



ESG REPORT

2023



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About this report

This report describes Clarity Pharmaceuticals Ltd and its subsidiaries (Clarity's or the Group's) Environmental, Social and Governance (ESG) framework and practices as well as the Group's interactions with its stakeholders, the broader community, and the environment. In developing this ESG report, Clarity has been guided by recognised standards of ESG reporting, in particular, SASB's Biotechnology & Pharmaceuticals Sustainability Accounting Standard.

This report pertains to Clarity and its controlled entities during the reporting period from 1 July 2022 to 30 June 2023 (FY2022-2023). All dollar values refer to Australian dollars (AUD) unless otherwise specified.

Clarity acknowledges and pays respect to the past, present and future Traditional Custodians and Elders of the land of its headquarters, the Gadigal people of the Eora nation, and the Traditional Owners of Country throughout Australia.

2023 AT A GLANCE

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.

6 PRODUCTS IN CLINICAL TRIALS



2 RARE PAEDIATRIC DISEASE DESIGNATIONS



2 ORPHAN DRUG DESIGNATIONS



5 ACTIVE FDA INVESTIGATIONAL NEW DRUG APPLICATIONS



7 ACTIVE CLINICAL TRIALS IN ONCOLOGY



1 COMPLETED CLINICAL TRIAL IN ONCOLOGY

1 INVESTIGATOR-INITIATED TRIAL IN ONCOLOGY



61% OF WORKFORCE FEMALE



29% OF THE BOARD IS FEMALE



3 SCIENTIFIC AND CLINICAL CONFERENCES AND WORKSHOPS SPONSORED



4 CHARITIES SUPPORTED

COMPASSIONATE ACCESS GRANTED FOR A RANGE OF DIAGNOSTIC AND THERAPEUTIC PRODUCTS

OUR COMMITMENT TO ESG

Clarity's Executive Chairperson, Dr Alan Taylor

We are pleased to present Clarity's Environmental, Social and Governance report for the year ended 30 June 2023.



We are pleased to present Clarity's Environmental, Social and Governance report for the year ended 30 June 2023.

At Clarity, we strive to apply innovative thinking to all parts of our business – not just to our science, but also in the way we deal with the environmental, social and governance aspects, which are core to Clarity's values.

Clarity is focusing on developing "best-in-class", innovative, evidence-driven products based on our proprietary platform technology. We are driven by our ultimate mission of improving treatment outcomes for children and adults with cancer. As such, the social aspect of ESG is truly at the forefront of our mission and values.

We strive to employ and retain the best talent in the life sciences. Our team is at the core of our success and with only 41 employees across Australia and the US in the FY2022-2023, we have achieved remarkable progress. We continue to nourish a culture of inclusion, superior performance, and respect for shared values, and are committed to staff development, as evidenced by our high rates of training & development as well as internal promotion. We continue to place a value on diversity and inclusion through the entirety of our Company, creating flexible working arrangements to accommodate the needs of our team members. We want to ensure that Clarity continues being an employer of choice and a workplace to be proud of by all, regardless of their race, gender, nationality, family commitments, or any other attribute.

This commitment and enthusiasm of our small team has allowed us to progress the development of Clarity's three core product areas for a total of six products in eight clinical trials and an investigator-initiated trial (IIT) in the FY2022-2023.

Our SAR-bisPSMA product has continued to generate exciting data throughout the year in both theranostic and diagnostic trials. This product was designed to distinguish Clarity from the rest of the radiopharmaceuticals field in prostate cancer and the initial results already show great promise, especially for patients. The diagnostic ⁶⁴Cu-SAR-bisPSMA is progressing into a registrational Phase III trial, while the therapeutic ⁶⁷Cu-SAR-bisPSMA has progressed to its highest planned dose cohort, generating extremely promising results to date.

With our second product, SAR-Bombesin, we have also been exploring therapeutic and diagnostic benefits for prostate cancer patients, in particular those who have low or negative PSMA uptake. We successfully treated our first patient with ⁶⁷Cu-SAR-Bombesin in the theranostic Phase I/IIa trial, COMBAT, and completed recruitment into a diagnostic Phase II SABRE trial with ⁶⁴Cu-SAR-Bombesin. In addition to the SABRE trial, SAR-Bombesin is being investigated in an Investigator Initiated Trial (IIT) led by Prof Louise Emmett at St Vincent's Hospital, Sydney and the exciting initial data was presented at one of the most prestigious nuclear medicine conferences in the world, European Association of Nuclear Medicine (EANM) 2023 Congress in Vienna, Austria.

We consider this IIT another great success story of Australian scientists and clinicians working together to develop novel products that may change the lives of cancer patients.

With our third product, SARTATE, we remain committed to improving treatment outcomes for children with cancer in our theranostic ⁶⁴Cu/⁶⁷Cu-SARTATE trial for children with neuroblastoma. We have now successfully completed the first three cohorts of the trial and are recruiting in the final cohort of the dose escalation phase. We are also progressing a diagnostic ⁶⁴Cu-SARTATE product in neuroendocrine tumours (NETs).

Clarity receives strong support from its collaborators, a community of world leading researchers and clinicians. Australia is often seen as a country with great science that often performs poorly on measures of translation of science from the benchtop. Clarity was founded on the platform of great Australian science and today we continue to build our story, progressing basic research from the benchtop of some of the best universities in the country, through preclinical studies and into the clinic where it has the potential to improve the lives of people suffering from terminal disease such as cancer. We believe this is a guiding light for how translation can be accomplished in Australia and an example for our own ecosystem of how we can do this better for the future benefit to scientists, clinicians, universities, and all of the patients and their families through the treatment of disease.

Clarity's Targeted Copper Theranostic (TCT) platform enables a number of environmental advantages over the first- and current-generation radiopharmaceuticals due to the unique characteristics of copper isotopes. The therapeutic copper-67 completely removes the reliance on an antiquated fleet of nuclear reactors, where shutdowns and maintenance breaks are common, reduces radioactive waste, reliance on rare earth elements for source material and resolves the logistical and manufacturing inefficiencies associated with the rest of radiotherapies.

The diagnostic copper-64 is also enabling a number of environmental advantages due to its longer half-life and shelf-life. As the radiopharmaceutical field is rapidly expanding into the global oncology market, the environmental impact of producing and commercially distributing these products cannot be overlooked.

We are committed to continue embedding a sound ESG platform into the culture of our company as it grows. This report showcases how we are integrating ESG policies and practices into our overall strategic objectives and sets clear goals to ensure Clarity remains at the forefront of our industry within an ESG framework.

Our remarkable progress in developing a pipeline of three potentially "best-in-class" products is an outstanding achievement in the industry for a company of Clarity's size. We recognise and celebrate the efforts and commitment to our shared mission from our diverse and dedicated team and collaborators and we look forward to utilising our ESG platform as we continue generating exciting data in all of our trials.



Dr Alan Taylor
Executive Chairperson
Clarity Pharmaceuticals

We recognise and celebrate the efforts and commitment to our shared mission from our diverse and dedicated team and collaborators

OUR MISSION AND VALUES

MISSION

Our mission is to develop next-generation products that improve treatment outcomes for children and adults with cancer.

VALUES



INNOVATION

We strive to use novel solutions and state-of-the-art technology to foster innovation and promote positive change in the space of personalised medicine and targeted radiopharmaceuticals.



THOUGHT LEADERSHIP

We are determined to gain insight from industry thought leaders to ensure that our strategy is up to date with the most recent scientific and technologic advancements and to use cutting edge solutions to guarantee commercial success and significantly improve patient health.



COLLABORATION

We believe that collaboration on many different levels is the driving force behind progress and is at the core of Clarity's strategy. The Company promotes collaboration among its employees, shareholders, suppliers, customers, governments, universities, R&D institutes, and key opinion leaders in the industry with the aim of strengthening and diversifying its knowledge in the radiopharmaceutical field.



RELIABILITY AND TRUST

We aim to establish relationships that are based on strong mutual trust to create an environment where all parties involved work towards a common goal, knowing their input will be valued and respected. Members of the Company are expected to make and meet commitments and conduct business with professionalism and integrity.



HONESTY AND INTEGRITY

We are committed to acting honestly and with integrity in all of Clarity's dealings, both internally and externally. The Company commits to only dealing with partners who demonstrate dedication to responsible and professional business practices.



ENVIRONMENT

We are committed to acting responsibly towards the environment.

STAKEHOLDER ENGAGEMENT



ABOUT CLARITY

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.

