CLARITY PHARMACEUTICALS

Fully underwritten A$121M capital raise

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

Dr Alan Taylor, Executive Chairperson
Dr Colin Biggin, Managing Director and CEO

26 March 2024

Important Notice and Disclaimer

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This presentation (**Presentation)** is dated 26 March 2024 and has been prepared by Clarity Pharmaceuticals Ltd (ACN 143 005 341) (ASX: CU6) (**Clarity** or the **Company**) in relation to an offer by Clarity of new fully paid ordinary shares of Clarity (**New Shares**) by way of a fully underwritten private placement to 'sophisticated' and 'professional' investors (**Placement**) in accordance with sections 708(8) and 708(11) of the *Corporations Act 2001* (Cth) (**Corporations Act**) and a fully underwritten 1 for 33 pro rata accelerated non-renounceable entitlement offer to certain eligible shareholders of Clarity (**Entitlement Offer**) at an issue price of $2.55 per New Share (together, the **Offer**).

The Entitlement Offer is being made to eligible institutional shareholders and eligible retail shareholders under section 708AA of the Corporations Act as modified by the *ASIC Corporations (Non-Traditional Rights Issues) Instrument 2016/84* and *ASIC Corporations (Disregarding Technical Relief) Instrument 2016/73*.

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Bell Potter Securities Limited (ACN 006 390 722, AFSL 243 480) and Wilsons Corporate Finance Limited (ABN 65 057 547 323, AFSL 238 383) (the **Joint Lead Managers**) are acting as lead managers of the Offer.

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Executive Summary

Raising A$121m to fully fund the company's current clinical programs until early CY26

Company & technology overview

- Clarity 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 is a global leader in Targeted Copper Theranostics (TCTs), developed with its proprietary SAR Technology platform, which is the next-generation disruptive platform in radiopharmaceuticals that employs the "perfect pairing" of copper-64 and copper-67 for diagnosis and therapy, respectively.
- Clarity's next-generation TCTs provide solutions to the challenges associated with current-generation radiopharmaceuticals.

Compelling recent data and multiple near-term catalyst

- **CLARIFY** *(pivotal Phase III ^{64}Cu-SAR-bisPSMA diagnostic trial in high-risk prostate cancer (PC) prior to radical prostatectomy)* – first patient dosed in Dec 2023. Final results from the trial are intended to support an application to the FDA for the approval of ^{64}Cu-SAR-bisPSMA in pre-prostatectomy patients.
- **COBRA** *(Phase I/II ^{64}Cu-SAR-bisPSMA diagnostic trial in biochemical recurrence (BCR) of PC)* – trial data announced in Feb 2024 confirms that ^{64}Cu-SAR-bisPSMA is safe and highly effective in detecting PC lesions in this patient population. Trial data will inform registrational Phase III trial in patients with BCR of PC.
- **SECuRE** *(Phase I/IIa ^{64}Cu/^{67}Cu-SAR-bisPSMA theranostic trial in metastatic castrate-resistant prostate cancer (mCRPC))* – overall safety review of cohorts 1, 2 and 3 of single ascending dose trials showed promising efficacy data and a favourable safety profile. Safety Review Committee recommended the trial progress to cohort 4, the first multi-dose cohort, at the highest dose level of 12GBq. The first patient in cohort 4 has been treated in March 2024.

M&A activity from large pharma

- **Three blockbuster deals in the global radiopharmaceuticals sector over the last 6 months** – AstraZeneca / Fusion (US$2.4b[1]), Eli Lilly / Point Biopharma (US$1.4b), and Bristol Myers Squibb / Rayze Bio (US$4.1b) highlight the strong strategic interests in radiopharmaceutical assets.
- These acquisitions were completed while the target's lead programs were still in clinical trials, which is where Clarity is at today.
- **Extremely limited number of clinically advanced radiopharmaceutical companies remaining, which would provide big pharma with a platform entry point to radiopharmaceutical therapeutics.**
- The capital raising puts Clarity in a strong balance sheet position with respect to any inbound M&A activity.

Strong cash and funding position post capital raising

- A fully underwritten A$121m capital raising at A$2.55 per share representing a 10.5% discount to the closing price of Clarity's shares on 25 March 2024:
  - A$101m Placement to professional and sophisticated investors
  - A$20m Pro Rata Accelerated Non-Renounceable Entitlement Offer (ANREO) on a 1 for 33 basis to eligible shareholders
- Post completion of the capital raise, Clarity will have a pro forma cash balance of A$153.2m, which it expects will fully fund current clinical programs until early CY26.

[1] Including upfront cash portion and maximum potential contingent value payments

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

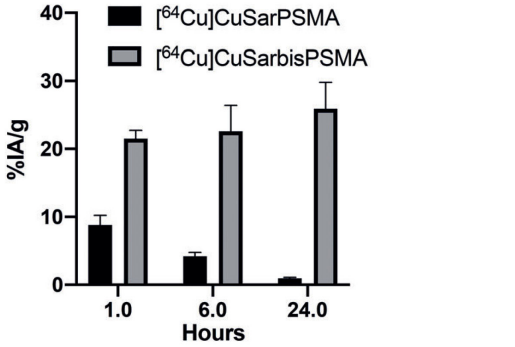
Clarity Pharmaceuticals is a clinical stage radiopharmaceutical company developing next-generation products to address the growing need for better diagnostics and treatments in oncology

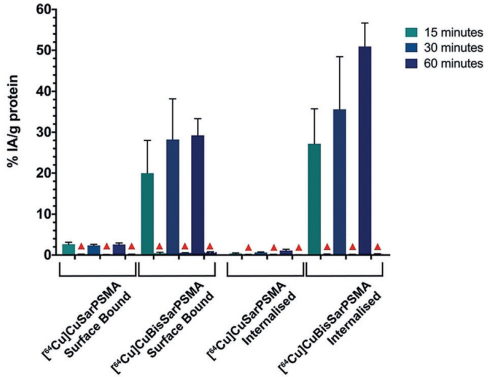
ASX code:	CU6
Share Price[1]	A$2.85
Cash at bank[2]	A$28.1M
Expected RDTI (May 2024)	A$10.1M
Shares on issue[3]	263.1M
Options on issue[3]	26.2M
Market cap (undiluted)[1]	A$749.9M

1. As at 25 March 2024
2. As at 20 March 2024
3. As at 22 March 2024

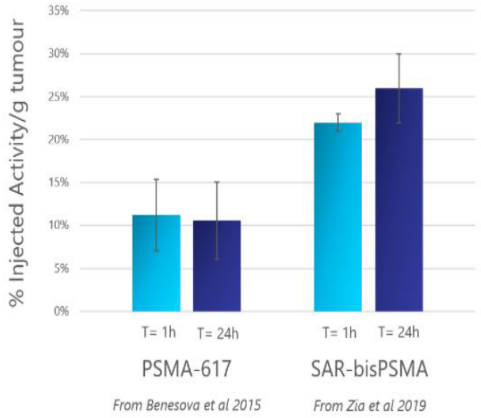
SAR-bisPSMA

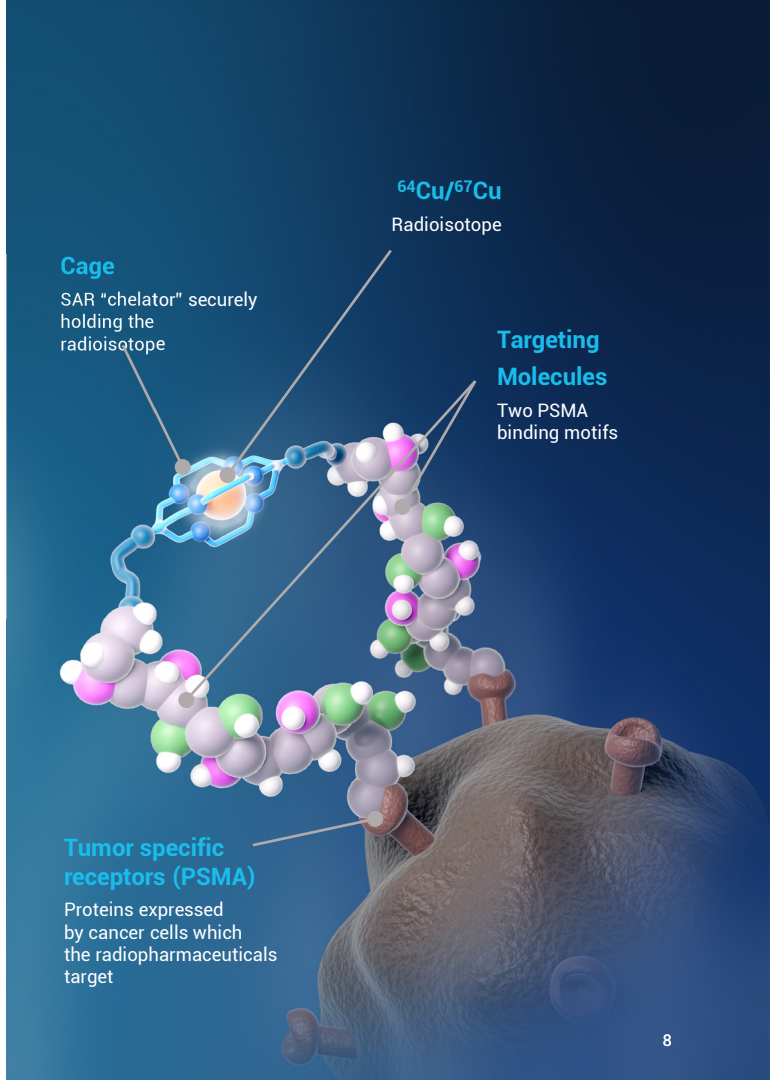
Superior performance of bisPSMA compared to monomer PSMA





