



# QUARTERLY ACTIVITY REPORT

SYDNEY, AUSTRALIA  
31 MARCH 2026



# HIGHLIGHTS OF THE QUARTER

During and since the quarter ending 31 March 2026

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## Cash Position

The Company remains well funded with a cash position of \$197.8 million at 31 March 2026, providing Clarity with a strong Balance Sheet to continue progressing its products towards commercialisation.

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## AMPLIFY trial

Clarity closed recruitment in the registrational Phase III AMPLIFY trial in the United States (US) and Australia following strong demand for study participation with a total of 232 participants dosed and imaged. The study had initially planned to image 220 participants with rising or detectable prostate-specific antigen (PSA) after initial definitive treatment.

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## Co-PSMA trial

The results of the Phase II head-to-head Co-PSMA investigator-initiated trial (IIT), led by Prof Louise Emmett at St Vincent's Hospital Sydney, comparing Clarity's <sup>64</sup>Cu-SAR-bisPSMA with standard-of-care (SOC) <sup>68</sup>Ga-PSMA-11 positron emission tomography (PET)/computed tomography (CT), were presented at the European Association of Urology (EAU) Congress 2026, Europe's largest urological conference, in London, UK, and were published in the associated European Urology journal.

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The Co-PSMA trial met its primary endpoint, demonstrating that <sup>64</sup>Cu-SAR-bisPSMA (next-day imaging) identified more than twice as many cancer lesions per patient than <sup>68</sup>Ga-PSMA-11 (mean per patient lesion 1.26 vs. 0.48, respectively,  $p < 0.0001$ ). The total number of lesions across all participants and proportion of participants with a positive scan were also higher with <sup>64</sup>Cu-SAR-bisPSMA (63 vs. 24 total number of lesions and 78% vs. 36% of participants with a positive scan for <sup>64</sup>Cu-SAR-bisPSMA [next-day imaging] vs. <sup>68</sup>Ga-PSMA-11, respectively). The patient-level true positive rate favoured <sup>64</sup>Cu-SAR-bisPSMA next-day imaging (71% vs. 29% for <sup>68</sup>Ga-PSMA-11). Importantly, the Co-PSMA trial imaging findings translated into clinically meaningful changes in patient care, with active planned management increasing from 66% based on <sup>68</sup>Ga-PSMA-11 results to 90% based on <sup>64</sup>Cu-SAR-bisPSMA findings. This highlights the impact of <sup>64</sup>Cu-SAR-bisPSMA on the management of patients with biochemical recurrence (BCR) and low PSA levels, a population in whom SOC prostate-specific membrane antigen (PSMA) PET scans frequently fail to visualise prostate cancer lesions.



# HIGHLIGHTS

## OF THE QUARTER CONT.

During and since the quarter ending 31 March 2026

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### SECuRE trial

Following the latest data review of the Cohort Expansion Phase (Phase II) of the SECuRE trial in January 2026, the Safety Review Committee (SRC) confirmed that the trial was to continue with no modifications to the protocol.

A total of nine participants who had evaluable data by the 25<sup>th</sup> of November 2025 were included in this assessment by the SRC, with the majority of participants receiving at least two cycles of 8 GBq of <sup>67</sup>Cu-SAR-bisPSMA each by the data cut-off date. All participants with evaluable data by the cut-off date showed a decrease in PSA, with 66.7% of participants having a reduction of more than 50% and 33.3% having a reduction of more than 80%.

To date, five patients achieved undetectable disease by radiographic assessment following <sup>67</sup>Cu-SAR-bisPSMA treatment in Clarity's SAR-bisPSMA theranostic program. Two participants from the Cohort Expansion Phase thus far have achieved undetectable disease as assessed by PSA and PSMA PET. On the 23<sup>rd</sup> of February a trial participant was reported to achieve undetectable disease by PSA after the first 8 GBq cycle, followed by a negative PSMA PET after the second cycle of <sup>67</sup>Cu-SAR-bisPSMA. The previous participant (announced on 15 January 2026), also in the Cohort Expansion Phase, achieved undetectable PSA after three cycles of 8 GBq <sup>67</sup>Cu-SAR-bisPSMA, and he continued to demonstrate undetectable disease on PSMA PET after the fourth cycle. Both participants remain with undetectable disease based on their last follow-up.

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### Supply and Manufacturing: Copper-64 supply

Clarity continues to bolster its supply chain in preparation for anticipated commercial launch of its diagnostic products with the signing of a large-scale Manufacturing Supply Agreement for copper-64 with Theragenics in March 2026. Their 134,000 square foot production facility with a fleet of 14 cyclotrons close to Atlanta, Georgia, has capacity to produce around 100 Ci (3.7 TBq) of copper-64 per day on a single cyclotron, which translates into thousands of patient doses per day on each cyclotron at 200 MBq per dose with a 48-hour shelf-life.

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### <sup>64</sup>Cu-SAR-bisPSMA

In April 2026, Clarity signed a Commercial Manufacturing Agreement for <sup>64</sup>Cu-SAR-bisPSMA with Nucleus RadioPharma. The Agreement relates to their state-of-the-art facility in Rochester, Minnesota, which is capable of manufacturing around 50,000 patient doses per year, and future production in Spring House, Pennsylvania. The Spring House facility is a 47,000 square foot site that is planned to open in 2028, enabling broad coverage across the northeast of the US with up to 600,000 doses of <sup>64</sup>Cu-SAR-bisPSMA per year. Together, these two facilities in Minnesota and Pennsylvania will provide access to key commercial markets with manufacturing and distribution to all 50 states in the US and select international sites, including Europe.

Additionally, in January 2026, Clarity's copper-64 and <sup>64</sup>Cu-SAR-bisPSMA supplier, SpectronRx, announced an expansion of its Indiana campus to boost radiopharmaceutical manufacturing. The Indiana site is designed for high-throughput production and is currently capable of supporting over 300,000 patient doses of <sup>64</sup>Cu-SAR-bisPSMA annually.

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### Team and Board

Clarity continues to grow a dedicated and knowledgeable team, united by the mission of improving treatment outcomes for people with cancer. During the reporting period, there were two additions to the Senior Executive Team. Chris Horvath joined in January 2026 as Chief Commercial Officer and in the same month Juliane Foley was welcomed as the new Vice President of Regulatory Affairs.

Clarity's Executive Director, Dr Colin Biggin, stepped down from the Board in April 2026 and will continue in his role as Chief Operating Officer. This change at the Board level is aligned with Clarity's commitment to strong corporate governance as prescribed in the Australian Securities Exchange (ASX) Corporate Governance Principles and Recommendations. As the Company prepares for commercial launch, it is increasingly important to build a strong independent presence at Board level.

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 31 March 2026.



## Executive Chairperson's Letter

Dear fellow Shareholders,

I am pleased to share the progress accomplished by Clarity during and since the quarter ending 31 March 2026.

We are very excited to be moving closer to commercial launch of our products and are in active preparation across all of our departments to align our Company to this important milestone. Our clinical trials are progressing well as we continue to generate important data to support New Drug Applications (NDAs). We are further strengthening our supply and manufacturing strategy with large-scale isotope and product manufacturing secured to deliver commercial-scale production and distribution across all 50 states in the US from day one of anticipated product approval. Our team is also growing rapidly as we continue to attract some of the best talent in the industry with world-class expertise and knowledge in radiopharmaceuticals. This includes Chris Horvath, who joined us in January 2026 as Chief Commercial Officer, bringing over two decades of biopharmaceutical experience, including senior commercial leadership roles at POINT Biopharma, AdvanCell and Novartis/Advanced Accelerator Applications, where he led the global launches of PSMA-targeted platforms, including Pluvicto® and Locametz®.

We also welcomed Juliane Foley to the senior executive team as Vice President of Regulatory Affairs in January 2026. Juliane is a Regulatory Affairs leader with over 30 years of experience leading pharmaceutical regulatory teams in the US and globally, including her roles as the Head of Americas Regulatory Affairs with GE HealthCare, where she led a regulatory team to achieve many Americas Health Authority approvals, including US Food and Drug Administration (FDA) approval of a novel positron emission tomography (PET) radiopharmaceutical.