Targeted Copper Theranostic Platform

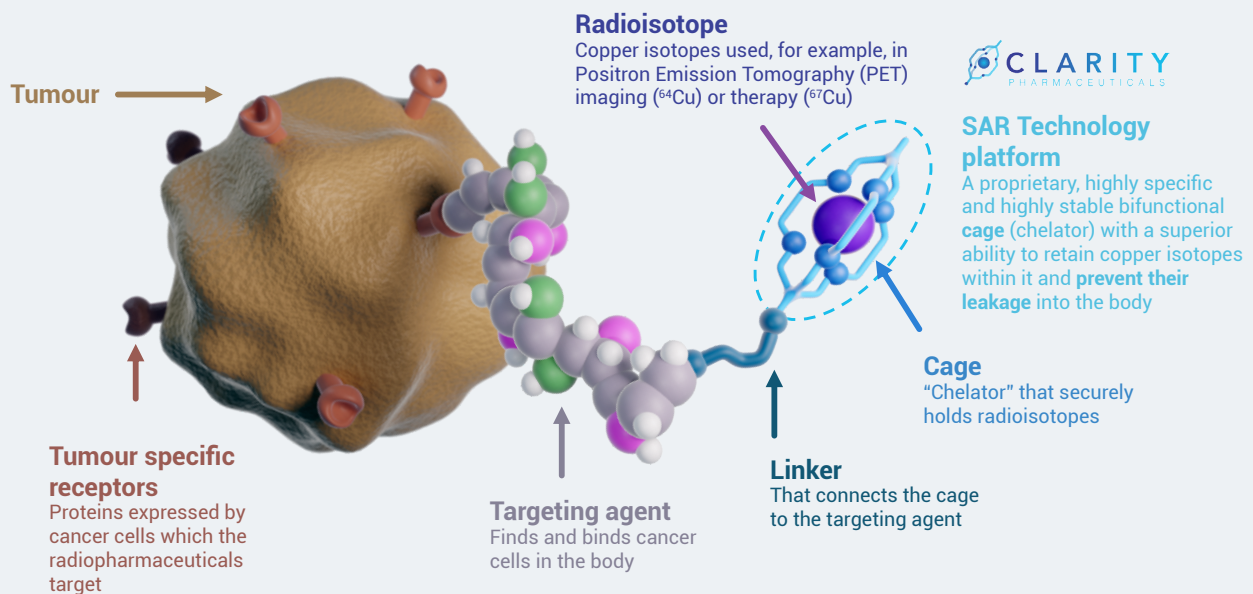
Clarity is a global leader in next-generation radiopharmaceuticals with its Targeted Copper Theranostic (TCT) platform of products.

Clarity has used its Proprietary SAR Technology, a true platform technology, to enable TCTs and develop three products with the potential for best-in-class performance.

TCTs offer significant supply, logistical and environmental advantages over the current generation of radiopharmaceutical products.

Perfect Pairing

Clarity's TCTs are a disruptive platform that employs the "perfect pairing" of copper isotopes, copper-64 (^{64}Cu or Cu-64) for imaging and copper-67 (^{67}Cu or Cu-67) for therapy, which deliver a compelling combination of high accuracy and high precision in the treatment of a range of cancers.



CORE PRODUCT PORTFOLIO

Clarity's three core product areas, being SARTATE, SAR-bisPSMA and SAR-Bombesin, are currently in clinical development for both diagnosis and treatment of various cancers and address unmet clinical needs.

Clarity's three core products, SAR-bisPSMA, SAR-Bombesin and SARTATE, are all TCTs based on the SAR Technology that employs a chelator (or "cage") that securely holds copper isotopes inside. Each product contains a distinct targeting agent, binding to different receptors that are present on different cancer cells. By using isotopes of copper inside the chelator, these products can be used to diagnose (with Cu-64) or treat (with Cu-67) a range of cancers in children and adults.

SAR-bisPSMA

has been optimised with two targeting agents that bind to prostate specific membrane antigen (PSMA), which is present in the majority of prostate cancers.

SAR-Bombesin

targets the gastrin releasing peptide receptor (GRPr), a receptor present across a range of cancers, including breast and prostate cancers.

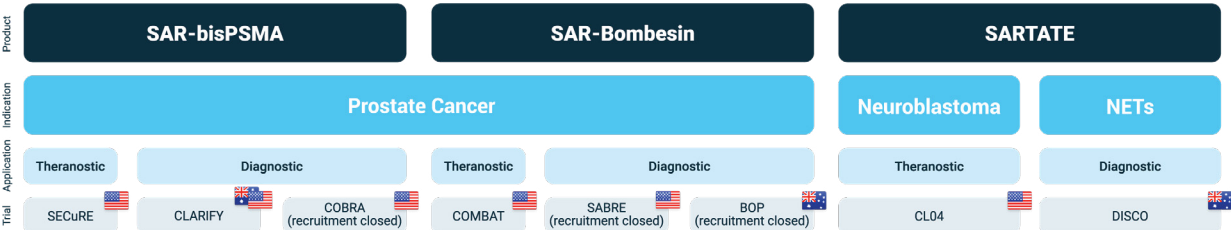
SARTATE

targets the somatostatin receptor 2 (SSTR2), which is present in an aggressive childhood cancer, neuroblastoma, as well as neuroendocrine tumours (NETs), among other cancers.

TCTs provide a scalable, dependable, cost-effective and environmentally friendly way to expand radiopharmaceuticals into the global oncology market.

CLINICAL TRIALS IN INDICATIONS WITH UNMET NEEDS

Clarity is actively progressing seven clinical trials of its three key products, SARTATE, SAR-bisPSMA and SAR-Bombesin. The trials are conducted in three theranostic (therapeutic and diagnostic) and four diagnostic indications. In addition to the Clarity sponsored trials, an investigator-initiated trial (IITs) with Clarity’s SAR-Bombesin product has closed recruitment, reported initial results and is currently awaiting full data analysis.



As of 23 November 2023

Clarity is conducting multiple clinical trials for each of its three key products, exploring both diagnostic and therapeutic opportunities, to expand their potential applications in a range of cancers. Clarity has a targeted clinical development strategy with the goal of commercialising diagnostic products in the United States (US) with the Food and Drug Administration (FDA) first, generating revenue to fund late-stage therapeutic trials.

In addition to these core clinical-stage products, SAR Technology is used in Clarity's Discovery Program, which explores new targeting agents, thereby creating new TCTs to expand the existing platform.

Clarity is committed to continuing its collaboration with thought leaders in the radiopharmaceutical field, scientists, researchers and clinicians to develop future-generation innovative treatments that can potentially improve treatment outcomes for children and adults with cancer.



ORPHAN AND RARE PAEDIATRIC CANCER

Clarity is developing both diagnostic and therapeutic treatments for neuroblastoma, an orphan and rare paediatric disease.

Clarity is developing both diagnostic and therapeutic products for neuroblastoma, an orphan and rare paediatric disease. Orphan diseases are those that affect less than 200,000 people in the US¹. A 'rare paediatric disease' (RPD) is a serious or life-threatening disease primarily affecting individuals aged 18 years or younger that impacts fewer than 200,000 people in the US².

Neuroblastoma most often occurs in children younger than 5 years of age and presents when the tumour grows and causes symptoms. It is the most common type of cancer to be diagnosed in the first year of life and accounts for around 15% of paediatric cancer mortality³. High-risk neuroblastoma accounts for approximately 45% of all cases. Patients with high-risk neuroblastoma have the lowest 5-year survival rates at 40%-50%⁴.

SARTATE is a next generation, highly targeted theranostic radiopharmaceutical. It is being developed for diagnosing, staging, and subsequently treating cancers that express somatostatin receptor 2 (SSTR2), including neuroblastoma. The SARTATE product can be used with ⁶⁴Cu for imaging or ⁶⁷Cu for therapy.

Clarity's CL04 trial is a theranostic (diagnostic and therapeutic) clinical trial in paediatric patients with high-risk neuroblastoma (NCT04023331)⁵. It is a multi-centre,

dose-escalation, open label, non-randomised, Phase I/IIa clinical trial with up to 34 participants currently conducted in the US. Not only the safety and tolerability of both ⁶⁴Cu-SARTATE and ⁶⁷Cu-SARTATE are being assessed, but also the effectiveness of ⁶⁷Cu-SARTATE as a treatment for neuroblastoma. Participants who show uptake of ⁶⁴Cu-SARTATE in lesions will continue in the trial and will receive treatment with ⁶⁷Cu-SARTATE.

