



2021 YEAR IN REVIEW

ASX: CU6



Clarity Pharmaceuticals (ASX: CU6) (“Clarity” or the “Company”), 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 first Annual Newsletter as a listed entity for the calendar year ending 31 December 2021.

Despite the unprecedented challenges imposed by the global pandemic, this year has been extraordinary for Clarity.

Not only have we completed the largest biotechnology Initial Public Offering (IPO) on the Australian Securities Exchange (ASX), raising \$92 million, but also significantly progressed clinical development of our pipeline of Targeted Copper Theranostics (TCT), commencing three new trials this year (including two trials in prostate cancer), closing a diagnostic trial of SAR-Bombesin following the exciting preliminary results, and expanding the theranostic trial in neuroblastoma to five sites.

To support our clinical growth and take full advantage of therapeutic, manufacturing and logistical benefits of TCT, Clarity has been actively extending its manufacturing and logistical footprint. We have also progressed our preclinical and discovery programs and continued bolstering our IP portfolio to support the comprehensive platform of TCT.

Our team is excited to further build on the important milestones we have achieved to date and continue delivering on our ultimate goal of developing better treatments for children and adults with cancer in the new year.

Highlights of 2021

Currently actively recruiting in four clinical trials, with additional trials scheduled to commence early in 2022.

Commenced recruitment in two clinical trials for our optimised PSMA agent, SAR-bisPSMA, in prostate cancer in July 2021

- Completed the dosimetry phase in the SECuRE trial for the treatment of prostate cancer
- Achieved 50% recruitment milestone in the PROPELLER trial for the imaging of prostate cancer

Early completion of the C-BOBCAT diagnostic trial with ⁶⁴Cu SAR-Bombesin in October 2021 with plans to commence US-based clinical trials of this product in early 2022

Execution of US radiopharmaceutical manufacturing agreements with Evergreen Theragnostics, Inc in September 2021 and with Cardinal Health in December 2021

Entered into a supply agreement with NorthStar Medical Radioisotopes for commercial supply of copper-67 exclusively to Clarity in May 2021.

Strengthened our IP position with the assignment of all of our patents from the University of Melbourne, grant of SAR-bisPSMA patent in the US and a further patent application covering formulations of SAR-bisPSMA entering the national phase in a number of jurisdictions.

Successfully completed the largest biotechnology Initial Public Offering (IPO) on the Australian Securities Exchange (ASX), raising \$92 million and strong cash position with \$101.7 million held at 30 September 2021.

China Grand Pharmaceutical and Healthcare Holdings Limited (“China Grand”) option agreement and ongoing negotiations on the licensing deal.



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 ⁶⁴Cu SAR-Bombesin in October, the company is now actively recruiting in four clinical trials, with additional trials scheduled to commence early next year. The anticipated studies include but are not limited to two US-based diagnostic trials of ⁶⁴Cu SAR-Bombesin and ⁶⁴Cu SAR-bisPSMA in prostate cancer.

This year has been transformational for Clarity's clinical development as we commenced recruitment in two clinical trials of our optimised PSMA agent, SAR-bisPSMA, in prostate cancer, expanded the theranostic trial of SARTATE™ in children with neuroblastoma to a total of five clinical sites in the US and opened recruitment in the Phase II diagnostic trial of SARTATE™ in neuroendocrine tumours (NETs) in Australia. In addition to the clinical development, Clarity is also actively progressing its preclinical and discovery programs, looking to build a pipeline of novel radiopharmaceuticals in the TCT platform.

CLARITY'S CLINICAL DEVELOPMENT PIPELINE

Indication	Product	Therapeutic/Target	Discovery	Preclinical	Phase I	Phase 2	Phase 3
Prostate Cancer	SAR-bisPSMA	Theranostic					
	SAR-bisPSMA	Diagnostic					
	SAR-BBN	Diagnostic					
	SAR-BBN	Theranostic					
Neuroblastoma	SARTATE	Theranostic					
	SARTATE	Diagnostic					
NETs	SARTATE	Diagnostic					
Pan cancer (GRPr positive tumours)	SAR-BBN	Diagnostic					
SAR Discovery Platform	Undisclosed	Undisclosed					
	Undisclosed	Undisclosed					

Current progress

12 month progress



SAR-bisPSMA

SAR-bisPSMA is a next generation, highly targeted theranostic radiopharmaceutical, being developed for diagnosing, staging and subsequently treating prostate cancer that expresses 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. Preclinical data confirms that both uptake and retention are higher for ^{64}Cu SAR-bisPSMA than that of the single PSMA binding motif utilised by other marketed PSMA binding radiopharmaceutical products.