In line with Clarity's commitment to strong corporate governance as prescribed in the Australian Securities Exchange (ASX) Corporate Governance Principles and Recommendations, and as the Company prepares for commercial launch, it is increasingly important to build a strong independent presence at Board level. As such, Dr Colin Biggin stepped down from the Board in April 2026 and will continue in his role of Chief Operating Officer (COO). We want to thank Colin for his assistance at the Board level for over six years. He has been a great contributor over that time and will continue delivering at the executive level towards our shared goal of improving treatment outcomes for people with cancer.

With a strong team, supportive shareholder base, commitment to the highest standard of research and development, strong regulatory strategy and solid foundation of supply and manufacturing, we clearly differentiate ourselves from our competitors in the radiopharmaceutical field and continue to build an incredible Australian science success story. A testament to that are the outstanding results in the Co-PSMA investigator-initiated trial (IIT), led by Prof Louise Emmett at St Vincents Hospital Sydney. The results were presented at the European Association of Urology (EAU) Congress 2026 on the 16<sup>th</sup> of March 2026 in London, UK, and the study manuscript was published in European Urology<sup>1</sup>, the official journal of the EAU Congress with an impressive impact factor of 25.2.

In this head-to-head trial, comparing  $^{64}\text{Cu}$ -SAR-bisPSMA to  $^{68}\text{Ga}$ -PSMA-11, we have seen our diagnostic product identifying more than twice as many cancer lesions per patient than standard-of-care (SOC) with mean per patient lesion 1.26 vs. 0.48, respectively ( $p < 0.0001$ ).  $^{64}\text{Cu}$ -SAR-bisPSMA next-day imaging showed benefits compared to  $^{68}\text{Ga}$ -PSMA-11 across a number of metrics: higher total number of lesions across all participants (63 vs. 24, respectively), proportion of participants with a positive scan (78% vs. 36%, respectively), patient-level true positive rate (71% vs. 29%, respectively), lesion uptake (median maximum standardised uptake value [SUVmax] 13.6 vs. 5.3, respectively) and an almost perfect agreement across the three independent blinded readers for the  $^{64}\text{Cu}$ -SAR-bisPSMA scans (Cohen's Kappa 0.94 vs. 0.75 for  $^{68}\text{Ga}$ -PSMA-11). Importantly, these imaging findings translated into clinically meaningful changes in patient care, with a marked difference between  $^{64}\text{Cu}$ -SAR-bisPSMA and  $^{68}\text{Ga}$ -PSMA-11 (planned management changes observed in 44% of patients following  $^{64}\text{Cu}$ -SAR-bisPSMA imaging). Active planned management increased from 66% based on  $^{68}\text{Ga}$ -PSMA-11 results to 90% based on  $^{64}\text{Cu}$ -SAR-bisPSMA findings. This highlights the impact of  $^{64}\text{Cu}$ -SAR-bisPSMA on the management of patients with biochemical recurrence (BCR) and low prostate-specific antigen (PSA) levels, a population in whom SOC prostate-specific membrane antigen (PSMA) PET scans frequently fail to visualise prostate cancer lesions. Taken altogether, these results show that  $^{64}\text{Cu}$ -SAR-bisPSMA may redefine the diagnostic pathway in this patient population through more precise and timely salvage treatment strategies with curative intent.

Our team and collaborators have done the hard work and followed the highest standards of clinical research in developing this product with the view to become the gold standard in PSMA PET imaging. We have seen incredible results with evidence of improved diagnostic performance under every condition we have tested  $^{64}\text{Cu}$ -SAR-bisPSMA, from the head-to-head PROPELLER study against  $^{68}\text{Ga}$ -PSMA-11 in pre-prostatectomy patients with only same-day imaging<sup>2</sup>, to the COBRA trial<sup>3</sup> in BCR where any SOC imaging agent could have been used and participant selection criteria had no limitation on upper PSA levels (median 0.9 ng/mL, range 0.25 – 17.6), to this latest head-to-head Co-PSMA trial against  $^{68}\text{Ga}$ -PSMA-11 in BCR patients with low PSA (median 0.43, interquartile range [IQR]: 0.31– 0.63).

The next step for us now in getting  $^{64}\text{Cu}$ -SAR-bisPSMA to the blockbuster PSMA PET market is to complete our two registrational Phase III trials with  $^{64}\text{Cu}$ -SAR-bisPSMA, AMPLIFY<sup>4</sup> and CLARIFY<sup>5</sup>, collecting final data to go into the regulatory filings. We have now closed recruitment in AMPLIFY<sup>6</sup> and are finishing recruitment into the CLARIFY study shortly. With this goal in sight, we have been building out large-scale copper-64 production and locking in large-scale  $^{64}\text{Cu}$ -SAR-bisPSMA product manufacture with the signing of a Manufacturing Supply Agreement with Theragenics in March and a Commercial Manufacturing Agreement with Nucleus RadioPharma in April. Together with Clarity's existing copper-64 supply agreements with SpectronRx and Nusano, as well as a  $^{64}\text{Cu}$ -SAR-bisPSMA commercial manufacturing agreement with SpectronRx, these two new agreements further enhance Clarity's broad network of high-volume production in distinct US geographies, building a tiered approach with regional distribution. The network is designed to support commercial-scale demand with secure, seamless and abundant supply and manufacturing from product launch day.



On the theranostic product development side, we continue seeing impressive data as we are actively progressing recruitment in the Cohort Expansion (Phase II) of the SECuRE<sup>7</sup> trial in metastatic castration-resistant prostate cancer (mCRPC). We have seen outstanding results to date with five patients so far achieving undetectable disease by radiographic assessment following <sup>67</sup>Cu-SAR-bisPSMA treatment. This includes three participants who received up to four cycles of 8 GBq and two participants who received up to three cycles of 12 GBq. This is an incredible result for a small Phase I/IIa trial where recruitment is still ongoing, and we look forward to sharing more data as it becomes available to us.

Overall, preliminary data in the Cohort Expansion Phase is encouraging and favourably complements results from the Dose Escalation cohorts, demonstrating excellent efficacy and safety of <sup>67</sup>Cu-SAR-bisPSMA and continuing to provide a strong foundation for the development of a protocol and optimal dosing for our registrational Phase III clinical trial with this therapy product. This theranostic space is the area where we can create the largest impact on improving treatment outcomes for patients with cancer, and our team is extremely motivated to progress <sup>67</sup>Cu-SAR-bisPSMA through the SECuRE trial, to pivotal Phase III, to NDA and finally to the market where we have an opportunity to make a positive change in the lives of so many men with prostate cancer.

We remain well funded with \$197.8m in cash as at 31 March 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

<sup>64</sup>Cu-SAR-bisPSMA represents a genuine leap forward in PET imaging. When disease becomes visible, it enables more confident salvage decisions. Clearer images. Higher confidence. Real management change."

Dr Alan Taylor



# 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 <sup>64</sup>Cu) for imaging and copper-67 (Cu-67 or <sup>67</sup>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.

## SAR-bisPSMA

has been optimised with two targeting agents that bind to prostate-specific membrane antigen (PSMA), which is present in the majority of prostate cancers.

## SAR-Bombesin

targets the gastrin-releasing peptide receptor (GRPR), a receptor present across a range of malignancies, including prostate, breast and other cancers.

## SARTATE

targets the somatostatin receptor 2 (SSTR2), which is present in neuroendocrine tumours (NETs), breast cancer and other malignancies.

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: one theranostic trial (SECuRE) and two Phase III diagnostic trials (AMPLIFY and CLARIFY).

The investigator-initiated trial (IIT, Co-PSMA) at St Vincent's Hospital Sydney led by Prof Louise Emmett with <sup>64</sup>Cu-SAR-bisPSMA has recently been completed, reaching its primary endpoint, with data 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 25.2.

