CLARITY
PHARMACEUTICALS

# INTERIM REPORT

**and Half-Year Financial Statements**

SYDNEY, AUSTRALIA
28 FEBRUARY 2022

# Key Financials

- Cash balance at 25 February 2022 - 97.5 million
- Net operating cash outflows of $8.7 million for the period, up from $4 million in the prior corresponding period (pcp), reflecting increased investment in research & development (R&D) and clinical trial costs.
- Loss for the period of $13.7 million up from $4.9 million in the pcp. Increased loss driven by higher operation spend together with a $6.8 million Share Based Payments expense relating to options granted to China Grand (please refer Corporate Update below for further information)
- Successfully completed the largest biotechnology Initial Public Offering (IPO) on the Australian Securities Exchange (ASX), raising $92 million
- Received the FY21 R&D tax incentive cash refund of $3.3 million in February 2022

# Operational Highlights

- Actively recruiting patients across four clinical trials
- Two clinical trials for the optimised PSMA agent, SAR-bisPSMA, in prostate cancer, which commenced in July 2021, are progressing well:
  - Completed the dosimetry phase in the US-based SECuRE trial for the treatment of prostate cancer in November 2021
  - Achieved 50% recruitment milestone in the Australia-based PROPELLER trial for the imaging of prostate cancer in December 2021
- A third prostate cancer trial with $^{64}$Cu-SAR-bisPSMA COBRA trial received a Study May Proceed confirmation from the US Food and Drug Administration (FDA) in February 2022 with plans to commence recruitment of patients with biochemical recurrence of prostate cancer in the second quarter of 2022
- Early completion of the C-BOBCAT diagnostic trial with $^{64}$Cu SAR-Bombesin in October 2021 with plans to commence US-based clinical trials of this product during 2022
- Completed cohort 1 in the neuroblastoma therapy trial with $^{67}$Cu SARTATE™ in the US, advancing to the next dose level with the first patient in cohort 2 successfully treated in February 2022
- Execution of US radiopharmaceutical manufacturing agreements with Evergreen Theragnostics, Inc in September 2021 and with Cardinal Health in December 2021
- Reinforced the IP position around the optimised PSMA targeting agent, SAR-bisPSMA, with the patent application covering formulations of SAR-bisPSMA entering the national phase in a number of jurisdictions, including the USA, Europe and China
- Filed six provisional patents, while moving other patent applications ahead through the various stages of the patenting process

**Clarity Pharmaceuticals** (ASX: CU6) ("Clarity" or the "Group"), an Australian-based clinical stage radiopharmaceutical company developing next-generation products to address the growing need for the use of radiopharmaceuticals in oncology, is pleased to release its interim report and financial results for the half-year ended 31 December 2021.

**Executive Chairman Alan Taylor said:** "During the reporting period Clarity reached focal milestones across all key areas of our business, including corporate, clinical, operations and regulatory functions. The unforeseen challenges imposed by the global pandemic did not stop Clarity from exceeding the goals we set for ourselves as we completed the largest biotechnology Initial Public Offering (IPO) on the Australian Securities Exchange (ASX), raising $92 million, while also significantly progressing clinical development of our pipeline of Targeted Copper Theranostics (TCT)."

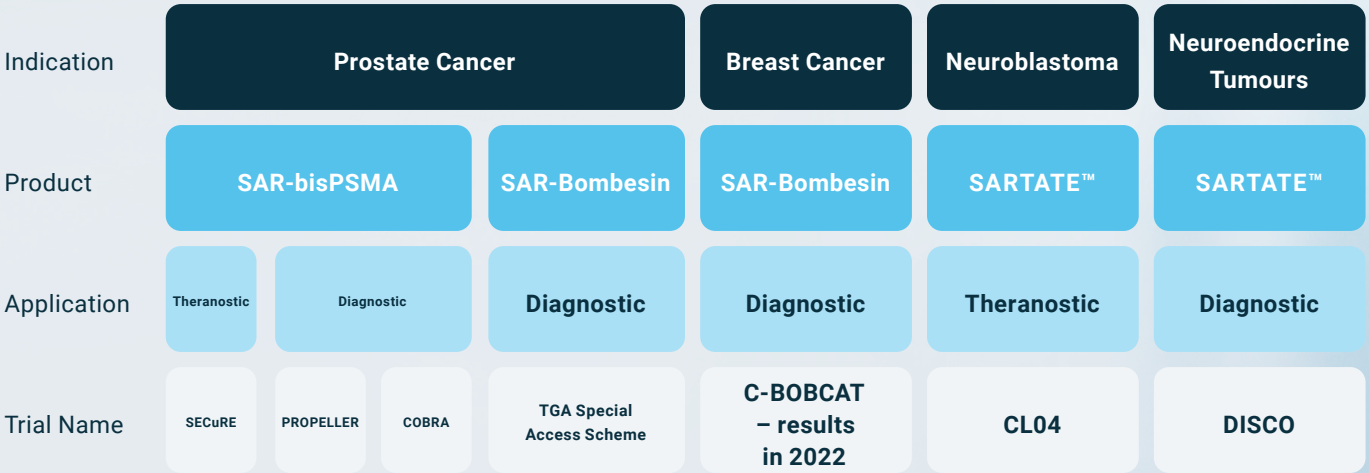
Since 1 July 2021, Clarity launched three new clinical trials in prostate cancer (two diagnostic and one theranostic trial), closed a diagnostic trial of SAR-Bombesin following the exciting preliminary results, and progressed the theranostic neuroblastoma trial to cohort 2 at the increased dose level.

Clarity has significantly expanded its manufacturing and logistical footprint in order to allow for seamless clinical growth as well as future commercialisation of its products, ensuring the Group fully leverages clinical, manufacturing and logistical benefits of the TCT platform.

The Group also progressed its preclinical and discovery programs and continued to bolster its IP portfolio to support the comprehensive platform of TCT. Clarity continued to attract exceptional talent, growing its team and Board of Directors to achieve a unique mix of expertise that enables the development of next-generation radiopharmaceuticals.

