CLARITY
PHARMACEUTICALS

QUARTERLY ACTIVITY REPORT

SYDNEY, AUSTRALIA
31 DECEMBER 2024

HIGHLIGHTS OF THE QUARTER

During and since the quarter ending 31 December 2024

Cash Position

The Company's cash position at the end of the December quarter was $111.2 million, with a further $11 million receivable for the FY24 research and development tax incentive (RDTI). Net operating cash outflows for the December quarter were $18.0 million. This combined funding of circa $122 million is expected to provide cash runway through to mid-2026.

SECuRE Trial

Clarity progressed cohort 4 of the SECuRE trial. The first three participants in cohort 4 completed their Dose Limiting Toxicity (DLT) period after 2 doses of 12 GBq of ^{67}Cu-SAR-bisPSMA and a Safety Review Committee (SRC) meeting was completed. Preliminary efficacy assessment from cohort 4 showed that all 3 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.

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 with final participant completing final dose as planned. An SRC meeting will be undertaken shortly after the completion of the six-week DLT period.

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

A patient with metastatic castrate-resistance prostate cancer (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 U.S. Food and Drug Administration [FDA] Expanded Access Program [EAP]) had achieved a complete response (assessed by computed tomography [CT], prostate-specific membrane antigen (PSMA) positron emission tomography [PET] and 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, with no signs of recurrent or metastatic disease.

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 during the quarter showing the durability of response almost 6 months after the administration of ^{67}Cu-SAR-bisPSMA. All of the data on ^{67}Cu-SAR-bisPSMA is currently being used to plan the expanded cohort phase, which is expected to commence this current quarter.

HIGHLIGHTS OF THE QUARTER CONT.

During and since the quarter ending 31 December 2024

Fast-Track Designation

During the quarter, Clarity applied to the U.S. FDA for Fast Track Designation (FTD) for ^{64}Cu-SAR-bisPSMA for PET imaging of PSMA-positive prostate cancer lesions in patients with biochemical recurrence (BCR) of prostate cancer following definitive therapy and was recently awarded FTD well within the allotted 60-day period. This milestone builds on Clarity's earlier receipt of an FTD for ^{64}Cu-SAR-bisPSMA in patients with suspected metastasis of prostate cancer who are candidates for initial definitive therapy. These 2 FTDs enable the Company to accelerate the development of its comprehensive diagnostic program with this ^{64}Cu-SAR-bisPSMA.

AMPLIFY Trial

In a formal meeting on October 2024, the U.S. FDA provided positive feedback on a pivotal Phase III trial, AMPLIFY, planned for ^{64}Cu-SAR-bisPSMA diagnostic in prostate cancer patients with BCR. 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/pre-definitive treatment. Combined, these trials will enable Clarity to address the 2 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

In the quarter, 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. Recruitment has commenced with the first 2 participants dosed within days of the trial launch.

World-leading conferences

Clarity's clinical data on the SAR-bisPSMA product was presented at the European Association for Nuclear Medicine (EANM) 2024 Congress on 19-23 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 within the Scientific Programme. Additionally, a theranostic case report highlighting complete response to ^{67}Cu-SAR-bisPSMA in a patient with mCRPC was presented, showcasing the strength of Clarity's clinical data.

Two abstracts for Clarity's diagnostic COBRA and CLARIFY trials with ^{64}Cu-SAR-bisPSMA have been accepted for presentation at the upcoming American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU) 2025. An abstract from the COBRA study has also been selected for presentation at the American Urological Association (AUA) Annual Meeting 2025. The data to be presented shows that ^{64}Cu-SAR-bisPSMA identifies more lesions and earlier than currently approved PSMA PET agents.

DISCO

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 with SARTATE in patients with NETs, which demonstrated that imaging at later time points may lead to better identification of disease.

HIGHLIGHTS OF THE QUARTER CONT.

During and since the quarter ending 31 December 2024

Discovery Program

Clarity expanded its pipeline with a novel Fibroblast Activation Protein (FAP)-targeted radiopharmaceutical called SAR-bisFAP. The "bis" is reference to the drug having two targeting agents, or dimer form. The Company has again successfully utilised this dimer approach that was first used to develop the dimer SAR-bisPSMA that substantially increased uptake and retention in lesions compared to the monomer structures. Similarly, Clarity developed a superior FAP-targeted product over the monomer, with two targeting arms based on the industry-leading FAP inhibitor and incorporating the proprietary SAR Technology. SAR-bisFAP is a promising pan-cancer product for the potential diagnosis and treatment of various cancers with copper-64 and copper-67, respectively. Clarity is currently conducting additional preclinical investigations to enable a Phase I clinical trial, which could commence in late 2025.

Supply & Manufacturing

Clarity strengthened its supply and manufacturing with the signing of 2 agreements during the quarter.

^{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 ^{64}Cu 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 U.S., allowing central distribution from the Indiana facility to all 50 states on demand.

Team

Ms Michelle Parker was appointed as Chief Executive Officer (CEO) in October. Ms Parker brings more than 20 years of industry experience, spanning nuclear medicine, PET and pharmaceuticals in Australia and internationally. She joined Clarity over 6 years ago and is a long-time member of its Senior Executive Team. Ms Parker previously held the position of Chief Clinical Officer, heading Clarity'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.

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 small but extraordinary Team and brilliant collaborators.

Clarity Pharmaceuticals (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 Quarterly Activity Report and Appendix 4C for the three months ending 31 December 2024.

Executive Chairperson's Letter

Dear fellow Shareholders,

I am delighted to share the latest milestones achieved by Clarity during and since the quarter ending 31 December 2024 as we progress our pipeline of best-in-class products.

Entering this new year, there is a lot to look forward to in 2025. 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 some news on the progress of our SECuRE theranostic trial shortly as it is progressing through the highest dose level cohort of the trial with up to 4 doses of ^{67}Cu-SAR-bisPSMA. Once we complete the dose escalation phase, we will be entering a cohort expansion (Phase II) of the trial. We are also excited to continue monitoring patients who received multiple doses of this product through the EAP and have shown durable responses to treatment to date, with a great safety profile.

Clarity's first diagnostic pivotal trial, CLARIFY, continues to actively recruit in over 20 centres and image pre-prostatectomy patients. Our team and collaborators are working tirelessly to launch our second Phase III trial with ^{64}Cu-SAR-bisPSMA in biochemically recurrent (BCR) prostate cancer called AMPLIFY in the coming months, following discussions with and positive feedback from the U.S. Food and Drug Administration (FDA) regarding trial design. Most recently, we applied for our second Fast Track Designation (FTD) for ^{64}Cu-SAR-bisPSMA for positron emission tomography (PET) imaging of prostate-specific membrane antigen (PSMA)-positive prostate cancer lesions in patients with BCR of prostate cancer following definitive therapy. Our application was granted well within the 60-day period reserved by the FDA, reflecting the high unmet need for novel diagnostics and the high quality of the data we presented to the FDA. Being able to now fast-track the development of ^{64}Cu-SAR-bisPSMA for patients with BCR as well as for patients prior to initial definitive therapy is incredibly exciting and will allow us to work closely with the FDA to facilitate the development process and accelerate the approval of what could become a best-in-class diagnostic.

