CLARITY
PHARMACEUTICALS

QUARTERLY ACTIVITY REPORT

SYDNEY, AUSTRALIA
31 JULY 2025

HIGHLIGHTS OF THE QUARTER

During and since the quarter ending 30 June 2025

Cash Position and RDTI

The Company remains well funded at 30 June 2025 with a cash position of $84.1 million. Net operating cash outflows for the June quarter were $9.1 million inclusive of the $11.1 million Research and Development Tax Incentive (RDTI) received in April.

Capital Raise

On the 28th of July, Clarity successfully completed a $203 million Placement with a small group of institutional investors who are close to the Company. The issue price of the Placement was $4.20 per share, which represented a 2.2% premium to Clarity's previous closing price and an 18.0% premium to Clarity's 15-day Volume Weighted Average Price ("VWAP").

Following completion of the Placement, the pro-forma cash balance of the Company at 30 June 2025 is approximately $288 million, providing Clarity with an enviable Balance Sheet to continue progressing its products towards commercialisation.

SECuRE trial

Clarity successfully treated the first of the planned 24 participants with metastatic castration-resistant prostate cancer (mCRPC) in the Cohort Expansion Phase (Phase II) of the SECuRE trial with a dose of 8 GBq of ^{67}Cu-SAR-bisPSMA in April. This participant is being treated with the combination of 8 GBq of ^{67}Cu-SAR-bisPSMA with enzalutamide (androgen receptor pathway inhibitor [ARPI]), as per the recent protocol amendment to include a subset of participants in the Cohort Expansion Phase to receive this combination. The SECuRE trial protocol has also been amended to focus on participants at earlier stages of disease, in the pre-chemotherapy setting. Recruitment in the Cohort Expansion Phase of the trial is currently ongoing.

AMPLIFY trial

Clarity successfully commenced the enrolment to the diagnostic Phase III trial of ^{64}Cu-SAR-bisPSMA in participants with biochemical recurrence (BCR) of prostate cancer, AMPLIFY, and imaged its first participant in May. As a pivotal trial, the final study results are intended to provide sufficient evidence to support an application to the US Food and Drug Administration (FDA) for approval of ^{64}Cu-SAR-bisPSMA as a new diagnostic imaging agent in BCR of prostate cancer. Recruitment into the trial is ongoing.

Co-PSMA trial

Study enrolment in the Co-PSMA Investigator-Initiated Trial (IIT) led by Prof Louise Emmett at St Vincent's Hospital Sydney was successfully completed, with 50 patients recruited. The Co-PSMA study is 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 in patients with low prostate-specific antigen (PSA) who are candidates for curative salvage therapy. Trial data is currently being analysed with initial results expected to be announced in the coming months.

HIGHLIGHTS OF THE QUARTER CONT.

During and since the quarter ending 30 June 2025

DISCO trial

Clarity announced topline results from its diagnostic Phase II trial of ^{64}Cu-SARTATE in participants with known or suspected neuroendocrine tumours (NETs). The data confirmed that ^{64}Cu-SARTATE is safe and highly effective compared to SOC imaging at detecting lesions in patients with NETs. ^{64}Cu-SARTATE was deemed safe and well tolerated.

^{64}Cu-SARTATE lesion detection substantially outperformed that of ^{68}Ga-DOTATATE where the former detected 393 - 488 lesions, and the latter identified 186 - 265 lesions among 45 study participants across the readers. Out of all the lesions identified by the readers, 230 - 251 were deemed to be discordant and 93.5% of those (average across readers) were only detected on the ^{64}Cu-SARTATE positron emission tomography (PET) / computed tomography (CT) scans. Approximately half of all the discordant lesions had an available standard-of-truth (SOT), such as histopathology or conventional imaging. The identified discordant lesions yielded a lesion-level sensitivity of 93.4% to 95.6% (95% confidence interval [CI]: 65.1, 99.5) for ^{64}Cu-SARTATE (across both timepoints) and only 4.4% to 6.6% (95% CI: 0.5, 34.9) for ^{68}Ga-DOTATATE across both readers.

Based on the exciting preliminary results of the DISCO trial, Clarity will commence next steps to conduct a registrational Phase III study of ^{64}Cu-SARTATE in NETs with the US FDA guidance.

SABRE trial

Clarity announced topline results from its diagnostic Phase II trial of ^{64}Cu-SAR-Bombesin in participants with prostate-specific membrane antigen (PSMA)-negative BCR of prostate cancer following definitive therapy. The data from the SABRE trial showed that ^{64}Cu-SAR-Bombesin was safe, well tolerated and effective in detecting prostate cancer recurrence in this patient population.

The trial enrolled 53 patients. ^{64}Cu-SAR-Bombesin identified lesions in approximately 35% and 28% of participants on same-day and next-day imaging, respectively (average across readers). Forty-nine lesions in total were identified on ^{64}Cu-SAR-Bombesin PET/CT scans (average across readers and imaging days). The participant-level correct detection rate (CDR) was 14.9% (95% CI: 6.2, 28.3) on same-day imaging and ranged from 4.3% to 14.9% (95% CI: 0.5 - 28.3) on next-day imaging across the readers. The CDR results were substantially impacted by the large number of lesions that were detected, but unable to be verified by biopsies (not clinically feasible in many cases) and by the low sensitivity of follow-up SOC imaging.

Despite biopsy not being SOC for this patient population, approximately 16% of patients who were positive on ^{64}Cu-SAR-Bombesin PET/CT were biopsied in the SABRE study. All lesions assessed by histopathology were positive for prostate cancer, indicating a 100% true-positive rate among those biopsied lesions

Based on these positive results, Clarity has commenced discussions with key medical experts to determine the most effective pathway for registration of ^{64}Cu-SAR-Bombesin and to explore its development in a range of large oncology indications with high unmet needs.

HIGHLIGHTS OF THE QUARTER CONT.

During and since the quarter ending 30 June 2025

World-leading conferences

The COBRA and SECuRE trials were presented at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting 2025 and the American Society of Clinical Oncology (ASCO) Annual Meeting 2025. Pre-clinical results using Clarity's $^{64/67}$Cu-SAR-trastuzumab product in mice bearing HER2-positve xenografts as a model for breast cancer therapy were showcased as an oral presentation at SNMMI. The COBRA trial was also presented at the American Urological Association (AUA) Annual Meeting in April.

Refocus on high-priority programs

Following a thorough review of Clarity's portfolio of clinical-stage assets as well as an in-depth analysis of the markets and their potential risks, the Company is prioritising the development of $^{64/67}$Cu-SAR-bisPSMA for both diagnostic and therapeutic applications in prostate cancer as well as the development of ^{64}Cu-SARTATE in NETs and ^{64}Cu-SAR-Bombesin in breast and prostate cancers.

Clarity will also continue to progress its Discovery Program, aiming to bring key assets, such as SAR-bisFAP and SAR-trastuzumab, to the clinic.

As part of this prioritisation process, the CL04 trial with $^{64/67}$Cu-SARTATE in paediatric high-risk neuroblastoma and the COMBAT trial with $^{64/67}$Cu-SAR-Bombesin in low PSMA mCRPC are being closed.

Supply and manufacturing

Clarity continues to strengthen its supply and manufacturing network with the signing of two agreements during the reporting period, bolstering reliable, universal access to copper-64 and ^{64}Cu-SAR-bisPSMA in the US for a commercial rollout upon successful completion of Clarity's Phase III registrational trials and subsequent US FDA New Drug Application (NDA) approvals.

Copper-64

In April, Clarity signed a high-volume commercial-scale agreement with Nusano for the production of copper-64 (Cu-64 or ^{64}Cu) isotope. Their 190,000 square foot facility in West Valley City, Utah is capable of producing more than 1,000 Ci (37,000 GBq) of copper-64 per day at capacity, which translates into more than 18,000 patient doses per day at 200 MBq per dose, with a 48-hour shelf-life, far in excess of commercial-scale demands across multiple large indications.

^{64}Cu-SAR-bisPSMA

In June, Clarity entered into a Commercial Manufacturing Agreement with SpectronRx for the production of ^{64}Cu-SAR-bisPSMA. SpectronRx's facility in Indiana will provide on-demand commercial-scale manufacturing of both copper-64 and ^{64}Cu-SAR-bisPSMA under one roof and enable distribution to all 50 states. This facility is planned to be producing up to 400,000 patient-ready doses of ^{64}Cu-SAR-bisPSMA annually from the one facility. The Agreement also includes an option to expand into similar additional sites, allowing Clarity to fine-tune its commercial supply and distribution approach in the future as a multi-layered strategy.

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 people with cancer, is pleased to release its Quarterly Activity Report and Appendix 4C for the three months ending 30 June 2025.

Executive Chairperson's Letter

Dear fellow Shareholders,

I am pleased to share the progress achieved by Clarity during and since the quarter ending 30 June 2025 as we progress our pipeline of best-in-class products.

As we are concluding the last quarter of the 2024-2025 financial year, we are pleased with the progress and developments achieved during this time and look forward to sharing more exciting news in the next few months as we progress our clinical programs.