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

	Theranostic	Diagnostic
<b>SAR-bisPSMA</b>	<p><b>SECuRE</b> – Phase I/IIa theranostic trial for identification and treatment of PSMA-expressing metastatic castrate-resistant prostate cancer (mCRPC) using <sup>64</sup>Cu/<sup>67</sup>Cu-SAR-bisPSMA in the US (<a href="#">NCT04868604</a>)<sup>7</sup>. Cohort Expansion Phase, recruitment ongoing.</p>	<p><b>AMPLIFY</b> – registrational Phase III positron emission tomography (PET) imaging trial of participants with biochemical recurrence (BCR) of prostate cancer following definitive therapy using <sup>64</sup>Cu-SAR-bisPSMA in the US and Australia (<a href="#">NCT06970847</a>)<sup>4</sup>. Recruitment completed.</p> <p><b>CLARIFY</b> – registrational Phase III PET imaging trial of participants with high-risk prostate cancer prior to radical prostatectomy using <sup>64</sup>Cu-SAR-bisPSMA in the US and Australia (<a href="#">NCT06056830</a>)<sup>5</sup>. Recruitment ongoing.</p> <p><b>Co-PSMA</b> – Phase II head-to-head comparison of <sup>64</sup>Cu-SAR-bisPSMA vs. <sup>68</sup>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 (<a href="#">NCT06907641</a>)<sup>8</sup>. Full data released.</p>
<b>SARTATE</b>		<p><b>DISCO</b> – Phase II PET imaging trial of participants with known or suspected NETs using <sup>64</sup>Cu-SARTATE in Australia (<a href="#">NCT04438304</a>)<sup>9</sup>. Topline data announced.</p> <p><b>Registrational <sup>64</sup>Cu-SARTATE trial in NETs</b> – multi-centre, single arm, non-randomised, open-label Phase III diagnostic clinical trial of <sup>64</sup>Cu-SARTATE PET in approximately 70 participants. In planning.</p>
<b>SAR-Bombesin</b>		<p><b>SABRE</b> – Phase II PET imaging trial of participants with PSMA-negative BCR of prostate cancer using <sup>64</sup>Cu-SAR-Bombesin in the US (<a href="#">NCT05407311</a>)<sup>10</sup>. Topline data announced.</p>

# 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.**

Results from the Co-PSMA IIT run by Prof Louise Emmett were presented at an oral session of the EAU Congress 2026 in London, UK on the 13-16 of March 2026. Clarity also presented data from the DISCO trial, investigating  $^{64}\text{Cu}$ -SARTATE in patients with NETs, in an abstract and poster at the prestigious American Society of Clinical Oncology

(ASCO) Gastrointestinal (GI) Cancers Symposium 2026 held on the 8-10 of January.

The abstract was titled "Diagnostic performance of  $^{64}\text{Cu}$ -SARTATE compared to  $^{68}\text{Ga}$ -DOTATATE in patients with known or suspected neuroendocrine tumors with focus on liver findings".

The AMPLIFY and CLARIFY trials were also presented at the American Society for Radio Oncology Multidisciplinary Radiopharmaceutical Therapy Symposium (ASTRO MRPTS) 2026 in February and AMPLIFY was presented at the ASCO Genitourinary Cancers Symposium in February (ASCO GU, trials in progress).

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## FAST TRACK DESIGNATION

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

The  $^{67}\text{Cu}$ -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  $^{64}\text{Cu}$ -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.

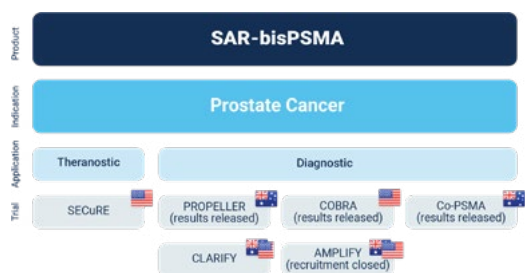
These three FTDs demonstrate the quality of the data generated to date on the  $^{64}\text{Cu}$ -SAR-bisPSMA and  $^{67}\text{Cu}$ -SAR-bisPSMA products and their potential to address serious unmet needs in prostate cancer. The FTDs will enable Clarity to accelerate the development of its comprehensive 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

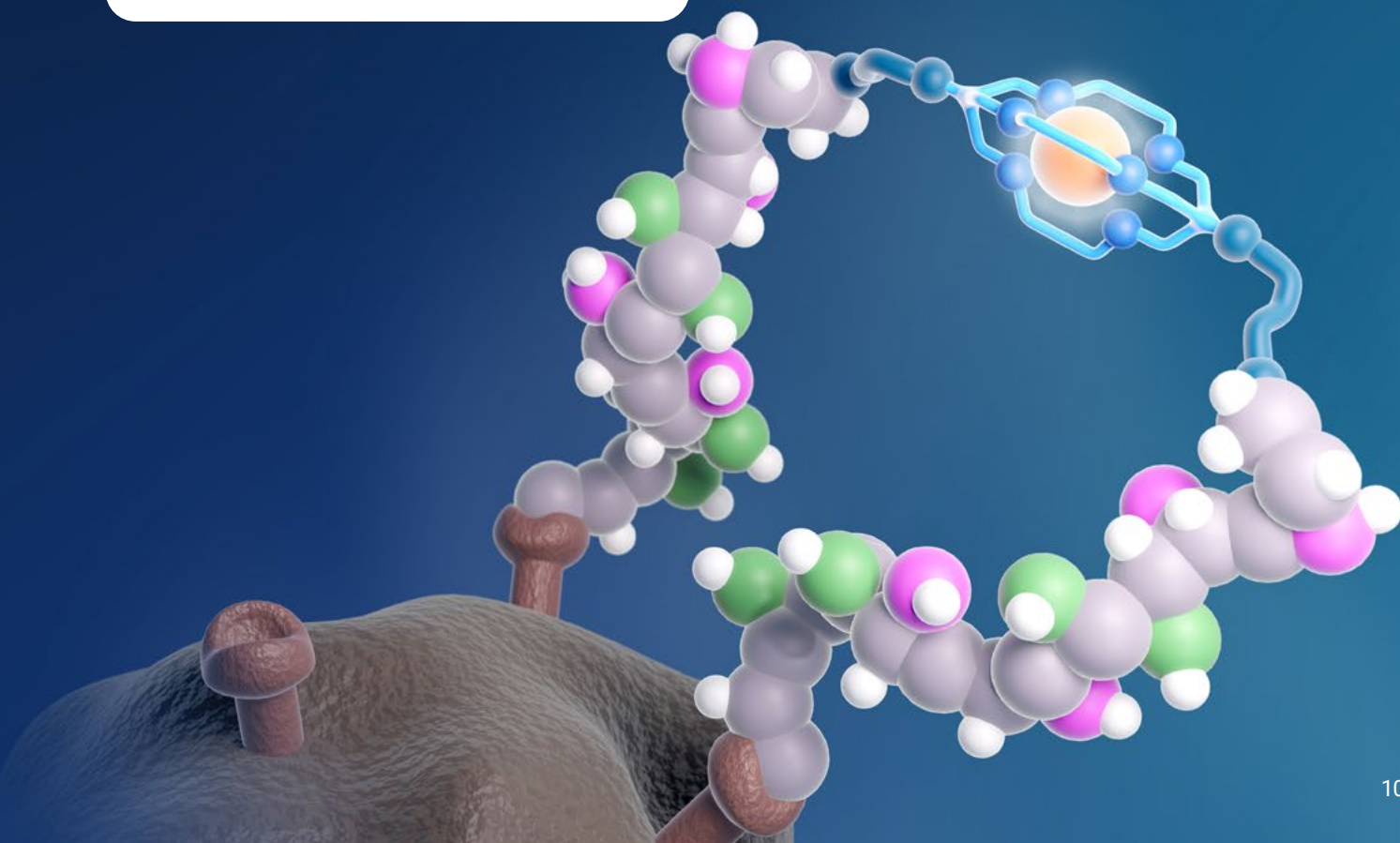
**SAR-bisPSMA is a next generation, theranostic radiopharmaceutical with optimised dual PSMA-targeting agent aimed at improving uptake and retention of the product in tumours**



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 ( $^{64}\text{Cu}$ ) for imaging ( $^{64}\text{Cu}$ -SAR-bisPSMA) or copper-67 ( $^{67}\text{Cu}$ ) for therapy ( $^{67}\text{Cu}$ -SAR-bisPSMA).

In addition to the therapy program in metastatic castration-resistant prostate cancer (mCRPC) with  $^{64}\text{Cu}$ -SAR-bisPSMA and  $^{67}\text{Cu}$ -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  $^{64}\text{Cu}$ -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 $^{64}\text{Cu}$ -SAR-bisPSMA trial

During the reporting period, recruitment remains ongoing in Clarity's first Phase III registrational trial, CLARIFY (NCT06056830)<sup>5</sup>, for  $^{64}\text{Cu}$ -SAR-bisPSMA as a diagnostic agent in patients with prostate cancer prior to undergoing radical prostatectomy. Trial recruitment is expected to complete in 2026.