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





Zia et al., 2019. Ang.Chem

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$1.1Bn in 2023

Lantheus: PYLARIFY® (^{18}F-DCFPyL) sales Q4 23: ~US$230M

Telix: Illuccix® (generic PSMA-11 kit) sales Q4 23: ~ US$95M

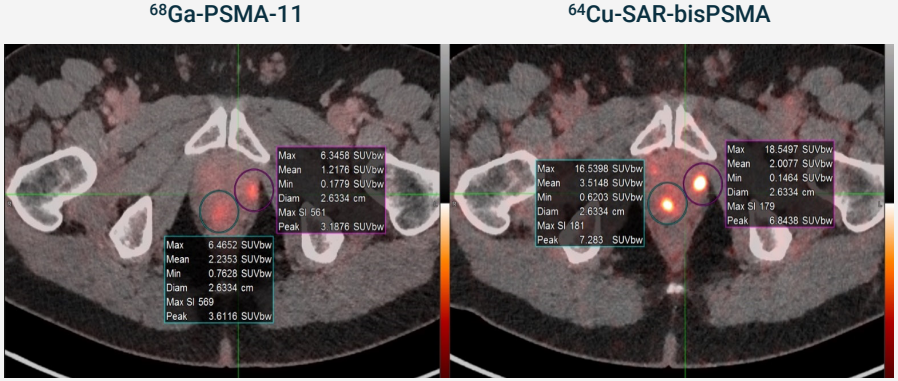
→

Specificity - High ✓

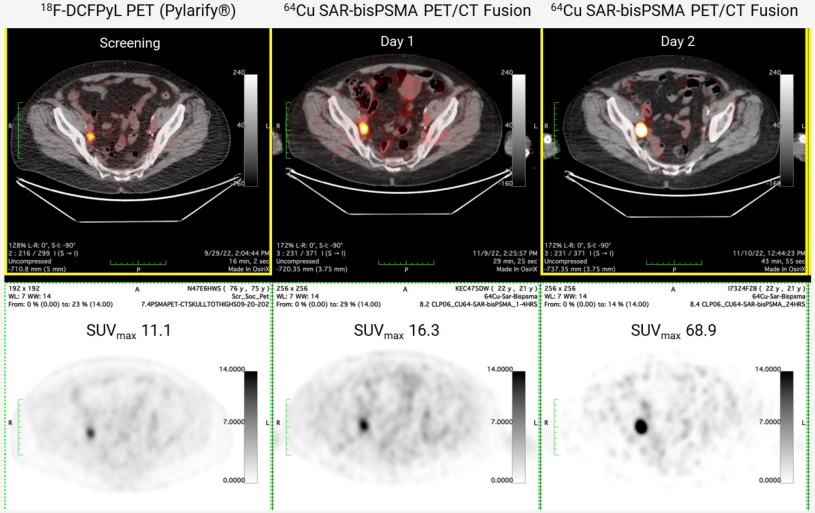
Sensitivity - Low ✗

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

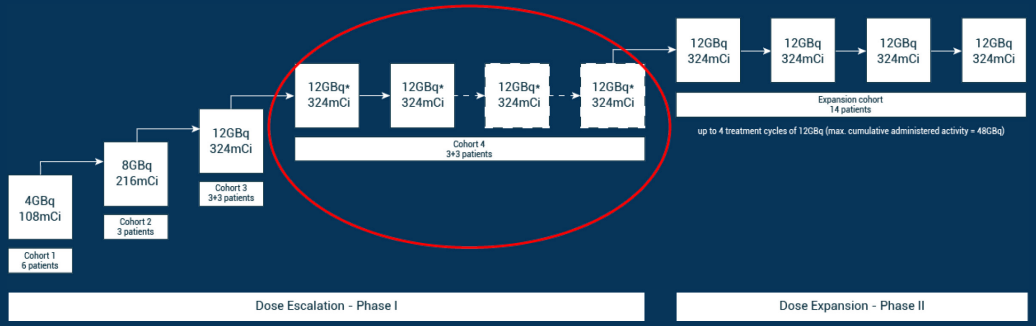


Comparison with PYLARIFY® – COBRA study



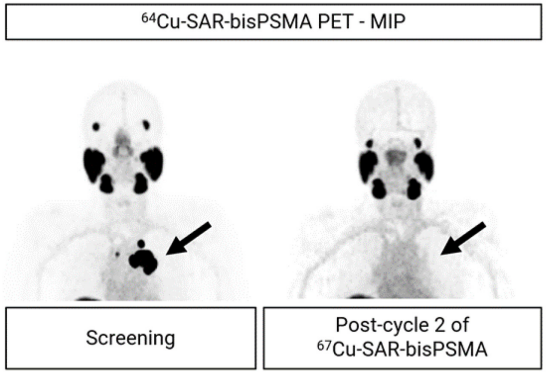
^{67}Cu-SAR-bisPSMA in mCRPC: Now in cohort 4 (SECuRE)

- No Dose Limiting Toxicities with single cycles at 12GBq
- Now in multi-dose (12GBq cycles) cohort 4, two doses with up to four doses agreed by Safety Review Committee
- In cohorts 2 and 3, almost 80% of patients showed PSA reduction >35% from a single therapy cycle and almost 1 in 2 showed a PSA reduction >80% at time of last data extract
- After cohort 4, the study moves into multi-dose cohort expansion
- Two therapy cycles given to a patient at 8GBq showed a drop in PSA to undetectable levels and a near complete response at the time of last assessment

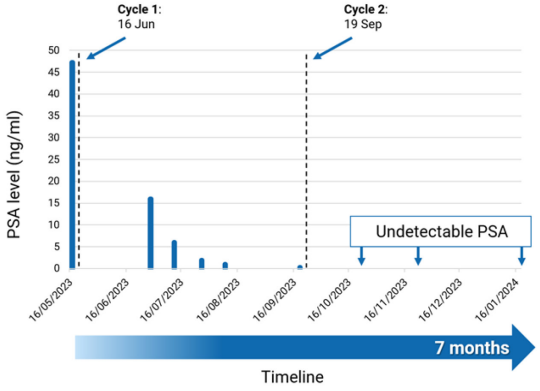


SECuRE

^{64}Cu-SAR-bisPSMA PET/CT imaging before and after two cycles of 8GBq of ^{67}Cu-SAR-bisPSMA



PSA reduction following 2 doses of ^{67}Cu-SAR-bisPSMA



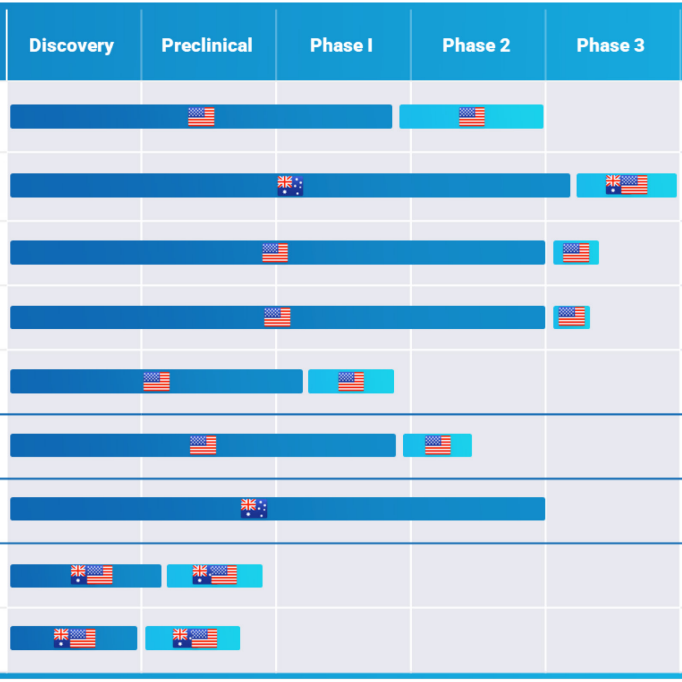
CLARITY PHARMACEUTICALS

Clinical development in multiple cancers

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

Clinical development pipeline as of 22 March 2024

Indication	Product	Application	Current Trial	Next Milestone
Prostate Cancer	SAR-bisPSMA	Theranostic mCRPC	SECURE	Phase II dose expansion open (2H 24)
	SAR-bisPSMA	Diagnostic in pre-radical prostatectomy	CLARIFY	CLARIFY Phase III 50% recruitment (2H 24)
	SAR-bisPSMA	Diagnostic in BCR PCa	COBRA	COBRA additional data (1H 24)
	SAR-BBN	Diagnostic in BCR PCa	SABRE	SABRE topline data (2H 24)
	SAR-BBN	Theranostic mCRPC	COMBAT	Cohort 2 open for recruitment (2H 24)
Neuroblastoma	SARTATE	Theranostic	CL04	Phase II dose expansion open (2H 24)
NETs	SARTATE	Diagnostic	DISCO	DISCO Phase II top line data (1H 25)
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 Investigational New Drug Applications

Strong Strategic Interest in Radiopharmaceutical Assets

Date	Target	Acquirer	Acquisition value[1]	Main asset
Mar 24	Fusion Pharmaceuticals	AstraZeneca plc (LON:AZN)	US$2.4bn[2] (A$3.6 bn)	^{225}Ac-PSMA I&T for mCRPC
Dec 23	RayzeBio, Inc.	Bristol-Myers Squibb Company (NYSE:BMY)	US$4.1bn (A$6.2 bn)	^{225}Ac-DOTATATE
Oct 23	POINT Biopharma Global Inc.	Eli Lilly (NYSE:LLY)	US$1.4bn (A$2.1 bn)	Early Phase FAP product & production Facility. *Main clinical assets already licensed to Lantheus in 2022*

Note: 1. All transactions were completed in USD, assumes AUD / USD exchange rate of $1.5184
2. Including upfront cash portion and maximum potential contingent value payments

"The willingness of large pharma companies to pay high premiums for radiopharmaceutical companies further demonstrates the burgeoning interest in the field"

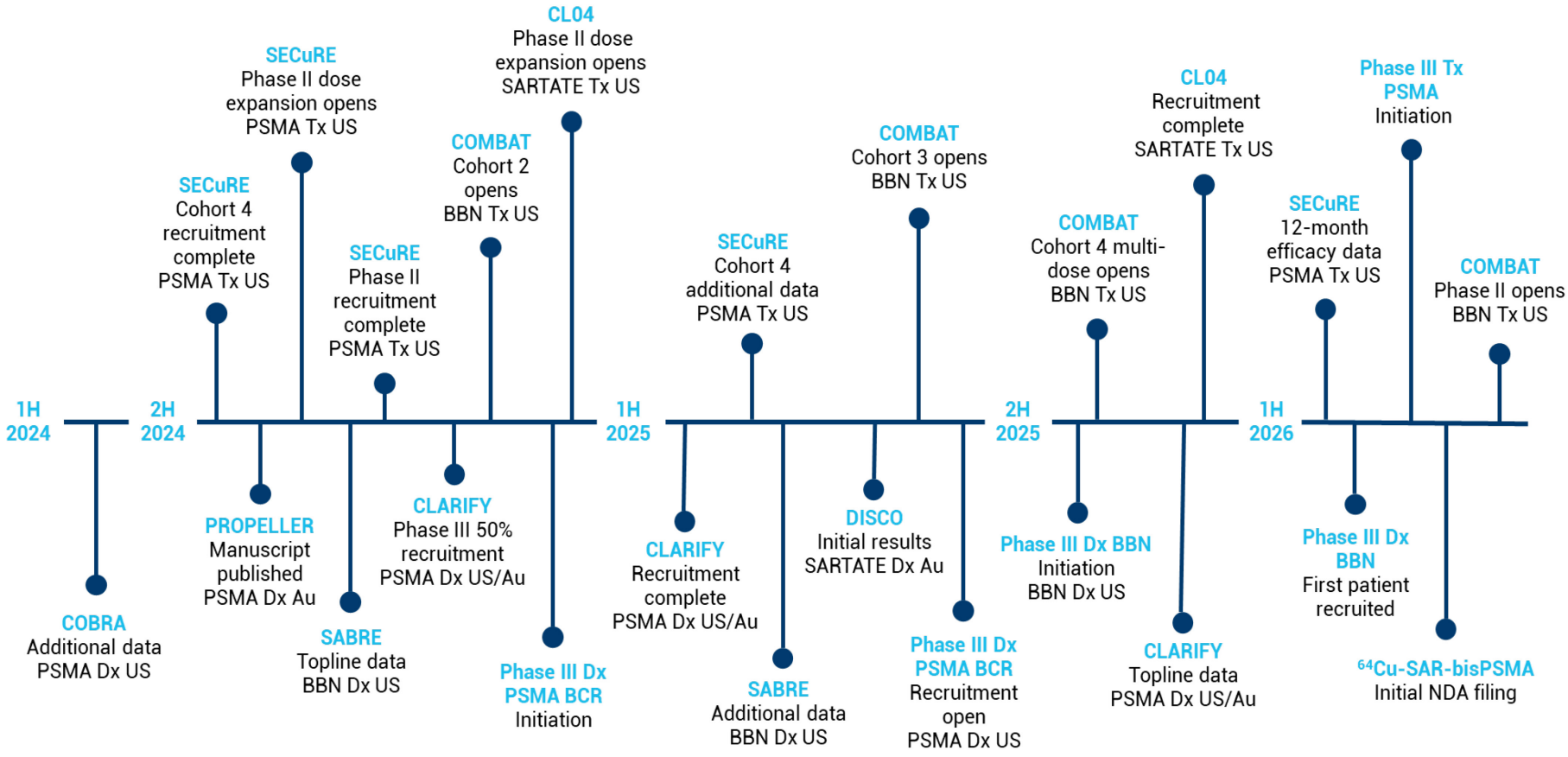
- Nature, March 2024

Clarity's copper platform, strong prostate pipeline and therapeutic and diagnostic efficacy data represents an attractive opportunity to grow a significant radiopharmaceutical franchise in oncology and other indications