In 2020, the FDA awarded Clarity two Orphan Drug Designations (ODDs), one for ⁶⁴Cu-SARTATE as a diagnostic agent for the clinical management of neuroblastoma and one for ⁶⁷Cu-SARTATE as a therapy for neuroblastoma, as well as two Rare Paediatric Disease Designations (RPDDs) for these two products.

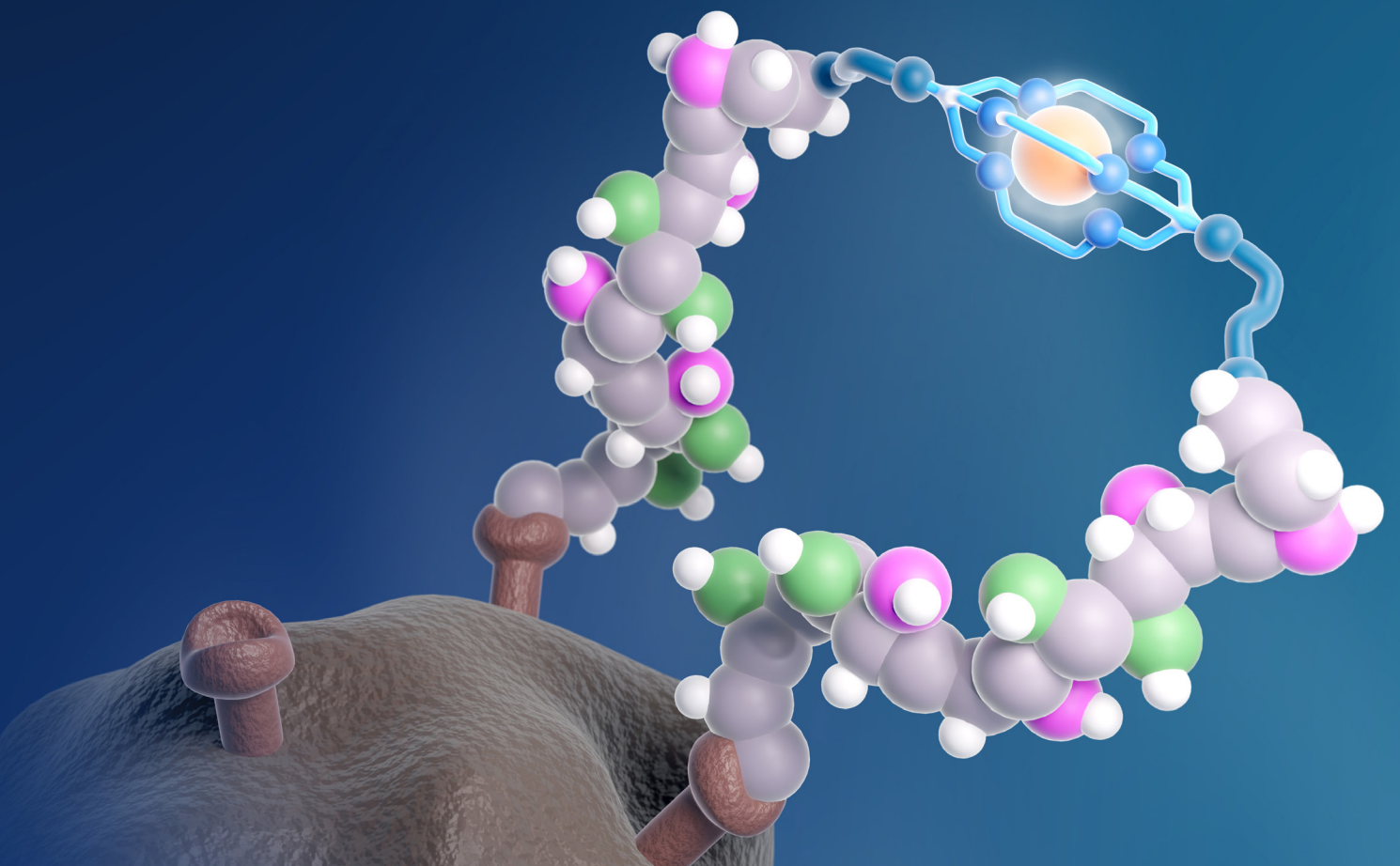
The RPD program by the US FDA is intended to facilitate development of new drugs for the prevention and treatment of RPDs. As part of this program, the FDA provides various incentives including the potential for a Priority Review Voucher (PRV) to be awarded. PRVs are incentives meant to spur the development of new treatments for diseases that would otherwise not attract development interest from companies due to the smaller market opportunities.



LARGE ONCOLOGY INDICATIONS

Prostate cancer is the second most common cancer diagnosed in men globally and the fifth leading cause of cancer death worldwide⁶. The American Cancer Institute estimates in 2023 there will be 288,300 new cases of prostate cancer in the US and around 34,700 deaths from the disease⁷.

Prostate cancer is a key focus of Clarity's TCT program. It is an indication with several patient categories with high unmet needs. As such, Clarity is progressing two product areas with both diagnostics and therapies, being a total of 4 products, in prostate cancer indications, SAR-bisPSMA and SAR-Bombesin, with two theranostic trials and three diagnostic trials progressing well. The diagnostic program is evolving rapidly and a registrational Phase III trial with SAR-bisPSMA in pre-prostatectomy prostate cancer patients is expected to commence recruitment in late 2023. Additionally, two diagnostic trials with SAR-bisPSMA and SAR-Bombesin in BCR prostate cancer closed recruitment successfully in 2023 and data from these trials will drive Phase III planning in these indications. During and since the reporting period, a diagnostic Investigator-Initiated Trial (IIT) with Clarity's ⁶⁴Cu-SAR-Bombesin product, led by Prof Louise Emmett, was completed with initial data presented at the European Association of Nuclear Medicine (EANM) Annual Meeting 2023, one of the most prestigious nuclear medicine conferences in the world. Clarity's strategy is to get diagnostic products to market first in order to fund the development of late stage therapy programs.



SAR-bisPSMA

SAR-bisPSMA is a next generation, theranostic radiopharmaceutical with optimised dual PSMA-targeting agents to improve uptake and retention of the product in tumours. It is being developed for diagnosing, staging and subsequently treating cancers that express PSMA. The product uses either copper-64 (^{64}Cu) for imaging (^{64}Cu -SAR-bisPSMA) or copper-67 (^{67}Cu) for therapy (^{67}Cu -SAR-bisPSMA).

SAR-bisPSMA was developed at the bench top of the University of Melbourne in collaboration with Professor Paul Donnelly with the intent of overcoming the shortfalls of the current generation of PSMA-targeting products which show only moderate uptake in tumours and tend to wash off the receptor over time. SAR-bisPSMA was optimised with two PSMA-targeting agents, which not only increased the amount of product in the lesions, but also increased how long the product was retained in the lesions over time, making it an ideal candidate for diagnosis and therapy.

Clarity's theranostic Phase I/IIa SECURE trial (NCT04868604)⁸ in metastatic Castrate-Resistant Prostate Cancer (mCRPC) with ^{64}Cu -SAR-bisPSMA and ^{67}Cu -SAR-bisPSMA is progressing well through the dose escalation phase. The highest dose level cohorts will assess both single and double doses of ^{67}Cu -SAR-bisPSMA at 12GBq, which will then be followed by a Phase II multi-dose cohort expansion, pending safety evaluation.

Clarity is also running two diagnostic trials in line with advice received from the US FDA to address the two relevant patient populations for registration of ^{64}Cu -SAR-bisPSMA:

- Registrational Phase III CLARIFY trial (NCT06056830)⁹ in pre-prostatectomy/pre-definitive treatment of patients with confirmed prostate cancer – expected to open for recruitment in CY2023.
- Phase II COBRA trial (NCT05249127)¹⁰ in patients with biochemical recurrence (BCR) of prostate cancer – top line data expected in CY2023.

SAR-Bombesin

SAR-Bombesin is a highly targeted pan-cancer theranostic radiopharmaceutical. It is being developed for diagnosing and selecting patients for subsequent treatment of cancers that express a specific receptor called the Gastrin Releasing Peptide receptor (GRPr), including prostate and breast cancers. Like all Clarity products, the SAR-Bombesin product uses copper-64 (^{64}Cu) for imaging (^{64}Cu -SAR-Bombesin) or copper-67 (^{67}Cu) for therapy (^{67}Cu -SAR-Bombesin).

