CLARITY
PHARMACEUTICALS

QUARTERLY ACTIVITY REPORT

SYDNEY, AUSTRALIA
30 SEPTEMBER 2026



HIGHLIGHTS OF THE QUARTER

During and since the quarter ending 30 September 2026

Cash Position

The Company remains well funded with a cash position of $152.9 million at 30 September 2026, providing Clarity with a strong Balance Sheet to continue progressing its programs towards commercialisation.

CLARIFY Trial

On 27 October, the registrational Phase III CLARIFY trial dosed the planned target of 383 participants with untreated, histopathology-confirmed prostate cancer with high-risk features. Patient follow-up is now ongoing, in line with the trial protocol. Topline data are anticipated to be released in the first half of calendar year 2027, along with the topline results from the AMPLIFY trial in biochemical recurrence (BCR) of prostate cancer.

Real-World Case Profiles

Ten patients with BCR of prostate cancer and negative/equivocal standard-of-care (SOC) prostate-specific membrane antigen (PSMA) positron emission tomography (PET), i.e. ^{68}Ga-PSMA-11 and/or ^{18}F-DCFPyL, accessed ^{64}Cu-SAR-bisPSMA through compassionate use programs, such as Special Access Scheme (SAS) in Australia and Expanded Access Program (EAP) in the US (data cut-off 3 August 2026). Lesions were detected in 8 (80%) patients and a total of 19 lesions were identified on next-day imaging. The two patients with negative ^{64}Cu-SAR-bisPSMA scans had prostate-specific antigen (PSA) levels below <0.2 ng/mL.

Five patients with BCR of prostate cancer (PSA 0.3 – 13.3 ng/mL) who had a previously negative SOC PSMA PET/computed tomography (CT) on the Siemens Biograph Vision Quadra system, also had lesions identified by ^{64}Cu-SAR-bisPSMA PET/CT both on the same- and next-day imaging, using the same PET system.

SECuRE Trial

The Cohort Expansion (Main Group) of the Phase I/IIa SECuRE trial achieved its recruitment target in October 2026. The enrolled sixteen participants with metastatic castration-resistant prostate cancer (mCRPC) are being evaluated for the efficacy and safety of up to six cycles of 8 GBq of ^{67}Cu-SAR-bisPSMA. Recruitment remains ongoing for additional participants in the Cohort Expansion to be treated with the combination of 8 GBq ^{67}Cu-SAR-bisPSMA with enzalutamide (an androgen receptor pathway inhibitor [ARPI]).

In August, a preliminary assessment of the safety and efficacy of the 8 GBq ^{67}Cu-SAR-bisPSMA dose level (up to 6 doses allowed) was performed in all trial participants who received 8 GBq treatment cycles by the data cut-off of 20 July 2026, comprising of 16 participants from the ongoing Cohort Expansion phase and 3 participants from cohort 2 of the Dose Escalation phase (19 participants in total). PSA declines were substantial with 74% of evaluable participants at data cut-off achieving PSA25 (i.e. reductions of ≥25% in PSA), 63% PSA50, 53% PSA75 and 26% PSA90 (median number of cycles administered: 2). A total of 81% (n=13) of the evaluable participants for radiographic assessment at data cut-off (n=16) achieved disease control (50% [n=8] stable disease and 31% [n=5] complete response/undetectable disease). The majority of adverse events (AEs) were mild or moderate (Grade 1/2) and transient.

Two new participants that were evaluable at data cut-off in the Cohort Expansion phase of the SECuRE trial achieved undetectable disease/complete response as assessed by Response Evaluation Criteria in Solid Tumors 1.1 (RECIST, included in the above complete response count). This brings the total number of participants who have achieved a complete response (assessed by RECIST) or undetectable disease (assessed by bone scan and/or PSA) across the ^{67}Cu-SAR-bisPSMA program to seven, five of whom were from the 8GBq dose cohorts, based on the most recent clinical assessments.

HIGHLIGHTS OF THE QUARTER

During and since the quarter ending 30 September 2026

EANM Annual Congress 2026

Data on ^{64}Cu-SAR-bisPSMA and ^{67}Cu-SAR-bisPSMA were presented at the prestigious European Association of Nuclear Medicine (EANM) Annual Congress 2026, held on October 17-21 in Vienna, Austria. These included:

- Top-Rated Oral Presentation of data from the Co-PSMA investigator-initiated trial (IIT) with ^{64}Cu-SAR-bisPSMA, led by Prof Louise Emmett from St Vincent's Hospital, Sydney.
- Three-patient case report on detection of prostate cancer recurrence using ^{64}Cu-SAR-bisPSMA following negative SOC PSMA PET scan on Siemens Biograph Vision Quadra.
- Case reports from the theranostic Phase I/IIa SECuRE trial on two participants with mCRPC who achieved undetectable disease following ^{67}Cu-SAR-bisPSMA treatment as reported this year.

Team

Clarity continues to grow its dedicated and knowledgeable team as the Company prepares for commercialisation of its products, attracting and retaining some of the best talent in the industry who possess a unique range of skills, as well as extensive experience in the global radiopharmaceutical market. During the reporting period, Michelle Hickey joined the Senior Executive Team as Senior Vice President, Targeted Copper Theranostic (TCT) Commercial Operations. Ms Hickey is a seasoned technical operations executive, bringing three decades of diverse biopharmaceutical experience to Clarity.

Board

In July 2026, Allison Rossiter joined the Board as an Independent Non-Executive Director. Ms Rossiter is an experienced healthcare executive with 25 years of global leadership across diagnostics, pharmaceuticals and medical technology.



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 September 2026.



Executive Chairperson's Letter

Dear fellow Shareholders,

I am pleased to share the progress accomplished by Clarity during and since the quarter ending 30 September 2026. This quarter we continued to achieve important milestones, bringing us closer to launch for our diagnostic SAR-bisPSMA product. We have two registrational Phase III trials with ^{64}Cu-SAR-bisPSMA, CLARIFY and AMPLIFY, which successfully completed recruitment and are in the process of patient follow-up, in line with the trials' protocols. Our development of ^{64}Cu-SAR-bisPSMA through these trials aims to address a high unmet need in patient care for the accurate initial staging of prostate cancer and detection of recurrent disease (CLARIFY and AMPLIFY trials, respectively). While currently approved prostate-specific membrane antigen (PSMA) positron emission tomography (PET) agents are an important imaging tool for the detection and staging of prostate cancer, these agents have reported sensitivities of 27%-40%, according to their respective Phase III pivotal studies, based on the detection of pelvic lymph node metastases prior to prostatectomy (verified by histopathology)[1-6]. Importantly, none of these agents achieved the prespecified primary endpoint thresholds for sensitivity in their respective pivotal trials[1-6]. This means that the currently approved PSMA PET agents did not detect prostate cancer in the pelvic lymph nodes in more than half of the study participants in whom such metastases were confirmed by histopathology.

We believe ^{64}Cu-SAR-bisPSMA is well positioned to address this limitation, become a best-in-class next-generation diagnostic, dominate and further expand the blockbuster PSMA PET market. Clinical trials to date and real-world case profiles have demonstrated improved diagnostic performance of ^{64}Cu-SAR-bisPSMA with more prostate cancer lesions detected and increased product uptake compared to standard-of-care (SOC) PSMA PET agents[7-10]. The most recently published Phase II head-to-head Co-PSMA trial in 50 patients with biochemical recurrence (BCR) following prostatectomy and prostate-specific antigen (PSA) levels of 0.2-0.75 ng/mL showed that ^{64}Cu-SAR-bisPSMA next-day (24-hour) imaging outperformed ^{68}Ga-PSMA-11 PET in the number of patients with a positive scan (78% vs. 36%), true-positive rate (71% vs. 29%, among 34 evaluable participants with a reference standard), overall number of lesions (2.6x as many lesions per participant), number of anatomical regions with tracer uptake and, importantly, informed changes in planned management in 44% of participants, with active treatment planned for 90% following ^{64}Cu-SAR-bisPSMA imaging versus 66% following ^{68}Ga-PSMA-11 imaging[8]. These results were not only published in European Urology journal with an impressive impact factor of 29.1, but were also recently showcased at the prestigious European Association of Nuclear Medicine (EANM) Congress held in Vienna as a Top-Rated Oral Presentation, highlighting the significance of these findings for the fields of urology and nuclear medicine. These data corroborate previously reported improved diagnostic performance of ^{64}Cu-SAR-bisPSMA vs. SOC PSMA PET in both the PROPELLER[7] and COBRA[9] trials.

Further to the growing body of data generated in clinical trials, we continue receiving requests for compassionate access to ^{64}Cu-SAR-bisPSMA. Ten patients with BCR of prostate cancer and negative/equivocal SOC PSMA PET (^{68}Ga-PSMA-11 and/or ^{18}F-DCFPyL) have received ^{64}Cu-SAR-bisPSMA via Special Access Scheme (SAS) in Australia and Expanded Access Program (EAP) in the United States (US), and 80% (8) of them had lesions detected on next-day imaging (total of 19 lesions), further leading to management change in all of these patients with a positive scan (data cut-off 3 August 2026). Importantly, ^{64}Cu-SAR-bisPSMA next-day imaging detected disease in all five patients whose previous standard-of-care scans on the Siemens Biograph Vision Quadra, one of the most advanced whole body PET systems currently available, were negative.

