



# QUARTERLY ACTIVITY REPORT

SYDNEY, AUSTRALIA  
31 MARCH 2025

For personal use only



# HIGHLIGHTS OF THE QUARTER

During and since the quarter ending 31 March 2025

## Cash Position and RDTI

The Company's cash position at the end of the March quarter was \$95.1 million, with a further \$11.1 million received in April for the FY24 research and development tax incentive (RDTI), inclusive of interest. This combined funding of circa \$106 million is expected to provide cash runway through to the second half of calendar 2026.

## Refocus on high-priority programs

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

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

As part of this prioritisation process, the CL04 trial with  $^{64/67}\text{Cu}$ -SARTATE in paediatric high-risk neuroblastoma and the COMBAT trial with  $^{64/67}\text{Cu}$ -SAR-Bombesin in low prostate-specific membrane antigen (PSMA) metastatic castration-resistant prostate cancer (mCRPC) will be closed.

## SECURE trial

Clarity successfully treated the first of the planned 24 participants in the Cohort Expansion Phase (Phase II) of the SECURE trial with a dose of 8 GBq of  $^{67}\text{Cu}$ -SAR-bisPSMA in April. This follows the recent successful completion of the Dose Escalation Phase of the SECURE trial in March. Based on the safety and efficacy assessment of all cohorts of the study, the Safety Review Committee (SRC) recommended the trial progress to the Cohort Expansion Phase at the 8 GBq of  $^{67}\text{Cu}$ -SAR-bisPSMA dose level and to increase the number of cycles from up to 4 to up to 6.

This first participant in the Cohort Expansion Cohort will be treated with the combination of 8 GBq of  $^{67}\text{Cu}$ -SAR-bisPSMA with enzalutamide (androgen receptor pathway inhibitor [ARPI]), as per the recent protocol amendment to include a subset of participants in the Cohort Expansion Phase to receive this combination. The SECURE trial protocol has also been amended to bring  $^{67}\text{Cu}$ -SAR-bisPSMA to participants at earlier stages of their disease, in the pre-chemotherapy setting.

## World-leading conferences

In February, Clarity presented 2 abstracts at the 2025 American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU) on the COBRA and CLARIFY trials with  $^{64}\text{Cu}$ -SAR-bisPSMA. An overview of Clarity's diagnostic portfolio using  $^{64}\text{Cu}$ -SAR-bisPSMA (PROPELLER, COBRA, CLARIFY and AMPLIFY) was presented at the 2025 Annual International Prostate Cancer Update (IPCU). The COBRA data was also presented at the 2025 PSMA & Beyond Conference in March and at the American Urological Association (AUA) Annual Meeting in April. The data presented at these world-leading conferences show that  $^{64}\text{Cu}$ -SAR-bisPSMA identifies more lesions and earlier than currently approved PSMA positron emission tomography (PET) agents.

For personal use only



# HIGHLIGHTS OF THE QUARTER CONT.

During and since the quarter ending 31 March 2025

---

## Fast Track Designation

Clarity has 3 US Food and Drug Administration (FDA) Fast Track Designations (FTDs) for its SAR-bisPSMA agent, 1 for a therapeutic and 2 for diagnostic prostate cancer indications. Most recently, the therapeutic  $^{67}\text{Cu}$ -SAR-bisPSMA product was granted an FTD for the treatment of adult patients with PSMA-positive mCRPC who have been previously treated with ARPI. Earlier in the quarter, an FTD was also granted for the diagnostic  $^{64}\text{Cu}$ -SAR-bisPSMA product for positron emission tomography (PET) imaging of PSMA-positive prostate cancer lesions in patients with biochemical recurrence (BCR) of prostate cancer following definitive therapy. These 2 FTDs, in conjunction with the FTD previously received for  $^{64}\text{Cu}$ -SAR-bisPSMA for PET imaging of PSMA-positive prostate cancer lesions in patients with suspected metastasis who are candidates for initial definitive therapy, demonstrate the quality of the data generated to date on the SAR-bisPSMA products in addressing serious unmet needs in prostate cancer.

The 3 FTDs granted to Clarity provide a number of benefits that would reduce the review time needed to bring  $^{64}\text{Cu}$ -SAR-bisPSMA and  $^{67}\text{Cu}$ -SAR-bisPSMA to market, potentially improving the diagnosis and treatment of prostate cancer patients sooner.

---

## Discovery Platform

Clarity added a new asset into the Targeted Copper Theranostic (TCT) portfolio, SAR-trastuzumab, which targets HER2, a receptor overexpressed in many cancers, including some types of breast, lung, and gastric cancers. Clarity will focus its development on HER2-positive breast cancer, renewing its focus on this important indication, and intends to conduct a Phase I/IIa theranostic study in HER2-positive breast cancer patients to address a significant unmet clinical need.

Pre-clinical data on SAR-trastuzumab has recently been published.  $^{64}\text{Cu}$ -SAR-trastuzumab was shown to target HER2-positive cancer cells to a very high level.  $^{67}\text{Cu}$ -SAR-trastuzumab was shown to reduce the growth of HER2-expressing tumours in a dose-dependent manner and improved the survival of mice treated with the product.

---

Clarity has signed a Supply Agreement with EirGenix, Inc. for the clinical development and future commercial supply of clinical-grade Good Manufacturing Practice (GMP) trastuzumab biosimilar, EG12014.

---

## Copper-64 Supply

Clarity strengthened its supply of the copper-64 ( $\text{Cu-64}$  or  $^{64}\text{Cu}$ ) isotope in the US and Australia with the signing of two new Supply Agreements.

In the US, Clarity has signed a high volume commercial-scale agreement with Nusano. Their 190,000 square foot facility in West Valley City, Utah is capable of producing more than 1,000 Ci (37,000 GBq) of copper-64 per day at capacity, which translates into more than 18,000 patient doses per day at 200 MBq per dose, with a 48 hour shelf-life, far in excess of commercial scale demands across multiple large indications. The copper-64 supply from Nusano will complement Clarity's existing network of US-based suppliers to ensure seamless, abundant production of this diagnostic isotope as the Company is progressing a number of late-stage clinical trials and fast approaching commercialisation.

In Australia, Clarity signed a Supply Agreement with The University of Queensland (UQ) Centre for Advanced Imaging at the Australian Institute for Bioengineering and Nanotechnology (AIBN). This Agreement will facilitate seamless supply of the isotope and expand the manufacturing capability of the diagnostic  $^{64}\text{Cu}$ -SAR-bisPSMA product for Clarity's 2 Phase III registrational trials, CLARIFY and AMPLIFY, as well as the Co-PSMA Investigator-Initiated Trial (IIT) at St Vincent's Hospital, Sydney led by Prof Louise Emmett. The Agreement will also support the roll-out of Clarity's pre-clinical programs, including the SAR-bisFAP and SAR-trastuzumab programs.

For personal use only

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 2025.



For personal use only

## Executive Chairperson's Letter

Dear fellow Shareholders,

I am pleased to share the progress achieved by Clarity during and since the quarter ending 31 March 2025 as we progress our pipeline of best-in-class products.

This year is shaping up to be an interesting one with many new developments and news unravelling not only at Clarity or in the radiopharmaceutical sector, but also in the US economy and the global geo-political environment. While the fundamentals of our Company remain unchanged, with unwavering focus on science and the highest standard of clinical research towards commercialisation, the recent turbulence in the financial markets have had an effect on Clarity, necessitating some adjustments in order for us to succeed in reaching our ultimate goal of improving treatment outcomes for people with cancer.

Clarity's products continue to generate exciting data and progress through clinical development with substantial momentum, but unfortunately our share price has been significantly affected by a number of events external to the Company since the US Presidential election in November 2024. These include a fall of over 30% in the XBI (US Biotech Index) from its peak in November 2024 to its low in April 2025, corrections in global market indices, including the S&P500 and NASDAQ in the US, as well as

the All Ordinaries and the ASX200 in Australia; changes within the US Food and Drug Administration (FDA); global tariff and trade war concerns and the collapse of Opthea in the local market.

With the recent receipt of an \$11.1 million R&D Tax Incentive (inclusive of interest) offered by the Australian Government, we now have approximately \$106 million in cash to progress our pipeline of Targeted Copper Theranostics (TCTs). Nevertheless, our Board of Directors thought it would be prudent to make some adjustments to our programs to stretch out the funding runway during the current period of volatility in our key focus market, the US. As a result, our Board made the difficult yet important decision to close 2 of our theranostic trials at this time, CL04 with <sup>64/67</sup>Cu-SARTATE in neuroblastoma and COMBAT with <sup>64/67</sup>Cu-SAR-Bombesin in prostate cancer. This step was not associated with any safety concerns or adverse findings related to these respective products, making this a disheartening outcome. However, theranostic trials, such as CL04 and COMBAT, require a significant level of investment from the Company compared to diagnostic programs, bear a higher degree of risk and have a longer path to market. As such, we are confident that focusing the Company's strategy on high-value clinical and Discovery programs that have high probabilities of success and provide early opportunities for commercialisation is the right path forward.

Our key focus and priority will be on our lead product, <sup>64/67</sup>Cu-SAR-bisPSMA, for both diagnostic and therapeutic applications in prostate cancer. SAR-bisPSMA was recently awarded three US Food and Drug Administration (FDA) Fast Track Designations (FTDs) based on the data from comparator diagnostic trials versus standard-of-care (SOC) prostate-specific membrane antigen (PSMA) imaging, as well as the Dose Escalation Phase of the SECURE trial. We did a deep dive and found that products with three or more FTDs are extremely rare. For example, a blockbuster drug called Zanubrutinib, which accounted for USD1.3 billion in revenue in 2023, was granted FTDs for the treatment of patients with Waldenström macroglobulinemia, relapsed or refractory marginal zone lymphoma who have received at least

one anti-CD20-based regimen and relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy. We believe our 3 FTDs place us in a strong position to disrupt the PSMA-targeted diagnostic and therapeutic markets with their potential size of well in excess of US\$10 billion.

