



# QUARTERLY ACTIVITY REPORT

SYDNEY, AUSTRALIA  
31 OCTOBER 2025

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# HIGHLIGHTS OF THE QUARTER

During and since the quarter ending 30 September 2025

## Capital Raise and Cash Position

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

The Company remains well funded at 30 September 2025 with a cash position of \$253.1 million, providing Clarity with a strong Balance Sheet to continue progressing its products towards commercialisation.

## Co-PSMA trial

The Co-PSMA Investigator-Initiated Trial (IIT), led by Prof Louise Emmett at St Vincent's Hospital Sydney, achieved its primary endpoint with a significantly higher number of prostate-specific membrane antigen (PSMA)-positive prostate cancer lesions detected using  $^{64}\text{Cu}$ -SAR-bisPSMA compared to standard-of-care (SOC)  $^{68}\text{Ga}$ -PSMA-11 positron emission tomography/computed tomography (PET/CT) in patients in biochemical recurrence with low prostate-specific antigen (PSA) levels. Study enrolment was successfully completed in July 2025, with 50 patients recruited. Full results of this study will be presented at an upcoming international conference.

## Discovery: SAR-bisFAP

Pre-clinical data on Clarity's pan-cancer theranostic,  $^{64/67}\text{Cu}$ -SAR-bisFAP, was presented at the World Molecular Imaging Conference (WMIC) 2025 in Anchorage, Alaska in October 2025 by Dr Michele De Franco, a research fellow at the Memorial Sloan Kettering Cancer Center (MSK) and Clarity's collaborator.

The dual-targeting  $^{64}\text{Cu}$ -SAR-bisFAP showed superior tumour targeting and retention in fibroblast activation protein (FAP) expressing pre-clinical models compared to  $^{64}\text{Cu}$ -SAR-FAP, and  $^{67}\text{Cu}$ -SAR-bisFAP also showed improved efficacy in therapeutic pre-clinical studies compared to  $^{67}\text{Cu}$ -SAR-FAP monomer or an industry benchmark,  $^{177}\text{Lu}$ -FAP-2286.

## Supply and Manufacturing: Copper-67

In October 2025, Clarity entered into a Supply Agreement for copper-67 with Nusano, Inc. ("Nusano"). Nusano's 190,000 square foot state-of-the-art facility in West Valley City, Utah is expected to begin operations in late 2025 with copper-67 isotope supply planned to commence in 2026. The copper-67 supply from Nusano further expands Clarity's growing network of US-based suppliers, including NorthStar Medical Radioisotopes, LLC ("NorthStar") and Idaho State University Idaho Accelerator Center (IAC).

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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 2025.

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## 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 2025 as we advance our exciting pipeline of assets. In this first quarter of the FY2025-2026 we have already achieved some very important milestones in corporate, clinical and operational areas of our business. At the start of the quarter, we successfully completed a \$203 million institutional placement, putting us in a strong financial position to realise our clinical development plans in the coming years. This was a significant achievement given the challenges in the global markets over the last 12 months and some unfortunate events in our local Australian biotech sector, as well as the exposure to index funds that we have experienced, resulting in extraordinary volatility in our share price. Despite all of these obstacles, our team's drive and motivation to better the lives of people living with cancer prevailed, and we continued to strengthen the fundamentals of our Company, translating high-quality science into impactful clinical research.

As a result of our continuous commitment to improving the lives of cancer patients, we have seen some important progress in the development of our key product, SAR-bisPSMA. Most recently, the Co-PSMA investigator-initiated trial (IIT) achieved its primary endpoint with the identification of a significantly higher number of prostate-specific membrane antigen (PSMA)-positive prostate cancer lesions detected using  $^{64}\text{Cu}$ -SAR-bisPSMA compared to standard-of-care (SOC)  $^{68}\text{Ga}$ -PSMA-11 positron emission tomography/computed tomography (PET/CT) in patients with biochemical recurrence and low prostate-specific antigen (PSA) levels. Further data analysis is ongoing, and the full results are being prepared for submission and presentation at leading world congresses by Prof Louise Emmett. The Co-PSMA findings continue to build on the growing body of evidence of the enhanced diagnostic performance of  $^{64}\text{Cu}$ -SAR-bisPSMA compared to SOC PSMA PET agents, which are known to have low sensitivity. Improvements in sensitivity, as observed with all diagnostic agents, play a pivotal role in guiding more informed treatment decisions, enabling earlier and more accurate detection of cancer and ultimately improving patient outcomes.

The PSMA PET imaging space is a blockbuster market, worth around US\$2 billion per year in the US alone, with growth expectations of over US\$3 billion by 2029. Sadly, this entire market currently consists of products that have low sensitivity, while the development pipeline of new products, excluding  $^{64}\text{Cu}$ -SAR-bisPSMA, offers no differentiation from the existing agents, with some new entrants commercialising the unpatented  $^{68}\text{Ga}$ -PSMA-11 agent, which has been capitalised on by three separate groups already. We believe that with the clinical and logistical benefits offered by  $^{64}\text{Cu}$ -SAR-bisPSMA we could not only become the new SOC in PSMA PET but grow the market opportunity further by diagnosing prostate cancer earlier, while lesions are still very small, and enabling broader geographic reach.