Accurate diagnosis and effective treatment of prostate cancer is a key focus for Clarity. As such, in July 2021 the company commenced recruitment in two clinical trials of SAR-bisPSMA in prostate cancer: a US-based Phase I/IIa theranostic clinical trial for the treatment of prostate cancer (the SECuRE trial); and an Australian-based Phase I diagnostic clinical trial for the diagnosis of early-stage prostate cancer (the PROPELLER trial).

SECuRE trial with $^{64/67}\text{Cu}$ SAR-bisPSMA

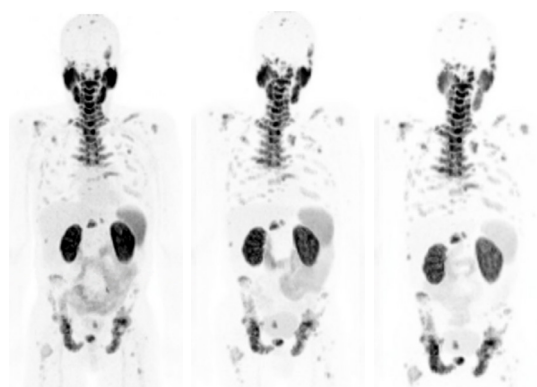
In November, Clarity has announced completion of the recruitment for the dosimetry phase of the $^{64/67}\text{Cu}$ SAR-bisPSMA SECURE trial (NCT04868604)¹ and shared preliminary results.

We are now collating the data for the Safety Review Committee and look forward to progressing the therapy dose-escalation early in 2022 at all seven sites selected for the trial in the US.

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 and the images confirm the preclinical results of high tumour targeting and retention whilst indicating washout in other tissues. 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 able to visualise bone involvement. 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.

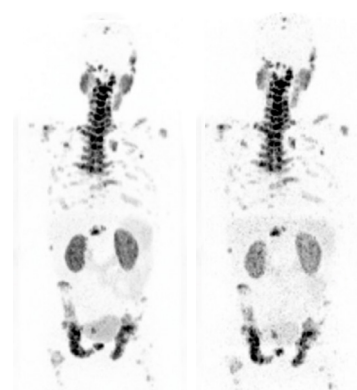
PET scans in a patient with metastatic castrate-resistant prostate cancer imaged over multiple timepoints between 1 and 72 hours post administration of ^{64}Cu SAR-bisPSMA (Normalized Voxel Intensity)



1 Hour Post Injection

12 Hour Post Injection

24 Hour Post Injection



48 Hour Post Injection

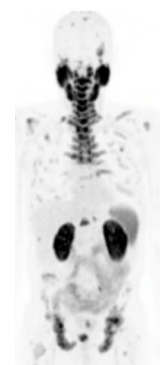
72 Hour Post Injection

^{64}Cu SAR-bisPSMA PET/CT

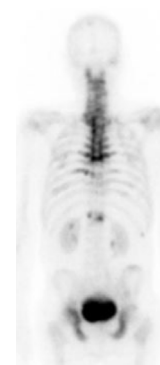
Comparison of 1h ^{64}Cu SAR-bisPSMA PET with $^{99\text{m}}\text{Tc}$ -MDP Bone Scan



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



1h ^{64}Cu SAR-bisPSMA PET



$^{99\text{m}}\text{Tc}$ -MDP WB Bone Scan

PROPELLER trial with ^{64}Cu SAR-bisPSMA

The PROPELLER trial is recruiting quickly, having achieved 50% recruitment milestone in December with 15 of 30 participants have been 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 patients with confirmed prostate cancer prior to radical prostatectomy (NCT04839367)². The main goals of the PROPELLER trial are to:

