistant prostate cancer (mCRPC)
- Dose escalation phase aims to find the highest dose of ^{67}Cu SAR-bisPSMA that can be given safely and expand patient numbers at that dose in dose expansion

Trial design

Theranostic multi-centre, single arm, dose escalation study with a cohort expansion planned for up to 44 patients



Status

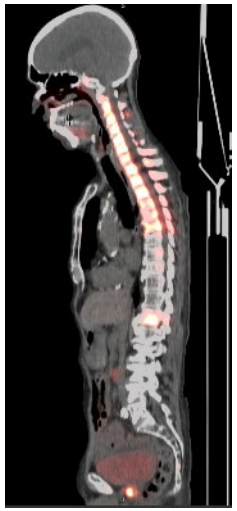
- Dosimetry phase with ^{64}Cu SAR-bisPSMA in mCRPC completed
- First patient treated in the dose escalation phase

Next milestone

- Advance to next dose cohort

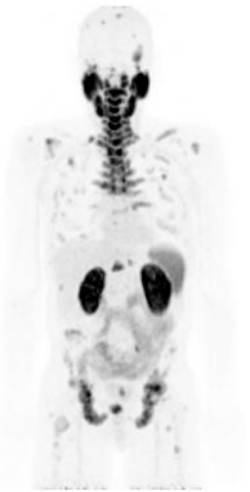
Preliminary imaging results from the dosimetry phase

^{64}Cu SAR-bisPSMA PET/CT

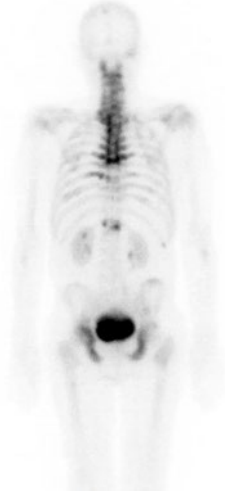


12hr ^{64}Cu SAR-bisPSMA PET/CT Fused Sagittal

Comparison of 1h ^{64}Cu SAR-bisPSMA PET with ^{99m}Tc-MDP Bone Scan



1h ^{64}Cu SAR-bisPSMA PET



^{99m}Tc-MDP WB Bone Scan

SECuRE clinicaltrials.gov identifier: NCT04868604

CLARITY

SAR-bisPSMA diagnostics

PSMA diagnostics are set to become a blockbuster market with >$1.1B in the US

Pre-definitive treatment setting

PROPELLER

Compares ^{64}Cu SAR-bisPSMA to ^{68}Ga PSMA-11in participants with untreated prostate cancer who are planned for radical prostatectomy

Trial design

Phase I multi-centre, blinded review, dose ranging, non-randomised study in 30 patients across Australia

Status

- Fully recruited, analysis underway

Next milestones

- Topline data in Q4 2022
- Discussions with US FDA on Phase III diagnostic trial design; trial planned to commence in 2023

PROPELLER clinicaltrials.gov identifier: (NCT04839367)

Biochemical recurrence (BCR) setting

COBRA

Investigates the safety and tolerability of ^{64}Cu SAR-bisPSMA as well as its ability to correctly detect recurrence of prostate cancer in participants with BCR of prostate cancer following definitive therapy

Trial design

Phase I/II multi-centre, single arm, non-randomised study in up to 50 patients across the US

Status

- >50% recruited

Next milestones

- 100% recruitment in Q1 2023
- Top-line data expected Q3 2023

COBRA clinicaltrials.gov identifier: (NCT05249127)

