CLARITY PHARMACEUTICALS

INTERIM REPORT

and Half-Year Financial Statements

Sydney, Australia
28 February 2025

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CONTENTS

KEY OPERATIONAL HIGHLIGHTS

Clinical and Regulatory Highlights

SECuRE Trial

Clarity continues to progress cohort 4 of the SECuRE trial. The first three participants in cohort 4 to receive 2 doses of 12 GBq of ^{67}Cu-SAR-bisPSMA completed their Dose Limiting Toxicity (DLT) period and a Safety Review Committee (SRC) meeting was completed.

Recruitment of the additional three participants into cohort 4 of the dose escalation phase of the SECuRE trial is now complete, and the participants are currently in the safety and efficacy follow-up period. Preliminary efficacy assessment from cohort 4 showed that all participants had reductions in prostate-specific antigen (PSA) levels following 2 doses of 12 GBq of ^{67}Cu-SAR-bisPSMA, with the largest drop being 98.2% to date. An SRC meeting will be held in early March following the completion of the six-week DLT period of all participants.

Fast-Track Designations

During and since the reporting period, Clarity received 3 US FDA Fast Track Designations (FTDs) for its SAR-bisPSMA agent. The ^{64}Cu-SAR-bisPSMA product was granted 2 FTDs for PET imaging of PSMA-positive prostate cancer lesions in 2 indications: patients with suspected metastasis who are candidates for initial definitive therapy and patients with biochemical recurrence (BCR) of prostate cancer following definitive therapy. More recently, ^{67}Cu-SAR-bisPSMA was granted an FTD for the treatment of adult patients with PSMA-positive mCRPC who have been previously treated with androgen receptor pathway inhibition (ARPI).

The 3 FTDs granted to Clarity provide a number of benefits that would reduce the review time needed to bring ^{64}Cu-SAR-bisPSMA and ^{67}Cu-SAR-bisPSMA to market, potentially improving the diagnosis and treatment of prostate cancer patients sooner.

AMPLIFY Trial

In a formal meeting in October 2024, the US FDA provided positive feedback on a pivotal Phase III trial, AMPLIFY, which will aim to investigate the ability of ^{64}Cu-SAR-bisPSMA PET/computed tomography (CT) to detect recurrence of prostate cancer. AMPLIFY is Clarity's second registrational trial with ^{64}Cu-SAR-bisPSMA. The first is the CLARIFY trial for patients with confirmed prostate cancer pre-prostatectomy treatment. Combined, these trials will enable Clarity to address the two major prostate cancer patient populations for registration of ^{64}Cu-SAR-bisPSMA. Patient recruitment for the AMPLIFY trial is expected to commence in the coming months.

Co-PSMA Trial

Prof Louise Emmett at St Vincent's Hospital Sydney launched a new Investigator-Initiated Trial (IIT), evaluating the performance of Clarity's diagnostic product, ^{64}Cu-SAR-bis-PSMA, in comparison to standard-of-care (SOC) ^{68}Ga-PSMA-11 product for the detection of prostate cancer recurrence, with curative intent. Recruitment has commenced, with the first participants dosed within days of the trial launch.

DISCO Trial

The last patient assessment for the Phase II diagnostic ^{64}Cu-SARTATE trial, DISCO, was successfully completed in November 2024. A total of 45 patients were enrolled and imaged in the trial, assessing the performance of Clarity's SARTATE imaging product as a potential new method to diagnose and manage neuroendocrine tumours (NETs). The DISCO trial aims to build on earlier findings of SARTATE in patients with NETs, which demonstrated that imaging at later time points may lead to better identification of disease.

KEY OPERATIONAL HIGHLIGHTS

BOP Trial

The manuscript for the ^{64}Cu-SAR-Bombesin Phase II diagnostic trial in patients with BCR of prostate cancer was published in the Journal of Nuclear Medicine in August 2024. In the BOP IIT, ^{64}Cu-SAR-Bombesin was found to be safe and able to detect prostate cancer in 44% of patients in BCR who had a negative or equivocal SOC PSMA PET imaging.

World-leading conferences

Clarity's clinical data on the SAR-bisPSMA product was presented at a number of world-leading conferences. Most recently, 2 abstracts for Clarity's diagnostic COBRA and CLARIFY trials with ^{64}Cu-SAR-bisPSMA were presented at the American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU) 2025. An overview of the Clarity's diagnostic portfolio using ^{64}Cu-SAR-bisPSMA (PROPELLER, COBRA, CLARIFY and AMPLIFY) was presented at the 2025 Annual International Prostate Cancer Update (IPCU). The data shows that ^{64}Cu-SAR-bisPSMA identifies more lesions and earlier than currently approved PSMA PET agents.

In October, an abstract covering key aspects of Clarity's diagnostic ^{64}Cu-SAR-bisPSMA clinical trial, COBRA, was selected as a Top-Rated Oral Presentation at the European Association for Nuclear Medicine (EANM) 2024 Congress. Additionally, another oral presentation was delivered at the same conference (a theranostic case report). This presentation described a complete response to ^{67}Cu-SAR-bisPSMA treatment in a heavily pre-treated patient with mCRPC, showcasing the strength of Clarity's clinical data.

Discovery Platform

$^{64/67}$Cu-SAR-trastuzumab

Clarity renewed its focus on the breast cancer market, spearheaded by its $^{64/67}$Cu-SAR-trastuzumab product. Trastuzumab is an antibody that targets HER2, which is expressed in many cancers, including some types of lung, gastric and breast cancers. Through pioneering work in collaboration with the University of Melbourne, the trastuzumab antibody was combined with Clarity's proprietary SAR chelator and radiolabelled with copper-64 for diagnostic imaging and copper-67, forming a radioimmunotherapy (RIT) product. ^{64}Cu-SAR-trastuzumab was shown to target HER2-positive cancer cells to a very high level pre-clinically. ^{67}Cu-SAR-trastuzumab was shown to reduce the growth of HER2-expressing tumours in a dose-dependent manner and improved the survival of mice treated with the product.

Clarity intends to conduct a Phase I/IIa theranostic study with $^{64/67}$Cu-SAR-trastuzumab in HER2-positive breast cancer patients to address a significant unmet clinical need.

$^{64/67}$Cu-SAR-bisFAP

Clarity developed a novel Fibroblast Activation Protein (FAP)-targeted radiopharmaceutical called SAR-bisFAP, representing a new opportunity to improve the diagnostic (with copper-64) and treatment (with copper-67) options for patients with different cancers (e.g. breast, colorectal, pancreatic, lung, brain and ovarian cancers). The product was developed with the intent of overcoming the low uptake and retention in tumours of other FAP-targeted radiopharmaceuticals in development. The dimer SAR-bisFAP has shown increased tumour uptake and retention over 24 hours in pre-clinical models in comparison to other FAP radiopharmaceuticals in development as well as to a monomer equivalent (SAR-monoFAP). Clarity is currently conducting additional pre-clinical investigations to enable a Phase I clinical trial, which could commence in late 2025.

KEY OPERATIONAL HIGHLIGHTS

^{225}Ac-bisPSMA

Clarity has been conducting research combining the bisPSMA targeting agent with actinium-225 (Ac-225 or ^{225}Ac). To date, the program with ^{225}Ac-bisPSMA has focused on identifying a lead candidate from a number of different analogues. Clarity's SAR-bisPSMA product has shown impressive pre-clinical and clinical evidence to date, and the dual targeting of the product enables increased uptake and retention in prostate cancer tumours compared to the mono-targeted form of the product. By combining the optimised bisPSMA with Ac-225, Clarity has the opportunity to complement its beta-particle therapy product, ^{67}Cu-SAR-bisPSMA, with an alpha-particle therapy product, ^{225}Ac-bisPSMA.

Supply and Manufacturing

^{67}Cu-SAR-bisPSMA

In November 2024, Clarity signed a Master Services Agreement (MSA) and a ^{67}Cu-SAR-bisPSMA Clinical Supply Agreement with Nucleus RadioPharma who will manufacture the drug product at their new state-of-the-art facility in Rochester, MN. These agreements complement the existing agreement with NorthStar Medical Radioisotopes, LLC for ^{67}Cu-SAR-bisPSMA production to expand drug manufacturing in anticipation of recruitment demand for Phase II and III trials of this product.

Copper-64 and ^{64}Cu-SAR-bisPSMA

In October 2024, the Company signed a ^{64}Cu-SAR-bisPSMA product Clinical Manufacturing Agreement with SpectronRx, building on the earlier MSA and associated Supply Agreement for the copper-64 isotope. The Agreement ensures abundant and seamless supply of the product for Clarity's 2 Phase III registrational trials, CLARIFY and AMPLIFY. SpectronRx will produce both the ^{64}Cu isotope and the ^{64}Cu-SAR-bisPSMA product at the same location in the US, allowing central distribution from the Indiana facility to all 50 states on demand.

Actinium-225

In July 2024 Clarity entered into an agreement with TerraPower Isotopes (TerraPower) for the supply of the therapeutic alpha-emitting isotope, Ac-225 for the Company's TAT program with ^{225}Ac-bisPSMA. TerraPower has a unique Ac-225 manufacturing process in the US that has the potential to provide the scale and dependability required for commercial manufacturing at a purity level appropriate for clinical use.

Trastuzumab biosimilar: EG12014

In February 2025, Clarity signed a Supply Agreement with EirGenix, Inc. ("EirGenix") for the clinical development and future commercial supply of clinical-grade Good Manufacturing Practice (GMP) trastuzumab biosimilar, EG12014. The supply enables the development of a radiolabelled product, $^{64/67}$Cu-SAR-trastuzumab, for use in clinical trials.

KEY CORPORATE HIGHLIGHTS

Key Financials

$111.2m

LIQUID ASSETS

Well-funded with liquid assets of $111.2 million as at 31 December 2024

$11m

FY2024 R&D TAX INCENTIVE

Research and Development Tax Incentive is expected to provide a further $11 million in cash funding

TOGETHER, CLARITY HAS CASH RUNWAY THROUGH TO MID 2026

Admission to the ASX200

In December 2024, Clarity entered the top 200 companies listed on the Australian Securities Exchange (ASX) with inclusion in the S&P/ASX200 index. This milestone is a proud moment for Australian science as Clarity originally emerged from Australian benchtop science and grew into one of the Top 200 companies listed on the ASX in only three years after listing. The inclusion is testament to the hard work and dedication of Clarity's extraordinary Team and brilliant collaborators.

Team & Board

To align with the pace of Clarity's growth, the Company made a number of changes at the executive level during the reporting period. Ms Michelle Parker was appointed as Chief Executive Officer (CEO) in October, bringing more than 20 years of industry experience, spanning nuclear medicine, PET and pharmaceuticals in Australia and internationally. Dr Colin Biggin will continue his operational focus on further strengthening Clarity's manufacturing and supply chains in preparation for commercial launch in the role of Chief Operating Officer (COO) and will remain an Executive Director on Clarity's Board.

Other changes to the senior executive team include the promotion of Dr Othon Gervasio to Chief Medical Officer, the internal appointment of Dr Matt Harris to Chief Scientific Officer, and both Ms Eva Lengyelova, Vice President (VP) of Clinical Development, and Mary Bennett, Head of Human Resources, joining the senior executive team.

At the Board level, Non-Executive Director, Mr Rob Thomas, retired from the Board following the completion of his tenure on 23 August 2024 and in line with the announcement dated 16 January 2024. Non-Executive Director, Dr Chris Roberts, was appointed Chair of the Audit and Risk Committee and has joined the Nomination and Remuneration Committee. Dr Thomas Ramdahl joined the Audit and Risk Committee, and fellow Non-Executive Director, Ms Rosanne Robinson, has taken the role of Lead Independent Director.

Clarity Pharmaceuticals Ltd (ASX: CU6) ("Clarity" or the "Company"), a clinical stage radiopharmaceutical company with a mission to develop next-generation products that improve treatment outcomes for children and adults with cancer, is pleased to release its interim report and financial results for the half-year ended 31 December 2024.

Executive Chairperson's Letter

Dear fellow Shareholders,

On behalf of the entire team at Clarity, I am delighted to present Clarity's interim report and half-yearly financial statements.

We are excited to share our most recent updates as Clarity continues to make remarkable progress in developing our pipeline of Targeted Copper Theranostic (TCT) products. We would like to thank our Shareholders for their support as we continue our endeavours and address the growing demand for radiopharmaceuticals in oncology with our 3 key products in clinical development, as well as through our Discovery Program. These programs focus on current indications in our clinical program and explore the development of products in other areas of high unmet needs to continue delivering on our goal of improving treatment outcomes for children and adults with cancer.

Clarity's progress during the first half of this financial year has stemmed from years of focus and dedication from our team and collaborators, and we continue to adhere to high standards for science, clinical research and development. We clearly differentiate ourselves from our competitors in the radiopharmaceutical field and continue to build an incredible Australian science success story. This great science is at the heart of our Company and has led to our enviable position of having a strong intellectual property portfolio of some 27 patent families, coupled with data that holds promise of best-in-class products across our pipeline. While some companies may choose to repurpose assets that have been previously developed by other players in the radiopharmaceutical field, at Clarity, we continue to drive innovation from the benchtop through to all phases of pre-clinical and clinical development. We aspire to a new paradigm of diagnostics and therapeutics in the large market of prostate cancer in the first instance and then moving into a range of other indications, both within oncology and in other disease areas. Nothing represents our feats in science to date more than receiving 3 Fast Track Designations (FTDs) in 6 months for the one molecule, SAR bisPSMA, an accomplishment we believe is unprecedented. These designations are provided by the United States (US) Food and Drug Administration (FDA) for high unmet need indications and are very difficult to achieve. It is extraordinary to receive 3 in just 6 months, highlighting the critical need for novel diagnostics and therapies in prostate cancer and our unique position with one molecule in this large indication representing a market valued well in excess of tens of billions of dollars annually.

All of our key products in clinical development, namely SAR-bisPSMA, SAR-Bombesin and SARTATE, are progressing well through trials in both theranostic and diagnostic applications, and there are a lot of exciting milestones to look forward to in this calendar year. Our lead product, SAR-bisPSMA, continues to generate exceptional data in diagnostic and theranostic trials as well as under the Expanded Access Programs (EAP), and we are fully committed to bringing it to prostate cancer patients in need of improved diagnostic and treatment options. We look forward to sharing the progress of our SECuRE theranostic trial in March following the completion of Cohort 4 and move towards the cohort expansion phase (Phase II), where we will focus on assessing the efficacy of the product. We are also pleased to continue monitoring patients who have received multiple doses of ^{67}Cu-SAR-bisPSMA through the EAP and have shown durable responses to treatment to date with a favourable safety profile. The recent granting of an FTD for the ^{67}Cu-SAR-bisPSMA for the treatment of adult patients with PSMA-positive mCRPC who have been previously treated with androgen receptor pathway inhibition (ARPI) will allow us flexibility to develop ^{67}Cu-SAR-bisPSMA in both pre- and post-chemotherapy patients in the mCRPC setting, with initial focus on the largest market segment.

The diagnostic ^{64}Cu-SAR-bisPSMA product is progressing in 2 indications of prostate cancer: pre-definitive therapy and biochemical recurrence (BCR). The receipt of 2 FTDs, one for each of these indications, will enable us to progress this promising product through clinical trials, facilitate the development process and accelerate the approval of what could become a best-in-class diagnostic. Our 2 registrational Phase III trials with ^{64}Cu-SAR-bisPSMA, CLARIFY and AMPLIFY, are progressing well, with the former actively recruiting pre-prostatectomy participants in over 20 centres and the latter about to launch in BCR of prostate cancer in the coming months, following discussions with and positive feedback from the US FDA regarding its design. As CLARIFY continues to recruit, our utmost priority is to commence recruitment on AMPLIFY as soon as possible in order to aim to submit ^{64}Cu-SAR-bisPSMA in both indications simultaneously through the FDA.

The receipt of these FTDs reflects the quality of data from the ^{64}Cu-SAR-bisPSMA and ^{67}Cu-SAR-bisPSMA products, which have been presented at a number of world leading conferences. In February 2025 we presented 2 abstracts on the CLARIFY and COBRA diagnostic trials at the American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU) 2025. In that same month, an overview of Clarity's diagnostic portfolio using ^{64}Cu-SAR-bisPSMA (PROPELLER, COBRA, CLARIFY and AMPLIFY trials) was presented at the 2025 Annual International Prostate Cancer Update (IPCU) conference. At the European Association for Nuclear Medicine (EANM) 2024 Congress in October 2024 an abstract covering the completed COBRA trial was selected as a Top-Rated Oral Presentation. The data presented from the COBRA study shows that ^{64}Cu-SAR-bisPSMA identifies more lesions and earlier than currently approved prostate-specific membrane antigen (PSMA) positron emission tomography (PET) agents. A theranostic case report highlighting a complete response to ^{67}Cu-SAR-bisPSMA treatment under the EAP was also showcased as an oral presentation at the EANM Congress. This patient remains with undetectable PSA for almost 16 months and continues to demonstrate an outstanding clinical benefit from the treatment almost 21 months after receiving the first dose of ^{67}Cu-SAR-bisPSMA.

With the COBRA and PROPELLER trials already highlighting the diagnostic advantages of ^{64}Cu-SAR-bisPSMA compared to standard-of-care diagnostic imaging agents, we are now going one step further with the Investigator-Initiated Trial (IIT), Co-PSMA, led by our long-term collaborator and one of the world's leading theranostic experts, Prof Louise Emmett, at St Vincent's Hospital Sydney. Co-PSMA is a head-to-head Phase II imaging trial in 50 patients with BCR of prostate cancer, evaluating the performance of ^{64}Cu-SAR-bisPSMA in direct comparison to ^{68}Ga-PSMA-11 for the detection of prostate cancer recurrence. Recruitment into this trial is progressing well, and we eagerly anticipate the results in the hope of demonstrating a higher detection rate of prostate cancer with ^{64}Cu-SAR-bisPSMA further substantiating the results seen in our COBRA trial.

While SAR-bisPSMA is our lead product, we are excited to progress our SAR-Bombesin and SARTATE agents and are anticipating results in the diagnostic SABRE trial with ^{64}Cu-SAR-Bombesin in prostate cancer and DISCO trial with ^{64}Cu-SARTATE in neuroendocrine tumours (NETs) in the coming months. Both of these studies are Phase II trials and could enable Clarity to progress these products into pivotal Phase III studies, bringing these important PET imaging agents closer to entering the market.