Most recently, we successfully completed the Dose Escalation Phase of the SECuRE theranostic trial with favourable safety and efficacy data for <sup>67</sup>Cu-SAR-bisPSMA and treated our first participant in the Cohort Expansion (Phase II) stage. We will look to efficiently progress the Phase II in 24 participants with metastatic castration-resistant prostate cancer (mCRPC) at an 8 GBq of <sup>67</sup>Cu-SAR-bisPSMA dose level. We are particularly excited about the data from the Dose Escalation Phase in mCRPC participants in the pre-chemotherapy setting with 92% of these participants (12/13) demonstrating prostate-specific antigen (PSA) drops greater than 35%. PSA reductions greater than 50% were reached in 61.5% (8/13) of participants, and reductions of 80% or more were achieved in 46.2% (6/13) of participants. These outstanding results were achieved despite many of the 13 pre-chemotherapy participants having considerable disease burden, being heavily pre-treated, and the majority of them only receiving a single dose of <sup>67</sup>Cu-SAR-bisPSMA. As a result, we are focused on bringing <sup>67</sup>Cu-SAR-bisPSMA to earlier lines of prostate cancer therapy. We are also investigating the benefits of combination therapy, where a subset of participants in the SECuRE trial will be treated with <sup>67</sup>Cu-SAR-bisPSMA and enzalutamide based on the results from Prof Emmett's Enza-p trial and in consultation with global thought leaders in the prostate cancer space.

In diagnostic indications, we look forward to early commercialisation following the completion of 2 Phase III diagnostic trials, CLARIFY and AMPLIFY, in pre-prostatectomy and biochemical recurrence (BCR) settings, respectively. We are also eagerly awaiting the outcomes of a head-to-head Phase II investigator-initiated trial (IIT), Co-

PSMA, led by Prof Lousie Emmett at St Vincent's Hospital Sydney, that seeks to evaluate the performance of <sup>64</sup>Cu-SAR-bisPSMA against SOC <sup>68</sup>Ga-PSMA-11 in participants with BCR of prostate cancer.

As we continue generating promising data with this optimised asset and progressing it through clinical development, we believe SAR-bisPSMA has blockbuster potential.

As part of our refocus, we will also look to progress our 2 diagnostic programs: in NETs with <sup>64</sup>Cu-SARTATE and in prostate cancer with <sup>64</sup>Cu-SAR-Bombesin in the first instance, pending positive results from the respective Phase II studies. The DISCO trial in NETs and the SABRE trial in BCR of prostate cancer have both successfully completed all study participant assessments and are currently undergoing data cleaning activities. The topline data from those trials are expected to be announced in the coming months. We will continue investigating these products in larger therapeutic and diagnostic indications, such as breast cancer. We are also excited to progress our Discovery Program, aiming to bring key assets, such as SAR-bisFAP and SAR-trastuzumab, to the clinic.

We believe that our refocus will allow the most efficient allocation of resources, demonstrates strong alignment with Clarity's core diagnostic and therapeutic strategies and is in line with our long-term value creation objectives.

As we continue progressing our key programs and get closer to commercialisation, we are also cognisant of the fact that a robust supply and manufacturing strategy is imperative for successful adoption of radiopharmaceutical products and their expansion in the oncology practice. The current market leaders in PSMA PET imaging face several limitations associated with their short half-life (less than 2 hours vs. 12.7 hours for copper-64). These include short shelf-lives, restricted availability throughout the imaging site's workday, narrow imaging windows and limited geographical reach.



At Clarity, we are determined to overcome these limitations and lay a strong foundation for the successful roll-out of TCTs globally. As such, during and since the quarter we continued to strengthen our supply strategy with the signing of 2 Supply Agreements for copper-64. In the US, we secured a commercial-scale agreement for copper-64 with Nusano who are expected to begin supply in early 2026 from their state-of-the-art facility in Utah. Nusano's proprietary accelerator-based technology is a game-changer for high-volume cost-effective mass production of copper-64, being capable of producing more than 18,000 patient doses per day at 200 MBq per dose, with a 48 hour shelf-life. Combined with Clarity's existing copper-64 supply network in the US, this is well in excess of commercial-scale demands across multiple large oncology indications. The ability to make isotopes and products in the US for the treatment of the American people is an important advantage in the current geopolitical and economic environment. By building a supply chain that is fully integrated, from high-volume isotope production to centralised product manufacture and to delivery of these ready-to-use diagnostics to imaging sites in every state of the US on time and on demand, we are aiming to build a model that is impervious to economic and political instability.

In Australia, we signed a Supply Agreement for copper-64 with The University of Queensland (UQ) advanced imaging at the Australian Institute for Bioengineering and Nanotechnology (AIBN). This supply will help to expand the manufacturing capability of the diagnostic  $^{64}\text{Cu}$ -SAR-bisPSMA product for the Phase III CLARIFY and AMPLIFY registrational trials and the SECURE theranostic trial in Australia, as well as for the Co-PSMA IIT.

AIBN's copper-64 supply will also support the advancement of Clarity's pre-clinical programs, including SAR-bisFAP and SAR-trastuzumab trials. We are passionate about building a successful Australian life-sciences story and benefiting Australian patients and their treating clinicians. As such, this agreement with the UQ AIBN not only builds on years of close ties between Clarity and the Australian scientific and clinical communities but also reflects our strong focus on continued partnership and synergies that can be derived from these important collaborations. We are dedicated to continuing to work with the leading R&D organisations in Australia and giving back to the scientific and clinical community in our country.

We remain well funded to continue leveraging the powerful momentum of impressive data, strong science and the radiopharmaceutical sector and look forward to progressing our differentiated platform of diagnostic and therapeutic assets with the goal of improving outcomes for cancer patients in need of novel treatments and diagnostics around the world. We again thank our shareholders for your support and look forward to providing further updates on the continued progress of our therapy and diagnostic programs.

Yours sincerely,

Dr Alan Taylor  
Executive Chairperson  
Clarity Pharmaceuticals Ltd



# CLINICAL & REGULATORY DEVELOPMENT OVERVIEW

Clarity is a global leader in next-generation radiopharmaceuticals with its Targeted Copper Theranostic (TCT) platform of products. Clarity's products use the "perfect pairing" of copper isotopes, copper-64 (Cu-64 or  $^{64}\text{Cu}$ ) for imaging and copper-67 (Cu-67 or  $^{67}\text{Cu}$ ) for therapy, which deliver a compelling combination of high accuracy and high precision in the treatment of a range of cancers.

Clarity's 3 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 3 programs are in clinical development for the diagnosis and/or treatment of various cancers addressing unmet clinical needs. In addition to these core products, Clarity's SAR Technology, as well as other proprietary platforms and know-how, are used in the Company's extensive Discovery Program, which explores a range of new products, thereby creating a pipeline of new radiopharmaceuticals to expand the existing portfolio.

For personal use only

## 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 cancers, including prostate, breast and other cancers

## SARTATE

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

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 3 lead products, SAR-bisPSMA, SARTATE and SAR-Bombesin, are actively progressing through 6 clinical trials: 1 theranostic trial with its lead product, SAR-bisPSMA, 5 diagnostic trials, including 2 Phase III registrational trials, CLARIFY and AMPLIFY, and an Investigator-Initiated Trial (IIT) at St Vincent's Hospital Sydney.

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

For personal use only

	Theranostic	Diagnostic
SAR-bisPSMA	<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 and Australia (<a href="#">NCT04868604</a>)<sup>1</sup></p>	<p><b>CLARIFY</b> – Registrational Phase III positron emission tomography (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>2</sup></p> <p><b>AMPLIFY</b> – Registrational PET imaging trial of participants with biochemical recurrence (BCR) of prostate cancer following definitive therapy using <sup>64</sup>Cu-SAR-bisPSMA (in start-up)</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>3</sup></p>
SARTATE		<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>4</sup></p>
SAR-Bombesin		<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>5</sup></p>

# CLINICAL & REGULATORY DEVELOPMENT OVERVIEW

## FAST TRACK DESIGNATION

**The United States (US) Food and Drug Administration (FDA) granted Clarity 3 Fast Track Designations (FTD) for the SAR-bisPSMA agent.**

The <sup>67</sup>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 <sup>64</sup>Cu-SAR-bisPSMA diagnostic product was granted 2 FTDs for PET imaging of PSMA-positive prostate cancer lesions in 2 indications:

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

The FDA's FTD is designed to expedite the development and regulatory review of novel drugs addressing serious conditions with significant unmet medical needs. For SAR-bisPSMA, it provides a number of product development advantages. The designations pave the way for a faster review process once Clarity submits its product approval applications.

Additionally, it enables more frequent communication with the FDA, allowing for rapid resolution of queries during development. Furthermore, Clarity can submit completed sections of its application as they are ready, rather than waiting for the entire package to be finished before it can be lodged with the FDA. These benefits would reduce the review time needed to bring this innovative and proprietary molecule to the prostate cancer imaging and therapy markets.

These 3 FTDs demonstrate the quality of the data generated to date on the <sup>64</sup>Cu-SAR-bisPSMA and <sup>67</sup>Cu-SAR-bisPSMA products in addressing serious unmet needs in prostate cancer. The FTDs will enable Clarity to accelerate the development of its comprehensive program with the optimised SAR-bisPSMA agent to be used in patients with prostate cancer throughout the management of their cancer, from initial diagnosis to late-stage disease. This represents an important opportunity to disrupt and considerably advance the diagnostic and treatment landscapes of the large prostate cancer market.

