



ESG REPORT

2022





CONTENTS

OUR COMMITMENT TO ESG.....	5
OUR MISSION AND VALUES	6
STAKEHOLDER ENGAGEMENT	7
ABOUT CLARITY	8
CORE PRODUCT PORTFOLIO.....	9
CLINICAL TRIALS IN INDICATIONS WITH UNMET NEEDS	10
ORPHAN AND RARE PAEDIATRIC CANCER	11
LARGE ONCOLOGY INDICATIONS	12
COMPASSIONATE USE OF CANCER TREATMENTS.....	13
PATIENT HEALTH AND SAFETY	14
SUPPORTING AUSTRALIAN RESEARCH AND DEVELOPMENT.....	15
OUR PEOPLE	16
COMMUNITY ENGAGEMENT.....	20
ENVIRONMENT.....	22
GOVERNANCE.....	25
CORPORATE DIRECTORY	28

About this report

This report describes Clarity Pharmaceuticals Ltd's Environmental, Social and Governance (ESG) framework and practices, and our interactions with stakeholders, the broader community and the environment. In developing this ESG report, Clarity Pharmaceuticals Ltd (Clarity) has been guided by recognised standards of ESG reporting.

This report pertains to Clarity and its controlled entities during the reporting period from 1 July 2021 to 30 June 2022 (2022). 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.

2022 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 CLARITY SPONSORED CLINICAL TRIALS IN ONCOLOGY



2 INVESTIGATOR-INITIATED TRIALS IN ONCOLOGY

63% OF WORKFORCE FEMALE



33% OF NON-BOARD SENIOR EXECUTIVE ROLES HELD BY FEMALES



3 SCIENTIFIC AND CLINICAL CONFERENCES AND WORKSHOPS SPONSORED



2 CHARITIES SUPPORTED



COMPASSIONATE ACCESS GRANTED FOR A RANGE OF DIAGNOSTIC AND THERAPEUTIC PRODUCTS

OUR COMMITMENT TO ESG

I'm pleased to present Clarity's ESG report for the year ended 30 June 2022.

Clarity is fundamentally based on a platform of innovative drug development, and we strive to apply innovative thinking to all parts of our business – not just the scientific side, but also in the way we deal with the environmental, social and governance aspects, which are core to Clarity's values.



Clarity's ultimate mission is to improve treatment outcomes for children and adults with cancer. Our 34 employees across Australia and the US are impassioned by our purpose, and this has created a culture of inclusion, diversity, superior performance, and respect for shared values we have built throughout the years.

This enthusiasm has allowed our small team to achieve exceptional milestones and progress the development of Clarity's three core product areas for a total of six products in seven clinical trials and two investigator-initiated trials, along with new products in our research and development pipeline.

Our first product to enter clinical trials, SARTATE, is in development for neuroblastoma, an aggressive childhood cancer, as a theranostic (therapy and diagnostic) product and for neuroendocrine tumours as a stand-alone diagnostic product. Our next product is SAR-bisPSMA, an optimised PSMA agent in clinical development for prostate cancer as a stand-alone diagnostic as well as a theranostic product. Our third product, SAR-Bombesin, a pan-cancer agent which is being developed for breast and prostate cancer, is also progressing in a number of clinical trials, including theranostic and diagnostic studies.

Clarity's SAR Technology also allows us to explore new, exciting products for the treatment of a range of cancers with high unmet need. These products are in our Discovery Platform as we continue to develop and progress next-generation products.

Clarity receives strong support from its collaborators, a community of world leading researchers and clinicians. The Company was founded on the platform of great Australian science and continues to work closely with thought leaders while progressing its technology and products towards commercialisation. We continue to emphasise collaboration and translation of science, progressing basic research from the lab, through preclinical studies and into the clinic where it has the potential to improve the lives of people suffering from serious disease.

We are determined 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 clinical, preclinical, and regulatory development 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 to grow Clarity's Board of Directors, Advisory Board and team of employees, consultants, and collaborators.