Approximately 20% of prostate cancer patients with BCR are PSMA-PET negative^{11,12,13,14} and approximately 25% of mCRPC patients have low or no uptake of a PSMA-targeting tracer¹⁵. These patients are unlikely to show meaningful uptake of PSMA-targeted products, such as ^{68}Ga -PSMA-11 for imaging, and therefore may not be eligible for a PSMA-targeted treatment, such as ^{177}Lu -PSMA-617. Currently these patients have few therapy options available to treat their cancer. SAR-Bombesin is being investigated in three clinical trials in prostate cancer indications:

- Theranostic Phase I/IIa COMBAT trial in the US (NCT05633160)¹⁶ in patients with mCRPC – cohort 1 recruiting.
- Diagnostic Phase II SABRE trial in the US (NCT05407311)¹⁷ in patients with BCR of prostate cancer – recruitment completed, study ongoing with results planned for CY2024.
- Diagnostic Phase IIa trial in Australia (BOP NCT05613842)¹⁸ in patients with BCR and mCRPC – IIT led by Prof Louise Emmett – recruitment completed, BCR cohort results presented at EANM 2023.

While the clinical development path for SAR-Bombesin is focused on prostate cancer with negative or low PSMA expression, there is a significant opportunity to expand its use into the broader group of prostate cancer patients who have both GRPr and PSMA expression on their cancers, as well as into other cancers that express GRPr, such as breast cancer.

MANUFACTURING AND SUPPLY: THE GAME CHANGER IN RADIOPHARMACEUTICALS

As radiopharmaceuticals become a standard-of-care treatment option in a number of cancers and become more relevant in large indications, logistical and manufacturing considerations cannot be overlooked. With the projected future growth of radiopharmaceuticals, the current generation of radiopharmaceuticals already struggle to meet the demands of large oncology indications, such as prostate cancer.

TCTs' key differentiators are their logistical and manufacturing advantages associated with the perfect pairing of copper isotopes for diagnostic imaging (copper-64) and therapy (copper-67). Combined with clinical benefits, which Clarity is actively exploring through its clinical program, these differentiators are the reason TCTs are considered the next generation of radiopharmaceuticals. They enable Clarity to employ the big pharma model of centralised manufacturing of both diagnostic and therapeutic products under current Good Manufacturing Practice (cGMP), something that the current generation of products is lacking.

Establishing dependable, scalable, and sustainable manufacturing processes and supply chain is critical when considering the roll-out of radiopharmaceuticals into the large oncology market. A number of radiopharmaceuticals have shown significant benefit to patients but failed at delivering these life-saving treatments to them and their healthcare providers due to supply chain and manufacturing constraints.

The advantages of TCTs over the current-generation products show promise of launching the radiopharmaceuticals from what is now a small, niche industry and into the large oncology market, potentially offering an improved treatment paradigm with more readily available products for children and adults with cancer.

Copper-67

Copper-67 is a therapeutic isotope that is produced on electron accelerators, which are relatively inexpensive and infinitely scalable in all geographies of the world, including the US, Europe and Asia. Other commonly used therapeutic isotopes are produced on a small number of aging nuclear reactors with frequent supply interruptions and shutdowns^{19,20,21,22}. Outages at any of these reactors often cause shortages of therapeutic isotopes worldwide.

Clarity's partner, NorthStar, is now routinely producing copper-67 at its state-of-the-art production accelerator facility in Wisconsin, US. Their large-scale production of copper-67 uses a highly efficient, environmentally preferable electron accelerator technology and, under the Master Supply Agreement, NorthStar supply copper-67 exclusively to Clarity to support its TCT programs.

NorthStar complements Clarity's ongoing supply from the Idaho Accelerator Center (IAC), a research institute of Idaho State University (ISU), which

pioneered a new process for therapeutic copper-67 production and has been supplying copper-67 for all of the Company's pre-clinical and clinical development over the last 8 years.

To enhance its ongoing collaboration with ISU and IAC, Clarity has established a Center of Excellence. This initiative is aimed at advancing the commercial readiness of TCTs that are in clinical development. Additionally, it offers ISU students innovative career opportunities in the field of theranostic radiopharmaceuticals.



Copper-64

Copper-64 is a diagnostic imaging isotope that facilitates a significantly longer product shelf-life than most commonly used radio-diagnostics on the market, allowing for central manufacture and direct distribution. In contrast, current-generation diagnostics are based on isotopes with shorter half-lives²³ that have to be produced at or near the treatment centres to deliver the products to patients before they expire. This requires an expensive and extensive network of cyclotrons, radioisotope generators and radiopharmacies.

Copper-64 is produced in large volumes on cyclotrons and the finished diagnostic products can potentially be shipped for administration to any treatment centre in the US or Australia with a PET camera, meaning more hospitals and treatment facilities can be reached with Clarity's TCT products and more patients can be diagnosed in regional areas where the current-generation of PET diagnostics are unavailable.

This is especially relevant to diseases such as prostate cancer in the US where a significant majority of patients are treated in a community setting rather than large hospitals.

TCT manufacturing

TCTs can be produced on-demand in a centralised cGMP facility, thus allowing the finished radiopharmaceutical product to be delivered directly to hospitals and clinics for patient dose administration. All TCT products are manufactured at room temperature, significantly lowering the risk of batch failures, which historically has been a challenge for current-generation radiopharmaceuticals that require heating the biological targeting agents to 90°C during manufacture²⁴.

COMPASSIONATE USE OF CANCER TREATMENTS

Compassionate use refers to a potential pathway for a patient with a serious or immediately life-threatening disease or condition to gain access to an investigational medical product prior to health authority approval for treatment outside of clinical trials when no comparable or satisfactory alternative therapeutic options are available²⁵.

Compassionate use programs are important for selected patients in need. Multiple studies have shown a clear survival benefit and increased response with the use of innovative treatments. Drug approval is a lengthy procedure that might exceed the time frame of a life-threatening disease for a patient. Compassionate use provides options to patients with unmet needs while also generating safety and efficacy data about the product²⁶.

As a leader in next-generation radiopharmaceuticals, Clarity recognises the importance of supporting patients in cases where there are no satisfactory authorised medicines or clinical trials for which they are eligible. The Company also acknowledges the need for strict controls and processes regarding approval of medicines before making them available. As such, there is a comprehensive program and process in place for considering and approving the use of Clarity's products under compassionate use where the potential benefits outweigh the risks to the patients. Clarity has adopted clear rules and guidelines to consider these requests from the treating clinicians, focusing on the best interest of patients throughout the process.

Several patients have received various diagnostic or therapeutic products from Clarity's portfolio under the Expanded Access Program (EAP under the FDA in the US) or Special Access Scheme (SAS under the Therapeutics Goods Administration in Australia). Clarity's therapeutic product currently investigated in mCRPC in the SECuRE trial, ⁶⁷Cu-SAR-bisPSMA, was used outside of the trial under the EAP. During and since the reporting period, clinicians requested additional therapy cycles of ⁶⁷Cu-SAR-bisPSMA under the EAP for SECuRE trial participants in cohorts 1 and 2.

⁶⁷Cu-SAR-bisPSMA SPECT/CT images depicted on Figure 1 were collected 48 hours after the first and fourth administrations of 4GBq of ⁶⁷Cu-SAR-bisPSMA in a patient from cohort 1 who received three additional cycles under the EAP. Images collected following the fourth therapy cycle demonstrate a reduction in the intensity of the therapeutic ⁶⁷Cu-SAR-bisPSMA product uptake at the lesion sites outlined in the images. A reduction of greater than 50% in PSA levels was observed in this participant following the first administration of 4GBq of therapeutic ⁶⁷Cu-SAR-bisPSMA and a drop of greater than 90% in PSA was observed after the fourth cycle of 4GBq of ⁶⁷Cu-SAR-bisPSMA.