The quality of data from the ^{64}Cu- and ^{67}Cu-SAR-bisPSMA products continues to impress the nuclear medicine, urology and oncology communities, and we are very proud to continue showcasing our most recent findings at some of the world's leading conferences. At the European Association for Nuclear Medicine (EANM) 2024 Congress in October, an abstract covering the completed COBRA trial was selected as a Top-Rated Oral Presentation within the Scientific Programme, and a theranostic case report highlighting a complete response to ^{67}Cu-SAR-bisPSMA treatment under the EAP was also selected for an oral presentation. 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. We now look forward to presenting 2 abstracts on the COBRA and CLARIFY diagnostic trials with ^{64}Cu-SAR-bisPSMA at the upcoming American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU) 2025 and an abstract from the COBRA study at the American Urological Association (AUA) Annual Meeting 2025. The data to be presented from the COBRA study indicates that ^{64}Cu-SAR-bisPSMA identifies more lesions and earlier than currently approved PSMA PET agents.

We already have indications of the diagnostic advantages of ^{64}Cu-SAR-bisPSMA compared to standard-of-care diagnostic imaging agents based on the PROPELLER and COBRA trials. 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 superior detection of prostate cancer with ^{64}Cu-SAR-bisPSMA.

To support all of our trials and avoid the supply and logistical issues of current-generation products based on Ga-68, F-18 and Lu-177 isotopes and ensure abundant and reliable supply of copper isotopes and products for our growing programs, we continue building our supply and manufacturing platform. With the signing of 2 agreements this quarter, we secured additional capacity for the ^{67}Cu-SAR-bisPSMA drug product with Nucleus RadioPharma. Nucleus also recently announced an expansion plan to build additional manufacturing capacity in Arizona and Pennsylvania, with both locations covered under our Master Supply Agreement, 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 Cu-64 supply. 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 U.S.

While we continue to generate data with our clinical stage products, we are also looking into new opportunities for leveraging our proprietary SAR Technology and our 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 in need of novel treatments. Similar to the incredibly fast and successful story of developing the proprietary bisPSMA molecule from the benchtop through a successful industry-academic collaboration with the University of Melbourne some 5 years ago, and moving it into Phase III trials in phenomenal time, we are now taking a similar route with our SAR-bisFAP pan-cancer product. By utilising some novel chemistry to overcome the low uptake and retention in tumours of similar agents in development and with a clear understanding of their limitations, we developed a dimer fibroblast activation protein (FAP)-targeting molecule and combined it with our SAR chelator to enable the use of the perfect pairing of copper isotopes. The results we have seen to date with SAR-bisFAP are very promising, and we look forward to progressing it into the clinic later this year. We also continue to translate a number of promising targets from the benchtop and through pre-clinical development and look forward to sharing the progress on these with our shareholders shortly.

Our team remains an absolute priority at Clarity, especially during this rapid growth phase. We continue to prioritise a flat structure, place focus on diversity and support our growing team in the U.S. 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 level. 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 in Clinical Development and People & Culture, respectively.

Although our focus every day is to build an incredible team of talented people who continue to work tirelessly to achieve impeccable outcomes by developing new products that lead to the better treatment of patients with cancer, we continue to thank our shareholders for their incredible support. During the quarter 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. And although this has introduced a number of new shareholders to the register, 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, with the top 10 making up 35% ownership of the Company, and the top 20 owning 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 all.

Clarity remains well funded with $111.2 in the bank together with an 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 this week 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 diagnostic and therapeutic assets with the goal of improving outcomes for cancer patients in need of novel 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 therapy and diagnostic programs.

Yours sincerely,

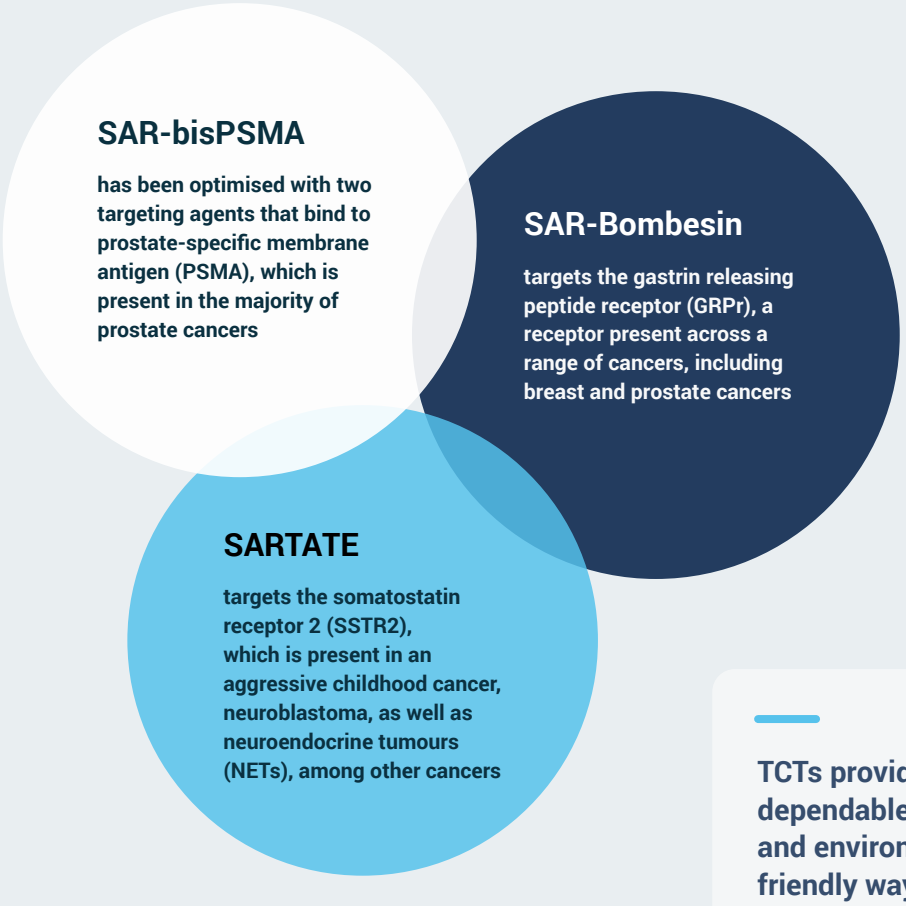
Dr Alan Taylor
Executive Chairperson
Clarity Pharmaceuticals Ltd

CLINICAL 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 three 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 three 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.