Achieving this milestone in a head-to-head trial against a SOC competing product is a phenomenal outcome, and will help to further validate <sup>64</sup>Cu-SAR-bisPSMA as best-in-class as we continue to progress two registrational trials, AMPLIFY and CLARIFY, with two Fast Track Designations (FTDs) under our belt for diagnostic applications and a strong focus on commercialisation.

While progressing our clinical development pipeline with key focus on SAR-bisPSMA in the first instance remains the key priority, we are dedicated to growing our pipeline of products in a range of indications with high unmet needs through collaborations with key opinion leaders and world-leading research organisations. Due to this dedication to high quality research and development, we have recently progressed a new optimised product, SAR-bisFAP, starting from the benchtop and now preparing for clinical translation of this promising pan-cancer agent in 2026. During the quarter, some important data from pre-clinical studies with SAR-bisFAP was presented at the World Molecular Imaging Conference (WMIC) 2025 by Dr Michele De Franco, a research fellow at the Memorial Sloan Kettering Cancer Center (MSK) and Clarity's collaborator. Fibroblast activation protein (FAP) targeted products represent an exciting new generation of radiopharmaceuticals with the potential to target a range of cancer indications, and we look forward to exploring its benefits in clinical trials.

Clarity has also continued strengthening our operations footprint during the quarter as our trials progress, highlighting the importance of an abundant and efficient supply chain. With outstanding preliminary clinical trial data generated to date on <sup>67</sup>Cu-SAR-bisPSMA from our Phase I/IIa SECURE trial and an FTD in the US for this optimised product, we look forward to progressing our theranostic program into a Phase III trial, pending final study findings. As such, in this quarter we focused on copper-67 isotope

supply and signed a Supply Agreement with Nusano, whose 190,000 square foot state-of-the-art facility in West Valley City, Utah, is expected to begin operations in 2025, with copper-67 isotope supply planned to commence in mid-2026. The copper-67 supply from Nusano further expands Clarity's growing network of US-based suppliers, including NorthStar and the Idaho State University Idaho Accelerator Center. Clarity's ability to make products, from isotope manufacture to finished product, in the US for the treatment of the American people is an important advantage in the current geo-political and economic environment, especially given the recently imposed 100% tariff on imports of branded pharmaceutical products to the US that has taken effect from October 1. By building a supply chain that is fully integrated, from high-volume isotope production to centralised product manufacture and to delivering these ready-to-use diagnostic and therapeutic radiopharmaceuticals to imaging and treatment sites in every state of the US on time and on demand, we are aiming to create a model that is impervious to political dynamics.

We are in a strong financial position to continue leveraging the powerful momentum of impressive data, strong science and growth in the radiopharmaceutical sector as we work on our US-focused commercialisation strategy. We look forward to progressing our differentiated platform of diagnostic and therapeutic assets with the goal of better treating people with cancer around the world. We again thank our shareholders for your support and look forward to providing further updates on the continued progress of our therapy and diagnostic programs.

Yours sincerely,

Dr Alan Taylor  
Executive Chairperson  
Clarity Pharmaceuticals Ltd.



# CORPORATE & FINANCE SUMMARY

Clarity successfully completed a \$203 million Placement with a small group of institutional investors who are close to the Company on the 28th of July 2025.

The issue price of the Placement was \$4.20 per share, which represented a 2.2% premium to Clarity's previous closing price and an 18.0% premium to Clarity's 15-day Volume Weighted Average Price ("VWAP").

Following completion of the Placement, Clarity's cash balance at 30 September 2025 is \$253.1 million, providing Clarity with an enviable Balance Sheet to continue progressing its products towards commercialisation.

**"The Placement received phenomenal support, evidenced by the raising of over \$200 million at not only a premium to the last closing share price, but a substantial premium to the share price observed for almost the entirety of CY2025. This places Clarity in a strong position where we can work to complete a number of high value-driving clinical trials, including our pivotal diagnostic Phase III trials, as we progress our products towards commercialisation,"**

**- Dr Alan Taylor**

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# 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.

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## 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 (CLARIFY and AMPLIFY).

An 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 topline data awaiting presentation at world-leading congresses.

Earlier in CY2025 Clarity also shared positive topline data with the <sup>64</sup>Cu-SARTATE and <sup>64</sup>Cu-SAR-Bombesin products from its diagnostic Phase II trials, DISCO in NETs and SABRE in PSMA-negative biochemically recurrent (BCR) prostate cancer patients who are negative on standard-of-care (SOC) imaging, respectively. Based on these results, Clarity is exploring next steps for further late-stage development of <sup>64</sup>Cu-SARTATE and <sup>64</sup>Cu-SAR-Bombesin with the guidance of the US Food and Drug Administration's (FDA) and key medical experts.