⁶⁷Cu-SAR-bisPSMA SPECT-CT (Fixed Scaling)

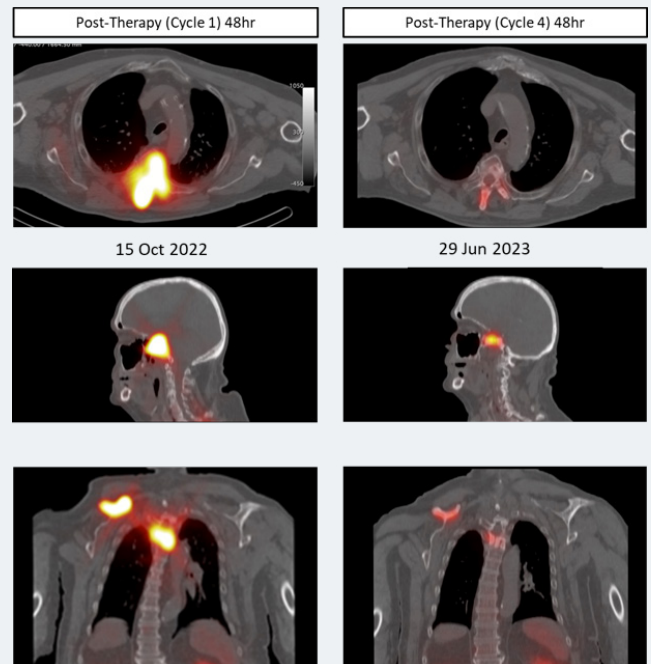


Figure 1. SPECT/CT imaging at 48hrs following cycle 1 (Oct 2022) and cycle 4 (Jun 2023) of 4GBq ⁶⁷Cu-SAR-bisPSMA showing considerable reduction in uptake of the product at the time of the 4th therapy cycle.

PATIENT HEALTH AND SAFETY

Clarity prioritises patient well-being in clinical trials and compassionate use programs involving its products. The Company is generating a body of preclinical and clinical safety and efficacy data.

Patient well-being is Clarity's top priority, and the Company maintains stringent measures and ethical practices to safeguard patient health throughout the trial process and management of its compassionate use programs. This involves rigorous adherence to Good Clinical Practice (GCP) guidelines and pharmacovigilance to safeguard the safety & well-being of patients. Quality assurance and quality control processes are in place to maintain high standards throughout each trial's lifecycle.

Clarity maintains a comprehensive quality system and conducts regular audits to guarantee the highest standards and quality across all its partnerships and operations, encompassing both internal and external aspects. Ensuring quality during clinical trials is a pivotal aspect of drug development and regulatory approval.



SUPPORTING AUSTRALIAN RESEARCH AND DEVELOPMENT

Australian science is at the heart of Clarity and the Company is committed to supporting and progressing local research and development.

The SAR Technology that underpins the TCT platform was invented and developed in Australia, at the Australian National University, University of Melbourne and Australian Nuclear Science and Technology Organisation. Clarity in-licensed the patent portfolio from these leading institutes and translated the findings from the bench-top to preclinical studies and all the way to the clinic where it continues to explore potential treatment benefits that it could bring to people suffering from cancer.

Clarity continues to work closely with Prof. Paul Donnelly of the University of Melbourne's Bio21 Institute on optimising and using the technology that forms the basis of the TCT products. To illustrate how significant this partnership has been, with his team at the Bio21 Institute, Prof. Donnelly developed PSMA targeting compounds using the SAR Technology. Initially the compounds synthesised had limited application, but with some clever and groundbreaking chemistry, the team was able to develop the PSMA dimer that is known as SAR-bisPSMA. This optimised product performs significantly better than the monomer compound SAR-PSMA and with those preclinical results in hand, this innovation enabled the translation to clinical development at Clarity. The Company is now seeing some very promising clinical results from its theranostic and diagnostic trials with SAR-bisPSMA, indicating "best-in-class" potential for these products.

In continual collaboration with Clarity for over a decade, Prof. Donnelly and his team also developed SARTATE and contributed significantly to the development of the SAR-Bombesin product.

In addition to the University of Melbourne, Clarity has supported a number of local Australian research organisations with funding and co-contributions to grants. In FY2022-2023, Clarity contributed to a successful grant application to establish the ARC Research Hub for Advanced Manufacture of Targeted Radiopharmaceuticals (AMTAR), in partnership with the University of Queensland, other universities and

radiopharmaceutical companies, both in Australia and overseas. AMTAR is an ~AUD15 million project, that aims to establish a manufacturing platform for new medical technologies and addresses industry-led challenges for translation of biologics as molecular radiopharmaceuticals. It aims to build capacity in biomanufacturing, radiobiology and radiochemistry. The program establishes a dedicated manufacturing pipeline, future-proofing production and securing supply chain of next-generation medical technologies. AMTAR will create significant onshore capability in radiopharmaceuticals and ensure the supply chain is fully supported in Australia. In collaboration with researchers in AMTAR at the University of Queensland, Clarity is soon to embark on 5 years of research along the lines of the themes of the Research Hub.

Clarity continues to collaborate closely with Australian researchers and clinicians. Prof Louise Emmett and her team at St Vincent's Hospital have been deeply involved and influential in progressing Clarity's SAR-Bombesin and SAR-bisPSMA products through 3 clinical trials, including IITs. During and since the reporting period, she has presented exciting initial data from her Phase II IIT of Clarity's diagnostic ⁶⁴Cu-SAR-Bombesin in prostate cancer at one the most prestigious nuclear medicine conferences in the world, European Association of Nuclear Medicine (EANM) 2023 Congress in Vienna, Austria.

In addition to the clinicians, researchers, trial sites and research institutes mentioned above, Clarity has been working closely with other Australian organisations, including Peter MacCallum Cancer Centre, Royal North Shore Hospital, Nepean Hospital, Royal Adelaide Hospital, GenesisCare SJOG Medical Clinic, South Australian Health and Medical Research Institute (SAHMRI) and many more.

Clarity is committed to translating great Australian science and giving back to the scientific community in hopes that the bright solutions invented by local researchers will help to improve people's lives.

OUR PEOPLE

Clarity is committed to its Core Values, which are built into its team culture and shared by its directors, managers, employees, contractors, and consultants.

The Company's Senior Executive Team promotes these values and aspires to foster a positive culture in the workplace. The values are instilled and emphasised through onboarding, team meetings and briefings. They are also supported by the Company's written policies and are embedded into its performance management system.

Clarity operates in an industry which requires a highly specialised and skilled workforce and where employee retention is crucial given the long-term nature of clinical development programs. The Company's greatest asset is its people and we strive to continue to maintain an

environment that nurtures and rewards our staff. With 41 employees in Australia and the US as of 30 June 2023, Clarity has achieved numerous significant milestones in this financial year in nine clinical trials, and an R&D pipeline and Discovery Program through the development of further novel modalities, which is an exceptional accomplishment in the industry. This achievement is testament to Clarity's inclusive culture, which aims to support its employees, promote diversity and flexible work conditions and build a high-performance environment with a strong sense of community.



INNOVATION



THOUGHT
LEADERSHIP



COLLABORATION



RELIABILITY AND
TRUST



HONESTY AND
INTEGRITY



ENVIRONMENT





Clarity is committed to making the Company a safe and rewarding place to work

Workplace labour practices & remuneration

Clarity has a workplace culture supported by a suite of policies ensuring its employees are treated and remunerated fairly. Clarity operates in Australia and the US and is mindful of the laws and regulations in the states that it employs staff. All staff have individual contracts which are in accordance with local legislation. All staff members are free to join representative associations.

Clarity's remuneration structure aims to:

- **Attract and retain exceptional people** to lead and manage the Company and to support internal development of executive talent, recognising that Clarity is operating in a competitive global radiopharmaceutical industry environment
- **Drive sustainable growth to shareholders**, as executives are set both short-term and long-term performance targets which are linked to the core activities necessary to build competitive advantage and shareholder value.
- **Motivate and reward superior performance** by the executive team whilst aligning performance elements/KPIs to the interests of shareholders.
- **Create a respectful, positive workplace culture** based on superior performance and core company values through appropriately structured individual assessments.

Clarity has a culture of internal promotion, and promoted 12% of its staff members to senior positions in FY22-23.

Health and safety

Clarity is committed to making the company a safe and rewarding place to work. It has policies and procedures in place to keep its staff safe, including a Work From Home policy, aiming to keep employees safe at home while they work remotely.

Clarity aims to:

- Identify and eliminate workplace hazards.
- Provide training to all employees to ensure they work in a safe and healthy manner and are aware of their responsibilities.
- Encourage employees to continuously improve health and safety practices and procedures.
- Prevent serious harm through early intervention and, if injured, support the employees through appropriate rehabilitation.
- Ensure all contractors, subcontractors and visitors are aware of the Company's health and safety management plan.
- Ensure compliance with prevailing health and safety legislation together with relevant regulations and codes of practice.
- Ensure all employees who are injured receive appropriate medical treatment and complete any necessary documentation in relation to the incident.
- Ensure first aid equipment and training is made available when in the office or on-site.