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

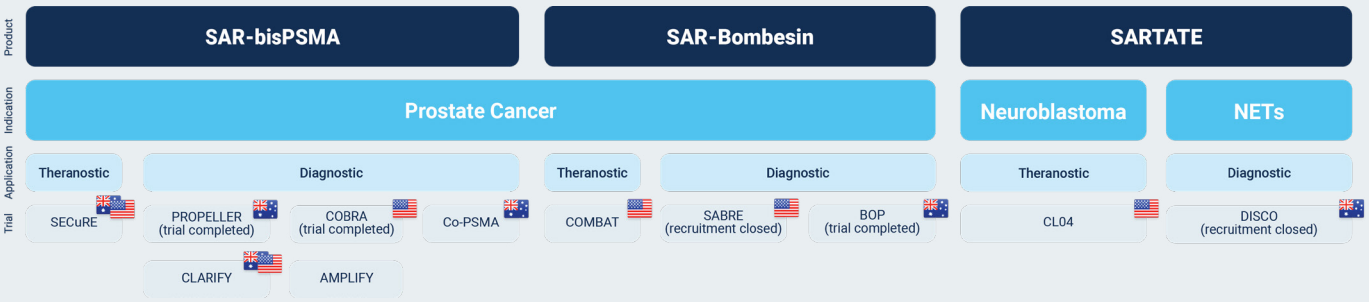
CLINICAL DEVELOPMENT OVERVIEW

Clarity's three lead products, SAR-bisPSMA, SAR-Bombesin and SARTATE, are actively progressing through eight clinical trials: three theranostic trials and five diagnostic trials, including two 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 U.S. 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 U.S. 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 U.S. (NCT05249127)[5]
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 U.S. (NCT05633160)[2]	**SABRE** – Phase II PET imaging trial of participants with PSMA-negative BCR of prostate cancer using ^{64}Cu-SAR-Bombesin in the U.S. (NCT05407311)[6]
SARTATE	**CL04** – Phase I/IIa theranostic trial in paediatric participants with high-risk neuroblastoma using ^{64}Cu/^{67}Cu-SARTATE in the U.S. (NCT04023331)[3]	**DISCO** – Phase II PET imaging trial of participants with known or suspected NETs using ^{64}Cu-SARTATE in Australia (NCT04438304)[7]

CLINICAL DEVELOPMENT OVERVIEW

Clarity is conducting or supporting multiple clinical trials for each of its 3 key products to explore both diagnostic and therapeutic opportunities, as well as expand their potential applications in a range of cancers.



FAST TRACK DESIGNATION

The U.S. Food and Drug Administration (FDA) granted Fast Track Designation (FTD) for ^{64}Cu-SAR-bisPSMA for positron emission tomography (PET) imaging of PSMA-positive prostate cancer lesions in patients with biochemical recurrence (BCR) of prostate cancer following definitive therapy.

This milestone builds on Clarity's earlier receipt of an FTD for ^{64}Cu-SAR-bisPSMA in patients with suspected metastasis of prostate cancer who are candidates for initial definitive therapy[8]. These 2 FTDs enable the Company to accelerate the development of its comprehensive late-stage diagnostic program with this product.

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 ^{64}Cu-SAR-bisPSMA, it provides a number of product development advantages. The designation paves 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 prostate cancer imaging agent to market, potentially improving diagnosis and treatment planning for patients sooner.

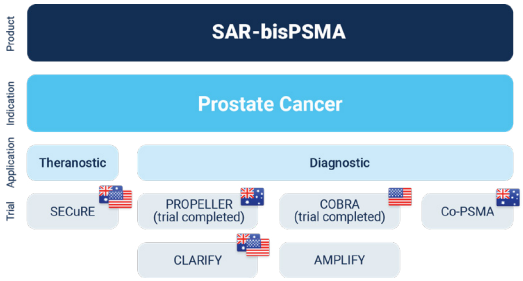
"The news is especially timely as Clarity is actively preparing to commence recruitment for our second registrational trial, AMPLIFY, in the coming months. The FTD will allow us to work closely with the FDA to facilitate the development process and accelerate the approval of what could become a best-in-class diagnostic,"

Dr Alan Taylor

PRODUCT UPDATES

SAR-bisPSMA: PROSTATE CANCER

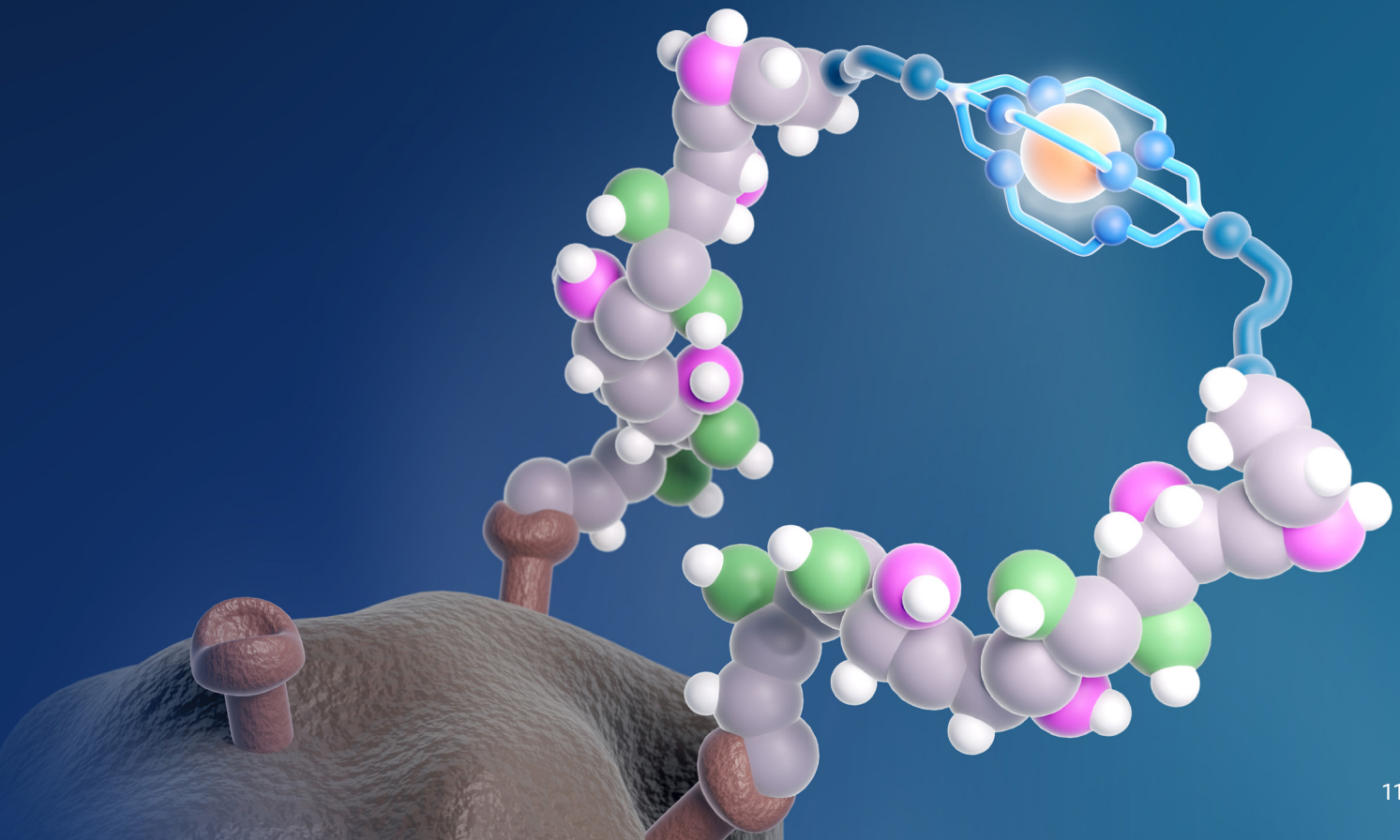
SAR-bisPSMA is a next-generation, theranostic radiopharmaceutical with optimised dual PSMA-targeting agents to improve uptake and retention of the product in tumours