Alan Taylor
Executive Chairperson, Clarity Pharmaceuticals

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. It is the core of the Clarity's strategy. The Company promotes collaboration among its employees, shareholders, suppliers, customers and 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

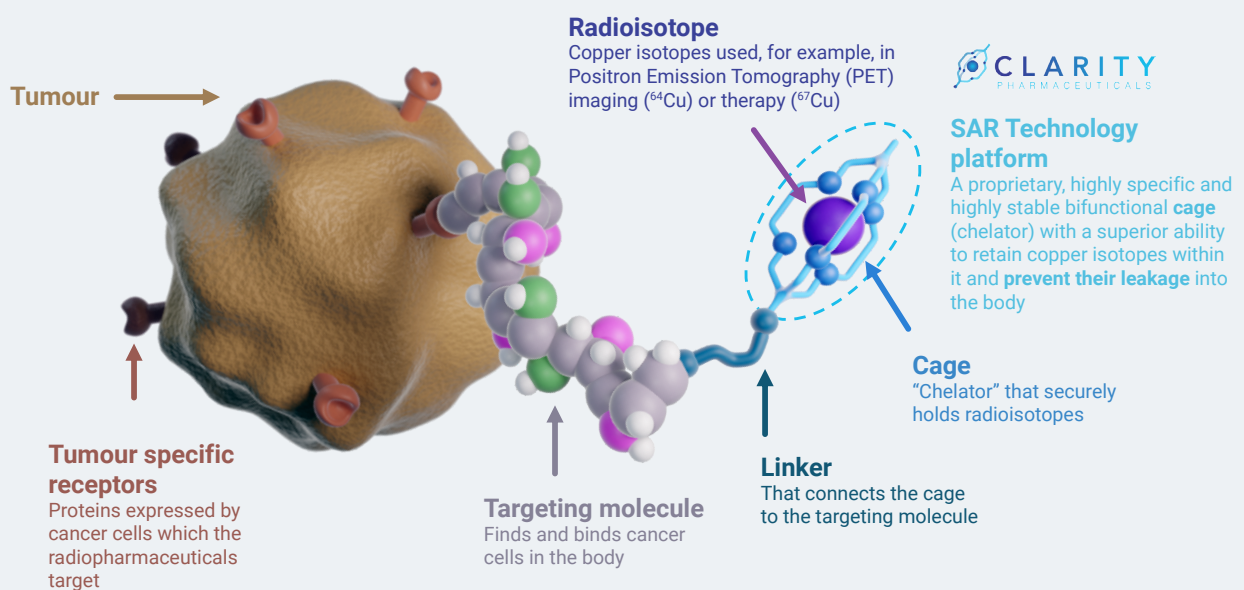
Clarity is a clinical stage radiopharmaceutical company with a mission to develop next-generation products that improve treatment outcomes for children and adults with cancer.

Targeted Copper Theranostic Platform

Clarity is the global leader in innovative radiopharmaceuticals with its Targeted Copper Theranostic (TCT) platform of products. TCTs are enabled by the proprietary SAR Technology, which securely holds radioisotopes of copper inside a specialised cage called a chelator to prevent their leakage into the body. The cage is linked with targeting molecules that seek and bind to cancer cells. By becoming part of the molecule, the cage enables radioactive properties of the copper isotopes to diagnose and treat cancerous tumours.

Perfect Pairing

Clarity's TCTs are a disruptive platform that employs the *perfect pairing* of copper-64 (^{64}Cu or Cu-64) and copper-67 (^{67}Cu or Cu-67) isotopes for diagnosis and therapy, respectively. TCTs deliver a compelling combination of high accuracy and high precision in the treatment of a range of cancers, while providing supply, logistical and environmental advantages over the current generation of radiopharmaceuticals.



CORE PRODUCT PORTFOLIO

Clarity's three core product areas, being SARTATE, SAR-bisPSMA and SAR-Bombesin, are all based on the SAR Technology.

Each product area contains a different targeting molecule, connected with the SAR cage through a linker. Each of the three molecules bind to different receptors that are present on different cancer cells. By using isotopes of copper inside the SAR cage, these products can be used to diagnose (with Cu-64) or treat (with Cu-67) a range of different cancers in children and adults.

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.