In FY2022-2023, Clarity had no reported lost time to injuries.

OUR PEOPLE CONT.

Diversity

Clarity hires staff based on talent, ability, and commitment to the team effort. The Company acknowledges the contribution of diverse skills and talents of its directors, officers, employees, contractors and consultants. Through this philosophy, Clarity's team comprises people representing a broad range of backgrounds, recognising the positive outcomes that can be achieved through a diverse workforce. To support and promote this contribution, the Company offers flexible work conditions and provides flexible return to work arrangements for staff who take parental or carer leave.


Clarity believes that by embracing diversity in its workforce, this enables the Company to:

- Attract, retain, and motivate employees from the widest possible pool of talented candidates.
- Develop and retain an appropriate skills base in the Company.
- Make more informed and innovative decisions, drawing on a wide range of ideas, experiences, approaches, and perspectives that employees from diverse backgrounds, and with differing skill sets, bring to their roles.
- Better represent the diversity of all of the Company's stakeholders.

Gender diversity within the Group is set out in the following table.

	June 2023		June 2022
	No.	%	No.
Total Women employed (non-senior)	24	75%	24
Women in non-board senior executive roles	2	29%	2
Women in board positions	2	29%	2

In the FY2022-2023, five women were promoted to senior positions due to their exceptional performance. Clarity also has made progress towards its goal to achieve a minimum of 30% gender balance at a Board level, in accordance with the 30% Club Australia goal. The Club launched in May 2015 with the primary objective of campaigning for 30% women on boards of ASX 300 companies.



Over 26% of Clarity's employees have a PhD and over 96% of the Company staff have a bachelor degree or higher education level.

Training & development

Clarity has a highly educated team with over 26% of its employees at a PhD level and over 96% of employees who have a bachelor degree or higher education level.

Clarity's Quality Assurance team monitor and issue current Good Clinical Practice (cGCP) and current Good Manufacturing Practice (cGMP) training the staff according to their roles so that staff are appropriately qualified, and their training is up to date. The Quality team organise additional training on a case-by-case basis as appropriate to an individual's role. Clarity staff and consultants receive ongoing training on Clarity's Quality Management System documents and processes. This ensures best practice and quality throughout the organisation.

In addition, Clarity has policies in place for its employees wishing to continue their education and training with the Company's support and has resources set aside for staff training and development.

Over 73% of Clarity's employees participated in external training, development and/or education programs in the last financial year, including scientific conferences, professional development courses, Good Practice learning and programs aimed at acquiring

new skills and knowledge.

The biotechnology industry requires highly specialised and skilled workforce and attracts motivated and driven people. Clarity is committed to the training and development of its employees and supports their endeavours for professional and personal growth not only with financial contributions, but also flexible working arrangements to accommodate the time it takes to undertake the programs.

Community

Clarity's team has a strong understanding of how their work improves treatment outcomes for children and adults with cancer and how this benefits the broader community. The Group organises regular in-person and remote events for its team and enables volunteering opportunities with selected organisations that share its values and goals, to ensure development of a strong team culture. Events such as Run2Cure with Neuroblastoma Australia and volunteering opportunities with Story Factory are examples of these engagements.

COMMUNITY ENGAGEMENT

Clarity's mission is to improve treatment outcomes for children and adults with cancer and we believe our social benefit to society can be further extended beyond our own products.

The EVAN Foundation - Treats and Treasures Carts Program

In the US, Clarity is supporting The EVAN Foundation's the Treats and Treasures Carts program. The EVAN Foundation is a charity that is making a difference every day in the fight against neuroblastoma and other childhood cancers, whether in the laboratory, the clinic or the hospital. The Treats & Treasures Carts Program is a simple but impactful initiative that brings smiles to over 1,300 childhood cancer patients a week across 18 participating hospitals in the US and Canada.



Patients and family members get to choose from a wide selection of healthy snacks, candy, chips, toys, games, stuffed animals, blankets, books and other fun items. All at no cost to them. The Carts provide paediatric cancer patients a welcome break from treatment and a moment of control and empowerment during an incredibly challenging time.

Neuroblastoma Australia

Neuroblastoma Australia is an Australian charity focused on raising awareness of this aggressive childhood cancer and funding leading research projects for the development of better, safer treatments for children with this insidious disease.



Neuroblastoma
AUSTRALIA

In FY2022-2023 Clarity became the Platinum Sponsor for the Run2Cure fun run organised by Neuroblastoma Australia. In addition to financial contributions, Clarity's employees and their families participate in the annual fun run.

The Kids' Cancer Project

The Kids' Cancer Project is an independent national charity in Australia supporting childhood cancer research. Since 2005 with strong community support, they have committed \$70 million dollars to scientific studies to help children with many types of cancer. In FY2022-2023, Clarity supported the Kids' Cancer Project's Christmas for a Cure initiative, the pinnacle annual event for the charity that brings together an ensemble of Researchers & Funding Recipients, Family Ambassadors, Corporate Partners, Community Champions and a live panel of Sporting Heroes.



COMMUNITY ENGAGEMENT CONT.

Story Factory

Story Factory was founded in 2012 in Redfern, an inner-city suburb of Sydney, near Clarity's head office and in the heart land of the Gadigal people of the Eora Nation. Story Factory is a not-for-profit creative writing centre. Based in Redfern, an inner-city suburb of Sydney close to Clarity's head office, Story Factory has a mission to enrich the lives of young people in under-resourced communities through creative writing and storytelling. Story Factory's storytelling workshops have been designed by creative writing experts to build writing skills, confidence, and creativity: essential for young people to shape a better future.

Clarity and Story Factory share a number of goals, including bettering the lives of children who are disadvantaged by either their health, social status or other challenges. Both organisations are committed to supporting the local community and developing the next generation of talent to continue strengthening Australian science, research and development.



In FY2022-2023, Clarity continued to fund a partial salary for an Indigenous Storyteller engaged by Story Factory to support local young Aboriginal and Torres Strait Islander people to improve their writing skills and find their voices. During that time, Story Factory worked with over 900 Aboriginal and/or Torres Strait Islander young people. The Storyteller, supported by Clarity, directly worked with Indigenous young people, designed programs with Indigenous-specific content and participated in the development of Story Factory's Reflect Reconciliation Action Plan, a Reconciliation Australia-endorsed plan to improve its Indigenous programs. The Storyteller has an important role in community engagement and advisory support to provide greater benefits for the Aboriginal and Torres Strait Islander young people enrolled in the program.

IN FY2022-2023 THE STORYTELLER, SUPPORTED BY CLARITY, ACHIEVED:

209 Creative writing workshops delivered

570 Young people directly supported

143 Indigenous young people directly supported

919 Indigenous young people indirectly supported across the organisation

STORY FACTORY USED AN EXTERNAL CONSULTANT TO EVALUATE THEIR IMPACT AND FOUND THAT:

78% of students enjoyed writing in our workshops

74% of students felt they were better at writing after participating in story Factory workshops

75% of students increased their literacy skills

90% of students were reported to have increased their literacy skills

85% of students were reported to have increased their confidence in writing

89% of teachers reported that their students' newly developed skills transferred to writing outside of workshops

100% of teachers reported that they changed their teaching practice as a result of participating in the Storyteller's workshop

ENVIRONMENT

Clarity's platform of TCTs has significant environmental advantages over current generation radiopharmaceuticals using other isotopes due to the manufacturing methods for copper-64 (Cu-64 or ⁶⁴Cu) and copper-67 (Cu-67 or ⁶⁷Cu) and the logistical advantages their use confers.

Benefits relating to the use of Cu-67

The radioisotope components of the current- and next-generation theranostic treatments – ¹⁷⁷Lu and ⁶⁷Cu, respectively – have similar physical characteristics that contribute to their efficacy as radiopharmaceutical therapies. However, they significantly differ regarding the environmental impact from their manufacturing. ⁶⁷Cu production represents a more environmentally friendly and sustainable, large-scale production model compared to ¹⁷⁷Lu, based on the following key environmental factors:

1. ⁶⁷Cu production uses a readily available transition metal, zinc, as its source material, in comparison to ¹⁷⁷Lu that uses rare earth elements, lutetium or ytterbium, as the source material. The mining of rare earth elements is a highly specialised and resource intensive process that carries much heavier environmental impact compared to the mining of other more abundant transition metals, such as zinc, which is used in the production of ⁶⁷Cu.