SAR-bisPSMA is being developed for diagnosing, staging and subsequently treating cancers that express prostate-specific membrane antigen (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 U.S. 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 of multiple doses of 12 GBq of ^{67}Cu-SAR-bisPSMA 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 assessed with the SRC recommending the study proceed as planned and enrol a further 3 participants to complete cohort 4.

Recruitment into cohort 4 is now complete, and the additional 3 participants are currently in the safety and efficacy follow-up period assessing multiple administrations of ^{67}Cu-SAR-bisPSMA.

The largest drop in prostate-specific antigen (PSA) in cohort 4 to date is a decline of 98% (from a baseline of 157.4 ng/mL), and it remains in a downward trend based on the latest assessment. This participant, who had failed multiple lines of therapy prior to receiving ^{67}Cu-SAR-bisPSMA (e.g. 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 thus far, evaluated by PSMA positron emission tomography (PET) imaging with ^{64}Cu-SAR-bisPSMA (Figure 1).

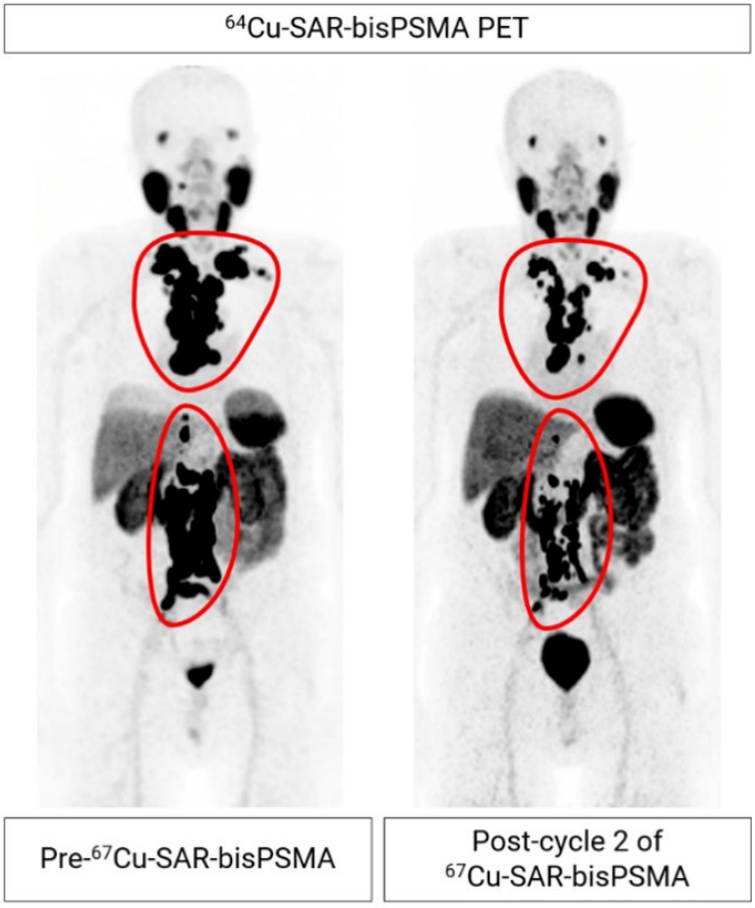


Figure 1. mCRPC patient from cohort 4 showing extensive metastasis of prostate cancer to the lymph nodes (regions highlighted by the red lines). Considerable reduction in tumour volume (60.6%) observed following 2 doses of ^{67}Cu-SAR-bisPSMA. Images show as maximum intensity projections.

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 will take place to assess safety and efficacy.

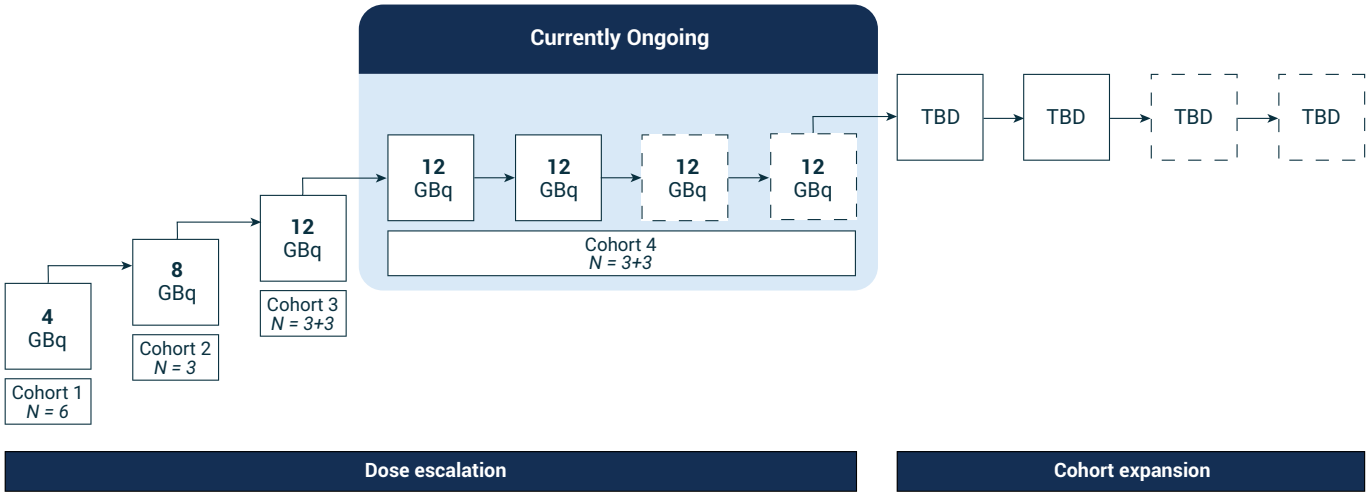


Figure 2. SECuRE Study Design.