Most recently, we have announced the successful completion of a $203 million institutional placement. It was no small feat given the challenges in the global markets for the last 8 months and some unfortunate events in our local Australian biotech sector, as well as the exposure to index funds we have experienced with entering into the ASX200 and ASX300 indices, which resulted in an increasing number of short positions in our Company, reaching approximately 10% of our current total number of shares on issue. Despite all of these obstacles, our team never lost its drive and motivation, united by our purpose to better the lives of people living with cancer, and we continued strengthening the fundamentals of our Company, being high-quality science and clinical research.

This led to a number of exciting milestones across all areas of the business and allowed us to complete a fast, well-executed and sizeable placement to a small number of institutional investors who are close to the Company. The Placement received phenomenal support, evidenced by the raising of over $200 million at not only a 2.2% premium to Clarity's previous closing price and an 18.0% premium to Clarity's 15-day Volume Weighted Average Price (VWAP), but a substantial premium to the share price observed for almost the entirety of CY2025. We thank our shareholders for their incredible support and look forward to continuing to generate shareholder value growth while we work towards our ultimate goal of improving treatment outcomes for people with cancer.

As we move closer to accomplishing this important mission, progressing late-stage clinical trials towards commercialisation, we have reached significant milestones with every product in clinical development during this quarter. Our key product, SAR-bisPSMA, advanced into the Dose Expansion Phase (Phase II) of the SECuRE trial and recruitment is now ongoing at the 8 GBq of ^{67}Cu-SAR-bisPSMA dose level. On the diagnostic front, we have commenced our second Phase III diagnostic trial with ^{64}Cu-SAR-bisPSMA, AMPLIFY, and recruited the first participant with biochemical recurrence (BCR) of prostate cancer into the trial at XCancer in Omaha, Nebraska. In addition to Clarity-sponsored trials, our long-standing collaborator and world-leading expert in the theranostic space, Prof Louise Emmett at St Vincent's Hospital, successfully completed recruitment in her Investigator-Initiated Trial (IIT), Co-PSMA, evaluating the performance of ^{64}Cu-SAR-bisPSMA in comparison to standard-of-care (SOC) ^{68}Ga-PSMA-11 for the detection rate of sites of prostate cancer recurrence. This is a head-to-head trial, and its results will be critical in building on the body of data supporting our plan to improve diagnostics in prostate cancer with ^{64}Cu-SAR-bisPSMA. Prof Emmett and her team have already started analysing the trial results and we look forward to sharing initial data in the coming months.

Reflecting the high quality and significance of the clinical trial data generated with ^{64}Cu-SAR-bisPSMA to date is its acceptance for presentation at a number of world-leading conferences in oncology and theranostics. The COBRA and SECuRE trials were presented at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting 2025 and the American Society of Clinical Oncology (ASCO) Annual Meeting 2025. The COBRA trial was also presented at the American Urological Association (AUA) Annual Meeting 2025. This data also formed the basis for Clarity's three Fast Track Designations (FTDs) for SAR-bisPSMA, one in therapy and two in diagnostic settings, placing us in a strong position to progress the development of this optimised product towards commercialisation.

In addition to SAR-bisPSMA, we also shared some exciting topline data with ^{64}Cu-SARTATE and ^{64}Cu-SAR-Bombesin in the DISCO and SABRE trials, respectively. The DISCO data demonstrates a considerable advantage of our ^{64}Cu-SARTATE compared to SOC ^{68}Ga-DOTATATE imaging when detecting lesions in patients with neuroendocrine tumours (NETs). ^{64}Cu-SARTATE detected almost double the number of lesions compared to the SOC (393 to 488 lesions in comparison to only 186 to 265 lesions by ^{68}Ga-DOTATATE among 45 study participants across the readers). Where standard of truth (SOT), such as histopathology or conventional imaging, was available, we saw a very high lesion-level sensitivity of 93.4% – 95.6% in comparison to just 4.4% – 6.6% for ^{68}Ga-DOTATATE for discordant findings (i.e. lesions only present on one of the scans). In addition to identifying more lesions with our product, lesions detected by ^{64}Cu-SARTATE also exhibited high uptake with low background on the positron emission tomography (PET) scans, making it easier for the readers to identify those lesions. We look forward to sharing additional data readouts from the DISCO trial and presenting the results at future international medical conferences.

In the meantime, we plan to rapidly progress discussions with the US Food and Drug Administration (FDA) to initiate a diagnostic registrational Phase III study, as a first key step in expanding SARTATE into the theranostic field of NETs, as well as other somatostatin receptor 2 (SSTR2)-expressing cancers, with the copper-64/copper-67 pair. If the findings from the DISCO trial are substantiated in a registrational Phase III study and lead to regulatory approval by the US FDA, ^{64}Cu-SARTATE may play an important role in improving diagnostic accuracy, lesion detection and staging of patients with NETs. These factors could improve clinical decision-making and treatment outcomes, potentially positioning ^{64}Cu-SARTATE as a best-in-class agent for the diagnosis of NETs.

Our SABRE trial has also generated some exciting data, setting a new benchmark by seeking to identify prostate cancer lesions that do not express prostate-specific membrane antigen (PSMA). This was Clarity's first sponsored study with ^{64}Cu-SAR-Bombesin, a product that targets gastrin-releasing peptide receptor (GRPR), and it showed that our product can provide a solution where the current diagnostic options fall short, improving lesion detection beyond what is achievable with SOC PSMA-targeted imaging. As seen in the SABRE trial, some patients have widespread metastatic disease that remains completely undetectable by all available SOC imaging for extended periods. These patients deserve access to advanced diagnostic tools, such as ^{64}Cu-SAR-Bombesin PET, that can reveal otherwise hidden disease and open the door to more informed and effective treatment options. Up to approximately 43% of participants in the SABRE trial had a positive ^{64}Cu-SAR-Bombesin PET/computed tomography (CT) scan, demonstrating the potential scale of the diagnostic gap this novel agent may help address, when no disease is identified by SOC imaging. The encouraging findings from SABRE and other trials with ^{64}Cu-SAR-Bombesin, such as the BOP and C-BOBCAT clinical studies, as well as other trials with GRPR-targeted agents in other cancers, highlight the broad potential of ^{64}Cu-SAR-Bombesin to become a best-in-class diagnostic agent in a number of indications.

We look forward to working with key regulatory groups, such as the US FDA, to explore various avenues and indications with SAR-Bombesin, as we continually strive to improve diagnostic and theranostic options for patients and their clinicians.

We now have three exceptional diagnostic agents in various stages of clinical development, ^{64}Cu-SAR-bisPSMA, ^{64}Cu-SARTATE and ^{64}Cu-SAR-Bombesin, and all three are showing impressive efficacy compared to SOC imaging. We look forward to sharing additional data readouts from all trials and progressing discussions with key medical experts to determine the most effective pathway for registration, particularly with ^{64}Cu-SAR-Bombesin as the pathway to commercialisation for ^{64}Cu-SAR-bisPSMA and ^{64}Cu-SARTATE is clearly defined and quickly progressing.

To support the late-stage clinical trials, with subsequent New Drug Applications (NDA) with the US FDA on the horizon, Clarity has continued to expand its manufacturing and supply chain footprint. Given the promising data in the diagnostic trials, Clarity signed a commercial-scale Supply Agreement for copper-64 with Nusano, whose 190,000 square foot state-of-the-art facility in West Valley City, Utah is expected to begin production in 2025 with copper-64 isotope supply planned to commence in early 2026. The accelerator-based proprietary technologies employed by Nusano are particularly well suited for cost-effective mass production of copper-64.

The Nusano facility is capable of producing more than 18,000 patient doses per day at 200 MBq per dose, with a 48-hour shelf-life, well in excess of commercial-scale demands across multiple large oncology indications in line with Clarity's commercialisation strategy.

With our lead ^{64}Cu-SAR-bisPSMA product actively recruiting in two registrational trials and Co-PSMA awaiting trial results, we are now also prepared to roll out large-scale manufacturing and distribution of ^{64}Cu-SAR-bisPSMA on day one of commercialisation as we entered into a Commercial Manufacturing Agreement with SpectronRx for this product, complementing supply and manufacturing agreements Clarity has secured to date.

SpectronRx's facility in Indiana will provide on-demand commercial-scale manufacturing of both copper-64 and ^{64}Cu-SAR-bisPSMA under one roof and enable distribution to all 50 states. By the time of commercialisation, the Indiana facility will have increased its current production to up to 400,000 patient-ready doses of ^{64}Cu-SAR-bisPSMA annually, and the Agreement also includes an option to expand production to similar additional facilities across the US. This approach will allow us to fine-tune our commercial supply and distribution approach in the future as a multi-layered strategy, ensuring that we are able to fulfil the growing needs of clinicians and patients across the country on all levels: nationally, regionally and locally.

The ability to make isotopes and products in the US for the treatment of the American people is an important advantage in the current geo-political and economic environment. By building a supply chain that is fully integrated, from high-volume isotope production, to centralised product manufacture and to delivering these ready-to-use diagnostics to imaging sites in every state of the US on time and on demand, we are aiming to create a model that is impervious to economic and political instability.