The clinical-stage products are quickly progressing and giving hope to patients in need of better diagnostics and treatments, however, we are not stopping at that. With our unique ability to always put science first to address more indications with high unmet needs and identify products with large potential to improve outcomes for patients, we have been progressing our Discovery Program and announced a number of exciting milestones in the reporting period. Renewing our focus on breast cancer, we are now progressing the SAR-trastuzumab products, alongside SAR-Bombesin, SARTATE and SAR-bisPSMA in this indication. It is estimated that 316,950 women will be diagnosed with invasive breast cancer in 2025 in the US, with 42,170 dying from the disease, and we hope that our programs can help to improve these statistics and provide much-needed novel treatments for women suffering from this insidious disease. Another promising pan-cancer product we have progressed recently is SAR-bisFAP, which could be used in a range of cancers, including breast, colorectal, pancreatic, lung, brain and ovarian cancers. We are currently conducting additional investigations on SAR-bisFAP to enable a Phase I clinical trial, which could commence in late 2025. Beyond our TCT program, we are also exploring Targeted Alpha-particle Therapy with the ^{225}Ac-bisPSMA program to provide additional options to prostate cancer patients in later-stage disease. We look forward to progressing these programs into the clinic while translating a number of additional promising targets from the benchtop and through pre-clinical development and look forward to sharing the progress on these with our shareholders shortly.

Given the significant progress with our platform of products in development, building a strong supply and manufacturing network has been an important area of focus. With the perfect pairing of copper-64 and copper-67 having natural advantages over current-generation products based on gallium-68, fluorine-18 and lutetium-177 isotopes, we can avoid their associated supply and logistical issues and ensure abundant and reliable supply of copper isotopes and products for our growing programs. In the reporting period, we secured additional capacity for the ^{67}Cu-SAR-bisPSMA drug product with Nucleus RadioPharma. Nucleus announced an expansion plan to build new facilities in Arizona and Pennsylvania, with both locations covered under our Master Supply Agreement (MSA), providing additional manufacturing capacity in the future for Phase III trials and commercialisation. We have also signed a ^{64}Cu-SAR-bisPSMA product Clinical Manufacturing Agreement with SpectronRx, building on an earlier MSA for copper-64. This allows us to lock in seamless supply of the isotope and product for the rapidly progressing diagnostic pivotal trials, with distribution from a central location at SpectronRx's Indiana facility to all of the US. Supporting our progress in the Discovery Program, we also signed a Supply Agreement with TerraPower Isotopes for actinium-225 to be used in our ^{225}Ac-bisPSMA program and a Supply Agreement with EirGenix, Inc. for clinical-grade Good Manufacturing Practice (GMP) trastuzumab for the SAR- trastuzumab program.

Our team remains an absolute priority at Clarity, especially during this rapid growth phase. We continue to prioritise a flat structure, with high levels of engagement and empowerment, place focus on diversity, hiring the best talent in the market and support our growing team in the US and Australia through their professional development. We have made a number of adjustments to address our long-term focus on clinical development, including at the Senior Executive and Board levels. As such, Michelle Parker moved to Chief Executive Officer (CEO) after exceptional leadership over the last 6 years, leading the growth of the largest group within Clarity, our clinical group. Eva Lengyelova and Mary Bennett also joined our Senior Executive Team, focusing on their respective functions of Clinical Development and People & Culture. At the Board level, Non-Executive Director, Mr Rob Thomas, retired following the completion of his tenure on 23 August 2024 and in line with the announcement

dated 16 January 2024. Non-Executive Director, Dr Chris Roberts, was appointed Chair of the Audit and Risk Committee and has joined the Nomination and Remuneration Committee. Dr Thomas Ramdahl joined the Audit and Risk Committee, and fellow Non-Executive Director, Ms Rosanne Robinson, has taken the role of Lead Independent Director.

Whilst our focus every day is to build an incredible, talented and engaged team that continues to work tirelessly to achieve impeccable outcomes by developing new products for cancer patients, we thank our Shareholders for their incredible support. In December 2024, we had the remarkable milestone of entering the ASX200, a phenomenal achievement for a biotech company grown from the benchtop of Australian science, and to achieve this in just over 3 years since listing on the ASX has been incredible. Despite having a number of new shareholders registering recently, including a number of large index funds as well as many short-term traders and hedge funds, we continue to have a very tight register of committed shareholders. The top 10 shareholders make up 35% ownership of the Company, and the top 20 own over half of the company, numbers that have stayed relatively constant for some years. This long-term support from our shareholders has been a key differentiator for Clarity as we continue along our path, and with our Board and team making up a significant share of the Company's ownership, we thank you all for your commitment and look forward to sharing Clarity's successes with you.

Clarity remains well funded with $111.2m in cash and term deposits together with the FY2024 R&D Tax Incentive receivable of $11 million, and we continue leveraging the powerful momentum of impressive data, strong science and the radiopharmaceutical sector. The sector continues to have multi-billion-dollar mergers and acquisitions, the most recent with Lantheus acquiring Evergreen for up to US$1 billion, as the world of pharmaceuticals continues to recognise the modality of radiopharmaceuticals as a key pillar in the fight against cancer. Our Company continues to grow a differentiated platform of assets with the goal of improving outcomes for cancer patients in need of novel diagnostic tests and treatments around the world. We again thank our shareholders for your support and look forward to providing further updates on the continued progress of our therapeutic and diagnostic programs.

Yours sincerely,

Dr Alan Taylor
Executive Chairperson
Clarity Pharmaceuticals Ltd

CLINICAL & REGULATORY DEVELOPMENT OVERVIEW

Clarity is a global leader in next-generation radiopharmaceuticals with its Targeted Copper Theranostic (TCT) platform of products. Clarity's products use the "perfect pairing" of copper isotopes, copper-64 (Cu-64 or ^{64}Cu) for imaging and copper-67 (Cu-67 or ^{67}Cu) for therapy, which deliver a compelling combination of high accuracy and high precision in the treatment of a range of cancers.

Clarity's 3 core clinical-stage theranostic products, SAR-bisPSMA, SAR-Bombesin and SARTATE, each contain a different targeting agent that binds to specific receptors that are present on different cancer cells.

The 3 theranostic products are in clinical development for both the diagnosis and treatment of various cancers addressing unmet clinical needs. In addition to these core products, Clarity's SAR Technology, as well as other proprietary platforms and know-how, are used in the Company's extensive Discovery Program, which explores a range of new products, thereby creating a pipeline of new radiopharmaceuticals to expand the existing portfolio.

CLINICAL & REGULATORY DEVELOPMENT OVERVIEW

Clarity's 3 lead products, SAR-bisPSMA, SAR-Bombesin and SARTATE, are actively progressing through 8 clinical trials: 3 theranostic trials, 5 diagnostic trials, including 2 Phase III registrational trials, CLARIFY and AMPLIFY, and an Investigator-Initiated Trial (IIT) at St Vincent's Hospital Sydney.

	Theranostic	Diagnostic
SAR-bisPSMA	**SECuRE** – Phase I/IIa theranostic trial for identification and treatment of PSMA-expressing metastatic castrate-resistant prostate cancer (mCRPC) using ^{64}Cu/^{67}Cu-SAR-bisPSMA in the US and Australia (NCT04868604)[1]	**CLARIFY** – Registrational Phase III PET imaging trial of participants with high-risk prostate cancer prior to radical prostatectomy using ^{64}Cu-SAR-bisPSMA in the US and Australia (NCT06056830)[4] **AMPLIFY** – Registrational PET imaging trial of participants with biochemical recurrence (BCR) of prostate cancer following definitive therapy using ^{64}Cu-SAR-bisPSMA (in start-up) **COBRA** – Phase I/II PET imaging trial of participants with BCR of prostate cancer following definitive therapy using ^{64}Cu-SAR-bisPSMA in the US (NCT05249127)[5] **Co-PSMA** – Phase II imaging IIT in 50 patients with BCR post-radical prostatectomy who are being considered for curative salvage radiotherapy led by Prof Louise Emmett at St Vincent's Hospital Sydney
SAR-Bombesin	**COMBAT** – Phase I/IIa theranostic trial for identification and treatment of mCRPC that is expressing the GRPr, in participants who are ineligible for ^{177}Lu-PSMA-617, using ^{64}Cu/^{67}Cu-SAR-Bombesin in the US (NCT05633160)[2]	**SABRE** – Phase II PET imaging trial of participants with PSMA-negative BCR of prostate cancer using ^{64}Cu-SAR-Bombesin in the US (NCT05407311)[6] **BOP** – Phase II PET imaging IIT of participants with negative PSMA PET or low PSMA expression disease in patients with suspected BCR of prostate cancer and patients with mCRPC using ^{64}Cu-SAR-Bombesin led by Prof Louise Emmett at St Vincent's Hospital Sydney (NCT05613842)[7]
SARTATE	**CL04** – Phase I/IIa theranostic trial in paediatric participants with high-risk neuroblastoma using ^{64}Cu/^{67}Cu-SARTATE in the US (NCT04023331)[3]	**DISCO** – Phase II PET imaging trial of participants with known or suspected NETs using ^{64}Cu-SARTATE in Australia (NCT04438304)[8]

FAST TRACK DESIGNATIONS

The United States (US) Food and Drug Administration (FDA) granted Clarity 3 Fast Track Designations (FTD) for the SAR-bisPSMA agent.

^{64}Cu-SAR-bisPSMA was granted 2 FTDs for PET imaging of PSMA-positive prostate cancer lesions in 2 indications:

- patients with suspected metastasis who are candidates for initial definitive therapy; and
- patients with BCR of prostate cancer following definitive therapy.

^{67}Cu-SAR-bisPSMA was granted an FTD for the treatment of adult patients with PSMA-positive mCRPC who have been previously treated with androgen receptor pathway inhibition (ARPI).

The FDA's FTD is designed to expedite the development and regulatory review of novel drugs addressing serious conditions with significant unmet medical needs. For SAR-bisPSMA, it provides a number of product development advantages. The designations pave the way for a faster review process once Clarity submits its product approval applications.

Additionally, it enables more frequent communication with the FDA, allowing for rapid resolution of queries during development. Furthermore, Clarity can submit completed sections of its application as they are ready, rather than waiting for the entire package to be finished before it can be lodged with the FDA. These benefits would reduce the review time needed to bring this innovative and proprietary molecule to the prostate cancer imaging and therapy markets.

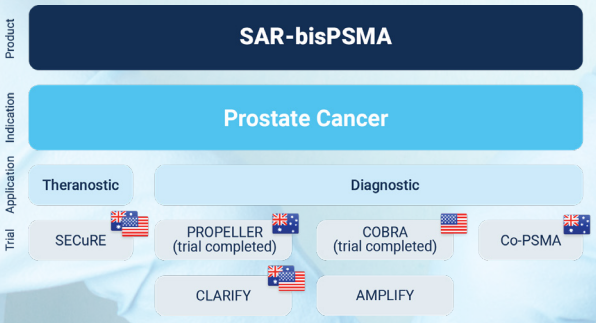
These 3 FTDs demonstrate the quality of the data generated to date on the ^{64}Cu-SAR-bisPSMA and ^{67}Cu-SAR-bisPSMA products in addressing serious unmet needs in prostate cancer. The FTDs will enable Clarity to accelerate the development of its comprehensive program with the optimised SAR-bisPSMA agent to be used in patients with prostate cancer throughout the management of their cancer, from initial diagnosis to late-stage disease, with an opportunity to completely change the entire treatment landscape for the large prostate cancer market.

"Receiving 3 FTDs for the one molecule, SAR-bisPSMA, within the last 6 months is an incredible achievement for Clarity, highlighting how impressive our science and development are, the significance of the diagnostic and therapeutic data so far, and the high unmet need for better therapies and diagnostics in prostate cancer,"

Dr Alan Taylor

PRODUCT UPDATES

SAR-bisPSMA
PROSTATE CANCER



SAR-bisPSMA is a next-generation, theranostic radiopharmaceutical with optimised dual prostate-specific membrane antigen (PSMA)-targeting agents to improve uptake and retention of the product in tumours.

SAR-bisPSMA 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).

In addition to the therapy program in metastatic castration-resistant prostate cancer (mCRPC) with ^{64}Cu-SAR-bisPSMA and ^{67}Cu-SAR-bisPSMA, Clarity is also running multiple diagnostic trials in line with advice received from the US Food and Drug Administration (FDA) to address the two relevant patient populations for registration of ^{64}Cu-SAR-bisPSMA:

- pre-definitive treatment (including prostatectomy) in patients with confirmed prostate cancer; and
- patients with biochemical recurrence (BCR) of prostate cancer.

SECuRE: Theranostic ^{64}Cu/^{67}Cu-SAR-bisPSMA trial

In October 2024, the Safety Review Committee (SRC) completed the review of the safety data of the first 3 participants in cohort 4 of the SECuRE trial (NCT04868604)[1] who received 2 doses of 12 GBq of ^{67}Cu-SAR-bisPSMA. The safety profile assessed in those participants was favourable, confirming the preliminary safety findings of previous cohorts (single-dose cohorts, 1, 2 and 3). Almost all adverse events (AEs) in those participants were mild to moderate, with the majority having resolved or improved at the last assessment. No dose limiting toxicities (DLTs) were reported in this cohort, with the SRC recommending the study proceed as planned and enrol a further 3 participants to complete cohort 4.

Recruitment of the additional 3 participants into cohort 4 of the dose escalation phase of the SECuRE trial is now complete, and the participants are currently in the safety and efficacy follow-up period. Following completion of the follow-up up period, the SRC will meet in March 2025.

The largest drop in prostate-specific antigen (PSA) in cohort 4 to date is a decline of 98.2% (from a baseline of 157.4 ng/mL). This participant, who had failed multiple lines of therapy prior to receiving ^{67}Cu-SAR-bisPSMA (androgen deprivation therapy [ADT], androgen receptor pathway inhibitor [ARPI] and an investigational agent), has already had a radiographic partial response based on the investigator's assessment of Response Evaluation Criteria in Solid Tumours v1.1 (RECIST) criteria. Preliminary analysis showed a reduction of 60.6% in tumour volume evaluated by PSMA positron emission tomography (PET) imaging with ^{64}Cu-SAR-bisPSMA (**Figure 1**).

Preliminary data shows that the majority of participants in the SECuRE study enrolled to date had bone metastasis (77%), high median PSA level at baseline (112.86 ng/mL, range 0.1 - 1503.1) and were heavily pre-treated (59% of participants received 3 or more lines of therapy). Despite how heavily pre-treated these participants were, and how much disease they had, 73% of them across all cohorts (including the lowest dose cohort of ^{67}Cu-SAR-bisPSMA at 4 GBq, single dose) showed reductions in PSA levels. The majority of patients that had an increase in PSA were on the lowest dose cohort 1 (4 GBq, single administration). PSA reductions of greater than 50% were seen in 45% of all trial participants, despite the overwhelming majority of participants only receiving a single dose of ^{67}Cu-SAR-bisPSMA (4, 8 or 12 GBq) in the trial. In cohorts 2, 3 and 4 (8 and 12 GBq single dose and 12 GBq multi-dose, respectively), in which most participants also only received 1 dose of ^{67}Cu-SAR-bisPSMA, PSA reductions of greater than 35% were observed in almost 75% of participants and PSA was reduced by 80% or more in almost half of the participants so far, as patients continue in follow-up.

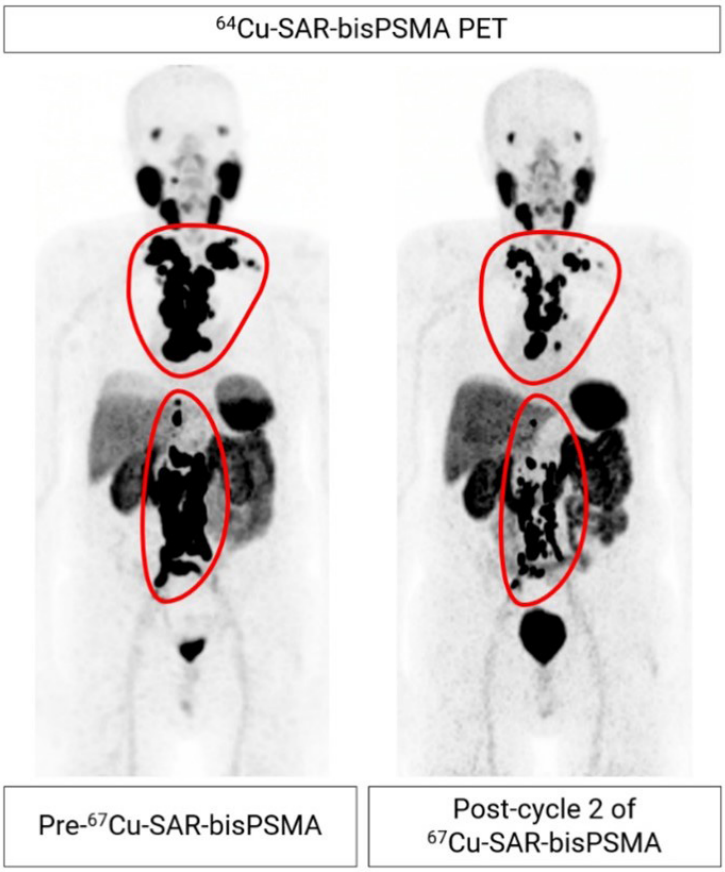


Figure 1. mCRPC patient from cohort 4 showing extensive metastasis to the lymph nodes (regions highlighted by the red lines). Considerable reduction in tumour volume (60.6%) observed following 2 doses of ^{67}Cu-SAR-bisPSMA (PSMA-avid tumour burden reduction assessed by ^{64}Cu-SAR-bisPSMA PET). Images shown as maximum intensity projections.

About the SECuRE trial

SECuRE is a Phase I/IIa theranostic trial for identification and treatment of an advanced form of prostate cancer, mCRPC. It is a multi-centre, single arm, dose escalation study with a cohort expansion. The aim of this trial is to determine the safety and tolerability of both ^{64}Cu-SAR-bisPSMA and ^{67}Cu-SAR-bisPSMA, as well as the efficacy of ^{67}Cu-SAR-bisPSMA as a therapy.

In this theranostic trial, Clarity first uses its imaging product, ^{64}Cu-SAR-bisPSMA, to visualise PSMA expressing lesions and select participants who are most likely to respond well to subsequent therapy with ^{67}Cu-SAR-bisPSMA. In the dose escalation phase of this study, each subsequent cohort of participants receive an increased dose of the therapeutic drug until the optimal dose is determined.

In cohort 1, each participant received a single administration of 4 GBq of ^{67}Cu-SAR-bisPSMA, in cohort 2 the dose was increased to 8 GBq, and cohort 3 was the last to assess single doses of ^{67}Cu-SAR-bisPSMA at the highest dose level of 12 GBq. The ongoing cohort 4 is the first to assess multiple doses of ^{67}Cu-SAR-bisPSMA at the dose level of 12 GBq, with participants receiving a minimum of 2 and a maximum of 4 doses of ^{67}Cu-SAR-bisPSMA at 12 GBq (**Figure 2**).

Cohort 4 is designed as a “3+3” cohort, where the first 3 participants received 2 therapy cycles, followed by an SRC meeting before commencing recruitment of the final 3 participants, which is now complete. Following a 6-week period after these participants receive their 2 doses, another SRC meeting will take place to assess safety and efficacy of the cohort.