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

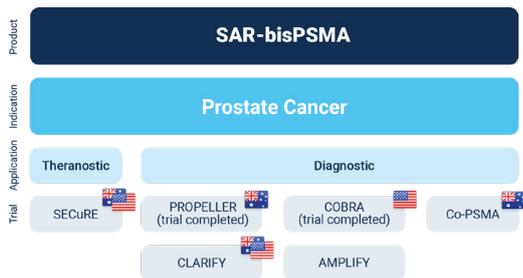
**Dr Alan Taylor**

For personal use only

# PRODUCT UPDATES

## SAR-bisPSMA: PROSTATE CANCER

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

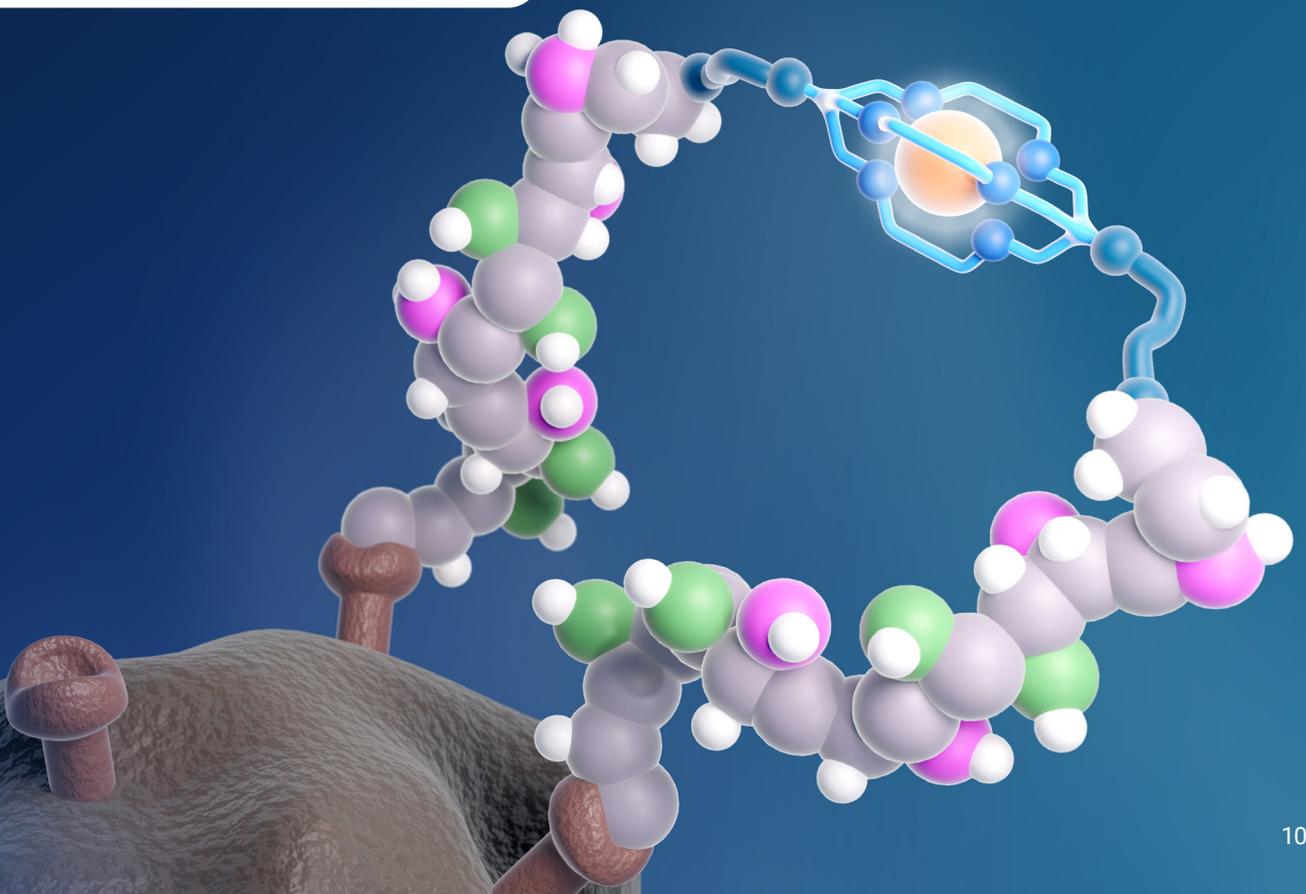


SAR-bisPSMA is being developed for diagnosing, staging and subsequently treating cancers that express prostate-specific membrane antigen (PSMA). The product uses either copper-64 ( $^{64}\text{Cu}$ ) for imaging ( $^{64}\text{Cu}$ -SAR-bisPSMA) or copper-67 ( $^{67}\text{Cu}$ ) for therapy ( $^{67}\text{Cu}$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

For personal use only



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

Clarity treated its first participant in the Cohort Expansion Phase (Phase II) of the SECURE trial (NCT04868604)<sup>1</sup> with their first dose of 8 GBq of  $^{67}\text{Cu}$ -SAR-bisPSMA in April 2025. This follows a successful completion of the Dose Escalation Phase in March 2025 with the Safety Review Committee (SRC) recommending the trial progress to the Phase II at the 8 GBq of  $^{67}\text{Cu}$ -SAR-bisPSMA dose level with an increase of the number of cycles from up to 4 to up to 6 based on the safety and efficacy data demonstrated in every cohort of the study.

The Dose Escalation Phase of the SECURE trial included cohorts 1-4 where 68% of participants have shown reductions in prostate-specific antigen (PSA) levels, despite the vast majority of 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 so far (including 2 partial responses and 1 complete response observed to date based on the Response Evaluation Criteria in Solid Tumors v1.1 [RECIST] assessment).

**The complete response was seen in a patient dosed twice at 12 GBq. This is the second complete response recorded following  $^{67}\text{Cu}$ -SAR-bisPSMA treatment, the first being the patient previously reported to have a complete response following 2 doses at 8 GBq (first dose administered through the SECURE trial, and a second dose administered under the the United States [US] Food and Drug Administration [FDA] Expanded Access Program [EAP]).**

$^{67}\text{Cu}$ -SAR-bisPSMA has shown a favourable safety profile across all cohorts. The majority of reported adverse events (AEs) were Grade 1-2, with anaemia and thrombocytopenia being the most prevalent among the haematological events. No overall trends in other haematological parameters or renal safety were observed in any of the cohorts. Only 1 Dose Limiting Toxicity (DLT) has been reported in the trial (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  $^{177}\text{Lu}$ -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, which included a very high PSA and being heavily pre-treated, 1 cycle of  $^{67}\text{Cu}$ -SAR-bisPSMA was still able to reduce his PSA by 10.7% (to 1341.80 ng/mL).

### Pre-chemotherapy participants

Thirteen participants across cohorts 1-4 in the SECURE trial were naïve to taxanes in the mCRPC setting (pre-chemotherapy), including 2 in cohort 1 and 3 in cohort 2. The majority of pre-chemotherapy participants had bone metastases (69.2%) with a median PSA of 42.41 ng/mL (range 0.1-182.4) at study entry. Almost half of these participants received  $\geq 3$  lines of therapy prior to trial enrolment (46.2%).

Despite the heavy disease burden and the majority of participants only receiving single doses of  $^{67}\text{Cu}$ -SAR-bisPSMA, there was an outstanding result observed in the pre-chemotherapy setting. Out of the total of 13 pre-chemotherapy participants across all cohorts, 12 had 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. Disease control based on the RECIST assessment was also observed in 11 out of 12 pre-chemotherapy participants (92%) who had measurable disease at baseline. One participant reached a complete response with 2 doses of 12 GBq in cohort 4, 2 participants had partial responses (cohort 2 and cohort 4), and 8 participants achieved stable disease at this time.

Three participants in the pre-chemotherapy setting of the SECuRE trial had previously been treated with actinium-225 based radioligand therapies (RLT) and, in 1 case, in combination with lutetium-177 based therapy. All 3 participants showed reductions in PSA levels following treatment with <sup>67</sup>Cu-SAR-bisPSMA in the trial. Notably, 1 of these 3 participants showed a PSA reduction of 83.4% following the administration of 2 doses of 12 GBq of <sup>67</sup>Cu-SAR-bisPSMA in cohort 4, despite being heavily pre-treated. The lines of therapy administered to the patient prior to the SECuRE trial enrolment included androgen deprivation therapy (ADT), 2 androgen receptor pathway inhibitors (ARPIs), autologous cellular immunotherapy, and investigational agents (immunotherapy and <sup>177</sup>Lu-PSMA-I&T plus <sup>225</sup>Ac-J591).

Safety assessment in pre-chemotherapy participants was comparable to the overall patient population with most AEs being Grade 1 and Grade 2.

### SECuRE Trial Design and Protocol

SECuRE is a Phase I/IIa theranostic trial for identification and treatment of an advanced form of prostate cancer, mCRPC. It is a multi-centre, single arm, dose escalation study with a cohort expansion. The aim of this trial is to determine the safety and tolerability of both <sup>64</sup>Cu-SAR-bisPSMA and <sup>67</sup>Cu-SAR-bisPSMA, as well as the efficacy of <sup>67</sup>Cu-SAR-bisPSMA as a therapy.

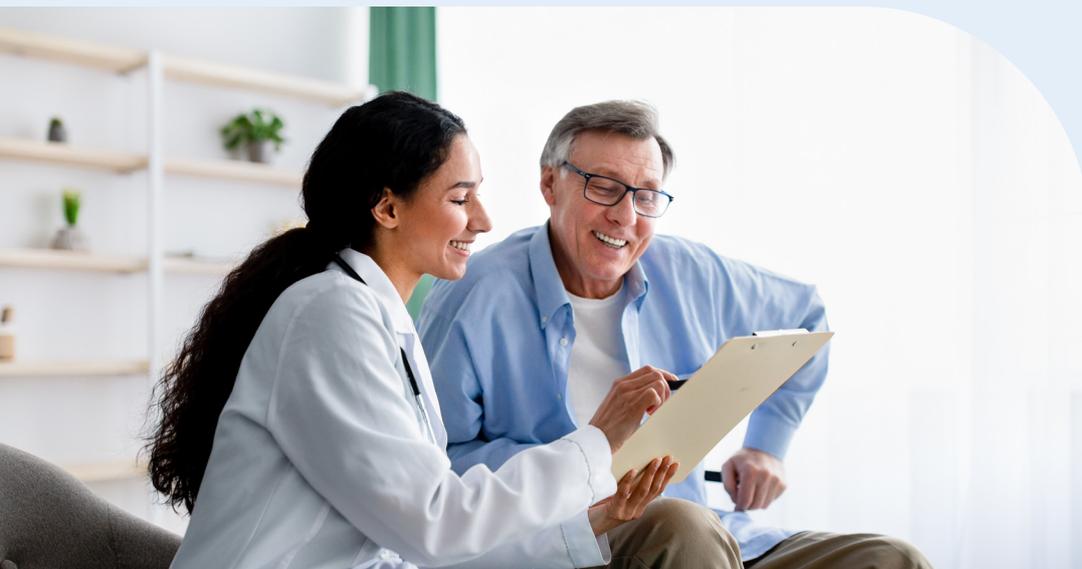
In this theranostic trial, Clarity first uses its imaging product, <sup>64</sup>Cu-SAR-bisPSMA, to visualise PSMA-expressing lesions and select participants who are most likely to respond well to subsequent therapy with <sup>67</sup>Cu-SAR-bisPSMA. The study consists of the Dose Escalation Phase (Phase I) and the Cohort Expansion Phase (Phase II).