**Dr Taylor said:** "We are very excited to continue the pace we picked up in 2021 to further grow our company, delivering exciting milestones in 2022 and building towards commercialisation of our TCT products, in pursuit of our ultimate goal of developing better treatments for children and adults with cancer."

Clarity's pipeline includes the following indications of cancer, products and clinical trials to date:



# CLINICAL DEVELOPMENT

Clarity continues to generate strong results in the clinical development of the products in the TCT platform. With the earlier completion of the C-BOBCAT trial with $^{64}$Cu SAR-Bombesin in October, the G now actively recruiting in four clinical trials. Additionally, the US-based $^{64}$Cu SAR-bisPSMA COBRA trial is currently in the start-up phase with recruitment anticipated to commence in the second quarter of 2022 and a US-based $^{64}$Cu SAR-Bombesin trial is also scheduled to commence during 2022.

| Indication | Product | | Discovery | Preclinical | Phase 1 | Phase 2 | Phase 3 | Next Milestone |
|---|---|---|---|---|---|---|---|---|
| Prostate Cancer | SAR-bisPSMA | Theranostic mCRPC | | | | | | First therapy treatment |
| | SAR-bisPSMA | Diagnostic in pre-radical prostatectomy | | | | | | Recruitment complete |
| | SAR-bisPSMA | Diagnostic in BCR PCa | | | | | | 1st patient treated in COBRA |
| | SAR-BBN | Diagnostic in BCR PCa | | | | | | Open IND for $^{64}$Cu SAR-BBN |
| | SAR-BBN | Theranostic | | | | | | Open IND for $^{67}$Cu-SAR-BBN |
| Neuroblastoma | SARTATE™ | Theranostic | | | | | | Cohort 2 completed |
| | SARTATE™ | Diagnostic | | | | | | Open IND for NB Dx |
| NETs | SARTATE™ | Diagnostic | | | | | | 50% recruitment in DISCO |
| Pan cancer (GRPr positive tumours) | SAR-BBN | Diagnostic | | | | | | 1st patient in GRPr +ve tumour |
| SAR Discovery Platform | Undisclosed | Undisclosed | | | | | | |
| | Undisclosed | Undisclosed | | | | | | |

Current Progress | 12 Months Progress

All US studies are conducted under IND

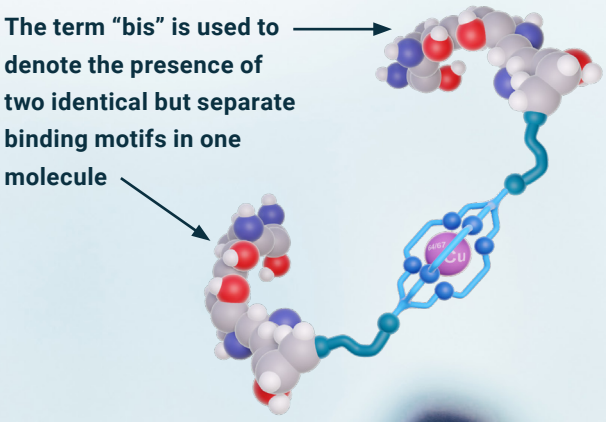
As of 28 February 2022

Note clinical development pipeline is indicative only and is subject to review

# SAR-bisPSMA – Prostate Cancer

SAR-bisPSMA is a next generation, highly targeted theranostic radiopharmaceutical, being developed for diagnosing, staging and subsequently treating cancers that express Prostate Specific Membrane Antigen (PSMA).

SAR-bisPSMA derives its name from the word “bis”, which reflects the novel approach of connecting two PSMA binding motifs to Clarity’s SAR chelator technology to increase tumour uptake and retention in cancerous tissues. Preliminary clinical data from the PROPELLER trial is aligning with preclinical data where product uptake appears to be higher for $^{64}$Cu SAR-bisPSMA than that of the first-generation PSMA agents that use a single PSMA binding motif. The PET imaging data acquired in the SECuRE trial to date also looks very promising with high tumour targeting and retention.



# $^{67}$Cu SAR-bisPSMA therapy program

Clarity continues to progress its prostate cancer therapy program at key sites in the US.

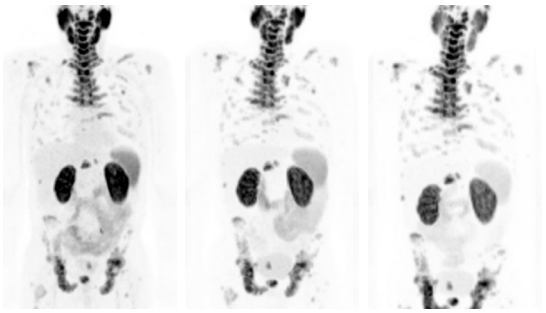
In November 2021, Clarity announced the completion of recruitment for the dosimetry phase of the US-based $^{64/67}$Cu SAR-bisPSMA SECuRE trial (NCT04868604)[1] and shared preliminary results. The Safety Review Committee assessed the data from the dosimetry phase and recommended commencing the dose escalation phase of the trial. Clarity looks forward to progressing the study following some updates to the protocol in the second quarter of 2022.

The SECuRE trial is a Phase I/IIa theranostic trial for identification and treatment of PSMA-expressing metastatic castrate-resistant prostate cancer (mCRPC) using TCT. $^{64}$Cu SAR-bisPSMA is used to visualise PSMA expressing lesions and select candidates for subsequent $^{67}$Cu SAR-bisPSMA therapy. The initial dosimetry phase utilised $^{64}$Cu SAR-bisPSMA to determine biodistribution and dosimetry of the products in humans. The SECuRE trial is a multi-centre, single arm, dose escalation study with a cohort expansion planned for up to 44 patients in the US. The aim of this trial is to determine the safety and efficacy of $^{67}$Cu SAR-bisPSMA as a therapy.