- Three major deals in the global radiopharmaceuticals sector over the last 6 months highlights the strong strategic interest in radiopharmaceuticals
- Extremely limited number of clinically advanced radiopharmaceutical companies remaining globally which would provide pharmaceutical companies with a platform entry point to radiopharmaceutical therapeutics
- Clarity's TCT platform, potential best-in-class assets in large indications, strong IP position and significant supply chain advantages differentiates Clarity in the market
- Exciting efficacy and safety data in therapies and diagnostics has attracted interest from a range of pharmaceutical companies
- A strong Balance Sheet allows Clarity to fully exploit its platform, products and positioning to maximise shareholder value

Key upcoming milestones

Dx = Diagnostics
Tx = Theranostics



Offer Summary

Offer Summary

Clarity is conducting a fully underwritten capital raising of approximately A$121 million comprising an institutional private placement and a pro rata accelerated non-renounceable entitlement offer (together, the 'Offer')

Offer Structure	• A fully underwritten capital raising of approximately A$121 million which comprises: – a 1 for 33 pro-rata accelerated non-renounceable entitlement offer to eligible shareholders of Clarity to raise approximately A$20 million (**Entitlement Offer**), comprising an Institutional Entitlement Offer to raise approximately A$8 million and a Retail Entitlement Offer to raise approximately A$12 million; and – an institutional private placement (**Placement**) of approximately A$101 million • The Entitlement Offer is non-renounceable and entitlements will not be tradeable or otherwise transferable • Approximately 47.4 million new fully paid ordinary shares in Clarity (**New Shares**) to be issued under the Offer, representing approximately 18% of existing ordinary shares on issue in Clarity (**Shares**)
Offer Price	• The Offer will be conducted at a fixed price of A$2.55 per New Share (**Offer Price**) which represents: – a discount of 10.5% to the closing price of Clarity's shares on 25 March 2024 (which was A$2.85) – a discount of 12.5% to the 5-day VWAP of A$2.915 up to and including 25 March 2024 – a discount of 9.1% to the TERP (Theoretical Ex Rights Price)
Institutional Offer	• The institutional component of the Entitlement Offer and the Placement will be conducted on 26 March 2024 • Rights shares equivalent in number to those not taken up under the Institutional Entitlement Offer will be offered to certain eligible institutional investors under an institutional bookbuild process • The institutional component of the Entitlement Offer will be extended to certain existing eligible institutional shareholders in Australia, Hong Kong, Singapore and New Zealand
Retail Entitlement Offer	• The retail component of the Entitlement Offer (**Retail Entitlement Offer**) is expected to open on Thursday, 4 April 2024 and close at 5.00pm on Friday, 19 April 2024 • The Retail Entitlement Offer will not be extended to any retail shareholders outside Australia and New Zealand • Eligible retail shareholders that do not take up their entitlement by the close of the Retail Entitlement Offer (being shortfall shares), will be subscribed for by the Underwriter (defined below)
Record Date	• 7.00pm (Sydney, Australia time) on Thursday, 28 March 2024
Ranking	• New Shares issued under the Entitlement Offer and Placement will rank pari passu with existing Shares from their date of issue
Underwriter and Joint Lead Managers	• Bell Potter Securities Ltd is acting as sole underwriter (**Underwriter**) and Joint Lead Manager to the Offer and Wilsons Corporate Finance Ltd is Joint Lead Manager to the Offer

Sources and Uses of Funds

Sources of Funds	A$m
Estimated Cash Reserves at Offer Date	28.1
Offer	121.0
R&D Tax Incentive (FY23-FY25)	10.1
Total Sources	**159.2**

Uses of Funds	A$m
Pre-Clinical	8.5
Clinical	111.0
Regulatory	7.1
Patents	1.8
Commercial	10.2
Working Capital and Costs of the Offer	20.6
Total Uses	**159.2**

The funds raised under the Offer will be used to advance Clarity's clinical portfolio and strengthen its balance sheet

- Post completion of the Offer, Clarity will have a pro-forma cash balance of A$153.2m (net of costs of the Offer)
- Clarity expects it will be funded for its current clinical program through to early 2026

Offer Timetable

Announcement of underwritten offer	Tuesday, 26 March 2024
Placement & Institutional Entitlement Offer Opens	Tuesday, 26 March 2024
Announcement of results of Placement and Institutional Entitlement Offer and recommence trading of shares on ASX	Thursday, 28 March 2024
Record date for Retail Entitlement Offer (7.00pm Sydney, Australia time)	Thursday, 28 March 2024
Retail Entitlement Offer documentation despatched and Retail Entitlement Offer opening date	Thursday, 4 April 2024
Settlement of shares issued under the Placement and Institutional Entitlement Offer	Friday, 5 April 2024
Issue and quotation of shares issued under the Placement and Institutional Entitlement Offer	Monday, 8 April 2024
Retail Entitlement Offer close date (5.00pm Sydney, Australia time)	Friday, 19 April 2024
Announcement of results of Retail Entitlement Offer	Wednesday, 24 April 2024
Settlement of shares issued under the Retail Entitlement Offer	Friday, 26 April 2024
Issue of shares under the Retail Entitlement Offer	Monday, 29 April 2024
Quotation and normal trading of Retail Entitlement Offer shares	Tuesday, 30 April 2024

The timetable is indicative only and dates and times are subject to change without notice

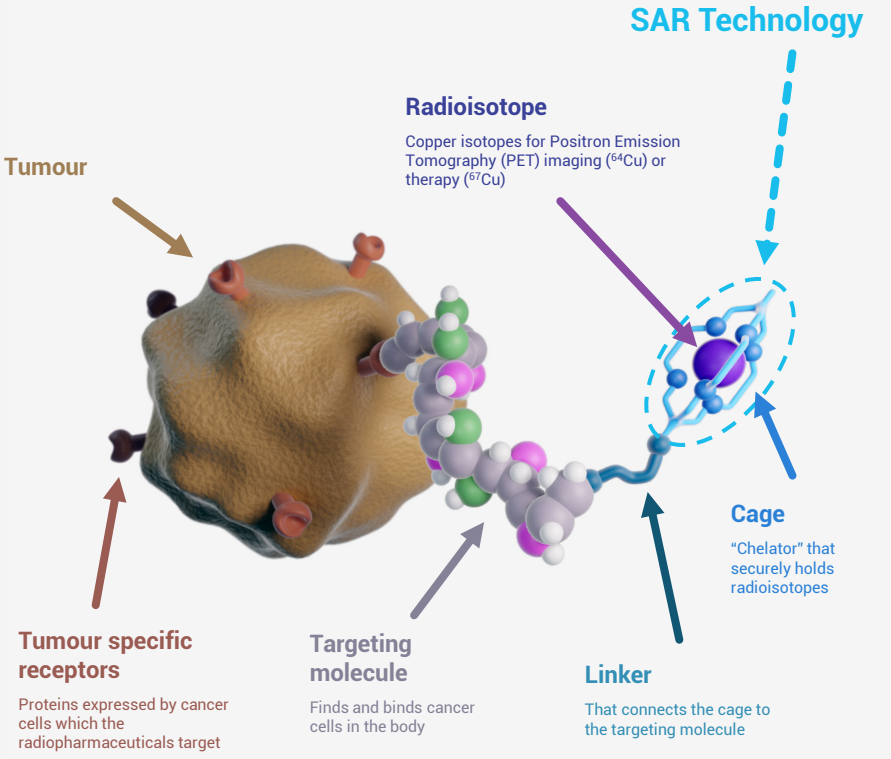
Company Overview

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

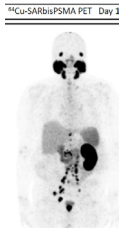


Why Copper?

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

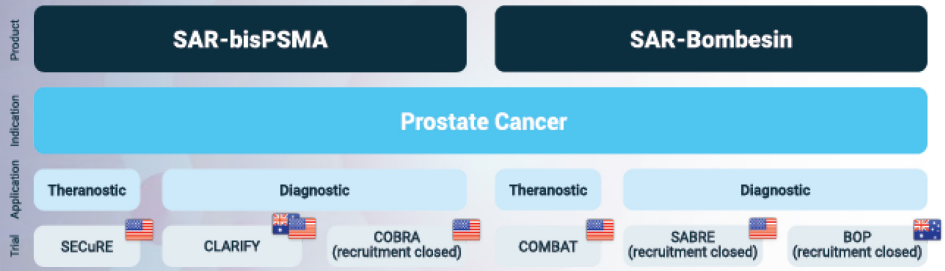
	Copper-67	Lutetium-177
Half life	2.6 days	6.7 days
Decay mode	Beta emitter	Beta emitter
Range in tissue	~0.7mm	~0.7 mm
Production mode	Electron accelerators	Nuclear reactors
Cost to scale supply	~US$15M	>US$1Bn
Time to scale supply	<18 months	~10 years