SAR-bisPSMA

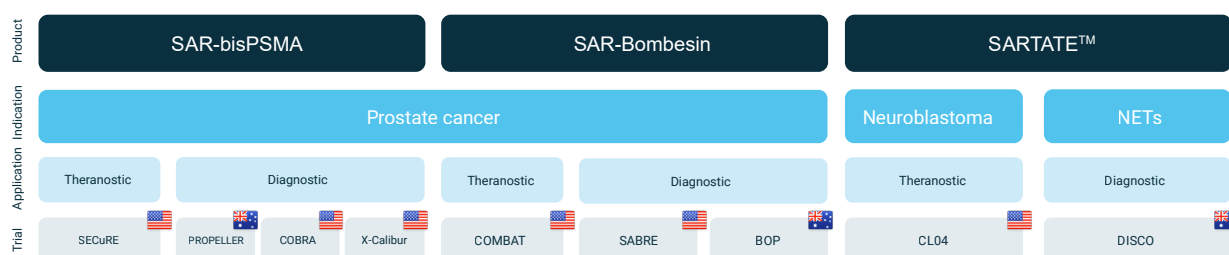
targets the Prostate Specific Membrane Antigen (PSMA), present in the majority of prostate cancers and other cancers.

SAR-Bombesin

targets the Gastrin Releasing Peptide receptor (GRPr), which is present in many cancers, including breast and prostate cancers.

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 these seven trials, sponsored by Clarity, two investigator-initiated trials (IITs) with Clarity's products are ongoing.



Clarity is conducting multiple clinical trials for each of its three key products to explore both diagnostic and therapeutic modalities, as well as expand their potential applications in a range of cancers to address different patient groups.

In addition to the current three clinical-stage core product areas, the SAR Technology is used in Clarity's Discovery Program which explores new

targeting molecules, thereby creating new TCTs to expand the existing platform. Clarity is committed to continuing the collaboration with thought leaders in the radiopharmaceutical field, scientists, researchers and clinicians to develop next-generation innovative treatments that can potentially improve the treatment paradigm for people with cancer.



ORPHAN AND RARE PAEDIATRIC CANCER

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

Orphan diseases are those that affect less than 200,000 people in the United States¹. 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 United States.²

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 neuroblastoma 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 copper-64 (⁶⁴Cu) for imaging (⁶⁴Cu SARTATE) or copper-67 (⁶⁷Cu) for therapy (⁶⁷Cu SARTATE).

Clarity's CL04 trial is a theranostic (diagnosis and therapy) 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.

In 2020, the US Food and Drug Administration (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 same 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 one of the largest indications in oncology as it is the second most common cancer diagnosed in men globally and the fifth leading cause of cancer death worldwide⁶. The National Cancer Institute estimates in 2022 there will be 268,490 new cases of prostate cancer in the US and around 34,500 deaths from the disease⁷.

Prostate cancer is a key focus of Clarity's TCT program. It is an indication with several patient populations with high unmet needs. As such, Clarity is progressing two theranostic and three diagnostic clinical trials and is involved in two IITs with two of its core products, SAR-bisPSMA and SAR-Bombesin.

With the projected future growth of radiopharmaceuticals, the current generation of radiopharmaceuticals may struggle to meet the demands of large oncology indications. Due to the radioactive nature of these products, their shelf-life is relatively short, and they must be produced consistently to meet current demand. There are frequent supply interruptions associated with the production of therapeutic isotopes on a limited number of ageing nuclear reactors where shutdowns are common^{8,9,10,11}. Other supply and logistical challenges and inefficiencies relate to the short shelf-life of current generation diagnostic isotopes¹² and quality issues in production of the products¹³.

Unlike these current generation products, Clarity's unique TCT platform has potential to enable a uniquely scalable supply chain with logistical, manufacturing and environmental benefits in addition to clinical advantages of high accuracy and precision in the treatment of prostate cancer.

Clarity's TCTs employ the perfect pairing of copper isotopes. The therapeutic isotope, copper-67, is produced on electron-accelerators instead of nuclear reactors and the diagnostic isotope, copper-64, is produced in large scale on biomedical cyclotrons. The radioactive half-lives of Cu-64 and Cu-67 enable a suitable shelf-life of products which allows for central manufacture of ready-to-use radiopharmaceuticals, potentially allowing the entire supply chain to be controlled in-house, similar to the big pharma manufacturing and supply model. Central manufacture alleviates the need for radiopharmacy facilities on-site, meaning that more hospitals and treatment facilities can be reached with Clarity's TCT products, and more patients can be diagnosed, including in regional areas. This is especially relevant to diseases such as prostate cancer in the United States where a significant majority of patients are treated in a community setting rather than large hospitals.