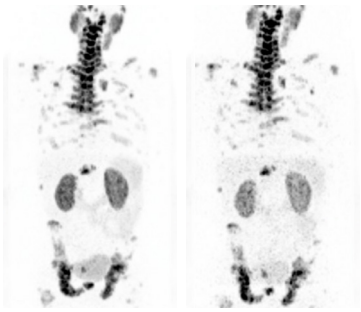
The PET imaging data acquired in the SECuRE trial to date looks very promising with high tumour targeting and retention. The comparison to the standard of care bone scan (the recommended modality for bone imaging in clinical trials according to the Prostate Cancer Clinical Trials Working Group 3), indicates that $^{64}$Cu SAR-bisPSMA is an exciting target for the diagnosis of prostate cancer. This further supports the emerging evidence of increased sensitivity and specificity of PSMA PET tracers for detecting micrometastatic disease compared to conventional imaging. With the recently updated US National Comprehensive Cancer Network Guidelines® now allowing FDA-approved PSMA PET agents to be used as an alternative to conventional imaging, Clarity is looking forward to progressing this product quickly through clinical trials.

SECuRE

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

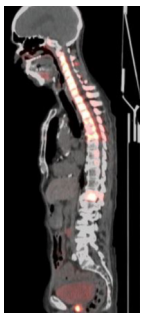


1 Hour Post Injection | 12 Hours Post Injection | 24 Hours Post Injection



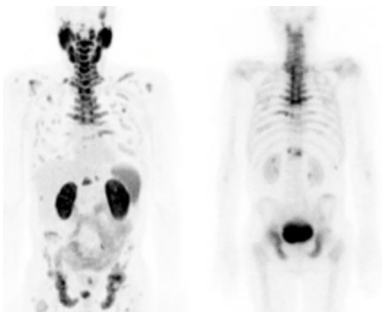
48 Hours Post Injection | 72 Hours Post Injection

**$^{64}$Cu SAR-bisPSMA PET/CT**



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

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



1 hour $^{64}$Cu SAR-bisPSMA PET | $^{99m}$Tc-MDP WB Bone Scan

# $^{64}$Cu SAR-bisPSMA diagnostic program

Clarity has two active clinical programs with its SAR-bisPSMA product as a prostate cancer diagnostic agent.

The PROPELLER study is in participants with newly confirmed prostate cancer, while the COBRA study is in participants with suspected biochemical recurrence (BCR) of prostate cancer. Clarity has previously received advice from the US FDA that its prostate diagnostic clinical program with $^{64}$Cu SAR-bisPSMA is addressing the two relevant patient populations for registration: pre-prostatectomy/pre-definitive treatment as well as patients with suspected biochemical recurrence.

# PROPELLER trial with $^{64}$Cu SAR-bisPSMA

In December 2021, Clarity announced a 50% recruitment milestone in its PROPELLER trial (NCT04839367)[2], with 15 of 30 participants recruited.

The PROPELLER trial is a Phase I Positron Emission Tomography (PET) imaging trial of participants with confirmed prostate cancer using $^{64}$Cu SAR-bisPSMA. It is a multi-centre, blinded review, dose ranging, non-randomised study of $^{64}$Cu-SAR-bisPSMA administered to participants with confirmed prostate cancer prior to radical prostatectomy. The main goals of the PROPELLER trial are to:

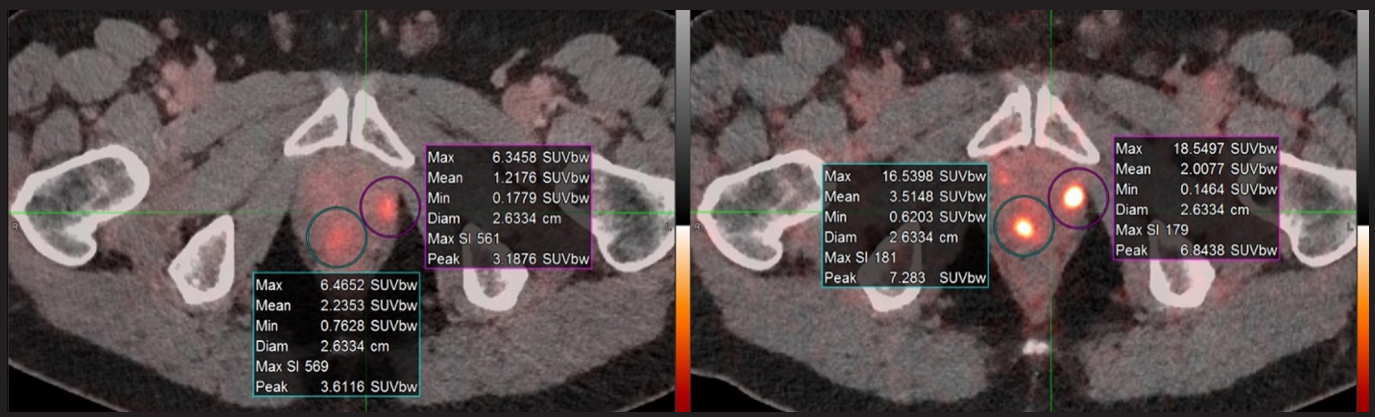
1. Determine the safety and tolerability of $^{64}$Cu SAR-bisPSMA in participants with untreated, confirmed prostate cancer and planned for radical prostatectomy;
2. Examine $^{64}$Cu SAR-bisPSMA at different dose levels;
3. Determine the ability of $^{64}$Cu SAR-bisPSMA to detect primary prostate cancer; and
4. Compare diagnostic properties of $^{64}$Cu SAR-bisPSMA against $^{68}$Ga PSMA-11, the standard of care for prostate cancer imaging in Australia.

The preliminary data from the participants imaged in the PROPELLER trial to date looks very promising as it supports the evidence of high uptake of $^{64}$Cu SAR-bisPSMA in the tumours that has been shown in the pre-clinical studies. These initial results are encouraging for further development of this product as a diagnostic, and the higher uptake also make it an exciting therapeutic target with $^{67}$Cu.

**$^{68}$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**

$^{68}$Ga PSMA-11 (~200MBq)

$^{64}$Cu SAR-bisPSMA (~200MBq)




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

# COBRA trial with $^{64}$Cu SAR-bisPSMA

In February 2022, Clarity announced that the Group has received a confirmation from the US Food and Drug Administration (FDA) that the diagnostic $^{64}$Cu SAR-bisPSMA trial, COBRA (NCT05249127)[3] may proceed.