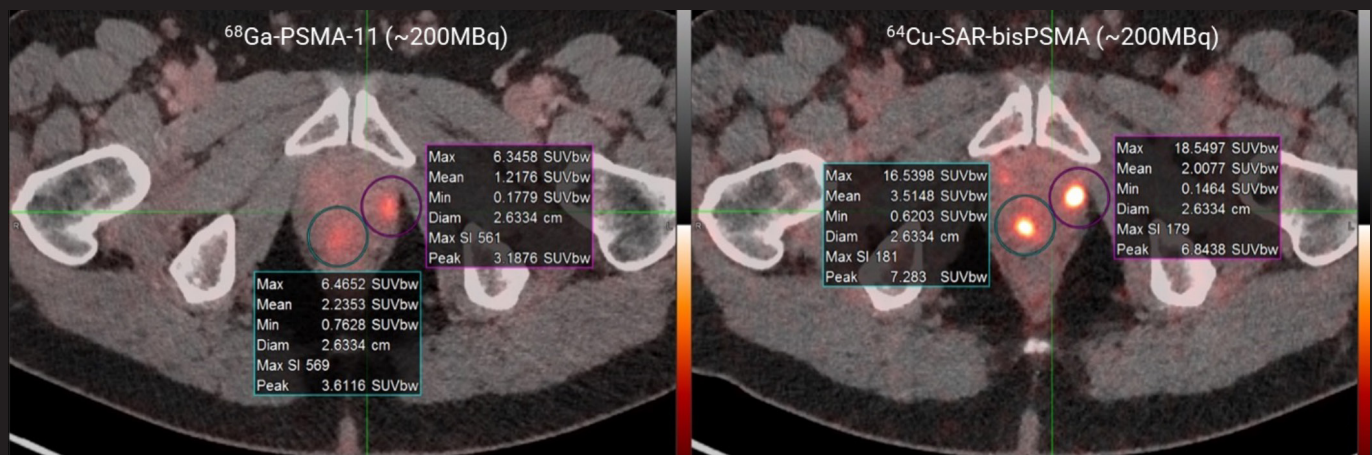
1. Determine the safety and tolerability of ^{64}Cu SAR-bisPSMA in participants with untreated, confirmed prostate cancer and planned for radical prostatectomy;
2. Examine ^{64}Cu SAR-bisPSMA at different dose levels;
3. Determine the ability of ^{64}Cu SAR-bisPSMA to detect primary prostate cancer; 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 patients 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 and retention also make it an exciting therapeutic target with ^{67}Cu .

Given the encouraging preliminary results from the PROPELLER trial, Clarity is looking to continue the development of ^{64}Cu SAR-bisPSMA as a diagnostic for patients with prostate cancer with a further imaging trial anticipated to commence in 2022 in the US.

^{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



SARTATE™

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

Clarity's theranostic ⁶⁴Cu/⁶⁷Cu SARTATE™ neuroblastoma trial (NCT04023331)³ is progressing well in the US since its commencement in July 2020 at Memorial Sloan Kettering Cancer Center in New York. It is a multi-centre, dose-escalation, open label, non-randomised, theranostic clinical trial in paediatric patients with high-risk neuroblastoma (CL04).

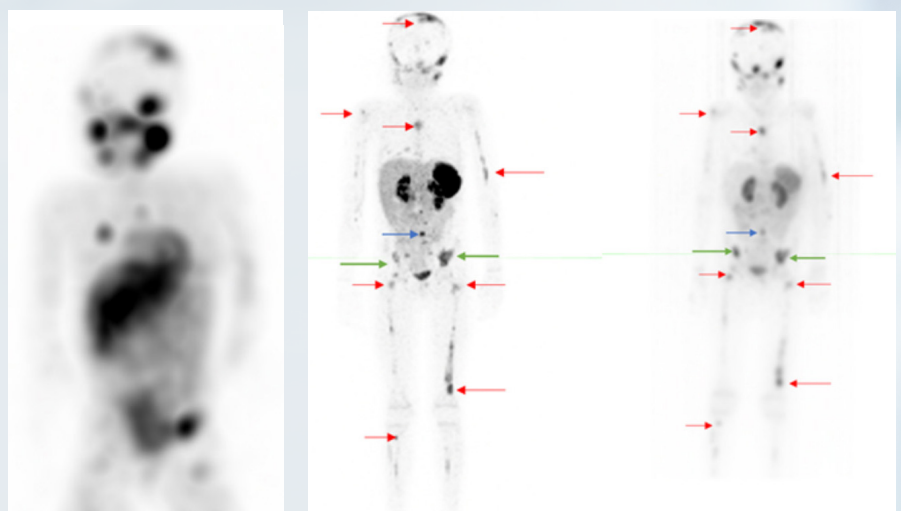
The trial is a Phase I/IIa with up to 34 patients where not only the safety of both ⁶⁴Cu SARTATE™ and ⁶⁷Cu SARTATE™ are assessed, but also the effectiveness of ⁶⁷Cu SARTATE™ as a treatment for neuroblastoma. Patients who show uptake of ⁶⁴Cu SARTATE™ in tumour will continue in the trial and will receive treatment with ⁶⁷Cu SARTATE™. CL04 has now been expanded to a total of five clinical sites across the US and although neuroblastoma has a much smaller patient population than prostate cancer, we look forward to building upon the promising data to date and progressing through the dose-escalation phase of this trial during 2022.

Clarity has also received a number of requests from Australian clinicians for access to ⁶⁴Cu SARTATE™, and we will look to work more closely with these sites in the new year to provide access to this important imaging tool for local clinicians and children who suffer from neuroblastoma.