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

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 available¹⁴.

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 product.¹⁵

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.

An example of compassionate use of Clarity's products was conducted in collaboration with Prof Louise Emmett at St Vincent's Hospital, with subsequent data published. The Therapeutic Goods Administration (TGA) enabled access to Clarity's

SAR-Bombesin product under the TGA Special Access Scheme (SAS; Australia's equivalent of the compassionate access scheme). The Scheme allows certain health practitioners to access unapproved therapeutic goods for a single patient. SAS applications can only be submitted by registered practitioners.¹⁶

The patients who received Clarity's products under the SAS in this case had a history of prostate cancer treatment with rising PSA levels, however, their cancer could not be detected using currently approved radiopharmaceuticals or other imaging modalities. An accurate diagnosis is essential for choosing the optimal treatment paradigm for prostate cancer patients. As such, the patients were granted access to the SAR-Bombesin product, which enabled imaging of the disease. Data on these patients has been published^{17,18} and led to an investigator-initiated trial of prostate cancer patients with SAR-Bombesin at St Vincent's Hospital led by Prof Louise Emmett, and a US Phase II trial under an investigational new drug application through the US FDA.

Several patients in the US have also received diagnostic and therapeutic products from Clarity's portfolio during the last year under US FDA Compassionate Use programs. This included providing additional therapy cycles on request for children with neuroblastoma as part of Clarity's CL04 trial.

PATIENT HEALTH AND SAFETY

Clarity places utmost importance on the health and safety of the patients undergoing clinical trials and participating in compassionate use programs with its products.

The Company is generating a body of preclinical and clinical safety and efficacy data for its products and adheres to all regulatory requirements in the regions it operates.

Clarity has an extensive quality system and ongoing auditing program to ensure the highest quality and standards across all its vendors and activities both internally and externally.



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 initially invented by Australian co-ordination chemist Prof Alan Sargeson and his team at the Australian National University many decades ago. He developed a cage, also known as a chelator, that is capable of holding copper isotopes inside. The chelator was called a sarcophagine (SAR), which derives from the word sarcophagus, implying that the isotopes were held inside the cage securely. Prof Paul Donnelly and his team at the School of Chemistry and Bio21 Institute of Molecular Science and Biotechnology, University of Melbourne, continued the research and modified the cage to make it bifunctional so that it could not only securely hold the isotopes inside, but also link to targeting molecules that are capable of binding to receptors on cancer cells. The ability to combine radioactive properties of copper isotopes with a targeted treatment approach opened the opportunity to develop the TCT platform of products for treating a range of cancers.

Clarity was founded in 2010 when the Company licensed the SAR Technology patent portfolios from the University of Melbourne and the Australian Nuclear Science and Technology Organisation (ANSTO) to explore potential treatment benefits that it could bring to people suffering from cancer. Clarity continues to work closely with Prof Donnelly on optimising the technology and the TCT products based on it. 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 2022, it contributed to the Australian Research Council (ARC) Training Centre for Innovation in Biomedical Imaging Technology (CIBIT), funding the research and training of a PhD student at the University of Queensland's Centre for Advanced Imaging. The Training Centre aims to improve the health of Australians, and was established with the Australian Government, with ARC funding of \$4.7 million and \$3.8 million in industry partner contributions, including Clarity's.

As Clarity's core products generated substantial preclinical data and moved into clinical development in patients, the Company continued to collaborate closely with Australian researchers and clinicians. Clarity's first-in-human study on SARTATE, a radiopharmaceutical that targets somatostatin receptor 2 (SSTR2), was conducted in neuroendocrine tumours (NETs) by Prof Rod Hicks at the Peter MacCallum Cancer Centre and proved to be a success. This study was a proof-of-concept, enabling the development of SARTATE in neuroblastoma, and facilitating the development of other products in the TCT platform. Another longstanding collaborator is Prof Louise Emmett and her team at St Vincent's Hospital who have been deeply involved and influential in progressing Clarity's SAR-Bombesin and SAR-bisPSMA products. Prof Emmett has progressed three clinical trials and IITs with these products and successfully imaged prostate cancer patients under a Special Access Scheme in Australia.