### Dose Escalation Phase

The Dose Escalation Phase of the study was primarily aimed at assessing safety of the <sup>64</sup>Cu-SAR-bisPSMA and <sup>67</sup>Cu-SAR-bisPSMA products and determining an optimal therapeutic dose for <sup>67</sup>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 <sup>67</sup>Cu-SAR-bisPSMA, in cohort 2 the dose was increased to 8 GBq and cohort 3 was the last to assess single doses of <sup>67</sup>Cu-SAR-bisPSMA at the highest dose level of 12 GBq. The recently completed cohort 4 was the first to assess multiple doses of <sup>67</sup>Cu-SAR-bisPSMA at the dose level of 12 GBq, with participants receiving a minimum of 2 and a maximum of 4 doses of <sup>67</sup>Cu-SAR-bisPSMA at 12 GBq.

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

Cohort 2 (single dose of 8 GBq of <sup>67</sup>Cu-SAR-bisPSMA) with 3 participants had the highest rate of PSA response in the trial, and all participants in the cohort had disease control based on the RECIST assessment (including 1 partial response). The PSA reductions were 81.4%, 95.2% and 99.4%. Only 1 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.



**Cohort Expansion Phase**

Based on these safety and efficacy data in the Dose Escalation Phase, where exceptional efficacy signals were observed at lower radiation doses, 8 GBq was chosen as an optimal dose for the Cohort Expansion Phase. Its participants will be administered with multiple doses of 8 GBq of <sup>67</sup>Cu-SAR-bisPSMA to assess safety and efficacy of the product.

The SECuRE trial protocol has been amended to include evaluation of mCRPC participants who have not received chemotherapy in the metastatic (pre-chemotherapy) setting in the Cohort Expansion Phase. This is aligned with Clarity's strategy of bringing <sup>67</sup>Cu-SAR-bisPSMA to participants with earlier stages of the disease and is based on the promising safety and efficacy data, especially in pre-chemotherapy participants of the SECuRE trial.

The protocol amendment also incorporates an increase in the number of participants in the Cohort Expansion Phase of the trial from 14 to 24, in which a subset of participants will receive the combination of <sup>67</sup>Cu-SAR-bisPSMA with enzalutamide, an ARPI. This change is aligned with the positive results of the Enza-p trial presented by Prof Emmett first at the European Society for Medical Oncology in 2023<sup>6</sup> and more recently at the American Society of Clinical Oncology Genitourinary Cancers (ASCO GU) Symposium in 2025<sup>7</sup>, which confirmed the hypothesis that targeting both androgen signalling and PSMA receptors concurrently would improve anti-cancer activity in mCRPC.

The protocol amendments are expected to further enhance the already positive results of <sup>67</sup>Cu-SAR-bisPSMA observed in the SECuRE trial to date. This strategy focuses on the commercialisation of the product firstly in the largest market for prostate cancer therapies in mCRPC, with pre-chemotherapy being 3 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.

In preparation for the Cohort Expansion Phase, Clarity rolled out its improved <sup>67</sup>Cu-SAR-bisPSMA product formulation. The enhanced formulation allows for room temperature stability, supply and scalability, which are essential for late-stage clinical trials and streamlined commercial-scale manufacture.

For personal use only



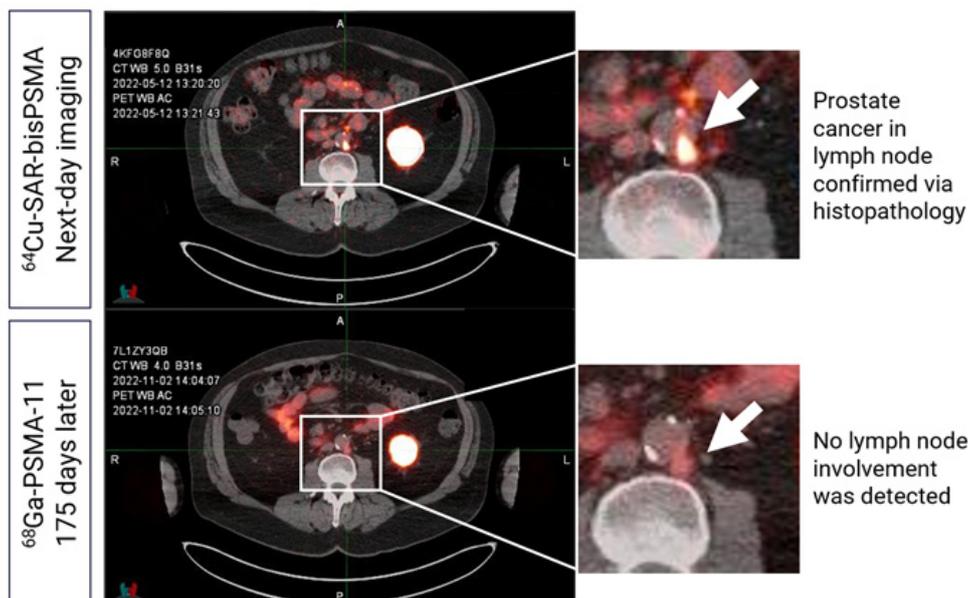
# AMPLIFY: Diagnostic Phase III registrational <sup>64</sup>Cu-SAR-bisPSMA trial

Following the positive guidance from the US FDA on a pivotal Phase III trial for <sup>64</sup>Cu-SAR-bisPSMA diagnostic in prostate cancer patients with BCR in October 2024, the trial, called AMPLIFY, is expected to commence in the coming months.

**AMPLIFY** (<sup>64</sup>Cu-SAR-bisPSMA Positron Emission Tomography: A Phase 3 Study of Participants with Biochemical Recurrence of Prostate Cancer) will be a non-randomised, single-arm, open-label, multi-centre, diagnostic clinical trial of <sup>64</sup>Cu-SAR-bisPSMA positron emission tomography (PET) in approximately 220 participants with rising or detectable PSA after initial definitive treatment. As a pivotal trial, the final study results are intended to provide sufficient evidence to support an application to the US FDA for approval of <sup>64</sup>Cu-SAR-bisPSMA as a new diagnostic imaging agent in prostate cancer.

The aim of the Phase III trial is to investigate the ability of <sup>64</sup>Cu-SAR-bisPSMA PET/computed tomography (CT) to detect recurrence of prostate cancer. Evaluation will be across 2 imaging timepoints, Day 1 (day of administration, same-day imaging) and Day 2 (approximately 24 hours post administration, next-day imaging).

The AMPLIFY trial is supported by compelling preclinical and clinical data to date, including the Phase I/II COBRA trial in patients with BCR of prostate cancer, and the Phase I PROPELLER trial in patients with confirmed prostate cancer pre-prostatectomy/pre-definitive treatment, which have been presented at leading medical conferences, including the prestigious European Association of Nuclear Medicine (EANM) Congress 2024 in October where an abstract was selected as a Top-Rated Oral Presentation. In February, abstracts outlining additional data from the COBRA trial were presented at the ASCO GU 2025 and at the 2025 Annual International Prostate Cancer Update (IPCU). The COBRA data was also presented at the 2025 PSMA & Beyond Conference in March and at the American Urological Association (AUA) Annual Meeting in April.



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

For personal use only

The COBRA trial assessed the safety and diagnostic performance of <sup>64</sup>Cu-SAR-bisPSMA to detect prostate cancer in patients with BCR of the disease and who had a negative or equivocal standard of care (SOC) scan at baseline. The data showed that <sup>64</sup>Cu-SAR-bisPSMA is safe, detected more lesions than approved SOC PSMA imaging agents for prostate cancer and much smaller lesions than anticipated, including a lesion with a diameter of less than 2 mm. The most recent findings from the COBRA trial established that <sup>64</sup>Cu-SAR-bisPSMA was able to detect lesions from 29 days to more than 6 months earlier than SOC PSMA PET agents (**Figure 1**). Additionally, in this subset of participants in the study who underwent follow-up SOC PSMA PET, 70% of participants had a positive scan on same-day imaging and 90% on next-day imaging using <sup>64</sup>Cu-SAR-bisPSMA, compared to 60% of participants using SOC PSMA PET where only same-day imaging is possible. The number of lesions across all participants (average sum of lesions across all readers) identified by <sup>64</sup>Cu-SAR-

bisPSMA was also higher (26.3 lesions on same-day imaging, 52.6 on next-day imaging) than that detected by SOC PET agents (20 lesions). Across all participants in the study, histopathology confirmed the presence of prostate cancer in lesions identified by <sup>64</sup>Cu-SAR-bisPSMA in up to 78% of cases in which biopsies were performed. This rate of true positivity was considerably higher compared to less sensitive methods (e.g. SOC imaging) used to verify the <sup>64</sup>Cu-SAR-bisPSMA PET findings. With regards to the biopsies, 100% of lesions which were located outside of the prostate bed were determined as positive for prostate cancer, with only 2 participants showing negative results. These 2 participants had lesions located in the prostate bed and had undergone the complete removal of their prostate as part of their initial treatment. The prostate bed is an area notoriously difficult to biopsy following surgery due to anatomical changes and scarring of surrounding tissues as a result of the procedure, which may lead to negative results despite the presence of cancer.

For personal use only

— **Investigators stated that they would change their intended treatment plan in approximately half (48%) of their patients due to the findings of the <sup>64</sup>Cu-SAR-bisPSMA PET**



## CLARIFY: Diagnostic Phase III registrational $^{64}\text{Cu}$ -SAR-bisPSMA trial

During the reporting period, Clarity progressed recruitment in its first Phase III registrational trial, CLARIFY ([NCT06056830](#))<sup>2</sup>, for  $^{64}\text{Cu}$ -SAR-bisPSMA as a diagnostic agent in patients with prostate cancer prior to undergoing radical prostatectomy, with recruitment now taking place in over 20 centres.

For personal use only

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 383 participants with confirmed prostate cancer who will be proceeding to radical prostatectomy and pelvic lymph node dissection (removal of lymph nodes from the pelvic region).

The aim of the Phase III trial is to assess the diagnostic performance of  $^{64}\text{Cu}$ -SAR-bisPSMA PET in detecting prostate cancer within the pelvic lymph nodes. Evaluation will be across 2 imaging timepoints, Day 1 (1-4 hours post administration, same-day imaging) and Day 2 (approximately 24 hours post administration, next-day imaging).

An abstract outlining details from the CLARIFY trial was presented at the ASCO GU 2025 in February. In the same month, the study was also presented at the Annual IPCU conference.

**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.**



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

The Co-PSMA (NCT06907641)<sup>3</sup> Investigator-Initiated Trial (IIT) evaluating the performance of Clarity's diagnostic product, <sup>64</sup>Cu-SAR-bisPSMA, in comparison to the SOC <sup>68</sup>Ga-PSMA-11 product for the detection of prostate cancer recurrence, is ongoing with recruitment progressing well.

