

# INTERIM REPORT

## and Half-Year Financial Statements

Sydney, Australia  
29 February 2024

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# KEY OPERATIONAL HIGHLIGHTS

## SECURE

Clarity's theranostic trial, SECURE, is investigating  $^{64}\text{Cu}/^{67}\text{Cu}$ -SAR-bisPSMA in metastatic castrate-resistant prostate cancer (mCRPC). Clarity successfully completed cohort 2 of the SECURE trial at 8GBq dose level and is now actively progressing cohort 3 at 12GBq, the highest dose level in the dose escalation phase of the trial. Participants in this cohort are treated with a single dose of 12GBq of  $^{67}\text{Cu}$ -SAR-bisPSMA and the cohort is progressing as planned.

### Patient Case Study: Two Cycles of 8GBq of $^{67}\text{Cu}$ -SAR-bisPSMA

The first mCRPC patient to ever receive two cycles of 8GBq of  $^{67}\text{Cu}$ -SAR-bisPSMA (one dose from the SECURE trial and one from the US Expanded Access Program [EAP]) exhibited a Prostate Specific Antigen (PSA) reduction to undetectable levels post-treatment, with favourable safety profile. The patient also had undetectable lesions using positron emission tomography (PET) imaging post-treatment. This case was presented at the Annual International Prostate Cancer Update conference.

### Patient Case Study: Four Cycles of 4GBq of $^{67}\text{Cu}$ -SAR-bisPSMA

A patient from cohort 1 of the SECURE trial who received a total of four cycles of 4GBq of  $^{67}\text{Cu}$ -SAR-bisPSMA (one dose from the SECURE trial and three from the EAP) exhibited a considerable reduction in the intensity of the therapeutic  $^{67}\text{Cu}$ -SAR-bisPSMA product uptake at the lesion sites. A reduction of greater than 90% in PSA was observed after the fourth cycle of 4GBq of  $^{67}\text{Cu}$ -SAR-bisPSMA.

## CLARIFY

Clarity's first Phase III clinical trial opened enrolment and recruited its first participant in December 2023. CLARIFY is a 383-patient diagnostic registrational study with  $^{64}\text{Cu}$ -SAR-bisPSMA in participants with high-risk prostate cancer prior to radical prostatectomy. The trial will examine the diagnostic potential of  $^{64}\text{Cu}$ -SAR-bisPSMA to detect regional nodal metastasis. In addition to investigating the benefits of Clarity's optimised bisPSMA product in this patient population, CLARIFY will look at the potential benefits of both same-day and next-day imaging, a benefit currently unique to the SAR technology platform.

## COBRA

Initial results of Clarity's first trial in patients with biochemical recurrence (BCR) of prostate cancer (with negative or equivocal standard of care [SOC] imaging) showed that  $^{64}\text{Cu}$ -SAR-bisPSMA is safe and highly effective in detecting prostate cancer lesions. In this patient group in whom SOC imaging was unable to identify the location of the cancer,  $^{64}\text{Cu}$ -SAR-bisPSMA identified prostate cancer in up to 80% of patients. The number of lesions detected by  $^{64}\text{Cu}$ -SAR-bisPSMA almost doubled from same-day (up to 80) to next-day imaging (up to 153), demonstrating the benefits of delayed scans. Next-day imaging is a feature with important clinical relevance and it is not offered by currently approved prostate specific membrane antigen (PSMA) agents. Clinicians reported they would change their treatment plan in approximately 50% of patients due to  $^{64}\text{Cu}$ -SAR-bisPSMA scans, signalling a potential material improvement in patient care.

# KEY OPERATIONAL HIGHLIGHTS

## COMBAT

Clarity treated the first participant in its theranostic  $^{64}\text{Cu}/^{67}\text{Cu}$ -SAR-Bombesin Phase I/IIa trial in mCRPC. The aim for the trial is to determine the safety and efficacy of  $^{67}\text{Cu}$ -SAR-Bombesin in participants with gastrin-releasing peptide receptor (GRPr) expressing mCRPC who are ineligible for therapy with  $^{177}\text{Lu}$ -PSMA-617.

## SABRE

Clarity achieved its recruitment target for the diagnostic  $^{64}\text{Cu}$ -SAR-Bombesin Phase II trial in participants with PSMA-negative BCR of prostate cancer following definitive therapy. Fifty-three patients have been imaged with  $^{64}\text{Cu}$ -SAR-Bombesin in the US. The primary objectives of the trial are to investigate the safety and tolerability of the product as well as its ability to correctly detect recurrence of prostate cancer. Results from the SABRE trial will guide the design of the registrational Phase III study in this patient population.