In addition to the clinicians, researchers, trial sites and research institutes mentioned above, Clarity has been working closely with other Australian organisations, including Westmead Hospital, Royal North Shore Hospital, Nepean Hospital, Royal Adelaide Hospital, GenesisCare SJOG Medical Clinic, South Australian Health and Medical Research Institute (SAHMRI), Austin Health 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 34 employees, Clarity has achieved several significant milestones this year and is progressing seven clinical trials, two IITs 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 pharmaceutical 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.

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.

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 2022		June 2021	
	No.	%	No.	%
Total Women employed	17	63%	9	56%
Women in non-board senior executive roles	2	33%	2	33%
Women in board positions	1	14%	1	17%

Clarity acknowledges that women are underrepresented on its Board of Directors. The Company is aiming to achieve the goal of 30% gender balance at a Board level by June 30 2023, 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 76% of Clarity's employees participated in external training, development and/or education programs in the last financial year

Training & development

Clarity's Quality team monitor and issue current Good Clinical Practice (cGCP) and current Good Manufacturing Practice (cGMP) training to 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 76% 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

NEUROBLASTOMA AUSTRALIA

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.



As such, we are working with Neuroblastoma Australia, 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.

In FY2022 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. Despite the global pandemic, around 60% of Clarity's employees at the time participated in the Run2Cure Local event in 2022.



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 committed to supporting young people, including young Aboriginal and Torres Strait Islander people, to improve their writing skills and find their voice. The latest Program for International Student Assessment data found that Indigenous young people were on average 3 years behind their non-Indigenous peers in literacy. To help reduce this gap, Story Factory has worked with more than 6,000 young Indigenous people since opening.

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 FY22, Clarity's contributions to Story Factory funded a partial salary for an Indigenous Storyteller engaged by Story Factory to support local young Aboriginal and Torres Strait Islander people. The Storyteller designs and delivers inspiring creative writing programs for marginalised young people and supports their students in improving their writing skills, increasing their motivation to learn and sharing their unique and diverse voices through writing.

IN THE PAST 12 MONTHS THE STORYTELLER'S CONTRIBUTION INCLUDES:

137 Creative writing workshops delivered

888 Young people supported

200 Indigenous young people supported

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

77% of students enjoyed writing in our workshops

73% of students felt they were better at writing after participating in story Factory workshops

75% of students increased their literacy skills

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.

Recent reports on the environmental impact of the production and distribution of Cu-64 and Cu-67 indicate this isotope pairing has a reduced carbon footprint compared to the current generation of theranostic radionuclide pairings, such as gallium-68 (Ga-68 ⁶⁸Ga) and lutetium-177 (Lu-177 and ¹⁷⁷Lu).¹⁹

Benefits relating to the use of Cu-67

No reliance on nuclear reactors

Unlike Lu-177, a commonly used isotope for therapeutic applications in radiopharmaceuticals, Clarity's alternative, Cu-67, does not require nuclear reactors for production. Several challenges arise from the reliance on nuclear reactors for production of radiopharmaceuticals. Firstly, there is only a small number of nuclear reactors suitable for production of medical isotopes globally and all the major reactors are located outside of the US. These reactors are rapidly ageing and approaching their end-of-life, leading to unplanned shutdowns and outages beyond their normal maintenance schedules. Each outage creates a ripple effect for global radiopharmaceutical supply where patients and their treating staff experience delays in accessing potentially life-saving treatments. Building a new nuclear reactor for production of medical isotopes requires significant amounts of time and large capital investments. The planned PALLAS reactor (a new medical isotopes reactor that will replace the ageing High Flux Reactor in Petten, Netherlands) was initially estimated to cost up to EUR800 million. Latest industry reports suggest investment levels could reach up to USD1 billion.²⁰


Cu-67 can be produced on electron accelerators (i.e., Rhodotrons) with a single unit having the potential to supply significant volumes of high purity and high specific activity Cu-67. Electron accelerators have a small footprint, are relatively inexpensive and infinitely scalable for future demand in comparison to medical nuclear reactors

No reliance on enriched uranium fuel

The nuclear reactors used to produce Lu-177 and other isotopes require enriched uranium fuel to create the neutron flux necessary to irradiate the starting material. Mining, purification and enrichment of uranium and preparation of nuclear fuel create a significant volume of long-lived radioactive waste. The nuclear fuel from a nuclear reactor will remain a safety concern for thousands of years to come and few countries have so far found a safe way to dispose of this uranium fuel. By comparison, production of Cu-67 on a Rhodotron requires only electricity.