From a mining perspective, zinc is considerably easier to obtain than either of the rare earth elements used in the production of ¹⁷⁷Lu. Zinc also has many widespread commercial applications outside of radiopharmaceuticals and is already routinely mined²⁷. Therefore, its sourcing for use in the radiopharmaceutical sector can be leveraged by mining practices already established for various industries.

2. ⁶⁷Cu is produced by electricity-powered electron accelerators or Rhodotrons and results in minimal production of contaminants or long-lived radioactive waste byproducts. In comparison, ¹⁷⁷Lu is produced by neutron capture in a nuclear reactor.

The nuclear reactors used to irradiate target materials for ¹⁷⁷Lu are fuelled with enriched uranium, which creates an array of environmental safety considerations and proliferation concerns²⁸. The nuclear fuel from a nuclear reactor will remain a safety concern for hundreds of thousands of years to come and few countries have so far found a safe way to dispose of this uranium fuel.


3. ⁶⁷Cu eliminates the reliance on a limited number of aging and government subsidised nuclear reactors, which are primarily located outside of the US.^{29,30} Nuclear reactor closures, scheduled maintenance breaks and unplanned shutdowns are common and have led to notable radiopharmaceutical supply issues, most recently throughout 2022.^{19,20,21,31,32} Options for expanding ¹⁷⁷Lu production capacity are severely limited as construction of a new nuclear reactor is costly, not environmentally preferable and involves significant regulatory burdens based on the requirements for licensure of a new reactor. These regulatory burdens lead to commissioning timelines for reactors that are measured in decades. As such, building new reactors will not solve the current issues of the limited and undependable reactor-based supply chain in the near future and access to reactors will become the bottleneck for ¹⁷⁷Lu production. In contrast, electron accelerators used to produce ⁶⁷Cu are primarily privately owned and interruptions or shutdowns that lead to radioisotope shortages are decidedly less likely to occur than those with nuclear-reactor produced radionuclides, such as ¹⁷⁷Lu. By using regionally located electron accelerators, ⁶⁷Cu drug product production and distribution can take place closer to where patients are treated. This reduces the need for international shipments for each patient dose and creates a fully integrated regional supply chain with a smaller carbon footprint.

ENVIRONMENT CONT.

As the radiopharmaceutical industry is expected to grow exponentially over the next decade with radiopharmaceutical products becoming a standard of care treatment option in a number of cancers, including large indications, the environmental impact of producing and commercially distributing these therapeutic radioisotopes is a critical element to consider and cannot be overlooked for the long-term sustainability of the industry.

Benefits of room temperature manufacture with TCTs

The SAR technology at the heart of Clarity's TCT platform allows manufacturing to take place at room temperature whereas many of the commonly used radiopharmaceutical technologies, including ^{177}Lu -based products, require heating products to 90°C during manufacturing. This process may lead to a significant number of batches which are influenced by this heating process and fail to pass the strict Quality Control steps required to release a product for human use. Batch failures lead to an unnecessary environmental footprint, while creating additional waste that needs to be disposed. Room temperature manufacturing reduces the probability of these batch fails and makes TCT production more environmentally friendly, less costly and minimises product quality concerns.



“In a field with too many unforeseen product outages and manufacturing issues, TCTs enable reliable and sustainable supply of radiopharmaceuticals,”

- Dr Alan Taylor

ENVIRONMENT CONT.

Benefits relating to the use of Cu-64

1. Longer shelf-life of diagnostic ⁶⁴Cu-based products

One of the key advantages associated with the use of ⁶⁴Cu relates to its 12.7-hour half-life. This half-life enables a product shelf-life of ~48hours, which is a considerably longer shelf-life compared to diagnostic radiopharmaceuticals that use fluorine-18 (e.g. 10 hour shelf-life for PYLARIFY³³) or gallium-68 (4 hours shelf life for LOCAMETZ³⁴). Product shelf-life describes the length of time the radiopharmaceutical products can be used once the drug product is prepared.

2. Production via central manufacture

The longer shelf-life of ⁶⁴Cu-based products translates into the ability to centrally manufacture and ship ready-to-use diagnostics to treatment facilities from a single manufacturing site, similar to the big pharma supply model.

Current-generation diagnostic radiopharmaceuticals, such as ⁶⁸Ga and ¹⁸F, cannot be manufactured and supplied this way and require having radiopharmacy facilities near or at the site where patient imaging takes place. This means that every treatment site must have local access to ⁶⁸Ga and ¹⁸F isotope production, radiopharmacy facilities and staff who are qualified to prepare radiopharmaceuticals. These requirements can be cost-prohibitive outside of large academic treatment centres. In the case of ⁶⁸Ga, there are additional challenges that must be taken into consideration. Its production is conducted on high-cost generators, which have a typical useable life of 6-9 months and a limit on the amount of ⁶⁸Ga that can be produced from the generators per day.


Industrial scale ⁶⁴Cu production on cyclotrons creates a high purity product free from radioactive contaminants and permits central manufacture of large volumes of ready-to-use radiopharmaceuticals. ⁶⁴Cu can be produced on existing infrastructure by utilising cyclotrons that are abundant as they are currently used to produce another medical isotope, ¹⁸F.

Due to the longer shelf life of Cu-64 based agents there is less risk of product expiring before being administered to patients, reducing waste from unused, expired products. This longer shelf life of ⁶⁴Cu based agents also enables delivery once a day to clinics as opposed to existing agents which often require multiple deliveries a day based on their short shelf lives.

These features lead to the following environmental advantages of employing Cu-64 isotopes:

1. No need for building additional production facilities close to the treatment centres.
2. No risk of generator breakthrough of long-lived radioactive material.
3. No radioactive waste for long-term storage.
4. More usable product with less expired and "wasted" product due to short shelf-lives.
5. Large product batches lead to less production cycles and hence fewer deliveries to end-users in the treatment facilities per day.

Clarity is committed to further exploring and using the environmental benefits of TCTs while also building supply networks that embed efficiencies into the manufacturing and logistics.



Clarity does not consider GHG emissions, water consumption, land use and ecological sensitivity markers to be material metrics at this time due to its small workforce of 41 employees in the US and Australia and limited office-space footprint where the majority of the employees work from home. However, as our team of employees, collaborators and suppliers grows globally, we will look to adopt and adhere to the best-practice in the field and continue embedding the values of environmental sustainability into our growth.

GOVERNANCE

Clarity's Corporate Governance Statement for FY2022-2023, setting out its key corporate governance principles and practices and their alignment with the ASX Corporate Governance Council's recommendations, was lodged with the ASX on 29 September 2023 and can also be found on the Investor Centre on [Clarity's website](#).

The Company has been listed on the ASX for just over two years and its Board remains committed to building a best-in-class Governance framework. The Board recognises that this is an ongoing process, and that the Company needs to continually assess and enhance its Governance function as the business develops and matures over time. The latest Corporate Governance Statement illustrates areas of progress and areas for improvement and growth. The process of continual review and enhancement of the Governance Framework remains a focus area for the Company and its Board.

Responsibility for the integration of ESG into the management and functions of the Company sits with the Board. It provides overall strategic guidance, financial management and controls for the Company through effective oversight of management. The Board ensures the activities of the Company comply with its Constitution. This is implemented and monitored through corporate governance frameworks, policies, and committees.

There are two key Board subcommittees:

- Audit and Risk Committee
- Nomination & Remuneration Committee

The membership of the Board and its committees are set out in Clarity's Annual Report 2023.

The Board is committed to ensuring that its policies and practices reflect good corporate governance consistent with the Australian Securities Exchange (ASX) Listing Rules and the ASX Corporate Governance Principles and Recommendations. As set out in its Code of Conduct, the Company is committed to conducting its business ethically and responsibly, acting only in ways that reflect well on the Company and in strict compliance with all laws and regulations. Clarity's corporate governance framework is elaborated in its governance policies:

- Code of Conduct
- Trading Policy
- Anti-bribery and Corruption Policy
- Privacy Policy
- Auditor Independence Policy
- Diversity and Inclusion Policy
- Disclosure and Communication Policy
- Whistleblowing Policy

Clarity's Corporate Governance Policies are regularly reviewed and updated. They are publicly available and can be found on the Company's Investor Centre:

<https://www.claritypharmaceuticals.com/investor-center>

Data protection and privacy

Clarity takes data security and data privacy seriously, and as such has been committed to making its team aware of potential security risks. Formal policies were put in place for data security and data privacy, as well as processes and protocols to deal with any potential future data breach. All members of the Clarity team, including non-employees with access to Clarity's systems, undertook cybersecurity awareness training, including phishing testing and follow-up sessions to train employees to identify potential threats.