Treatment plans were changed in all patients who had a positive ^{64}Cu-SAR-bisPSMA PET. Three of these cases were also presented at the EANM Annual Congress.

We look forward to the upcoming data readouts from both AMLIFY and CLARIFY trials in the first half of calendar year 2027. With strong data generated to date, supporting the development of ^{64}Cu-SAR-bisPSMA, we are already actively preparing for US Food and Drug Administration (FDA) New Drug Application (NDA) approval and subsequent launch of ^{64}Cu-SAR-bisPSMA in both the pre-definitive therapy and recurrence settings.

Our theranostic SECuRE trial has also reached important milestones during and since the reporting period. The Main Group in the Phase II Cohort Expansion achieved its recruitment target, enrolling sixteen participants with metastatic castration-resistant prostate cancer (mCRPC). Recruitment is still ongoing for additional participants in the Cohort Expansion to be treated with the combination of 8 GBq ^{67}Cu-SAR-bisPSMA with enzalutamide (an androgen receptor pathway inhibitor [ARPI]). We have observed strong efficacy with a favourable safety profile of ^{67}Cu-SAR-bisPSMA across all cohorts in the SECuRE trial to date (data cut-off 20 July 2026). Among patients who received 8 GBq ^{67}Cu-SAR-bisPSMA cycles, 63% had PSA reductions of ≥50% (PSA50), with over a quarter of patients reaching PSA90. Furthermore, almost a third of all evaluable patients treated at the 8 GBq dose level had achieved undetectable levels of disease and/or complete response across the ^{67}Cu-SAR-bisPSMA program at the date of the last assessment. Importantly, ^{67}Cu-SAR-bisPSMA at the 8 GBq dose level shows a favourable safety profile, with adverse events (AEs) being mostly mild to moderate and transient. This highlights the potential of this therapy in earlier stages of disease, aiming to help improve treatment outcomes of a broader prostate cancer patient population.

We look forward to providing a further update on the SECuRE trial shortly as our team and collaborators continue to generate a compelling body of high-quality data, advancing SAR-bisPSMA towards commercialisation. We believe this unique optimised molecule could improve the outcomes for prostate cancer patients across multiple stages of disease, from accurate lesion detection in the pre-prostatectomy and BCR settings through to treatment in mCRPC.

On our journey from the benchtop to launch in this blockbuster market, we continue to remain committed to building a dedicated, knowledgeable and diverse team, expanding our talent pool with world-class expertise in line with our preparation for commercialisation and ongoing clinical development. During the reporting period, we welcomed Michelle Hickey to our Senior Executive Team. Ms Hickey joined Clarity as Senior Vice President (SVP), Targeted Copper Theranostic (TCT) Commercial Operations and has three decades of diverse biopharmaceutical expertise. Her career spans work in multiple therapeutic areas including radiopharmaceuticals, small molecules, and biologics. Prior to Clarity, Michelle held senior leadership roles at Telix Pharmaceuticals and Clovis Oncology, where she was instrumental in the commercialisation of Rubraca®, Illuccix® and Gozellix®.

At the Board level, we welcomed Ms Allison Rossiter in July as an Independent Non-Executive Director. This has resulted in the total number of Clarity Directors remaining at six, with two Executive Directors and four Non-Executive Directors, with an independent Director majority. We are very pleased to welcome Ali, an experienced healthcare executive with 25 years of global leadership across diagnostics, pharmaceuticals and medical technology on three different continents. Her extensive knowledge of the commercial diagnostic space in particular will be invaluable to Clarity during this exciting phase of commercialisation of two of our diagnostic products into the oncology market.

We remain well funded with $152.9 million in cash as at 30 September 2026 to support our growth towards the commercial rollout of our products. We again thank our shareholders for their support and look forward to providing further updates on the continued progress of our therapeutic and diagnostic programs.

Yours sincerely,

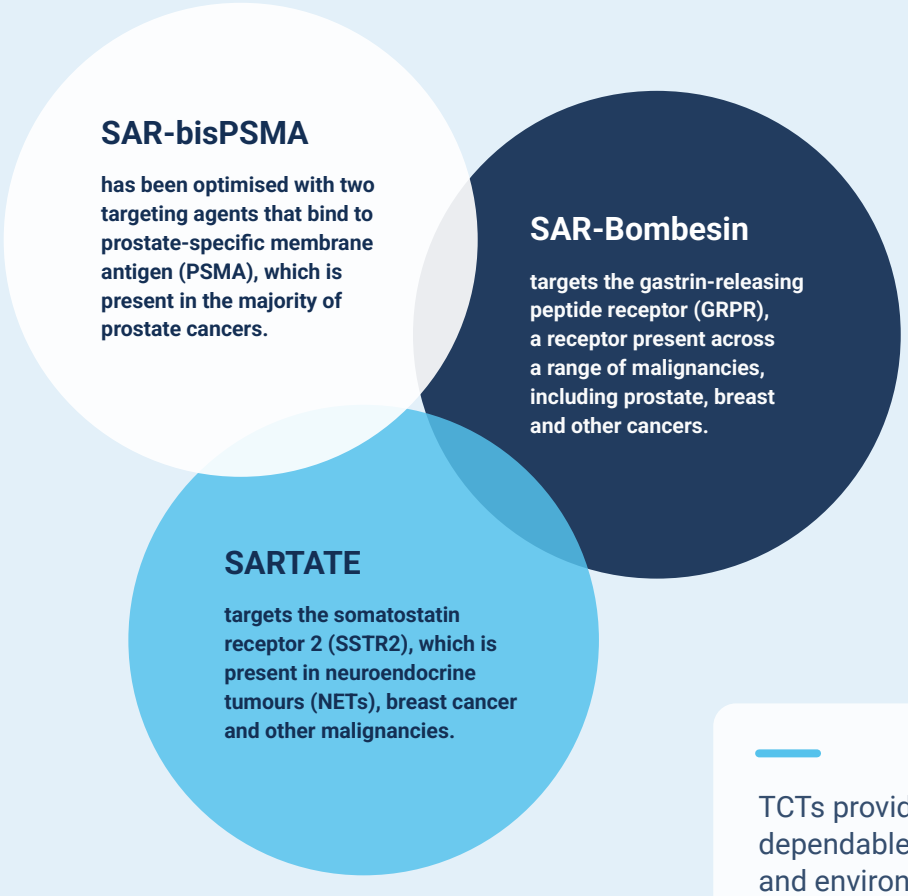
Dr Alan Taylor
Executive Chairperson, Clarity Pharmaceuticals

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 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 and targets, 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 three clinical trials: two registrational Phase III diagnostic trials, AMPLIFY and CLARIFY, both recently completing recruitment, and one theranostic trial, SECuRE, which closed recruitment of its main group during the quarter.

Data from the investigator-initiated trial (IIT, Co-PSMA) at St Vincent's Hospital Sydney led by Prof Louise Emmett with ^{64}Cu-SAR-bisPSMA was presented at the European Association of Urology (EAU) Congress 2026 in March, Europe's biggest urological conference, and published in European Urology, the official journal of EAU with an impressive impact factor of 29.1. The data was also selected as a Top-Rated Oral Presentation at the European Association of Nuclear Medicine (EANM) Annual Congress 2026, held on 17-21 October in Vienna, Austria.

Clarity will also be commencing a registrational Phase III trial with ^{64}Cu-SARTATE in NETs, following a successful End of Phase meeting with the United States (US) Food and Drug Administration (FDA).

	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)[11]. Cohort Expansion (Main Group) recruitment target achieved. Recruitment remains ongoing for additional participants in the Cohort Expansion to be treated with the combination of 8GBq ^{67}Cu-SAR-bisPSMA with enzalutamide.	**AMPLIFY** – registrational Phase III positron emission tomography (PET) imaging trial of participants with biochemical recurrence (BCR) of prostate cancer following definitive therapy using ^{64}Cu-SAR-bisPSMA in the US and Australia (NCT06970847)[12]. Recruitment completed. **CLARIFY** – registrational Phase III PET imaging trial of participants with high-risk prostate cancer prior to radical prostatectomy using ^{64}Cu-SAR-bisPSMA in the US and Australia (NCT06056830)[13]. Recruitment target achieved. **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)[14]. Full data published.
SARTATE		**DISCO** – Phase II PET imaging trial of participants with known or suspected NETs using ^{64}Cu-SARTATE in Australia (NCT04438304)[15]. Topline data announced. **Registrational ^{64}Cu-SARTATE trial in NETs** – multi-centre, single arm, non-randomised, open-label Phase III diagnostic clinical trial of ^{64}Cu-SARTATE PET in approximately 70 participants. In planning.

CLINICAL & REGULATORY DEVELOPMENT OVERVIEW

WORLD-LEADING CONFERENCES

Clarity continues to present important data on its pipeline of products in development

Clarity is generating positive data in clinical and pre-clinical studies with its pipeline of products in development. Given the high quality of scientific rigour applied in these trials and importance of the findings, the Company and its collaborators continue to present the data in world-leading congresses.