Three key product areas

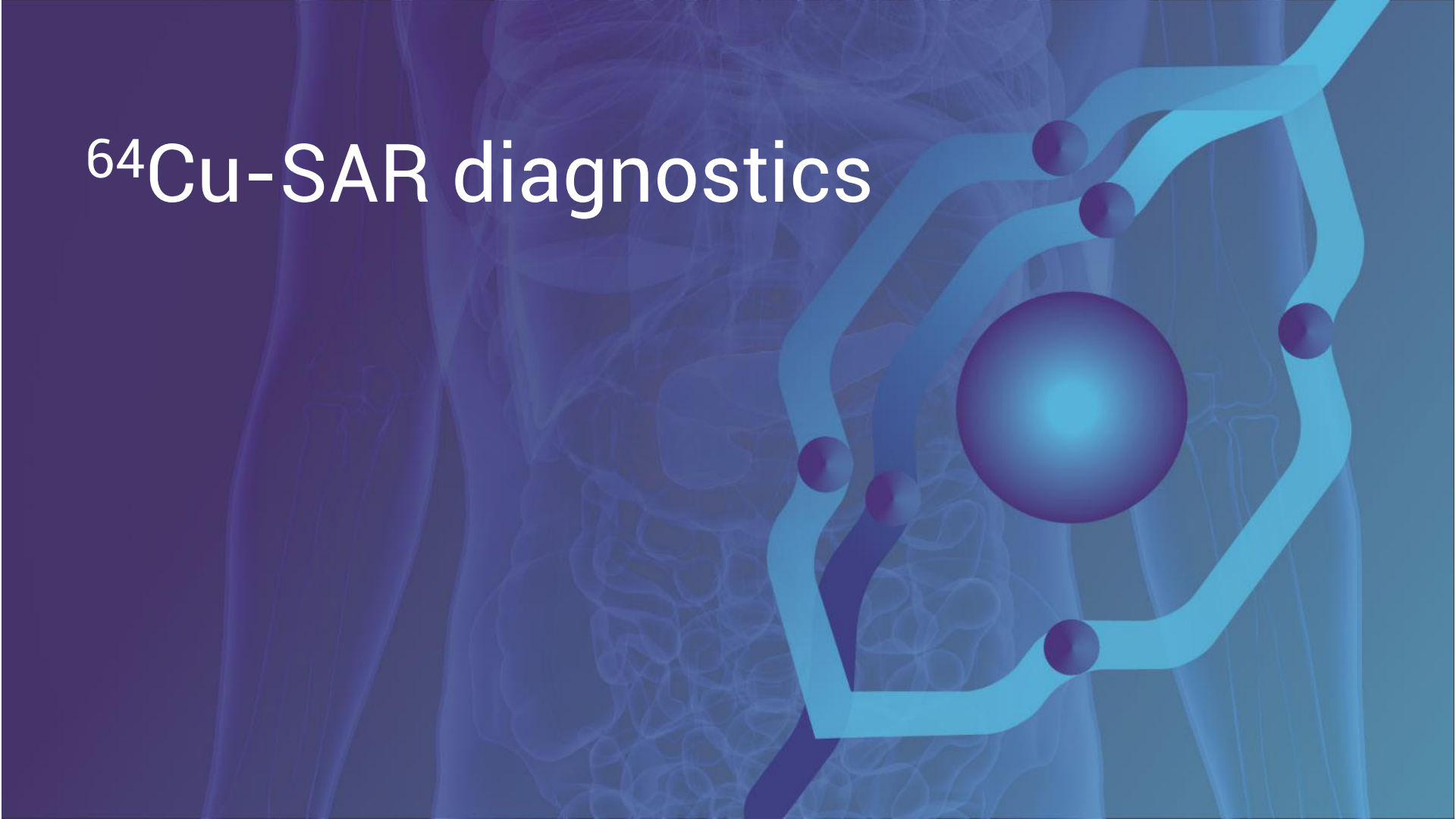
Prostate cancer

Two product areas: bisPSMA & Bombesin

Four products for diagnosis and therapy



^{64}Cu-SAR diagnostics

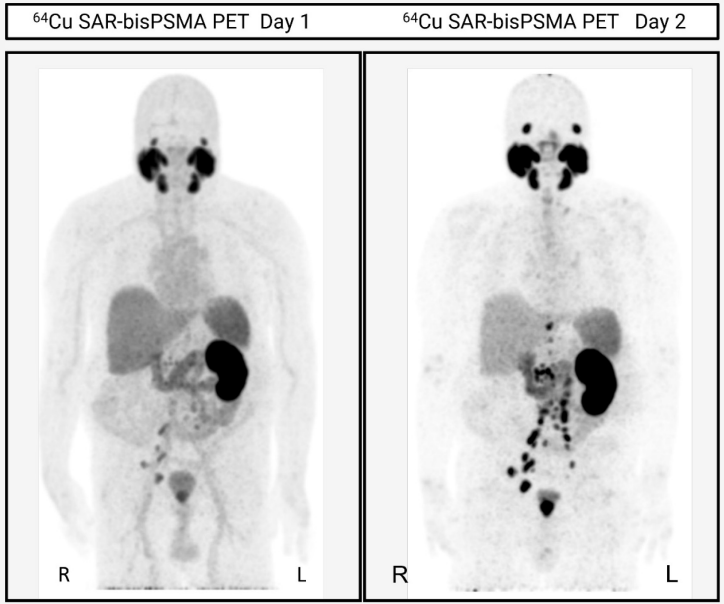


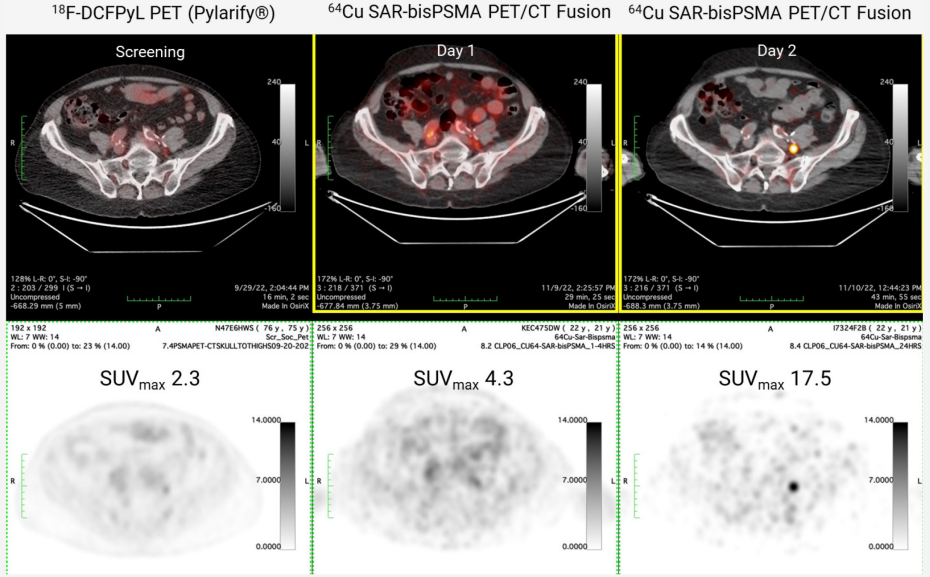
Copper brings significant additional advantages

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

Cu-64 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





SAR-Bombesin

SAR-Bombesin targets Gastrin Releasing Peptide receptor (GRPr) 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

SAR-Bombesin in prostate cancer

- 75%-100% of prostate cancers express GRPr
- ~25% 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 diagnostically and therapeutically in prostate cancer that is PSMA-negative or has a low expression of PSMA

SAR-Bombesin in PSMA-negative prostate cancer

SABRE

- **Phase II** Positron Emission Tomography (PET) imaging trial of participants with PSMA-negative biochemical recurrence (BCR) of prostate cancer following definitive therapy
- 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

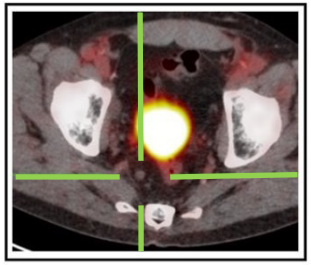
Status

- Recruitment complete

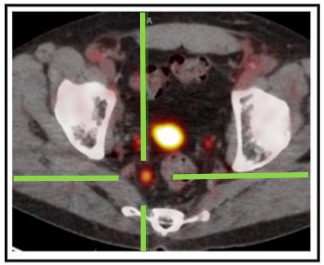
Next Milestone

- Topline data - 2H 2024

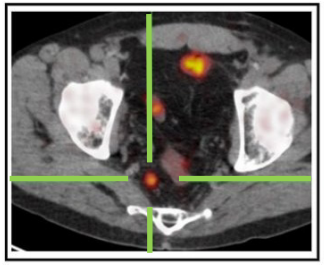
^{18}F-DCFPyl PET/CT (Pylarify®)



^{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.

SABRE ClinicalTrials.gov identifier: NCT05407311

CLARITY PHARMACEUTICALS

^{67}Cu-SAR therapeutics

Metastatic castration-resistant prostate cancer

Clarity is conducting two theranostic clinical trials in mCRPC with two products to treat PSMA-positive, PSMA-negative lesions and those with low PSMA expression

SAR-bisPSMA

SECuRE

- Phase I/IIa study of ^{64}Cu/^{67}Cu-SAR-bisPSMA for identification and treatment of PSMA-expressing mCRPC
- Theranostic multi-centre, single arm, dose escalation study with a cohort expansion planned for up to 44 patients
- 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 the dose expansion phase

Status

- Dosimetry phase with ^{64}Cu-SAR-bisPSMA in mCRPC completed
- Dose escalation phase underway
- Cohort 1 completed with no safety issues (4GBq single dose)
- Cohort 2 completed with no safety issues (8GBq single dose)
- Cohort 3 completed with no safety issues (12GBq single dose)
- Cohort 4 – first patient treated; all available slots allocated for the first 3 participants of cohort 4 (12GBq multi-dose)

Next milestone

- Cohort 4 completed - 2H 2024
- Dose expansion (Phase II) opens for recruitment - 2H 2024

SAR-Bombesin

COMBAT

- A Phase I/IIa theranostic study of ^{64}Cu-SAR-Bombesin and ^{67}Cu-SAR-Bombesin for identification and treatment of GRPR-expressing mCRPC in patients who are ineligible for therapy with ^{177}Lu-PSMA-617
- Theranostic, multi-centre, single arm, dose escalation/dose expansion study with a cohort expansion planned for up to 38 patients