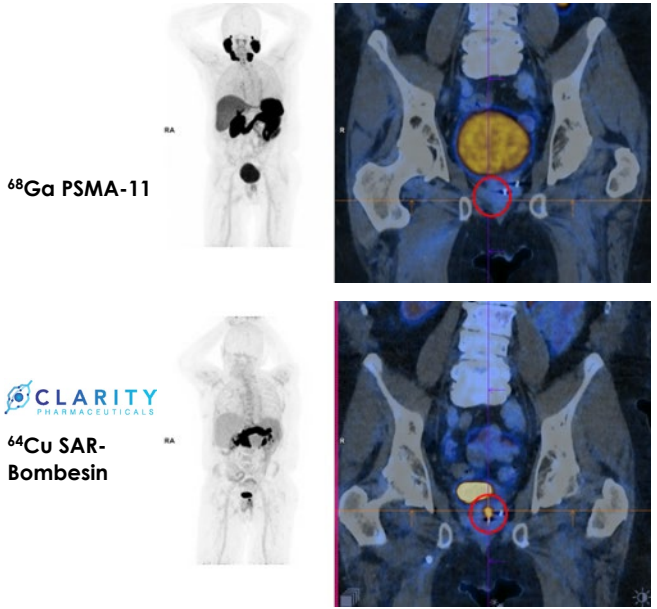
Two Phase III trials required for registration in prostate cancer: one in the pre-definitive treatment and one in the BCR setting. Clarity is expecting to commence registrational trials in 2023.

SAR-Bombesin – a pan cancer product

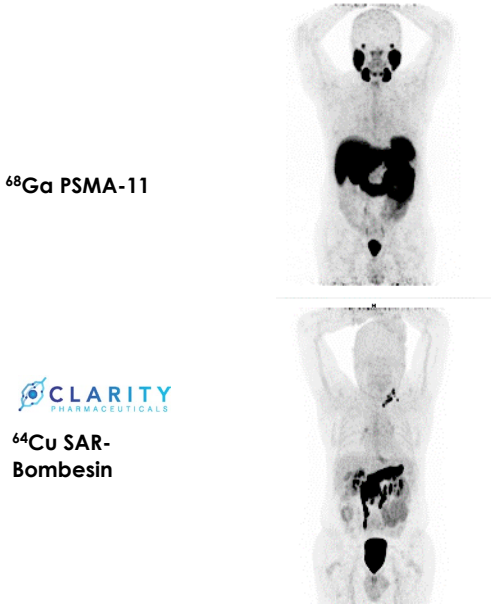
GRPr is a receptor that is overexpressed in a number of cancers including prostate, breast, colon, gastric, glioma, pancreatic, small cell lung and non-small cell lung cancer, as well as renal cell cancer

- **75%-100% of prostate cancers express GRPr**
- **83% of estrogen receptor (ER) positive breast cancers express GRPr**
- **~10%** of prostate cancer patients do not **express PSMA**
- PSMA negative prostate cancer patients will not respond to PSMA imaging or therapy
- SAR-Bombesin is now under investigation as a diagnostic imaging agent for PSMA-negative prostate cancer

SAR-Bombesin was able to locate tumours in PSMA-negative prostate cancers that are not visible with approved PSMA diagnostics



^{68}Ga PSMA-11 (top) images of a PSMA-negative patient with clinical signs of prostate cancer (a rising PSA score of 0.16 ng/mL) and ^{64}Cu SAR-Bombesin PET/CT images of the same patient (bottom)



^{68}Ga PSMA-11 (top) image of a PSMA-negative patient with history of prostate cancer (a rising PSA score of 25 ng/mL) and ^{64}Cu SAR-Bombesin PET/CT image of the same patient (bottom)

CLARITY

SAR-Bombesin in PSMA-negative prostate cancer

SABRE

SABRE: Copper-64 SAR-BBN in Biochemical Recurrence of prostate cancer

The primary objectives of the trial are to investigate the safety and tolerability of the product as well as its ability to correctly detect recurrence of PSMA-negative prostate cancer.

Trial design

- Phase II Positron Emission Tomography (PET) imaging trial of participants with PSMA-negative biochemical recurrence (BCR) of prostate cancer following definitive therapy.
- Multi-centre, single arm, non-randomised, open-label trial of ^{64}Cu-labelled SAR-Bombesin in 50 participants.