SECuRE

Cohort expansion of the SECuRE trial to assess the combination of ^{67}Cu-SAR-bisPSMA with enzalutamide

For a long time, Clarity has been working closely with many important global medical experts in the field of prostate cancer, including the Company's Clinical Advisory Board members Prof Louise Emmett and Prof Oliver Sartor, to optimise the development of all of its products in prostate cancer. Those discussions have led to a recent protocol amendment for the SECuRE trial, which aims to investigate ways to further improve the treatment outcomes for these patients. The protocol amendment is aligned with the positive results of the Enza-p trial presented by Prof Emmett first at the European Society for Medical Oncology in 2023[9] and more recently at the American Society of Clinical Oncology Genitourinary Cancers (ASCO GU) Symposium in 2025[10], which confirmed the hypothesis that targeting both androgen signalling and PSMA receptors concurrently would improve anti-cancer activity in mCRPC.

The latest SECuRE protocol amendment increased the number of participants in the cohort expansion phase from 14 to 24 patients in the mCRPC pre-chemotherapy setting, with a subset of patients to receive the combination therapy of ^{67}Cu-SAR-bisPSMA with enzalutamide. This protocol amendment has now been approved at many of the participating trial sites, and the changes are expected to further enhance the already positive results of ^{67}Cu-SAR-bisPSMA observed in the SECuRE trial to date. This strategy focuses on the commercialisation of the product firstly in the largest market for prostate cancer therapies in mCRPC, with pre-chemotherapy being 3 times larger than the post-chemotherapy setting, and creates opportunities for the use of ^{67}Cu-SAR-bisPSMA with a range of ARPIs in future clinical development.

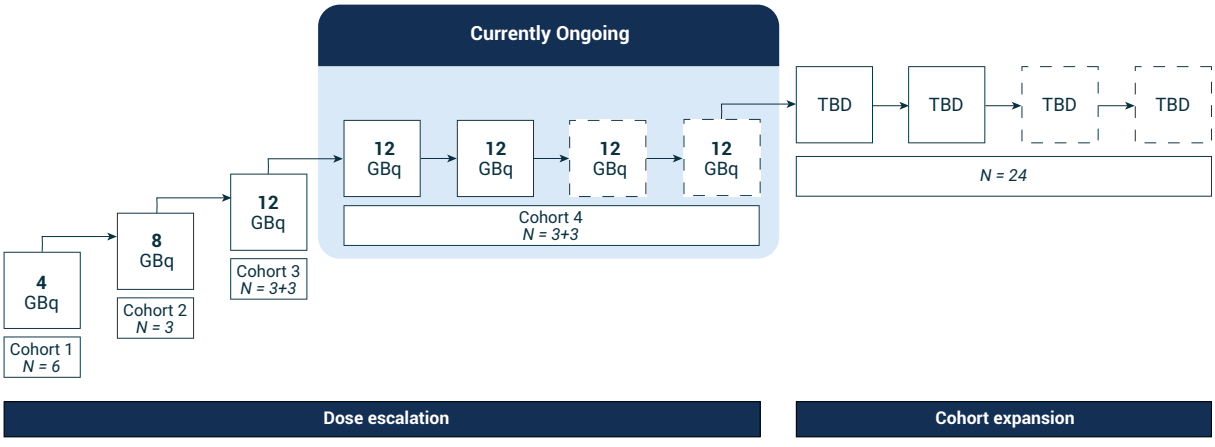


Figure 2. SECuRE Study Design

Patient Case Study: Complete response with 2 doses of 8 GBq of ^{67}Cu-SAR-bisPSMA

The first patient ever to be dosed with 2 cycles of ^{67}Cu-SAR-bisPSMA at 8 GBq achieved a complete response to treatment based on RECIST criteria and remains with undetectable disease for almost 16 months. This theranostic case report was selected by the European Association for Nuclear Medicine (EANM) 2024 Congress in October 2024 for an oral presentation.

The patient received the first cycle of ^{67}Cu-SAR-bisPSMA as part of cohort 2 of Clarity's theranostic trial, SECuRE, evaluating ^{64}Cu/^{67}Cu-SAR-bisPSMA in patients with mCRPC, and a second cycle under the US FDA Expanded Access Program (EAP), as requested by the patient's clinician. Prior to ^{67}Cu-SAR-bisPSMA, the patient had failed multiple lines of treatment, including chemotherapy, ADT, 2 ARPIs and an investigational agent.

A complete anatomical, molecular and biochemical response (no detectable cancer) was confirmed by computed tomography (CT) scan based on RECIST assessment, by ^{64}Cu-SAR-bisPSMA PET imaging and PSA, respectively.

The patient's PSA remains undetectable at the latest follow-up earlier this year (**Figure 3**). A PSMA PET conducted in October 2024 also showed no signs of recurrent or metastatic disease.

No AEs were reported as related to ^{64}Cu-SAR-bisPSMA. All AEs related to ^{67}Cu-SAR-bisPSMA either improved or resolved over time. Those included dry mouth, altered taste, thrombocytopenia (all Grade 1, improved), fatigue (Grade 2, resolved) and anaemia (Grade 3, improved to Grade 2).

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

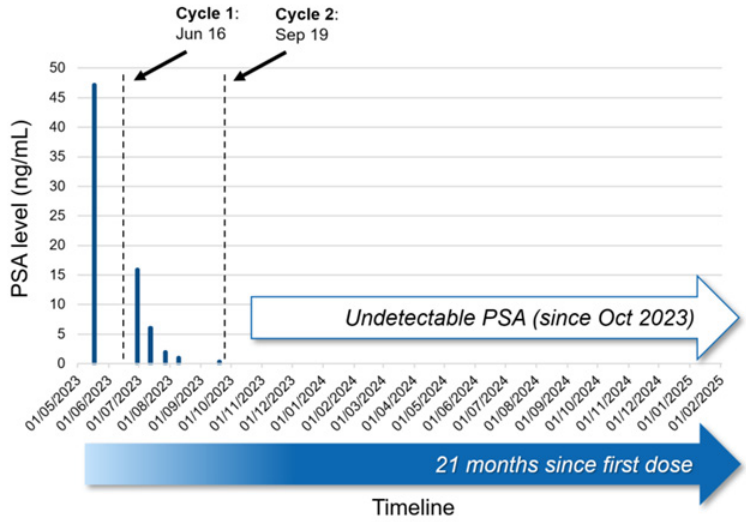


Figure 3. PSA reduction following 2 doses of ^{67}Cu-SAR-bisPSMA (8 GBq). A reduction of 99.4% in PSA was observed after the administration of the first cycle of ^{67}Cu-SAR-bisPSMA (from the baseline of 47.2 to 0.3 ng/ml). PSA reached undetectable levels following the administration of the second cycle of ^{67}Cu-SAR-bisPSMA. The patient's PSA remains undetectable for almost 16 months. Dash lines: administration of ^{67}Cu-SAR-bisPSMA. PSA limit of detection: 0.05 ng/ml. Data cut-off 13 January 2025.

Patient Case Study: Durable response after multiple cycles of ^{67}Cu-SAR-bisPSMA

A patient from cohort 1 of the SECuRE trial who went on to receive additional cycles under the EAP continues to derive clinical benefit 29 months after receiving his first dose of 4 GBq of ^{67}Cu-SAR-bisPSMA.

This patient had failed several lines of treatment prior to receiving ^{67}Cu-SAR-bisPSMA (i.e. ADT and 2 ARPIs) and, after receiving the lowest dose in the SECuRE trial of 4 GBq of ^{67}Cu-SAR-bisPSMA, had a reduction greater than 50% in PSA level. His clinician applied for additional 3 doses of 4 GBq of ^{67}Cu-SAR-bisPSMA under EAP, and a drop of 94% in PSA was observed after the fourth cycle.[9]

A ^{64}Cu-SAR-bisPSMA PET scan performed approximately 14 months after the patient's previous ^{67}Cu-SAR-bisPSMA treatment showed a reduction in tumour volume vs. baseline (41.6%) (**Figure 4**).

Most recently, this patient's clinician requested an additional dose of 8 GBq of ^{67}Cu-SAR-bisPSMA under the EAP following rising PSA levels. In the weeks following the administration of the fifth dose, a reduction in PSA of 57.4% was observed (vs. the most recent PSA peak value of 10.1 ng/mL) (**Figure 5**). The last assessment still shows a reduction in PSA of 45.5%, almost 6 months after the last dose administered. This patient continues to derive clinical benefit for over 29 months after receiving his first dose of ^{67}Cu-SAR-bisPSMA. The only reported AE in this patient related to the fifth dose of 8 GBq of ^{67}Cu-SAR-bisPSMA was mild thrombocytopenia (Grade 1), which is improving. No other related AEs were reported for this patient following the first 4 doses at 4 GBq.

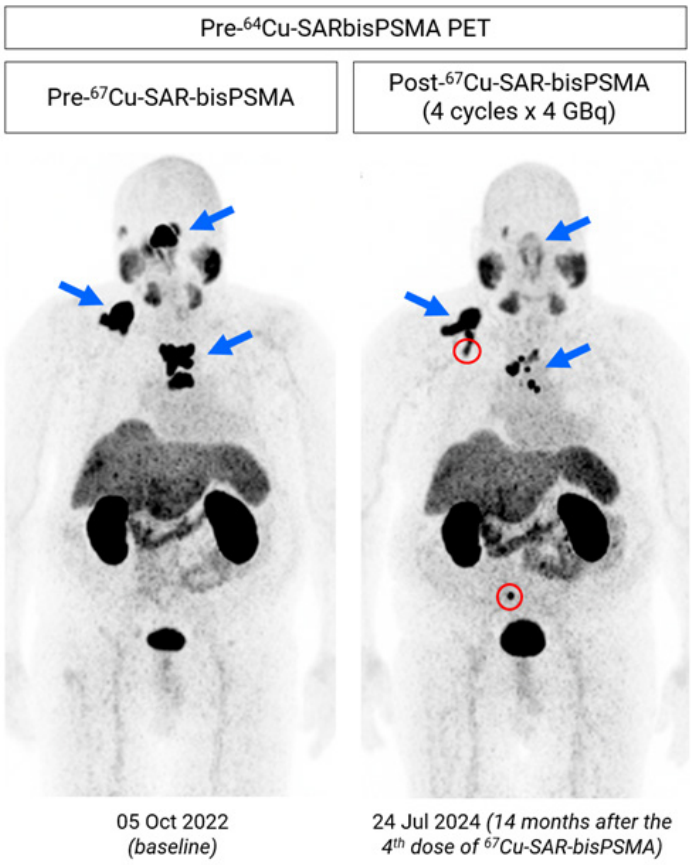


Figure 4. Images show considerable reduction in lesion uptake (^{64}Cu-SAR-bisPSMA PET) following 4 doses of ^{67}Cu-SAR-bisPSMA (4 GBq each; PET conducted approximately 14 months post-fourth cycle). Reduction in uptake (maximum standardised uptake value [SUVmax]) and tumour volume (PSMA-avid disease burden measured using ^{64}Cu-SAR-bisPSMA): 72.5% and 41.6%, respectively. New bone lesions identified (red circles) in the most recent image prior to the fifth dose. Post-treatment scans are pending. Images are displayed as maximum intensity projections.

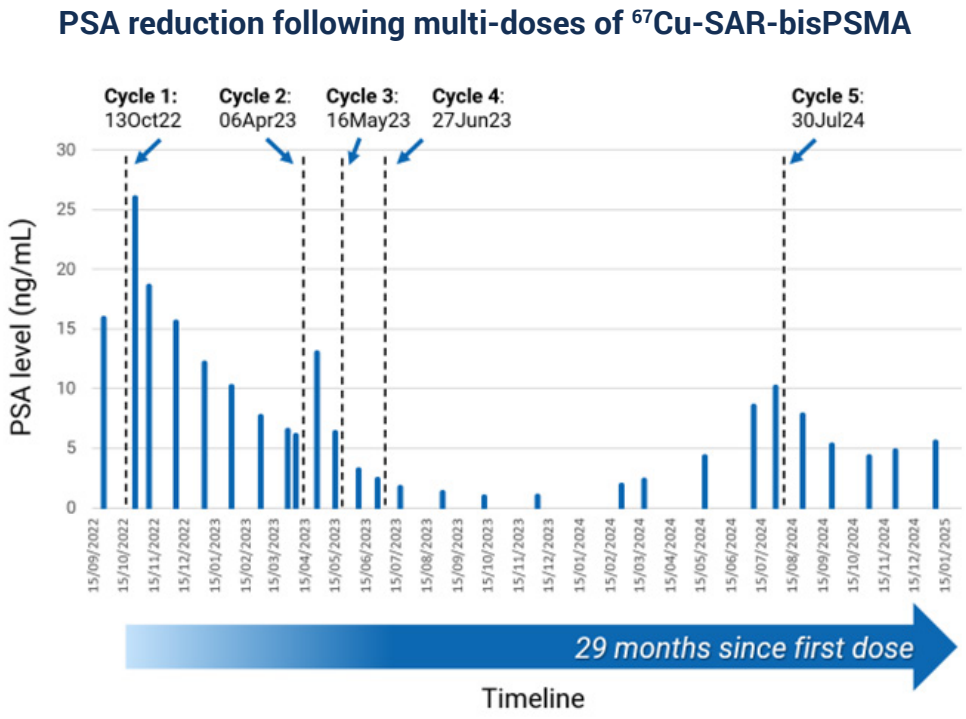


Figure 5. PSA reduction following multiple doses of ^{67}Cu-SAR-bisPSMA. Reduction of 94.4% observed following 4 cycles of ^{67}Cu-SAR-bisPSMA (4 GBq each). The fifth dose saw the patients PSA fall by 57.4%. The last assessment conducted during this reporting period still shows a reduction in PSA of 45.5%, almost 6 months after the last dose administered. Data cut-off 6 January 2025.

The duration of response and sustained clinical benefits in this patient demonstrate the potential of adaptive, flexible dosing regiments with ^{67}Cu-SAR-bisPSMA

AMPLIFY

AMPLIFY: Diagnostic Phase III registrational ^{64}Cu-SAR-bisPSMA trial

Clarity received positive guidance from the US FDA on a pivotal Phase III trial for ^{64}Cu-SAR-bisPSMA diagnostic in prostate cancer patients with BCR in October 2024. The trial, called AMPLIFY, is expected to commence in the coming months.

AMPLIFY (^{64}Cu-SAR-bisPSMA Positron Emission Tomography: A Phase 3 Study of Participants with Biochemical Recurrence of Prostate Cancer) will be a non-randomised, single-arm, open-label, multi-centre, diagnostic clinical trial of ^{64}Cu-SAR-bisPSMA PET in approximately 220 participants with rising or detectable PSA after initial definitive treatment. As a pivotal trial, the final study results are intended to provide sufficient evidence to support an application to the US FDA for approval of ^{64}Cu-SAR-bisPSMA as a new diagnostic imaging agent in prostate cancer.

The aim of the Phase III trial is to investigate the ability of ^{64}Cu-SAR-bisPSMA PET/CT to detect recurrence of prostate cancer. Evaluation will be across 2 imaging timepoints, Day 1 (day of administration, same-day imaging) and Day 2 (approximately 24 hours post administration, next-day imaging).

The AMPLIFY trial is supported by compelling pre-clinical and clinical data to date, including the Phase I/II COBRA trial in patients with BCR of prostate cancer, and the Phase I PROPELLER trial in patients with confirmed prostate cancer prior to undergoing radical prostatectomy. This data has been presented at leading medical conferences, including the prestigious European Association of Nuclear Medicine (EANM) Congress 2024 in October where an abstract for the COBRA trial was selected as a Top-Rated Oral Presentation. Most recently, abstracts outlining additional data from the COBRA trial were presented at the ASCO GU 2025 Cancer and at the 2025 Annual International Prostate Cancer Update (IPCU).

The COBRA trial assessed the safety and diagnostic performance of ^{64}Cu-SAR-bisPSMA to detect prostate cancer in patients with BCR of the disease and who had a negative or equivocal standard of care (SOC) scan at baseline.

The data showed that ^{64}Cu-SAR-bisPSMA is safe, and detected more lesions than approved SOC PSMA imaging agents for prostate cancer and much smaller lesions than anticipated, including a lesion with a diameter of less than 2 mm. The most recent findings from this trial established that ^{64}Cu-SAR-bisPSMA was able to detect lesions from 29 days to more than 6 months earlier than SOC PSMA PET agents (**Figure 6**). Additionally, in this subset of participants in the study who underwent follow-up SOC PSMA PET, 70% of participants had a positive scan on same-day imaging and 90% on next-day imaging using ^{64}Cu-SAR-bisPSMA, compared to 60% of participants using SOC PSMA PET where only same-day imaging is possible. The number of lesions across all participants (average sum of lesions across all readers) identified by ^{64}Cu-SAR-bisPSMA was also higher (26.3 lesions on same-day imaging, 52.6 lesions on next-day imaging) than that detected by SOC PET agents (20 lesions). Across all participants in the study, histopathology confirmed the presence of prostate cancer in lesions identified by ^{64}Cu-SAR-bisPSMA in up to 78% of cases in which biopsies were performed. This rate of true positivity was considerably higher compared to less sensitive methods (e.g. SOC imaging) used to verify the ^{64}Cu-SAR-bisPSMA PET findings. With regards to the biopsies, 100% of lesions which were located outside of the prostate bed were determined as positive for prostate cancer, with only 2 participants showing negative results. These 2 participants had lesions located in the prostate bed and had undergone the complete removal of their prostate as part of their initial treatment. The prostate bed is an area notoriously difficult to biopsy following surgery due to anatomical changes and scarring of surrounding tissues as a result of the procedure, which may lead to negative results despite the presence of cancer.

AMPLIFY

^{64}Cu-SAR-bisPSMA detects lymph node missed by ^{68}Ga-PSMA-11 (SOC PET performed ~6 months later)

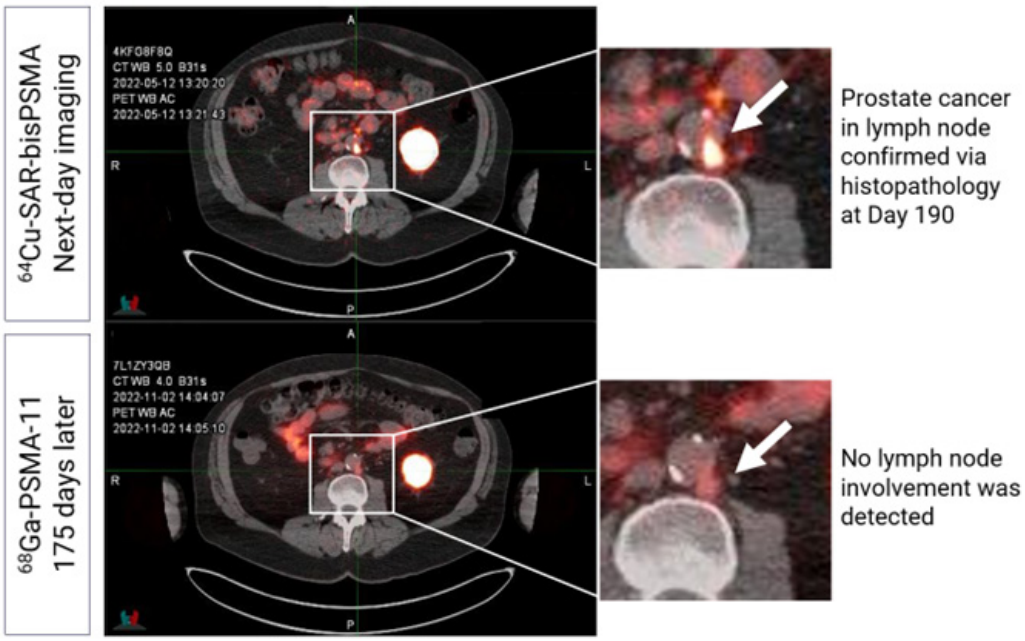


Figure 6. Retroperitoneal lymph node detected by ^{64}Cu-SAR-bisPSMA on next-day imaging. ^{68}Ga-PSMA-11 scan performed 176 days post-Day 0 (175 days post-Day 1) did not show tracer uptake. PET/CT fusion. Prostate cancer in lymph node was confirmed via histopathology.