**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), being conducted at clinical sites across the US and Australia. 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 this trial is to assess the diagnostic performance of  $^{64}\text{Cu}$ -SAR-bisPSMA positron emission tomography (PET) in detecting prostate cancer within the pelvic lymph nodes. Evaluation will be performed 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  $^{64}\text{Cu}$ -SAR-bisPSMA as a new diagnostic imaging agent for newly diagnosed prostate cancer patients.



## AMPLIFY: Diagnostic Phase III registrational <sup>64</sup>Cu-SAR-bisPSMA trial

The diagnostic Phase III AMPLIFY trial ([NCT06970847](#))<sup>4</sup> closed recruitment with 232 patients dosed and imaged following strong demand for study participation at sites in the US and Australia in March 2026.

**AMPLIFY** (<sup>64</sup>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 <sup>64</sup>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 <sup>64</sup>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).

AMPLIFY 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). AMPLIFY achieved its recruitment target in March 2026 and closed recruitment shortly after following the confirmation of 232 patients dosed and imaged successfully.

The data from this study will complement the Phase I/II COBRA<sup>3</sup> and Phase II Co-PSMA<sup>1</sup> trials. Both studies have demonstrated enhanced imaging capabilities of <sup>64</sup>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 <sup>64</sup>Cu-SAR-bisPSMA as a new diagnostic imaging agent in patients with BCR of prostate cancer, alongside results from the CLARIFY trial.**



# Co-PSMA: Investigator-initiated Phase II <sup>64</sup>Cu-SAR-bisPSMA trial

Results from the Co-PSMA ([NCT06907641](#))<sup>8</sup> investigator-initiated trial (IIT), led by Prof Louise Emmett at St Vincent's Hospital Sydney, were presented at the European Association of Urology (EAU) Congress 2026, Europe's largest urological conference, held in March 2026 in London, UK<sup>11</sup>. Full results were also published in *European Urology*<sup>1</sup>, the official journal of the EAU Congress, with an impressive impact factor of 25.2.

**Co-PSMA** ("Comparative performance of <sup>64</sup>Copper [<sup>64</sup>Cu]-SAR-bisPSMA vs. <sup>68</sup>Ga-PSMA-11 PET CT for the detection of prostate cancer recurrence in the setting of biochemical failure following radical prostatectomy") was a Phase II IIT evaluating the performance of Clarity's diagnostic product, <sup>64</sup>Cu-SAR-bisPSMA, in a head-to-head comparison to SOC <sup>68</sup>Ga-PSMA-11 in 50 prostate cancer patients with low PSA (0.2 – 0.75 ng/mL) who were candidates for curative salvage therapy. Eligible patients were required to have had radical prostatectomy with no salvage therapy. <sup>68</sup>Ga-PSMA-11 PET/CT was followed by <sup>64</sup>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.

The **primary endpoint** of the Co-PSMA study was to assess the difference in mean per patient lesion number. Using a paired means test, a sample size of 50 provided power of 90% to detect a minimum alternative mean difference greater than zero of 0.432. **Secondary endpoints** included management impact questionnaires between <sup>64</sup>Cu-SAR-bisPSMA and <sup>68</sup>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.

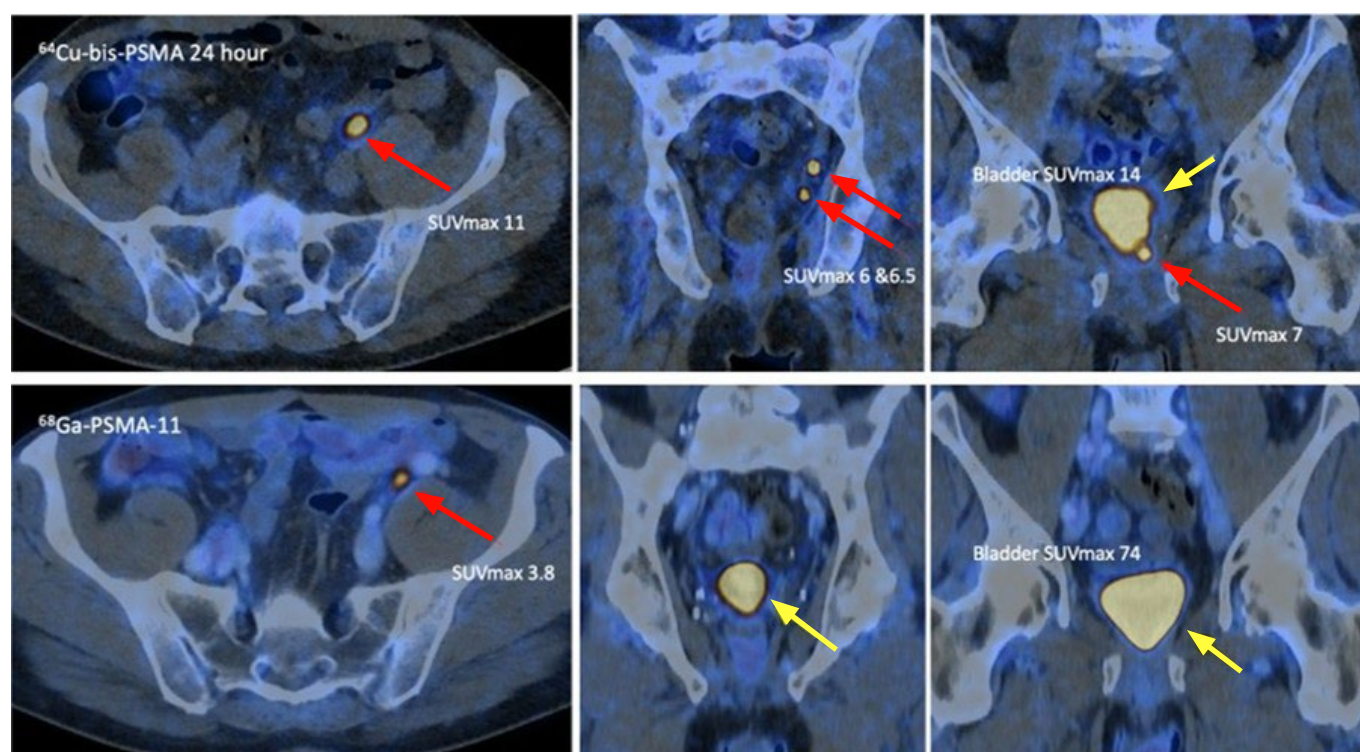
Overall, <sup>64</sup>Cu-SAR-bisPSMA PET/CT (24-hour imaging) was found to identify a higher number of disease recurrences than <sup>68</sup>Ga-PSMA-11 PET/CT with substantial management impact and a high true positive rate in men with BCR post-radical prostatectomy.



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  $^{68}\text{Ga}$ -PSMA-11 and  $^{64}\text{Cu}$ -SAR-bisPSMA imaging was only 2 days (IQR: 1 – 8 days), ruling out differences in lesion detection due to disease progression. This result is corroborated by previous findings from the COBRA trial, which demonstrated that  $^{64}\text{Cu}$ -SAR-bisPSMA was able to detect prostate cancer lesions that were still undetectable 6 months later with SOC PSMA imaging agents<sup>3</sup>. From an imaging perspective, acquisition times were consistent across  $^{68}\text{Ga}$ -PSMA-11 and both same-day and next-day  $^{64}\text{Cu}$ -SAR-bisPSMA scans, with PET scans acquired for 2 minutes per bed position.

On a per patient level, 36% (18/50) of participants were positive on  $^{68}\text{Ga}$ -PSMA-11 PET/CT, compared to 78% (39/50) on  $^{64}\text{Cu}$ -SAR-bisPSMA PET/CT (next-day imaging). The patient-level true positive rate also favoured  $^{64}\text{Cu}$ -SAR-bisPSMA next-day imaging (71% vs. 29% for  $^{68}\text{Ga}$ -PSMA-11).

The mean per-patient lesion for  $^{64}\text{Cu}$ -SAR-bisPSMA (24-hour imaging) was 1.26, compared to 0.48 for  $^{68}\text{Ga}$ -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;  $p < 0.0001$ ). In total,  $^{68}\text{Ga}$ -PSMA-11 identified 24 lesions across all participants, while 24-hour  $^{64}\text{Cu}$ -SAR-bisPSMA imaging detected 63 lesions (representative image in **Figure 1**). The increase in the number of lesions identified by  $^{64}\text{Cu}$ -SAR-bisPSMA was noted in the prostatic bed region (local recurrence), pelvic/extra-pelvic lymph nodes and bone (**Table 1**).