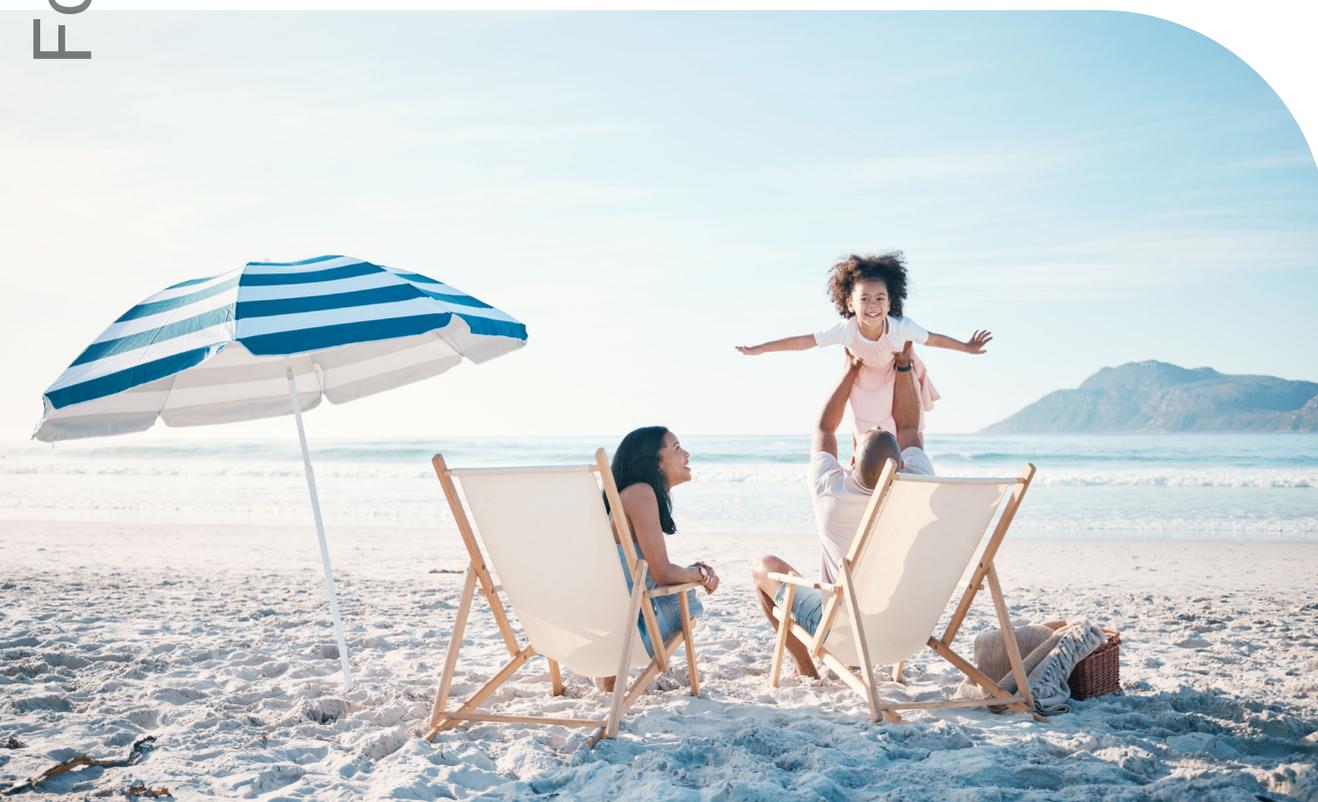
For personal use only

**Co-PSMA** stands for "Comparative performance of <sup>64</sup>Copper [<sup>64</sup>Cu]-SAR-bis-PSMA 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". It is led by **Prof Louise Emmett** at one of the most prominent hospitals in the country, St Vincent's Hospital Sydney.

The Co-PSMA trial is a prospective, Phase II imaging trial in 50 patients with BCR post-radical prostatectomy who are being considered for curative salvage radiotherapy. The primary objective of the study is to compare the detection rate of sites of prostate cancer recurrence, as determined by number of lesions per patient, between <sup>64</sup>Cu-SAR-bisPSMA and <sup>68</sup>Ga-PSMA-11 PET/CT.

**"As the diagnostic performance of <sup>64</sup>Cu-SAR-bisPSMA has been demonstrated through previous clinical trials, such as COBRA and PROPELLER, we eagerly await the results of this head-to-head comparison between <sup>64</sup>Cu-SAR-bisPSMA and <sup>68</sup>Ga-PSMA-11 PET in the hope of opening the opportunity for earlier detection of disease, which may lead to meaningful impact for the management of those patients,"**

**Dr Alan Taylor**



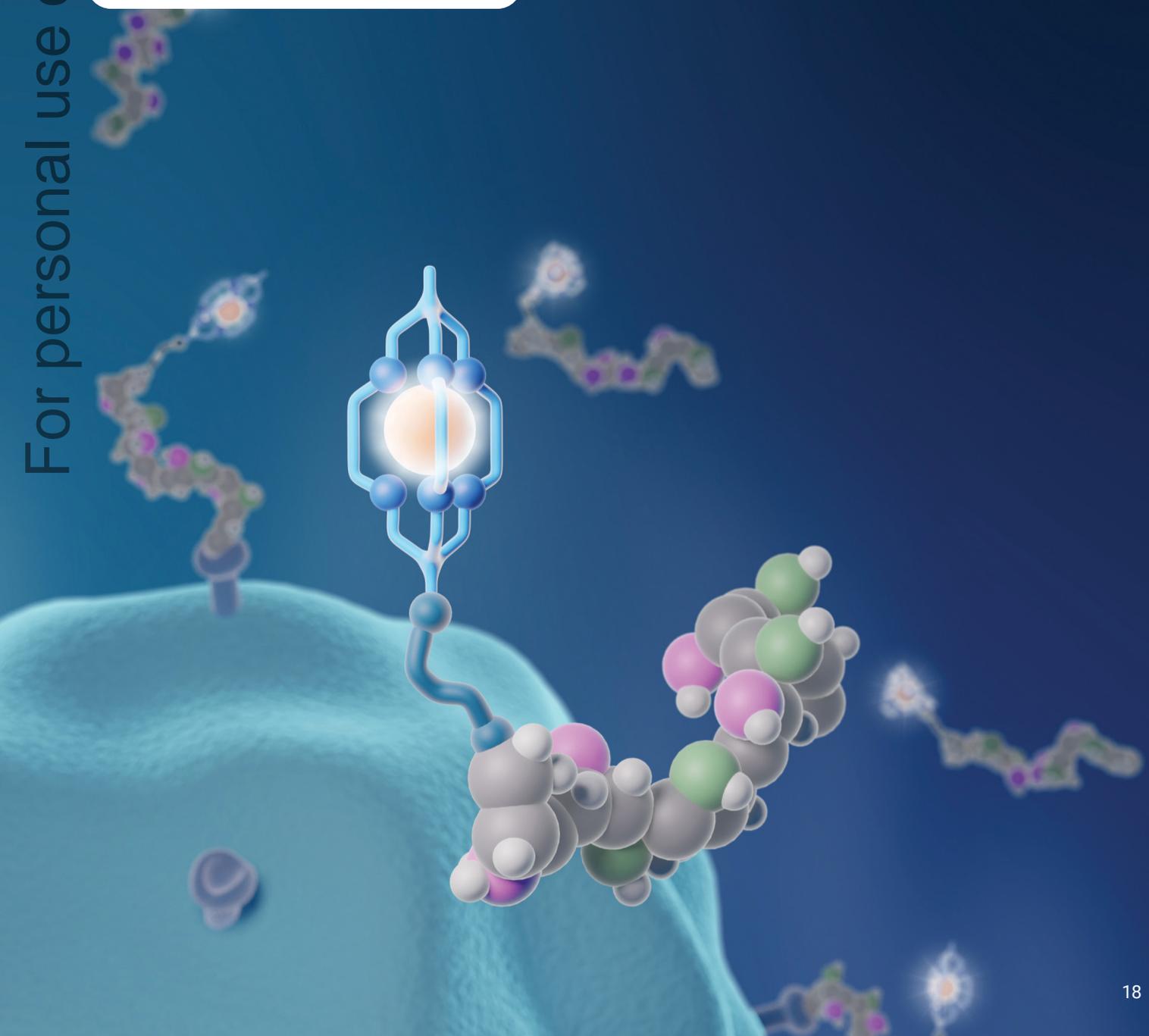
# SARTATE: NEUROENDOCRINE TUMOURS

**SARTATE is a next-generation, highly targeted theranostic radiopharmaceutical**

**SARTATE is being developed for diagnosing, staging and subsequently treating cancers that express somatostatin receptor 2 (SSTR2), including neuroendocrine tumours (NETs)**

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

For personal use only



## DISCO: Diagnostic <sup>64</sup>Cu-SARTATE NETs trial

The last patient assessment for the Phase II diagnostic <sup>64</sup>Cu-SARTATE trial, DISCO (NCT04438304)<sup>4</sup>, in patients with known or suspected neuroendocrine tumours (NETs) was completed and a total of 45 patients were enrolled and imaged in the trial.

**DISCO**, which derives from “Diagnostic Imaging Study of <sup>64</sup>Copper-SARTATE Using PET on Patients with Known or Suspected Neuroendocrine Tumours”, is assessing the performance of Clarity’s SARTATE imaging product as a potential new method to diagnose and manage NETs. The DISCO trial recruited participants with Gastroenteropancreatic NETs (GEP-NETs) across 4 sites in Australia, comparing the diagnostic performance of <sup>64</sup>Cu-SARTATE at approximately 4 and 20 hours post-administration to <sup>68</sup>Ga-DOTATATE at 1 hour.