In 2020, the US FDA granted Clarity two Rare Paediatric Disease

Designations, one for ⁶⁷Cu SARTATE™ for neuroblastoma therapy and one for ⁶⁴Cu SARTATE™ for the management of neuroblastoma, which may potentially allow the company to access two tradeable Priority Review Vouchers if the company is able to achieve successful US FDA New Drug Applications for SARTATE™ in neuroblastoma. PRVs have recently transacted at approximately US\$100m per voucher.

SARTATE™ diagnostic and therapeutic imaging relative to MIBG imaging in the same patient



¹²³I MIBG
Current Standard of Care

⁶⁴Cu SARTATE™
PET screening 4 hours

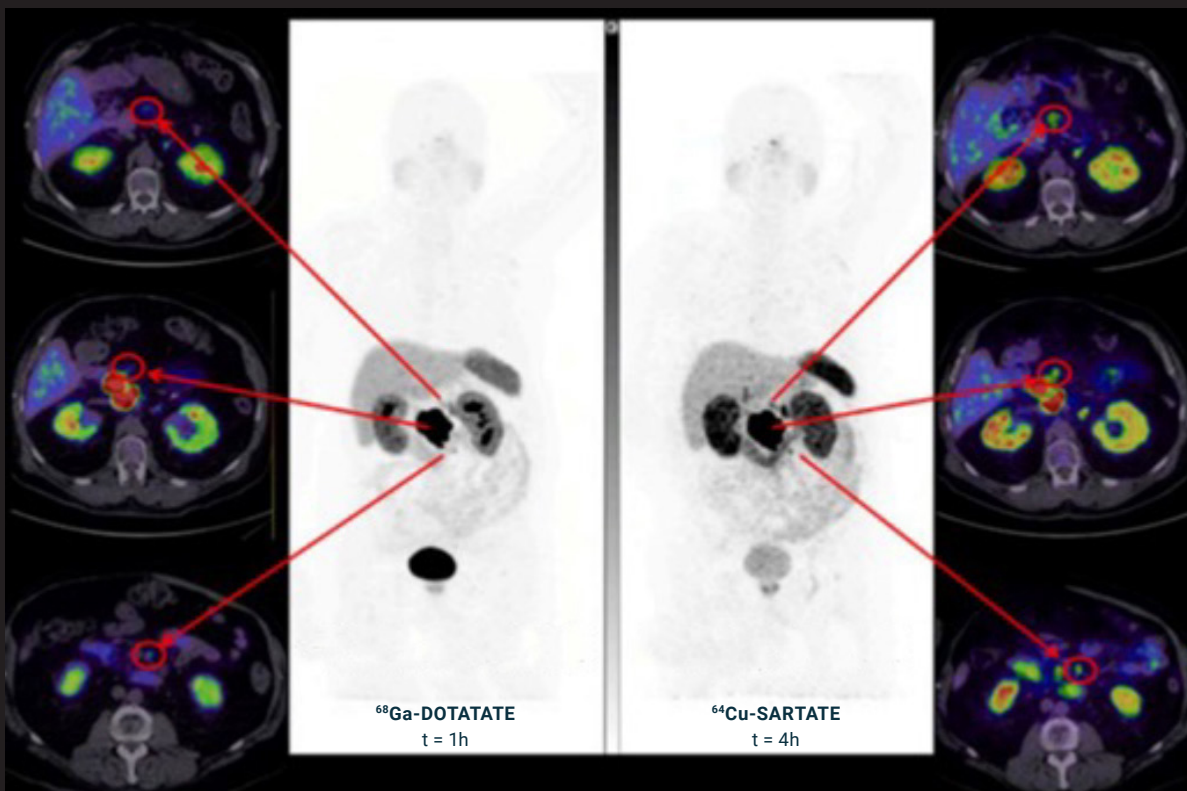
⁶⁷Cu SARTATE™
SPECT scan 24 hours

SARTATE™ NETs

In April 2021, Clarity commenced a **Diagnostic Imaging Study of Copper-64 SARTATE™ (DISCO) using PET on patients with known or suspected NETs in Australia** (NCT04438304)⁴. The DISCO trial is assessing the performance of ⁶⁴Cu 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 patients across three sites in Australia that compares the diagnostic performance of ⁶⁴Cu SARTATE™ at four and 20 hours post-administration to the current standard of care, ⁶⁸Ga DOTATATE, at one hour.

The DISCO trial is building on the promising data from the SARTATE™ NETs Phase I study, a successfully completed diagnostic imaging clinical trial evaluating ⁶⁴Cu SARTATE™ in patients with grade one or two NETs, which was led by Professor Rodney Hicks at the Peter MacCallum Cancer Centre, Australia. Ten participants were enrolled in this study and PET/CT imaging scans were performed over 20 hours. The product was shown to be safe and able to identify SSTR2 positive tumours. It was found to be comparable to ⁶⁸Ga DOTATATE (NETSPOT®), when imaged at one hour, while comparable or improved lesion detection over ⁶⁸Ga DOTATATE was observed at 4 hours.