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	Theranostic	Diagnostic
<b>SAR-bisPSMA</b>	<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>1</sup> . Cohort Expansion Phase, recruitment ongoing.	<p><b>AMPLIFY</b> – Registrational Phase III positron emission tomography (PET) imaging trial of participants with BCR of prostate cancer following definitive therapy using <sup>64</sup>Cu-SAR-bisPSMA in the US and Australia (<a href="#">NCT06970847</a>)<sup>2</sup>. Recruitment ongoing.</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>3</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>4</sup>. Primary endpoint reached.</p>
<b>SARTATE</b>		<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>5</sup> . Topline data announced.
<b>SAR-Bombesin</b>		<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>6</sup> . Topline data announced.

# CLINICAL & REGULATORY DEVELOPMENT OVERVIEW

## WORLD-LEADING CONFERENCES

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

Clarity is generating exceptional data in clinical and pre-clinical trials 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.

Most recently, the COBRA data with  $^{64}\text{Cu}$ -SAR-bisPSMA in prostate cancer patients with BCR was presented at the Annual Prostate Cancer Foundation Scientific Retreat on the 23-25 October 2025 in Carlsbad, CA. The poster is titled " $^{64}\text{Cu}$ -SAR-bisPSMA PET/CT and SOC PSMA PET/CT in Biochemical Recurrence of Prostate Cancer: A Close-Up of the Phase II COBRA Trial".

During the same time period, Clarity also showcased its data from the DISCO trial, investigating  $^{64}\text{Cu}$ -SARTATE in patients with NETs, at the North American Neuroendocrine Tumour Society in Austin, TX. The poster is titled "DISCO: Safety, Tolerability and Diagnostic performance of  $^{64}\text{Cu}$ -SARTATE compared to  $^{68}\text{Ga}$ -DOTATATE in patients with known or suspected neuroendocrine tumors".

Pre-clinical data on Clarity's SAR-bisFAP pan-cancer theranostic was presented at the World Molecular Imaging Conference 2025 on the 29 September - 3 October in Anchorage, Alaska as a poster (see Discovery section for more details).

## 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:

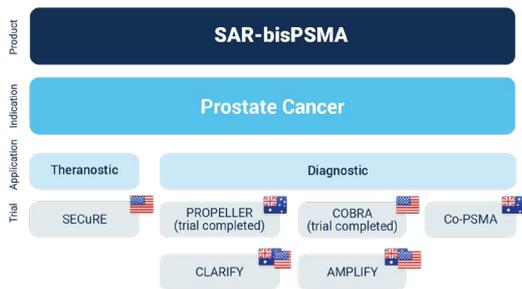
- patients with suspected metastasis who are candidates for initial definitive therapy; and
- patients with BCR of prostate cancer following definitive therapy.

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 disrupt and 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 to improve uptake and retention of the product in tumours