**Figure 1.** PET/CT of the 24-hour  $^{64}\text{Cu}$ -SAR-bisPSMA (top: axial left, coronal centre and right) and  $^{68}\text{Ga}$ -PSMA-11 (bottom: axial left, coronal centre and right). The  $^{64}\text{Cu}$ -SAR-bisPSMA PET/CT identified multiple sites of recurrence (pelvic lymph nodes and fossa), while a single pelvic lymph node was reported on  $^{68}\text{Ga}$ -PSMA-11 PET/CT (red arrows). Bladder depicted by yellow arrows. Adapted and reproduced with permission from Prof Louise Emmett.

Variable	<sup>68</sup> Ga-PSMA-11	24-hour <sup>64</sup> 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 <sup>68</sup>Ga-PSMA-11 and <sup>64</sup>Cu-SAR-bisPSMA scans.

At 24 hours, <sup>64</sup>Cu-SAR-bisPSMA demonstrated higher lesion uptake compared to <sup>68</sup>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 <sup>64</sup>Cu-SAR-bisPSMA scans, whereas the agreement was lower for <sup>68</sup>Ga-PSMA-11. This means the readers reached the same conclusions when assessing the <sup>64</sup>Cu-SAR-bisPSMA scans far more often than when assessing the <sup>68</sup>Ga-PSMA-11 scans in a blinded fashion (almost perfect level of agreement for <sup>64</sup>Cu-SAR-bisPSMA, Cohen's Kappa 0.94 vs. 0.75 for <sup>68</sup>Ga-PSMA-11).

Importantly, these imaging findings translated into clinically meaningful changes in patient care, with a marked difference between <sup>64</sup>Cu-SAR-bisPSMA and <sup>68</sup>Ga-PSMA-11 (planned management changes observed in 44% of patients following <sup>64</sup>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 <sup>68</sup>Ga-PSMA-11 results to 90% based on <sup>64</sup>Cu-SAR-bisPSMA findings.

This highlights the impact of <sup>64</sup>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 <sup>64</sup>Cu-SAR-bisPSMA improves the detection of prostate cancer compared to the current SOC PSMA PET agents which have lower sensitivity in patients with low PSA levels<sup>12,13</sup>. In the Phase II COBRA trial, <sup>64</sup>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 <sup>64</sup>Cu-SAR-bisPSMA PET compared with only 60% on SOC PSMA PET. Overall, next-day imaging with <sup>64</sup>Cu-SAR-bisPSMA identified more than 2.6 times lesions than SOC PSMA PET<sup>3</sup>.

**The COBRA data, combined with the Co-PSMA IIT results, will complement the anticipated findings from the Phase III registrational trial, AMPLIFY, which recently reached its target number of participants<sup>6</sup> and closed recruitment. Together, they are intended to be submitted to the US FDA for a market authorisation of <sup>64</sup>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 <sup>18</sup>F-Choline/Fluciclovine to PSMA-targeted PET/CT".<sup>1</sup>

## SECuRE: Theranostic $^{64}\text{Cu}/^{67}\text{Cu}$ -SAR-bisPSMA trial

In January 2026, following a data review of the Cohort Expansion Phase (Phase II) of the SECuRE trial ([NCT04868604](#))<sup>7</sup>, the Safety Review Committee (SRC) recommended that the trial continue as planned with no modifications to the protocol. The interim results assessed by the SRC were collected from nine participants enrolled in the cohort that had evaluable data by the cut-off date of the 25<sup>th</sup> of November 2025 and continue to show promising efficacy and a favourable safety profile of  $^{67}\text{Cu}$ -SAR-bisPSMA.

The majority of the nine participants had bone metastasis at enrolment (66.7%) and received multiple lines of previous treatments (more than 5 previous anti-cancer regimens, 55.6%). Median PSA prior to  $^{67}\text{Cu}$ -SAR-bisPSMA treatment was 18.9 ng/mL (range 1.5 - 30.2 ng/mL). Six out of these nine participants received at least two cycles of 8 GBq of  $^{67}\text{Cu}$ -SAR-bisPSMA each, with two of them also receiving concomitant enzalutamide.

Of the nine participants included in this SRC analysis, six had at least two PSA results following their  $^{67}\text{Cu}$ -SAR-bisPSMA treatment by the data cut-off date. Of these six participants, thus far four (66.7%) showed reductions in PSA of 50% or more (PSA50) and two (33.3%) showed reductions of 80% or more (PSA80).

The safety profile of  $^{67}\text{Cu}$ -SAR-bisPSMA remains favourable in the Cohort Expansion, with the majority of related adverse events (AEs) being Grade 1 or 2. The most common related AEs were nausea and lymphopenia (observed in three out of nine participants [33.3%], for each AE).

The only AE that was Grade 3 or above was lymphopenia observed in three participants, some of whom had bone metastasis at baseline and/or had received multiple lines of therapy, including taxane and an investigational agent, prior to enrolment in the SECuRE study.

There have been no overall renal toxicity or electrocardiogram (ECG) changes observed in these participants. In the combination enzalutamide arm, no new AEs (or worsening of AEs) related to  $^{67}\text{Cu}$ -SAR-bisPSMA have been observed to date.

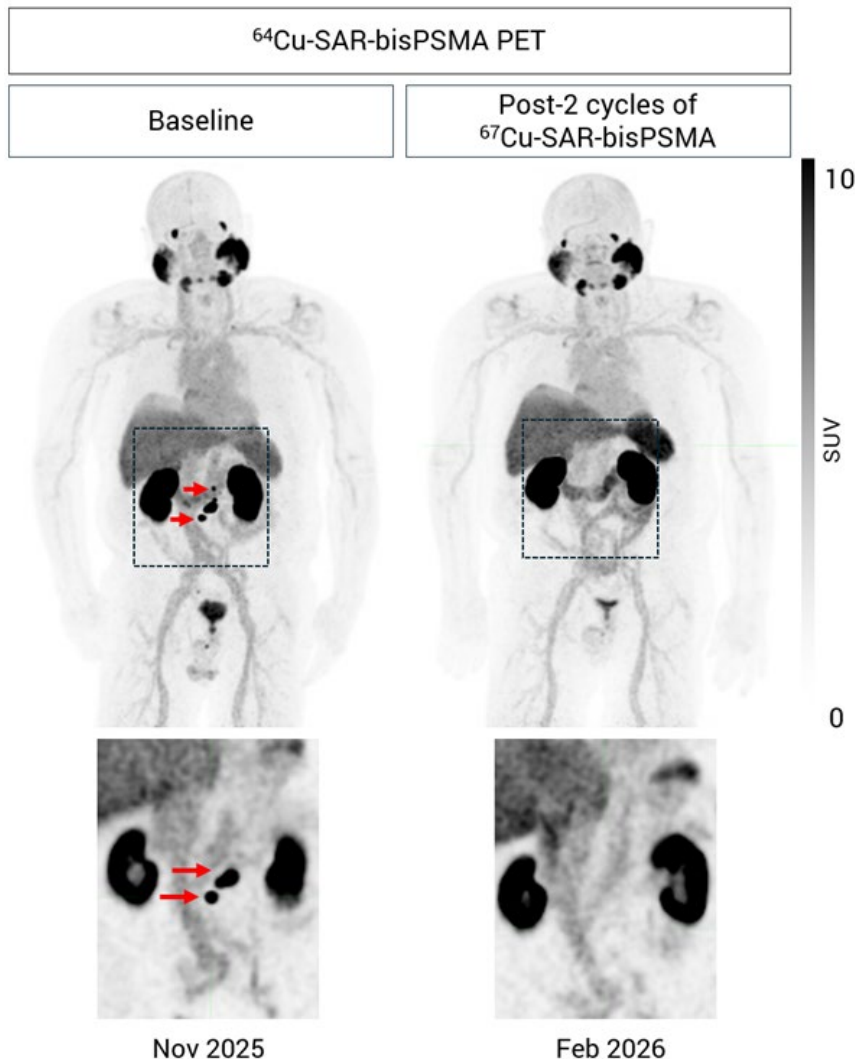


## Five participants have achieved undetectable disease by radiographic assessment following <sup>67</sup>Cu-SAR-bisPSMA treatment

A total of five participants has achieved undetectable disease by radiographic assessment following <sup>67</sup>Cu-SAR-bisPSMA treatment in Clarity’s SAR-bisPSMA theranostic program to date (three participants who received up to four cycles of 8 GBq, and two participants who received up to three cycles of 12 GBq)<sup>14-16</sup>.