We are in a strong financial position to continue leveraging the powerful momentum of impressive data, strong science and the radiopharmaceutical sector as we work towards commercialisation. We look forward to progressing our differentiated platform of diagnostic and therapeutic assets with the goal of improving outcomes for cancer patients in need of novel treatments and diagnostics 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,

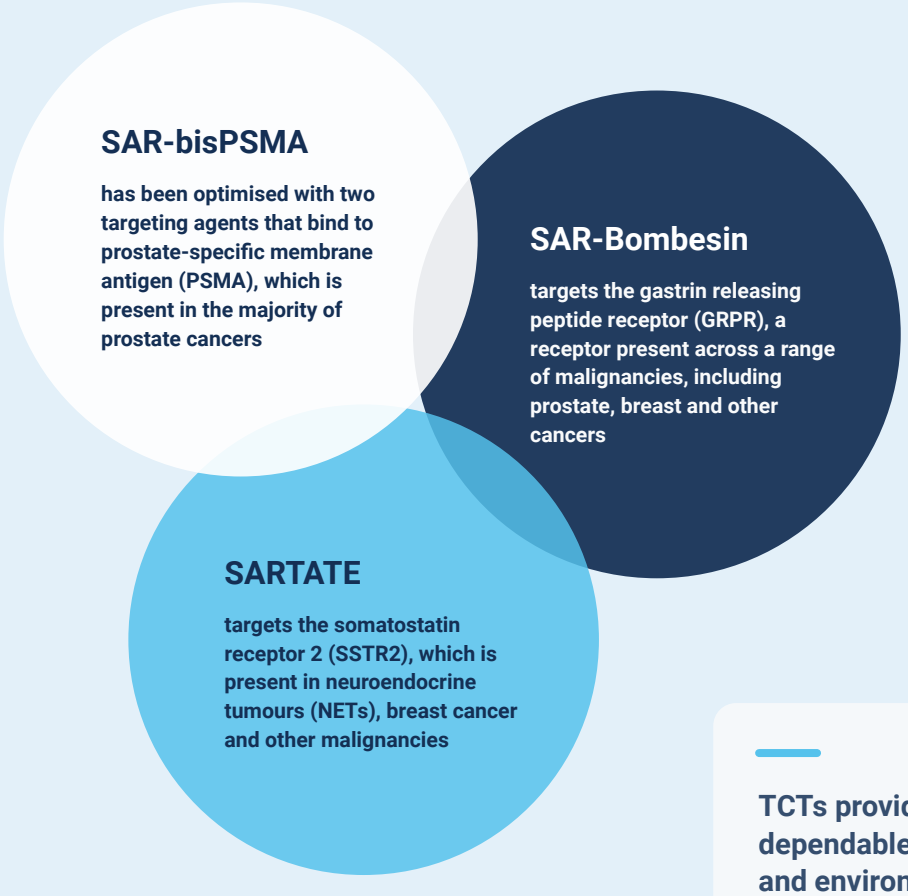
Dr Alan Taylor
Executive Chairperson
Clarity Pharmaceuticals Ltd

CLINICAL & 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 three core clinical-stage programs, SAR-bisPSMA, SARTATE and SAR-Bombesin, each contain a different targeting agent that binds to specific receptors that are present on different cancer cells.

The three programs are in clinical development for the diagnosis and/or 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 & REGULATORY DEVELOPMENT OVERVIEW

Clarity's lead product, SAR-bisPSMA, is actively progressing through four clinical trials: one theranostic trial (SECuRE), two Phase III diagnostic trials (CLARIFY and AMPLIFY) and an Investigator-Initiated Trial (IIT, Co-PSMA) at St Vincent's Hospital Sydney.

Clarity also shared positive topline data with the ^{64}Cu-SARTATE and ^{64}Cu-SAR-Bombesin products from its diagnostic Phase II trials, DISCO in NETs and SABRE in PSMA-negative biochemically recurrent (BCR) prostate cancer patients who are negative on standard-of-care (SOC) imaging, respectively. Based on these results, Clarity is taking next steps for further late-stage development of ^{64}Cu-SARTATE and ^{64}Cu-SAR-Bombesin with the guidance of the US Food and Drug Administration's (FDA) and key medical experts.

	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 (NCT04868604)[1]. Cohort Expansion Phase, recruitment ongoing.	**CLARIFY** – Registrational Phase III positron emission tomography (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)[2]. Recruitment ongoing. **AMPLIFY** – Registrational PET imaging trial of participants with BCR of prostate cancer following definitive therapy using ^{64}Cu-SAR-bisPSMA in the US and Australia (NCT06970847)[3]. Recruitment ongoing. **Co-PSMA** – Phase II head-to-head comparison of ^{64}Cu-SAR-bisPSMA vs ^{68}Ga-PSMA-11 in patients with BCR considered for curative salvage radiotherapy conducted by Prof Louise Emmett at St Vincent's Hospital Sydney as an Investigator-Initiated Trial (NCT06907641)[4]. Recruitment completed.
SARTATE		**DISCO** – Phase II PET imaging trial of participants with known or suspected NETs using ^{64}Cu-SARTATE in Australia (NCT04438304)[5]. Topline data announced.
SAR-Bombesin		**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]. Topline data announced.

CLINICAL & REGULATORY DEVELOPMENT OVERVIEW

FAST TRACK DESIGNATION

Clarity has three US FDA Fast Track Designations (FTD) for the SAR-bisPSMA agent.

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

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

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

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 three 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. This represents an important opportunity to disrupt and considerably advance the diagnostic and treatment landscapes of the large prostate cancer market.

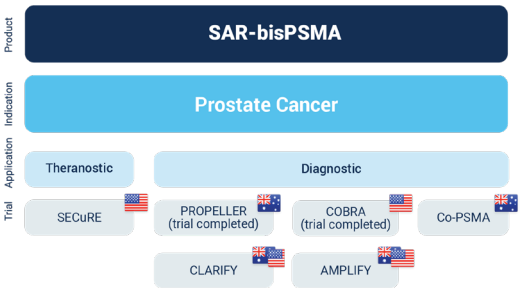
"These designations will allow us to work closely with the FDA to facilitate the development process and accelerate the approval of what could become best-in-class therapy and diagnostic agents, and our team and collaborators are committed to making this our priority in order to achieve our ultimate goal of improving treatment outcomes for people with cancer,"

Dr Alan Taylor

PRODUCT UPDATES

SAR-bisPSMA: PROSTATE CANCER

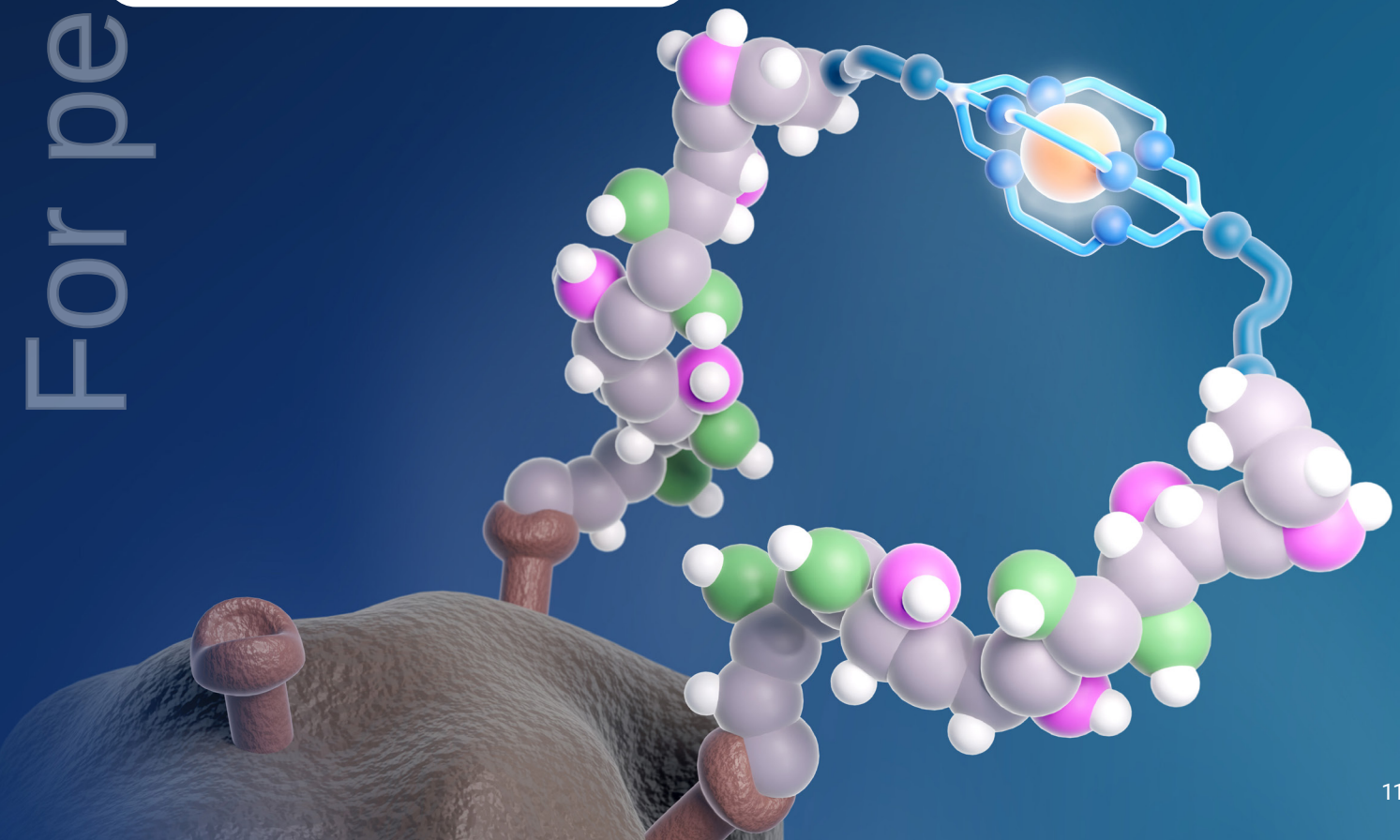
SAR-bisPSMA is a next-generation theranostic radiopharmaceutical with optimised dual PSMA-targeting agent to improve uptake and retention of the product in tumours