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

The first patient ever to be dosed with two 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 presented at the European Association for Nuclear Medicine (EANM) 2024 Congress in October 2024 as 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 U.S. 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 during the reporting period 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).

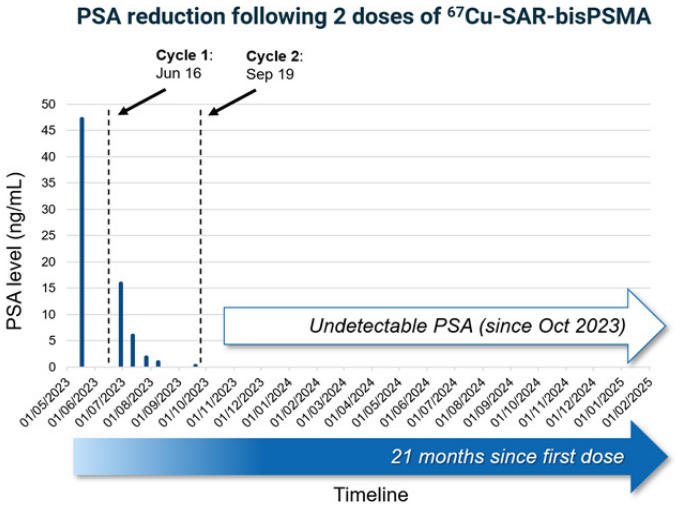


Figure 3. PSA reduction following 2 doses of ^{67}Cu-SAR-bisPSMA (8 GBq). A reduction of 99.4% in PSA was observed after the administration of the first cycle of ^{67}Cu-SAR-bisPSMA (from the baseline of 47.2 to 0.3 ng/ml). PSA reached undetectable levels following the administration of the second cycle 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.

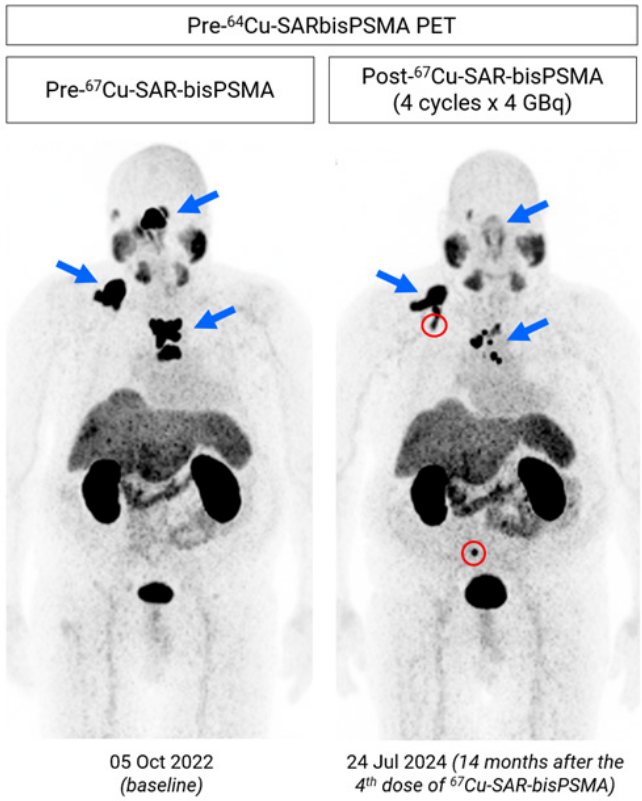


Figure 4. Images show considerable reduction in lesion uptake (^{64}Cu-SAR-bisPSMA PET) following 4 doses of ^{67}Cu-SAR-bisPSMA (4 GBq each; PET conducted approximately 14 months post-fourth cycle). Reduction in uptake (maximum standardised uptake value [SUVmax]) and tumour volume: 72.5% and 41.6%, 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.

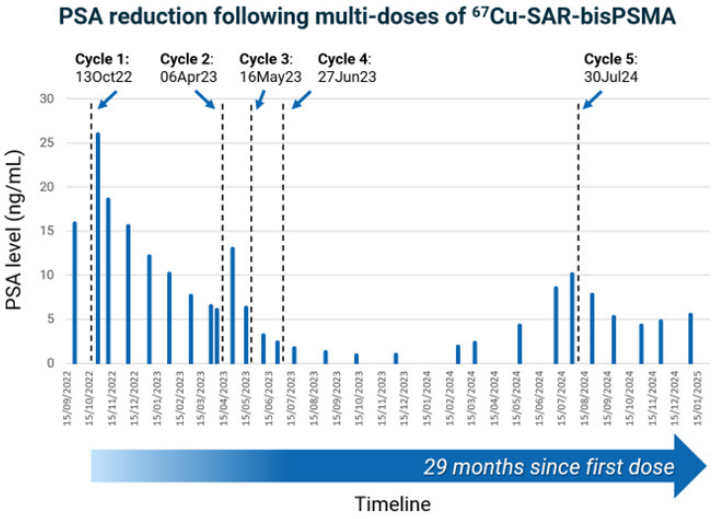


Figure 5. PSA reduction following multiple doses of ^{67}Cu-SAR-bisPSMA. Reduction of 94.4% observed following 4 cycles of ^{67}Cu-SAR-bisPSMA (4 GBq each). The fifth dose saw the patients PSA fall by 57.4%. The last assessment conducted during this reporting period still shows a reduction in PSA of 45.5%, almost 6 months after the last dose administered. Data cut-off 06 January 2025.

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

Clarity received positive guidance from the U.S. 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 U.S. 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 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-prostatectomy/pre-definitive treatment, which have been presented at leading medical conferences, including the prestigious European Association of Nuclear Medicine (EANM) Congress 2024 in October where an abstract was selected as a Top-Rated Oral Presentation. Most recently, abstracts outlining data from the COBRA trial were accepted for presentation at the ASCO GU 2025 Cancer Symposium and the American Urological Association (AUA) Annual Meeting 2025.