Data on ^{64}Cu-SAR-bisPSMA and ^{67}Cu-SAR-bisPSMA were presented at the EANM Annual Congress 2026 on 17-21 October in Vienna, Austria. These included:

- Top-Rated Oral Presentation of data from the Co-PSMA IIT with ^{64}Cu-SAR-bisPSMA, led by Prof Louise Emmett from St Vincent's Hospital, Sydney.
- Three-patient case report on detection of prostate cancer recurrence using ^{64}Cu-SAR-bisPSMA following negative standard-of-care (SOC) PSMA PET scan on Siemens Biograph Vision Quadra.
- Case reports from the theranostic Phase I/IIa SECuRE trial[11] on two participants with mCRPC who achieved undetectable disease following ^{67}Cu-SAR-bisPSMA treatment as reported this year.

Data from the Phase II COBRA trial with ^{64}Cu-SAR-bisPSMA in prostate cancer patients with BCR was presented at the Theranostics and Imaging Centre of Excellence (ProsTIC) Preceptorship (3-5 September, Melbourne, Australia).

Data from Clarity's preclinical program with $^{64/67}$Cu-SAR-bisFAP, a pan-cancer theranostic, was presented at the Gordon Research Symposium (GRS) Radionuclide Theranostics for the Management of Cancer in Newry, Maine, by Dr. Michele De Franco, a research fellow at the Memorial Sloan Kettering Cancer Center (MSKCC) and Clarity's collaborator.

FAST TRACK DESIGNATION

Clarity has three US FDA Fast Track Designations (FTDs) 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.

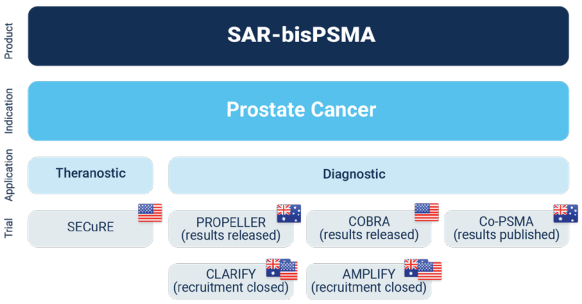
These three FTDs demonstrate the quality of the data generated to date on the ^{64}Cu-SAR-bisPSMA and ^{67}Cu-SAR-bisPSMA products and their potential to address serious unmet needs in prostate cancer. The FTDs will enable Clarity to accelerate the development of its comprehensive program with the optimised 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 considerably advance the diagnostic and treatment landscapes of the large prostate cancer market.

PRODUCT UPDATES

SAR-bisPSMA: PROSTATE CANCER

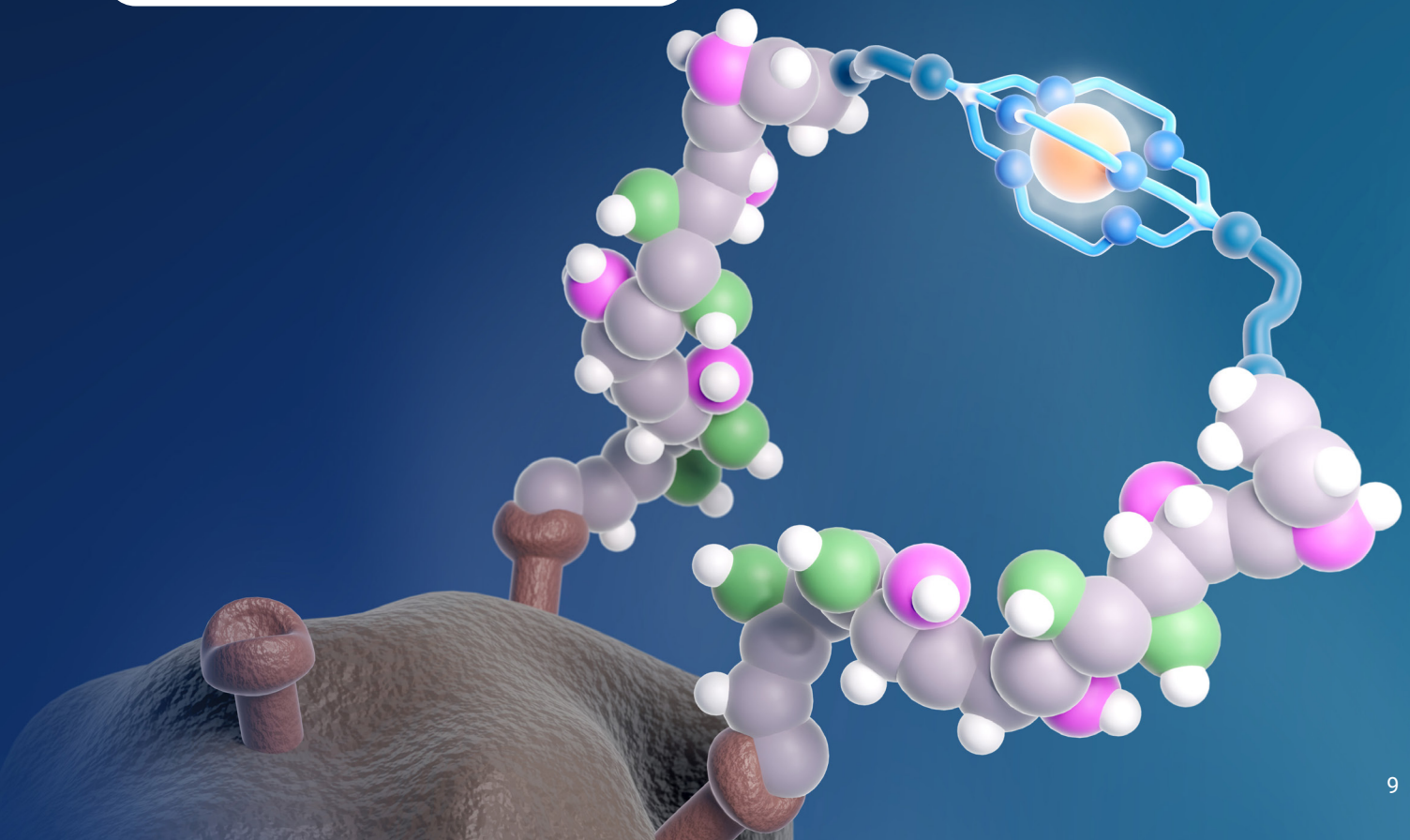
SAR-bisPSMA is a next-generation, theranostic radiopharmaceutical with optimised dual PSMA-targeting agent aimed at improving uptake and retention of the product in tumours



SAR-bisPSMA is being developed for detecting, staging and subsequently treating prostate cancer that expresses prostate-specific membrane antigen (PSMA). The product uses 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.



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

The registrational Phase III CLARIFY trial (NCT06056830)[13] dosed the planned target of 383 participants in the study

CLARIFY (Positron Emission Tomography Using ^{64}Cu-SAR-bisPSMA in Participants With High-risk Prostate Cancer Prior to Radical Prostatectomy: A Prospective, Single-arm, Multi-center, Blinded-review, Phase 3 Diagnostic Performance Study) is the first Phase III registrational trial for Clarity, being conducted in the United States (US) and Australia. It is a non-randomised, open-label study of ^{64}Cu-SAR-bisPSMA in participants with untreated, histopathology-confirmed prostate cancer with high-risk features who are proceeding to radical prostatectomy (removal of the prostate) with pelvic lymph node dissection (removal of lymph nodes from the pelvic region).

The primary endpoints of the study are the sensitivity and specificity of ^{64}Cu-SAR-bisPSMA to detect prostate cancer within the pelvic lymph nodes compared to the standard of truth (histopathology), assessed independently for Day 1 (1-4 hours post-administration, same-day imaging) and Day 2 (approximately 24 hours post-administration, next-day imaging). CLARIFY builds on the findings from the Phase I PROPELLER study (first-in-human multi-centre trial involving 30 participants). The study demonstrated improved diagnostic performance of same-day ^{64}Cu-SAR-bisPSMA positron emission tomography (PET) compared to ^{68}Ga-PSMA-11 PET in the pre-prostatectomy setting, including approximately 30% greater lesion detection, 2-3 times higher tracer uptake and contrast as well as higher proportion of participants with more lesions identified by ^{64}Cu-SAR-bisPSMA vs. ^{68}Ga-PSMA-11 (73% vs. 27%, respectively; average across readers for participants with discordant lesion findings; **Figures 1 and 2**)[7]. The improved diagnostic performance of next-day vs. same-day ^{64}Cu-SAR-bisPSMA PET observed in the COBRA and Co-PSMA trials in BCR supports the hypothesis that next-day imaging may also offer incremental benefits in the pre-prostatectomy setting, to be assessed in the CLARIFY study.