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 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

Clarity treated the first participant in the Cohort Expansion Phase (Phase II) of the SECuRE trial (NCT04868604)[1] with their first dose of 8 GBq of ^{67}Cu-SAR-bisPSMA in April. This follows the Safety Review Committee's (SRC) recommendation to progress the trial to Phase II at the 8 GBq of ^{67}Cu-SAR-bisPSMA dose level with an increase of the number of cycles from up to 4 to up to 6 based on the safety and efficacy data demonstrated in the Dose Escalation Phase (Phase I).

This first participant in the Cohort Expansion Phase is being treated with the combination of 8 GBq of ^{67}Cu-SAR-bisPSMA with enzalutamide (androgen receptor pathway inhibitor [ARPI]), as per the protocol amendment to incorporate an increase in the number of participants in this cohort from 14 to 24, in which a subset of participants will receive this combination therapy. These changes are aligned with the positive results from the Enza-p trial[7] and ongoing discussions with and advice from key global medical experts in the field of prostate cancer, including the Company's Clinical Advisory Board members, Prof Louise Emmett and Prof Oliver Sartor, as well as the SRC.

The recently amended protocol for this cohort will also focus on the evaluation of mCRPC participants in the pre-chemotherapy setting, aligning with Clarity's strategy of bringing ^{67}Cu-SAR-bisPSMA to earlier stages of disease. This is based on the promising safety and efficacy data, especially in pre-chemotherapy participants, treated in the SECuRE trial to date. In the Dose Escalation Phase (Phase I), preliminary data showed that 92% of pre-chemotherapy participants (12/13) demonstrated prostate-specific antigen (PSA) drops greater than 35%, PSA reductions greater than 50% were reached in 61.5% (8/13) of participants, and reductions of 80% or more were achieved in 46.2% (6/13) of participants. These outstanding results were achieved despite many of the 13 pre-chemotherapy participants having considerable disease burden, being heavily pre-treated, and the majority of them only having received a single dose of ^{67}Cu-SAR-bisPSMA[8].

The Cohort Expansion Phase of the SECuRE trial is expected to further build on the already positive results of ^{67}Cu-SAR-bisPSMA observed 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 three 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.

Participants in the Cohort Expansion Phase will also be receiving Clarity's improved ^{67}Cu-SAR-bisPSMA product formulation, which was rolled-out prior to the commencement of this phase of the trial. The enhanced formulation allows for room temperature stability, supply and scalability, all of which are essential for late-stage clinical trials and streamlined commercial-scale manufacture.

SECuRE Trial Design and Protocol

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 Phase. 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.

Dose Escalation Phase

The Dose Escalation Phase of the study was primarily aimed at assessing safety of the ^{64}Cu-SAR-bisPSMA and ^{67}Cu-SAR-bisPSMA products and determining an optimal therapeutic dose for ^{67}Cu-SAR-bisPSMA. As such, each subsequent cohort of participants in the SECuRE trial received an increased dose of the therapeutic drug until the optimal dose was 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 had the highest single dose level of 12 GBq of ^{67}Cu-SAR-bisPSMA. Cohort 4 assessed 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.

^{67}Cu-SAR-bisPSMA showed a favourable safety profile across cohorts 1-4, and the majority of reported adverse events (AEs) were mild or moderate (Grade 1-2), with anaemia and thrombocytopenia being the most prevalent among the haematological events.

Based on the data from cohorts 1-4, the SECuRE trial progressed to the Cohort Expansion (Phase II) at an 8 GBq dose level as per the SRC recommendation, with an increase in the total number of cycles from up to 4 to up to 6. This recommendation was based on the favourable safety profile of ^{67}Cu-SAR-bisPSMA observed to date.

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

Clarity commenced the diagnostic Phase III trial of ^{64}Cu-SAR-bisPSMA in participants with BCR of prostate cancer, AMPLIFY (NCT06970847)[3], with the first participant receiving the product in May at XCancer in Omaha, Nebraska (NE).

AMPLIFY (^{64}Cu-SAR-bisPSMA Positron Emission Tomography: A Phase 3 Study of Participants with Biochemical Recurrence of Prostate Cancer) is a non-randomised, single-arm, open-label, multi-centre, diagnostic clinical trial of ^{64}Cu-SAR-bisPSMA positron emission tomography (PET) in approximately 220 participants with rising or detectable PSA after initial definitive treatment at multiple clinical sites across the US and Australia. 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 AMPLIFY trial is to investigate the ability of ^{64}Cu-SAR-bisPSMA PET/computed tomography (CT) to detect recurrence of prostate cancer. 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).

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[9,10].

These earlier studies demonstrated an excellent safety profile and exciting efficacy results, especially in comparison to current standard-of-care (SOC) imaging. PROPELLER showed improved diagnostic performance of ^{64}Cu-SAR-bisPSMA compared to ^{68}Ga-PSMA-11 on same-day imaging, including higher number of lesions identified and 2 - 3 times statistically significant higher lesion uptake and tumour-to-background ratio, favouring ^{64}Cu-SAR-bisPSMA. The COBRA trial showed that more lesions and more patients with a positive scan were identified on ^{64}Cu-SAR-bisPSMA PET compared to conventional scans and on next-day vs. same-day imaging. ^{64}Cu-SAR-bisPSMA also allowed for the identification of lesions in the 2-mm range. The most recent findings from the COBRA trial demonstrated that ^{64}Cu-SAR-bisPSMA was able to detect lesions from 29 days to more than 6 months earlier than SOC PSMA PET agents.

The COBRA data has been presented at leading medical conferences this quarter, including the 2025 Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting, the American Society of Clinical Oncology (ASCO) 2025 Annual Meeting and the American Urological Association (AUA) Annual Meeting.

"The data to date and the reliability of ^{64}Cu-SAR-bisPSMA PET interpretations have important clinical implications, as they could ensure more consistent diagnoses, broad clinical applicability and effective treatment planning, ultimately leading to improved patient outcomes,"

Dr Alan Taylor

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)[2], for ^{64}Cu-SAR-bisPSMA as a diagnostic agent in patients with prostate cancer prior to undergoing radical prostatectomy, with enrolment 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 approximately 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 in detecting 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).

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

Study enrolment in the Co-PSMA (NCT06907641)[4] Investigator-Initiated Trial (IIT) was successfully completed, with 50 patients recruited. The Co-PSMA trial aims to evaluate the performance of Clarity's diagnostic product, ^{64}Cu-SAR-bisPSMA, in comparison to the SOC ^{68}Ga-PSMA-11 product for the detection of prostate cancer recurrence.

Co-PSMA (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) is led by Prof Louise Emmett at one of the most prominent institutions in Australia, St Vincent's Hospital Sydney.

The Co-PSMA trial is a prospective, Phase II imaging trial in 50 patients with BCR of prostate cancer. Eligible patients were required to have had radical prostatectomy with no salvage therapy and a PSA between 0.2 and 0.75 ng/ml.

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.