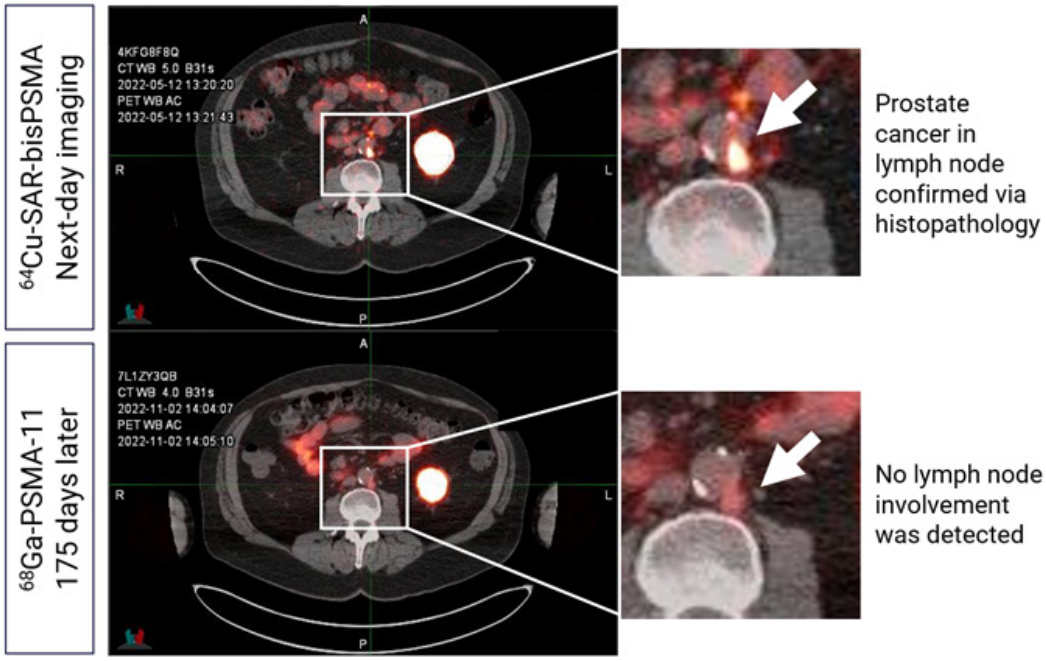


Figure 6. Retroperitoneal lymph node detected by ^{64}Cu-SAR-bisPSMA on next-day imaging. ^{68}Ga-PSMA-11 scan performed 176 days post-Day 0 (175 days post-Day 1) did not show tracer uptake. PET/CT fusion. Prostate cancer in lymph node was confirmed via histopathology.

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 to date 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 (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 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, which 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, 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.

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 quarter, Clarity progressed recruitment in its first Phase III registrational trial for ^{64}Cu-SAR-bisPSMA as a diagnostic agent in patients with prostate cancer prior to undergoing radical prostatectomy, with recruitment now progressing in over 20 centres.

CLARIFY (NCT06056830)[4] 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 two 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 accepted for presentation at the American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU) 2025 in February. In the same month, the study will also be presented at the upcoming Annual International Prostate Cancer Update.

The study is continuing as planned with final results intended to provide sufficient evidence to support an application to the U.S. 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, an Investigator-Initiated Trial (IIT) evaluating the performance of Clarity's diagnostic product, ^{64}Cu-SAR-bis-PSMA, in comparison to the SOC ^{68}Ga-PSMA-11 product for the detection of prostate cancer recurrence, was launched and successfully commenced recruitment, which is now ongoing.

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.

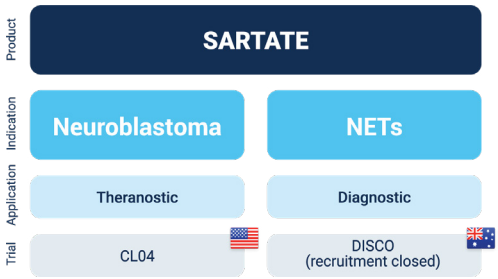
The Co-PSMA trial is a prospective, Phase II imaging trial in 50 patients with BCR post-radical prostatectomy who are being considered for curative salvage radiotherapy. The primary objective of the study is to compare the detection rate of sites of prostate cancer recurrence, as determined by number 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 as we progress towards our ultimate goal of better treating people with cancer,"

Dr Alan Taylor

SARTATE:
NEUROBLASTOMA & NETs

SARTATE is a next-generation, highly targeted theranostic radiopharmaceutical



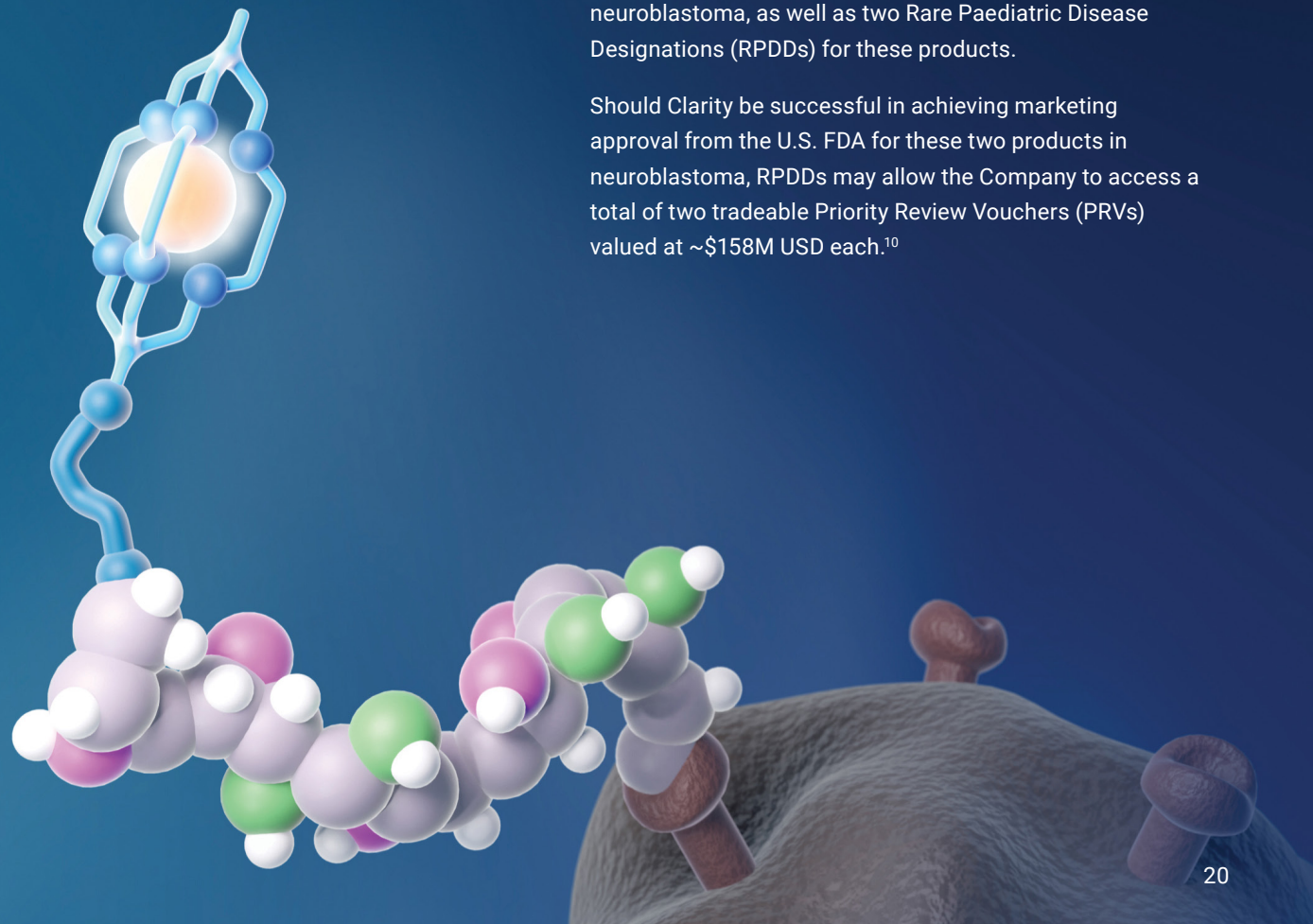
SARTATE is being developed for diagnosing, staging and subsequently treating cancers that express somatostatin receptor 2 (SSTR2), including neuroblastoma and neuroendocrine tumours (NETs). Like all Clarity products, the SARTATE product can be used with copper-64 (^{64}Cu) for imaging (^{64}Cu-SARTATE)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