Investigators stated that they would change their intended treatment plan in approximately half (48%) of their patients due to the findings of the ^{64}Cu-SAR-bisPSMA PET

CLARIFY: Diagnostic Phase III registrational ^{64}Cu-SAR-bisPSMA trial

During the reporting period, Clarity progressed recruitment in its first Phase III registrational trial, CLARIFY (NCT06056830)[4], for ^{64}Cu-SAR-bisPSMA as a diagnostic agent in patients with prostate cancer prior to undergoing radical prostatectomy, with recruitment now taking place in over 20 centres.

CLARIFY is the first Phase III registrational trial for Clarity and the first trial to evaluate the benefits of same-day and next-day imaging in prostate cancer patients prior to undergoing radical prostatectomy (total removal of the prostate). It is a non-randomised, open-label clinical trial in 383 participants with confirmed prostate cancer who will be proceeding to radical prostatectomy and pelvic lymph node dissection (removal of lymph nodes from the pelvic region).

The aim of the Phase III trial is to assess the diagnostic performance of ^{64}Cu-SAR-bisPSMA PET to detect prostate cancer within the pelvic lymph nodes. Evaluation will be across 2 imaging timepoints, day 1 (1-4 hours post administration, same-day imaging) and day 2 (approximately 24 hours post administration, next-day imaging).

An abstract outlining details from the CLARIFY trial has recently been presented at the ASCO GU 2025 in February. In the same month, the study was also presented at the Annual IPCU conference.

The study is ongoing with final results intended to provide sufficient evidence to support an application to the US FDA for approval of ^{64}Cu-SAR-bisPSMA as a new diagnostic imaging agent for newly diagnosed prostate cancer patients

Co-PSMA: Investigator-initiated Phase II ^{64}Cu-SAR-bisPSMA trial

In November 2024, an Investigator-Initiated Trial (IIT) evaluating the performance of Clarity's diagnostic product, ^{64}Cu-SAR-bisPSMA, in comparison to the standard-of-care (SOC) ^{68}Ga-PSMA-11 product for the detection of prostate cancer recurrence, was launched and successfully commenced recruitment.

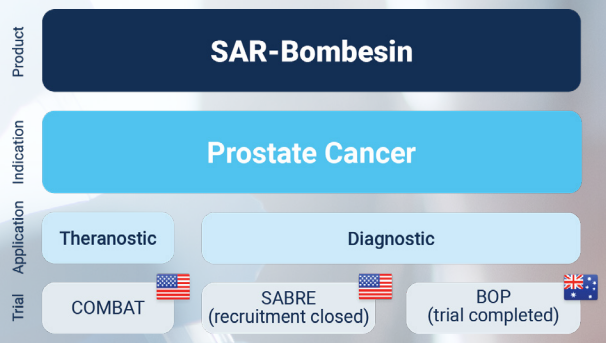
The trial, named Co-PSMA, stands for "Comparative performance of ^{64}Copper [^{64}Cu]-SAR-bis-PSMA vs ^{68}Ga-PSMA-11 PET CT for the detection of prostate cancer recurrence in the setting of biochemical failure following radical prostatectomy". It is led by Prof Louise Emmett at one of the most prominent hospitals in the country, St Vincent's Hospital Sydney.

The Co-PSMA trial is a prospective, Phase II imaging trial in 50 patients with BCR post-radical prostatectomy who are being considered for curative salvage radiotherapy. The primary objective of the study is to compare the detection rate of sites of prostate cancer recurrence, as determined by number of lesions per patient, between ^{64}Cu-SAR-bisPSMA and ^{68}Ga-PSMA-11 PET/CT.

"As the diagnostic performance of ^{64}Cu-SAR-bisPSMA has been demonstrated through previous clinical trials, such as COBRA and PROPELLER, we eagerly await the results of this head-to-head comparison between ^{64}Cu-SAR-bisPSMA and ^{68}Ga-PSMA-11 PET in the hope of opening the opportunity for earlier detection of disease, which may lead to meaningful impact for the management of those patients,"

Dr Alan Taylor

SAR-BOMBESIN
PROSTATE CANCER



SAR-Bombesin is a highly targeted pan-cancer theranostic radiopharmaceutical.

It is being developed for diagnosing, staging and subsequently treating cancers that express a specific receptor called the gastrin-releasing peptide receptor (GRPr), including prostate and breast cancer. 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 20-25% of prostate cancer patients with BCR and approximately 25% of mCRPC patients have low or no uptake of PSMA-targeting tracer[12-16]. 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 Pluvicto®. Currently these patients have few therapy options available to treat their cancer.

SAR-Bombesin is currently being investigated in two clinical trials in prostate cancer indications:

- theranostic Phase I/IIa trial in the US (COMBAT)[2] in patients with mCRPC;
- diagnostic Phase II trial in the US (SABRE)[6] in patients with BCR of prostate cancer.

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 a 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, lung and pancreatic cancers.

COMBAT

COMBAT: Theranostic ^{64}Cu/^{67}Cu-SAR-Bombesin prostate cancer trial

Recruitment into the theranostic ^{64}Cu/^{67}Cu-SAR-Bombesin Phase I/IIa trial in mCRPC, COMBAT (NCT05633160)[2], is ongoing.

COMBAT is a theranostic trial for identification and treatment of mCRPC that is expressing the GRPr using ^{64}Cu/^{67}Cu-SAR-Bombesin in participants who are ineligible for therapy with ^{177}Lu-PSMA-617. The aim for the trial is to determine the safety and efficacy of ^{67}Cu-SAR-Bombesin in this patient group.

SAR-Bombesin is a pan-cancer product and the open Investigator Drug Application (IND) offers exciting opportunities for exploring new theranostic indications with this versatile agent

SABRE: Diagnostic ^{64}Cu-SAR-Bombesin prostate cancer trial

Data review and analysis is ongoing for Clarity's US-based diagnostic ^{64}Cu-SAR-Bombesin trial for patients with PSMA-negative prostate cancer, SABRE (NCT05407311)[6], with topline results to be shared in the coming months.

SABRE is a Phase II multi-centre, single arm, non-randomised, open-label trial in participants with suspected recurrence of their prostate cancer and who have negative or equivocal findings of prostate cancer on standard of care imaging, including approved PSMA agents.

The primary objectives of the trial are to investigate the safety and tolerability of ^{64}Cu-SAR-Bombesin, as well as its ability to correctly detect the recurrence of prostate cancer.

In the SABRE trial, 53 participants were enrolled. ^{64}Cu-SAR-Bombesin PET/CT imaging took place on the day of product administration (same-day imaging) and approximately 24 hours later (next-day imaging).

In **Figure 7**, the images in the cross hairs on same-day and next-day scans following ^{64}Cu- SAR-Bombesin administration clearly identify a pelvic lymph node, while there was no uptake with ^{18}F-DCFPyL, (Pylarify®) an FDA-approved PSMA PET agent.

Pre-clinical data, along with successful C-BOBCAT and BOP investigator-initiated clinical trials, have already shown the utility of SAR-Bombesin and its potential to identify disease in some patient subgroups where conventional diagnostic imaging has failed. Clarity looks forward to reporting data from the SABRE trial and, subject to these results, progressing the ^{64}Cu-SAR-Bombesin product into a registrational Phase III trial for first approvals in the US.

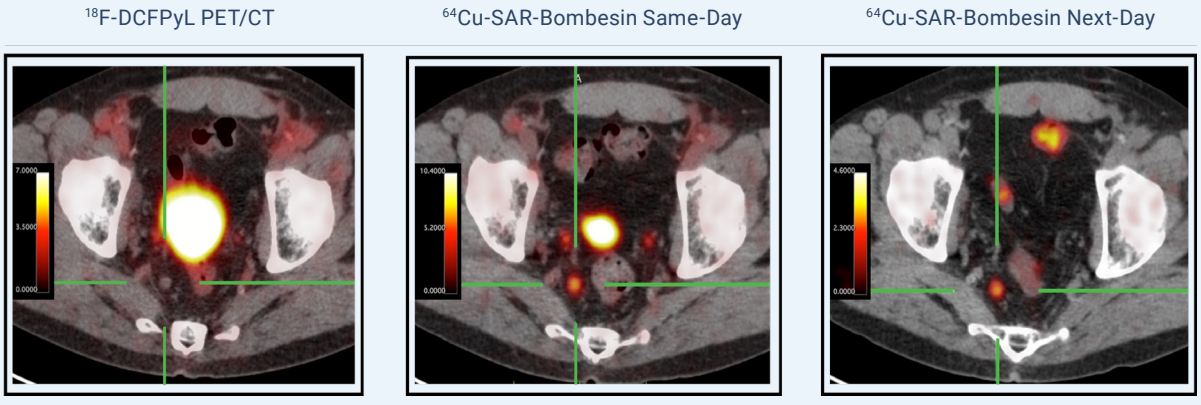


Figure 7. ^{64}Cu SAR-Bombesin detected a positive lymph node on scans performed on 2 different days (same-day and next-day scans). No uptake was observed using ^{18}F-DCFPyL (Pylarify®) PET/CT. A subsequent biopsy, performed and assessed locally by the study site, has confirmed prostate cancer.

BOP: Diagnostic ^{64}Cu-SAR-Bombesin investigator-initiated prostate cancer trial

Initial data from the diagnostic BOP (NCT05613842)[7] trial in patients with BCR of prostate cancer, evaluating ^{64}Cu-SAR-Bombesin, was presented at the European Association of Nuclear Medicine (EANM) 2024 Congress. Full manuscript was published in the Journal of Nuclear Medicine in August 2024[17].

BOP was a Phase II IIT in 30 participants led by Prof Louise Emmett at St Vincent's Hospital, Sydney. The IIT assessed the safety of ^{64}Cu-SAR-Bombesin as well as the diagnostic performance across 2 different groups of men with prostate cancer:

1. Participants with BCR of prostate cancer who had negative PSMA PET imaging scans or low PSMA expressing disease; and
2. Participants with mCRPC who were not suitable for PSMA-targeted therapy.

Participants received 200 MBq of ^{64}Cu-SAR-Bombesin and PET imaging was performed at 1 and 3 hours after injection and at an optional 24 hours time point after injection. Results from the BCR cohort showed PSA doubling time of 4.2 months (range 2.8 – 7.5; PSA median 0.69 ng/ml, range 0.28 – 2.45) prior to entering the study.

No AEs from ^{64}Cu-SAR-Bombesin administration were reported.

^{64}Cu-SAR-Bombesin was found to be safe and able to detect prostate cancer in 44% (11/25) of patients with BCR of prostate cancer who had a negative or equivocal SOC PSMA PET.

"This could be the difference between having an incorrect negative cancer detection leading to cancer progression and having an effective treatment plan that may lead to long-term remission,"

Dr Alan Taylor

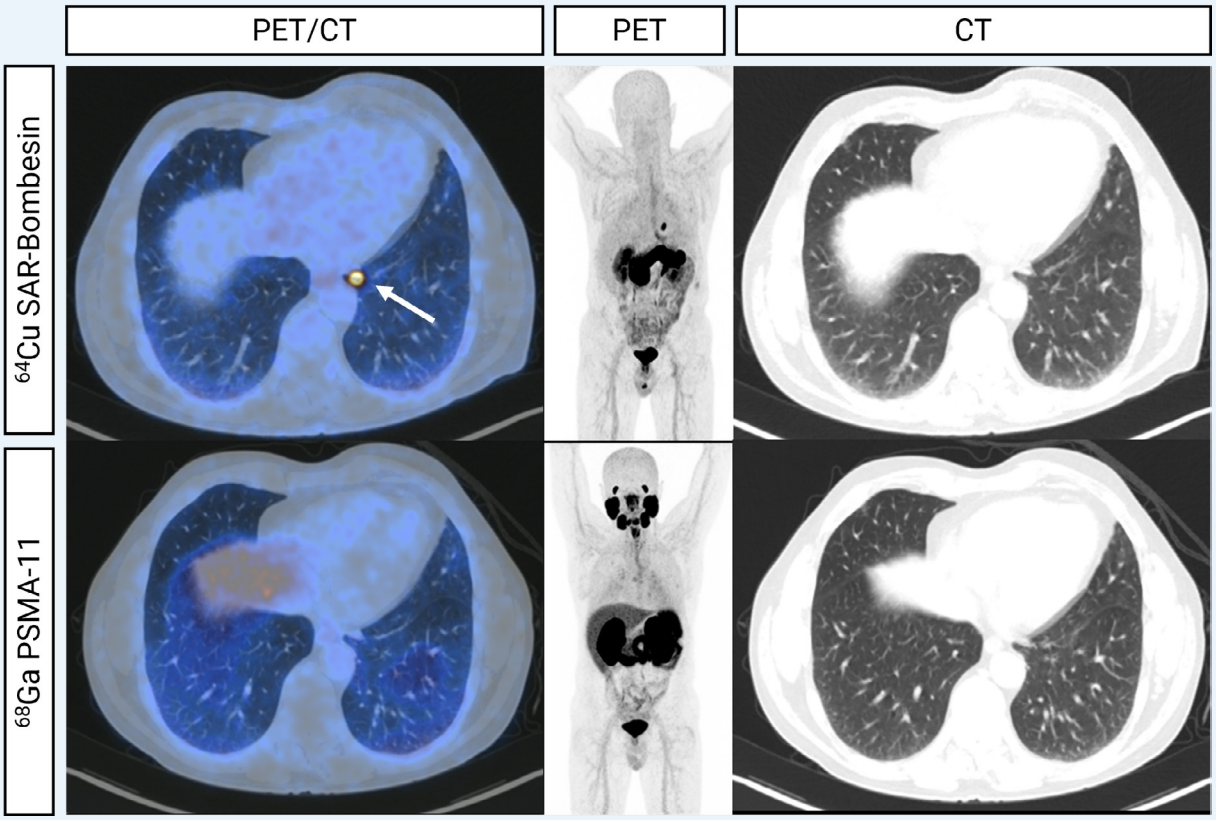


Figure 8. Fused, maximum intensity projections (MIP) and CT (left to right) images from ^{64}Cu-SAR-Bombesin (top) and ^{68}Ga-PSMA-11 (bottom) PET of a patient demonstrating a left subpleural lesion with ^{64}Cu-SAR-Bombesin uptake (arrow) without SOC PSMA uptake. This patient underwent a lobectomy with histopathology demonstrating metastatic prostate cancer.

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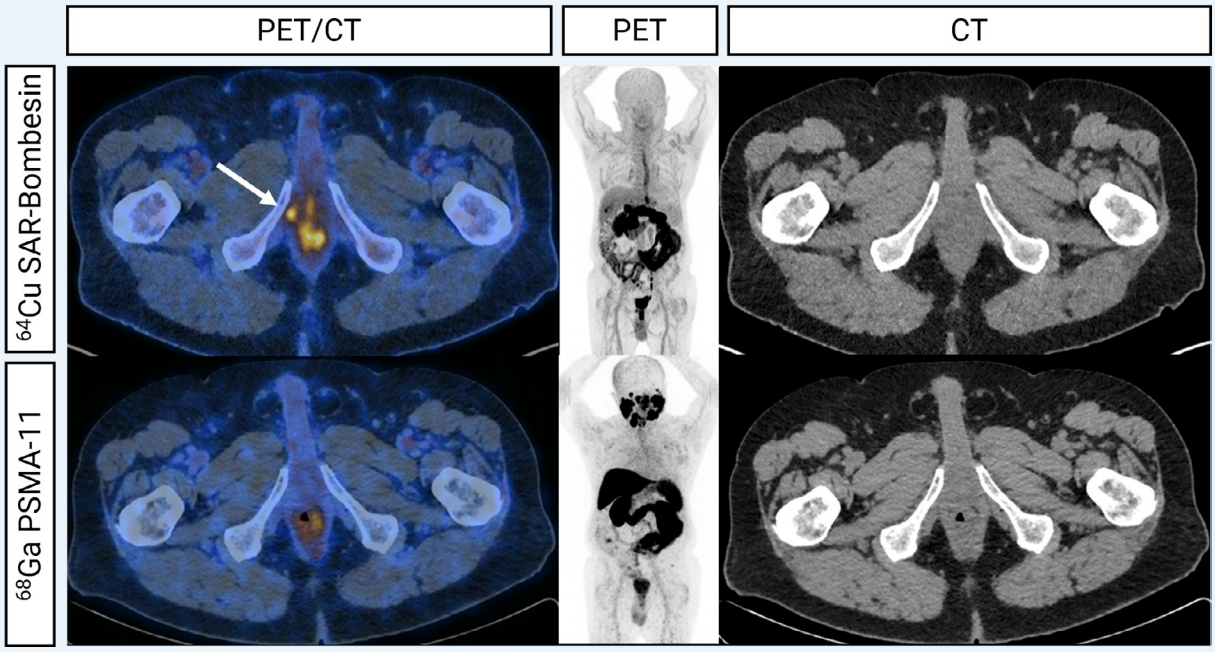

Figure 9. Fused, MIP and CT (left to right) images from ^{64}Cu-SAR-Bombesin (top) and ^{68}Ga-PSMA-11 (bottom) PET of a patient demonstrating uptake at the right urethral anastomosis on ^{64}Cu-SAR-Bombesin alone (arrow). This patient was managed with local radiotherapy with improvement in PSA post-treatment.

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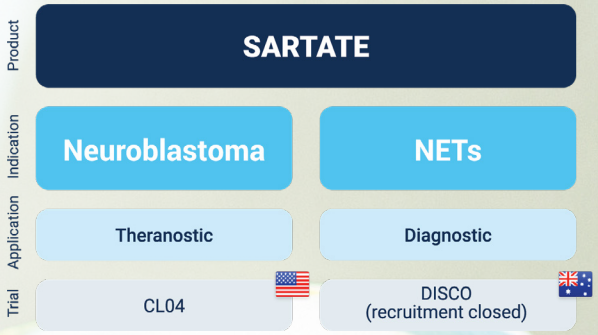
SARTATE NEUROBLASTOMA AND NETs



SARTATE is a next-generation, highly targeted theranostic radiopharmaceutical.