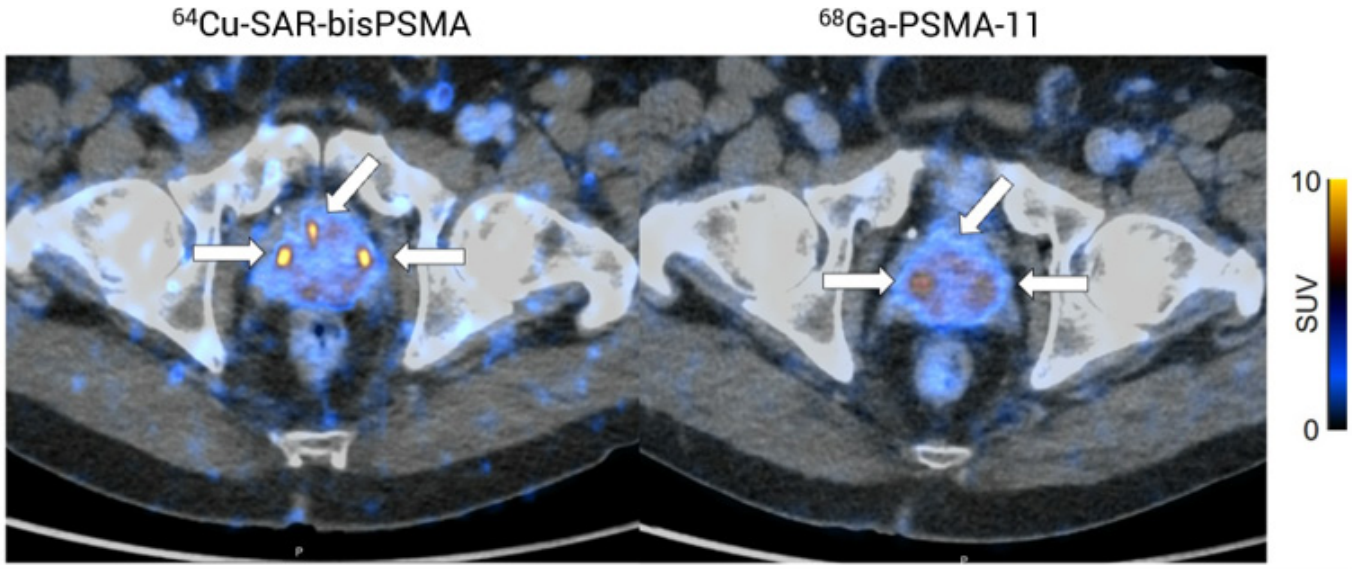


Figure 1. Intra-individual concordant lesion comparison of PSMA PET/computed tomography (CT) between ^{64}Cu-SAR-bisPSMA (left image) and ^{68}Ga-PSMA-11 (right image). The same participant is shown with concordant intraprostatic lesions indicated by white arrows, illustrating greater lesion conspicuity and tracer uptake with ^{64}Cu-SAR-bisPSMA.

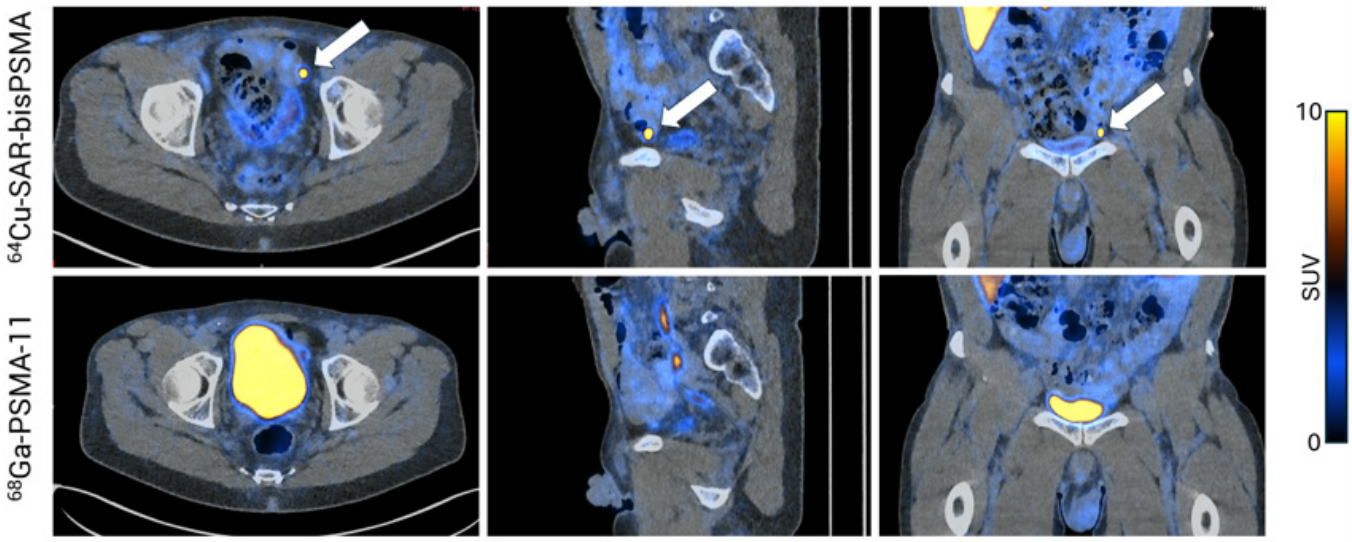


Figure 2. ^{64}Cu-SAR-bisPSMA and ^{68}Ga-PSMA-11 PET/CT images of a participant demonstrating difference in pelvic lymph node detection. One pelvic lymph node in the left pelvic region was detected by both readers on ^{64}Cu-SAR-bisPSMA scan (arrow; top images) but not on the ^{68}Ga-PSMA-11 scan (bottom images). Pelvic lymph node involvement by prostate cancer was confirmed via histopathology in this participant.

The CLARIFY trial is the first to determine the sensitivity and specificity of the SAR-bisPSMA product, based on the appropriate assessment of true positive, true negative, false positive and false negative lesions that can only be accurately determined using histopathology specimens (in this case, pelvic lymph nodes that are surgically removed during prostatectomy).

Topline data from the CLARIFY trial are anticipated to be released in the first half of calendar year 2027, along with topline results from the AMPLIFY trial, which is investigating ^{64}Cu-SAR-bisPSMA in patients with BCR of prostate cancer[12]. As a pivotal trial, the final CLARIFY 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 patients prior to undergoing definitive therapy.



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

The AMPLIFY (NCT06970847)[12] trial is currently in the process of patient follow-up, in line with the trial protocol, following the successful completion of recruitment in March 2026 with 232 patients dosed and imaged after strong demand for study participation at sites in the US and Australia. The final participant assessment is anticipated in the coming weeks.

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 PET in participants with rising or detectable prostate-specific antigen (PSA) after initial definitive treatment at clinical sites across the US and Australia.

The aim of the AMPLIFY trial is to investigate the ability of ^{64}Cu-SAR-bisPSMA PET/CT to detect recurrence of prostate cancer. Evaluation will be across two imaging timepoints, Day 1 (day of administration, same-day imaging) and Day 2 (approximately 24 hours post administration, next-day imaging). The co-primary endpoints are participant-level correct detection rate and region-level positive predictive value, assessed independently for Day 1 and Day 2. AMPLIFY initially commenced in May 2025, seeking to enrol approximately 220 participants, and the first trial participant was imaged in the same month at XCancer with Dr Luke Nordquist (Omaha, NE).

The data from this study will complement the Phase I/II COBRA[9] and Phase II Co-PSMA[8] trials. Both studies have demonstrated enhanced diagnostic performance of ^{64}Cu-SAR-bisPSMA over standard-of-care (SOC) PSMA PET imaging in patients with BCR of prostate cancer.

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 patients with BCR of prostate cancer, alongside results from the CLARIFY trial.

The AMPLIFY trial closed recruitment in March 2026 with 232 patients dosed and imaged following strong demand for study participation at sites in the US and Australia



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

Results from the Co-PSMA (NCT06907641)[14] investigator-initiated trial (IIT), led by Prof Louise Emmett at St Vincent's Hospital Sydney, were showcased as a Top-Rated Oral Presentation at the European Association of Nuclear Medicine (EANM) Annual Congress 2026 on October 17-21 in Vienna, Austria.

Co-PSMA (Comparative performance of ^{64}Copper [^{64}Cu]-SAR-bisPSMA vs. ^{68}Ga-PSMA-11 PET CT for the detection of prostate cancer recurrence in the setting of biochemical failure following radical prostatectomy) was an IIT led by Prof Louise Emmett at St Vincent's Hospital, Sydney, evaluating the performance of Clarity's diagnostic product, ^{64}Cu-SAR-bisPSMA, in a head-to-head comparison to SOC ^{68}Ga-PSMA-11 product in prostate cancer patients with low PSA (0.2 – 0.75 ng/mL).

Eligible patients were required to have had radical prostatectomy with no salvage therapy. ^{68}Ga-PSMA-11 PET/CT was followed by ^{64}Cu-SAR-bisPSMA PET/CT (at 1 hour and 24 hours post-injection, same-day and next-day imaging, respectively), on the same digital PET camera. This head-to-head intra-patient design enables direct comparison of diagnostic performance of each product, while eliminating confounding factors (e.g. disease characteristics, PSA levels and patient selection), which can affect comparisons across separate studies or patient cohorts.