Clarity is progressing two 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) in the U.S. (NCT04023331)[3];
- DISCO diagnostic trial in Australia (NCT04438304)[7].

Neuroblastoma, an aggressive childhood cancer, is Clarity's key focus with the SARTATE product. In 2020, the U.S. 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 U.S. 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.[10]



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

The last patient assessment for the Phase II diagnostic ^{64}Cu-SARTATE trial, DISCO (NCT04438304)[7], in patients with known or suspected neuroendocrine tumours (NETs) was completed successfully. A total of 45 patients were enrolled and imaged in the trial.

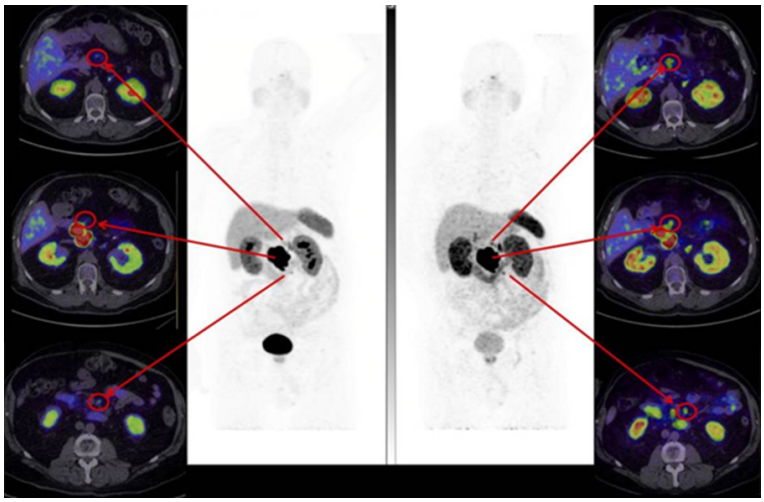
DISCO, which derives from "Diagnostic Imaging Study of ^{64}COpper-SARTATE Using PET on Patients with Known or Suspected Neuroendocrine Tumours", is assessing the performance of Clarity's SARTATE imaging product as a potential new method to diagnose and manage NETs. The DISCO trial recruited participants 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 (LPLV) 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[11]. Delayed imaging (at 4 and 24 hours vs 1 hour) showed a progressive increase in lesion-to-liver ratio (Table 1). Figure 7 provides an example of improved lesion detection based on an increase in lesion-to-background ratio observed with delayed imaging[11].

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.



"We believe that SARTATE could become a best-in-class product in NETs, playing an important role in improving accurate staging, lesion identification and treatment outcomes for these patients,"

Dr Alan Taylor

Figure 7. 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

SAR-bisFAP

Clarity's unique SAR technology is able to be combined with different target agents to address different conditions, allowing the Company to continue expanding its product portfolio to meet further areas with unmet needs. In the quarter, Clarity developed a potential pan-cancer agent, SAR-bisFAP, representing a new opportunity to improve the diagnostic and treatment options for patients with different cancers.

FAP 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[12]. 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[13]. 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).

	^{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.

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..

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.

SUPPLY & MANUFACTURING: THE GAME CHANGER FOR RADIOPHARMACEUTICALS

Targeted Copper Theranostics (TCTs) hold a number of competitive advantages, including clinical benefits, which Clarity is actively exploring through its clinical program.

However, the key differentiators, which hold promise of taking radiopharmaceuticals into the large oncology market, are the logistical, manufacturing and environmental advantages associated with the production of copper isotopes for diagnostic imaging (copper-64) and therapy (copper-67).

These differentiators are the reason TCTs are considered the next generation of radiopharmaceuticals as they enable Clarity to employ the big pharma model of centralised manufacturing under Good Manufacturing Practice (GMP) of both diagnostic and therapeutic products under one roof. Clarity continued to expand and strengthen its supply chain with multiple new agreements in the lead up to Phase III clinical trials and commercialisation.

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 U.S. with new agreements made during the quarter.

23

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 U.S., 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[14].