Status

- First patient treated in cohort 1
- Recruitment ongoing

Next milestone

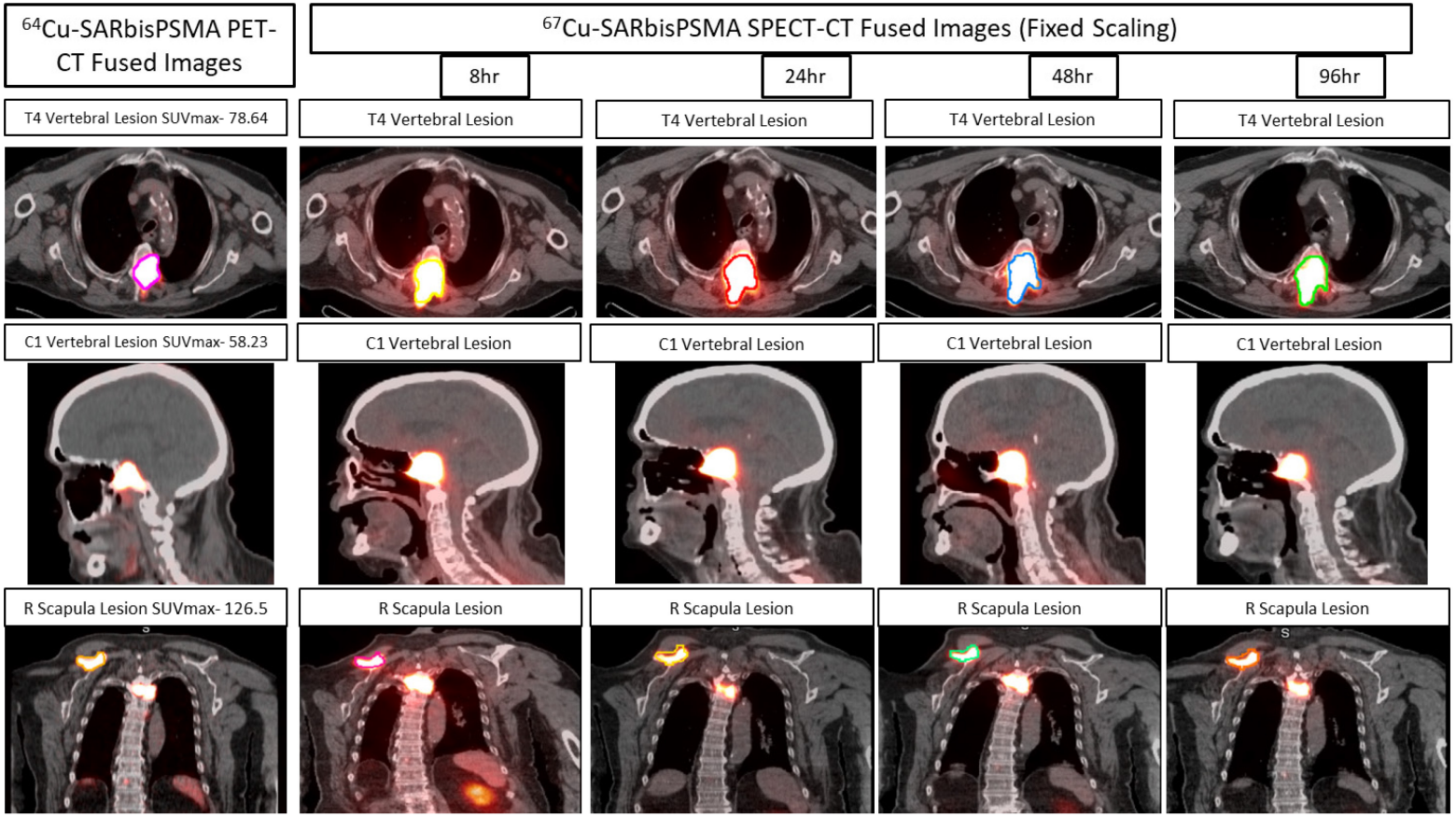
- Cohort 2 open for recruitment – 2H 2024

CLARITY PHARMACEUTICALS

SECuRE clinicaltrials.gov identifier: NCT04868604

COMBAT ClinicalTrials.gov identifier: NCT05633160

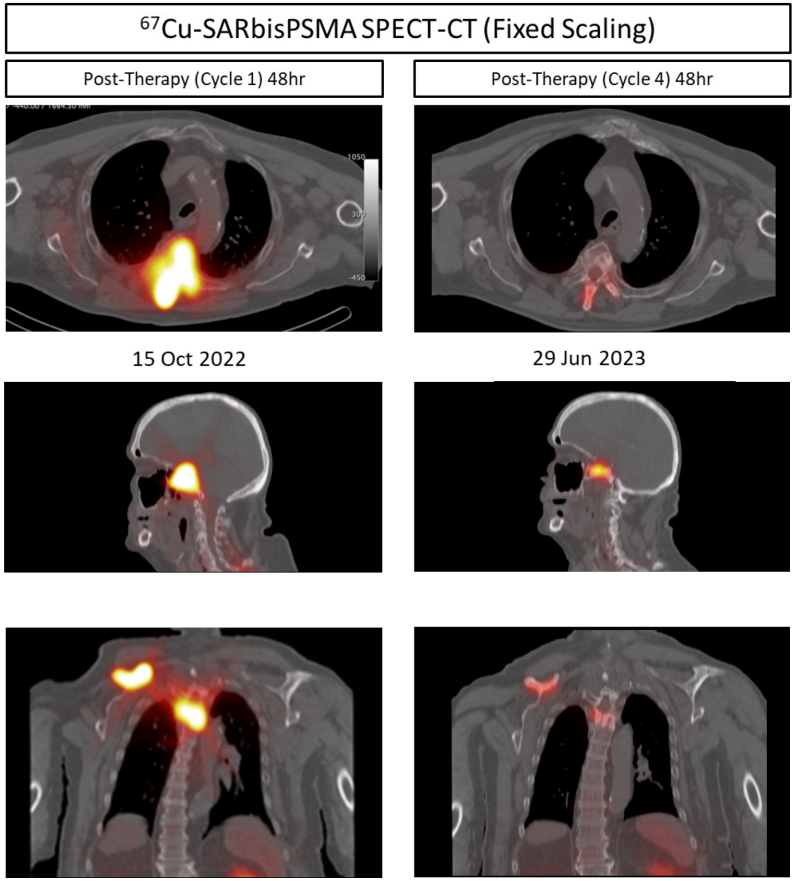
SECuRE cohort 1 - 4GBq dose level



US FDA Expanded Access Program

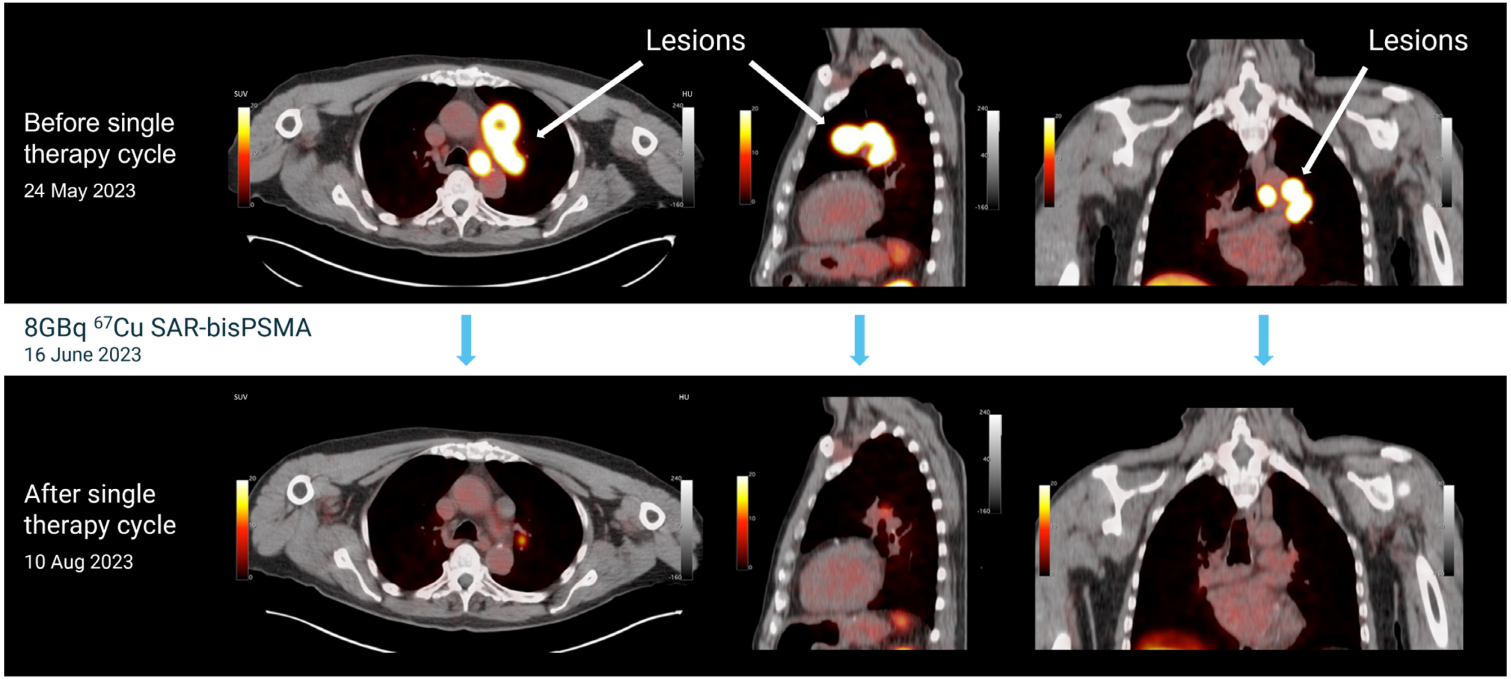
- Additional therapy cycles of ^{67}Cu-SAR-bisPSMA at the lowest 4GBq dose level have been requested under the US FDA Expanded Access Program (EAP)
- Early data indicates positive effects
- SPECT-CT images (on the right) demonstrate a reduction in the intensity of product uptake at the tumour sites after four doses, signaling tumour shrinkage
- Same patient experienced a reduction in PSA levels >50% following the first dose, and a >90% decline in PSA after dose 4

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



SECuRE cohort 2 - 8GBq dose level (single cycle)

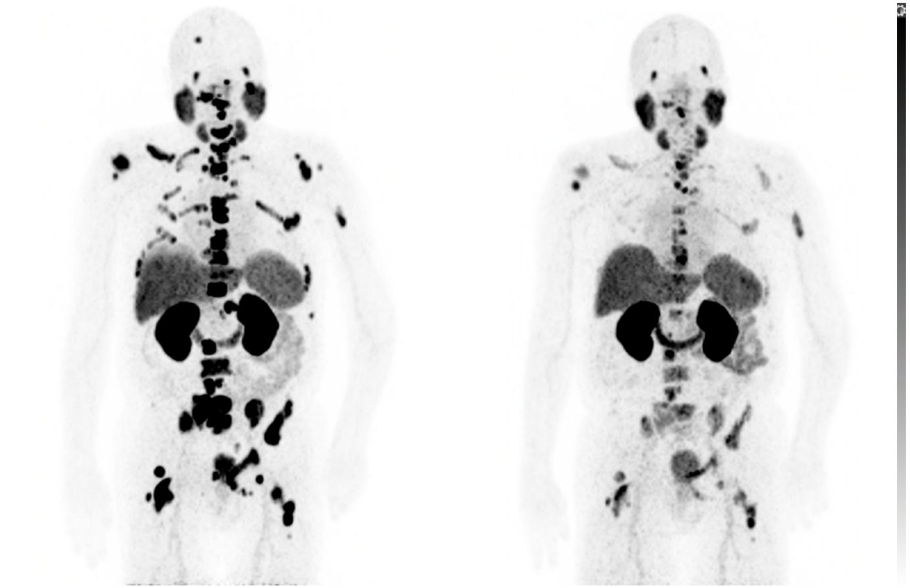
- No Dose Limiting Toxicities with single cycle at 8GBq
- The first 2 participants are exhibiting a PSA reduction of greater than 95% and the last participant is showing a drop of greater than 80%
- Significant reduction in uptake of the diagnostic dose after a single 8GBq therapy cycle



^{64}Cu-SAR-bisPSMA PET/CT imaging before and after a single cycle of 8GBq ^{67}Cu-SAR-bisPSMA (cohort 2)

SECuRE cohort 3 – 12GBq dose level (single dose)