COBRA (**CO**pper-64 SAR-BisPSMA in **B**iochemically **R**ecurrent prost**A**te cancer) is a Phase I/II Positron Emission Tomography (PET) trial of participants with biochemical recurrence (BCR) of prostate cancer following definitive therapy. It is a multi-centre, single arm, non-randomised, open-label trial of $^{64}$Cu-labelled SAR-bisPSMA in up to 50 participants. The primary objectives of the trial are to investigate safety and tolerability of $^{64}$Cu-SAR-bisPSMA as well as its ability to correctly detect recurrence of prostate cancer.

Clarity is excited to be progressing this stand-alone diagnostic trial as it heads towards registering the $^{64}$Cu SAR-bisPSMA product in the US. The Group is planning to commence recruitment in the trial in the second quarter of 2022.

# SARTATE™ – Neuroblastoma and NETs

SARTATE™ is a next generation, highly targeted theranostic radiopharmaceutical which is being developed for diagnosing, staging and subsequently treating cancers that express somatostatin receptor 2 (SSTR2), including neuroblastoma and neuroendocrine tumours (NETs).

## SARTATE™ Neuroblastoma

In January 2022, Clarity completed cohort 1 and advanced to cohort 2 in the $^{64}$Cu/$^{67}$Cu SARTATE™ Neuroblastoma CL04 trial (NCT04023331)[4].

The Safety Review Committee (SRC) assessed the data from cohort 1 in three participants who received therapy with $^{67}$Cu SARTATE™ at a dose of 75MBq/kg body weight and had no dose limiting toxicities.

The SRC recommended to progress the trial to cohort 2, without modification, increasing the dose from 75MBq/kg to 175MBq/kg body weight. Additional therapy cycles of $^{67}$Cu SARTATE™ have been requested by clinical sites and are being administered to participants in cohort 1. As part of the trial, particpants have also received multiple doses of $^{64}$Cu SARTATE™ for the imaging of tumours to assess disease localisation and eligibility for therapy. At the time of the latest SRC meeting, no adverse events had been reported relating to the administration of $^{64}$Cu-SARTATE™.

**In February 2022, the first participant in cohort 2 was treated with $^{67}$Cu SARTATE™ at an increased dose of 175MBq/kg body weight.**

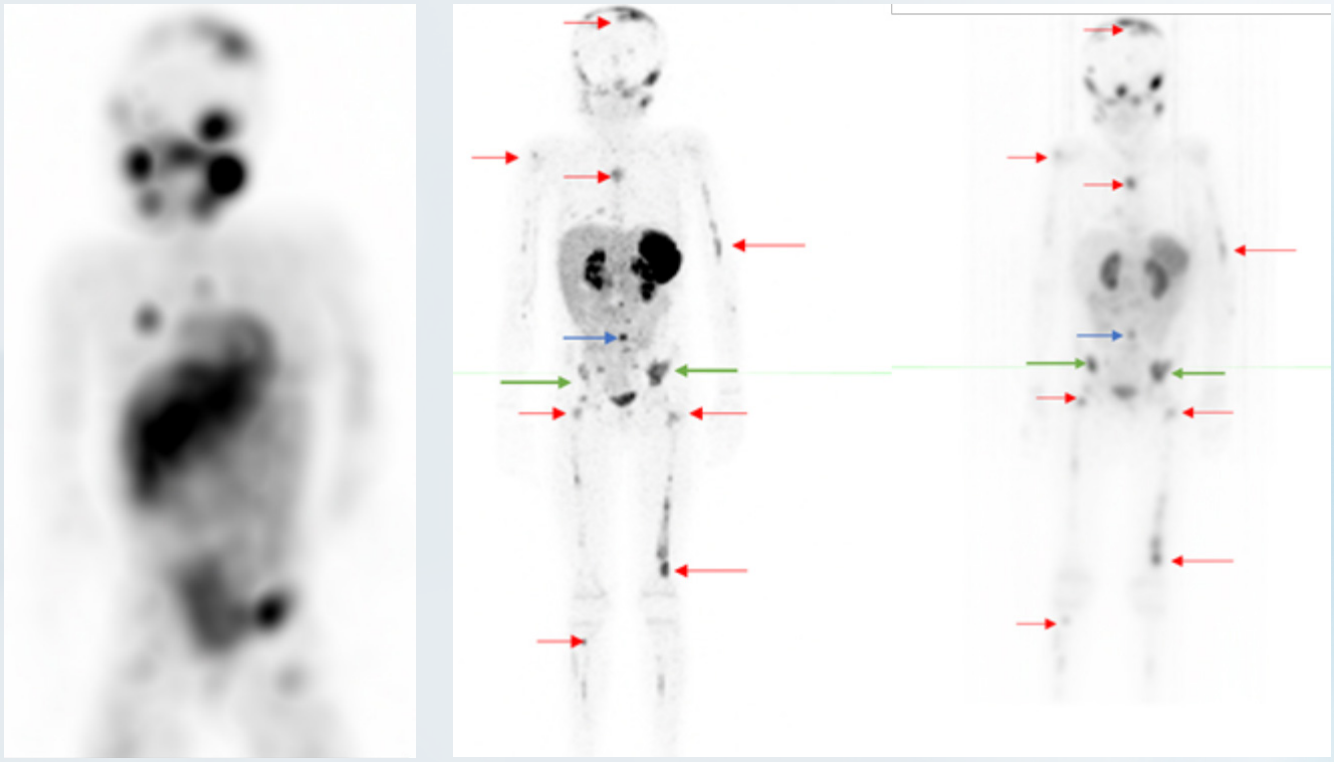
The increase in administered $^{67}$Cu SARTATE activity between cohorts 1 and 2 is significant in radiation-sensitive disease, such as neuroblastoma. In cohort 2 administered activities are more than doubled in comparison to cohort 1.

Clarity looks forward to continuing recruitment in cohort 2, building upon the encouraging initial data from cohort 1 and further gathering evidence of diagnostic and therapeutic benefits of the SARTATE™ product for the treatment of children with neuroblastoma.