SARTATE is being developed for diagnosing, staging and subsequently treating cancers that express somatostatin receptor 2 (SSTR2), including neuroblastoma and neuroendocrine tumours (NETs). Like all Clarity products, the SARTATE product can be used with copper-64 (^{64}Cu) for imaging (^{64}Cu-SARTATE) or copper-67 (^{67}Cu) for therapy (^{67}Cu-SARTATE).

Clarity is progressing 2 trials with the SARTATE product, one theranostic trial in neuroblastoma and one diagnostic trial in neuroendocrine tumours (NETs):

- **CL04** theranostic trial with an open Investigational New Drug (IND) application in the US (NCT04023331)[3]
- **DISCO** diagnostic trial in Australia (NCT04438304)[8]

Neuroblastoma, an aggressive childhood cancer, is Clarity's key focus with the SARTATE product. In 2020, the US FDA awarded Clarity two Orphan Drug Designations (ODDs) in this important indication, one for ^{64}Cu-SARTATE as a diagnostic agent for the clinical management of neuroblastoma and one for ^{67}Cu-SARTATE as a therapy of neuroblastoma, as well as two Rare Paediatric Disease Designations (RPDDs) for these products.

Should Clarity be successful in achieving marketing approval from the US FDA for these two products in neuroblastoma, RPDDs may allow the Company to access a total of two tradeable Priority Review Vouchers (PRVs) valued at ~$158M USD each.[18]

CL04: Theranostic ^{64}Cu/^{67}Cu-SARTATE neuroblastoma trial

Clarity is progressing the CL04 theranostic trial(NCT04023331)[3] in neuroblastoma patients.

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

In the dose escalation phase of the trial, each subsequent cohort will receive an increase in the therapeutic dose administered. Generally speaking, a higher therapeutic dose is usually associated with greater therapeutic response, up to a certain threshold where toxicity may occur. The CL04 trial is designed to gradually increase the dose of ^{67}Cu-SARTATE administered to participants in each cohort, until the Maximum Tolerated Dose (MTD) is reached:

- Cohort 1 – 3 participants received an initial single dose of 75MBq/kg body weight ^{67}Cu-SARTATE
- Cohort 2 – 3 participants received an initial single dose of 175MBq/kg body weight ^{67}Cu-SARTATE
- Cohort 3 – 3 participants received an initial single dose of 275MBq/kg body weight ^{67}Cu-SARTATE
- Cohort 4 – 6 participants received an initial single dose of 375 MBq/kg body weight ^{67}Cu-SARTATE
- Cohort 5 – 3 to 6 participants to receive an initial single dose of 475 MBq/kg body weight ^{67}Cu-SARTATE

Cohort 4 of the trial has completed enrolment, with all 6 participants assessed for DLTs. One participant with rapidly progressing disease and intracranial metastases experienced a DLT (swelling of the brain, Grade 5). In the opinion of the investigator, this event was due to progressive disease. As the contribution of ^{67}Cu-SARTATE to the event could not be fully ruled out, the SRC classified this event as a DLT. Consequently, the protocol was amended to exclude patients with similar disease characteristics.

Nonetheless, the SRC has recommended increasing the dose of ^{67}Cu-SARTATE to 475 MB/kg in a new cohort as part of the dose escalation phase. The addition of this cohort at a higher dose of ^{67}Cu-SARTATE reflects the investigators' confidence in the potential clinical benefits of the treatment for this indication of such significant unmet need.

Cohort 5 recently commenced recruitment at sites which have Institutional Review Board (IRB) approvals in place and consenting of patients permitted following required protocol training in mid-February. Remaining sites will be opened once approvals are received. No patients are currently enrolled in this cohort.

Some participants in the completed cohorts have received additional therapy cycles of ^{67}Cu-SARTATE in addition to the single therapy cycle administered under the CL04 trial. These subsequent therapy cycles are strictly contingent on the investigators' assessment that the participant is demonstrating therapeutic benefit after the first dose.

DISCO: Diagnostic ^{64}Cu-SARTATE NETs trial

The last patient assessment for the Phase II diagnostic ^{64}Cu-SARTATE trial, DISCO (NCT04438304)[8], in patients with known or suspected neuroendocrine tumours (NETs) was completed successfully. A total of 45 patients were enrolled and imaged in the trial.

DISCO, which derives from "Diagnostic Imaging Study of ^{64}COpper-SARTATE Using PET on Patients with Known or Suspected Neuroendocrine Tumours", is assessing the performance of Clarity's SARTATE imaging product as a potential new method to diagnose and manage NETs. The DISCO trial recruited participants with Gastroenteropancreatic NETs (GEP-NETs) across four sites in Australia, comparing the diagnostic performance of ^{64}Cu-SARTATE at approximately 4 and 20 hours post-administration to ^{68}Ga-DOTATATE at 1 hour.

The trial was originally planned for up to 63 patients based on an expected discordance level between imaging with Clarity's ^{64}Cu-SARTATE and the current standard of care, ^{68}Ga-DOTATATE. The sample size was adjusted to 45 patients based on the results of the pre-planned early assessment of the images collected during the trial with the aim of generating sufficient evidence to plan for a Phase III trial in this indication. This enabled recruitment to successfully close early, and the last patient last visit was completed in November 2024.

The trial aims to build on earlier work with SARTATE in patients with NETs, which demonstrated that imaging at later time points, enabled by the longer half-life of copper-64 in comparison to gallium-68, may lead to better identification of disease[19]. Delayed imaging (at 4 and 24 hours vs 1 hour) showed a progressive increase in lesion-to-liver ratio (Table 1). Figure 10 provides an example of improved lesion detection based on an increase in lesion-to-background ratio observed with delayed imaging[19].

"We believe that SARTATE could become a best-in-class product in this and other indications expressing the same target receptor, SSTR2, playing an important role in improving accurate staging, lesion identification and treatment outcomes for these patients,"

- Dr Alan Taylor

Ratio 1	Median	Ratio 2	Median	Difference	95% CI	P*
^{68}Ga-DOTATATE to liver (1 hr)	3.92	^{64}Cu-SARTATE to liver (1 hr)	5.45	1.35	0.7, 2.2	0.004
^{68}Ga-DOTATATE to liver (1 hr)	3.92	^{64}Cu-SARTATE to liver (4 hr)	6.70	3.86	1.5, 6.4	0.002
^{64}Cu-SARTATE to liver (4 hr)	6.70	^{64}Cu-SARTATE to liver (24 hrs)	16.69	6.75	3.4, 10.3	0.002

Table 1. Comparison of lesion-to-liver ratios of ^{68}Ga-DOTATATE and ^{64}Cu-SARTATE. Progressive increase in lesion-to-liver ratio with delayed imaging using ^{64}Cu-SARTATE. *Paired Wilcoxon test on 10 patients. CI = confidence interval.

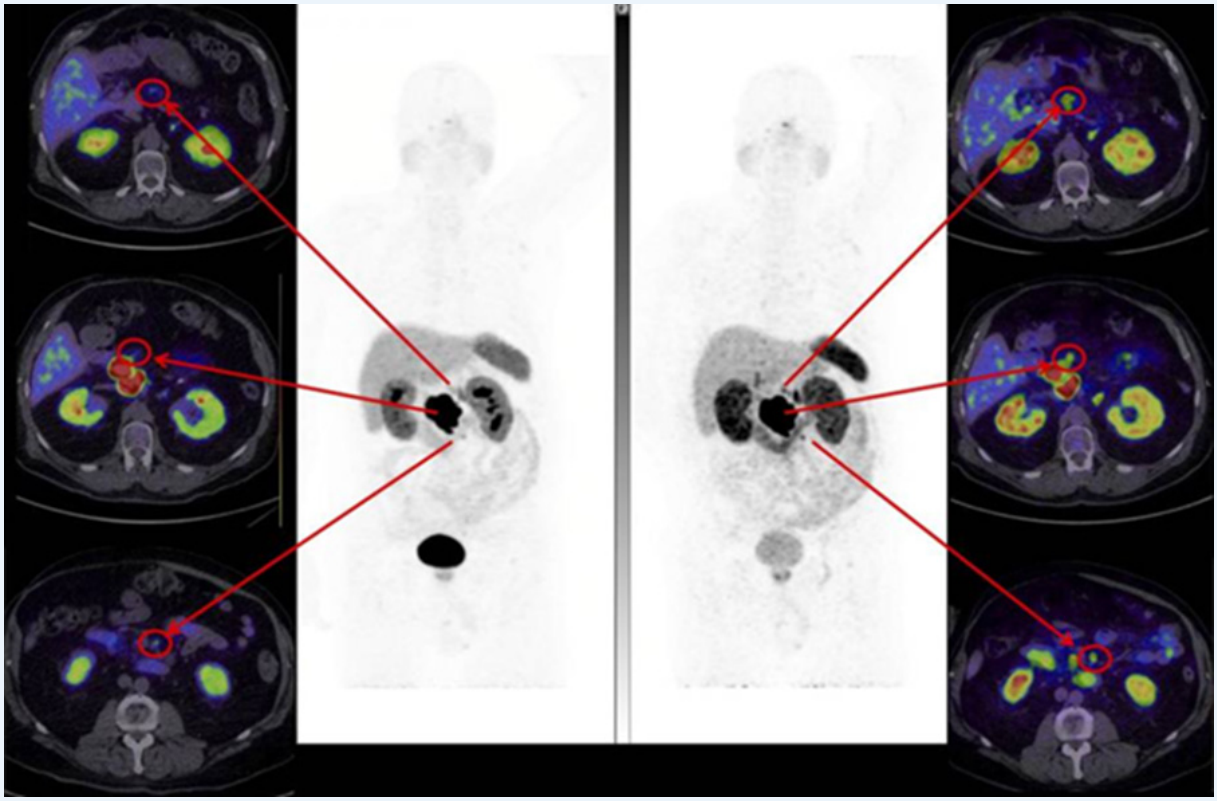


Figure 10. Lesion detection comparing ^{68}Ga-DOTATATE and ^{64}Cu-SARTATE. Hicks et al. (2019) determined superior lesion detection at 4 hrs with ^{64}Cu-SARTATE. High lesion contrast on ^{64}Cu-SARTATE images at 4 hrs (right) better defines regional nodal disease than ^{68}Ga-DOTATATE images at 1 hr (left) in patient with large pancreatic primary tumour.

DISCOVERY PROGRAM

In addition to progressing its key products that are already in clinical development, Clarity is expanding its product pipeline with a new generation of radiopharmaceuticals through its Discovery Program to meet further areas with unmet needs.

In the reporting period, Clarity announced a number of advancements in its Discovery Program, representing new opportunities to improve the diagnostic and treatment options for patients with different cancers:

- SAR- trastuzumab
- SAR-bisFAP
- Targeted Alpha-particle Therapy

SAR-trastuzumab

Clarity added a new asset, $^{64/67}$Cu-SAR-trastuzumab, into the Targeted Copper Theranostic (TCT) portfolio. Trastuzumab is an antibody that targets HER2, which is expressed in many cancers, including some types of lung, gastric and breast cancers[20]. This novel theranostic asset will initially focus on breast cancer and, combined with SAR-Bombesin, SARTATE and SAR-bisPSMA, will bolster Clarity's renewed focus on this important indication.

Through pioneering work in collaboration with the University of Melbourne, the trastuzumab antibody was combined with Clarity's proprietary SAR chelator and radiolabelled with copper-64 (Cu-64 or ^{64}Cu) for diagnostic imaging and copper-67 (Cu-67 or ^{67}Cu), forming a radioimmunotherapy (RIT)[21]. ^{64}Cu-SAR-trastuzumab was shown to target HER2-positive cancer cells to a very high level pre-clinically. ^{67}Cu-SAR-trastuzumab was shown to reduce the growth of HER2-expressing tumours in a dose-dependent manner, as well as to improve the survival of mice treated with the product (**Figure 11**).

Clarity intends to conduct a Phase I/IIa theranostic study with $^{64/67}$Cu-SAR-trastuzumab in HER2-positive breast cancer patients to address a significant unmet clinical need. This subtype of breast cancer is characterised by aggressive behaviour and poor prognosis[22]. Despite recent advances in the treatment of patients with early HER2-positive breast cancer, relapse still occurs in up to 25% of patients within 10 years[23].

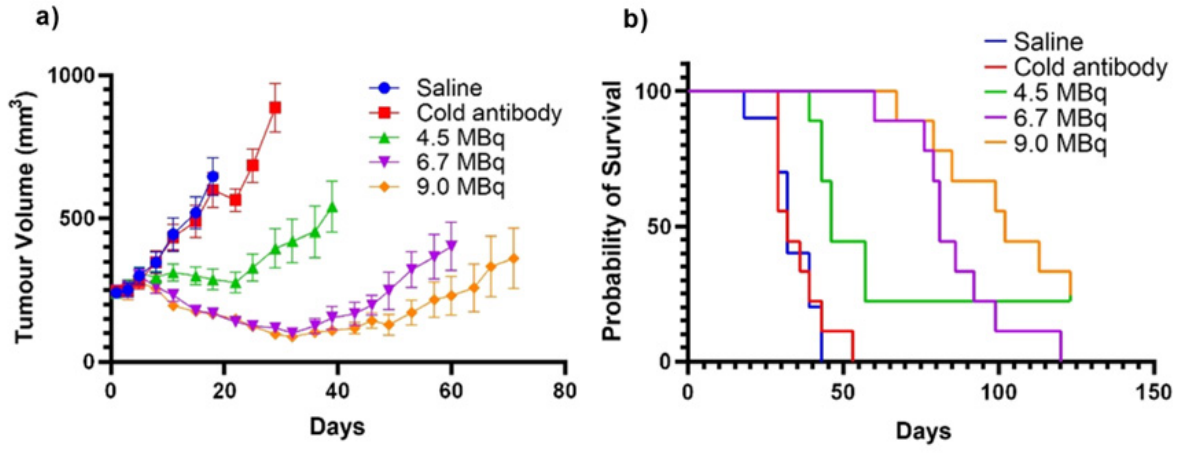


Figure 11. Treatment of HER2-positive tumours with ^{67}Cu-SAR-trastuzumab. Pre-clinical model of HER2-expressing tumours (SKOV-3 xenograft) was used to assess the anti-tumour effect of ^{67}Cu-SAR-trastuzumab, compared to unlabelled SAR-trastuzumab or saline (control groups). A: Treatment with a single dose of ^{67}Cu-SAR-trastuzumab, at either 4.5, 6.7 or 9.0 MBq, inhibited tumour growth by 88%, 120% and 119% at 18 days post-administration respectively, compared to control groups (i.e. slowing of tumour growth at the 4.5 MBq dose, and reduction in tumour size at higher doses at day 18). B: ^{67}Cu-SAR-trastuzumab effectively increased the survival of all treated groups.[21]

SAR-bisFAP

Clarity has developed a proprietary fibroblast activation protein (FAP)-targeted radiopharmaceutical product that can be used with the perfect pairing of copper isotopes for the diagnosis (with copper-64) and treatment (with copper-67) of cancer. The SAR-bisFAP product has shown strong tumour targeting, retention and pharmacokinetic data to date in pre-clinical models and has the potential to be used as an agent in various indications due to FAP's association with a broad range of cancers.

FAP is a promising pan-cancer target for both imaging and treatment of cancer as it is expressed on cancer associated fibroblasts (CAFs), a particular cell type found in the tumour microenvironment (cancer 'infrastructure' called the tumour stroma). CAFs are found in a broad range of cancers, such as breast, colorectal, pancreatic, lung, brain and ovarian cancers, but only minimally in normal tissue[24]. CAFs form part of the environment surrounding the cancer cells, and they can promote cancer growth and the spread of the tumour throughout the body[25]. Targeting the tumour stroma is an alternative way to treat cancer whereby the architecture of the tumour mass is targeted rather than the tumour cells directly.

SAR-bisFAP was developed with the intent of overcoming the low uptake and retention in tumours of other FAP-targeted radiopharmaceuticals in development. Clarity developed this agent by creating a dimer molecule with an industry leading FAP inhibitor, bisFAP, and combining it with its proprietary SAR chelator technology, enabling the use of copper-64 for imaging and copper-67 for the targeted treatment of various cancers.

The dimer SAR-bisFAP has shown increased tumour uptake and retention over 24 hours in pre-clinical models in comparison to other FAP radiopharmaceuticals in development as well as to a monomer equivalent (SAR-monoFAP).

In addition to comparing the mono and dimer versions of the product, Clarity compared the dimer, ^{64}Cu-SAR-bisFAP, to an industry standard FAP-targeted monomer called ^{68}Ga-FAPI-46. Using a FAP-expressing melanoma cell line (SK-MEL187) in this experiment, at 1 hour post-injection ^{64}Cu-SAR-bisFAP had approximately 4 times the uptake in the cancer compared to ^{68}Ga-FAPI-46. The potential improvements in uptake and retention of SAR-bisFAP compared to first-generation mono-FAP compounds are key attributes for the development of next-generation FAP-targeted radiopharmaceuticals.

	^{64}Cu-SAR-monoFAP	^{64}Cu-SAR-bisFAP
Time point	Tumour uptake (%IA/g)	
1 hour	4.8 ± 0.6	7.6 ± 2.1
4 hours	4.1 ± 0.1	11.6 ±1.1
24 hours	0.8 ± 0.2	6.2 ±0.6

Table 2. Biodistribution of ^{64}Cu-SAR-monoFAP or ^{64}Cu-SAR-bisFAP in a pre-clinical cancer model. In a pre-clinical cancer model utilising a FAP-expressing glioblastoma cell line (U87MG), the biodistribution of ^{64}Cu-SAR-monoFAP and ^{64}Cu-SAR-bisFAP were assessed. The Table shows measurements of how much of the products accumulated in the cancer, which is expressed as the percentage of the injected activity (%IA/g) at either 1, 4, or 24 hours post-injection. The monomer had moderate uptake at 1 hour, which decreased over 24 hours. The dimer had a higher uptake at 1 hour, rising further to 11.6 %IA/g at 4 hours. At 24 hours, the dimer had 6.2 %IA/g, which is approximately 8 times greater retention than the monomer.

Clarity is currently conducting additional investigations to enable a Phase I clinical trial, which could commence in late 2025. Research into the potential clinical use of Clarity's FAP agent has begun with several pre-clinical studies in diagnostics with ^{64}Cu-SAR-bisFAP, which will be followed by exploring treatment opportunities of cancers based on their unmet medical needs using ^{67}Cu-SAR-bisFAP.

Targeted Alpha-particle Therapy

Clarity has been conducting research and pre-clinical studies to assess the potential combination of the bisPSMA targeting agent with actinium-225 (Ac-225 or ^{225}Ac), an alpha-emitting radioisotope. With the signing of the supply agreement for Ac-225 with TerraPower Isotopes in July 2024, Clarity is now well positioned to develop a best-in-class Targeted Alpha-particle Therapy (TAT) program with ^{225}Ac-bisPSMA to complement its treatment paradigm in prostate cancer, particularly in later-stage prostate cancer patients.