Status

- Recruitment ongoing in the US

Next Milestone

- 50% recruitment in Q1 2023

- Clarity is preparing for a **US-based theranostic trial** with ^{64}Cu/ ^{67}Cu SAR-Bombesin
- Open IND expected Q4 2022

BOP

BOP IIT: Copper-64 SAR Bombesin in Prostate Specific Membrane Antigen (PSMA) negative Prostate Cancer

Assesses the safety of ^{64}Cu-SAR-Bombesin and looks at the diagnostic potential across two different groups of men:

- Participants with suspected biochemical recurrence (BCR) of their prostate cancer who have negative PSMA positron emission tomography (PET) imaging scans or low PSMA expression disease
- Participants with metastatic castrate resistant prostate cancer (mCRPC) who are not eligible for PSMA therapy

Trial design

- Phase II investigator-initiated trial (IIT) in up to 30 patients led by Prof Louise Emmett at St Vincent's Hospital, Sydney

Status

- 50% recruited as of 02/11/22

Next Milestone

- 100% recruitment in Q3 2023

CLARITY

SABRE ClinicalTrials.gov identifier: NCT 05407311

SARTATE™

CL04

SARTATE™ CL04: ^{67}Cu-SARTATE™ Peptide Receptor Radionuclide Therapy Administered to Pediatric Patients With High-Risk, Relapsed, Refractory Neuroblastoma

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

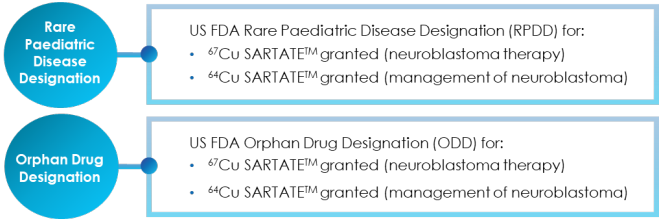
Trial design

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

Status

- *Cohort 1 complete, no safety issues*
- *Cohort 2 complete, no safety issues*
- *Cohort 3 commenced recruitment*

Regulatory milestones



- **RPDDs may potentially allow to access 2 Priority Review Vouchers, which are tradeable and have recently transacted at US$110M**

CL04 ClinicalTrials.gov identifier: NCT 04023331

DISCO: Diagnostic Imaging Study of Copper-64 SARTATE using PET on patients with known or suspected NETs

Assesses the performance of imaging agent ^{64}Cu SARTATE™ in participants with known or suspected gastroenteropancreatic NETs as a potential new way to help diagnose and manage NETs

- Aims to capture and highlight the significant advantages of the longer half-life (12.7 hours) of copper-64, related to imaging and product supply which are relevant to Clarity's entire pipeline of products in development

Trial design

- Phase II multi-centre, single arm, non-randomised, blinded-review study in up to 63 participants
- Compares diagnostic performance of ^{64}Cu SARTATE™ at 4 and 20 hours to the current standard of care, ^{68}Ga DOTATATE, at 1 hour