Superior lesion detection at 4h with ⁶⁴Cu-SARTATE in the same patient compared to ⁶⁸Ga-DOTATATE images at 1h in the same patient



SAR-Bombesin

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).

The diagnostic trial of ^{64}Cu SAR-Bombesin (C-BOBCAT), led by Prof Louise Emmett at St Vincent's Hospital Sydney, has progressed well since its commencement in July 2020 and shown promising preliminary results in breast cancer patients. C-BOBCAT is a pilot trial 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).

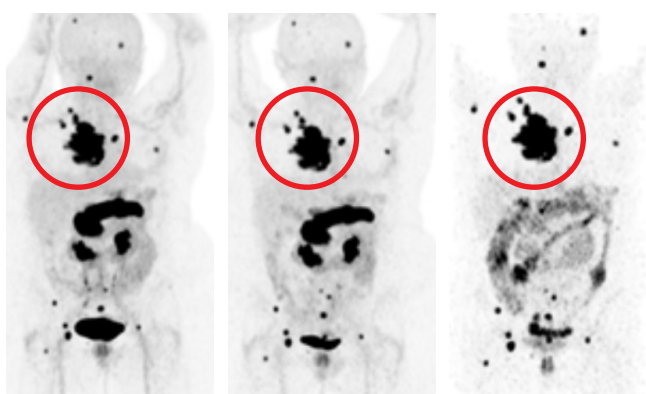
C-BOBCAT was closed early in October 2021 having been used in 7 patients with ER/PR positive metastatic breast cancer under the C-BOBCAT trial and a number of patients were treated with ^{64}Cu SAR-Bombesin via the Therapeutic Goods Administration (TGA) Special Access Scheme (SAS) in both breast and prostate cancer patients. The diagnostic program generated evidence of the utility and potential superiority in some patient subgroups compared to conventional imaging (e.g. $^{99\text{m}}\text{Tc}$ bone scan, ^{18}F FDG).

The high uptake and strong product retention visualised by PET imaging of patients at 1, 3 and 24 hours after product administration suggest significant potential for therapy applications with ^{67}Cu SAR-Bombesin.

Clarity has received overwhelming interest from clinicians in using SAR-Bombesin for better management of PSMA-negative prostate cancer, with early clinical evidence being very promising as the company looks to explore the clinical development of SAR-Bombesin in the US and Australia. Clarity is continuing to be asked for access to this product under the TGA's SAS for PSMA-negative prostate cancer, and given our experience and networks in prostate cancer, we are excited to move this product forward in clinical development in 2022.

The final data from the C-BOBCAT trial will be presented 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

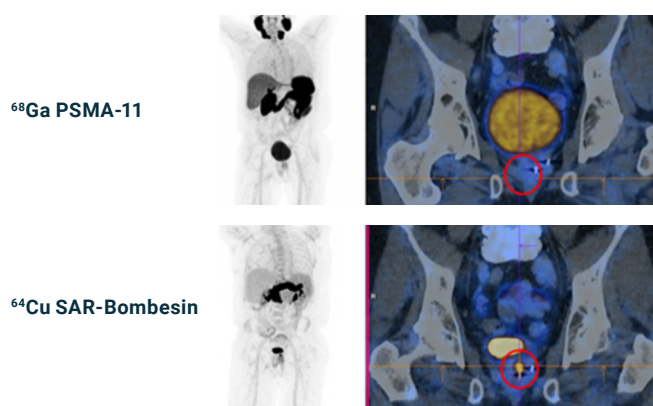


T = 1 hour

T = 4 hours

T = 24 hours

^{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 AND SUPPLY OF RADIOPHARMACEUTICALS