"If the Co-PSMA trial confirms that ^{64}Cu-SAR-bisPSMA can detect more lesions than ^{68}Ga-PSMA-11 in this patient group with such low PSA, this may improve image-guided therapy, potentially avoiding complications and improving outcomes,"

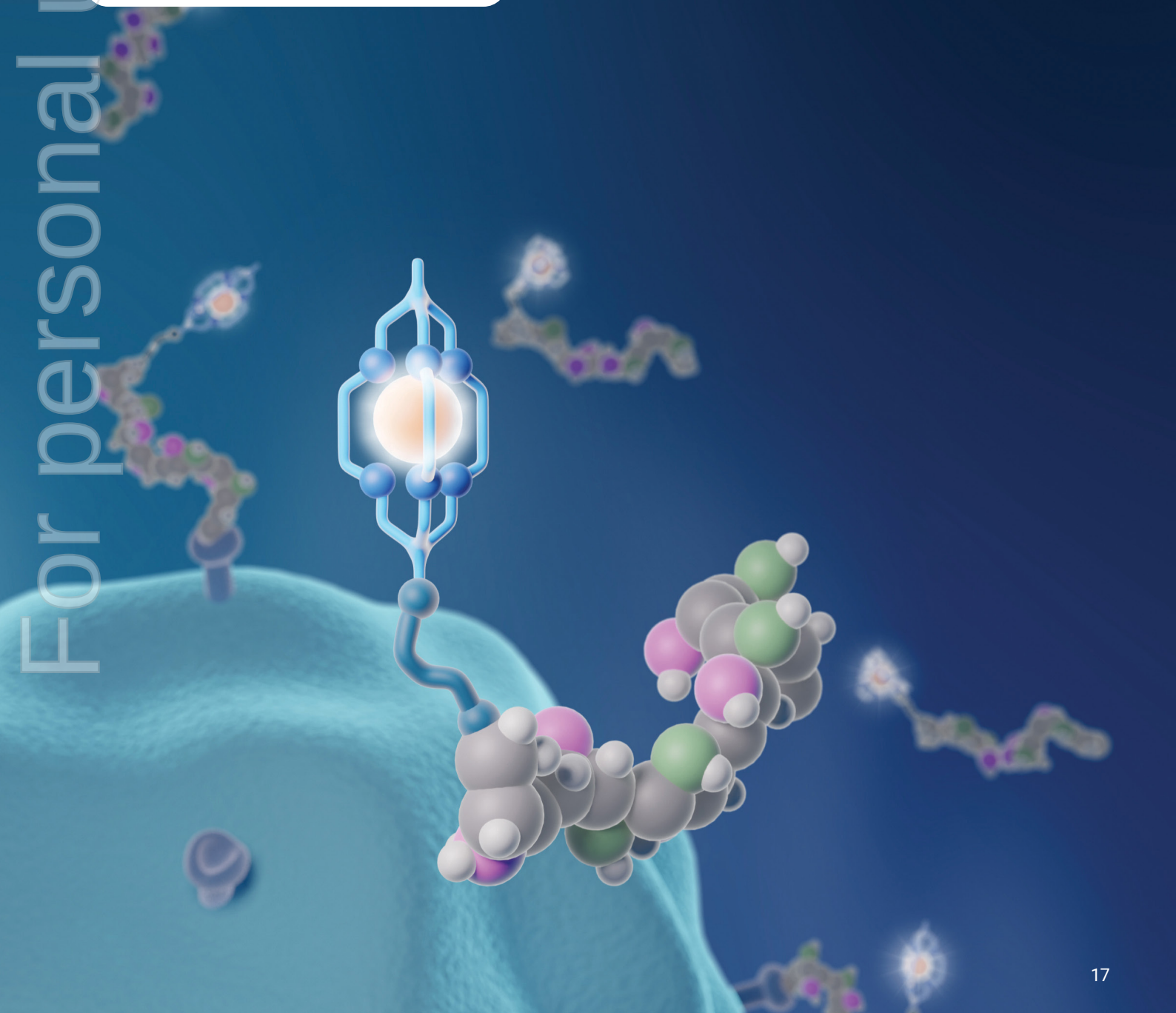
Prof Louise Emmett

SARTATE:
NEUROENDOCRINE TUMOURS

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 neuroendocrine tumours (NETs).

Clarity is prioritising the development of SARTATE into early commercialisation with a focus on NETs imaging in the first instance.



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

Topline data from the Phase II diagnostic ^{64}Cu-SARTATE trial, DISCO (NCT04438304)[5], in patients with known or suspected NETs confirms that ^{64}Cu-SARTATE is safe and highly effective compared to standard-of-care (SOC) imaging at detecting lesions in patients with NETs.

DISCO Trial Design

DISCO (**"D**iagnostic **I**maging **S**tudy of ^{64}**CO**pper-SARTATE Using PET on Patients with Known or Suspected Neuroendocrine Tumours) assessed the performance of Clarity's SARTATE imaging product as a potential new method to diagnose and manage NETs. The trial aimed to build on earlier clinical evidence using ^{64}Cu-SARTATE in patients with NETs, which showed excellent imaging characteristics and suggested that ^{64}Cu-SARTATE PET/CT provides comparable or superior lesion detection to ^{68}Ga-DOTATATE PET/CT, especially in the liver[11].

DISCO recruited participants with Gastroenteropancreatic NETs (GEP-NETs) across 4 sites in Australia, comparing the diagnostic performance of ^{64}Cu-SARTATE PET at an average of 4 hours (between 3 and 5 hours) and approximately 20 hours post-administration (same-day and next-day imaging, respectively) to the current SOC, ^{68}Ga-DOTATATE PET. Participants were required to have undergone a pre-study ^{68}Ga-DOTATATE PET/CT scan within 5 weeks, but not closer than 6 hours prior to the administration of ^{64}Cu-SARTATE as part of their routine clinical care.

The trial was initially designed to enrol up to 63 patients, based on the anticipated lesion-level discordance rate between ^{64}Cu-SARTATE and ^{68}Ga-DOTATATE PET. Following a pre-planned early analysis of the data collected during the study, the sample size was adjusted to 45 patients, allowing for an earlier enrolment completion.

Study participants were dosed with 200 MBq of ^{64}Cu-SARTATE. Both the ^{64}Cu-SARTATE and ^{68}Ga-DOTATATE PET/CT scans were reviewed by 2 blinded central readers. Participants were followed up for up to 12 months to complete additional investigations (e.g. biopsy and conventional imaging) and obtain the standard-of-truth (SOT) used to verify discordant findings between the scan pairs. The verification of discordant findings against the SOT evidence (as true- or false-positive findings) was completed by an independent central assessor, distinct from the central readers evaluating the ^{64}Cu-SARTATE and ^{68}Ga-DOTATATE scans. Lesion-level sensitivity was calculated for the discordant lesions between the scan pairs, with each true-positive discordant lesion on one scan considered a false-negative lesion on the other scan, and each false-positive discordant lesion on one scan considered a true-negative lesion on the other scan.

Topline Results

The results indicate that lesion detection by ^{64}Cu-SARTATE (regardless of imaging timepoint) substantially outperformed that of ^{68}Ga-DOTATATE. ^{64}Cu-SARTATE detected 393 to 488 lesions, and ^{68}Ga-DOTATATE identified 186 to 265 lesions among 45 participants across the readers (**Figure 1**).

Out of all lesions identified by the readers, 230 - 251 were deemed to be discordant between ^{64}Cu-SARTATE and ^{68}Ga-DOTATATE PET/CT, with 93.5% (average across readers and imaging days) of these discordant lesions detected on the ^{64}Cu-SARTATE scans only. A previously completed Phase I study demonstrated a 1.7 fold increase (median of 6.70 vs. 3.92, p=0.002) in contrast (i.e. lesion-to-background ratio) for ^{64}Cu-SARTATE PET/CT performed at 4 hours post-administration compared to ^{68}Ga-DOTATATE PET/CT[11]. This improvement in contrast may explain the detection of additional lesions observed in the DISCO trial. The average lesion SUVmax, representing the highest concentration of ^{64}Cu-SARTATE uptake in lesions, was notably high, ranging from 37.42 to 43.90 across both imaging days in the DISCO trial.

Approximately half of all discordant lesions had an available SOT, which yielded a lesion-level sensitivity of 93.4% to 95.6% (95% confidence interval [CI]: 65.1, 99.5) for ^{64}Cu-SARTATE, including both timepoints, and only 4.4% to 6.6% (95% CI: 0.5, 34.9) for ^{68}Ga-DOTATATE.

^{64}Cu-SARTATE was deemed safe and well tolerated. Only 7 (15.6%) trial participants experienced ^{64}Cu-SARTATE-related AEs, the majority of which were mild (Grade 1) gastrointestinal events, commonly observed in NET patients, and typically resolved within 2 days of onset. No serious treatment-emergent AEs were observed in the study.

Based on the findings of the DISCO trial to date, Clarity will commence the next steps to conduct a registrational Phase III study of ^{64}Cu-SARTATE in NETs with the US FDA's guidance.