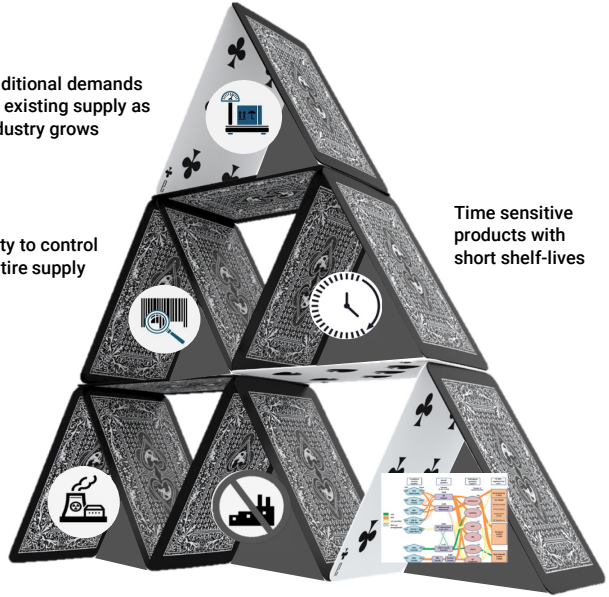
^{64}Cu-SAR-bisPSMA PET - MIP	
Pre-^{67}Cu-SAR-bisPSMA	Post-^{67}Cu-SAR-bisPSMA



- Participant from cohort 3 showing reduction in uptake of ^{64}Cu-SAR-bisPSMA in prostate cancer lesions. The participant was treated with ADT, ARPI, chemotherapy and 2 investigational agents prior to enrolling in the SECuRE study (PSA 270.9 ng/ml at study entry). The participant received a single dose of ^{67}Cu-SAR-bisPSMA (12GBq), which led to the reduction in uptake of ^{64}Cu-SAR-bisPSMA in the lesions.
- PSA reduction: 92.3%.
- Total body tumour reduction: SUVmax from 51.7 to 19.0 (63.2% reduction) and tumour volume from 1,040.9 to 635.4 ml (39.0% reduction).
- MIP: Maximum intensity projection.

The Supply Differentiator

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

SNMI 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

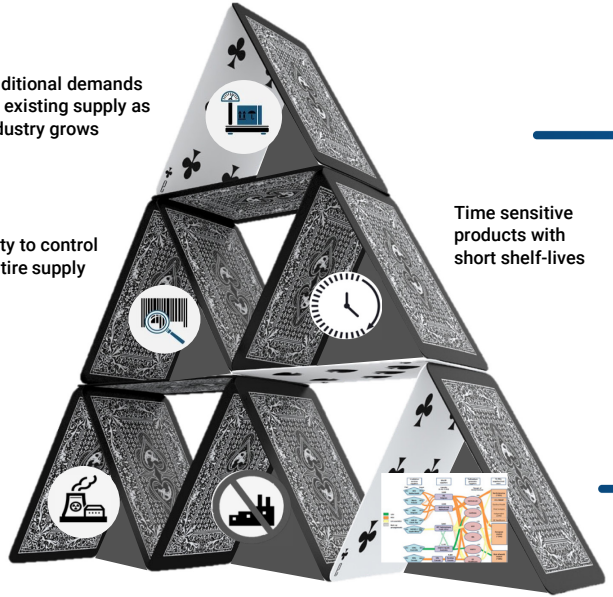
New strategies are needed to address access and availability of radiopharmaceuticals to enable timely and equitable patient access

"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

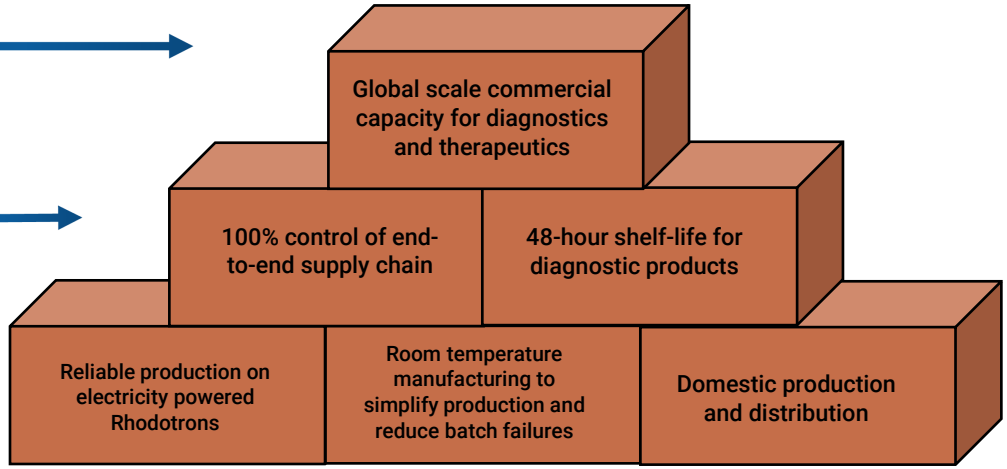
Time sensitive products with short shelf-lives

Reliance on ageing nuclear reactor fleet

Manufacturing outages

Complex international supply chains

Clarity's TCT Solution



MANUFACTURING

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

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

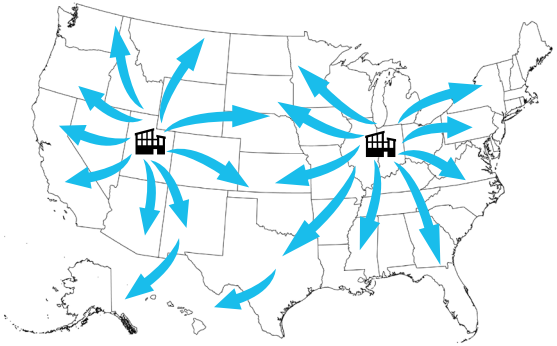
"We have patients on months long waiting lists when this may be all the time they have, and so it's been really disheartening to have to deal with these things"

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

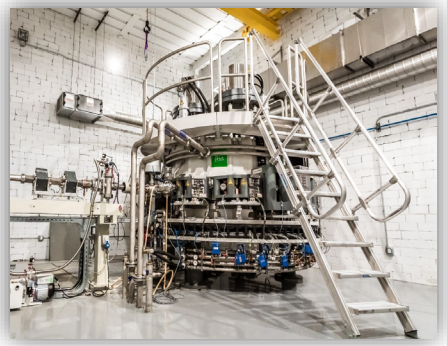
Next-generation theranostics provide solutions to the challenges with current-generation radiopharmaceuticals

Opportunities with ^{64}Cu (half-life = 12.7h)

- Can be mass produced on cyclotrons with solid targetry
- Every US zip code covered from 1 location
- Patient flexibility with product shelf life of up to 48 hours
- Operational flexibility with imaging timepoints up to 72 hours
- 9-22 times lower exposure than commonly used ^{18}F products
- Ability to centralise investments and supply the United States
- Delivered as a ready-to-use cGMP product



Opportunities with Rhodotron produced ^{67}Cu



- Commercially available high powered rhodotron with a small footprint (10' diameter and 11' tall)
- 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**

Access to reactors will soon become the bottleneck for ^{177}Lu[1]

1. *https://jnm.snmjournals.org/content/jnumed/early/2023/08/17/jnumed.123.265907.full.pdf*

Summary

Global leader in Targeted Copper Theranostics (TCTs)

- **Exciting efficacy and safety data to date with therapy and imaging**
- **Extensive pipeline** of TCTs based on ^{64}Cu for diagnosis and ^{67}Cu for therapy
- Multiple therapeutic and diagnostic trials in progress, including a **Phase III registrational trial**
- TCTs address the current **manufacturing and logistical** limitations in the growth of radiopharmaceuticals
- TCTs are **scalable, sustainable and dependable**
- **Broad and defensible IP portfolio** of patent families across the SAR Technology platform, pipeline and products
- Pipeline includes large and orphan indications, with **focus on the US for first approvals**
- Led by **an experienced management team and Board** with significant years of active involvement in the radiopharmaceutical industry
- **Highly active M&A sector** with numerous recent acquisitions

Risk Factors & Foreign Selling Restrictions

Risk Factors

Speculative nature of investment	The Company does not generate revenue and does not have a product that is capable of generating revenue without completing clinical trials and obtaining regulatory approvals. The Shares carry no guarantee of profitability, dividend payments, returns of capital or an increase in the share price. As a result, an investment in the Company should be considered speculative, and potential investors should consult their professional advisers before deciding whether to apply for Shares. The Company will need to successfully develop and commercialise products in order to generate revenue and to become, and then remain, profitable. In particular, the Company will need to successfully complete clinical trials for the Company's products and obtain all relevant regulatory approvals from regulatory bodies in the United States, together with other relevant jurisdictions such as Europe, for those product candidates and for the manufacturing, marketing and sale of the Company's products in those jurisdictions. As at the date of this Presentation, there is no guarantee that the Company will succeed in these activities. Should the Company be successful in these activities, there is still a risk that the Company may never generate enough revenue to achieve profitability or declare any dividends.
Success of clinical trials is not guaranteed	The Company's ability to generate revenue and become, and remain, profitable will largely depend on whether the Company's clinical trials are successful and whether the Company is able to demonstrate, through these clinical trials, that the Company's products are suitable for commercialisation. The Company seeks to minimise its clinical trial risk by using targeted diagnostic products as part of its clinical trial process to select patients who are likely to respond to treatment with its therapeutic products. However, the success of the Company's clinical trials and the development of the Company's products, and therefore the Company's ability to generate revenue, is not guaranteed. The development of radiopharmaceutical products is typically comprised of three different phases of drug development, with each individual phase carrying a risk of failure. In particular, the Company's products are at risk of failing safety and efficacy steps throughout each individual development phase. In addition, the commencement and completion of clinical trials may be delayed due to various factors, such as unanticipated safety issues, issues relating to the correct dosage of the Company's product, lack of effectiveness during clinical trials, delays in patient recruitment, the inability to effectively monitor patients during or after treatment, the failure of medical investigators to follow clinical protocols, reliance on clinical research organisations and the termination of license agreements that are required in order to complete the clinical trials. If the Company's clinical trials fail or experience material delays, it is likely that shareholder returns will be materially adversely affected.