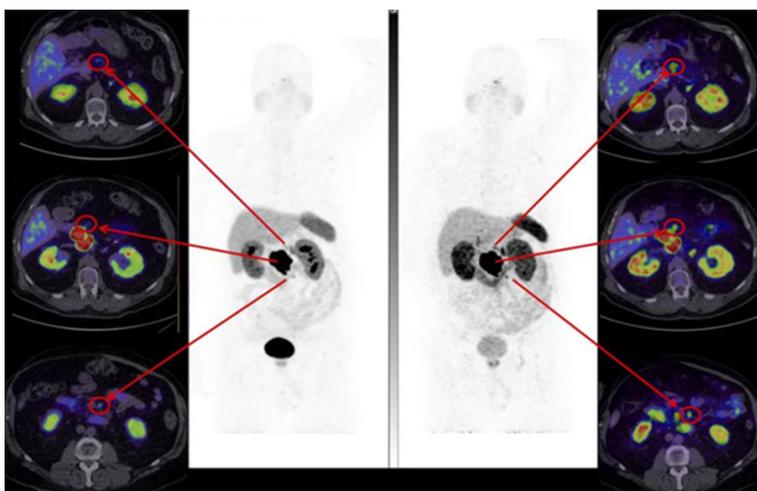
The trial was originally planned for up to 63 patients based on an expected discordance level between imaging with Clarity’s <sup>64</sup>Cu-SARTATE and the current standard of care, <sup>68</sup>Ga-DOTATATE. The sample size was adjusted to 45 patients based on the results of the pre-planned early

assessment of the images collected during the trial with the aim of generating sufficient evidence to plan for a Phase III trial in this indication. This enabled recruitment to successfully close early, and the last patient last visit was completed in November 2024.

The trial aims to build on earlier work with SARTATE in patients with NETs, which demonstrated that imaging at later time points, enabled by the longer half-life of copper-64 in comparison to gallium-68, may lead to better identification of disease<sup>8</sup>. Delayed imaging (at 4 and 24 hours vs 1 hour) showed a progressive increase in lesion-to-liver ratio (**Table 1**). **Figure 2** provides an example of improved lesion detection based on an increase in lesion-to-background ratio observed with delayed imaging<sup>8</sup>.

Ratio 1	Median	Ratio 2	Median	Difference	95% CI	P*
<sup>68</sup> Ga-DOTATATE to liver (1 hr)	3.92	<sup>64</sup> Cu-SARTATE to liver (1 hr)	5.45	1.35	0.7, 2.2	0.004
<sup>68</sup> Ga-DOTATATE to liver (1 hr)	3.92	<sup>64</sup> Cu-SARTATE to liver (4 hr)	6.70	3.86	1.5, 6.4	0.002
<sup>64</sup> Cu-SARTATE to liver (4 hr)	6.70	<sup>64</sup> Cu-SARTATE to liver (24 hrs)	16.69	6.75	3.4, 10.3	0.002

**Table 1. Comparison of lesion-to-liver ratios of <sup>68</sup>Ga-DOTATATE and <sup>64</sup>Cu-SARTATE.** Progressive increase in lesion-to-liver ratio with delayed imaging using <sup>64</sup>Cu-SARTATE. \*Paired Wilcoxon test on 10 patients. CI = confidence interval.



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

Dr Alan Taylor

**Figure 2. Lesion detection comparing <sup>68</sup>Ga-DOTATATE and <sup>64</sup>Cu-SARTATE.** Hicks et al. (2019) determined superior lesion detection at 4 hrs with <sup>64</sup>Cu-SARTATE. High lesion contrast on <sup>64</sup>Cu-SARTATE images at 4 hrs (right) better defines regional nodal disease than <sup>68</sup>Ga-DOTATATE images at 1 hr (left) in patient with large pancreatic primary tumour.

# SAR-BOMBESIN: PROSTATE CANCER

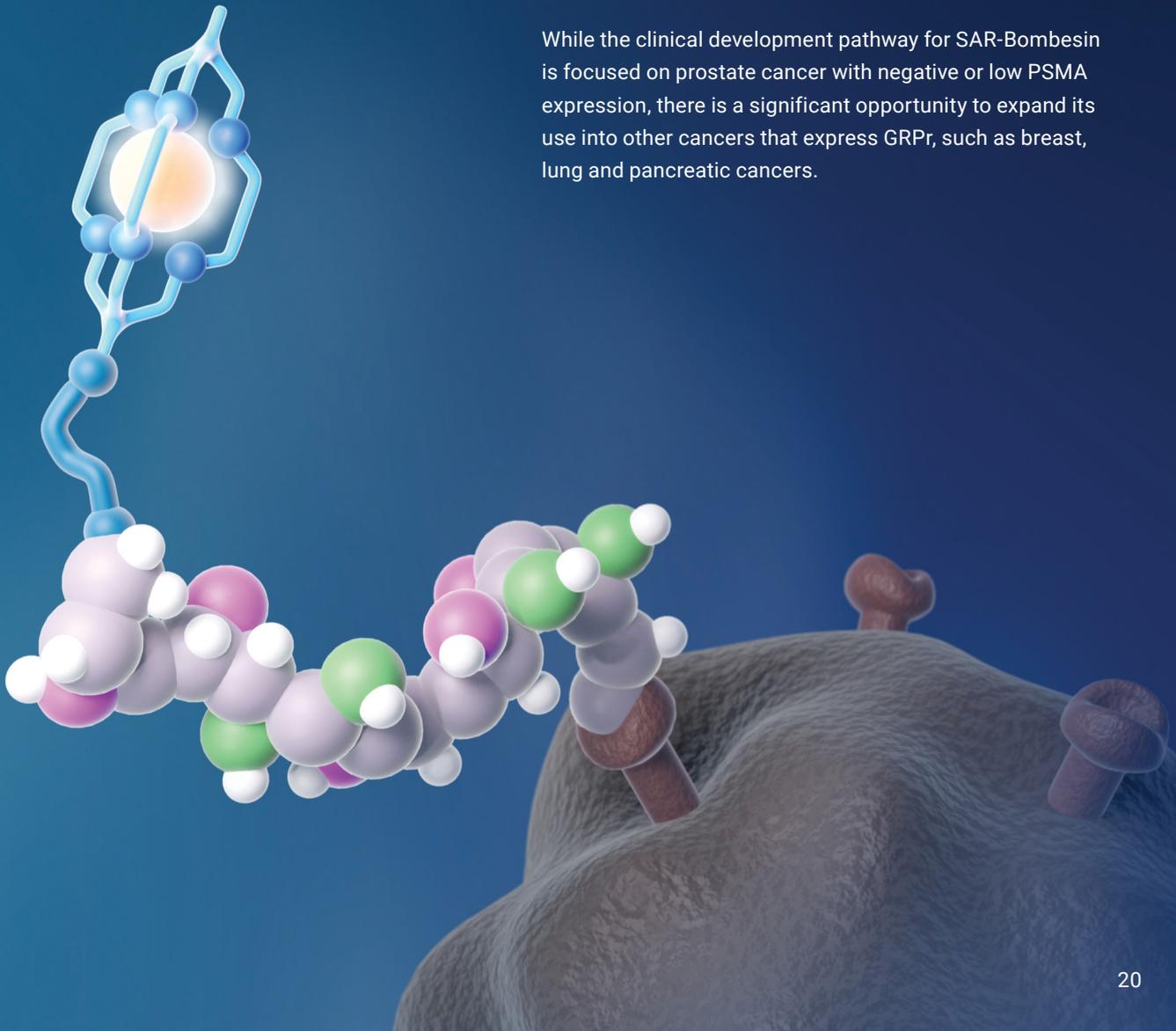
**SAR-Bombesin (SAR-BBN) is a next-generation, highly targeted pan-cancer theranostic radiopharmaceutical**

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

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

Approximately 20-25% of prostate cancer patients with BCR have low or no uptake of PSMA-targeting tracer<sup>9-12</sup>. These patients are unlikely to show meaningful uptake of PSMA-targeted products, such as <sup>68</sup>Ga-PSMA-11.

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



## SABRE: Diagnostic <sup>64</sup>Cu-SAR-Bombesin prostate cancer trial

Data review and analysis is ongoing for Clarity’s US-based diagnostic <sup>64</sup>Cu-SAR-Bombesin trial for patients with PSMA-negative prostate cancer, SABRE (NCT05407311)<sup>5</sup>, with topline results to be shared in the coming months.

For personal use only

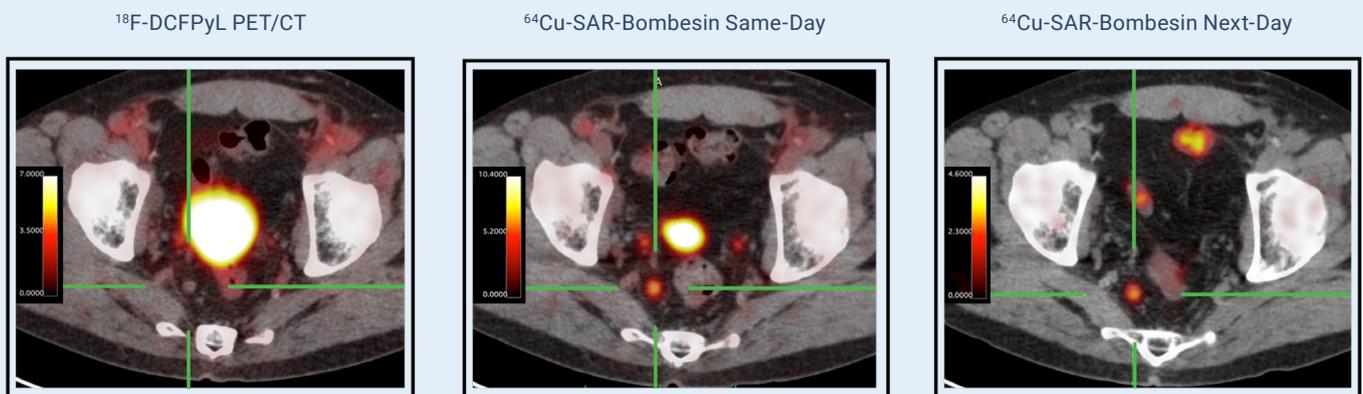
**SABRE** is a Phase II multi-centre, single arm, non-randomised, open-label trial in participants with suspected recurrence of their prostate cancer and who have negative or equivocal findings of prostate cancer on SOC imaging, including approved PSMA agents.

The primary objectives of the trial are to investigate the safety and tolerability of <sup>64</sup>Cu-SAR-Bombesin, as well as its ability to correctly detect the recurrence of prostate cancer.

In the SABRE trial, 53 participants were enrolled. <sup>64</sup>Cu-SAR-Bombesin PET/CT imaging took place on the day of product administration (same-day imaging) and approximately 24 hours later (next-day imaging).

In **Figure 3** the images in the cross hairs on same-day and next-day scans following <sup>64</sup>Cu-SAR-Bombesin administration clearly identify a pelvic lymph node, while there was no uptake with <sup>18</sup>F-DCFPyL (Pylarify®), an FDA-approved PSMA PET agent.