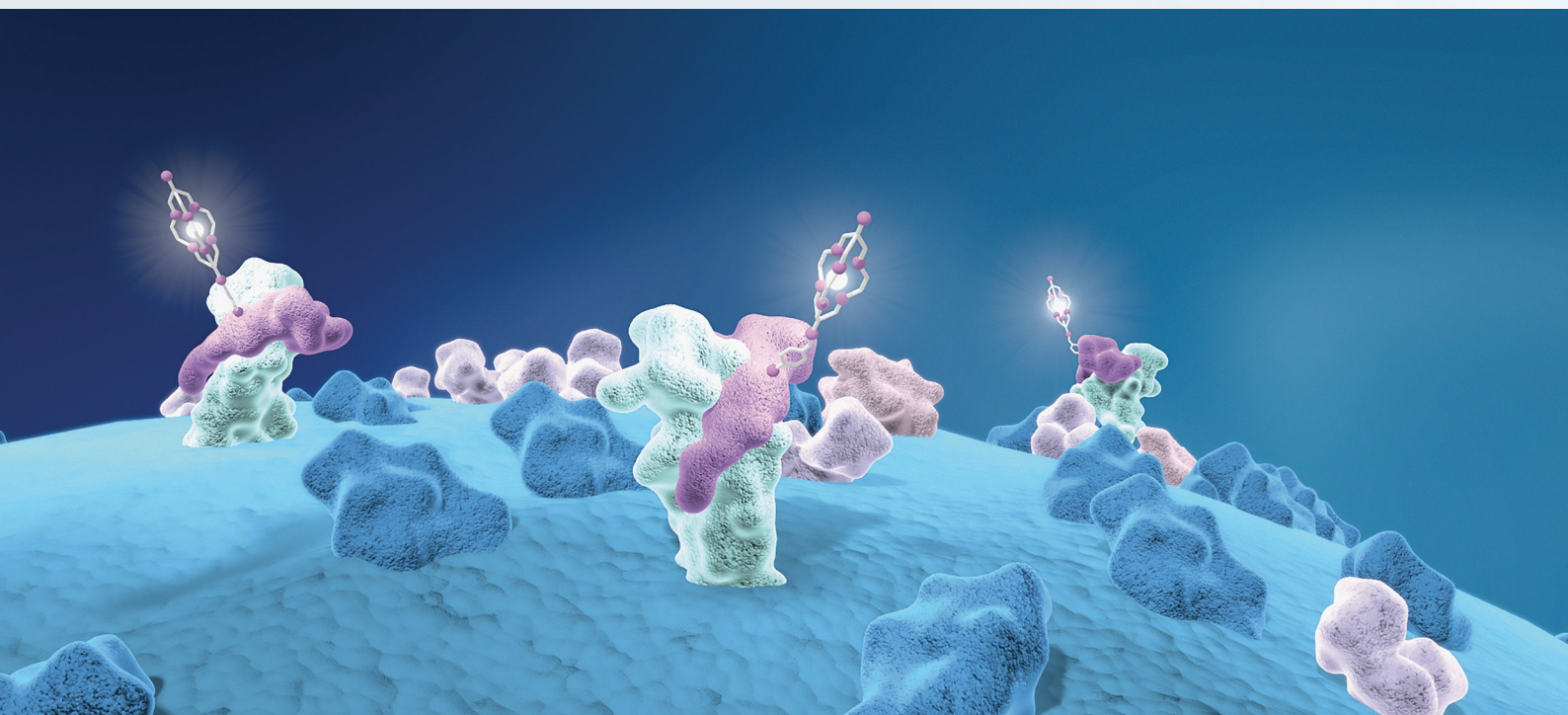
Manufacturing and logistics

The manufacturing and logistics are critical for the supply of radiopharmaceuticals. To support clinical growth and future commercialisation, Clarity has been actively extending its manufacturing and logistical footprint in the US by signing a number of key agreements and securing key memberships, 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
- Copper-67 supply agreement with **NorthStar Medical Isotopes, LLC.** for the exclusive supply of copper-67 to Clarity on 23 May
- Membership and a Board position on the **Council on Radionuclides and Radiopharmaceuticals, Inc (CORAR)** on 22 September

These agreements and membership will support the rollout of the TCT platform and getting "ready-to-use" TCT products to patients at any location in the US.

Clarity's ongoing clinical trials help to validate our on-demand distribution model where products have been shipped to the trial sites across Australia and the US from central manufacturing facilities with minimal delays or interruptions. There is a significant demand for the new generation of radiopharmaceuticals that can supply multiple large indications in the oncology space and shift the radiopharmaceutical field towards the "big pharma" model with central manufacture of ready-to-use products. This shift has potential to significantly improve patient care by focusing on the needs of patients and enable their treating staff to access critical treatments that are safe and efficacious, on time and at any treatment centre with a PET camera.



The radiopharmaceutical field and radioisotope supply

Radiopharmaceuticals are a relatively small sector in the larger oncology market; however, it is expected to grow from US\$6B in 2021 to US\$33B in 2031 globally.⁶

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 deliveries⁷. 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 ⁶⁴Cu and ⁶⁷Cu provide both manufacturing and supply advantages compared to the current generation of radiopharmaceuticals, offering potentially significant benefits in the commercialisation and clinical development of TCT.

DIAGNOSTIC RADIOISOTOPES

Current diagnostic radiopharmaceuticals that rely on gallium-68 (⁶⁸Ga) or fluorine-18 (¹⁸F) 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^{8,9}. 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, ⁶⁴Cu based diagnostics can be produced on cyclotrons at commercial scale (>500 patient doses per run). Importantly, the 12.7 hour half-life of ⁶⁴Cu 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 nuclear reactors globally. Most recently, the EU, currently the world’s biggest producer of molybdenum-99, 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, next year.¹⁰ These shortages are also expected to impact the roll-out of lutetium-177 (¹⁷⁷Lu) based products, which will severely hinder the growth of radiopharmaceuticals moving forward.