Prospective intra-patient comparisons of diagnostic agents are uncommon in nuclear medicine due to their operational complexity, yet they provide some of the most robust data for comparing the relative performance of imaging agents. As a result, Co-PSMA provides particularly strong evidence that differences in diagnostic performance are due to the imaging agent itself rather than differences in patient populations.

The **primary endpoint** of the Co-PSMA study was to assess the difference in mean per patient lesion number.

Secondary endpoints included management impact questionnaires between ^{64}Cu-SAR-bisPSMA and ^{68}Ga-PSMA-11 and accuracy of the PET findings determined using a comprehensive reference standard, including biopsy, response to targeted treatment without androgen deprivation therapy (ADT), PSA rise without treatment or corroborative imaging.

The study met its primary endpoint and demonstrated improved diagnostic performance across multiple parameters, including 2.63 times more lesions per patient identified by ^{64}Cu-SAR-bisPSMA PET/CT (next-day imaging) vs. ^{68}Ga-PSMA-11 ($p < 0.0001$). ^{64}Cu-SAR-bisPSMA PET/CT next-day imaging also found a higher number of participants with a positive scan and true positive rate. Importantly, ^{64}Cu-SAR-bisPSMA PET/CT led to substantial management impact compared to ^{68}Ga-PSMA-11 in men with BCR post-radical prostatectomy and low PSA.

The manuscript was published and selected as an Editor's Choice article in the European Urology in March 2026[8], the official journal of the European Association of Urology (EAU) Congress, with an impressive impact factor of 29.1.

Participants enrolled had a median PSA of 0.43 (interquartile range [IQR]: 0.31 – 0.63) and 74% had an International Society of Urological Pathologists (ISUP) grade of 3 or higher. The median interval between ^{68}Ga-PSMA-11 and ^{64}Cu-SAR-bisPSMA imaging was only 2 days (IQR: 1 – 8 days), making it unlikely that the differences in lesion detection were due to disease progression.

This result is corroborated by previous findings from the COBRA trial, which demonstrated that ^{64}Cu-SAR-bisPSMA was able to detect prostate cancer lesions that were still undetectable 6 months later with SOC PSMA imaging agents[9].

From an imaging perspective, acquisition times were consistent across ^{68}Ga-PSMA-11 and both same-day and next-day ^{64}Cu-SAR-bisPSMA scans (2 minutes per bed position). The mean per-patient lesion for ^{64}Cu-SAR-bisPSMA (24-hour imaging) was 1.26, compared to 0.48 for ^{68}Ga-PSMA-11, with a difference of 0.78 (95% confidence interval [CI]: 0.52 – 1.04), ratio 2.63 (95% CI: 1.64 – 4.20) (primary endpoint; p< 0.0001). On a per patient level, 36% (18/50) of participants were positive on ^{68}Ga-PSMA-11 PET/CT, compared to 78% (39/50) on ^{64}Cu-SAR-bisPSMA PET/CT (next-day imaging). The patient-level true positive rate also favoured ^{64}Cu-SAR-bisPSMA next-day imaging (71% vs. 29% for ^{68}Ga-PSMA-11). In total, ^{68}Ga-PSMA-11 identified 24 lesions across all participants, while 24-hour ^{64}Cu-SAR-bisPSMA imaging detected 63 lesions (representative image in **Figure 3**). The increase in the number of lesions identified by ^{64}Cu-SAR-bisPSMA was noted in the prostatic bed region (local recurrence), pelvic/extra-pelvic lymph nodes and bone (**Table 1**).

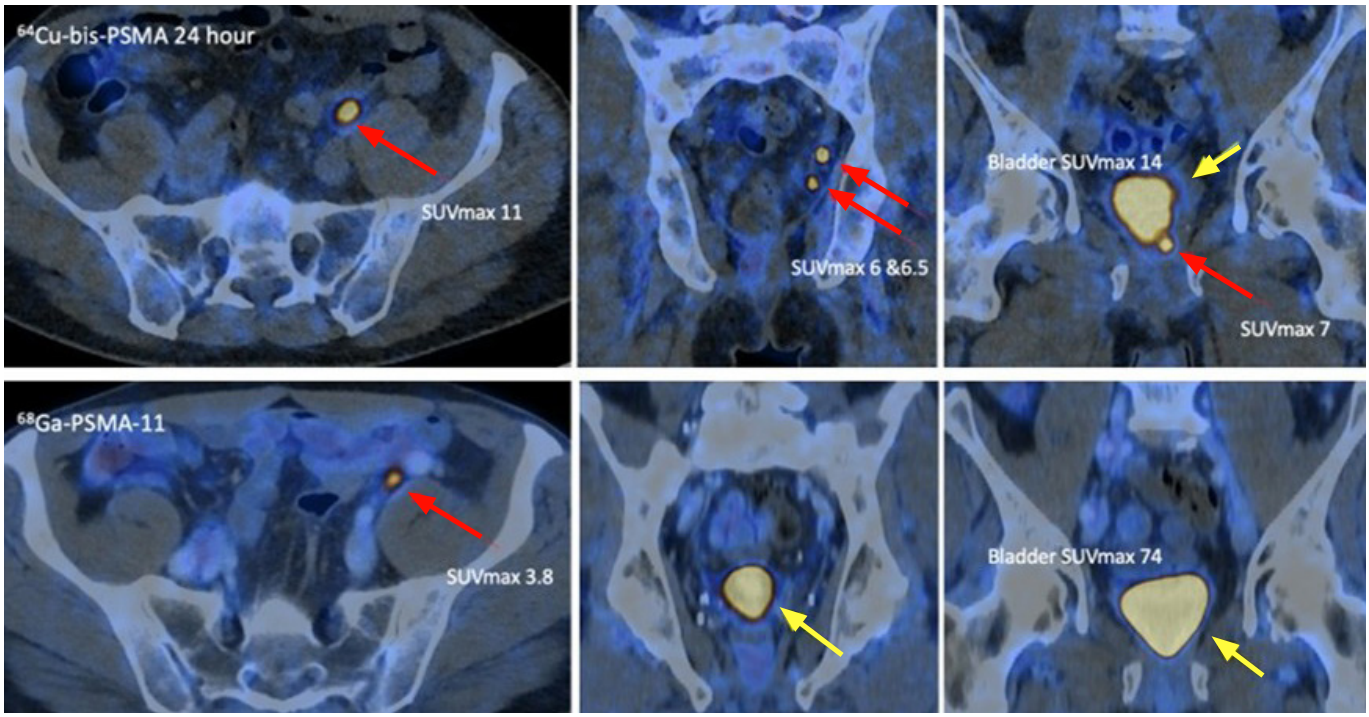


Figure 3. PET/CT of the 24-hour ^{64}Cu-SAR-bisPSMA (top: axial left, coronal centre and right) and ^{68}Ga-PSMA-11 (bottom: axial left, coronal centre and right). The ^{64}Cu-SAR-bisPSMA PET/CT identified multiple sites of recurrence (pelvic lymph nodes and fossa), while a single pelvic lymph node was reported on ^{68}Ga-PSMA-11 PET/CT (red arrows). Bladder depicted by yellow arrows. Adapted and reproduced with permission from Prof Louise Emmett.

Variable	^{68}Ga-PSMA-11	24-hour ^{64}Cu-SAR-bisPSMA
Number of participants with a positive scan, n/N (%)	18/50 (36%)	39/50 (78%)
Total number of lesions identified (across participants), n	24	63
Location of recurrence, n/N (%)		
Local recurrence	11/50 (22%)	28/50 (56%)
Pelvic or extra-pelvic lymph nodes	4/50 (8%)	10/50 (20%)
Bone	5/50 (10%)	8/50 (16%)
Viscera (lung)	1/50 (2%)	1/50 (2%)

Table 1. Comparison between ^{68}Ga-PSMA-11 and ^{64}Cu-SAR-bisPSMA scans.

At 24 hours, ^{64}Cu-SAR-bisPSMA demonstrated higher lesion uptake compared to ^{68}Ga-PSMA-11 (median maximum standardised uptake value [SUVmax] 13.6 vs. 5.3), and lower background bladder activity (median SUVmax 12.0 vs. 34.5), improving tumour-to-background contrast. These imaging attributes, which allow better visualisation of the fossa and thus detection of low volume local recurrence, likely contributed to an almost perfect agreement across the three independent blinded readers for the ^{64}Cu-SAR-bisPSMA scans, whereas the agreement was lower for ^{68}Ga-PSMA-11. This means the readers reached the same conclusions when assessing the ^{64}Cu-SAR-bisPSMA scans far more often than when assessing the ^{68}Ga-PSMA-11 scans in a blinded fashion (almost perfect level of agreement for ^{64}Cu-SAR-bisPSMA, Cohen's Kappa 0.94 vs. 0.75 for ^{68}Ga-PSMA-11).