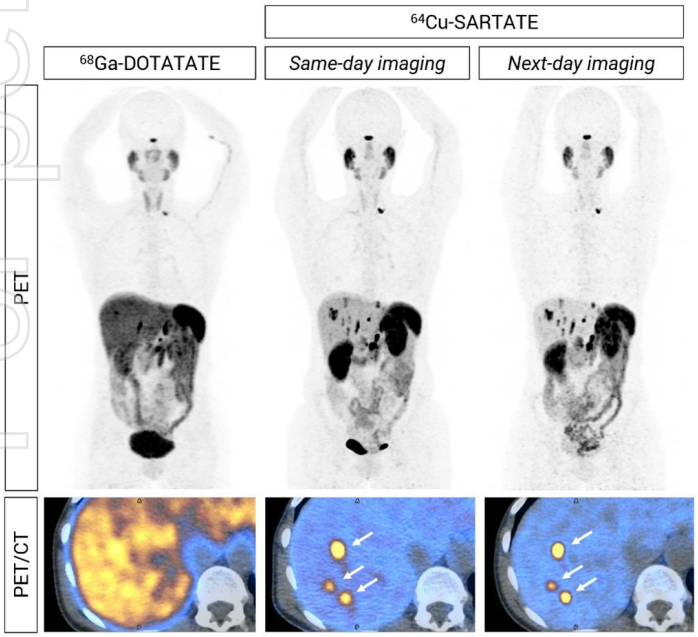


Figure 1. 59-year-old participant with functional NETs. ^{68}Ga-DOTATATE PET/CT was performed 26 days prior to the ^{64}Cu-SARTATE PET/CT (same-day imaging). PET (top images): top left image shows higher background on the ^{68}Ga-DOTATATE PET. Top centre and right PET images show multiple lesions detected by ^{64}Cu-SARTATE against a low background. Images are shown as maximum intensity projections. PET/CT fusion (bottom images): axial sections show intense liver uptake on the ^{68}Ga-DOTATATE PET/CT (bottom left), which limits the ability to distinguish lesions from the background, and 3 clearly defined lesions are visible on the ^{64}Cu-SARTATE PET/CT (arrows; bottom centre and right images, same-day and next-day imaging, respectively). Mean maximum standardised uptake value (SUVmax) of lesions shown in the ^{64}Cu-SARTATE PET/CT images: 16.1 and 16.5 on same-day and next-day imaging, respectively. Lesions in the liver have been verified as true-positive based on other scans, including diagnostic CT and magnetic resonance imaging (MRI). Fused images are shown with consistent scaling for visual comparison.

SAR-BOMBESIN: PROSTATE CANCER

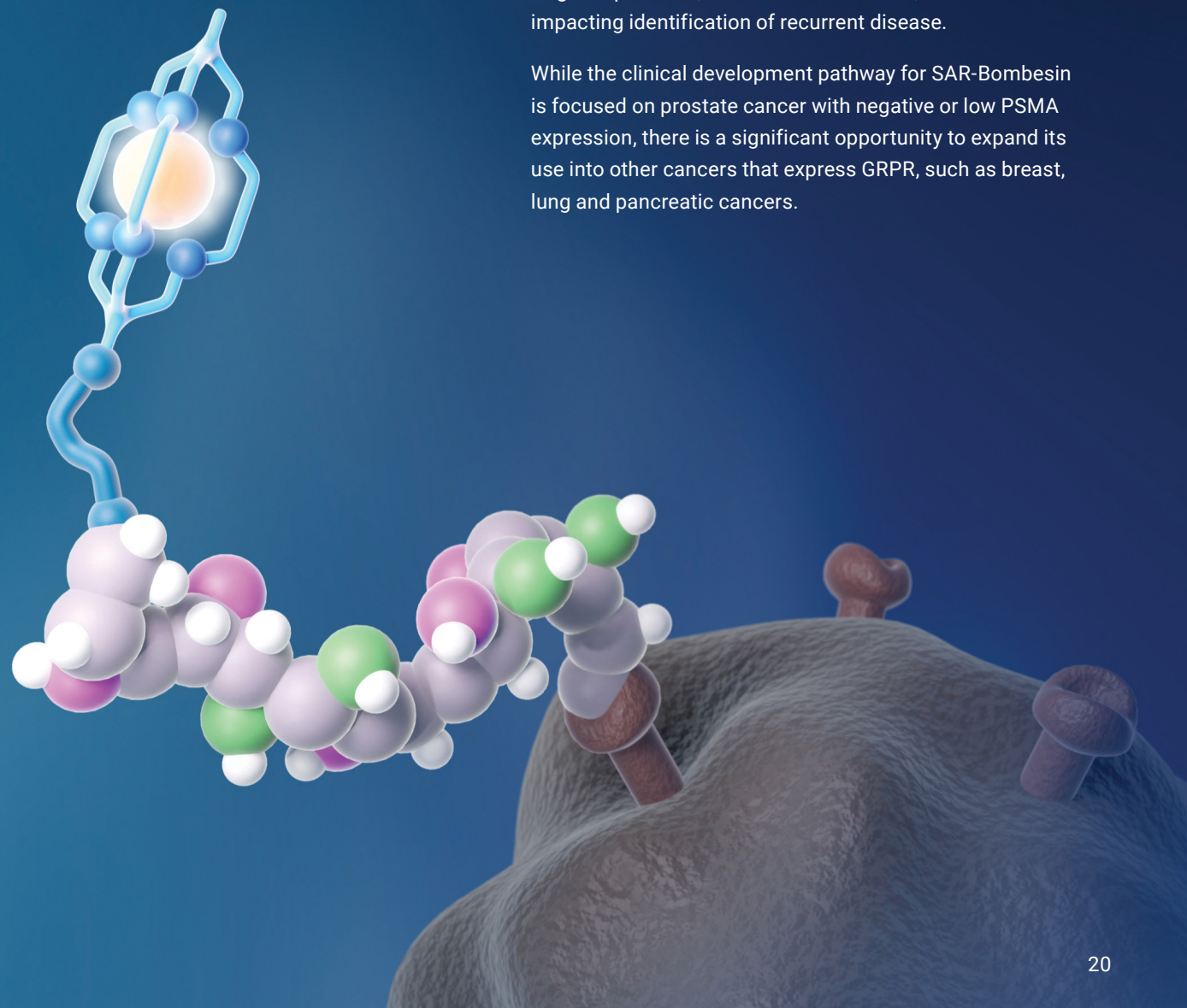
SAR-Bombesin (SAR-BBN) is a next-generation, highly targeted pan-cancer theranostic radiopharmaceutical

SAR-Bombesin is being developed for diagnosing, staging and subsequently treating cancers that express a receptor called the gastrin-releasing peptide receptor (GRPR), including prostate and breast cancers.

Clarity is progressing the development of SAR-Bombesin with a focus on prostate cancer imaging in the first instance.

Approximately 20-25% of prostate cancer patients with BCR have low or no uptake of PSMA-targeting tracer[12-15]. These patients are unlikely to show meaningful uptake of PSMA-targeted products, such as ^{68}Ga-PSMA-11, therefore impacting identification of recurrent disease.

While the clinical development pathway for SAR-Bombesin is focused on prostate cancer with negative or low PSMA expression, there is a significant opportunity to expand its use into other cancers that express GRPR, such as breast, lung and pancreatic cancers.



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

Topline data from the Phase II diagnostic ^{64}Cu-SAR-Bombesin trial, SABRE (NCT05407311)[6], confirms that ^{64}Cu-SAR-Bombesin was safe, well tolerated and effective at detecting prostate cancer in patients with BCR who are negative or equivocal on SOC scans, including PSMA PET.

SABRE Trial Design

SABRE (Copper-64 **SA**R-Bombesin in **B**iochemical **R**ecurrence of prostate cancer) was a Phase II multi-centre, single arm, non-randomised, open-label copper-64 labelled SAR-Bombesin PET imaging trial of patients with PSMA-negative BCR of prostate cancer following definitive therapy. To be considered for inclusion in the study, candidates were required to demonstrate negative or equivocal findings for prostate cancer on approved PSMA PET (^{68}Ga-PSMA-11 or ^{18}F-DCFPyL), anatomical imaging (CT and/or MRI) and any other SOC imaging, if available. The primary objectives of the trial were to investigate the safety and tolerability of the product as well as its ability to correctly detect recurrence of prostate cancer.

Study participants were dosed with 200 MBq of ^{64}Cu-SAR-Bombesin and underwent PET/CT scans at 1 - 4 hours and 24 ± 6 hours post-dose (same-day and next-day imaging, respectively). The scans were interpreted by three blinded central readers. To determine the efficacy of ^{64}Cu-SAR-Bombesin imaging, the same-day and next-day PET/CT results of the central readers were assessed against a composite reference standard that was determined by an independent, blinded, central expert panel. The reference standard consisted of histopathology, follow-up SOC imaging and/or confirmed PSA response to focal therapy.

The co-primary efficacy endpoints were participant-level correct detection rate (CDR, defined as the proportion of true-positive participants out of all scanned participants who had at least one evaluable reference standard datapoint collected) and region-level positive predictive value (PPV, defined as the proportion of true-positive regions out of all positive regions on the ^{64}Cu-SAR-Bombesin PET/CT scan with corresponding evaluable composite reference standard data), assessed independently for same-day and next-day imaging timepoints.

The design of the SABRE study followed advice from the FDA to achieve the highest standards in clinical research in the BCR setting. Based on this guidance, the expert panel, who determined the reference standard, was blinded to the results of the ^{64}Cu-SAR-Bombesin scans and distinct from the central readers assessing the ^{64}Cu-SAR-Bombesin scans. This approach removed potential biases in the assessment of the reference standard, which was not the case for other studies conducted in this setting.