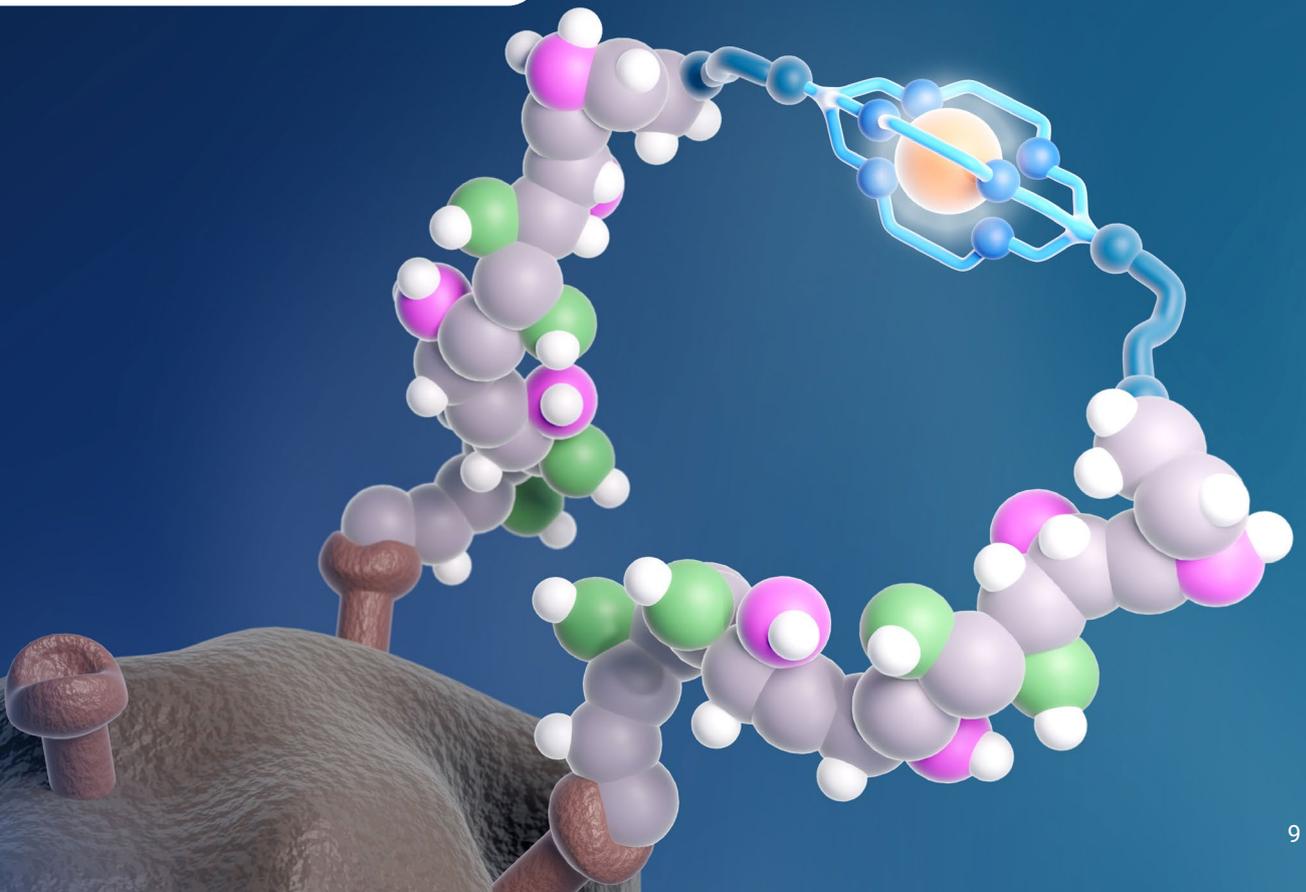


SAR-bisPSMA is being developed for diagnosing, staging and subsequently treating prostate cancer that expresses prostate-specific membrane antigen (PSMA). The product uses copper-64 ( $^{64}\text{Cu}$ ) for imaging ( $^{64}\text{Cu}$ -SAR-bisPSMA) or copper-67 ( $^{67}\text{Cu}$ ) for therapy ( $^{67}\text{Cu}$ -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.

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

Clarity continued to progress recruitment into the Cohort Expansion Phase (Phase II) of the SECuRE trial ([NCT04868604](#))<sup>1</sup>, assessing the safety and efficacy of  $^{67}\text{Cu}$ -SAR-bisPSMA for the treatment of prostate cancer at the 8 GBq dose level.

### SECuRE Trial Overview

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

In this theranostic trial, Clarity first uses its imaging product,  $^{64}\text{Cu}$ -SAR-bisPSMA, to visualise PSMA-expressing lesions and select participants who are most likely to respond well to subsequent therapy with  $^{67}\text{Cu}$ -SAR-bisPSMA.

### Dose Escalation Phase - Completed

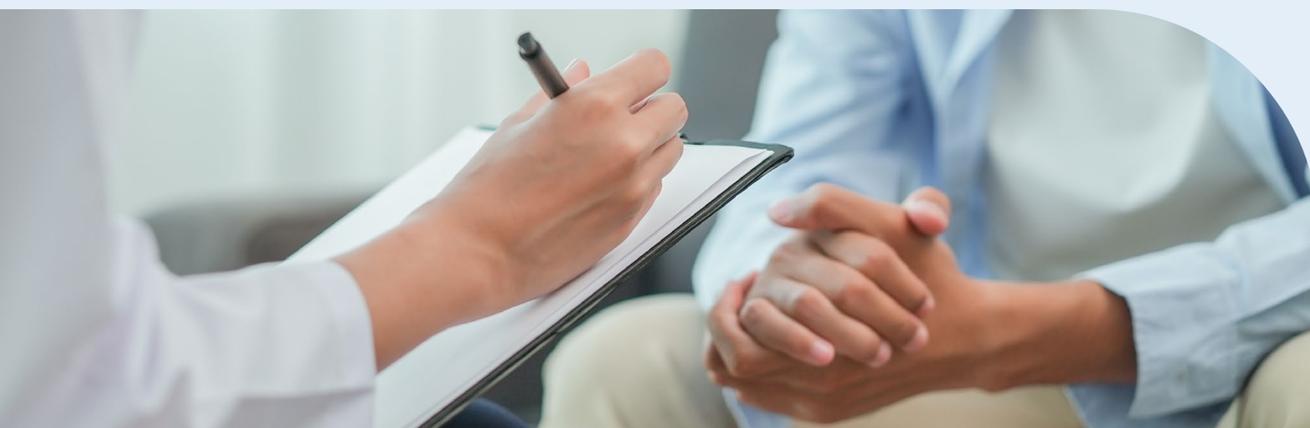
The Dose Escalation Phase of the study was primarily aimed at assessing safety of the  $^{64}\text{Cu}$ -SAR-bisPSMA and  $^{67}\text{Cu}$ -SAR-bisPSMA products and determining an optimal therapeutic dose for  $^{67}\text{Cu}$ -SAR-bisPSMA. As such, each subsequent cohort of participants in the SECuRE trial received an increased dose of the therapeutic drug until the optimal dose was determined. In cohort 1, each participant received a single administration of 4 GBq of  $^{67}\text{Cu}$ -SAR-bisPSMA, in cohort 2 the dose was increased to 8 GBq, and cohort 3 had the highest single dose level of 12 GBq of  $^{67}\text{Cu}$ -SAR-bisPSMA. Cohort 4 assessed multiple doses of  $^{67}\text{Cu}$ -SAR-bisPSMA at the dose level of 12 GBq, with participants receiving a minimum of two and a maximum of four doses of  $^{67}\text{Cu}$ -SAR-bisPSMA.