To date, the program with ^{225}Ac-bisPSMA has focused on identifying a lead candidate from a number of different analogues. This is achieved by assessing the biodistribution, tumour uptake, radiolabelling efficiency and product stability of the different analogues in order to select the best one to progress to clinical development.

Clarity's SAR-bisPSMA product has shown impressive results in a number of pre-clinical and clinical trials conducted thus far, and the dual targeting of the product enables increased uptake and retention in prostate cancer tumours compared to the mono-targeted form of the product. By combining the optimised bisPSMA with Ac-225, Clarity has the opportunity to complement its beta-particle therapy product, ^{67}Cu-SAR-bisPSMA with an alpha-particle therapy product, ^{225}Ac-bisPSMA.

Developing both alpha- and beta-emitting therapy products for prostate cancer puts Clarity in a unique position to offer powerful treatment approaches to improve outcomes for these patients as using each product at different stages of the disease would provide more options for patient care.

MANUFACTURING & SUPPLY CHAIN

Establishing dependable and sustainable manufacturing processes and supply chains is critical when considering the roll-out of radiopharmaceuticals into the large oncology market. Some current-generation radiopharmaceuticals have shown significant benefit to the patients but have failed at delivering these life-saving treatments to patients and their healthcare providers due to supply chain and manufacturing issues.

Clarity has continued to expand its manufacturing and supply chain footprint, creating additional capacity and flexibility to supply products to any state in the US with multiple new agreements made during the reporting period.

Copper-67

Copper-67 (Cu-67 or ^{67}Cu) is a therapeutic isotope produced on electron accelerators, which are relatively inexpensive and readily scalable in all geographies of the world, including the US, Europe and Asia.

Other commonly used therapeutic isotopes, such as lutetium-177 (Lu-177 or ^{177}Lu), are produced on a small number of aging nuclear reactors worldwide, many of which are approaching the end of their "useful life". This results in planned and unplanned shutdowns, causing shortages of therapeutic isotopes worldwide[26].

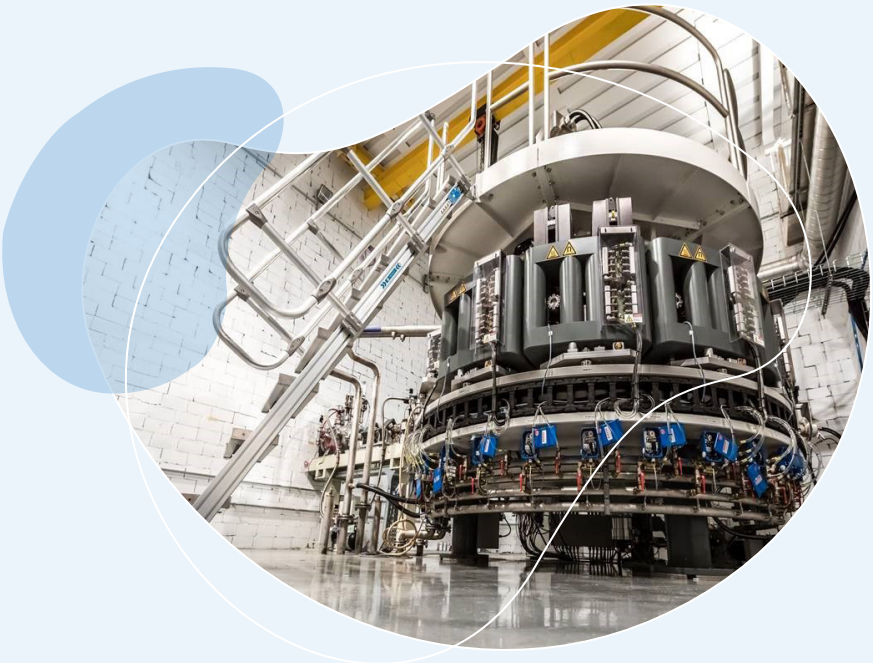
Geopolitical considerations are also vital as Russia remains the predominant supplier of stable isotopes used in the production of a variety of isotopes. Clarity remains unaffected by supply disruptions due to its strategy of developing reliable, scalable and environmentally preferred solutions to radionuclide sourcing with all radioisotope supply coming from the US.

Cu-67 based product supply

As Clarity is actively progressing its Phase I/II trial with ^{67}Cu-SAR-bisPSMA, SECuRE, and continues to generate promising data with this product, the Company continues to build supply chain capacity ahead of a Phase III trial and commercialisation. As such, Clarity entered into a Master Services Agreement (MSA) and Clinical Manufacturing Agreement for ^{67}Cu-SAR-bisPSMA with Nucleus RadioPharma, an innovative contract development and manufacturing organisation (CDMO) in the radiopharmaceutical industry, dedicated to the development and manufacturing of targeted radiotherapies.

This agreement builds on the earlier MSA and Clinical Supply Agreements with NorthStar for the production of both ^{67}Cu and ^{67}Cu-SAR-bisPSMA.

Nucleus RadioPharma's facility in Minnesota enables ^{67}Cu-SAR-bisPSMA manufacturing and distribution to all 50 states in the US. Their current expansion plans for building additional manufacturing capacity in Arizona and Pennsylvania[27] are also in line with the timelines for development of Clarity's ^{67}Cu-SAR-bisPSMA product, ensuring broad drug supply throughout the US.



Copper-64

Copper-64 (Cu-64 or ^{64}Cu) is a diagnostic imaging isotope with an ideal half-life of 12.7 hours, which facilitates a significantly longer product shelf-life (up to 48 hours) compared to most commonly used radio-diagnostics on the market. This helps to overcome the acute supply restraints of current-generation radiodiagnostics based on gallium-68 (Ga-68 or ^{68}Ga) with a half-life of ~1 hour and fluorine-18 (F-18 or ^{18}F) with a half-life of ~2 hours.

The longer shelf-life of copper-64 based diagnostics enables centralised manufacture, as opposed to the current-generation prostate-specific membrane antigen (PSMA) Positron Emission Tomography (PET) diagnostics that require an expensive and extensive network of cyclotrons, radioisotope generators and radiopharmacies next to imaging sites due to the shorter half-life and shelf-life of Ga-68 and F-18. Cu-64 is produced on cyclotrons, with a single cyclotron able to supply the entire Phase III diagnostic clinical program.

Those characteristics of Cu-64 also allow for wider geographic distribution, which can improve patient access to this important diagnostic tool. This has the potential to reduce disparities in prostate cancer care and ensure that all patients, regardless of geographic location, can benefit from the latest advances in diagnostic imaging.

Cu-64 based product supply

Clarity is actively recruiting into its Phase III trial with ^{64}Cu-SAR-bisPSMA in pre-prostatectomy setting, CLARIFY, and is preparing to launch its second registrational trial with this product in prostate cancer patients with biochemical recurrence, AMPLIFY, in the coming months. To provide reliable, universal access in the US for these trials, Clarity entered into a Clinical Manufacturing Agreement with SpectronRx for the production of the diagnostic ^{64}Cu-SAR-bisPSMA product in October 2024. This agreement builds on the earlier MSA and Supply Agreement for the production of the ^{64}Cu isotope, now allowing for a streamlined manufacturing process of both the isotope and the ^{64}Cu-SAR-bisPSMA product at the same facility.

SpectronRx's facility enables on-demand ^{64}Cu-SAR-bisPSMA manufacturing and distribution to all 50 states in the US. The agreement with SpectronRx complements Clarity's existing supply network, providing a layered and abundant supply approach, which is unique in the radiopharmaceutical space.

Actinium-225

In July 2024 Clarity entered into an agreement with TerraPower Isotopes (TerraPower) for the supply of the therapeutic alpha-emitting isotope, Ac-225 for Clarity's first Targeted Alpha-particle Therapy (TAT) program with bisPSMA.

TerraPower has a unique Ac-225 manufacturing process in the US that has the potential to provide the scale and dependability required for commercial manufacturing at a purity level appropriate for clinical use. This avoids having to supply Ac-225 from Russia and use sources containing significant Ac-227 contamination (a radionuclide more radiotoxic than plutonium) and fits into Clarity's strategy of developing sustainable, scalable and environmentally preferred solutions of next-generation radiopharmaceutical products.

Clarity will continue adding Ac-225 suppliers to its network as the manufacturing process continues to develop and progress to meet standards for clinical and commercial use.

Trastuzumab biosimilar: EG12014

In February 2025, Clarity signed a Supply Agreement with EirGenix, Inc. ("EirGenix") for the clinical development and future commercial supply of clinical-grade Good Manufacturing Practice (GMP) trastuzumab biosimilar, EG12014. The supply enables the development of a radiolabelled product using Clarity's SAR Technology, $^{64/67}$Cu-SAR-trastuzumab, for use in clinical trials with a focus on breast cancer.

TEAM & BOARD

The team is at the heart of Clarity's success and is what drives the Company forward. Over the years, Clarity has assembled an exceptional team, including Board of Directors and Advisory Board, and continues to attract some of the best talent in the industry who possess a unique range of skills and expertise, as well as extensive experience in the global radiopharmaceutical market.

Clarity continues its efforts to build a team with world-class expertise and knowledge in radiopharmaceutical development and commercialisation, supporting the rapid growth of the Company and its pipeline of products in development.

To align with the pace of Clarity's growth, the Company has made a number of changes at the executive level.

Ms Michelle Parker, a long-time member of Clarity's senior executive team, was invited to join the Board in September 2024 as an Executive Director and promoted to Chief Executive Officer (CEO), effective 11 October 2024. Michelle brings more than 20 years of industry experience to the role of CEO, spanning nuclear medicine, positron emission tomography and pharmaceuticals in Australia and internationally. She joined Clarity over 6 years ago and is a long-time member of the Senior Executive Team. Prior to Michelle's appointment to the role of CEO, she held the position of Clarity's Chief Clinical Officer, heading the Company's largest division, Clinical Operations.

Dr Colin Biggin will continue his operational focus on further strengthening Clarity's manufacturing and supply chains in preparation for commercial launch in the role of Chief Operating Officer (COO) and will remain an Executive Director on Clarity's Board.

Other changes to the Senior Executive Team include the promotion of Dr Othon Gervasio to Chief Medical Officer and the internal appointment of Dr Matt Harris to Chief Scientific Officer. Ms Eva Lengyelova was promoted to Executive Vice President (EVP), Clinical Development and Ms Mary Bennett to Head, People & Culture. Eva and Mary also both joined the Senior Executive Team.

In line with the announcement dated 16 January 2024, Clarity's Non-Executive Director, Mr Rob Thomas, retired from the Board following the completion of his tenure on 23 August 2024. Non-Executive Director, Dr Chris Roberts, was appointed Chair of the Audit and Risk Committee and also joined the Nomination and Remuneration Committee. Thomas Ramdahl joined the Audit and Risk Committee, and fellow Non-Executive Director, Ms Rosanne Robinson, took the role of Lead Independent Director.

One third of Clarity's Board and 40% of Clarity's Senior Executive Team are female, demonstrating Clarity's belief in the importance of gender diversity and the value it brings to leadership. The Company celebrates its gender diversity and looks forward to continuing to support our female leaders in their professional development and career aspirations. This support has helped facilitate around 77% of the promotions due to exceptional performance in the FY2023-2024 being female.

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FINANCIAL REPORT

OF CLARITY PHARMACEUTICALS LTD

FOR THE HALF YEAR ENDED

31 DECEMBER 2024

DIRECTORS' REPORT

FOR THE HALF-YEAR ENDED 31 DECEMBER 2024

The Directors of Clarity Pharmaceuticals Ltd (Clarity Pharmaceuticals) present their report together with the financial statements of the consolidated entity, being Clarity Pharmaceuticals (the Company) and its controlled entities (the Group) for the half-year ended 31 December 2024.

DIRECTOR DETAILS

The following persons were Directors of Clarity Pharmaceuticals during or since the end of the half-year:

Dr Alan Taylor	Executive Chair
Ms Michelle Parker	Chief Executive Officer and Managing Director (appointed to the board effective 20 September 2024, appointed to current role effective 11 October 2024)
Dr Colin Biggin	Chief Operating Officer (Chief Executive Officer and Managing Director until change to current role effective 11 October 2024)
Ms Rosanne Robinson	Lead Independent Director (appointed effective 26 August 2024)
Dr Christopher Roberts	Non-Executive Director
Dr Thomas Ramdahl	Non-Executive Director
Mr Rob Thomas	Lead Independent Director (retired effective 23 August 2024)

RESULT

The loss for the half-year was $23.5 million (2023: $17.2 million loss). In the six months to December 2024, there was an increase in research and development expenditure, up $8.9 million to $28.6 million, reflecting an increase in clinical trial activities.

STATEMENT OF FINANCIAL POSITION

The Group's financial position compared to the prior year was as follows:

- Liquid assets of $111.2 million (30 June 2024: $136.5 million) comprising cash on hand of $3.0 million (30 June 2024: $47.9 million) and term deposits of $108.2 million (30 June 2024: $88.6 million).
- Net assets decreased to $127.4 million from $146.3 million at 30 June 2024.

The Board believes the Group is well placed to support its programs throughout financial year 2025.

REVIEW OF OPERATIONS

Corporate Overview

During the reporting period, management remained focused on executing Clarity Pharmaceuticals' goal of improving outcomes for adults and children with cancer and continued to progress the clinical program in multiple indications with high unmet needs, strengthen supply chain and manufacturing capabilities and build its discovery platform in order to bring novel solutions to more patient populations.

Testament to the great achievements made by the Company and the progress made with its exciting pipeline of potential best-in-class theranostic agents, in December 2024 Clarity Pharmaceuticals entered the top 200 companies listed on the Australian Securities Exchange (ASX) with inclusion in the S&P/ASX200 index. This milestone is a proud moment for Australian science as Clarity Pharmaceuticals originally emerged from Australian benchtop science and grew into one of the Top 200 companies listed on the ASX in only three years after listing. The inclusion is a testament to the hard work and dedication of Clarity Pharmaceuticals' small but extraordinary team and collaborators.

The Company remains well funded with a cash balance of $101.2 million as at the date of this report, together with a 2024 financial year R&D tax incentive receivable of $11.0 million. This puts the Company in a strong position to execute its clinical, regulatory and operational objectives.

Clinical and regulatory

Clarity Pharmaceuticals' 3 lead products, SAR-bisPSMA, SAR-Bombesin and SARTATE, are actively progressing through 8 clinical trials: 3 theranostic trials and 5 diagnostic trials, including two Phase III registrational trials, CLARIFY and AMPLIFY, and an Investigator-Initiated Trial (IIT) at St Vincent's Hospital Sydney.

SAR-bisPSMA – Prostate Cancer

SECuRE: Theranostic ^{64}Cu/^{67}Cu-SAR-bisPSMA trial

SECuRE (NCT04868604) is a Phase I/IIa theranostic trial for identification and treatment of an advanced form of prostate cancer, metastatic castration-resistant prostate cancer (mCRPC). It is a multi-centre, single arm, dose escalation study with a cohort expansion. The aim of this trial is to determine the safety and tolerability of both ^{64}Cu-SAR-bisPSMA and ^{67}Cu- SAR-bisPSMA, as well as the efficacy of ^{67}Cu-SAR-bisPSMA as a therapy.

Clarity Pharmaceuticals successfully completed cohorts 1, 2 and 3 of the SECuRE trial, which were single-dose cohorts (4 GBq, 8 GBq and 12 GBq, respectively). Cohort 4 is the first multi-dose cohort in the trial and is designed as a "3+3" cohort, where the first 3 participants received 2 therapy cycles followed by a Safety Review Committee (SRC) meeting before commencing recruitment of the final 3 participants.

In October 2024, the SRC completed the review of the safety data of the first 3 participants in cohort 4 of the SECuRE trial who received 2 doses of 12 GBq of ^{67}Cu-SAR-bisPSMA. The safety profile assessed in those participants remains favourable, confirming the preliminary safety findings of previous cohorts (single dose cohorts, 1, 2 and 3). Almost all adverse events (AEs) in the 3 participants in cohort 4 were mild to moderate, with the majority having resolved or improved at the last assessment. No dose limiting toxicities (DLTs) were reported in this cohort, with the SRC recommending the study proceed as planned and enrol a further 3 participants to complete cohort 4.

Recruitment of the additional 3 participants into cohort 4 of the dose escalation phase of the SECuRE trial is now complete, and the participants are currently in the safety and efficacy follow-up period. An SRC meeting will be held shortly, following the completion of the six-week DLT period of all participants.

A recent SECuRE protocol amendment increased the number of participants in the cohort expansion phase from 14 to 24 patients in the mCRPC pre-chemotherapy setting, with a subset of patients to receive the combination therapy of ^{67}Cu-SAR-bisPSMA with enzalutamide. This protocol amendment has now been approved at many of the participating trial sites, and the changes are expected to further enhance the already positive results of ^{67}Cu-SAR-bisPSMA observed in the SECuRE trial to date. This strategy focuses on the commercialisation of the product firstly in the largest market for prostate cancer therapies in mCRPC, with pre-chemotherapy being 3 times larger than the post-chemotherapy setting and creates opportunities for the use of ^{67}Cu-SAR-bisPSMA with a range of androgen receptor pathway inhibitors (ARPIs) in future clinical development.

Patient case study: Complete response with 2 doses of 8GBq of ^{67}Cu-SAR-bisPSMA
A patient with mCRPC who received two cycles of 8 GBq of ^{67}Cu-SAR-bisPSMA (the first dose through the SECuRE trial and the second dose under the US Food and Drug Administration [FDA] Expanded Access Program [EAP]) achieved a complete response (assessed by computed tomography [CT], prostate-specific membrane antigen (PSMA) positron emission tomography [PET] and prostate-specific antigen [PSA]). This patient continues to show undetectable levels of PSA for almost 16 months following treatment, confirmed at the latest follow-up. A follow-up PSMA PET has also been conducted during reporting period, with no signs of recurrent or metastatic disease.

A theranostic case report on this patient was selected by the European Association of Nuclear Medicine (EANM) 2024 Congress in October for oral presentation.

Patient case study: Durable response after multiple cycles of ^{67}Cu-SAR-bisPSMA
A patient from cohort 1 who had a reduction in PSA of 94.4% following the administration of 4 doses of 4 GBq of ^{67}Cu-SAR-bisPSMA (first dose through the SECuRE trial and 3 doses under the EAP) received an additional EAP dose (8 GBq) following a recent rise in their PSA. This fifth dose of ^{67}Cu-SAR-bisPSMA was administered approximately 14 months after the previous dose and over 2 years since the first dose. This last dose led to a reduction in PSA of 57.4% (vs. the latest peak in PSA value of 10.1 ng/mL), with the latest assessment showing the durability of response almost 6 months after the administration of ^{67}Cu-SAR-bisPSMA.