Risk Factors

The Company may not obtain the required regulatory approvals	The Company will need to obtain ongoing approvals from the United States Food and Drug Administration (FDA) in the United States, the Therapeutic Goods Administration in Australia and the European Medicines Agency in Europe in order to run its studies and clinical trials in those jurisdictions. The Company will also need new approvals from these regulators in order to further develop and to market its products in each of the United States, Australia and Europe, respectively. In addition, the Company will require approvals from equivalent regulatory authorities in other countries should the Company wish to conduct clinical trials or commercialise its products in those jurisdictions. The Company has five open Investigational New Drug (IND) applications covering all six current clinical stage products that received clearance to proceed to clinical trials from the FDA and has received approvals from the FDA for two Orphan Drug Designations (ODD) and two Rare Paediatric Disease Designations (RPDD). There is no guarantee that the Company will continue to receive the regulatory approvals that are necessary for the Company to run studies and clinical trials or to commercialise its products (including the INDs, OODs and RPDDs referred to above) in any jurisdiction. Whether the Company successfully obtains these regulatory approvals is, ultimately, outside of the Company's control and dependent on the decisions of the regulatory bodies in each relevant jurisdiction. If the Company does not receive the regulatory approvals that are required, the Company will not be able to commercialise its products or generate revenue in the relevant jurisdictions, which may have a material adverse impact on shareholder returns. In addition, the Company may experience delays in the application process for its regulatory approvals. The regulatory bodies in each jurisdiction have extensive discretion in their approval processes, and may request additional information from the Company, or further testing and trials, prior to considering the Company's regulatory application or granting the Company regulatory approval. If the Company experiences any delays in obtaining the necessary regulatory approvals, this may in turn delay the Company's ability to commercialise its products and generate revenue. This risk has the potential to materially and adversely impact the Company's planned future revenue, margins and profitability and reduce the value of an investment in the Shares.
Competitive industry	Clarity is operating in the pharmaceutical industry with a focus on the global oncology and radiopharmaceutical markets, which are competitive and subject to rapid and significant technological change. The Board considers that the Company has, as at the date of this Presentation, a competitive advantage in these markets for its products due to the versatility of the SAR Technology platform that enables the Company to focus on developing new products and intellectual property for new indications of cancer through its Discovery Program. However, these circumstances may change over time as there is always a risk of new entrants to the market, and the risk that an existing radiopharmaceutical company or another company within the oncology market may disrupt the Company's business operations and anticipated market share. The Company cannot predict the timing and scale of new competitors that may emerge. In particular, the rise of the oncology and radiopharmaceutical industries may lead to a number of large corporations acquiring significant market share, either through expanding their product development or acquiring smaller companies that are in the development phase. As a result, many of the Company's current and potential competitors may obtain access to greater capital resources, research and development facilities, regulatory and operational experience, manufacturing and marketing experience and production facilities. There is a risk that the Company's competitors will succeed in developing alternative products that are safer, more effective or commercially superior to those being developed by the Company. If the Company is unable to compete effectively or expand its business, the Company's products could be rendered obsolete or otherwise uncompetitive, which may materially and adversely impact the Company's planned future revenue, margins and profitability and reduce the value of an investment in the Shares.

Risk Factors

Clarity requires protection and maintenance of its intellectual property

The Company currently has title to a number of key patents and patent applications in respect of the technology that forms the basis of a number of its product candidates. The success of the Company is therefore partly dependent on the Company's ability to continue to obtain and maintain commercially beneficial patents and to protect the intellectual property that it owns. The risks that the Company faces with respect to the patents and patent applications that it owns, and any future patents/patent applications that may be acquired or licensed, include but are not limited to the following:

- although the Company holds a portfolio of patents that have been granted, including those that cover composition of matter for the SAR Technology and key products, patent applications that have been lodged and are yet to be granted and patent applications that may be lodged by the Company in the future may not result in granted patents;
- the Company may experience delays in obtaining the grant of future patents;
- any request by the Company to obtain an extension to the term of a patent may not be granted or, if it is granted, the patent may be granted on the condition that revisions to the patent are imposed;
- the patents that are granted to the Company may not necessarily protect the Company's commercial activities;
- the patents that the Company owns or licences may be challenged at any time;
- other entities may independently develop similar, duplicate or alternative technologies to those of the Company;
- other entities may design workarounds to the Company's technology;
- other entities may own intellectual property that is relevant to the Company's technology or activities; and
- the value of the Company's intellectual property rights may diminish if a patent is not granted with respect to any patent application. Additionally, any information that is contained in the patent application will be publicly available information and as a result will not be subject to any confidentiality restrictions.

The degree of protection that the Company may have with respect to its intellectual property rights is uncertain and subject to the risks detailed above as well as other potential unanticipated risks. In addition, the Company's intellectual property rights may be subject to change as laws and regulations relating to the scope and validity of patents continues to evolve.

If the Company is required to engage in legal proceedings with respect to its intellectual property – either to defend legal actions or claims against its intellectual property, or to assert an intellectual property right – the Company may incur extensive costs and may further experience delays in the development or commercialisation of its product candidates. Additionally, if a third party is successful in making a claim against the Company, the Company may be liable to pay damages or be required to refrain from using certain patents or other intellectual property.

There is also a risk that third parties may already be in possession of intellectual property that is relevant to the Company's business, which may prevent the Company from being able to successfully reach its goals and objectives. For example, the Company may be developing a product that is in the process of being registered by another third party. Alternatively, the Company may seek to license or acquire (i) intellectual property from a third party, (ii) design workarounds to third party intellectual property rights, or (iii) challenge a third-party with respect to their intellectual property rights either through the courts or at an administrative stage if required. There is no guarantee that the Company will be able to obtain, or use, intellectual property that it acquires through any of these means. In addition, the Company cannot guarantee that its employees, third parties or consultants will not breach confidentiality, or infringe or otherwise exploit the Company's intellectual property, which could cause the Company to suffer a material loss.

These risks may materially and adversely impact the Company's planned future revenue, margins and profitability and reduce the value of an investment in the Shares.

Risk Factors

Reliance on key suppliers including for the supply of ^{64}Cu and ^{67}Cu	The Company does not have its own facilities from which to manufacture its products and it therefore relies on third parties for the supply of the critical materials that are necessary for the manufacture of its product candidates. These third parties include suppliers of radioisotopes, consumable and vial suppliers, and suppliers of certain precursor elements of radiopharmaceuticals. If these third parties are no longer able to provide such materials or services to the Company, the Company may be required to seek alternative suppliers which may cause delays to its clinical trial programs. Copper-64 (^{64}Cu) and copper-67 (^{67}Cu) are critical materials necessary for the manufacture of the Company's product candidates. The Company's existing supply of ^{64}Cu and ^{67}Cu are sufficient for the Company's current clinical trials program and early commercialisation. The Company is working with its existing suppliers and expanding its network of to further develop supplies of ^{64}Cu and ^{67}Cu for additional commercial demand. However, if the Company does not receive a sufficient supply of ^{64}Cu and ^{67}Cu on an ongoing basis, this could have an adverse impact on its ability to commercialise its products and therefore its ability to earn revenue. The Company will continue to be reliant upon third parties for the supply of ^{64}Cu and ^{67}Cu. Reliance on external supply of isotopes is, however, common in the radiopharmaceutical market.

Risk Factors

Reliance on contract development and manufacturing organisations and logistics partners

The Company relies on third parties to produce and manufacture its product candidates. Manufacturing radiopharmaceutical product candidates is a complex process, and contract development and manufacturing organisations (**CDMO's**) are typically in high demand. The Company's product candidates need to be produced at a high quality and on a consistent basis in accordance with a specific manufacturing process. Both the manufacture and delivery processes for the Company's product candidates, including the use of radioactive materials, must be completed in compliance with regulations applicable to local and international markets.

As the Company relies on the CDMO's and logistics partners to manufacture and deliver its product candidates, the Company does not have control over issues that may arise during these processes, including potential difficulties with raw materials, equipment malfunctions and failures by personnel within the CDMO's or logistics partners to follow the appropriate protocols and procedures. For example, if certain materials required in the manufacturing process are stored incorrectly and suffer contamination or insufficient refrigeration, this could materially impact operations and delay the Company's clinical trials and product development.

Minor deviations in any part of the manufacturing process including sourcing materials, filing, labelling, packaging, storage, delivery and quality control testing may result in failures or manufacturing shut-downs, delays in product batch releases, product recalls, spoilage or regulatory action. If the CDMO's or logistics partners that the Company uses engage in or suffer such deviations, this may result in the need for the Company to revise its manufacturing processes, change suppliers or alter its delivery processes, which could potentially result in increased costs and the loss of efficiencies for the Company due to an unexpected allocation of resources and time. If such issues remain unresolved, there is a risk that the Company's clinical trials may be delayed, which could result in adverse consequences for the Company and shareholders, including causing significant delays to the Company's development program.

As radiopharmaceutical products have a short half-life (being typically less than a week) due to radioactive decay, it is critical that the Company has effective manufacturing and delivery processes in order to achieve commercial success. These logistical preparations are costly and time-consuming to establish, and any failure in these processes could negatively impact the Company's operations.

Risk Factors

Lack of acceptance of radiopharmaceuticals by the medical community	If there are any adverse results in the clinical trials of the Company's product candidates or in the clinical trials of the Company's competitors that are developing similar products, or any negative publicity with respect to the safety or efficacy of radiopharmaceutical products and treatments, this could result in the Company's products not being accepted or used by the medical community or the general public. This may have a material adverse effect on the Company's business and financial position.
Development program may be delayed	There may be delays in achieving critical milestones set out by the Company. These include completing clinical trials, obtaining regulatory or reimbursement approvals, establishing commercial manufacturing and commencing product launch and sales. If the Company experiences any material delays, this may have a material adverse effect on the Company's business and financial position.
Risk associated with the use of radiopharmaceuticals	The Company deals with radiopharmaceutical products that use radioactive materials, which generate medical and other regulated wastes. There are a number of risks associated with the use, possession and disposal of these materials and waste products, including physical injury and accidental environmental contamination. The storage, design and manufacturing processes for these radioactive materials may not entirely eliminate the risk of employees of the Company and others being exposed to radiation and radioactive materials. There is a risk that, at times, the Company may need to alter its storage and manufacturing processes in order to remain in compliance with radio-protection laws in the jurisdictions in which the Company operates. The Company is unable to completely eliminate all risk of accidental contamination or injury from these materials and waste products. Consequently, the Company is at risk of being held liable for any damages or losses that are suffered as a result of an accidental contamination or the injury to an employee or other person, and these damages could fall outside, or exceed the limits of, the Company's current insurance coverage. If this was to occur, it may adversely impact the Company's financial position, business operations and reputation.
Reliance on key personnel	The Company is heavily reliant on the capabilities of its key management personnel who have extensive experience in, and knowledge of, the Company's technology, its business and the market in which it operates. In particular, the loss of one or more of each of the executive directors, being Alan Taylor and Colin Biggin, or any other key executives or management, and any delay in sourcing their replacement, may adversely impact the ability of the Company to implement and expand its business and achieve its growth strategies. There is no guarantee that the Company will be able to retain its key management personnel or, in the event their employment is terminated, be able to replace them in a timely manner with qualified individuals who have the necessary skills and expertise. This could have a material adverse impact on the Company's business, operating or financial performance. In addition to the Company's key management personnel, the Company is also reliant on attracting and retaining qualified scientific and technical personnel who are experts in the radiopharmaceutical field. If the Company fails to attract or retain these key employees or contractors, the Company's business, including its research and development programs, could be adversely affected, which may in turn impact the Company's future product success and financial prospects. Additionally, as there is significant demand in the oncology and radiopharmaceutical market for expert qualified scientific and technical personnel, there is a likelihood that the Company's labour costs will increase in order to continue to attract and retain these personnel.