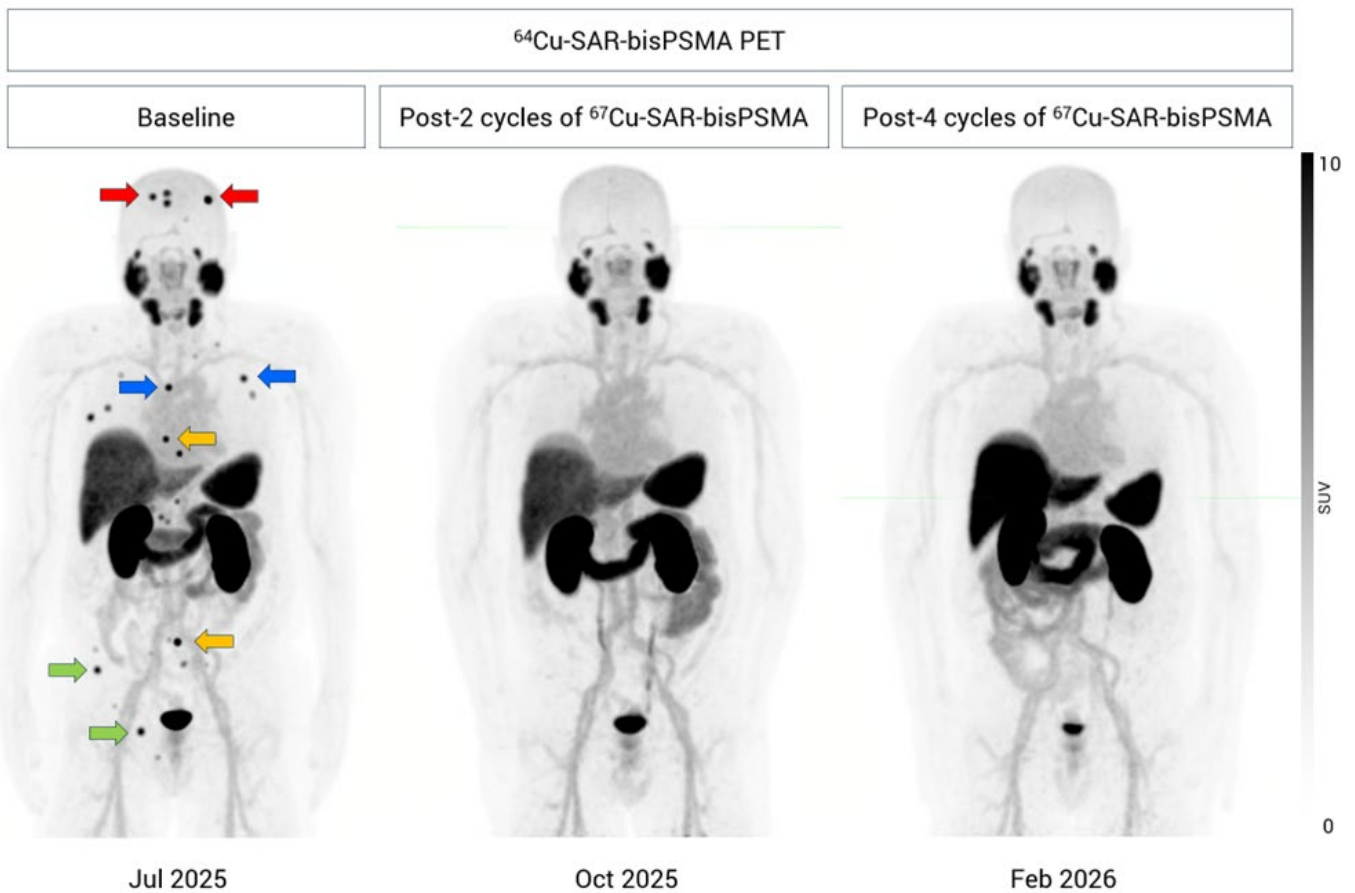
The latest SECURE trial participant to achieve undetectable PSA and negative PSMA PET in the Cohort Expansion Phase was a 76-year-old man who was initially diagnosed with prostate cancer 15 years ago. He had radical prostatectomy to treat the primary disease and radiotherapy for local recurrence, having progressed to metastatic disease in 2020.

Previous systemic anti-cancer treatments included an androgen receptor pathway inhibitor (ARPI) and ADT. In 2025, the disease progressed further, and he was enrolled into the Cohort Expansion Phase of the SECURE study with a baseline PSA of 3.25 ng/mL. Seven weeks after his first cycle of <sup>67</sup>Cu-SAR-bisPSMA, this participant achieved undetectable PSA levels. He proceeded to receive one more cycle of <sup>67</sup>Cu-SAR-bisPSMA, and no disease was observed on PSMA PET following the second dose (**Figure 2**). This participant exhibited mild (Grade 1) related AEs, including altered taste, dry eyes, eye pain, fatigue and salivary gland soreness (all resolved except fatigue). No haematological or renal AEs were observed as of the date of the announcement on the 23 February 2026<sup>15</sup>.



**Figure 2.** Lesion uptake of <sup>64</sup>Cu-SAR-bisPSMA PET at baseline (left images) and following two cycles of <sup>67</sup>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 <sup>64</sup>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.

The previous participant to achieve undetectable disease in the Cohort Expansion Phase was a 64-year-old man with bone metastases and baseline PSA of 5.4 ng/mL prior to entering the SECURE study. Following his first cycle of  $^{67}\text{Cu}$ -SAR-bisPSMA, this participant showed a dramatic 95.2% reduction in PSA. He went on to receive two more cycles of  $^{67}\text{Cu}$ -SAR-bisPSMA and achieved undetectable PSA levels. In a follow-up bone scan and CT no metastatic disease was observed. Following the first three cycles of  $^{67}\text{Cu}$ -SAR-bisPSMA, the participant exhibited mild (Grade 1) related AEs, most of which were gastrointestinal events, with no haematological or renal AEs<sup>16</sup>. One month after the administration of the fourth cycle (February 2026), no disease was identified on his PET scans. Notably, no new safety signals have been observed during and since the administration of the fourth cycle as of the date of the announcement on the 23 February 2026<sup>15</sup>.



**Figure 3.** Lesion uptake of  $^{64}\text{Cu}$ -SAR-bisPSMA PET at baseline (left), following two cycles of  $^{67}\text{Cu}$ -SAR-bisPSMA (8 GBq each; centre) and following four cycles of  $^{67}\text{Cu}$ -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.



The latest data from this Phase II study continues to confirm the favourable safety profile and promising efficacy seen in previous cohorts of the SECURE trial<sup>14</sup> and supports the continuation of the trial with the aim to progress to a registrational Phase III study.

## About the SECURE trial

SECURE is a Phase I/IIa theranostic trial for identification and treatment of participants with PSMA-expressing mCRPC using <sup>64</sup>Cu/<sup>67</sup>Cu-SAR-bisPSMA. <sup>64</sup>Cu-SAR-bisPSMA is used to visualise PSMA-expressing lesions and select candidates for subsequent <sup>67</sup>Cu-SAR-bisPSMA therapy. The trial is a multi-centre, single arm study, planning to enroll approximately 54 participants in the US. The overall aim of the trial is to determine the safety and efficacy of <sup>67</sup>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. Based on the data from the Dose Escalation Phase, which demonstrated a favourable safety profile and efficacy of <sup>67</sup>Cu-SAR-bisPSMA, the SECURE trial progressed to the Cohort Expansion at an 8 GBq dose level as per the SRC recommendation (up to 6 cycles per patient in total)<sup>14</sup>.