At the time of the Safety Review Committee (SRC) meeting following the Dose Escalation Phase, 68% of participants across cohorts 1-4 of the study showed reductions in prostate-specific antigen (PSA) levels, despite the vast majority of the participants (77%) only receiving a single dose of  $^{67}\text{Cu}$ -SAR-bisPSMA. Most of these participants had a high level of bone metastases at study entry (77.3%), a high median PSA of 112.86 ng/mL (range 0.1-1503.1) and were heavily pre-treated with  $\geq 3$  lines of therapy (63.6%). Disease control based on radiographic assessment (complete response + partial response + stable disease) was achieved in 78% of the participants. This includes two partial responses and one complete response based on the Response Evaluation Criteria in Solid Tumors v1.1 (RECIST) assessment conducted at the time of the SRC review of the Dose Escalation Phase.

Notably, 92% of pre-chemotherapy participants (12/13) across cohorts 1-4 demonstrated PSA drops greater than 35%, PSA reductions greater than 50% were reached in 61.5% (8/13) of participants, and reductions of 80% or more were achieved in 46.2% (6/13) of participants. These outstanding results were achieved despite many of the 13 pre-chemotherapy participants having considerable disease burden, being heavily pre-treated, and the majority of them only having received a single dose of  $^{67}\text{Cu}$ -SAR-bisPSMA<sup>7</sup>.

$^{67}\text{Cu}$ -SAR-bisPSMA showed a favourable safety profile across cohorts 1-4 with the majority of reported adverse events (AEs) being mild or moderate (Grade 1-2).

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Anaemia and thrombocytopenia were the most prevalent AEs among the haematological events. No overall trends in other haematological parameters or renal safety were observed in any of the cohorts. Only one dose-limiting toxicity (DLT) was reported in the Dose Escalation Phase (transient Grade 4 thrombocytopenia, which improved to Grade 3 after 2 weeks) in a patient in the highest dose cohort (cohort 4). This participant had a baseline PSA of 1503.12 ng/mL, had been treated with multiple lines of therapy, including chemotherapy in the mCRPC setting and multiple doses of <sup>177</sup>Lu-PSMA-617, and had bone metastases prior to entering the study. The participant's baseline characteristics may have contributed to the lowering of the platelet levels. Despite the unfavourable prognosis of this participant, one cycle of <sup>67</sup>Cu-SAR-bisPSMA was still able to reduce his PSA by 10.7% (to 1341.80 ng/mL).

Cohort 2 participants, administered with a single dose of 8 GBq of <sup>67</sup>Cu-SAR-bisPSMA, had the highest rate of PSA response in the trial, and all three participants had disease control based on the RECIST assessment (including one partial response). The PSA reductions were 81.4%, 95.2% and 99.4% at the time of the SRC meeting. Only one participant in this cohort developed <sup>67</sup>Cu-SAR-bisPSMA-related AEs (Grade 1 dry mouth and altered taste, both improved, and Grade 2 fatigue, resolved). No haematological toxicity was reported in the cohort.

**Dose Expansion Phase - Recruiting**

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

Recruitment is currently ongoing into the Dose Expansion Phase which will include 24 participants. A subset of patients will be treated with the combination of 8 GBq of <sup>67</sup>Cu-SAR-bisPSMA with enzalutamide (androgen receptor pathway inhibitor [ARPI]), in line with the positive results from the Enza-p trial<sup>8</sup> and ongoing discussions with and advice from key global medical experts in the field of prostate cancer, including the Company's Clinical Advisory Board members, Prof Louise Emmett and Prof Oliver Sartor, as well as the SRC.

Based on the promising results seen in the Dose Escalation Phase and aligning with Clarity's strategy of bringing <sup>67</sup>Cu-SAR-bisPSMA to earlier stages of disease, the Phase II is also focusing on the evaluation of mCRPC participants in the pre-chemotherapy setting.

The Cohort Expansion Phase of the SECURE trial is expected to further build on the already positive results of <sup>67</sup>Cu-SAR-bisPSMA thus far. This strategy focuses on the commercialisation of the product firstly in the largest market for prostate cancer therapies in mCRPC, with pre-chemotherapy being three times larger than the post-chemotherapy setting and creates opportunities for the use of <sup>67</sup>Cu-SAR-bisPSMA with a range of ARPIs in future clinical development.

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



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

Recruitment into the diagnostic Phase III trial of <sup>64</sup>Cu-SAR-bisPSMA in participants with BCR of prostate cancer, AMPLIFY ([NCT06970847](https://clinicaltrials.gov/ct2/show/study/NCT06970847))<sup>2</sup>, is ongoing.