Risk Factors

Product liability	Due to the innovative nature of the Company's products, the Company is exposed to the risk of product liability claims arising from defective products or products that are no longer viable, even where the Company has received prior regulatory approval. If the Company is subject to any product liability claims, this could result in the removal of regulatory approvals that the Company may have obtained. In addition, the Company may also incur unanticipated costs as a result of product liability claims, which may exceed or not be covered by the Company's insurance coverage.
Supply chain	Factors outside the control of the Company, for example COVID-19 or other similar events, may have a material adverse impact on the Company's supply chain. Restrictions on the manufacturing of ^{64}Cu and ^{67}Cu may restrict the ability of the Company to conduct clinical trials and other operations that are key to its business model such as research. This may materially impact the ability of the Company to meet its proposed development timetable and adversely impact the price of the Shares.
Liquidity risk	There is no guarantee that an active market in the Shares will continue, or that the market price of the Shares will increase. If a market is not sustained, it may be difficult for investors to sell their Shares. Furthermore, the market price for Shares may fall or be made more volatile because of a relatively low volume of trading. When trading volume is low, significant price movements can be caused by trading a relatively small number of Shares. If illiquidity arises, there is a risk that shareholders will be unable to realise their investment in the Company when they wish to do so.
Risk of shareholder dilution	In the future, the Company may elect to conduct further fundraisings through the issue of Shares, including for the purposes of raising proceeds for further research, clinical trials and/or acquisitions that the Company may decide to make. While the Company will be subject to the constraints of the ASX Listing Rules regarding the amount of capital it can issue within a 12 month period without obtaining shareholder approval, shareholders may be diluted as a result of such issues of Shares and may also experience a loss in value of their Shares. The Company also currently has 26.2 million Options on issue as at the date of this Presentation, representing approximately 10.0% of the undiluted share capital of the Company as at the date of this Presentation and will represent approximately 8.4% of the undiluted share capital of the Company as at completion of the Capital Raising. If all of these Options are exercised, then shareholders' interests may be significantly diluted. The Company may also in the future issue additional Options to eligible participants either under the Company's Equity Incentive Plan or otherwise to third parties such as consultants, advisers or strategic partners. If additional Options are issued and they are subsequently exercised by the relevant option holders, shareholders' interests may be significantly diluted and they may also experience a loss in value of their Shares.
The Company may need to raise future additional capital	As at the date of this Presentation, the Directors of the Company are of the view that the Company's current cash reserves plus the net proceeds from the Capital Raising will be sufficient to fund the Company's stated business objectives until early 2026. However, there can be no guarantee that this will be the case, particularly if the Company incurs or experiences unforeseen costs or delays. The Company may therefore need to raise additional capital in the future through debt or equity financings or other methods such as co-development arrangements or strategic alliances. If the Company does not succeed in eventually generating adequate revenue in order to fund its operations or is unable to obtain or raise capital from other sources on commercially acceptable terms, the Company's financial position and its business may be materially adversely affected.

Risk Factors

Exchange rate risk	The Company's functional currency is the Australian dollar. A considerable proportion of the Company's costs are incurred in foreign currencies, especially the US dollar. The Australian dollar value of foreign currency denominated costs will be affected by changes in currency exchange rates. The Company is likely to continue to engage in various transactions in foreign currencies (including, but not limited to, the supply of radioisotopes and clinical trial services to the Company, which currently are paid for by the Company in US dollars) and will therefore potentially be exposed to exchange rate fluctuations, to the extent such exposure is unhedged. This exchange rate exposure may have an adverse effect on the costs incurred by the Company and consequently the Company's overall financial position.
Epidemics and pandemics	In addition to force majeure events, the rapid spread of infectious disease to a large number of people within a short period of time may occur within or outside the countries in which the Company operates. In particular, a pandemic similar in nature to the 2002-03 outbreak of Severe Acute Respiratory Syndrome (SARS), the 2009 swine flu outbreak or COVID-19 outbreak may adversely affect general economic sentiment, the global economy, stock markets and other financial markets. Such events may also impact and delay the Company's ability to undertake clinical trials and cause issues with supplier delivery times. The impact of such delays could negatively impact the Company. The Company is unable to predict the impact that similar events may have on its business, operations and financial results in the future because of the numerous uncertainties created by the unprecedented nature of such events.
Cyber security incident risk	We collect and store sensitive business and other information, including intellectual property and trade secrets, on our networks. Our business operations are dependent upon the secure maintenance of this information. Despite our efforts to secure this information, there can be no assurance that cyberattacks and other threats from malicious persons and groups will not cause harm to or disrupt our business and operations. As a result, cyber security and the continued development and enhancement of our controls, processes and practices designed to protect our information systems from attack, damage or unauthorized access remain a priority for us. We may be required to expend additional resources to protect against cyber threats. A cyber-attack may result in a material adverse effect on our financial position and results of operations and harm our business reputation.
Price of shares	The price at which the Shares may be quoted on the ASX may regularly increase or decrease due to a number of factors. These factors may cause the Shares to trade at prices below the Offer Price. There can be no guarantee that the price of the Shares will increase, or not decrease. Some of the factors which may affect the price of the Shares include: • the results of clinical trials conducted by the Company; • the position taken by regulators in relation to the Company's applications for approval of its technology; • fluctuations in the domestic and international market for listed stocks; • general economic and geopolitical conditions, including interest rates, inflation rates, exchange rates, commodity and oil prices and wars; • changes to government fiscal, monetary or regulatory policies, legislation or regulation; • inclusion in or removal from market indices; • pandemic risk (including, for example, COVID-19); • the nature of the markets in which the Company operates; or • general operational and business risks.

Risk Factors

Taxation	The acquisition and disposal of Shares will have tax consequences, which will differ depending on the individual financial affairs of each investor. All potential investors in the Company are urged to obtain independent legal, financial and taxation advice about the consequences of acquiring Shares from a taxation point of view and also generally. To the maximum extent permitted by law, the Company, its officers and each of their respective advisers accept no liability and responsibility with respect to the taxation consequences of applying for Shares under the Offer. Further changes in tax law, or changes in the way taxation laws are interpreted, may impact the tax liabilities of the Company or the tax treatment of an investor's investment. In particular, both the level and basis of taxation may change. In addition, from time to time, the Australian Taxation Office may review the tax treatment of transactions entered into by the Company. Any actual or alleged failure to comply with, or a change in the application or interpretation of, tax rules that apply to the Company in respect of such transactions could increase its tax liabilities or expose it to legal, regulatory or other actions.
Expected future events may not occur	Certain statements in this Presentation constitute forward-looking statements, opinions and estimates. Such forward-looking statements, opinions and estimates rely on various contingencies and assumptions and involve known and unknown risks, uncertainties and other factors which may cause actual results, performance and achievements to be materially different from any future results, events, performance or achievements expressed or implied in such forward-looking statements, opinions and estimates. The actual performance of the Company or the radiopharmaceuticals or oncology markets may not be as expected and this may have a material adverse impact on the value of the Shares. Given these uncertainties, prospective investors should not place undue reliance on any forward-looking statement. In addition, under no circumstances should forward-looking statements be regarded as a representation or warranty by the Company or any other person referred to in this Presentation that a particular outcome or future event is guaranteed.
No guarantee in respect of investment	The above list of risk factors should not be viewed as an exhaustive list of the risks faced by the Company or investors in the Company. The above risk factors, as well as other risk factors not specifically referred to above or not yet contemplated by the Company, may affect the financial performance of the Company and the value of the Shares offered under the Offer. Accordingly, given the above risks and the fact that the Company is a clinical stage company and is not currently generating revenue, an investment in the Company should be regarded as speculative and neither the Company nor any of its Directors or any other party associated with the preparation of this Presentation guarantees that any specific objectives of the Company will be achieved or that any particular value of the Company or of the Shares, including those Shares that are the subject of the Offer, will be achieved. Furthermore, there is no guarantee that the Shares will remain continuously quoted on the ASX, which could materially impact the ability of shareholders to sell their Shares. Investors should consult their professional advisers (including stockbroker, lawyer, tax adviser, financial adviser or other independent financial adviser) before deciding whether to apply for Shares.

Foreign Selling Restrictions

This Presentation does not constitute an offer of New Shares in Clarity in any jurisdiction in which it would be unlawful. In particular, this Presentation may not be distributed to any person, and the New Shares may not be offered or sold, in any country outside Australia except to the extent permitted below.

Hong Kong

WARNING: This Presentation has not been, and will not be, registered as a prospectus under the *Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong*, nor has it been authorised by the Securities and Futures Commission in Hong Kong pursuant to the *Securities and Futures Ordinance (Cap. 571) of the Laws of Hong Kong* (the **SFO**). Accordingly, this Presentation may not be distributed, and the New Shares may not be offered or sold, in Hong Kong other than to "professional investors" (as defined in the SFO and any rules made under that ordinance).

No advertisement, invitation or document relating to the New Shares has been or will be issued, or has been or will be in the possession of any person for the purpose of issue, in Hong Kong or elsewhere that is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to New Shares that are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors. No person allotted New Shares may sell, or offer to sell, such securities in circumstances that amount to an offer to the public in Hong Kong within six months following the date of issue of such securities.

The contents of this Presentation have not been reviewed by any Hong Kong regulatory authority. You are advised to exercise caution in relation to the Offer. If you are in doubt about any contents of this document, you should obtain independent professional advice.

Singapore

This Presentation and any other materials relating to the New Shares have not been, and will not be, lodged or registered as a prospectus in Singapore with the Monetary Authority of Singapore. Accordingly, this Presentation and any other document or materials in connection with the offer or sale, or invitation for subscription or purchase, of New Shares, may not be issued, circulated or distributed, nor may the New Shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore except pursuant to and in accordance with exemptions in Subdivision (4) Division 1, Part 13 of the *Securities and Futures Act 2001 of Singapore* (the **SFA**) or another exemption under the SFA.

This Presentation has been given to you on the basis that you are an "institutional investor" or an "accredited investor" (as such terms are defined in the SFA). If you are not such an investor, please return this document immediately. You may not forward or circulate this Presentation to any other person in Singapore.

Any offer is not made to you with a view to the New Shares being subsequently offered for sale to any other party in Singapore. On-sale restrictions in Singapore may be applicable to investors who acquire New Shares. As such, investors are advised to acquaint themselves with the SFA provisions relating to resale restrictions in Singapore and comply accordingly.

New Zealand

This Presentation has not been registered, filed with or approved by any New Zealand regulatory authority under the *Financial Markets Conduct Act 2013 (NZ)* (**FMCA**).

The New Shares under the Entitlement Offer are not being offered to the public within New Zealand other than to existing shareholders of Clarity with registered addresses in New Zealand to whom the offer of the New Shares is being made in reliance on the *Financial Markets Conduct (Incidental Offers) Exemption Notice 2021 (NZ)*.

The New Shares under the Placement are not being offered or sold in New Zealand (or allotted with a view to being offered for sale in New Zealand) other than to a person who:

- is an investment business within the meaning of clause 37 of Schedule 1 of the FMCA;
- meets the investment activity criteria specified in clause 38 of Schedule 1 of the FMCA;
- is large within the meaning of clause 39 of Schedule 1 of the FMCA;
- is a government agency within the meaning of clause 40 of Schedule 1 of the FMCA; or
- is an eligible investor within the meaning of clause 41 of Schedule 1 of the FMCA.