Importantly, these imaging findings translated into clinically meaningful changes in patient care, with a marked difference between ^{64}Cu-SAR-bisPSMA and ^{68}Ga-PSMA-11 (planned management changes observed in 44% of patients following ^{64}Cu-SAR-bisPSMA imaging). The two most common modifications in treatment plan were changes from observation to active treatment (12/22), and changes in the radiation field (9/22). Active planned management increased from 66% based on ^{68}Ga-PSMA-11 results to 90% based on ^{64}Cu-SAR-bisPSMA findings. This highlights the impact of ^{64}Cu-SAR-bisPSMA on the management of patients with BCR and low PSA levels, a population in whom SOC PSMA PET scans frequently fail to visualise prostate cancer lesions.

These results from the Co-PSMA IIT further build on the growing body of evidence demonstrating that ^{64}Cu-SAR-bisPSMA improves the detection of prostate cancer compared to the current SOC PSMA PET agents, which have low detection rate in patients with low PSA levels[16-17]. In the Phase II COBRA trial, ^{64}Cu-SAR-bisPSMA was evaluated in patients with BCR who had a negative or equivocal scan at study entry. Among participants with a follow-up SOC PSMA PET, 90% were positive on 24-hour ^{64}Cu-SAR-bisPSMA PET compared with only 60% on SOC PSMA PET. Overall, next-day imaging with ^{64}Cu-SAR-bisPSMA identified more than 2.6 times lesions than SOC PSMA PET[9]. The COBRA data, combined with the Co-PSMA IIT results, will complement the anticipated findings from the Phase III registrational trial, AMPLIFY, which is expected to finalise patient follow-up shortly, following its recruitment completion in March 2026[18]. Together, these trials are intended to be submitted to the US FDA for a market authorisation of ^{64}Cu-SAR-bisPSMA in patients with BCR of prostate cancer.

The authors of the Co-PSMA publication wrote, "This is the first time that a PSMA-targeted imaging agent has demonstrated significantly improved imaging characteristics compared to those currently available, potentially marking an important step forward in imaging technology akin to that seen in the evolution from ^{18}F-Choline/Fluciclovine to PSMA-targeted PET/CT".



Real-world case profiles: detection of prostate cancer recurrence

An unmet need persists for improved PSMA imaging, despite availability of SOC PSMA PET agents. ^{64}Cu-SAR-bisPSMA is on track to close the diagnostic gap in BCR of prostate cancer for lesion detection following negative SOC PSMA PET. This next-generation diagnostic identified lesions in 8 out of 10 patients whose SOC PSMA PET was negative or equivocal in real-world case profiles.

Real-world evidence further supports the clinical utility of ^{64}Cu-SAR-bisPSMA in patients with BCR of prostate cancer. Ten patients with BCR of prostate cancer and negative/equivocal SOC PSMA PET (i.e. ^{68}Ga-PSMA-11 and/or ^{18}F-DCFPyL) accessed ^{64}Cu-SAR-bisPSMA through compassionate use programs, such as Special Access Scheme (SAS) and Expanded Access Program (EAP) (data cut-off 3 August 2026). The most recent PSA range of these patients prior to ^{64}Cu-SAR-bisPSMA administration was 0.10 – 13.3 ng/mL. All patients received ~200 MBq of ^{64}Cu-SAR-bisPSMA and underwent PET imaging next day post-injection with some patients also undergoing PET imaging the same day of injection, followed by monitoring of adverse events (AEs).

Lesions were detected in 8 (80%) patients, despite prior negative or equivocal scans using SOC PSMA PET agents, and a total of 19 lesions were identified on next-day imaging. The two patients with negative ^{64}Cu-SAR-bisPSMA scans had PSA levels below <0.2 ng/mL. The safety profile of ^{64}Cu-SAR-bisPSMA remains favourable with only one transient Grade 1 (mild) fatigue event observed in one patient.

These positive findings resulted in a change in clinical management for all patients in whom ^{64}Cu-SAR-bisPSMA detected prostate cancer recurrence, including initiation of targeted radiotherapy in four cases.

Additional real-world data demonstrated that ^{64}Cu-SAR-bisPSMA can identify disease that remains undetected even on advanced PET imaging platforms. In all five patients who had a negative/equivocal SOC PSMA PET on the Biograph Vision Quadra, ^{64}Cu-SAR-bisPSMA subsequently identified lesions.

Five patients with BCR of prostate cancer (PSA 0.3 – 13.3 ng/mL) who had a previously negative SOC PSMA PET/CT on the Siemens Biograph Vision Quadra system, were dosed and imaged with ^{64}Cu-SAR-bisPSMA PET/CT via compassionate use at 1-4 hours (same-day imaging) and 24-30 hours (next-day imaging) post-injection.

^{64}Cu-SAR-bisPSMA imaging was positive in all five patients. Next-day imaging enhanced lesion detection with twice as many lesions identified on next-day imaging compared with same-day imaging (12 vs. 6 lesions). It also led to increased product uptake: for the 6 lesions identified on both same-day and next-day imaging, mean SUVmax was 4.0 ± 1.6 and 7.6 ± 3.3, respectively.



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

The Main Group of the Phase II Cohort Expansion of the SECuRE trial (NCT04868604)[11] achieved its recruitment target. The enrolled sixteen participants with mCRPC are being evaluated for the efficacy and safety of up to six cycles of 8 GBq of ^{67}Cu-SAR-bisPSMA. Recruitment remains ongoing for additional participants in the Cohort Expansion to be treated with the combination of 8 GBq ^{67}Cu-SAR-bisPSMA with enzalutamide (an androgen receptor pathway inhibitor [ARPI]).

About the SECuRE Trial

SECuRE is a Phase I/IIa theranostic trial for identification and treatment of participants with PSMA-expressing mCRPC using ^{64}Cu/^{67}Cu-SAR-bisPSMA. ^{64}Cu-SAR-bisPSMA is used to visualise PSMA-expressing lesions and select candidates for subsequent ^{67}Cu-SAR-bisPSMA therapy. The trial is a multi-centre, single arm study. The overall aim of the trial is to determine the safety and efficacy of ^{67}Cu-SAR-bisPSMA for the treatment of prostate cancer.

The SECuRE trial consists of the Dose Escalation (Phase I) and Cohort Expansion (Phase II) Phases (**Figure 4**). Based on the data from the Dose Escalation Phase, which demonstrated a favourable safety profile and efficacy of ^{67}Cu-SAR-bisPSMA, the SECuRE trial progressed to the Cohort Expansion at an 8 GBq dose level as per the Safety Review Committee (SRC) recommendation in January 2026 (up to 6 cycles per patient in total)[19].

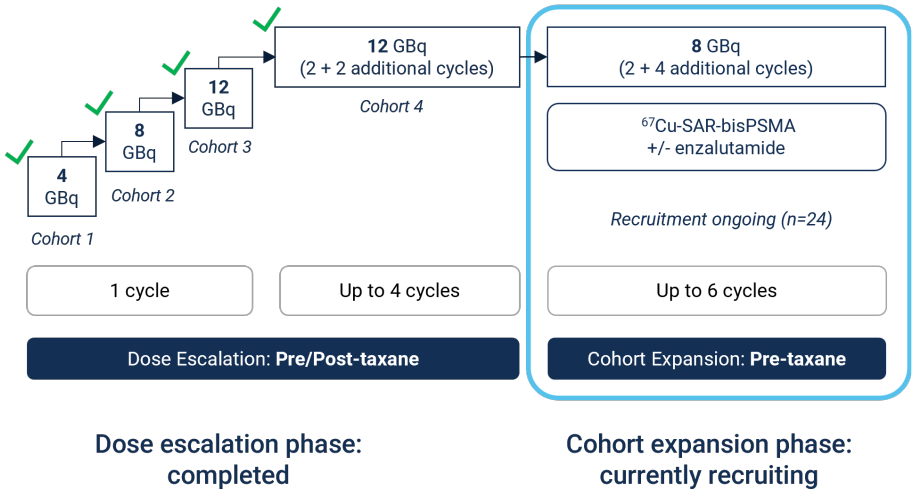


Figure 4. SECuRE Trial Design.



Preliminary assessment of the 8 GBq ^{67}Cu-SAR-bisPSMA dose cohorts

Patient population

The latest preliminary efficacy and safety assessment of the 8 GBq ^{67}Cu-SAR-bisPSMA dose level (up to 6 doses) was conducted in all trial participants who received 8 GBq treatment cycles by the data cut-off of 20 July 2026, comprising 16 participants from the ongoing Cohort Expansion phase and 3 participants from cohort 2 of the Dose Escalation phase (19 participants in total).

Most participants had bone metastases (63%) and had received multiple lines of therapy prior to being enrolled in the trial (79% received 5 or more previous anti-cancer regimens). Previous standard treatments included ADT, radiation, first- and/or second-generation ARPI, with some participants having received taxane-based therapy for metastatic hormone-sensitive disease. Some participants were exposed to an experimental PSMA T-Cell Engager prior to their enrolment into the SECuRE study.

The median number of treatment cycles of ^{67}Cu-SAR-bisPSMA across participants was two (range: 1-4, mean 2.1±1.0 [standard deviation, SD]). Three of these participants from the Cohort Expansion phase were treated with concomitant enzalutamide.