CLARIFY: Diagnostic ^{64}Cu-SAR-bisPSMA Phase III registrational trial
The **CLARIFY (**NCT06056830**) diagnostic trial** is a 383-patient registrational Phase III trial of participants with high-risk prostate cancer prior to radical prostatectomy. It opened for enrolment and recruited its first participant in December 2023. The trial will examine the diagnostic potential of ^{64}Cu-SAR-bisPSMA to detect regional nodal metastasis. In addition to investigating the benefits of Clarity Pharmaceuticals' optimised bisPSMA product in this patient population, CLARIFY will look at the potential benefits of both same-day and next-day imaging, a benefit currently unique to the SAR technology platform.

An abstract outlining details from the CLARIFY trial was presented at the American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU) 2025 in February. The study was also presented at the Annual International Prostate Cancer Update (IPCU) 2025 conference.

AMPLIFY: Diagnostic ^{64}Cu-SAR-bisPSMA Phase III registrational trial

Clarity Pharmaceuticals received positive feedback from the US FDA on a pivotal Phase III trial for ^{64}Cu-SAR-bisPSMA diagnostic in prostate cancer patients with biochemical recurrence (BCR) in a formal meeting in October 2024. The trial, called **AMPLIFY**, is expected to commence in the coming months. **AMPLIFY** (^{64}Cu-SAR-bisPSMA Positron Emission Tomography: A Phase 3 Study of Participants with Biochemical Recurrence of Prostate Cancer) will be a non-randomised, single-arm, open-label, multi-centre, diagnostic clinical trial of ^{64}Cu-SAR-bisPSMA PET in approximately 220 participants with rising or detectable PSA after initial definitive treatment. As a pivotal trial, the final study results are intended to provide sufficient evidence to support an application to the US FDA for approval of ^{64}Cu-SAR-bisPSMA as a new diagnostic imaging agent in prostate cancer, alongside results from CLARIFY.

The AMPLIFY trial is supported by compelling preclinical and clinical data to date, including the Phase I/II COBRA trial in patients with BCR of prostate cancer, and the Phase I PROPELLER trial in patients with confirmed prostate cancer pre-definitive treatment (pre-prostatectomy).

COBRA: Diagnostic ^{64}Cu-SAR-bisPSMA Phase I/II trial

The **COBRA** trial (NCT05249127) was a US-based Phase I/II PET imaging trial assessing the safety and diagnostic performance of ^{64}Cu-SAR-bisPSMA to detect prostate cancer in patients with BCR of the disease and who had a negative or equivocal standard-of-care (SOC) scan at baseline.

Data from the COBRA trial shows that ^{64}Cu-SAR-bisPSMA is safe, and detected more lesions than approved SOC PSMA imaging agents for prostate cancer, allowing it to detect much smaller lesions than anticipated, including a lesion with a diameter of less than 2 mm. The most recent findings from the COBRA trial established that ^{64}Cu-SAR-bisPSMA was able to detect lesions from 29 days to more than 6 months earlier than SOC PSMA PET agents. Additionally, in this subset of participants in the study who underwent follow-up SOC PSMA PET, 70% of participants had a positive scan on same-day imaging and 90% on next-day imaging using ^{64}Cu-SAR-bisPSMA, compared to 60% of participants using SOC PSMA PET where only same-day imaging is possible.

These results have been presented at leading medical conferences, including the prestigious EANM Congress 2024 in October where the abstract was selected as a Top-Rated Oral Presentation. Most recently, abstracts outlining data from the COBRA trial were presented at the ASCO GU 2025 Cancer Symposium and at the IPCU 2025.

Co-PSMA: Investigator-Initiated Phase II ^{64}Cu-SAR-bisPSMA trial

In November 2024, Prof Louise Emmett at St Vincent's Hospital Sydney launched a new IIT, **Co-PSMA**, evaluating the performance of Clarity Pharmaceuticals' diagnostic product, ^{64}Cu-SAR-bis-PSMA, in comparison to SOC ^{68}Ga-PSMA-11 product for the detection of prostate cancer recurrence. Recruitment is underway, with the first participants dosed within days of the trial launch. **Co-PSMA** stands for "Comparative performance of ^{64}Copper [^{64}Cu]-SAR-bis-PSMA vs ^{68}Ga- PSMA-11 PET CT for the detection of prostate cancer recurrence in the setting of biochemical failure following radical prostatectomy".

The Co-PSMA trial is a prospective, Phase II imaging trial in 50 patients with BCR post-radical prostatectomy who are being considered for curative salvage radiotherapy. The primary objective of the study is to compare the detection rate of sites of prostate cancer recurrence, as determined by number of lesions per patient, between ^{64}Cu-SAR-bisPSMA and ^{68}Ga-PSMA-11 PET/CT.

Fast Track Designation

During and since the reporting period, Clarity Pharmaceuticals received 3 US FDA Fast Track Designations (FTDs) for its SAR-bisPSMA agent. ^{64}Cu-SAR-bisPSMA product was granted 2 FTDs for PET imaging of PSMA-positive prostate cancer lesions in 2 indications: patients with suspected metastasis who are candidates for initial definitive therapy and patients with BCR of prostate cancer following definitive therapy. More recently, ^{67}Cu-SAR-bisPSMA was granted an FTD for the treatment of adult patients with PSMA-positive mCRPC who have been previously treated with ARPI.

The FDA's FTD is designed to expedite the development and regulatory review of novel drugs addressing serious conditions with significant unmet medical needs. The 3 FTDs granted to Clarity Pharmaceuticals provide a number of benefits that would reduce the review time needed to bring SAR-bisPSMA to market, potentially improving diagnosis and treatment planning for patients sooner.

These 3 FTDs demonstrate the quality of the data generated to date on the ^{64}Cu-SAR-bisPSMA and ^{67}Cu-SAR-bisPSMA products in addressing serious unmet needs in prostate cancer. The FTDs will enable Clarity Pharmaceuticals to accelerate the development of its comprehensive program with the optimised SAR-bisPSMA agent to be used in patients with prostate cancer throughout the management of their cancer, from initial to late-stage disease, with an opportunity to completely change the treatment landscape for the large prostate cancer market.

SAR-Bombesin – Prostate Cancer

COMBAT: Theranostic $^{64/67}$Cu-SAR-Bombesin trial

COMBAT (NCT05633160) is a theranostic trial for identification and treatment of mCRPC that is expressing the gastrin-releasing peptide receptor (GRPr) using ^{64}Cu/^{67}Cu-SAR-Bombesin in participants who are ineligible for therapy with ^{177}Lu-PSMA-617. The aim for the trial is to determine the safety and efficacy of ^{67}Cu-SAR-Bombesin in this patient group. Recruitment into the COMBAT trial ongoing.

SAR-Bombesin is a pan-cancer product, and the open Investigational New Drug (IND) with this agent offers exciting opportunities for exploring new theranostic indications.

SABRE: Diagnostic ^{64}Cu-SAR-Bombesin trial

SABRE (NCT05407311) is a Phase II multi-centre, single arm, non-randomised, open-label trial in participants with suspected recurrence of their prostate cancer and who have negative or equivocal findings of prostate cancer on SOC imaging, including approved PSMA agents. The primary objectives of the trial are to investigate the safety and tolerability of ^{64}Cu-SAR-Bombesin, as well as its ability to correctly detect the recurrence of prostate cancer. In the SABRE trial, 53 participants were enrolled. ^{64}Cu-SAR-Bombesin PET/CT imaging took place on the day of product administration (same-day imaging) and approximately 24 hours later (next-day imaging). The study is also investigating if delayed imaging allows for better identification of early disease in patients with low PSMA expression.

Recruitment target for the SABRE trial has been achieved and data review and analysis are ongoing.

BOP: Investigator-Initiated ^{64}Cu-SAR-Bombesin trial

BOP (NCT05613842) was a Phase II IIT in 30 participants led by Prof Louise Emmett at St Vincent's Hospital Sydney. The IIT assessed the safety of ^{64}Cu-SAR-Bombesin as well as the diagnostic performance across 2 different groups of men with prostate cancer:

- participants with BCR of prostate cancer who had negative PSMA PET imaging scans or low PSMA expressing disease; and
- participants with mCRPC who were not suitable for PSMA-targeted therapy.

Initial data from the diagnostic BOP trial in patients with BCR of prostate cancer, evaluating ^{64}Cu-SAR-Bombesin, was presented at the EANM 2023 Congress. The full manuscript in patients with BCR was published in the Journal of Nuclear Medicine in August 2024.

^{64}Cu-SAR-Bombesin was found to be safe and able to detect prostate cancer in 44% (11/25) of patients in BCR who had a negative or equivocal SOC PSMA PET imaging. No AEs were reported following ^{64}Cu-SAR-Bombesin administration.

SARTATE – Neuroblastoma and NETs

CL04: Theranostic ^{64}Cu/^{67}Cu-SARTATE neuroblastoma trial

CL04 (NCT04023331) is a multi-centre, dose-escalation, open label, non-randomised, theranostic clinical trial in paediatric patients with high-risk neuroblastoma. The trial is a Phase I/IIa where the safety and tolerability of both ^{64}Cu-SARTATE and ^{67}Cu-SARTATE are being assessed, and also the effectiveness of ^{67}Cu-SARTATE as a treatment for neuroblastoma. Participants who show uptake of ^{64}Cu-SARTATE in lesions will continue in the trial and will receive treatment with ^{67}Cu-SARTATE.

Recruitment into the CL04 trial is ongoing.

DISCO: Diagnostic ^{64}Cu-SARTATE NET trial

DISCO (NCT04438304) derives from "Diagnostic Imaging Study of ^{64}COpper-SARTATE Using PET on Patients with Known or Suspected Neuroendocrine Tumours (NETs)" and is assessing the performance of Clarity Pharmaceuticals' SARTATE imaging product as a potential new method to diagnose and manage NETs. The trial is comparing the diagnostic performance of ^{64}Cu-SARTATE at approximately 4- and 20-hours post-administration to ^{68}Ga-DOTATATE at 1 hour.

The last patient assessment for this Phase II ^{64}Cu-SARTATE trial was successfully completed in November 2024. A total of 45 patients with Gastroenteropancreatic NETs (GEP-NETs) were enrolled and imaged in the trial across 4 sites in Australia.

The DISCO trial aims to build on earlier findings with SARTATE in patients with NETs, which demonstrated that imaging at later time points may lead to better identification of disease.

Discovery Platform

Clarity Pharmaceuticals is expanding its product pipeline with a new generation of radiopharmaceuticals through its Discovery Program to meet further areas with unmet needs.

SAR-trastuzumab

Clarity Pharmaceuticals renewed its focus on the breast cancer market, spearheaded by its $^{64/67}$Cu-SAR-trastuzumab product. Trastuzumab is an antibody that targets HER2, which is expressed in many cancers, including some types of lung, gastric and breast cancers. Through pioneering work in collaboration with the

University of Melbourne, the trastuzumab antibody was combined with Clarity Pharmaceuticals' proprietary SAR chelator and radiolabelled with copper-64 for diagnostic imaging and copper-67, forming a radioimmunotherapy (RIT) product. ^{64}Cu-SAR-trastuzumab was shown to target HER2-positive cancer cells to a very high level pre-clinically. ^{67}Cu-SAR-trastuzumab was shown to reduce the growth of HER2-expressing tumours in a dose-dependent manner and improved the survival of mice treated with the product.

Clarity Pharmaceuticals intends to conduct a Phase I/IIa theranostic study with $^{64/67}$Cu-SAR-trastuzumab in HER2-positive breast cancer patients to address a significant unmet clinical need.

SAR-bisFAP

Recently, the Company developed a novel Fibroblast Activation Protein (FAP)-targeted radiopharmaceutical called SAR-bisFAP, representing a new opportunity to improve the diagnostic (with copper-64) and treatment (with copper-67) options for patients with different cancers (e.g. breast, colorectal, pancreatic, lung, brain and ovarian cancers). The product was developed with the intent of overcoming the low uptake and retention in tumours of other FAP-targeted radiopharmaceuticals in development. The dimer SAR-bisFAP has shown increased tumour uptake and retention over 24 hours in pre-clinical models in comparison to other FAP radiopharmaceuticals in development as well as to a monomer equivalent (SAR-monoFAP).

The potential improvements in uptake and retention of SAR-bisFAP compared to first-generation mono-FAP compounds are key attributes for the development of next-generation FAP-targeted radiopharmaceuticals.

Clarity Pharmaceuticals is currently conducting additional pre-clinical investigations to enable a Phase I clinical trial, which could commence in late 2025.

Targeted Alpha-particle Therapy

Clarity Pharmaceuticals has been conducting research combining the bisPSMA targeting agent with actinium-225 (Ac-225 or ^{225}Ac). To date, the program with ^{225}Ac-bisPSMA has focused on identifying a lead candidate from a number of different analogues.

Clarity Pharmaceuticals' SAR-bisPSMA product has shown impressive preclinical and clinical evidence to date, and the dual targeting of the product enables increased uptake and retention in prostate cancer tumours compared to the mono-targeted form of the product. By combining the optimised bisPSMA with Ac-225, Clarity Pharmaceuticals has the opportunity to complement its beta-particle therapy product, ^{67}Cu-SAR-bisPSMA, with an alpha-particle therapy product, ^{225}Ac-bisPSMA.

Manufacturing and Supply Chain

Targeted Copper Theranostics' (TCTs) key differentiators are their logistical, manufacturing and environmental advantages associated with the perfect pairing of copper isotopes for diagnostic imaging (copper-64) and therapy (copper-67). Clarity Pharmaceuticals continued to expand its manufacturing and supply chain footprint, creating additional capacity and flexibility to supply products to any ZIP-code in the US.

In November 2024, Clarity Pharmaceuticals signed a Master Services Agreement (MSA) and a ^{67}Cu-SAR-bisPSMA Clinical Supply Agreement with Nucleus RadioPharma who will manufacture the drug product at their new state-of-the-art facility in Rochester, MN. These agreements complement the existing agreement with NorthStar Medical Radioisotopes, LLC for ^{67}Cu-SAR-bisPSMA production to expand drug manufacturing in anticipation of recruitment demand for Phase II and III trials of this product.

In October 2024, the Company signed a ^{64}Cu-SAR-bisPSMA product Clinical Manufacturing Agreement with SpectronRx, building on the earlier MSA and associated Supply Agreement for the copper-64 isotope. The

Agreement ensures abundant and seamless supply of the product for Clarity Pharmaceuticals' 2 Phase III registrational trials, CLARIFY and AMPLIFY. SpectronRx will produce both the ^{64}Cu isotope and the ^{64}Cu-SAR-bisPSMA product at the same location in the US, allowing central distribution from the Indiana facility to all 50 states on demand.

In July 2024 Clarity Pharmaceuticals entered into an agreement with TerraPower Isotopes (TerraPower) for the supply of the therapeutic alpha-emitting isotope, actinium-225 (Ac-225 or ^{225}Ac) for the Company's TAT program with ^{225}Ac-bisPSMA. TerraPower has a unique actinium-225 manufacturing process in the US that has the potential to provide the scale and dependability required for commercial manufacturing at a purity level appropriate for clinical use.

Team and collaborators

The Company has built a diverse and high-performing team, including its Board of Directors, Advisory Board members and collaborators, who possess a range of skills and expertise, as well as extensive experience in the global radiopharmaceutical market.

To align with the pace of Clarity Pharmaceuticals' growth, the Company made a number of changes at the executive level during the reporting period. Ms Michelle Parker was appointed as Chief Executive Officer (CEO) in October 2024, bringing more than 20 years of industry experience, spanning nuclear medicine, PET and pharmaceuticals in Australia and internationally. Dr Colin Biggin will continue his operational focus on further strengthening Clarity Pharmaceuticals' manufacturing and supply chains in preparation for commercial launch in the role of Chief Operating Officer (COO) and will remain an Executive Director on Clarity Pharmaceuticals' Board.

Other changes to the senior executive team include the promotion of Dr Othon Gervasio to Chief Medical Officer, the internal appointment of Dr Matt Harris to Chief Scientific Officer, as well as Ms Eva Lengyelova, Vice President (VP) of Clinical Development and Ms Mary Bennett, Head of People & Culture, both joining the senior executive team.

At the Board level, Non-Executive Director, Mr Rob Thomas, retired from the Board following the completion of his tenure on 23 August 2024 and in line with the announcement dated 16 January 2024. Non-Executive Director, Dr Chris Roberts, was appointed Chair of the Audit and Risk Committee and has also joined the Nomination and Remuneration Committee. Dr Thomas Ramdahl joined the Audit and Risk Committee, and fellow Non-Executive Director, Ms Rosanne Robinson, has taken the role of Lead Independent Director.

EVENTS ARISING SINCE THE END OF THE REPORTING PERIOD

There are no matters or circumstances that have arisen since the end of the year that have significantly affected or may significantly affect either:

- the entity's operations in future financial years
- the results of those operations in future financial years; or
- the entity's state of affairs in future financial years.

AUDITOR INDEPENDENCE DECLARATION

A statement of independence has been provided by the Group's auditor, Grant Thornton, and is attached to this report.

Signed in accordance with a resolution of the Board of Directors.

Dr Alan Taylor
Chairperson
Date: 28 February 2025

Grant Thornton Audit Pty Ltd
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Auditor's Independence Declaration

To the Directors of Clarity Pharmaceuticals Ltd

In accordance with the requirements of section 307C of the *Corporations Act 2001*, as lead auditor for the review of Clarity Pharmaceuticals Ltd for the half-year ended 31 December 2024, I declare that, to the best of my knowledge and belief, there have been:

a no contraventions of the auditor independence requirements of the *Corporations Act 2001* in relation to the review; and

b no contraventions of any applicable code of professional conduct in relation to the review.