Pre-clinical data, along with the successful C-BOBCAT and BOP IITs, have already shown the utility of SAR-Bombesin and its potential to identify disease in some patient subgroups where conventional diagnostic imaging has failed. Clarity looks forward to reporting data from the SABRE trial and, subject to these results, progressing the <sup>64</sup>Cu-SAR-Bombesin product into a registrational Phase III trial for first approvals in the US.



**Figure 2.** <sup>64</sup>Cu-SAR-Bombesin detected a positive lymph node on scans performed on 2 different days (same-day and next-day scans). No uptake was observed using <sup>18</sup>F-DCFPyL (Pylarify®) PET/CT. A subsequent biopsy, performed and assessed locally by the study site, confirmed prostate cancer.

# DISCOVERY PROGRAM

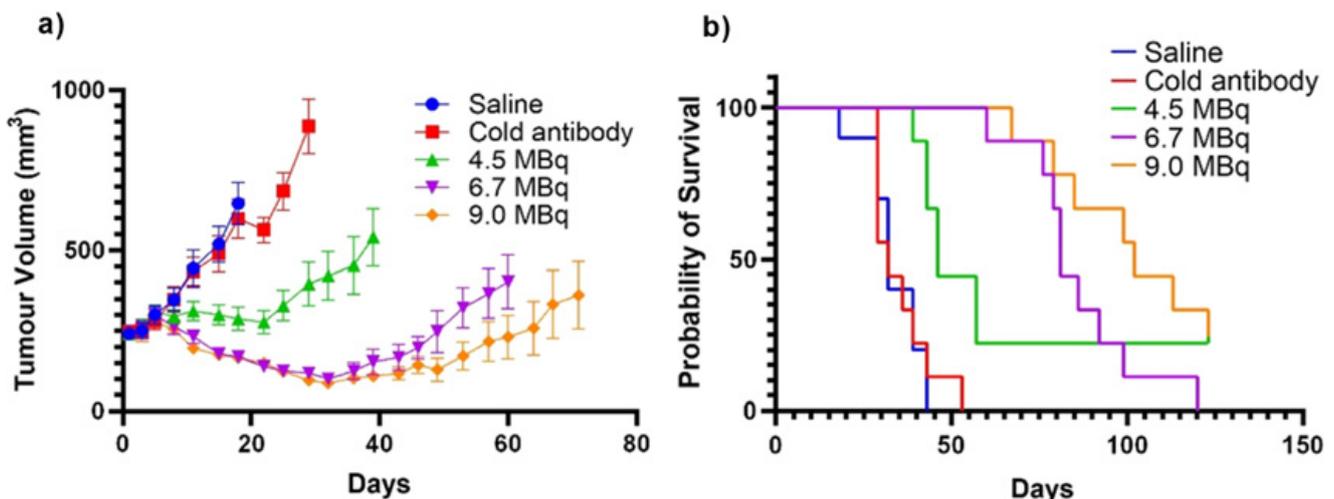
In addition to progressing its key products that are already in clinical development, Clarity is expanding its product pipeline with a new generation of radiopharmaceuticals through its Discovery Program to explore further areas with unmet needs.

## SAR-trastuzumab

Through pioneering work in collaboration with the University of Melbourne, Clarity complemented its Targeted Copper Theranostic (TCT) platform with a novel asset, SAR-trastuzumab. Clarity will focus on initially progressing this theranostic product in breast cancer, and, combined with SAR-Bombesin, SARTATE and SAR-bisPSMA, the product will bolster the Company's renewed focus on this important indication.

Trastuzumab is an antibody that targets HER2, which is expressed in many cancers, including some types of breast, lung and gastric cancers<sup>13</sup>. The antibody was combined with Clarity's proprietary SAR chelator and radiolabelled with copper-64 (Cu-64 or <sup>64</sup>Cu) for diagnostic imaging and copper-67 (Cu-67 or <sup>67</sup>Cu), forming a radioimmunotherapy (RIT)<sup>14</sup>. <sup>64</sup>Cu-SAR-trastuzumab was shown to target HER2-positive cancer cells to a very high level. <sup>67</sup>Cu-SAR-trastuzumab was shown to reduce the growth of HER2-expressing tumours in a dose-dependent manner, as well as to improve the survival of mice treated with the product (Figure 4).

Clarity intends to conduct a Phase I/IIa theranostic study with <sup>64/67</sup>Cu-SAR-trastuzumab in HER2-positive breast cancer patients to address a significant unmet clinical need. This subtype of breast cancer is characterised by aggressive behaviour and poor prognosis<sup>15</sup>. Despite recent advances in the treatment of patients with early HER2-positive breast cancer, relapse still occurs in up to 25% of patients within 10 years<sup>16</sup>.



**Figure 4. Treatment of HER2-positive tumours with <sup>67</sup>Cu-SAR-trastuzumab.** Pre-clinical model of HER2-expressing tumours (SKOV-3 xenograft) was used to assess the anti-tumour effect of <sup>67</sup>Cu-SAR-trastuzumab, compared to unlabelled SAR-trastuzumab or saline (control groups). A: Treatment with a single dose of <sup>67</sup>Cu-SAR-trastuzumab, at either 4.5, 6.7 or 9.0 MBq, inhibited tumour growth by 88%, 120% and 119% at 18 days post-administration respectively, compared to control groups (i.e. slowing of tumour growth at the 4.5 MBq dose, and reduction in tumour size at higher doses at day 18). B: <sup>67</sup>Cu-SAR-trastuzumab effectively increased the survival of all treated groups.<sup>14</sup>

# SUPPLY & MANUFACTURING: THE GAME CHANGER FOR RADIOPHARMACEUTICALS

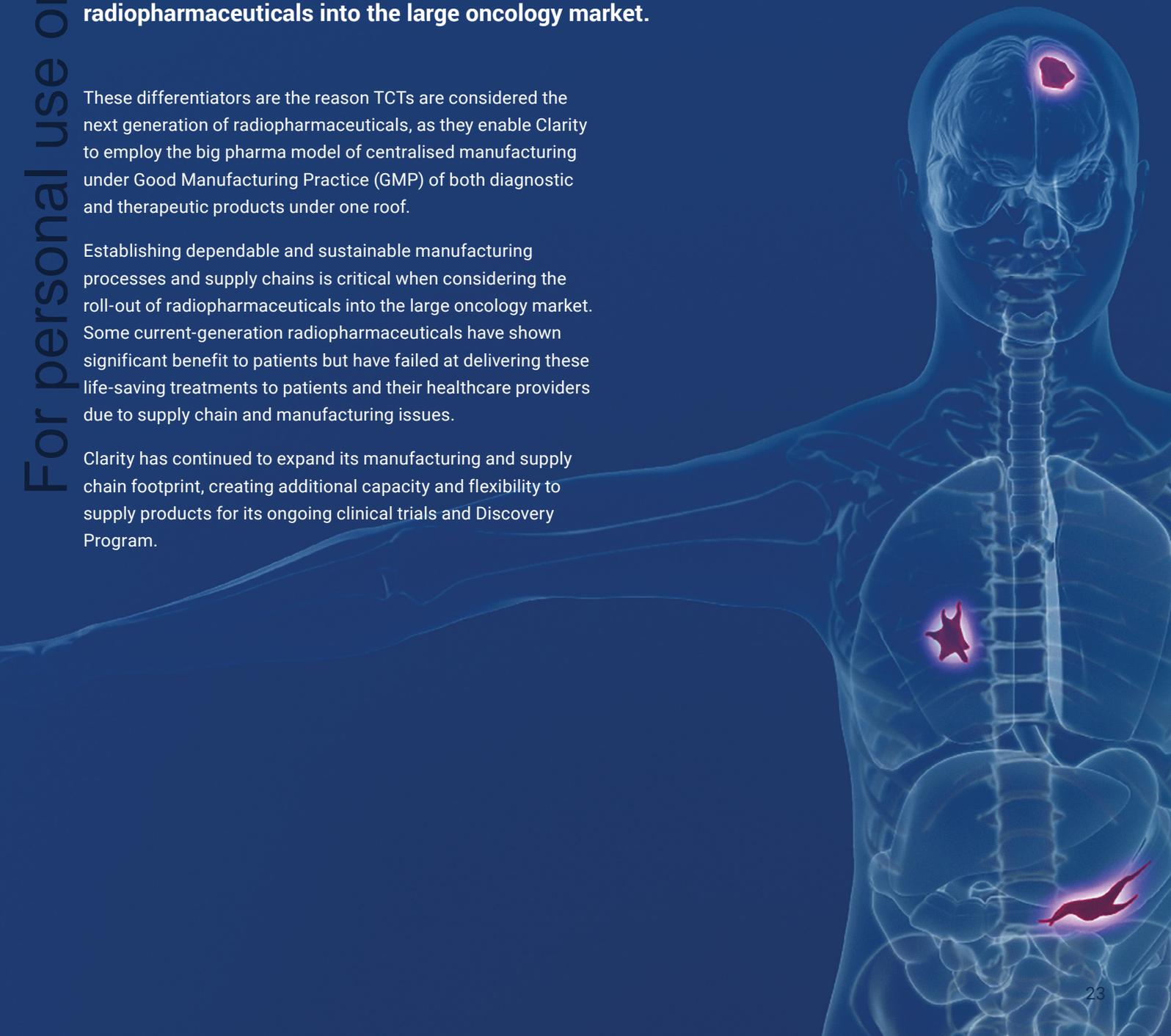
**Targeted Copper Theranostics (TCTs) hold a number of competitive advantages, including clinical benefits, which Clarity is actively exploring through its clinical program. The logistical, manufacturing and environmental advantages associated with the production of copper isotopes for diagnostic imaging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

These differentiators are the reason TCTs are considered the next generation of radiopharmaceuticals, as they enable Clarity to employ the big pharma model of centralised manufacturing under Good Manufacturing Practice (GMP) of both diagnostic and therapeutic products under one roof.

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

Clarity has continued to expand its manufacturing and supply chain footprint, creating additional capacity and flexibility to supply products for its ongoing clinical trials and Discovery Program.

For personal use only



# COPPER-64

**Copper-64 (Cu-64 or <sup>64</sup>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 <sup>68</sup>Ga) with a half-life of ~1 hour and fluorine-18 (F-18 or <sup>18</sup>F) with a half-life of ~2 hours.**

The longer shelf-life of Cu-64 based diagnostics enables centralised manufacture, as opposed to the current-generation prostate-specific membrane antigen (PSMA) Positron Emission Tomography (PET) diagnostics that require an expensive and extensive network of cyclotrons, radioisotope generators and radiopharmacies next to imaging sites due to the shorter half-life and shelf-life of Ga-68 and F-18.