Minimising radioactive waste

Cu-67 radionuclide production has an advantage over other medical isotopes, such as Lu-177, when it comes to by-products and radioactive waste. Current production methods for Lu-177 in a nuclear reactor create unwanted by-products from the irradiation. Some production methods for Lu-177 also create a long-lived radioactive impurity in the Lu-177 called Lu-177m. This stands in sharp contrast to the Cu-67 production method, which does not result in the creation of any long-lived radioactive waste during the irradiation due to the physics of the production process.



TCTs enable central manufacture and shipping of ready-to-use diagnostic products to treatment facilities from a single manufacturing site, similar to the big pharma supply model.

Input material

Current production methods for Lu-177 require a rare earth metal called ytterbium-176 (Yb-176) as a target material which has its own environmental impact due to the challenges of mining rare earth metals. It also depends on a fragile and limited supply chain. Clarity's Cu-67 is produced using a readily available metal target material, zinc-68 (Zn-68).

Benefits of room temperature production of ready-to-use 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 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. Room temperature manufacturing reduces the probability of these batch fails and makes TCT production more environmentally friendly, less costly and minimises product quality concerns.

Benefits relating to the use of Cu-64

Production via central manufacture

One of the key advantages associated with the use of Cu-64 relates to its 12.7-hour half-life. It translates into a product shelf-life of ~48hours which is a considerably longer shelf-life compared to diagnostic radiopharmaceuticals based on fluorine-18 (F-18; 10 hour shelf-life for PYLARIFY®²¹) or Ga-68 (4 hours shelf life for LOCAMETZ®²²). Product shelf-life describes the length of time the radiopharmaceutical products can be used once the drug product is prepared.

This advantage translates into the ability to centrally manufacture and ship ready-to-use diagnostic products to treatment facilities from a single manufacturing site, similar to the big pharma supply model.



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

Dr Alan Taylor

Current-generation diagnostic radiopharmaceuticals, such as Ga-68 and F-18, 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 Ga-68 and F-18 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 Ga-68, 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 Ga-68 that can be produced from the generators per day.

Industrial scale Cu-64 production on cyclotrons creates a high purity product, free from radioactive contaminants and permits central manufacture of large volumes of ready-to-use radiopharmaceuticals. Cu-64 can be produced on existing infrastructure by utilising cyclotrons that are abundant as they are currently used to produce another medical isotope, F-18. A single cyclotron can produce large batches of Cu-64 and the Cu-64 made on each run can be used for longer, reducing the need for multiple deliveries per day and creating more useable patient doses from a single production run than with such competing isotopes as Ga-68 or F-18.

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, meaning less CO₂ emissions from the transportation.

Clarity is committed to further exploring and using the environmental benefits of Targeted Copper Theranostics 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 34 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 2022, 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 15 September 2022 and can also be found on the Investor Centre on [Clarity's website](#).

The Company listed on the the Australian Securities Exchange (ASX) on 25 August 2021. In the years prior to listing, the Board made a commitment to establishing a best-in-class Governance framework and the Company diligently worked on gradually achieving this goal. Nevertheless, meeting the Governance requirements for the ASX listing was a significant undertaking for the Company given its comprehensive nature. Clarity's Board recognises that meeting the requirements 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 some areas of progress and areas where the Company recognises potential for improvement and growth. Clarity and its Board remain committed to making those advancements to be best-in-class among its biotechnology peers.

Responsibility for the integration of ESG into the management and functions of the Company sits with the Board. It provides overall strategic guidance and 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 2022.

The Board is committed to ensuring that its policies and practices reflect good corporate governance consistent with the 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 policies that can also be found on the Investor Centre of our website:

- 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/>

“Clarity is committed to being an ESG leader in the biotechnology industry. We recognise there are areas for improvement and are committed to transparency, clear goal setting and continuous monitoring.”

“The Social element of the ESG framework is 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 is strongly committed to continuing to promote Australian research and 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. Clarity will also continue strengthening the remaining two pillars of the framework, ensuring a robust Governance framework underpins our operations, and that we fully utilise the environmental benefits of our TCT platform on a global scale.