“Clarity is committed to being an ESG leader in the biotechnology industry and this year we have continued to strive for excellence while recognising there are areas for improvement. What has remained the same is our dedication to transparency, clear goal setting and continuous monitoring.”

The Social element of the ESG framework remains at the core of our Company. The ultimate goal of improving treatment outcomes for children and adults with cancer unites our team, drives our performance and defines our culture. Having been “born and bred” from great Australian science, Clarity continues to support and promote Australian research, working together with numerous local R&D organisations. We recognise gender equality at the Board level as a key priority under the Social pillar of ESG and have made steps towards this goal in the FY2022-2023.

The Environmental pillar is enabled by Clarity’s Targeted Copper Theranostic platform and the use of copper radioisotopes. Production of copper-64 and copper-67 has favourable environmental characteristics in comparison to other radioisotopes. Inefficient supply chains, the use of short-lived radioisotopes as well as the production of waste, particularly radioactive waste, associated with current-generation radiopharmaceuticals, present significant environmental issues for the sector.

As the radiopharmaceuticals are expected to grow exponentially over the next decade, the environmental impact is a crucial element to consider. Clarity stands in sharp contrast to the rest of the radiopharmaceuticals field and offers an environmentally preferable solution for the industry. We are committed to fully utilising the environmental benefits of our TCT platform on a global scale.

We will also continue strengthening the remaining pillar of the framework, ensuring a robust Governance framework underpins our operations.

Although Clarity remains focused on shareholder returns, we will continue to empathise, support and make change where possible to transform the lives of children and adults that need us most.

Dr Alan Taylor
Executive Chairperson
Clarity Pharmaceuticals



REFERENCES

1. Orphan Drug Act, US FDA, 21 CFR Part 316 <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-316>
2. Rare Pediatric Disease Priority Review Vouchers, U.S. Department of Health and Human Services Food and Drug Administration, July 2019 <https://www.fda.gov/media/90014/download>
3. N Colon & D H Chung 2011, Neuroblastoma, *Advances in Pediatrics* 58(1)
4. V Smith & J Foster 2018, High Risk Neuroblastoma Treatment Review, *Children* 5(9)
5. ClinicalTrials.gov Identifier: NCT04023331 clinicaltrials.gov/ct2/show/NCT04023331
6. Global Cancer Statistics 2020: GLOBOCAN Estimates of Incidence and Mortality Worldwide for 36 Cancers in 185 Countries <https://acsjournals.onlinelibrary.wiley.com/doi/10.3322/caac.21660>
7. American Cancer Society, Cancer Statistics Center <https://cancerstatisticscenter.cancer.org/?ga=2.79808020.284532473.1620009137-1916069442.1615761164#/cancer-site/Prostate>
8. ClinicalTrials.gov Identifier: NCT04868604 clinicaltrials.gov/ct2/show/NCT04868604
9. ClinicalTrials.gov Identifier: NCT06056830 clinicaltrials.gov/ct2/show/NCT06056830
10. ClinicalTrials.gov Identifier: NCT05249127 clinicaltrials.gov/ct2/show/NCT05249127
11. Afshar-Oromieh A, Holland-Letz T, Giesel FL, et al. Diagnostic performance of ⁶⁸Ga-PSMA-11 (HBED-CC) PET/CT in patients with recurrent prostate cancer: evaluation in 1007 patients. *Eur J Nucl Med Mol Imaging*. 2017 Aug;44(8):1258-1268
12. Ferraro DA, Rüschoff JH, Muehlethaler UJ, et al. Immunohistochemical PSMA expression patterns of primary prostate cancer tissue are associated with the detection rate of biochemical recurrence with ⁶⁸Ga-PSMA-11PET. *Theranostics*. 2020;10(14):6082-6094.
13. Baratto L, Song H, Duan H, et al. PSMA- and GRPR-Targeted PET: Results from 50 Patients with Biochemically Recurrent Prostate Cancer. *J Nucl Med*. 2021;62(11):1545-1549.
14. Mapelli P, Ghezzi S, Samanes Gajate AM, et al. ⁶⁸Ga-PSMA and ⁶⁸Ga-DOTA-RM2 PET/MRI in Recurrent Prostate Cancer: Diagnostic Performance and Association with Clinical and Histopathological Data. *Cancers (Basel)*. 2022;14(2):334.
15. Vlachostergios PJ, Niaz MJ, Sun M, et al. Prostate-Specific Membrane Antigen Uptake and Survival in Metastatic Castration-Resistant Prostate Cancer. *Frontiers in oncology*. 2021;11.
16. ClinicalTrials.gov Identifier: NCT05633160 clinicaltrials.gov/ct2/show/NCT05633160
17. ClinicalTrials.gov Identifier: NCT05407311 clinicaltrials.gov/ct2/show/NCT05407311
18. ClinicalTrials.gov Identifier: NCT05613842 clinicaltrials.gov/ct2/show/NCT05613842
19. Fischer, J.R. 2022, "Water leak in nuclear reactor expected to cause medical isotope shortage", 31 January 2022 www.dotmed.com/news/story/57018
20. Murphy, H. 2022, "Medical isotope shortage looms as 'unplanned' outage halts Mo-99, Lu-177 production", 26 January 2022 www.healthimaging.com/topics/molecular-imaging/isotope-shortage-reactor-halts-production
21. COMMUNICATION FROM THE NMEu EMERGENCY RESPONSE TEAM (ERT), "Unplanned Outage of the HFR Reactor", 24 January 2022
22. SmartBrief SNMMI, "Supply disruptions expected for Mo-99/Tc-99m" 01 November 2022 www.smartbrief.com/sharedSummary/index.jsp?briefId=94A57BF5-E8A1-4598-B740-5CB55226F136&issueId=3ED08DD3-B5F9-4873-B233-DDB1AA301A9A©Id=2688FEF9-7061-49CD-A7A1-D392C2F7A11E
23. SNMMI 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>
24. Novartis 2022, "Novartis provides update on production of radioligand therapy medicines", 5 May 2022 www.novartis.com/news/media-releases/novartis-provides-update-production-radioligand-therapy-medicines
25. US FDA, Expanded Access www.fda.gov/news-events/public-health-focus/expanded-access#:~:text=Sometimes%20called%20E2%80%9Ccompassionate%20use%20when%20no%20comparable%20or
26. Fountzilias E, Said R, Tsimberidou AM. Expanded access to investigational drugs: balancing patient safety with potential therapeutic benefits. *Expert Opin Investig Drugs*. 2018 Feb;27(2):155-162. doi: 10.1080/13543784.2018.1430137. Epub 2018 Jan 22. Erratum in: *Expert Opin Investig Drugs*. 2018 Feb;27(2):209. PMID: 29353505; PMCID: PMC6291242.
27. United States Geological Survey (USGS), "Zinc Statistics and Information" www.usgs.gov/centers/national-minerals-information-center/zinc-statistics-and-information
28. Vogel, W.V., van der Marck, S.C. and Versleijen, M.W.J. Challenges and future options for the production of lutetium-177. *European Journal of Nuclear Medicine and Molecular Imaging*. 2021 <https://link.springer.com/article/10.1007/s00259-021-05392-2>
29. World Nuclear Association, "Radioisotopes in Medicine", Jul 2023 <https://world-nuclear.org/information-library/non-power-nuclear-applications/radioisotopes-research/radioisotopes-in-medicine.aspx>
30. World Nuclear Association, "Research Reactors", Jun 2021 <https://world-nuclear.org/information-library/non-power-nuclear-applications/radioisotopes-research/research-reactors.aspx>
31. COMMUNICATION FROM THE NMEu EMERGENCY RESPONSE TEAM (ERT), "Update on Unplanned Outage of the HFR Reactor", 31 January 2022
32. Imaging Technology News, "SNMMI Issues Alert That HFR Outage Will Impact Isotope Supply", 26 January 2022 www.itnonline.com/content/snmml-issues-alert-hfr-outage-will-impact-isotope-supply
33. PYLARIFY[®] Prescribing Information www.accessdata.fda.gov/drugsatfda_docs/label/2021/214793s000lbl.pdf
34. LOCAMETZ[®] Prescribing Information www.novartis.com/us-en/sites/novartis_us/files/locametz.pdf

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