Those characteristics of Cu-64 also allow for wider geographic distribution, which can improve patient access to this important diagnostic tool. This has the potential to reduce disparities in prostate cancer care and ensure that all patients, regardless of geographic location, can benefit from the latest advances in diagnostic imaging.

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

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

This Agreement is an important part of a larger commercial manufacturing strategy, which Clarity will continue implementing as it gets closer to the filing of New Drug Applications (NDA) with the US Food and Drug Administration (FDA).

—  
**“This agreement with Nusano builds upon Clarity’s commercial supply strategy as we approach NDA filing. It will help ensure a seamless commercial launch, making PSMA diagnostics available nationwide, 24/7, offering a significantly improved patient experience compared to current PSMA diagnostic agents,”**

**Dr Alan Taylor**

In March 2025, Clarity also signed a new agreement for supply of Cu-64 isotope with The University of Queensland (UQ) at the Australian Institute for Bioengineering and Nanotechnology (AIBN). This Agreement will enable the Company to not only support its ongoing product development but also enhance the academia-clinical-industry collaboration in Australia.

The Agreement will provide additional capacity of Cu-64 to allow for an abundant and seamless supply of the isotope, expanding the manufacturing capability in Australia. This means that Australian sites participating in Clarity’s clinical trials (including the 2 registrational Phase III trials, AMPLIFY and CLARIFY, and the Investigator-Initiated Trial, Co-PSMA) will be able to maximise the number of Australians in need of novel treatments receiving these next-generation products.

The Agreement will also supply Cu-64 for theranostic pre-clinical programs conducted in Australia, including SAR-bisFAP and SAR-trastuzumab, supporting discovery of novel products for indications with high unmet needs.

# 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”. This results in planned and unplanned shutdowns, causing shortages of therapeutic isotopes worldwide<sup>17</sup>. Even with the current infrastructure, access to reactor production capacity will soon become a bottleneck for Lu-177<sup>18</sup>.

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

## TRASTUZUMAB BIOSIMILAR: EG12014

In February 2025, Clarity signed a Supply Agreement with EirGenix, Inc. (“EirGenix”) for the clinical development and future commercial supply of clinical-grade GMP trastuzumab biosimilar, EG12014. The supply enables the development of a radiolabelled product using Clarity’s SAR Technology, <sup>64/67</sup>Cu-SAR-trastuzumab, for use in clinical trials with a focus on breast cancer.



For personal use only

# FINANCIALS

Clarity's cash balance at 31 March 2025 was \$95.1 million

Net operating cash outflows for the March quarter were \$15.3 million, which is lower than the previous quarter's net outflow of \$18 million due to timing of payments on the Company's clinical trials, including some large prepayments made in the prior quarter. Operating cash outflows relate to payments for research and development, staff costs, administration, and general operating costs.

The Company's FY2024 Research & Development Tax Incentive of \$11,029,725 together with interest of \$116,479, totalling \$11,146,204 was received after the March quarter close, further bolstering the Group's cash position.

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

## Use of Funds

(Listing Rule 4.7C.2)

Uses of funds	Institutional Placement & Rights Issue Offer dated 26 March 2024 \$ million	% of Total Funds	Period* to 31 March 2025 \$ million	% of Total Funds
Pre-Clinical	\$8.5	5.3%	\$3.2	4.5%
Clinical	\$111.0	69.7%	\$46.5	65.6%
Regulatory	\$7.1	4.5%	\$2.1	3.0%
Patents	\$1.8	1.2%	\$0.8	1.1%
Corporate	\$10.2	6.4%	\$1.2	1.7%
Working Capital** and Costs of the Offer	\$20.6	12.9%	\$17.1	24.1%
Total uses	\$159.2	100%	\$70.9	100.0%

\* From 25 March 2024

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

As detailed in the Use of Funds table above, the expenditure for the period to 31 March 2025 is in accordance with the Use of Funds outlined in the Company's Offer document for the Institutional Placement and Rights Issue dated 26 March 2024 and there are no material variances against the estimated use of funds disclosed to-date.

## Related Party Transactions

(Listing Rule 4.7C.3)

Payments to related parties of the entity and their associates (6.1 of the Appendix 4C) totalled \$624,670 for the quarter. This amount includes director fees and salaries.

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

# REFERENCES

1. ClinicalTrials.gov Identifier: NCT04868604 [clinicaltrials.gov/ct2/show/NCT04868604](https://clinicaltrials.gov/ct2/show/NCT04868604)
2. ClinicalTrials.gov Identifier: NCT06056830 [clinicaltrials.gov/ct2/show/NCT06056830](https://clinicaltrials.gov/ct2/show/NCT06056830)
3. ClinicalTrials.gov Identifier: NCT06907641 [clinicaltrials.gov/ct2/show/NCT06907641](https://clinicaltrials.gov/ct2/show/NCT06907641)
4. ClinicalTrials.gov Identifier: NCT04438304 [clinicaltrials.gov/ct2/show/NCT04438304](https://clinicaltrials.gov/ct2/show/NCT04438304)
5. ClinicalTrials.gov Identifier: NCT05407311 [clinicaltrials.gov/ct2/show/NCT05407311](https://clinicaltrials.gov/ct2/show/NCT05407311)
6. Emmett et al. Enzalutamide and <sup>177</sup>Lu-PSMA-617 in poor-risk, metastatic, castration-resistant prostate cancer (mCRPC): A randomised, phase II trial: ENZA-p (ANZUP 1901). *Annals of Oncology*, Volume 34, S1325, 2023.
7. Emmett et al. Overall survival and quality of life with [177Lu] Lu-PSMA-617 plus enzalutamide versus enzalutamide alone in poor-risk, metastatic, castration-resistant prostate cancer in ENZA-p (ANZUP 1901). *American Society of Clinical Oncology Genitourinary Cancers (ASCO GU) Symposium*, 2025
8. Hicks R et al. First-in-human trial of <sup>64</sup>Cu-SARTATE PET imaging of patients with neuroendocrine tumours demonstrates high tumor uptake and retention, potentially allowing prospective dosimetry for peptide receptor radionuclide therapy. *The Journal of Nuclear Medicine*. 2019.
9. Afshar-Oromieh A, Holland-Letz T, Giesel FL, et al. Diagnostic performance of <sup>68</sup>Ga-PSMA-11 (HBED-CC) PET/CT in patients with recurrent prostate cancer: evaluation in 1007 patients. *Eur J Nucl Med Mol Imaging*. 2017 Aug;44(8):1258-1268.
10. Ferraro DA, Rüschoff JH, Muehlematter UJ, et al. Immunohistochemical PSMA expression patterns of primary prostate cancer tissue are associated with the detection rate of biochemical recurrence with <sup>68</sup>Ga-PSMA-11 PET. *Theranostics*. 2020;10(14):6082-6094.
11. Baratto L, Song H, Duan H, et al. PSMA- and GRPR-Targeted PET: Results from 50 Patients with Biochemically Recurrent Prostate Cancer. *J Nucl Med*. 2021;62(11):1545-1549.
12. Mapelli P, Ghezzi S, Samanes Gajate AM, et al. <sup>68</sup>Ga-PSMA and <sup>68</sup>Ga-DOTA-RM2 PET/MRI in Recurrent Prostate Cancer: Diagnostic Performance and Association with Clinical and Histopathological Data. *Cancers (Basel)*. 2022;14(2):334.
13. Iqbal & Iqbal. Human Epidermal Growth Factor Receptor 2 (HER2) in Cancers: Overexpression and Therapeutic Implications. *Mol Biol Int*. 2014.
14. Rudd et al. Potential theranostics of breast cancer with copper-64/67 sarcophagine-trastuzumab. *Chem Sci*. 2025.
15. Tapia et al. Clinical Impact of New Treatment Strategies for HER2-Positive Metastatic Breast Cancer Patients with Resistance to Classical Anti-HER Therapies. *Cancers*. 2023.
16. O'Shaughnessy et al. Risk of Recurrence in Patients With HER2+ Early-Stage Breast Cancer: Literature Analysis of Patient and Disease Characteristics. *Clin Breast Cancer*. 2023.
17. Brown, A. (2024, June 14). Radiopharma execs warn that lutetium could be at risk of shortage. *Endpoints News*. [endpts.com/radiopharma-exec-warn-that-lutetium-could-beat-risk-of-shortage/](https://endpts.com/radiopharma-exec-warn-that-lutetium-could-beat-risk-of-shortage/)
18. Zimmermann, R. (2023). Is Actinium Really Happening? *Journal of Nuclear Medicine*, [online] 64(10), pp.1516–1518. doi: <https://doi.org/10.2967/jnumed.123.265907>.

For more information, please contact:

## Clarity Pharmaceuticals

Dr Alan Taylor  
Executive Chairperson  
ataylor@claritypharm.com

Catherine Strong  
Investor/Media Relations  
catherine.strong@sodali.com | 0406 759 268

For personal use only

## 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 2025

<b>Consolidated statement of cash flows</b>	<b>Current quarter \$A'000</b>	<b>Year to date (9 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	(10,207)	(29,414)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(40)	(622)
(d) leased assets	-	-
(e) staff costs	(5,066)	(15,102)
(f) administration and corporate costs	(716)	(3,383)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	1,071	3,281
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	(385)	(410)
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>(15,343)</b>	<b>(45,650)</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	(49)	(153)
(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</b>	<b>Net cash from / (used in) investing activities</b>	<b>(49)</b>	<b>(153)</b>

<b>3.</b>	<b>Cash flows from financing activities</b>		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	311	2,168
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(10)	(192)
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>301</b>	<b>1,976</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	111,192	136,506
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(15,343)	(45,650)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(49)	(153)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	301	1,976

## 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	(1,021)	2,401
<b>4.6</b>	<b>Cash and cash equivalents at end of period</b>	<b>95,080</b>	<b>95,080</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	47,929	2,972
5.2	Call deposits <sup>1</sup>	47,151	108,220
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>95,080</b>	<b>111,192</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>	625
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

2. Note: Payments in 6.1 include Director fees and salaries

7. <b>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. 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.	[ ]	

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)	(15,343)
8.2 Cash and cash equivalents at quarter end (item 4.6)	95,080
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	<b>95,080</b>
8.5 <b>Estimated quarters of funding available (item 8.4 divided by item 8.1)</b>	6
<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 April 2025

*Board of Directors*

Authorised by: .....  
(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.