“Clarity has a global oncology focus, however, a key area for our Company is the community in which we live. We will continue to support local groups that align with our interests, including remaining a prominent sponsor for the Run2Cure fun run for Neuroblastoma Australia, and continuing as a partner to Story Factory which supports children in our own area of Redfern. Although Clarity remains focused on delivering superior returns to its shareholders, we will continue to empathise, support and make change where possible to transform the lives of children and adults that need us most.”

Clarity’s Executive Chairperson, Dr Alan Taylor.

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: NCT04839367
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. Fischer, J.R. 2022, "Water leak in nuclear reactor expected to cause medical isotope shortage", 31 January 2022 <https://www.dotmed.com/news/story/57018>
9. Murphy, H. 2022, "Medical isotope shortage looms as 'unplanned' outage halts Mo-99, Lu-177 production", 26 January 2022, <https://www.healthimaging.com/topics/molecular-imaging/isotope-shortage-reactor-halts-production>
10. COMMUNICATION FROM THE NMEu EMERGENCY RESPONSE TEAM (ERT), "Unplanned Outage of the HFR Reactor", 24 January 2022, <https://s3.amazonaws.com/rdcms-snmml/files/production/public/images/NMEU%20COMMUNICATION%2024%20JAN%202022%20Z.pdf>
11. SmartBrief SNMMI, "Supply disruptions expected for Mo-99/Tc-99m" 01 November 2022, <https://www.smartbrief.com/sharedSummary/index.jsp?briefId=94A57BF5-E8A1-4598-B740-5CB55226F136&issueId=3ED08DD3-B5F9-4873-B233-DDB1AA301A9A©Id=2688FEF9-7061-49CD-A7A1-D392C2F7A11E>
12. 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>
13. Novartis 2022, "Novartis provides update on production of radioligand therapy medicines", 5 May 2022, <https://www.novartis.com/news/media-releases/novartis-provides-update-production-radioligand-therapy-medicines>
14. US FDA, Expanded Access, <https://www.fda.gov/news-events/public-health-focus/expanded-access#:~:text=Sometimes%20called%20%E2%80%9Ccompassionate%20use%E2%80%9D%2C,trials%20when%20no%20comparable%20or>
15. 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.
16. Special Access Scheme, <https://www.tga.gov.au/resources/resource/forms/special-access-scheme>
17. Niketh J, Bao H, Emmett, L. ⁶⁴Cu-SAR-Bombesin PET-CT for the detection of biochemically recurrent PSMA-PET negative prostate cancer: a case series. 2022 ANZUP Annual Scientific Meeting. Program of Abstracts. Vol 18. Issue S1. P55. <https://doi.org/10.1111/ajco.13827>
18. Niketh J et al. [⁶⁴Cu]Cu-SAR-Bombesin ([⁶⁴Cu] Cu-SAR-BBN) PET-CT for the detection of biochemically recurrent PSMA-PET negative prostate cancer: a case series. Poster Abstracts – RANZCR ASM 2022. <https://www.claritypharmaceuticals.com/wp-content/uploads/2022/08/Cu-BBN-Poster-RANZCR-ASM.pdf>
19. J. Norenberg et al., Environmental Considerations Resulting from the Increased Use of Theranostics: Advantages of Targeted Copper Theranostics, *Journal of Nuclear Medicine* June 2022, 63 (supplement 2) 2655
20. MEDraysintell Nuclear Medicine (Part 1) Marketed Radiopharmaceuticals 2022 Edition
21. PYLARIFY® Prescribing Information, https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/214793s000lbl.pdf
22. LOCAMETZ® Prescribing Information, https://www.novartis.com/us-en/sites/novartis_us/files/locametz.pdf

CORPORATE DIRECTORY

For more information, please contact:

Clarity Pharmaceuticals

Dr Alan Taylor
Executive Chairperson
ataylor@claritypharm.com

Citadel-MAGNUS

Catherine Strong
Investor/Media Relations
cstrong@citadelmagnus.com | 0406 759 268

Principal Place of Business

National Innovation Centre
4 Cornwallis Street
Eveleigh NSW 2015

Registered Office

Clarity Pharmaceuticals Ltd
C/- Company Matters Pty Limited
Level 12, 680 George Street Sydney NSW 2000

ABN 36 143 005 341

Website

www.claritypharmaceuticals.com