**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 positron emission tomography (PET) in approximately 220 participants with rising or detectable PSA after initial definitive treatment at clinical sites across the US and Australia. As a pivotal trial, the final study results are intended to provide sufficient evidence to support an application to the US FDA for approval of <sup>64</sup>Cu-SAR-bisPSMA as a new diagnostic imaging agent in BCR of prostate cancer.

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).

The AMPLIFY trial is supported by compelling pre-clinical and clinical data to date, including the Phase I/II COBRA trial in patients with BCR of prostate cancer and the Phase I PROPELLER trial in patients with confirmed prostate cancer pre-definitive treatment (pre-prostatectomy)<sup>9,10</sup>. These earlier studies demonstrated an excellent safety profile and exciting efficacy results, especially in comparison to current standard-of-care (SOC) imaging. PROPELLER showed improved diagnostic performance of <sup>64</sup>Cu-SAR-bisPSMA compared to <sup>68</sup>Ga-PSMA-11 on same-day imaging, including higher number of lesions identified and 2-3 times statistically significant higher lesion uptake and tumour-to-background ratio, favouring <sup>64</sup>Cu-SAR-bisPSMA<sup>9</sup>. The COBRA trial showed that more lesions and more patients with a positive scan were identified on <sup>64</sup>Cu-SAR-bisPSMA PET compared to conventional scans and on next-day vs. same-day imaging. <sup>64</sup>Cu-SAR-bisPSMA also allowed for the identification of lesions in the 2-mm range and was able to detect lesions from 29 days to more than 6 months earlier than SOC PSMA PET agents (latest timepoint for follow-up in the trial)<sup>10</sup>.

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## 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>3</sup>, for  $^{64}\text{Cu}$ -SAR-bisPSMA as a diagnostic agent in patients with prostate cancer prior to undergoing radical prostatectomy.

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

The aim of this trial is to assess the diagnostic performance of  $^{64}\text{Cu}$ -SAR-bisPSMA 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.**

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

Co-PSMA (NCT06907641)<sup>4</sup> Investigator-Initiated Trial (IIT), led by Prof Louise Emmett at St Vincent's Hospital Sydney, achieved its primary endpoint with a significantly higher number of PSMA-positive prostate cancer lesions detected using <sup>64</sup>Cu-SAR-bisPSMA compared to SOC <sup>68</sup>Ga-PSMA-11 PET/CT in patients with BCR and low PSA levels. Study enrolment in the Co-PSMA trial was completed in July 2025 with 50 patients recruited.

Co-PSMA's official study title is "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". This Phase II IIT is evaluating the performance of Clarity's diagnostic product, <sup>64</sup>Cu-SAR-bisPSMA, in comparison to SOC <sup>68</sup>Ga-PSMA-11 in 50 patients with low PSA who are candidates for curative salvage therapy. Eligible patients were required to have had radical prostatectomy with no salvage therapy and a PSA level between 0.2 and 0.75 ng/mL.

The Co-PSMA trial has successfully met its primary endpoint, demonstrating that <sup>64</sup>Cu-SAR-bisPSMA PET/CT detects significantly more lesions per patient than the SOC, <sup>68</sup>Ga-PSMA-11 PET/CT. This result supports the

hypothesis that <sup>64</sup>Cu-SAR-bisPSMA can improve early detection of recurrence and staging of prostate cancer in patients with low PSA who are candidates for curative salvage therapy. Full analysis of all data generated in the Co-PSMA trial is underway, and results of this study will be presented at an upcoming international conference.

The Co-PSMA trial further builds on the growing body of evidence of the enhanced diagnostic performance of <sup>64</sup>Cu-SAR-bisPSMA compared to SOC PSMA PET agents, which are known to have low sensitivity, especially in patients with low PSA levels<sup>11,12</sup>. Improvements in sensitivity, as observed with all diagnostic agents, play a pivotal role in guiding more informed treatment decisions, enabling earlier and more accurate detection of prostate cancer recurrence and ultimately improving patient outcomes.

**"We look forward to Prof Emmett releasing the full Co-PSMA trial data at world-leading congresses as we continue to adhere to the highest standards of clinical research in our aspirations to bring a best-in-class diagnostic option to men with prostate cancer with clear evidence of superiority."**

**Dr Alan Taylor**



# DISCOVERY PROGRAM

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

## SAR-bisFAP

**Pre-clinical data on Clarity's pan-cancer theranostic,  $^{64/67}\text{Cu}$ -SAR-bisFAP, was presented at the World Molecular Imaging Conference (WMIC) 2025 in October in Anchorage, Alaska by Dr. Michele De Franco, a research fellow at the Memorial Sloan Kettering Cancer Center (MSK) and Clarity's collaborator.**