CL04 is a multi-centre, dose-escalation, open label, non-randomised, theranostic clinical trial in paediatric patients with high-risk neuroblastoma. The trial is a Phase I/IIa with up to 34 participants where not only the safety of both $^{64}$Cu SARTATE™ and $^{67}$Cu SARTATE™ are assessed, but also the effectiveness of $^{67}$Cu SARTATE™ as a treatment for neuroblastoma. Participants who show uptake of $^{64}$Cu SARTATE™ in tumour will continue in the trial and receive treatment with $^{67}$Cu SARTATE™.

In 2020, the US FDA granted Clarity two Rare Paediatric Disease Designations, one for $^{67}$Cu SARTATE™ for neuroblastoma therapy and one for $^{64}$Cu SARTATE™ for the management of neuroblastoma, which may potentially allow the Group to access two tradeable Priority Review Vouchers if the Group is able to achieve successful US FDA New Drug Applications for SARTATE™ in neuroblastoma. PRVs have recently transacted at approximately US$110m per voucher.[5]

**SARTATE™ diagnostic and therapeutic imaging relative to MIBG imaging in the same trial participant**



**$^{123}$I MIBG**
Current Standard of Care

**$^{64}$Cu SARTATE™**
PET screening 4 hours

**$^{67}$Cu SARTATE™**
SPECT scan 24 hours

# SARTATE™ NETs

Clarity's Diagnostic Imaging Study of Copper-64 SARTATE™ (DISCO) using PET on participants with known or suspected NETs in Australia (NCT04438304)[6] commenced in April 2021 and continues to recruit participants at three clinical sites in Australia.

The DISCO trial is assessing the performance of $^{64}$Cu SARTATE™ imaging agent in participants with known or suspected gastroenteropancreatic NETs as a potential new way to help diagnose and manage NETs. It is a Phase II study in up to 63 participants across three sites in Australia that compares the diagnostic performance of $^{64}$Cu SARTATE™ at four and 20 hours post-administration to the current standard of care, $^{68}$Ga DOTATATE, at one hour.

# SAR-Bombesin – Breast and Prostate Cancers

SAR-Bombesin is a highly targeted pan-cancer theranostic radiopharmaceutical being developed for identifying and selecting patients for subsequent treatment of their cancers that express gastrin releasing peptide receptor (GRPr).

## Diagnostic $^{64}$Cu SAR-Bombesin breast cancer C-BOBCAT trial

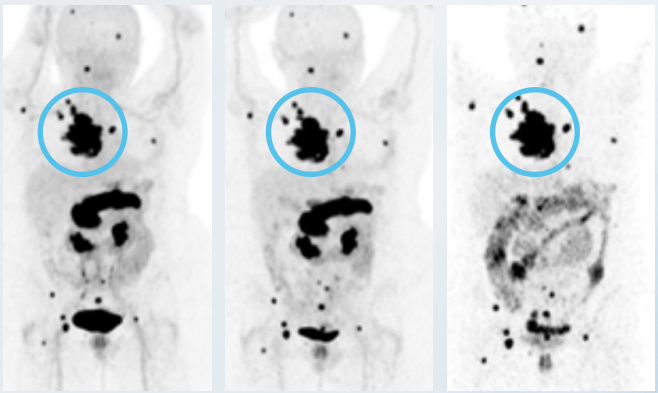
The diagnostic imaging trial of $^{64}$Cu SAR-Bombesin (C-BOBCAT), led by Prof Louise Emmett at St Vincent's Hospital Sydney, closed early in October 2021, having been used in seven patients with ER/PR positive metastatic breast cancer. The study has shown promising preliminary results in breast cancer patients.

The C-BOBCAT trial was a pilot assessment of the diagnostic value of $^{64}$Cu SAR-Bombesin PET/CT imaging for staging of hormone positive breast cancer patients with metastatic disease in comparison with standard of care imaging (CT, bone scan and $^{18}$F FDG PET/CT).

The diagnostic program generated evidence of the utility and potential superiority in some patient subgroups compared to conventional imaging (e.g. $^{99m}$Tc bone scan, $^{18}$F FDG). The high uptake visualised by PET imaging in 5 of the 7 patients scanned at 1, 3 and 24 hours after product administration suggest significant potential for therapy applications with $^{67}$Cu SAR-Bombesin.

The clinical data from the C-BOBCAT trial will be published in 2022 and Clarity will use the human clinical data from the trial for Investigational New Drug (IND) Application filings with the US Food and Drug Administration (FDA).

**$^{64}$Cu SAR-Bombesin in hormone positive metastatic breast cancer at 1h, 4h and 24h after administration demonstrating high uptake and retention within the tumour and clearance from the non-target organs**



T = 1 Hour | T = 4 Hours | T = 24 Hours

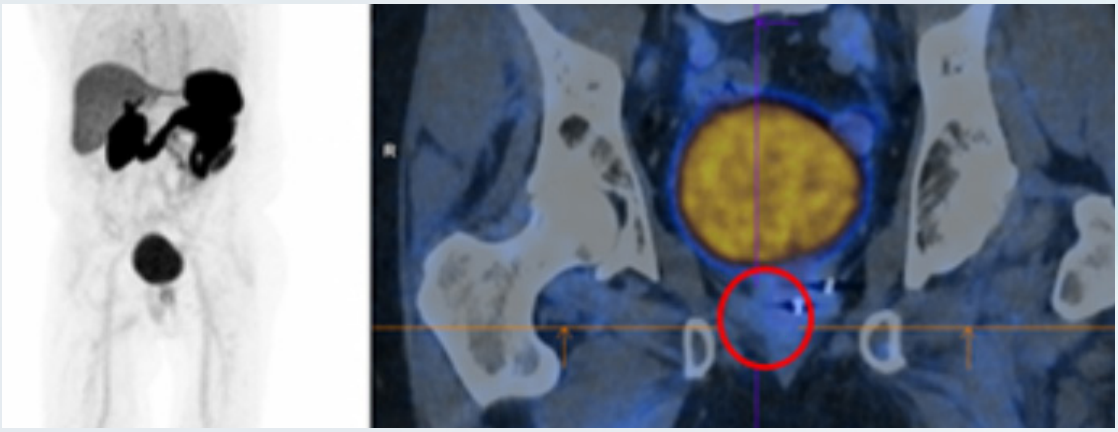
# $^{64}$Cu SAR-Bombesin in prostate cancer patients

Clarity received strong interest from clinicians in using SAR-Bombesin for better management of PSMA-negative prostate cancer, with early clinical evidence being very promising as the Group looks to explore the clinical development of SAR-Bombesin in the US and Australia.