Surprisingly, the United States is not a major source of radionuclides and imports almost all large-scale radionuclides, leaving the US dependent on foreign sources (Europe, Australia and South Africa).⁶ Given its reliance on the small and aging fleet of reactors in Europe, this poses an acute risk to US supply.

The production of ⁶⁷Cu 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 ⁶⁷Cu, which stands in stark contrast to nuclear reactor production of ¹⁷⁷Lu that requires both uranium fuel and the rare earth metal, ytterbium, as inputs for production, carrying environmental and supply risks.

All of this means that Clarity’s proprietary TCT approach addresses two substantial market challenges. By leveraging our inherent supply advantages with ⁶⁴Cu based diagnostics, we have created a supply chain which provides universal access in the US, even in phase I trials. Moreover, we offer dependability and scalability with our ⁶⁷Cu therapeutic platform, which is not possible with ¹⁷⁷Lu.

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.

In February 2021 Clarity has successfully completed the assignment of its key patent portfolio from the University of Melbourne, providing Clarity with the full rights and ownership of the patents.

Since then, Clarity has significantly strengthened patent protection of its optimised Prostate Specific Antigen (PSMA) targeting agent, SAR-bisPSMA, as the company entered two clinical trials in prostate cancer with this product in 2021 following very promising results from

preclinical studies. In May, the U.S. Patent and Trademark Office has granted the patent application for Clarity's SAR-bisPSMA compound and its variants. In November, the patent application covering formulations of SAR-bisPSMA has entered the national phase in multiple jurisdictions, including the USA, Europe and China. These milestones significantly bolster Clarity's already strong IP position on the targeting agent for imaging and treatment of prostate cancer.

The evolving patent protection on the SAR-bisPSMA agent 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. In December 2020 we also closed a pre-IPO \$25 million capital raise. With these two investment rounds we are now well funded, with almost **AU\$100 million in the bank**, to continue the clinical development of our pipeline of next-generation radiopharmaceutical products addressing the growing demand for the use of radiopharmaceuticals in oncology.

China Grand Pharmaceutical and Healthcare

China Grand Pharmaceutical and Healthcare Holdings Ltd (China Grand) has entered into discussions, on an exclusive basis, regarding a proposal for Clarity to grant China Grand a licence of the right to develop, manufacture and commercialise one or more of the Company's products in the Greater China territory (being Mainland China, Hong Kong (SAR), Macau (SAR) and Taiwan) on terms to be agreed. The negotiations of the license are ongoing. As part of these discussions, Clarity granted China Grand a total of 25,543,912 options at an exercise price of \$1.75 per option on the 1st of July 2021.

Clarity Team

At the core of Clarity's success is our people. Over time we have assembled an exceptional team, including our 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. We have continued to attract extraordinary talent, even with the drawbacks and hindrances presented by the pandemic, and expanded our clinical and operations teams to keep up with our clinical programs. Key additions in 2021 include Mr Robert Thomas to our Board and Mr Shaemus Gleason as an Executive Vice President, US Operations, amongst others.