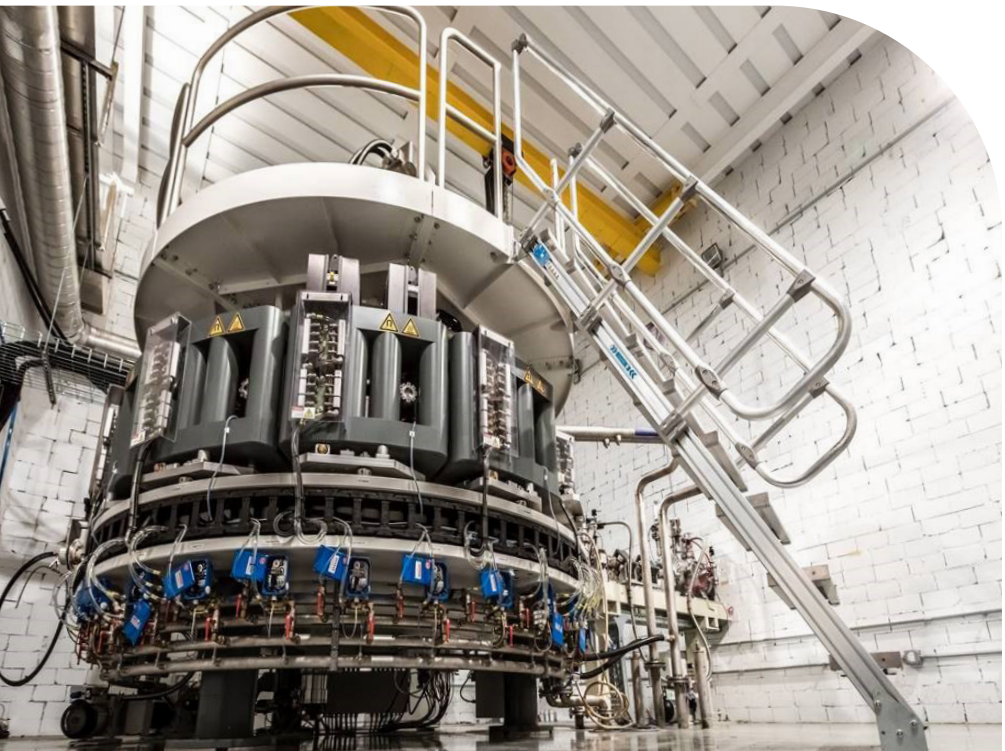
Geopolitical considerations are also vital as Russia remains the predominant supplier of stable isotopes used in the production of a variety of isotopes. Clarity remains unaffected by supply disruptions due to its strategy of developing reliable, scalable and environmentally preferred solutions to radionuclide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

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 U.S. Their current expansion plans for building additional manufacturing capacity in Arizona and Pennsylvania[15] are also in line with the timelines for development of Clarity's ^{67}Cu-SAR-bisPSMA product, ensuring broad drug supply throughout the U.S.



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 U.S. 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 U.S. The agreement with SpectronRx complements Clarity's existing supply network, providing a layered and abundant supply approach, which is unique in the radiopharmaceutical space.

TEAM & COLLABORATORS

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 deliver a unique range of skills and expertise together with extensive experience in the global radiopharmaceutical market.

To align with the pace of Clarity's growth and the rapidly increasing clinical focus, Ms Michelle Parker was appointed as 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. In September 2024, Michelle joined Clarity's Board as an Executive Director. 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.

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 with an overwhelming majority of the team comprising women and looks forward to continuing to support our female leaders in their professional development and career aspirations. This has led to around 76% of the promotions due to exceptional performance in the FY2023-2024 being women.

FINANCIALS

Clarity's cash balance at 31 December 2024 was $111.2 million.

Net operating cash outflows for the December quarter were $18.0 million, which is higher than the previous quarter's net outflow of $12.3 million, due mainly to timing of spend on the Company's clinical trial programmes, including large prepayments associated with the AMPLIFY and CLARIFY trials together with the Company's annual insurance renewals (which occur in October/November each year). Operating cash outflows relate to payments for research and development, staff costs, administration, and general operating costs.

The following table, "Use of Funds" reflects the Use of Funds included in the Company's capital raise documentation in March/April 2024.

Use of Funds

(Listing Rule 4.7C.2)

Uses of funds	Institutional Placement & Rights Issue Offer dated 26 March 2024 $ million	% of Total Funds	Period* to 31 December 2024 $ million	% of Total Funds
Pre-Clinical	$8.5	5.3%	$2.3	4.2%
Clinical	$111.0	69.7%	$34.1	62.5%
Regulatory	$7.1	4.5%	$1.3	2.4%
Patents	$1.8	1.2%	$0.8	1.5%
Corporate	$10.2	6.4%	$1.0	1.8%
Working Capital** and Costs of the Offer	$20.6	12.9%	$15.1	27.6%
Total uses	$159.2	100%	$54.6	100.0%

* From 25 March 2024

** The total cost of the Offer (including registry, ASX, legal, advisor and underwriting fees etc.) was $6.7 million, which was in line with the estimated costs.

As detailed in the Use of Funds table above, the expenditure for the period to 31 December 2024, is in accordance with the Use of Funds outlined in the Company's Offer document for the Institutional Placement and Rights Issue dated 26 March 2024 and there are no material variances against the estimated use of funds disclosed to-date.

Related Party Transactions

(Listing Rule 4.7C.3)

Payments to related parties of the entity and their associates (6.1 of the Appendix 4C) totalled $667,064 for the quarter. This amount includes director fees and salaries.

This Activities Report has been authorised for release by the Board of Directors.

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About Clarity Pharmaceuticals

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

claritypharmaceuticals.com

CLARITY
PHARMACEUTICALS

Appendix 4C

Quarterly cash flow report for entities subject to Listing Rule 4.7B

Name of entity	
Clarity Pharmaceuticals Ltd	
ABN	**Quarter ended ("current quarter")**
36 143 005 341	31 December 2024

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(12,536)	(19,207)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(237)	(582)
	(d) leased assets	-	-
	(e) staff costs	(4,413)	(10,036)
	(f) administration and corporate costs	(2,149)	(2,667)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	1,371	2,210
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	(45)	(25)
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(18,009)**	**(30,307)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(56)	(104)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	**Net cash from / (used in) investing activities**	**(56)**	**(104)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	451	1,857
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(55)	(182)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**396**	**1,675**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	123,669	136,506
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(18,009)	(30,307)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(56)	(104)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	396	1,675

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
4.5	Effect of movement in exchange rates on cash held	5,192	3,422
4.6	**Cash and cash equivalents at end of period**	**111,192**	**111,192**

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter $A'000	Previous quarter $A'000
5.1	Bank balances	2,972	21,254
5.2	Call deposits	108,220	102,415
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**111,192**	**123,669**

6.	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	667
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Note: Payments in 6.1 include Director fees and salaries

7.	**Financing facilities** *Note: the term "facility' includes all forms of financing arrangements available to the entity.* *Add notes as necessary for an understanding of the sources of finance available to the entity.*	**Total facility amount at quarter end $A'000**	**Amount drawn at quarter end $A'000**
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	**Total financing facilities**	-	-

7.5	**Unused financing facilities available at quarter end**	
7.6	Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.	

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(18,009)
8.2	Cash and cash equivalents at quarter end (item 4.6)	111,192
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	**111,192**
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	6

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer:

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer:

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer:

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: *31 January 2025*
.....

Authorised by: *Board of Directors*
.....
(Name of body or officer authorising release – see note 4)

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.