Grant Thornton Audit Pty Ltd
Chartered Accountants

L M Worsley
Partner – Audit & Assurance

Sydney, 28 February 2025

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

FOR THE HALF-YEAR ENDED 31 DECEMBER 2024

	Note	December 2024 $	December 2023 $
Finance income		2,878,114	1,099,718
Research and development tax incentive		4,688,383	5,418,247
Unrealised gain on foreign exchange of holdings		3,378,140	-
Income		**10,944,637**	**6,517,965**
Corporate and administration expenses	5	(5,918,519)	(3,910,302)
Research and development expenses	6	(28,561,659)	(19,705,623)
Loss before income tax		**(23,535,541)**	**(17,097,960)**
Income tax expense		(46,051)	(104,758)
Loss for the year from continuing operations		(23,581,592)	**(17,202,718)**
Loss for the year		(23,581,592)	**(17,202,718)**
Other comprehensive loss			
Exchange differences on translating foreign entity		43,505	(6,291)
Total comprehensive loss for the period		**(23,538,087)**	**(17,209,009)**

Earnings per Share	Note	December 2024 cents	December 2023 cents
Basic, loss for the year attributable to ordinary equity holders	7	(7.4)	(6.6)
Diluted, loss for the year attributable to ordinary equity holders	7	(7.4)	(6.6)

The accompanying notes form part of these financial statements

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

AS AT 31 DECEMBER 2024

	Notes	December 2024 $	June 2024 $
Assets			
Current			
Cash and cash equivalents	8	2,971,833	47,900,692
Financial assets	9	108,220,290	88,604,970
Research & development tax incentive receivable	10	15,712,961	11,024,578
Other receivables	10	1,922,405	1,610,115
Prepayments	11	7,649,454	4,921,024
Total current assets		136,476,943	**154,061,379**
Non-current			
Plant & equipment	12	571,833	554,802
Other financial assets	9	13,533	13,026
Total non-current assets		**585,366**	**567,828**
Total assets		137,062,309	**154,629,207**
Liabilities			
Current			
Trade and other payables	13	7,791,651	6,958,425
Employee entitlements	14	1,585,813	1,130,466
Total current liabilities		**9,377,464**	**8,088,891**
Non-current			
Employee entitlements	14	331,757	242,866
Total non-current liabilities		**331,757**	**242,866**
Total liabilities		**9,709,221**	**8,331,757**
Net assets		**127,353,088**	**146,297,450**
Equity			
Share capital	15	255,152,981	249,447,200
Share option reserve	16	8,411,359	9,523,415
Accumulated losses		(136,280,289)	(112,698,697)
Foreign currency translation reserve		69,037	25,532
Total equity		**127,353,088**	**146,297,450**

The accompanying notes form part of these financial statements

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

FOR THE HALF-YEAR ENDED 31 DECEMBER 2024

	Share Option Reserve $	Foreign Currency Reserve $	Share Capital $	Accumulated Losses $	Total $
Half-year ended 31 December 2023					
Balance at 1 July 2023	**6,723,640**	**5,977**	**132,820,320**	**(70,374,269)**	**69,175,668**
Loss for the year	-	-	-	(17,202,718)	(17,202,718)
Foreign currency translation	-	(6,291)	-	-	(6,291)
Total Comprehensive Loss	**-**	**(6,291)**	**-**	**(17,202,718)**	**(17,209,009)**
Transfer to share capital for options exercised	(591,371)	-	591,371	-	-
Ordinary shares issued on exercise of options	-	-	182,000	-	182,000
Capital raising costs	-	-	(3,831)	-	(3,831)
Share-based options	915,480	-	-	-	915,480
Balance at 31 December 2023	**7,047,749**	**(314)**	**133,589,860**	**(87,576,987)**	**53,060,308**
Half-year ended 31 December 2024					
Balance at 1 July 2024	**9,523,415**	**25,532**	**249,447,200**	**(112,698,697)**	**146,297,450**
Loss for the period	-	-	-	(23,581,592)	(23,581,592)
Foreign currency translation	-	43,505	-	-	43,505
Total Comprehensive Loss	**-**	**43,505**	**-**	**(23,581,592)**	**(23,538,087)**
Transactions with owners in their capacity as owners:					
Transfer to share capital for options exercised	(3,917,485)	-	3,917,485	-	-
Ordinary shares issued on exercise of options	-	-	1,877,002	-	1,877,002
Capital raising costs	-	-	(88,706)	-	(88,706)
Share-based options	2,805,429	-	-	-	2,805,429
Balance at 31 December 2024	**8,411,359**	**69,037**	**255,152,981**	**(136,280,289)**	**127,353,088**

The accompanying notes form part of these financial statements

CONSOLIDATED STATEMENT OF CASHFLOWS

FOR THE HALF-YEAR ENDED 31 DECEMBER 2024

	Notes	December 2024 $	December 2023 $
Cash Flows from Operating Activities			
Interest received		2,209,987	1,110,651
Payments to suppliers and employees		(32,490,735)	(27,705,850)
Income taxes paid		(24,868)	(104,758)
Net operating cash flows		**(30,305,616)**	**(26,699,957)**
Cash Flows from Investing Activities			
Investment in Term Deposits		(19,615,827)	18,994,474
Purchase of plant & equipment		(103,857)	(441,248)
Net investing cash flows		**(19,719,684)**	**18,553,226**
Cash Flows from Financing Activities			
Exercise of options		1,857,002	121,000
Cost of capital raising		(182,206)	(3,831)
Net financing cash flows		**1,674,796**	**117,169**
Net increase/(decrease) in cash held		(48,350,504)	(8,029,562)
Cash at the beginning of the financial year		47,900,692	31,213,092
Effect of exchange rate changes on cash and cash equivalents		3,421,645	(7,396)
Cash at the end of the financial year		**2,971,833**	**23,176,134**

The accompanying notes form part of these financial statements

NOTES TO THE FINANCIAL STATEMENTS

FOR THE HALF-YEAR ENDED 31 DECEMBER 2024

1. General information and statement of compliance

The financial report includes the consolidated financial statements and notes of Clarity Pharmaceuticals Ltd and Controlled Entities (Consolidated Group).

These interim financial statements are general purpose financial statements that have been prepared on an accruals basis in accordance with the Corporations Act 2001, Australian Accounting Standard AASB 134 *Interim Financial Reporting* and other authoritative pronouncements of the Australian Accounting Standards Board (AASB) and International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB). They have been prepared under the assumption that the Group operates on a going concern basis. Clarity Pharmaceuticals Ltd is a for-profit entity for the purpose of preparing the financial statements.

The consolidated financial statements for the half-year ended 31 December 2024 were approved and authorised for issue by the Board of Directors on 28 February 2025. The consolidated financial statements can be amended by the Board of Directors after the issue.

Going Concern

The Directors believe the Group will be able to continue as a going concern. The Group has a history of losses. The ability of the Group to continue as a going concern and be able to pay its debts as and when they fall due is contingent upon periodic capital raising to support research and development activities. To that end, the Group monitors cashflow closely against a detailed cashflow forecast which is periodically updated in line with actuals and changes in anticipated future spend to ensure the Group operates as a going concern. The combined cash position and forecast is reviewed by the Directors who continue to assess the funding requirements of the Group, including the potential to raise capital, if required.

The Group had cash and financial assets of $101.2 million at 28 February 2025.

Accordingly, at the date of this report the Directors believe that the cash and financial assets on hand will provide sufficient working capital for the Group to meet its foreseeable expenditure commitments and pay its debts as and when they fall due for the next 12 months.

2. Changes in accounting policies

The accounting policies adopted in the preparation of the consolidated financial statements are consistent with those followed in the preparation of the Group's previous annual consolidated financial statements for the year ended 30 June 2024.

The Group has not adopted any accounting standards that are issued but not yet effective. The Group has assessed the upcoming standards, interpretations or amendments and concluded there is no material impact expected from the adoption of these new standards, interpretations or amendments.

3. Operating Segments

The Group is a radiopharmaceutical development group with operations in Australia and the United States. As it has no commercial products it does not derive any commercial revenue. The Group does not currently consider that the risks and returns of the Group are affected by differences in its products or services, the geographical areas in which it operates, or its customers.

Group financial performance is evaluated by the Board of Directors (being the 'Chief Operating Decision Makers (CODM)') based on profit or loss before tax and cash flow for the group as a whole. As such the Group currently operates as one segment – Development of Radiopharmaceuticals. The activities of the group principally take place in Australia and the United States. The Group does not have any sales revenue hence is not able to report revenue by segment. Accordingly, it also does not have any customers. All assets and liabilities of the Group are attributable to the single segment.

4. Interests in subsidiaries

Set out below details of the subsidiary held directly by the Group:

Name of the Subsidiary	Country of Incorporation and principal place of business	Principal Activity	Proportion of ownership interests held by the group	
			31 Dec 2024	31 Dec 2023
Clarity Pharmaceuticals Europe SA	Belgium	Scientific Research & Development	100%	100%
Clarity Personnel Inc.	U. S. A.	Provision of US Personnel to the Group	100%	100%

5. Corporate and administration expenses

	Dec 2024 $	Dec 2023 $
Corporate and administration employment costs	(2,831,160)	(1,711,313)
Depreciation	(86,825)	(51,159)
Insurance, professional fees, rent and other	(3,000,534)	(1,676,898)
Unrealised loss on foreign exchange of holdings	-	(470,932)
	(5,918,519)	**(3,910,302)**

6. Research and development expenses

	Dec 2024 $	Dec 2023 $
Clinical trials and supporting activities	(17,987,271)	(13,787,643)
Research and development employment costs	(10,092,823)	(5,114,181)
Patents and related costs	(481,565)	(803,799)
	(28,561,659)	**(19,705,623)**

7. Earnings per share

	Dec 2024 Cents	Dec 2023 Cents
Basic earnings (loss) per share	(7.4)	(6.6)
Diluted earnings (loss) per share	(7.4)	(6.6)

Income and share data used in calculations of basic and diluted earnings per share:

	$	$
Net (Loss)	(23,581,592)	(17,202,718)

	Number	Number
Weighted average number of Ordinary shares on issue in the calculation of basic earnings per share	317,163,334	261,939,839
Effect of dilutive securities[1]	-	-
Adjusted weighted average number of Ordinary shares used in the calculation of diluted earnings per share	317,163,334	261,939,839

1. At 31 December 2024 there were 17,922,007 (June 2024: 25,200,861) share options on issue which have not been taken into account when calculating the diluted loss per share due to their anti-dilutive nature.

8. Cash and cash equivalents

Cash and cash equivalents consist of the following:

	Dec 2024 $	Jun 2024 $
Cash at bank – Australian Dollars	1,836,323	31,386,656
Cash at bank – US Dollars	1,076,983	1,154,856
Cash at bank – Euro	58,527	159,180
Term deposits – cash equivalents – Australian Dollars	-	15,200,000
	2,971,833	**47,900,692**

Term deposits with a maturity of less than 90 days from the date of acquisition are presented as cash equivalents.

9. Other financial assets

	Dec 2024 $	Jun 2024 $
Current		
Term deposits – Australian dollars	55,671,552	51,000,000
Term deposits – US dollars	52,548,738	37,604,970
	108,220,290	**88,604,970**

Term deposits with a maturity of less than 90 days from the date of acquisition are presented as cash equivalents. Term deposits are measured at face value, with interest recognised as income on an accrual basis.

Non-current		
Security deposit	13,533	13,026
	13,533	**13,026**

This security deposit represents one month's rental fees for the business premises. The landlord may deduct from the security deposit amounts owing to them in connection with the rental agreement. The security deposit will be returned to Clarity Pharmaceuticals within one month after the later of the termination of the agreement and Clarity Pharmaceuticals complying to the reasonable satisfaction of the landlord with all its obligations under the agreement.

10. Other receivables

	Dec 2024 $	Jun 2024 $
Research & development incentive receivable	15,712,961	11,024,578
Consumption taxes receivable	266,889	622,381
Interest receivable	1,655,516	987,734
	1,922,405	**1,610,115**

R&D Tax Incentive receivable at 31 December 2024 comprises $11,029,725 in respect of the year ended 30 June 2024 and $4,683,236 for the period July to December 2024 which is anticipated to be receivable as part of the Group's application for the year ending 30 June 2025. The receivable for the year ended 30 June 2025 is an estimate and is conditional on the 2025 application being successful. The Group considers it has sufficient R&D claim history to be able to reliably estimate the R&D tax refund at this interim period.

All amounts are short-term.

11. Prepayments

	Dec 2024 $	Jun 2024 $
Clinical trials and supporting activities	6,623,077	4,530,578
Corporate activities	1,013,739	302,298
Patents and related costs	12,638	88,148
	7,649,454	**4,921,024**

All amounts are short term. Prepayments for clinical trials includes upfront payments to clinical research organisations which will be recouped on completion of the clinical trial contract.

12. Plant & equipment

	Dec 2024 $	Jun 2024 $
Equipment	1,033,290	929,433
Less accumulated depreciation	(461,457)	(374,631)
	571,833	**554,802**
Balance as at 1 July	554,802	206,142
Additions	103,857	504,005
Disposals	-	(2,277)
Depreciation	(86,826)	(153,068)
Balance at the end of the period	**571,833**	**554,802**

13. Trade & other payables

Trade and other payables recognised consist of the following:

	Dec 2024 $	Jun 2024 $
Current:		
Trade creditors	3,386,381	2,084,373
Sundry creditors	2,736,354	3,092,025
Taxes Payable	235,347	214,164
Payroll liabilities	1,254,555	1,432,698
Superannuation payable	179,014	135,165
	7,791,651	**6,958,425**

All amounts are short-term. The carrying values of trade payables are a reasonable approximation of fair value.

Sundry creditors include expenses incurred but not yet paid for operations of $1,613,466 (June 2024: $827,234) and corporate costs of $633,008 (June 2024: $447,402).

14. Employee entitlements

	Dec 2024 $	Jun 2024 $
Current		
Annual leave liability	1,555,959	1,104,647
Long service leave liability	29,854	25,819
	1,585,813	**1,130,466**
Non-Current		
Long service leave liability	331,757	242,866

The current liability represents the Group's obligations to which employees have a current legal entitlement. It arises from accrued annual leave and long service leave entitlements at the reporting date. The non-current liability represents obligations to which employees will have a legal entitlement upon completion of a requisite service period, more than 12 months beyond the end of the year.

15. Equity

	Dec 2024 $	Jun 2024 $
Ordinary shares issued and fully paid	268,194,774	262,400,287
Cost of capital raising	(13,041,793)	(12,953,087)
Total contributed equity at the end of the period	**255,152,981**	**249,447,200**

	$	Number
Movement in ordinary shares on issue:		
Balance as at 1 July	249,447,200	311,645,897
Issue on exercise of share options	5,794,487	9,164,966
Transaction costs	(88,706)	-
Balance at the end of the period	255,152,981	320,810,863

16. Share option reserve

	Dec 2024 $	Jun 2024 $
Balance at the beginning of the period	9,523,415	6,723,640
Share options expensed – employees & consultants	2,805,429	4,172,677
Options exercised	(3,917,485)	(1,372,902)
Balance at the end of the period	**8,411,359**	**9,523,415**

The share option reserve represents the cumulative total expense attributed to vested options and the proportionate expense of options yet to fully vest. The expense of service-based options is determined using a Black-Scholes valuation. The expense of performance-based options is determined using a Monte Carlo simulation.

17. Related party transactions

Under an intercompany services agreement Clarity Pharmaceuticals Ltd paid management fees to its subsidiary Clarity Personnel Inc totalling $5,618,523. In the half-year ended 31 December 2024, non-executive directors' fees totalled $204,666. Executive directors' salaries and superannuation totalled $997,893. Executive bonuses of $466,231 were accrued for the period but unpaid at 31 Dec 2024.

18. Commitments & contingencies

The Company has intellectual property that is either licensed or assigned from the University of Melbourne, Australian Nuclear Science and Technology Organisation, Dr Kurt Gehlsen, University of Southern California, Memorial Sloane Kettering Cancer Center and University of Antwerp representing contingent liabilities totalling $10,313,266 (Jun 2024 $10,263,711). These contingent liabilities are intellectual property licence and assignment milestones payments which are dependent upon the success of the Group's clinical research, as well as future decisions regarding the clinical focus of the Company and are therefore not recognised in the statement of financial position. Milestones for each intellectual property agreement are for various clinical milestones, from filing regulatory applications to conducting clinical trials to entering Phase III trials, along with commencement of sales of radiopharmaceutical agents. It is anticipated that some milestones may be reached in the year ending 30 June 2025 which will result in payments to licensors totalling $83,696 (June 2024 $80,697).

19. Post-reporting date events

There are no matters or circumstances that have arisen since the end of the financial year that have significantly affected or may significantly affect:

- the operation of the Group;
- the results of those operations; or
- the state of affairs of the Group;

in future financial years.

DIRECTORS' DECLARATION

FOR THE HALF-YEAR ENDED 31 DECEMBER 2024

In the Directors' opinion:

- the attached financial statements for the half-year and notes of Clarity Pharmaceuticals Ltd are in accordance with the Corporations Act 2001, the Accounting Standards, the Corporations Regulations 2001 and other mandatory professional reporting requirements;
- the attached financial statements for the half-year comply with Australian Accounting Standards as issued by the Australian Accounting Standards Board as described in Note 1 to the financial statements;
- the attached financial statements for the half-year and notes give a true and fair view of its financial position as at 31 December 2024 and of its performance for the half-year ended on that date;
- there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.

Signed in accordance with a resolution of the Directors made pursuant to section 295(5)(a) of the Corporations Act 2001.

On behalf of the Directors

Dr Alan Taylor
Chairperson
Dated this 28th day of February 2025

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Independent Auditor's Review Report

To the Members of Clarity Pharmaceuticals Ltd

Report on the half year financial report

Conclusion

We have reviewed the accompanying half year financial report of Clarity Pharmaceuticals Ltd (the Company) and its subsidiaries (the Group), which comprises the consolidated statement of financial position as at 31 December 2024, and the consolidated statement of profit or loss and other comprehensive income, consolidated statement of changes in equity and consolidated statement of cash flows for the half year ended on that date, including material accounting policy information, other selected explanatory notes, and the directors' declaration.

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the accompanying half-year financial report of Clarity Pharmaceuticals Ltd does not comply with the *Corporations Act 2001* including:

a giving a true and fair view of the Group's financial position as at 31 December 2024 and of its performance for the half year ended on that date; and

b complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

Basis for Conclusion

We conducted our review in accordance with ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity*. Our responsibilities are further described in the *Auditor's Responsibilities for the Review of the Financial Report* section of our report. We are independent of the Company in accordance with the auditor independence requirements of the *Corporations Act 2001* and the ethical requirements of the Accounting Professional and Ethical Standards Board's APES *110 Code of Ethics for Professional Accountants (including Independence Standards)* (the Code) that are relevant to our audit of the annual financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

Directors' responsibility for the half-year financial report

The Directors of the Company are responsible for the preparation of the half-year financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001* and for such internal control as the Directors determine is necessary to enable the preparation of the half-year financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

Auditor's responsibility for the review of the financial report

Our responsibility is to express a conclusion on the half-year financial report based on our review. We conducted our review in accordance with Auditing Standard on Review Engagements ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity*, in order to state whether, on the basis of the procedures described, we have become aware of any matter that makes us believe that the half year financial report is not in accordance with the *Corporations Act 2001* including giving a true and fair view of the Group's financial position as at 31 December 2024 and its performance for the half-year ended on that date, and complying with Accounting Standard AASB 134 *Interim Financial Reporting* and the *Corporations Regulations 2001*.

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Grant Thornton Audit Pty Ltd

Chartered Accountants

L M Worsley
Partner – Audit & Assurance

Sydney, 28 February 2025

CORPORATE DIRECTORY

Directors

Dr Alan Taylor
Executive Chairman

Michelle Parker
Managing Director and
Chief Executive Officer

Dr Colin Biggin
Chief Operating Officer
Executive Director

Ms Rosanne Robinson
Non-Executive Director
Lead Independent Director
Chair of the Nomination of
Remuneration Committee

Dr Chris Roberts
Non-Executive Director
Chair of the Audit and Risk
Committee

Dr Thomas Ramdahl
Non-Executive Director

Company Secretary

Mr Robert Vickery

Chief Financial Officer

Mr David Green

Principal Place of Business

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