Cohort 2 of the Dose Escalation phase of the trial, where participants were dosed with 8 GBq of <sup>67</sup>Cu-SAR-bisPSMA, demonstrated a very low rate of related AEs while all

three participants achieved PSA declines of 80% or more (PSA80)<sup>14</sup>. The Dose Escalation Phase also showed high PSA response rates of the mCRPC in the pre-chemotherapy setting with a favourable safety profile: 92% of pre-chemotherapy participants (12/13) demonstrated PSA drops greater than 35%, 61.5% (8/13) of participants achieved PSA reductions greater than 50%, and 46.2% (6/13) of participants achieved PSA reductions of 80% or more<sup>14</sup>. These results supported the progress of the trial to its Cohort Expansion Phase using 8 GBq multi-dose in participants who had not received chemotherapy in the mCRPC setting.

Recruitment is currently ongoing into the Cohort Expansion Phase which will include 24 participants. A subset of participants will be treated with the combination of 8 GBq of <sup>67</sup>Cu-SAR-bisPSMA with enzalutamide (ARPI), in line with the positive results from the Enza-p trial<sup>17</sup> and previous discussions with and advice from key global medical experts in the field of prostate cancer.

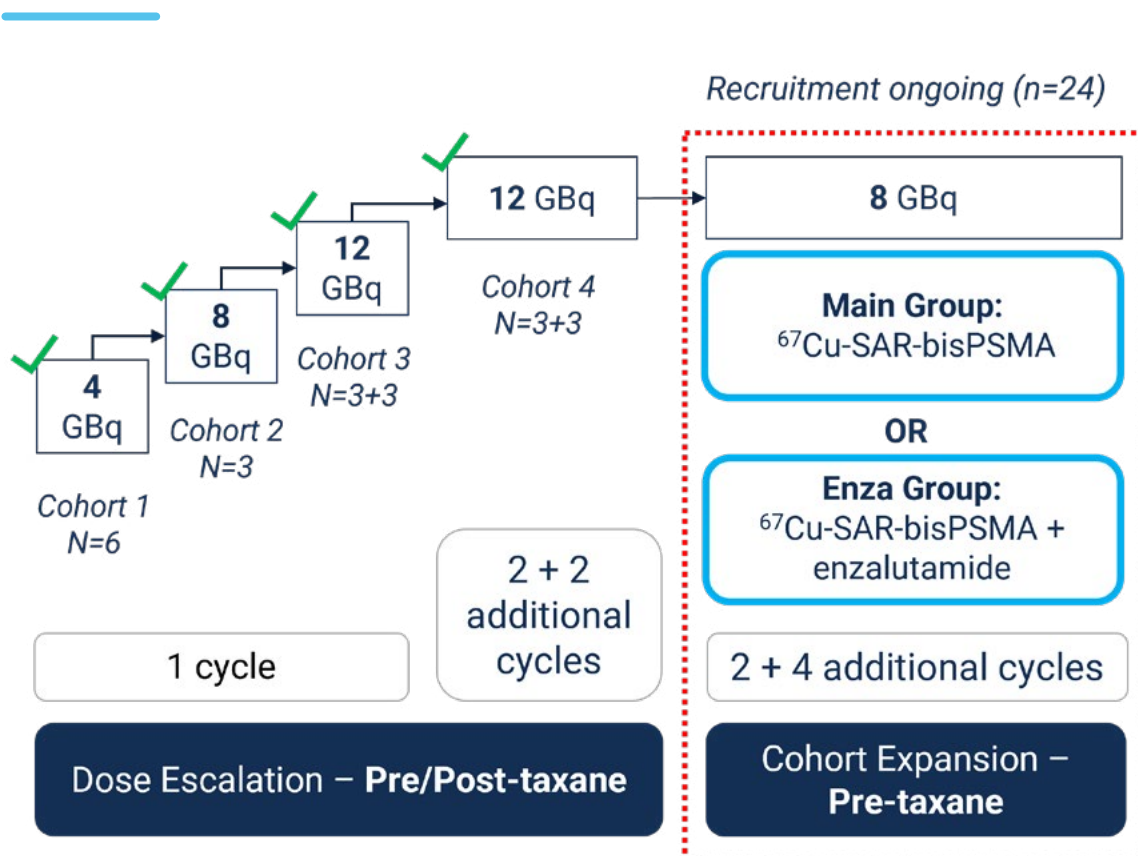


Figure 3. SECURE Trial Design.

# SUPPLY & MANUFACTURING: THE GAME CHANGER FOR RADIOPHARMACEUTICALS

**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, allowing for scalability into commercial manufacturing that the current generation of radiopharmaceuticals being developed do not have.**

These benefits are the reason Targeted Copper Theranostics (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 supply chain footprint, with a particular focus on strengthening its manufacturing network in this quarter, including large-scale agreements for both isotope and finished product manufacturing. As Clarity grows closer to commercial launch, a tiered, extensive supply network, allowing for on-demand production and distribution, is one of the key elements to a successful adoption of products into clinical practice.



# COPPER-64

Copper-64 (Cu-64 or  $^{64}\text{Cu}$ ) 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  $^{68}\text{Ga}$ ) with a half-life of ~1 hour and fluorine-18 (F-18 or  $^{18}\text{F}$ ) 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 in close proximity 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.

In March 2026, Clarity signed a large-scale Manufacturing Supply Agreement for copper-64 with Theragenics. Their 134,000 square foot production facility has a fleet of 14 cyclotrons close to Atlanta, Georgia, a major US transport hub, and will enable centralised, large-scale copper-64 production.

Theragenics have substantial cyclotron expertise with 40 years of routine radiometal production and considerable experience in production of radioisotopes for medical use. Combined with a sizeable fleet of high-current cyclotrons, this constitutes an opportunity for large-scale copper-64 manufacturing at the site. Theragenics have capacity to produce around 100 Ci (3.7 TBq) of copper-64 per day on a single cyclotron, which translates into thousands of doses per day on each cyclotron at 200 MBq per dose with a 48-hour shelf-life.

Together with Clarity's existing copper-64 supply agreements with SpectronRx and Nusano, this agreement with Theragenics further enhances Clarity's broad network of high-volume copper-64 manufacturers in distinct US geographies. The network is designed to support commercial-scale demand across multiple large oncology indications with secure, seamless and abundant supply of this diagnostic isotope.



## <sup>64</sup>Cu-SAR-bisPSMA manufacturing

**Clarity continues to build out its manufacturing capabilities ahead of <sup>64</sup>Cu-SAR-bisPSMA's anticipated commercial launch upon successful completion of Phase III registrational trials with this product, AMPLIFY<sup>4</sup> and CLARIFY<sup>5</sup>, and subsequent US Food and Drug Administration (FDA) New Drug Application (NDA) approval.**

In April 2026, Clarity signed a Commercial Manufacturing Agreement for <sup>64</sup>Cu-SAR-bisPSMA with Nucleus RadioPharma, an innovative contract development and manufacturing organisation (CDMO) in the radiopharmaceutical industry.

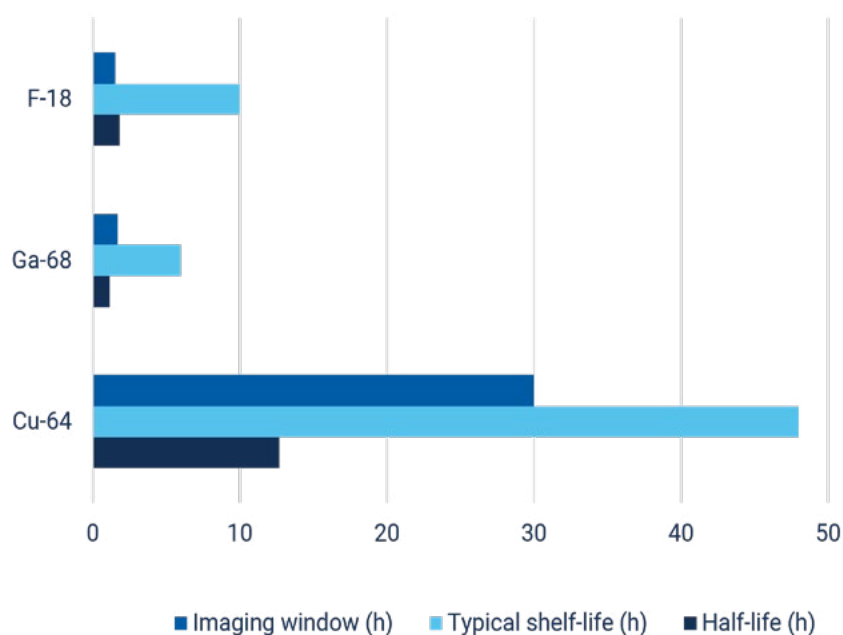
The Agreement relates to Nucleus RadioPharma's state-of-the-art facility in Rochester, Minnesota, which is capable of manufacturing around 50,000 patient doses per year, and future production in Spring House, Pennsylvania. The Spring House facility is a 47,000 square foot site that is planned to open in 2028, enabling broad coverage across the northeast of the US with up to 600,000 doses of <sup>64</sup>Cu-SAR-bisPSMA per year.