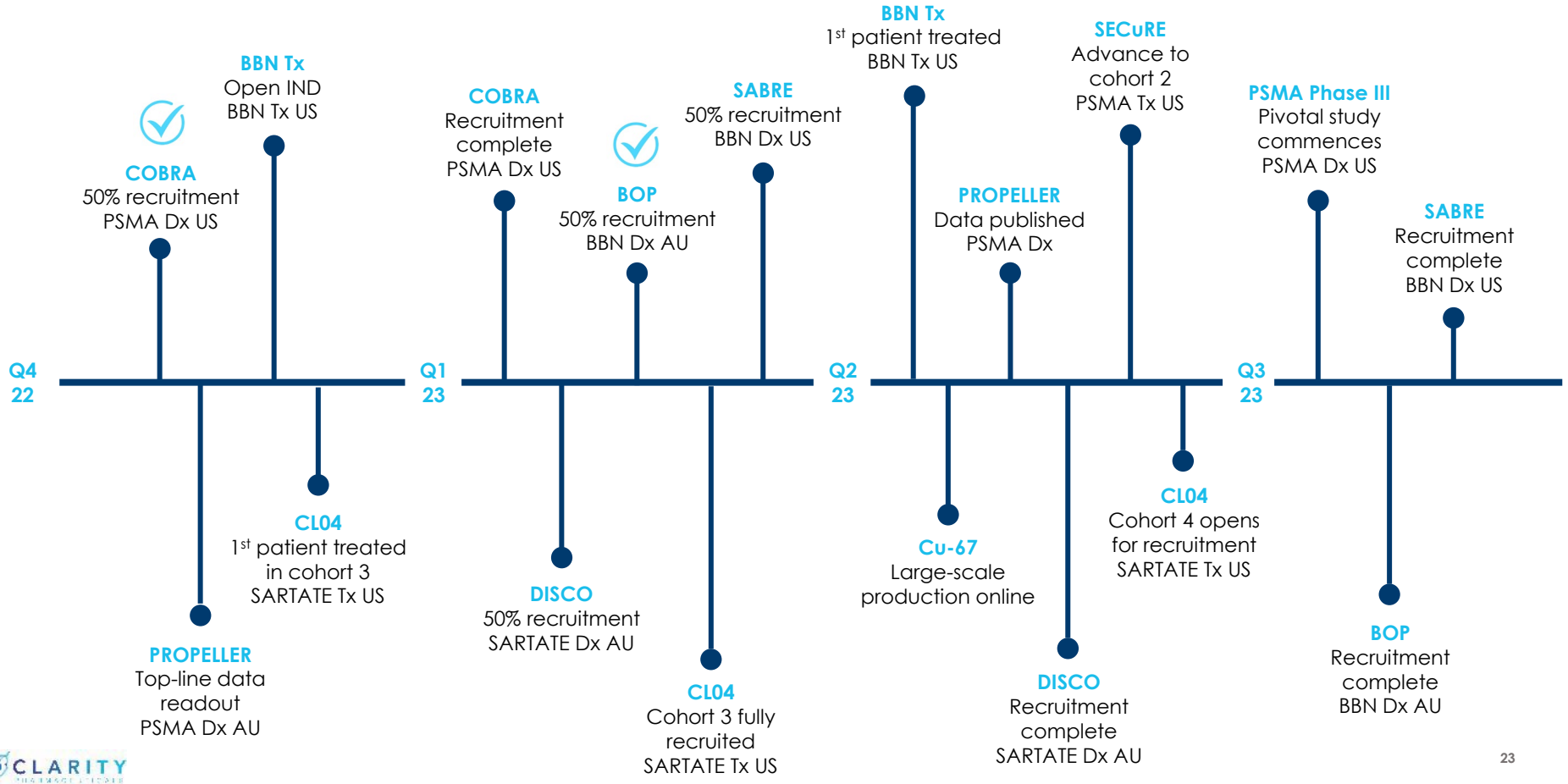
Status

- Currently recruiting at four sites with ^{64}Cu SARTATE™ manufactured centrally in Australia

DISCO ClinicalTrials.gov identifier: NCT 04438304

Inflection points over next 12 months

Dx = Diagnostics
Tx = Theranostics



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

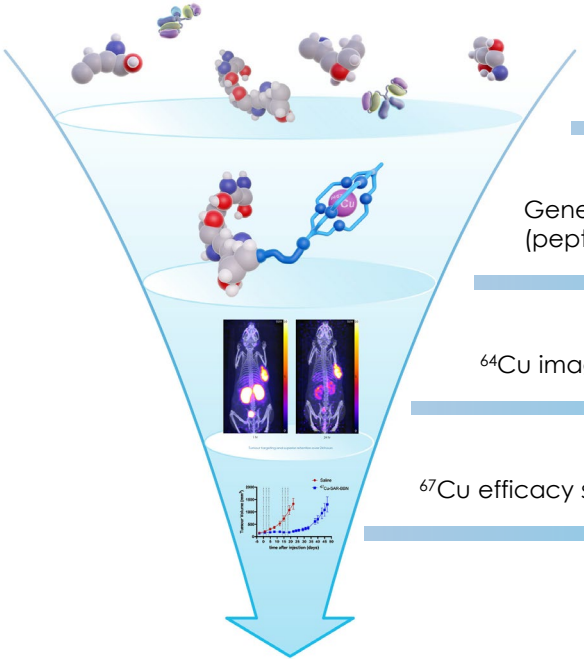
Pipeline Protection

- 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

Dr Jennifer Rosenthal
Director of Quality & Regulatory Affairs

Dr Matt Harris
Director of Technology

Dr Jeff Norenberg
Chief Scientific Officer

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 Viralytics Developers of Oncolytic Immunotherapies invicro

Thank you

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