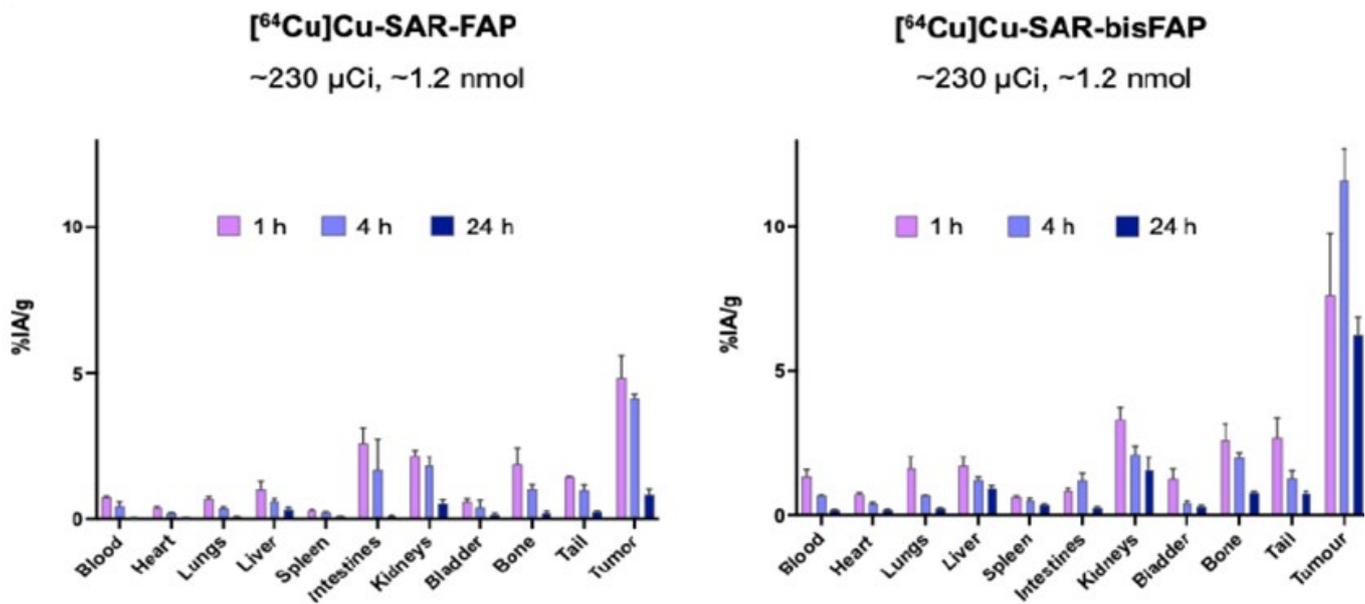
Clarity is developing  $^{64/67}\text{Cu}$ -SAR-bisFAP as potential pan-cancer theranostics targeting fibroblast activation protein (FAP), which is expressed on cancer associated fibroblasts (CAFs), a particular cell type found in the tumour microenvironment (cancer 'infrastructure' called the tumour stroma). FAP is found to be highly expressed in a broad range of cancers (e.g. breast, colorectal, pancreatic, lung, brain and ovarian cancers), but only minimally in normal tissue, making it a promising pan-cancer target for both imaging and treatment of cancers<sup>13</sup>. CAFs form part of the environment surrounding the cancer cells, and they can promote cancer growth and the spread of the tumour throughout the body<sup>14</sup>. Targeting the tumour stroma is an alternative way to treat cancer whereby the architecture of the tumour mass is targeted rather than the tumour cells directly.

As part of the optimisation process, Clarity developed and assessed two versions of the FAP-targeted product, one with a singular targeting molecule, SAR-FAP, and a dimeric version of the same molecule, SAR-bisFAP. Whilst both molecules have shown high tumour-specific uptake and targeting, the dual-targeting SAR-bisFAP has shown superior tumour targeting and retention in FAP-expressing mouse models (**Figure 1**).

Consistent with the enhanced tumour uptake observed using the dual-targeting  $^{64}\text{Cu}$ -SAR-bisFAP,  $^{67}\text{Cu}$ -SAR-bisFAP also showed improved efficacy in therapeutic mice studies, with a doubling in the median survival time of the mice who received 30 MBq of  $^{67}\text{Cu}$ -SAR-bisFAP compared to those who received 30 MBq of the  $^{67}\text{Cu}$ -SAR-FAP monomer or an industry benchmark,  $^{177}\text{Lu}$ -FAP-2286 (median survival time was 28.5, 14.5, and 11.5 days, respectively).

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**Figure 1.** Comparison between the ex vivo biodistribution of <sup>64</sup>Cu-SAR-FAP and <sup>64</sup>Cu-SAR-bisFAP in FAP-positive U-87 MG (human glioblastoma) xenografts, showing how much product accumulated in each location, expressed as the percentage of the injected activity (%IA/g), at 1, 4, and 24 hours post-injection.

Based on this data and results from previously completed pre-clinical studies, Clarity is aiming to progress the dual-targeting SAR-bisFAP theranostic products into human clinical studies, with a focus on the diagnostic in the first instance.