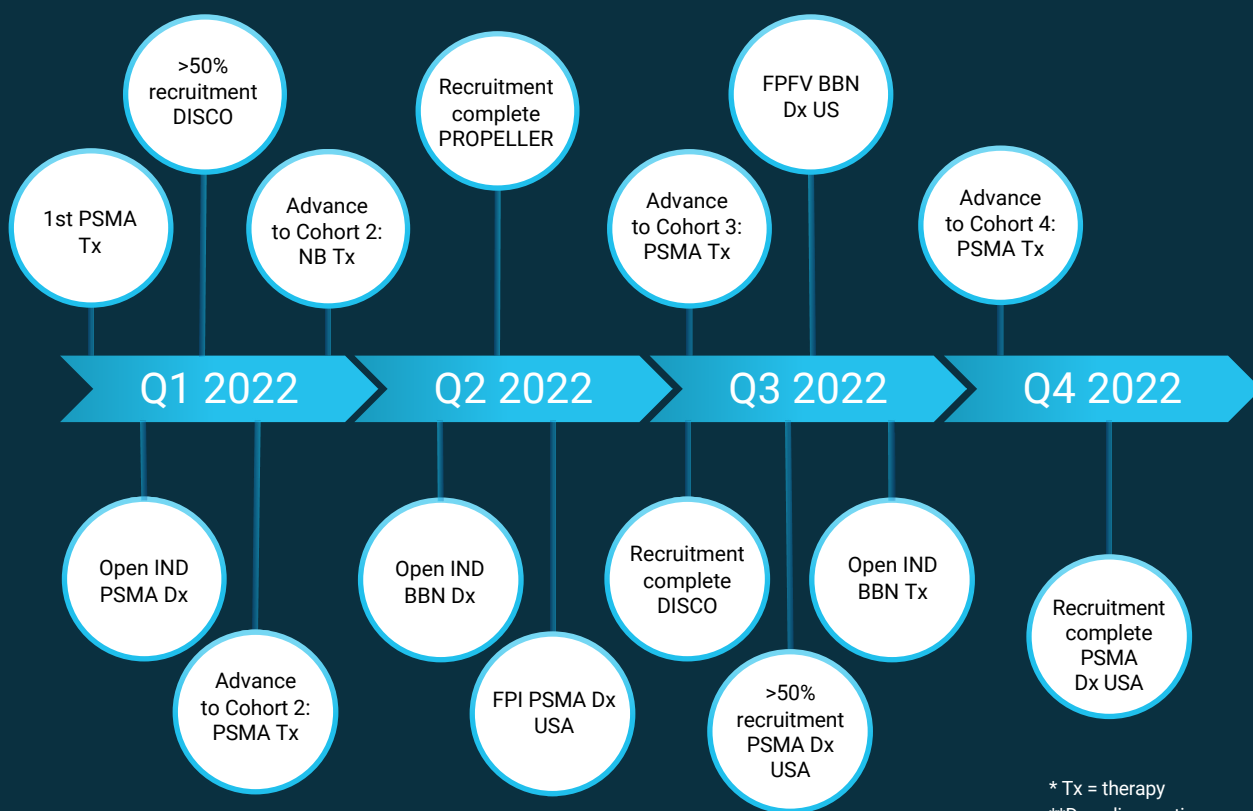
Environmental, Social and Governance (ESG) commitments

Clarity is committed to being an employer of choice and an investment for our shareholders to be proud of. As such, our goal is to be at the forefront of the ESG practices in the biotechnology sector. As part of this commitment, we are 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. We pride ourselves on a strong governance structure for a company of our size, with an exceptionally experienced Board and management team. We are ambitious with our social responsibility goals, already in evidence through the translation of great Australian science towards our ultimate goal of better treating children and adults with cancer.

Clarity has recently committed to further applying itself to social causes, including working closer with Australian groups focused on the management of neuroblastoma (given the theranostic neuroblastoma trial is being conducted in the US). We are also excited about our recent 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 in our local community of Redfern. We see ESG as a major area of focus for Clarity to clearly differentiate itself and will continue to update our shareholders on further progress in these areas.

INFLECTION POINTS IN 2022



* Tx = therapy
**Dx = diagnostic



References

1. **ClinicalTrials.gov Identifier: NCT04868604** <https://clinicaltrials.gov/ct2/show/NCT04868604>
2. **ClinicalTrials.gov Identifier: NCT04839367** <https://clinicaltrials.gov/ct2/show/NCT04839367>
3. **ClinicalTrials.gov Identifier: NCT04023331** <https://www.clinicaltrials.gov/ct2/show/NCT04023331>
4. **ClinicalTrials.gov Identifier: NCT04438304** <https://www.clinicaltrials.gov/ct2/show/NCT04438304>
5. **SNMMI, 6 August 2018, "Shortage of Germanium-68/Gallium-68 Generators for the Production of Gallium-68",** <https://s3.amazonaws.com/rdcms-snmml/files/production/public/Ga68%20shortage%20letter.pdf>
6. **MEDraysintell Nuclear Medicine, Report and Directory (Part 1) 8th Edition: June 2021**
7. **Xconomy: Why Good Drugs Sometimes Fail: The Bexxar Story,** <https://xconomy.com/national/2013/08/26/why-good-drugs-sometimes-fail-in-the-market-the-bexxar-story/>
8. **Ga-68 PSMA-11 Package Insert, Revised 12/2020,** https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212642s000lbl.pdf **accessed Nov 29, 2021**
9. **Fludeoxyglucose F18 Injection Package Insert, Revised 7/2010,** https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021870s004lbl.pdf **Accessed Nov 29, 2021**
10. **Ligtvoet, A., Scholten, C., Dave, A., King, R., Petrosova, L. and Chiti, A., Study on sustainable and resilient supply of medical radioisotopes in the EU, Goulart De Medeiros, M. and Joerger, A. editor(s), EUR 30690 EN, Publications Office of the European Union, Luxembourg, 2021, ISBN 978-92-76-37422-0, doi:10.2760/642561, JRC124565.**