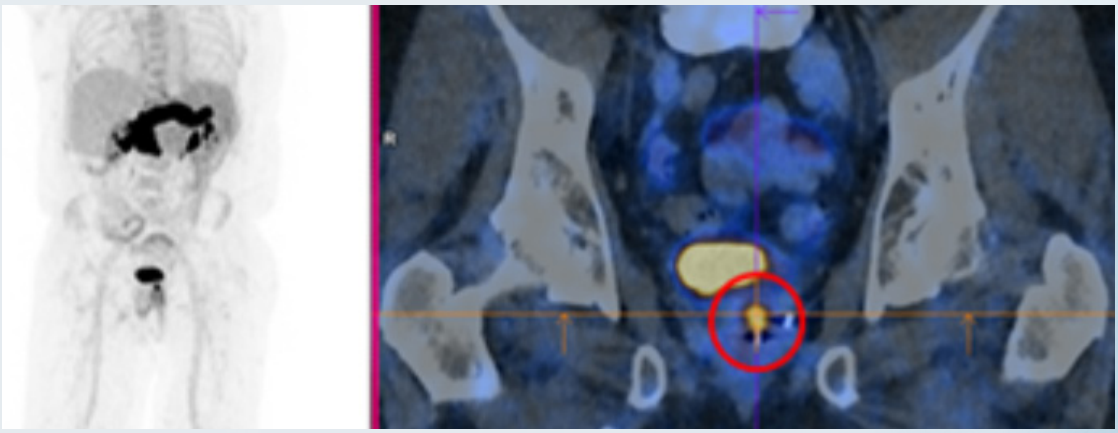
During the reporting period, Clarity responded to these requests for access to this product under the Therapeutic Goods Administration (TGA) Special Access Scheme (SAS) for PSMA-negative prostate cancer patients. Given Clarity's experience and networks in prostate cancer and following the feedback from clinicians who accessed SAR-Bombesin for prostate cancer patients under the TGA SAS, the Group is excited to move this product forward in clinical development in 2022.

**$^{68}$Ga PSMA-11 (top) images of a PSMA-negative patient with clinical signs of PC (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**



**$^{64}$Cu SAR-Bombesin**



# OPERATIONS & SUPPLY OF RADIOPHARMACEUTICALS

## Manufacturing and logistics

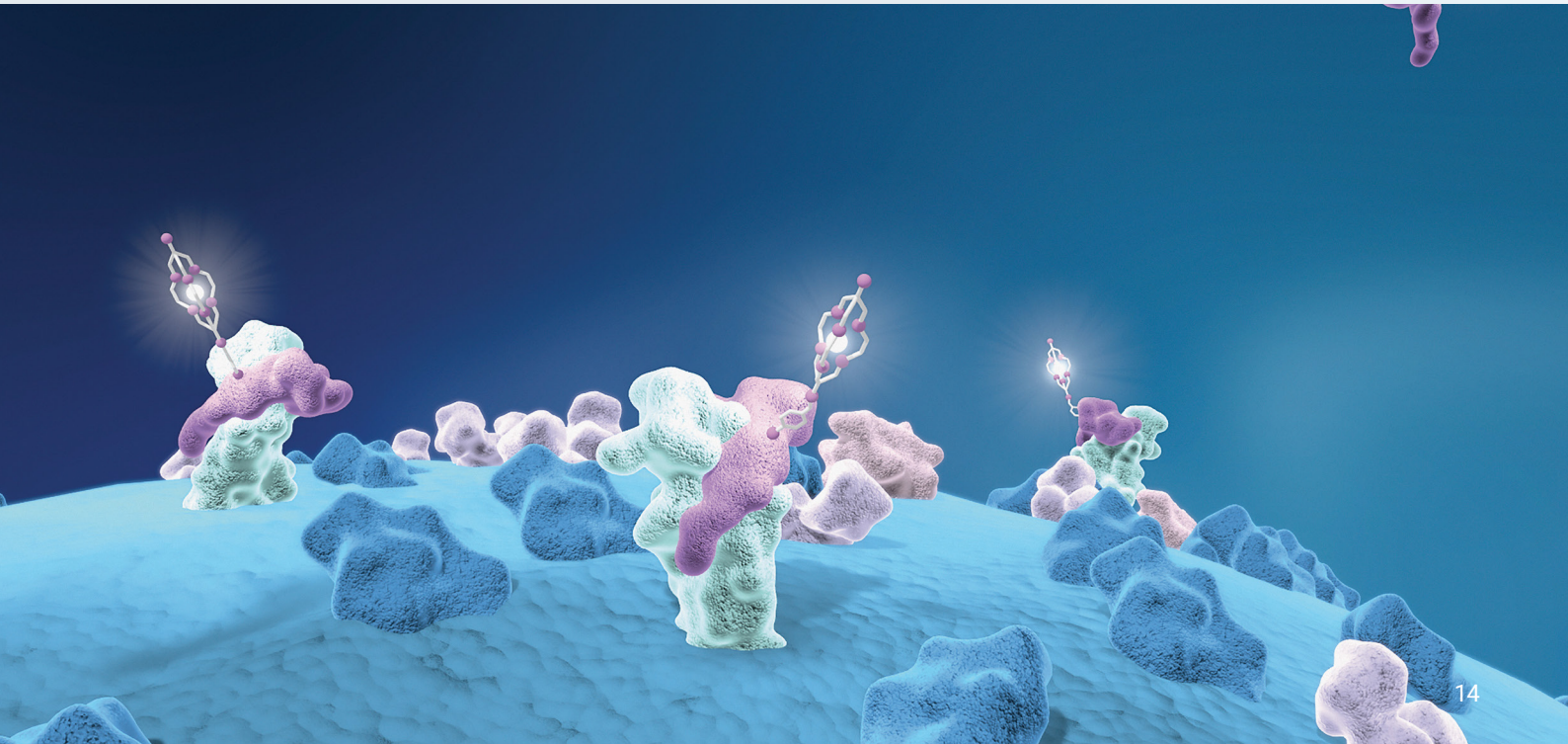
Manufacturing and logistics are critical for the commercial viability of radiopharmaceuticals. To support clinical growth and future commercialisation, Clarity has been actively extending its manufacturing and logistical footprint in the US by signing key agreements, including:

- Agreement with **Cardinal Health** covering cGMP manufacture and distribution of Clarity's TCT on 2 December.
- Agreement with **Evergreen Theragnostics, Inc.** covering cGMP manufacture and distribution of Clarity's TCT on 30 September.