# SUPPLY & MANUFACTURING: THE GAME CHANGER FOR RADIOPHARMACEUTICALS

**Targeted Copper Theranostics (TCTs) hold a number of competitive advantages, including clinical benefits, which Clarity is actively exploring through its clinical program. The logistical, manufacturing and environmental advantages associated with the production of copper isotopes for diagnostic imaging (copper-64) and therapy (copper-67) are key differentiators, allowing for scalability into commercial manufacturing that the current generation of radiopharmaceuticals being developed do not have.**

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

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

In line with this, Clarity has continued to expand its supply chain footprint, with a particular focus on strengthening its copper-67 supply network in this quarter.

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# COPPER-67

**Copper-67 (Cu-67 or <sup>67</sup>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 <sup>177</sup>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>15</sup>. Even with the current infrastructure, access to reactor production capacity will soon become a bottleneck for lutetium-177<sup>16</sup>.

In October 2025, Clarity signed a Supply Agreement for copper-67 with Nusano, Inc. (“Nusano”). Nusano’s 190,000 square foot state-of-the-art facility in West Valley City, Utah is expected to begin operations in late 2025 with copper-67 isotope supply planned to commence in mid-2026.

The proprietary accelerator-based technologies employed by Nusano are particularly well suited for high-volume mass production of copper-67. Nusano is uniquely positioned to regularly supply this therapeutic isotope for both Clarity’s clinical trials and commercial use based on the ease of production and readily available target material. Importantly, Nusano is setting up its own enriched stable isotope production for copper-67 starting materials in the near future, further reducing supply chain risks while allowing for a fully integrated production process in the United States.

The copper-67 supply from Nusano further expands Clarity’s growing network of US-based suppliers, including NorthStar Medical Radioisotopes, LLC (“NorthStar”) and Idaho State University Idaho Accelerator Center (IAC).

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**“In the current geopolitical environment, establishing fully integrated manufacturing capabilities is critical to reducing supply chain exposure to tariffs. Developing a reliable, sustainable and cost-efficient supply framework supports our clinical strategy and ensures scalability to meet future demand. Leveraging copper-67 further strengthens this position, as its production depends solely on electricity and readily available raw materials, mitigating many of the challenges associated with alternative therapeutic isotopes,”**

**Dr Alan Taylor**



# 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.

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# FINANCIALS

Clarity's cash balance at 30 September 2025 was \$253.1 million.

Net operating cash outflows for the September quarter were \$22.7 million, which is higher than the previous quarters net cash outflow of \$9.1 million. The level of spend is in line with expectations and forecast requirements to execute the Company's clinical trials and supply chain build out. It is notable that the previous quarter included the receipt of the FY24 Research & Development Tax Incentive (RDTI) \$11.1 million. If this receipt is excluded, the prior quarter comparative spend was \$20.2 million. Operating cash outflows relate to payments for R&D, staff costs, administration and general operating costs.

As noted above, the Company secured an additional \$192.9 million during the quarter (net of capital raising costs) which will be used to fund a number of important catalysts and milestones, including the Company's pivotal AMPLIFY and CLARIFY trials, amongst others, as well as commercialisation readiness through the build out of both the global commercial team and the continued execution of the Company's strategic manufacturing expansion.

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

## 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 \$1,402,265 for the quarter. This amount includes director fees, salaries and bonuses in respect of performance hurdles for the FY2024-2025.

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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)

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## Appendix 4C

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

**Name of entity**

Clarity Pharmaceuticals Ltd

**ABN**

36 143 005 341

**Quarter ended ("current quarter")**

30 September 2025

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (3 months) \$A'000</b>
<b>1. Cash flows from operating activities</b>		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(14,869)	(14,869)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(22)	(22)
(d) leased assets	-	-
(e) staff costs	(7,770)	(7,770)
(f) administration and corporate costs	(1,751)	(1,751)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	1,842	1,842
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	(125)	(125)
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>(22,695)</b>	<b>(22,695)</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	(16)	(16)
(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)	-	-
<b>2.6</b>	<b>Net cash from / (used in) investing activities</b>	<b>(16)</b>	<b>(16)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	203,638	203,638
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	29	29
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(10,755)	(10,755)
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</b>	<b>Net cash from / (used in) financing activities</b>	<b>192,912</b>	<b>192,912</b>

<b>4.</b>	<b>Net increase / (decrease) in cash and cash equivalents for the period</b>		
4.1	Cash and cash equivalents at beginning of period	84,118	84,118
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(22,695)	(22,695)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(16)	(16)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	192,912	192,912

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	(1,243)	(1,243)
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>253,076</b>	<b>253,076</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	182,084	47,684
5.2	Call deposits <sup>1</sup>	70,992	36,434
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>253,076</b>	<b>84,118</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>	1,402
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 for executive directors.*

7. <b>Financing facilities</b> <i>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.</i>	<b>Total facility amount at quarter end \$A'000</b>	<b>Amount drawn at quarter end \$A'000</b>
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.		

8. <b>Estimated cash available for future operating activities</b>	<b>\$A'000</b>
8.1 Net cash from / (used in) operating activities (item 1.9)	(22,695)
8.2 Cash and cash equivalents at quarter end (item 4.6)	253,076
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	<b>253,076</b>
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	11
<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: 31 October 2025  
 .....

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

**Notes**

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.
2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.
3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.
4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [name of board committee – eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.