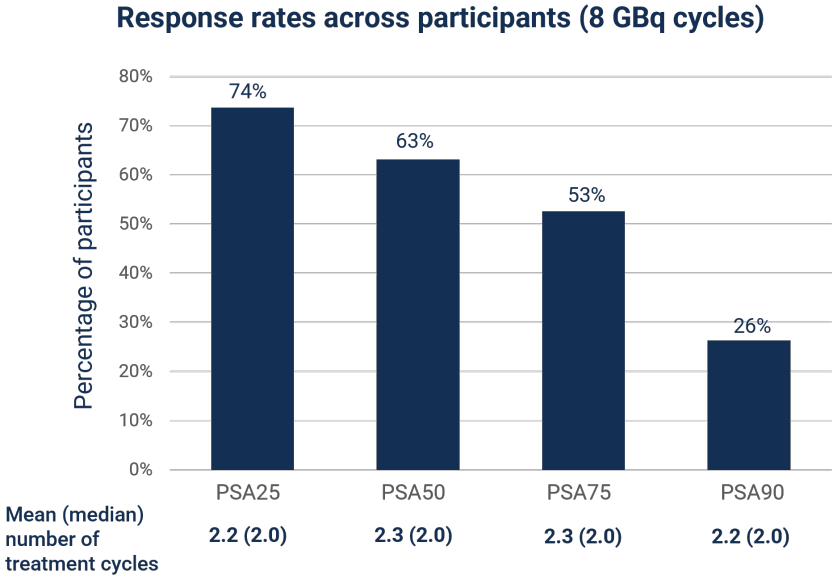
PSA and radiographic assessments

A substantial reduction in PSA was observed, with 74% (n=14) of participants achieving a PSA25 response (i.e. reductions of ≥25% in PSA), 63% (n=12) PSA50, 53% (n=10) PSA75, and 26% (n=5) PSA90 (**Figure 5**).

A total of 81% (n=13) of the participants who were evaluable for radiographic assessment (n=16) achieved disease control. This includes 50% (n=8) with stable disease and 31% (n=5) with complete response/undetectable disease (as assessed by Response Evaluation Criteria in Solid Tumors 1.1 [RECIST] and/or bone scan). Responses continue to mature in participants remaining on treatment.

Safety profile

Participants who received 8 GBq cycles, including those in the Cohort Expansion Phase, generally developed a lower prevalence and severity of related AEs compared to the overall trial population. The most frequently reported related AEs were dry mouth and nausea, each occurring in 9 (47%) and 8 (42%) participants, respectively. Anaemia and decreased neutrophil count were each reported in 4 (21%) participants, while fatigue was reported in 5 (26%) participants. Most events were low grade (mild/moderate) and transient, with two Grade 3 events (lymphocyte and white blood cell count decreases) occurring in 1 (5%) participant. No Grade ≥4 related events were reported.



The data from SECuRE continue to confirm the favourable safety profile and promising efficacy seen in previous cohorts and support the continuation of the trial with the aim to progress to a registrational Phase III trial

Figure 5. PSA responses of participants from cohort 2 (N=3) and Cohort Expansion (N=16) who received 1-4 doses of 8 GBq of ^{67}Cu-SAR-bisPSMA as of 20 July 2026.

Complete response/undetectable disease observed in seven participants in the ^{67}Cu-SAR-bisPSMA program

Two recent participants in the Cohort Expansion phase of the SECuRE trial who were evaluable at data cut-off (20 July 2026) achieved complete response as assessed by RECIST. Combined with the five similar and previously reported cases[20-22], this brings the total number of participants who achieved complete response or undetectable disease (assessed by RECIST, bone scan and/or PSA) across the ^{67}Cu-SAR-bisPSMA program to seven. Five out of these seven participants received treatment at the 8 GBq ^{67}Cu-SAR-bisPSMA dose level. This represents almost a third (31%) of all participants evaluable for radiographic assessment treated at the 8 GBq ^{67}Cu-SAR-bisPSMA dose level.

The median baseline PSA among these seven participants was 90.3 ng/mL (range 3.3 – 490.3). They had received a median of 5 prior anti-cancer regimens (range 4-7). Bone metastases were present in four of seven participants (57%). Among the participants who had received 8 GBq doses, the median number of cycles was 3 (range 1-4, mean 2.8±0.8 standard deviation [SD]). All seven participants had received prior second-generation ARPI.

Case Study 1

One SECuRE trial participant to achieve undetectable PSA and negative PSMA PET in the Cohort Expansion Phase was a 76-year-old man who was initially diagnosed with prostate cancer 15 years ago. He had radical prostatectomy to treat the primary disease and radiotherapy for local recurrence, having progressed to metastatic disease in 2020. Previous systemic anti-cancer treatments included an ARPI and ADT. In 2025, the disease progressed further with nodal metastases, and he was enrolled into the Cohort Expansion Phase of the SECuRE study with a baseline PSA of 3.25 ng/mL. He received two cycles of ^{67}Cu-SAR-bisPSMA across 2 months, with concomitant enzalutamide. His PSA declined by 94.2% to 0.19 ng/mL within 4 weeks of first cycle and was undetectable at 8 weeks, remaining undetectable at 28 weeks (last follow-up in June 2026), with a complete response per RECIST and undetectable disease on ^{64}Cu-SAR-bisPSMA PET/CT after two cycles of treatment (**Figure 6**). He experienced mostly mild and transient ^{67}Cu-SAR-bisPSMA-related AEs, with Grade 1 altered taste, dry eyes, eye pain, fatigue, salivary gland soreness (all resolved) as well as Grade 2 anaemia (ongoing at the last assessment).

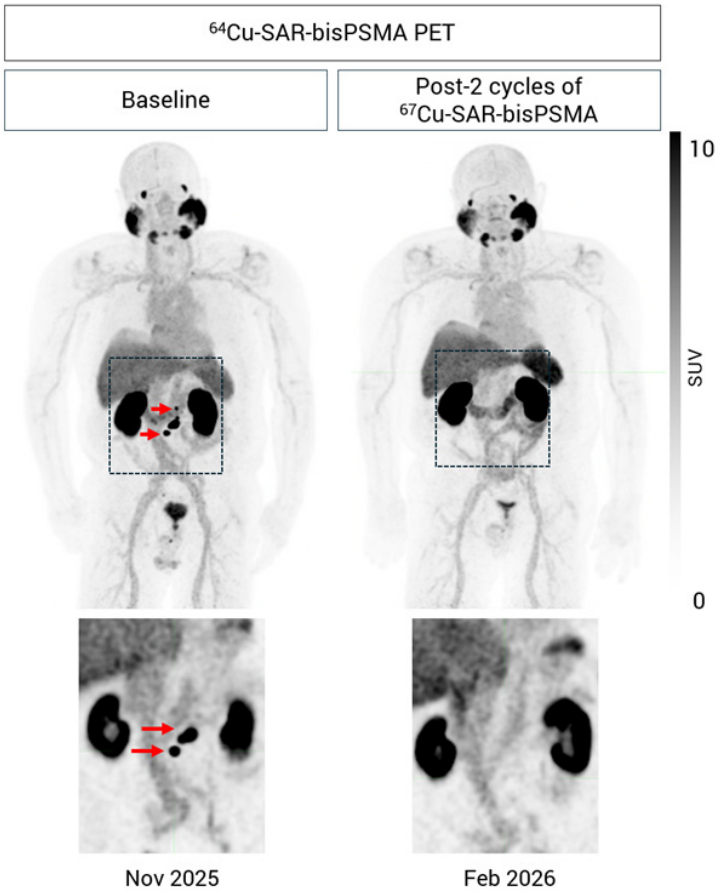


Figure 6. Lesion uptake of ^{64}Cu-SAR-bisPSMA PET at baseline (left images) and following two cycles of ^{67}Cu-SAR-bisPSMA (8 GBq each; right images). PET images on the right were acquired 1 month after the second cycle and show no lesion uptake of ^{64}Cu-SAR-bisPSMA compared to baseline. Red arrows indicate metastatic nodal lesions. Top images: maximum intensity projections. Bottom images: coronal sections of the corresponding insets. SUV: standardised uptake value.

Case Study 2

Another participant to achieve undetectable disease in the Cohort Expansion Phase was a 64-year-old man with metastatic bone disease and baseline PSA of 6.06 ng/mL prior to entering the SECuRE study. He received prior definitive radiotherapy and ADT, docetaxel for metastatic hormone-sensitive disease and enzalutamide for mCRPC with additional palliative stereotactic body radiotherapy.

He went on to receive four cycles of ^{67}Cu-SAR-bisPSMA across 5 months. His PSA declined by 95.7% to 0.26 ng/mL within 4 weeks of first cycle and became undetectable (limit of detection 0.02 ng/mL) after the third cycle, remaining undetectable at 48 weeks (last follow-up in June 2026). No metastatic disease was detected on follow-up bone scan and ^{64}Cu-SAR-bisPSMA PET/CT following treatment with ^{67}Cu-SAR-bisPSMA (**Figure 7**). He experienced mostly mild and transient ^{67}Cu-SAR-bisPSMA-related AEs, reporting Grade 1 nausea, vomiting, flu-like symptoms (all resolved).