These agreements are critical to the rollout of the TCT platform and getting "ready-to-use" TCT products to patients at any location in the US. They build on existing supply agreements, including the agreement with **NorthStar Medical Isotopes, LLC.** for the exclusive supply of copper-67 to Clarity.

Clarity also secured a **membership and a Board position on the Council on Radionuclides and Radiopharmaceuticals, Inc (CORAR)** on 22 September 2021, which provides the Group with a significant voice in shaping and improving the regulatory agenda around the use of radiopharmaceuticals in the US. Through its role at CORAR Clarity will advocate for the broader use of TCT and the building of infrastructure to support its growth, as well as inform the market of the advantages associated with copper-based radiopharmaceuticals.

Clarity's ongoing clinical trials help to validate its on-demand distribution model prior to the commercialisation of the TCT platform whereby products are shipped to trial sites across Australia and the US from central manufacturing facilities with minimal delays or interruptions.



# The radiopharmaceutical field and radioisotope supply

Radiopharmaceuticals is a relatively small field in the larger oncology market; however, it is forecast to grow from US$6B in 2021 to US$33B in 2031 globally[7].

As radiopharmaceuticals enter the “mainstream” of oncology treatments, they will be competing directly in indications where there are a number of available non-radiopharmaceutical therapies. To compete successfully, they will need to provide a customer and patient experience that is similar, if not better, than existing treatments in oncology like oral oncolytics.

Historically, an impediment to this success has been a reliance on international supply chains prone to disruptions, which create late or missed deliveries[8]. Radioisotopes must be produced according to industry and quality standards, and radiopharmaceuticals must be administered to patients within a small window of time before they expire, often only a few hours, adding to the complexity of the supply chain. When competing in the broader oncology market with agents like oral oncolytics, which have shelf lives measured in years, the short shelf life of radiopharmaceuticals necessitates a robust supply chain that avoids supply shortages and failures.

The physical properties of TCT based on $^{64}$Cu and $^{67}$Cu provide both manufacturing and supply advantages compared to the current generation of radiopharmaceuticals, offering potentially significant benefits in the clinical development and future commercialisation of TCT

### DIAGNOSTIC RADIOISOTOPES

Current diagnostic radiopharmaceuticals that rely on gallium-68 ($^{68}$Ga) or fluorine-18 ($^{18}$F) have a number of challenges due to the short half-life of these radionuclides, which requires them to be produced in or close to the treatment centre, and used within 3-12 hours[9,10]. As such, their production and distribution pose significant challenges in delivering critical imaging scans to cancer patients on time and makes scaling their production into new indications resource intensive in both capital and operational expenditures.

By contrast, $^{64}$Cu based diagnostics can be produced on cyclotrons at commercial scale (>500 patient doses per run). Importantly, the 12.7 hour half-life of $^{64}$Cu permits central manufacturing of ready-to-use radiopharmaceuticals and broad regional distribution from a single facility.

## THERAPEUTIC RADIOISOTOPES

The production of most therapeutic isotopes is reliant on a small number of aging nuclear reactors globally.

The most recent example of this is that in January 2022, the Nuclear Medicine Europe (NMEu) Emergency Response Team (ERT) released a statement that the High Flux Reactor (HFR) in Petten, Netherlands, did not resume operations after a planned shutdown on January 20, 2022, due to the detection of a water leak in the reactor beam tube cooling system.[11] A further update from NMEu ERT on 31 January 2022 informed that the first planned cycle scheduled from 20 January until 20 February 2022 was subsequently cancelled[12]. The delay of at least 2 months in HFR reactor restart has impacted and will continue to disrupt the supply of lutetium-177 ($^{177}$Lu) and other medical isotopes, such as iodine-131 ($^{131}$I) and molybdenum-99/technicium-99m ($^{99}$Mo/$^{99m}$Tc).[11,12]

In December, the EU, currently the world's biggest producer of $^{99}$Mo, a radioisotope used in 80% of all nuclear medicine procedures globally, flagged that the European research reactors are approaching their "end-of-life" and without replacing this ageing infrastructure, the EU could experience significant radioisotope shortages and impede access to vital treatments for its citizens. In October, The European Commission also flagged the possible shortage of another isotope crucial for the diagnosis and treatment of cancer, iodine-131 ($^{131}$I), next year.[13] These shortages are also expected to impact the roll-out of $^{177}$Lu based products, which may severely hinder the growth of radiopharmaceuticals moving forward.

The United States is not a major producer of radionuclides and imports almost all large-volume radionuclides, leaving the US dependent on foreign sources (Europe, Australia and South Africa).[7] Given its reliance on the small and aging fleet of reactors in Europe, this poses an acute risk to US supply.

**The production of $^{67}$Cu relies on electron accelerators, rather than nuclear reactors, which translates into a strategic ability to scale production as needed with additional electron accelerators and have purpose-built supply in commercially important markets, like the US. This unique approach also removes any reliance on the antiquated, unreliable and government subsidised nuclear reactor infrastructure.**

In addition, electron accelerators only require electricity and zinc to produce $^{67}$Cu, which stands in stark contrast to nuclear reactor production of $^{177}$Lu that requires both uranium fuel and the rare earth metal, ytterbium, currently sourced from Russia[7], as inputs for production, carrying environmental and supply risks.

## ENVIRONMENTAL CONSIDERATIONS

As the number of radiopharmaceutical patient treatments increases, environmental factors will impact the selection of theranostic radioisotopes. Production of $^{64}$Cu and $^{67}$Cu have:

- favorable environmental characteristics
- a relatively small infrastructure footprint
- do not use nuclear reactors or enriched uranium
- avoid the creation of long-lived radioactive impurities
- lack significant radioactive waste disposal issues; and
- use more readily available target materials which do not employ rare earth elements.