The SABRE study design also adopted a conservative approach to the analysis of both co-primary endpoints. If a lesion identified on the ^{64}Cu-SAR-Bombesin scan was not biopsied, and it was also not present on follow-up SOC imaging (a suboptimal reference standard with known low sensitivity and in a patient population that was negative on SOC imaging at screening), it was considered as false-positive in the analysis by default.

Topline Results

Fifty-three patients with negative or equivocal SOC scans at screening (which included approved PSMA PET and anatomical imaging) were enrolled and imaged. Forty-seven participants were evaluable for the primary efficacy endpoints. Approximately half of the participants enrolled had PSA less than or equal to 1.0 ng/mL at study entry.

The average detection rate (proportion of participants with a positive scan out of all participants with a scan) across readers using ^{64}Cu-SAR-Bombesin PET/CT was 35.2% on same-day imaging (24.5% - 43.4% range) and 27.7% on next-day imaging (17% - 37.7% range). Approximately 47 lesions were identified on same-day imaging (40 - 59 range) and approximately 52 on next-day imaging (24 - 95 range), despite these patients having negative or equivocal SOC scans prior to study entry, highlighting the potential clinical benefit that imaging with ^{64}Cu-SAR-Bombesin can provide. The most common site of lesion detection was in the lymph nodes (LNs) and the prostate regions.

The participant-level CDR was 14.9% (95% CI: 6.2, 28.3) on same-day imaging and ranged from 4.3% to 14.9% (95% CI: 0.5 - 28.3) on next-day imaging across the readers. Region-level PPV ranged from 22.6% to 47.1% (95% CI: 9.6 - 72.2) on same-day imaging and from 22.2% to 37.5% (95% CI: 2.8 - 61.7) on next-day imaging.

The CDR and PPV results were substantially impacted by the large number of lesions that were detected on the ^{64}Cu-SAR-Bombesin scans, but unable to be verified due to the lack of effective diagnostic options available for comparison and biopsy not being clinically appropriate in most cases. Three patients underwent biopsy (the 'gold standard' for verifying lesions) due to the findings of the ^{64}Cu-SAR-Bombesin scan and a total of four biopsies were performed. All biopsies were positive for prostate cancer, including two pelvic LNs, one extra-pelvic LN and one bone lesion.

Administration of ^{64}Cu-SAR-Bombesin at 200 MBq was shown to be safe and well tolerated. Only two participants had AEs related to ^{64}Cu-SAR-Bombesin with all being mild (Grade 1) and resolving within 2 days of onset.

Case Study

A participant with BCR of prostate cancer presented with a baseline PSA of 22.3 ng/mL, negative SOC PSMA PET (^{18}F-DCFPyL, **Figure 2**, left image) and equivocal CT at screening. Imaging with ^{64}Cu-SAR-Bombesin (middle image) revealed substantial disease burden with lesions detected in the pelvic LNs, extra-pelvic LNs, visceral/soft tissue, and bone. Subsequent biopsies of a right pelvic bone lesion and a supradiaphragmatic LN confirmed malignancy at both sites. A follow-up ^{18}F-DCFPyL PET scan, conducted approximately 4 months after the screening with ^{18}F-DCFPyL, failed to detect lesions in all regions except for the bone.

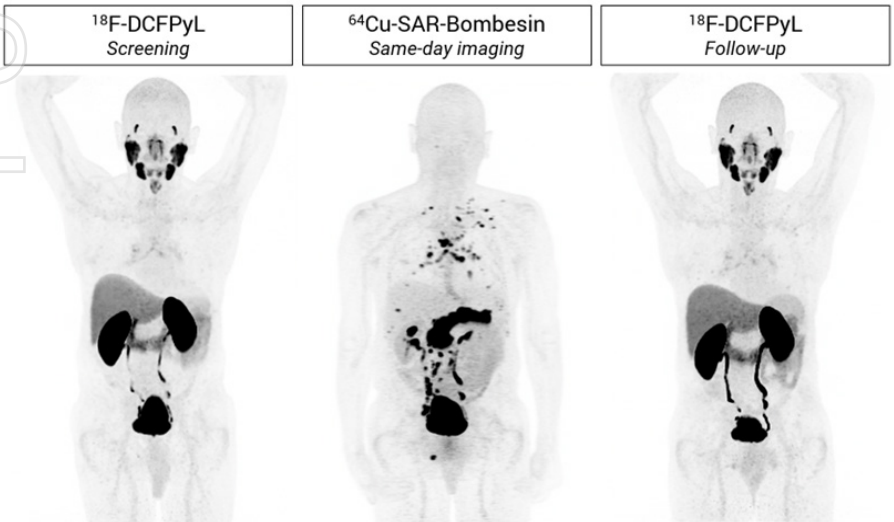


Figure 2. Detection of extensive metastatic disease by ^{64}Cu-SAR-Bombesin in a participant with BCR of prostate cancer. The initial ^{18}F-DCFPyL PSMA PET at screening was negative (left image), whereas same-day imaging with ^{64}Cu-SAR-Bombesin (middle image) detected widespread disease, including lesions in the right pelvic bone and a supradiaphragmatic LN, which were confirmed as prostate cancer by biopsy. A follow-up ^{18}F-DCFPyL scan approximately 11 weeks later (right image) was still unable to detect the extensive recurrence identified by the ^{64}Cu-SAR-Bombesin scan. Maximum intensity projection of PET imaging. Images are shown with consistent scaling for visual comparison.

SUPPLY & MANUFACTURING: THE GAME CHANGER FOR RADIOPHARMACEUTICALS

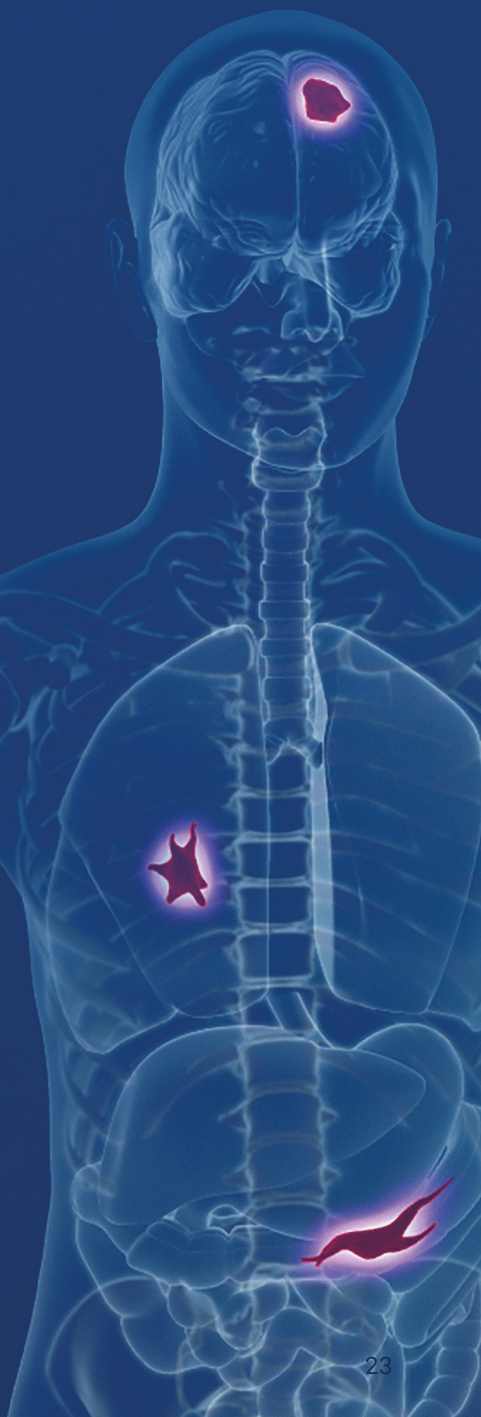
Targeted Copper Theranostics (TCTs) hold a number of competitive advantages, including clinical benefits, which Clarity is actively exploring through its clinical program. The logistical, manufacturing and environmental advantages associated with the production of copper isotopes for diagnostic imaging (copper-64) and therapy (copper-67) are key differentiators, which hold promise of taking radiopharmaceuticals into the large oncology market.

The logistical, manufacturing and environmental advantages associated with the production of copper isotopes for diagnostic imaging (copper-64) and therapy (copper-67) are key differentiators of Targeted Copper Theranostics (TCTs), allowing for scalability into commercial manufacturing that the current generation of radiopharmaceuticals being developed do not have.

These differentiators are the reason TCTs are considered the next generation of radiopharmaceuticals, as they enable Clarity to employ the model of centralised manufacturing under Good Manufacturing Practice (GMP) of both diagnostic and therapeutic products under one roof. Copper-64 and copper-67 both have well-established, large-scale production methods that can be seamlessly and fully integrated into high-volume operations with minimal investment and within a short timeframe.

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

In line with this, Clarity has continued to expand its manufacturing and supply chain footprint, with a particular focus on strengthening its commercial manufacturing network as the Company progresses multiple late-stage clinical trials, with subsequent New Drug Applications (NDA) with the US Food and Drug Administration (FDA) on the horizon.