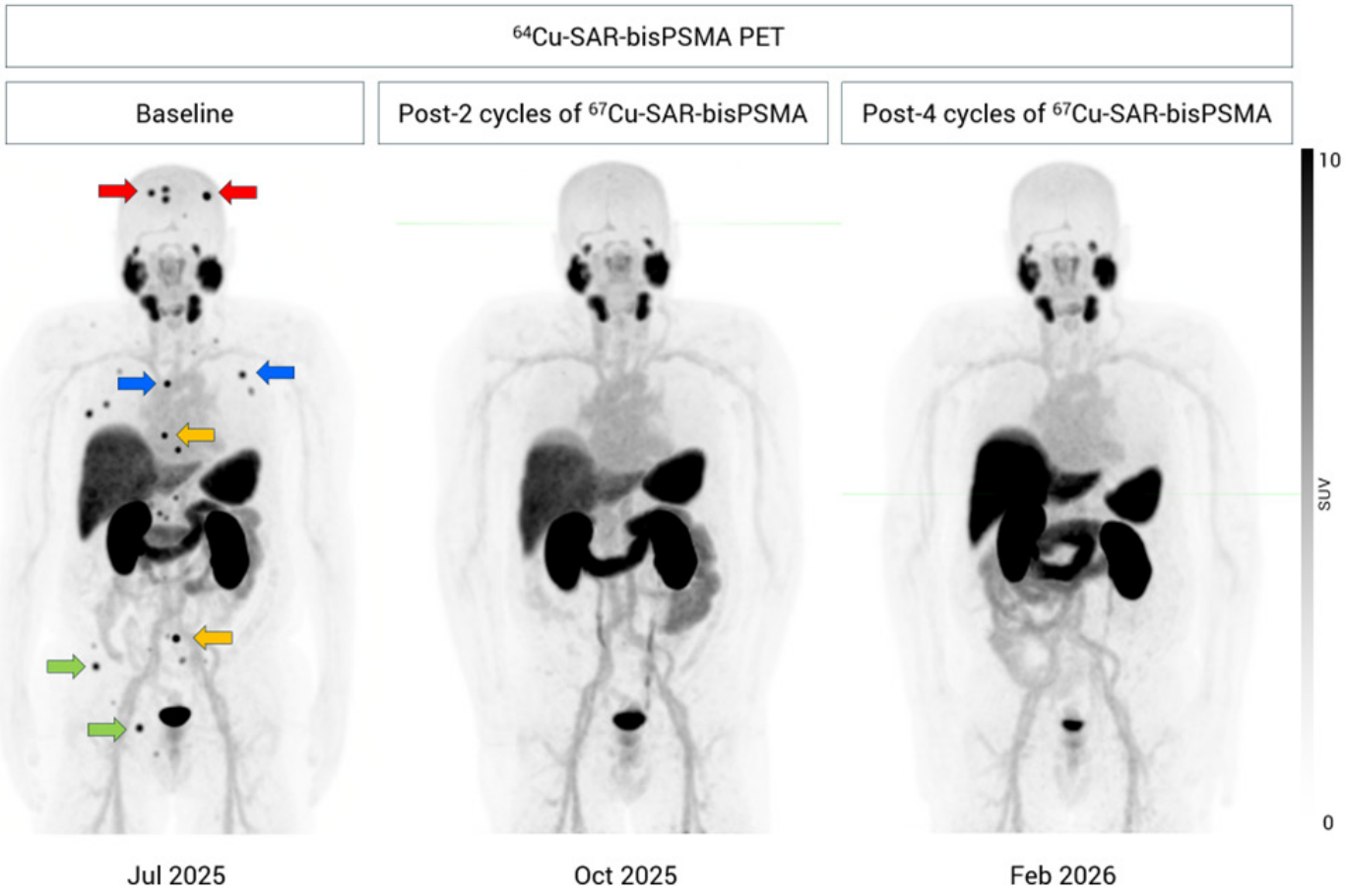


Figure 7. Lesion uptake of ^{64}Cu-SAR-bisPSMA PET at baseline (left), following two cycles of ^{67}Cu-SAR-bisPSMA (8 GBq each; centre) and following four cycles of ^{67}Cu-SAR-bisPSMA (right). Coloured arrows indicate representative metastatic bone lesions within each region: red – skull; blue – ribs and sternum; orange – spine; green – pelvis. No detectable disease was observed on the post-treatment PET. Images are shown as maximum intensity projections. SUV: standardised uptake value.

These case studies were presented at the EANM Annual Congress 2026 held on 17-21 October in Vienna, Austria

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 possess a unique range of skills and expertise, as well as extensive experience in the global radiopharmaceutical market.

Team

During and since the quarter, Clarity continued its efforts to grow a team with world-class expertise and knowledge in radiopharmaceuticals, supporting the emphasis on commercialisation and continued clinical development of its products.

In the reporting period, Michelle Hickey, Clarity's Senior Vice President (SVP), Targeted Copper Theranostic (TCT) Commercial Operations, joined the Company's Senior Executive Team. Ms Hickey is a seasoned technical operations executive, bringing three decades of diverse biopharmaceutical experience to Clarity. Her career spans work in multiple therapeutic areas including radiopharmaceuticals, small molecules and biologics. She is passionate about maintaining focus on the patients by facilitating a culture of quality while advancing science and operational excellence. She brings expertise in chemistry, manufacturing and controls (CMC) strategy, early and late phase clinical drug development, manufacturing, validation, commercial operations, supply chain and program management. Ms Hickey has previously held senior leadership roles at such companies as Telix Pharmaceuticals and Clovis Oncology, where she was instrumental in the commercialization of Rubraca®, Illuccix® and Gozellix®. Her foundational experience also includes key operational and quality positions at industry leaders such as Amgen and Wyeth Biopharma (Pfizer). Ms Hickey holds a B.S. in Biotechnology from Rochester Institute of Technology and a mini-MBA in Biopharma Innovation from Rutgers Business School.

Board

On July 16, Clarity welcomed Allison Rossiter to the Board as an Independent Director. Ms Rossiter is an experienced healthcare executive with 25 years of global leadership experience across diagnostics, pharmaceuticals and medical technology. Ms Rossiter has held senior leadership roles across all three Roche divisions, Pharmaceuticals, Diagnostics and Diabetes Care, and has lived and worked in the UK, Canada, the US and Australia. As Managing Director of Roche Diagnostics Australia, she led a major organisational transformation and Roche's national COVID-19 testing response. Ms Rossiter was later with an Australian Securities Exchange (ASX) listed diagnostics company and was most recently employed at Novartis as country president for Australia and New Zealand.



FINANCIALS

Clarity's cash balance at 30 September 2026 was $152.9 million

The Company remains well funded with a cash position of $152.9 million at 30 September 2026, providing Clarity with a strong Balance Sheet to continue progressing its products towards commercialisation. The Company holds over 66% of cash reserves in US dollars to match future budgeted clinical, operational and commercial spend in the US, providing Clarity with certainty that spend in the US is hedged over the budget period to maintain the Company's ability to match that US dollar spend. The continued strength of the Australian dollar has resulted in an unrealised exchange loss of $2.2 million at 30 September 2026, when those USD cash balances are converted into AUD for Australian statutory reporting purposes.

Net operating cash outflows for the September quarter were $23.1 million. The gross quarterly spend of $25.5 million is lower than the previous quarters spend of $31.2 million, however, it is in line with expectations and forecast requirements as the Company progresses the finalisatiion of the diagnostic AMPLIFY and CLARIFY Phase III clinical trials as well as its theranostic Phase I/IIa SECuRE study.

Operating cash outflows relate to payments for R&D, staff costs, administration and general operating costs.

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 $1,392,952 for the quarter. This amount includes director fees, salaries and bonuses.

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	30 September 2026

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (3 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(11,303)	(11,303)
	(b) product manufacturing and operating costs	(446)	(446)
	(c) advertising and marketing	(563)	(563)
	(d) leased assets	-	-
	(e) staff costs	(11,494)	(11,494)
	(f) administration and corporate costs	(1,417)	(1,417)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	2,337	2,337
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	(260)	(260)
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(23,146)**	**(23,146)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(27)	(27)
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 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**	**(27)**	**(27)**

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	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(1)	(1)
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**	**(1)**	**(1)**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	178,254	178,254
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(23,146)	(23,146)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(27)	(27)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(1)	(1)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (3 months) $A'000
4.5	Effect of movement in exchange rates on cash held	(2,182)	(2,182)
4.6	**Cash and cash equivalents at end of period**	**152,898**	**152,898**

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	78,958	57,208
5.2	Call deposits[1]	73,940	121,046
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)**	**152,898**	**178,254**

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]	1,393
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, salaries and bonuses.

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)	(23,146)
8.2	Cash and cash equivalents at quarter end (item 4.6)	152,898
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	**152,898**
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	7

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: *30 Oct 2026*

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.