To summarise, Clarity's proprietary TCT approach addresses three substantial market challenges. By leveraging its inherent supply advantages with $^{64}$Cu based diagnostics, Clarity has created a supply chain which provides universal access in the US, even in phase I trials. Moreover, the Group offers dependability and scalability with its $^{67}$Cu therapeutic platform, which is not possible with $^{177}$Lu, as illustrated by the recent HFR reactor shutdown[11,12]. Lastly, the production of $^{64}$Cu and $^{67}$Cu, has the potential to significantly reduce the environmental impact compared to first-generation theranostic radiopharmaceuticals based on $^{68}$Ga or $^{177}$Lu. This is highly relevant considering the forecasted growth of theranostics over the next decade.

# INTELLECTUAL PROPERTY (IP)

Clarity has an extensive patent portfolio generated from a patent strategy designed to cover its SAR Technology platform and its radiopharmaceutical products as well as a 'Discovery Program' focused on developing new products and new intellectual property for a range of indications of cancer in all major international jurisdictions.

Originating from pioneering work at the Australian National University, The University of Melbourne and Australian Nuclear Science and Technology Organisation, Clarity has expanded its patent base and works closely with experienced patent attorneys to protect the IP in accordance with the patent strategy.

Most recently, Clarity focused on significantly strengthening patent protection of its optimised optimised Prostate Specific Membrane Antigen (PSMA) targeting agent, SAR-bisPSMA, as the Group entered two clinical trials in prostate cancer with this product in 2021, SECuRE and PROPELLER, and received a Study May Proceed letter from the US FDA for a diagnostic COBRA trial in February 2022. In November, the patent application covering formulations of SAR-bisPSMA entered the national phase in multiple jurisdictions, including the USA, Europe and China.

Clarity continues to expand, improve and support its portfolio with the filing of six provisional patents during the reporting period, while moving other patent applications ahead through the various stages of the patenting process. The patent portfolio currently includes seventeen active patent families.

The evolving patent protection is testament to Clarity's aggressive patent strategy which allows us to achieve strong protection with any targeting agent and expand the product pipeline, gaining a sustainable competitive advantage in the radiopharmaceutical field.

# CORPORATE UPDATE

## The largest biotechnology IPO on ASX

On 25 August 2021 Clarity successfully completed the largest biotechnology IPO on the ASX, raising $92 million with Jefferies (Australia) Pty Ltd and Bell Potter Securities Limited as Joint Lead Managers and Underwriters. The listing was strongly supported by institutional, sophisticated and retail investors from Australia and overseas. Following the IPO and receiving a research and development tax incentive cash offset of $3.3m in February 2022, Clarity is well funded, with cash position of $97.5 million at 25 February 2022, to continue the clinical development of its pipeline of next-generation radiopharmaceutical products addressing the growing demand for the use of radiopharmaceuticals in oncology.

## China Grand Pharmaceutical and Healthcare

As noted in Clarity's Prospectus, the Company and China Grand agreed to enter exclusive discussions for the grant of a licence to permit China Grand to develop, manufacture and commercialise one or more of Clarity's products in the Greater China territory. In connection with those discussions, and in consideration for exclusivity, the Company and China Grand entered into an Option Deed on 1 July 2021, with an expiration date on the earlier of a number of events including a period of six months from the date of the Company listing on the ASX.

Under the Deed, the Company issued 25,543,912 options to China Grand to acquire shares at an exercise price of A$1.75. Those options lapsed and were cancelled at 5pm on 25 February 2022 (Expiry Date), being six months from Clarity's listing date, and the exclusivity period for the licencing negotiations also expired at that time. Clarity continues to progress strategic discussions in relation to its pipeline and technology globally and is now clear to negotiate the Greater China territory on a non-exclusive basis.

## Clarity Team

At the core of Clarity's success is its people. Over time the Group has assembled an exceptional team, including the Board of Directors and Scientific Advisory Board, who deliver a unique range of skills and expertise together with extensive experience in the global radiopharmaceutical market. Clarity has continued to attract extraordinary talent, even with the drawbacks and hindrances presented by the pandemic. During the period it has expanded its clinical, regulatory and operations teams in keeping with anticipated growth in the clinical programs. Key additions include Mr Rob Thomas who joined the Group's Board of Directors on 25 August 2021, bringing a wealth of experience in capital markets and corporate governance, and Dr Willie Regits as a Senior Director, Supply Chain and Corporate Radiation Safety Officer in the US.

## Environmental, Social and Governance (ESG) commitments

Clarity is committed to being an employer of choice and an investment for its shareholders to be proud of. As such, Clarity's goal is to be at the forefront of the ESG practices in the biotechnology sector. As part of this commitment, the Group is seeking to offer a more sustainable future for radiopharmaceuticals. This includes providing superior options for diagnosis and treatment of disease which are non-uranium sourced and do not have long-lived radioactive waste products, whilst avoiding the inefficiencies of diagnostic products which utilise shorter half-life isotopes. Clarity prides itself on a strong governance structure for a company of its size, with an exceptionally experienced Board and management team. The Group is ambitious with its social responsibility goals, already in evidence through the translation of great Australian science towards Clarity's ultimate goal of better treating children and adults with cancer.

In the reporting period Clarity announced further commitment to social causes. This included working closer with Australian groups focused on the management of neuroblastoma. Clarity is also excited about its partnership with Story Factory, a not-for-profit organisation focused on developing the creative writing skills and finding the voice of indigenous and non-indigenous children. Story Factory is based in Redfern near Clarity's head office. Clarity sees ESG as a major area of focus to clearly differentiate itself and will continue to update its shareholders on further progress in these areas.

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# About Clarity Pharmaceuticals

Clarity is a clinical stage radiopharmaceutical company focused on the treatment of serious disease. The Company is a leader in innovative radiopharmaceuticals, developing targeted copper theranostics based on its SAR Technology Platform for the treatment of cancer in children and adults.

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