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 radio-diagnostics 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 gallium-68 and fluorine-18.

The shelf-life of the copper-based diagnostics also allows for wider geographic distribution, which can improve patient access to this important imaging 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.

As Clarity has generated exceptional data to date and is currently running a number of late-stage clinical trials in the US and Australia, the Company continues strengthening its cost-effective, large-scale supply strategy for the commercial roll-out of its copper-64 based diagnostics.

In April 2025, Clarity signed a high-volume commercial-scale agreement with Nusano, Inc. ("Nusano") for supply of the copper-64 isotope. Nusano's 190,000 square foot state-of-the-art facility in West Valley City, Utah is expected to begin production in 2025 with copper-64 isotope supply planned to commence in early 2026. The accelerator-based proprietary technologies employed by Nusano are particularly well suited for cost-effective mass production of copper-64. The Nusano facility is capable of producing more than 1,000 Ci (37,000 GBq) of copper-64 per day at capacity, which translates into more than 18,000 patient doses per day at 200 MBq per dose, with a 48-hour shelf-life, well in excess of commercial-scale demands across multiple large oncology indications in line with Clarity's commercialisation strategy.

^{64}Cu-SAR-bisPSMA product supply

With multiple clinical trials with ^{64}Cu-SAR-bisPSMA ongoing, including two registrational trials, Clarity continues to bolster its supply network to support an efficient, reliable commercial roll-out of this diagnostic product. In line with this, in June Clarity entered into a Commercial Manufacturing Agreement with SpectronRx for the ^{64}Cu-SAR-bisPSMA product, enabling on-demand commercial-scale manufacturing of both copper-64 and ^{64}Cu-SAR-bisPSMA under one roof, with central distribution to all 50 states in the US.

SpectronRx's facility in Indiana will expand current production to up to 400,000 patient-ready doses of ^{64}Cu-SAR-bisPSMA annually by the time of commercialisation. The agreement also includes an option to expand production into similar additional sites throughout the US, substantially increasing the manufacturing capacity of patient-ready doses of ^{64}Cu-SAR-bisPSMA in regional hubs spread throughout the US. This enables Clarity to seamlessly move to larger commercial volumes to meet anticipated market demand while employing a multi-layered supply and distribution approach to fulfil the growing needs of clinicians and patients across the country on all levels: national, regional and local.

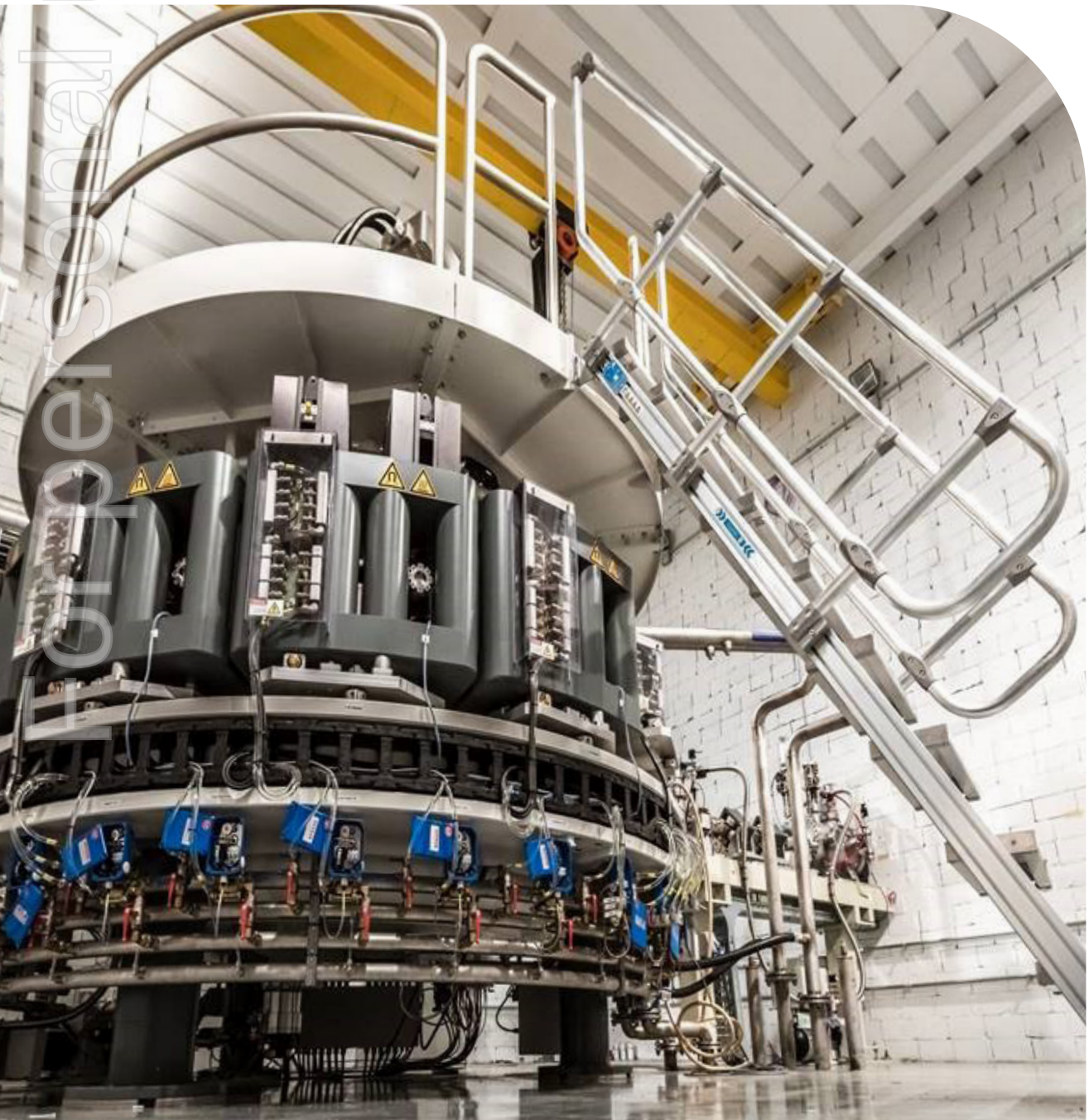
This agreement, together with other supply and manufacturing agreements Clarity has entered to date, ensures reliable, universal access to ^{64}Cu-SAR-bisPSMA in the US for a commercial roll-out upon the successful completion of Clarity's pivotal trials with this product and subsequent NDA approval.

The Commercial Manufacturing Agreement further builds on the Master Service Agreement and associated Supply Agreement for the copper-64 isotope with SpectronRx, as well as the Clinical Manufacturing Agreement for the production of ^{64}Cu-SAR-bisPSMA for Clarity's Phase III trials, CLARIFY and AMPLIFY.

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 ageing 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[16]. Even with the current infrastructure, access to reactor production capacity will soon become a bottleneck for lutetium-177[17].



FINANCIALS

Clarity's cash balance at 30 June 2025 was $84.1 million.

Net operating cash outflows for the June quarter were $9.1 million, which is lower than the previous quarter's net outflow of $15.3 million due to the receipt of $11.1 million for the FY24 Research & Development Tax Incentive (RDTI), offset by increased research and development (R&D) spend of $15.9 million following commencement of the AMPLIFY trial, in addition to Clarity's other ongoing clinical and pre-clinical programs. Operating cash outflows relate to payments for R&D, 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 30 June 2025 $ million	% of Total Funds
Pre-Clinical	$8.5	5.3%	$4.1	4.4%
Clinical	$111.0	69.7%	$64.4	69.3%
Regulatory	$7.1	4.5%	$2.7	2.9%
Patents	$1.8	1.2%	$1.3	1.4%
Commercial	$10.2	6.4%	$1.4	1.5%
Working Capital** and Costs of the Offer	$20.6	12.9%	$19.0	20.5%
Total uses	**$159.2**	**100%**	**$92.9**	**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 30 June 2025 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 $705,744 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.

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CLARITY
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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	30 June 2025

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(15,900)	(45,314)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(60)	(682)
	(d) leased assets	-	-
	(e) staff costs	(5,026)	(20,128)
	(f) administration and corporate costs	(1,038)	(4,421)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	2,065	5,346
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	(308)	(718)
1.7	Government grants and tax incentives	11,146	11,146
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(9,121)**	**(54,771)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(30)	(183)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 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**	**(30)**	**(183)**

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	237	2,405
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(1)	(193)
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**	**236**	**2,212**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	95,080	136,506
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(9,121)	(54,771)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(30)	(183)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	236	2,212

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
4.5	Effect of movement in exchange rates on cash held	(2,047)	354
4.6	**Cash and cash equivalents at end of period**	**84,118**	**84,118**

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	47,684	47,929
5.2	Call deposits[1]	36,434	47,151
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)**	**84,118**	**95,080**

1. Note: Call deposits represent term deposit accounts with expiry dates more than 90 days after balance date

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[2]	706
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

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)	(9,121)
8.2	Cash and cash equivalents at quarter end (item 4.6)	84,118
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	**84,118**
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	9

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 July 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.