Together, these two facilities in Minnesota and Pennsylvania will provide access to key commercial markets with manufacturing and distribution to all 50 states in the US and select international sites, including Europe.

In January 2026, SpectronRx, Clarity's commercial-scale copper-64 and <sup>64</sup>Cu-SAR-bisPSMA supplier, announced an expansion of its Indiana campus to boost radiopharmaceutical manufacturing<sup>18</sup>. The buildout includes a newly constructed 150,000-square-foot facility, aimed at scaling production of radiopharmaceuticals for therapeutic and diagnostic use.

The expansion enhances SpectronRx's ability to manage the full development and manufacturing lifecycle: from isotope production and early-stage R&D through to commercial-scale supply. The Indiana site is designed for high-throughput production and is currently capable of supporting over 300,000 patient doses of <sup>64</sup>Cu-SAR-bisPSMA annually.

### Comparison of isotope and product characteristics of current FDA-approved PSMA PET agents based on Ga-68 and F-18 with a Cu-64 SAR-based product



Clarity has agreements in place to supply copper-64 well in excess of the current PSMA imaging market demand at over 2 million patient doses of <sup>64</sup>Cu-SAR-bisPSMA per year at launch.

Pylarify TruVu, Posluma and Gozellix FDA approved product information. Accessed on 27 March 2026. <sup>64</sup>Cu-SAR-bisPSMA information: data on file.

# COPPER-67

Copper-67 (Cu-67 or  $^{67}\text{Cu}$ ) 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  $^{177}\text{Lu}$ ), are produced on a small number of ageing nuclear reactors worldwide, many of which are approaching the end of their “useful life” and are located outside of the United States. This results in planned and unplanned shutdowns, causing shortages of therapeutic isotopes worldwide<sup>19</sup>. Even with the current infrastructure, access to reactor production capacity might soon become a bottleneck for lutetium-177<sup>20</sup>.

“Clarity remains committed to building a secure, reliable and environmentally favourable supply chain for copper-67 in support of its theranostic clinical trials and in preparation for commercialisation as we look to improve treatment options for people with cancer.”

Dr Alan Taylor



# 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.**

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

During the reporting period, Clarity made some changes and additions to the senior executive team and the Board.

In January 2026, Chris Horvath joined the team as Chief Commercial Officer. He brings over two decades of biopharmaceutical experience spanning R&D, commercial leadership and corporate operations with deep expertise in oncology and radiopharmaceuticals. Prior to joining Clarity, Chris held senior commercial leadership roles at POINT Biopharma, AdvanCell and Novartis/Advanced Accelerator Applications, where he led the global launches of PSMA-targeted platforms, including Pluvicto® and Locametz®. Earlier in his career, he held progressively senior commercial roles at Janssen, Dendreon, Merck and Bayer, following his start as a research scientist at DuPont and the Novartis Institutes for BioMedical Research. Chris holds a Bachelor of Science in Chemistry and Biology from Wilfrid Laurier University, a Master of Science in Analytical Science from the University of Guelph and an MBA in Pharmaceutical Management and Marketing from Rutgers Business School.

Clarity also welcomed Juliane Foley to the senior executive team as Vice President of Regulatory Affairs in January 2026. Juliane is an experienced Regulatory Affairs leader with over 30 years of experience leading pharmaceutical

regulatory teams in the US and globally. Prior to joining Clarity, Juliane was the Head of Americas Regulatory Affairs with GE HealthCare. While with GE HealthCare, she led a team of Regulatory Professionals to achieve many Americas Health Authority approvals, including a US Food and Drug Administration (FDA) approval of a novel positron emission tomography (PET) radiopharmaceutical. Earlier in her career, Juliane consulted with Parexel and prior to that was with Mylan Pharmaceuticals (now Viatris) for 23 years focused on US complex dosage form Regulatory Affairs. Juliane holds a pre-Medical Bachelor of Science and a Master of Science in Administration from Saint Michael's College.

At the Board level, Dr Colin Biggin stepped down from his role of Executive Director and will continue as Chief Operating Officer (COO). As Clarity prepares for commercial launch, it is increasingly important to build a strong independent presence at Board level, as prescribed in the Australian Securities Exchange (ASX) Corporate Governance Principles and Recommendations. The Company will continue to work in this direction, seeking high-calibre independent leaders, with a mix of expertise and experience relevant to the needs of the Company, to join Clarity's Board.

**Clarity continues to expand its team, in line with its accelerating pace of clinical development and growing focus on commercialisation. The Company has around 94 employees as of the date of this report in both the US and Australia.**



# FINANCIALS

Clarity's cash balance at 31 March 2026 was \$197.8 million.

Net operating cash outflows for the March quarter were \$25.5 million. The quarterly spend is consistent with the previous quarter and in line with expectations and forecast requirements as the Company progresses its clinical trials, particularly AMPLIFY and CLARIFY, toward completion. At the same time the Company continues to invest in building out its supply chain for both copper-64 and copper-67 production, with just over \$1.4 million being spent on manufacturing readiness in the quarter. 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 \$675,443 for the quarter. This amount includes director fees and salaries.

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



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## For more information, please contact:

### Clarity Pharmaceuticals

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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](http://claritypharmaceuticals.com)



## Appendix 4C

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

**Name of entity**

Clarity Pharmaceuticals Ltd

**ABN**

36 143 005 341

**Quarter ended (“current quarter”)**

31 March 2026

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(17,288)	(51,769)
(b) product manufacturing and operating costs	(1,447)	(1,447)
(c) advertising and marketing	(37)	(59)
(d) leased assets	-	-
(e) staff costs	(6,634)	(20,136)
(f) administration and corporate costs	(1,082)	(3,987)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	1,107	4,487
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	(105)	(369)
1.7 Government grants and tax incentives	-	-
1.8 Other (provide details if material)	-	-
<b>1.9 Net cash from / (used in) operating activities</b>	<b>(25,486)</b>	<b>(73,280)</b>
<b>2. Cash flows from investing activities</b>		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(29)	(287)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 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)	-	-
<b>2.6 Net cash from / (used in) investing activities</b>	<b>(29)</b>	<b>(287)</b>

<b>3. Cash flows from financing activities</b>		
3.1 Proceeds from issues of equity securities (excluding convertible debt securities)	-	203,638
3.2 Proceeds from issue of convertible debt securities	-	-
3.3 Proceeds from exercise of options	1	30
3.4 Transaction costs related to issues of equity securities or convertible debt securities	-	(10,757)
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)	-	-
<b>3.10 Net cash from / (used in) financing activities</b>	<b>1</b>	<b>192,911</b>

<b>4. Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1 Cash and cash equivalents at beginning of period	226,249	84,118
4.2 Net cash from / (used in) operating activities (item 1.9 above)	(25,486)	(73,280)
4.3 Net cash from / (used in) investing activities (item 2.6 above)	(29)	(287)
4.4 Net cash from / (used in) financing activities (item 3.10 above)	1	192,911

Appendix 4C  
Quarterly cash flow report for entities subject to Listing Rule 4.7B

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
4.5	Effect of movement in exchange rates on cash held	(2,953)	(5,680)
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>197,782</b>	<b>197,782</b>

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	93,386	70,454
5.2	Call deposits <sup>1</sup>	104,396	155,795
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
<b>5.5</b>	<b>Cash and cash equivalents at end of quarter (should equal item 4.6 above)</b>	<b>197,782</b>	<b>226,249</b>

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 <sup>2</sup>	675
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.

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

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

<b>8. Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	(25,486)
8.2 Cash and cash equivalents at quarter end (item 4.6)	197,782
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	<b>197,782</b>
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	8
<i>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.</i>	
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: [ ]	
<i>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.</i>	

## 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: .....30/04/2026.....

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.