## BOP

Initial data from the BOP trial was presented at the European Association of Nuclear Medicine (EANM) 2023 Congress.  $^{64}\text{Cu}$ -SAR-Bombesin was found to be safe and able to detect prostate cancer lesions in over a third of participants with negative or equivocal SOC PSMA PET who were in the first cohort of the BOP trial with BCR of prostate cancer.

## CL04

Clarity successfully completed cohort 3 of the CL04 theranostic trial at the dose level of 275MBq/kg body weight and enrolment is ongoing into cohort 4 where participants each receive a single dose of 375MBq/kg body weight of  $^{67}\text{Cu}$ -SARTATE, the highest dose level in the dose escalation phase of the trial.

## DISCO

Recruitment successfully completed for the DISCO trial, a diagnostic Phase II study in neuroendocrine tumours (NETs). A total of 45 patients have been enrolled and imaged. DISCO aims to build on earlier work with SARTATE which demonstrated that imaging at later time points, enabled by the longer half-life of  $^{64}\text{Cu}$  in comparison to  $^{68}\text{Ga}$ , may lead to better identification of disease and the results of this trial will guide the study design for a Phase III trial in the NET indication.

## Discovery Platform

Clarity added a worldwide exclusive license from Memorial Sloan Kettering Cancer Center (MSK) to its intellectual property (IP) portfolio. The license is to IP covering cutting-edge technology that enables antibody "pre-targeting" for the diagnosis and treatment of cancer.

## Manufacturing and Logistics

During the reporting period, the large scale Cu-67 production from NorthStar Medical Radioisotopes' (NorthStar) Rhodotron facility was successfully validated across Clarity's therapeutic clinical program. Northstar produced Cu-67 is now in routine use in Clarity's ongoing trials.



## KEY FINANCIALS

**\$38m**  
CASH BALANCE

Well-funded with a cash balance of \$38 million as at 31 December 2023

**\$10.1m**  
R&D TAX INCENTIVE

Research and Development Tax Incentive is expected to provide a further \$10.1 million in cash funding

TOGETHER, CLARITY HAS CASH RUNWAY INTO LATE 2024

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Clarity Pharmaceuticals Ltd (ASX: CU6) ("Clarity" or the "Company"), a clinical stage radiopharmaceutical company with a mission to develop next-generation products that improve treatment outcomes for children and adults with cancer, is pleased to release its interim report and financial results for the half-year ended 31 December 2023.

## Executive Chairperson's Letter

Dear fellow Shareholders,

On behalf of the entire team at Clarity, I am delighted to present Clarity's interim report and half-yearly financial statements.

We are excited to share our most recent updates as Clarity continues to make remarkable progress in developing our pipeline of Targeted Copper Theranostic (TCT) products. We would like to thank our Shareholders for their support to continue our endeavours and address the growing demand for radiopharmaceuticals in oncology.

Our progress during the first half of this financial year has been nothing short of extraordinary, and our results speak for themselves. But these results stem from some years of focus and dedication from our team and collaborators, and it is important to continue to reflect on our past, as we clearly differentiate ourselves from our competitors and continue to build an incredible Australian science success story.

At the heart of our company is great science, and this has led to our enviable position of having a strong intellectual property portfolio of some 24 patent families, coupled with data that holds promise of best-in-class products across our pipeline. Importantly, while our competitors seek to develop generic or failed assets, we have sought to change the entire paradigm of diagnostics and therapies, firstly in the large market of prostate cancer, and then moving into a range of other indications, both within oncology and in other areas of disease.

We have made significant progress with all three of our key products in clinical development, namely SAR-bisPSMA, SAR-Bombesin and SARTATE, in both theranostic and diagnostic applications.



The most exciting achievement is the data generated with our SAR-bisPSMA product. It was developed at the benchtop of the University of Melbourne in collaboration with Professor Paul Donnelly to address the shortcomings of the current generation of prostate specific membrane antigen (PSMA) agents. SAR-bisPSMA was optimised with two PSMA-targeting agents, which not only increased the amount of product in the lesions but also increased how long the product was retained in the lesions over time, making it an ideal candidate for both diagnosis and therapy. We are now seeing clinical data confirming this hypothesis from both diagnostic and theranostic trials.

Our theranostic SECURE trial has been progressing swiftly and we successfully completed cohort 2 and advanced through cohort 3, the highest single dose cohort in the study. Cohort 3 is the last cohort to assess single doses of <sup>67</sup>Cu-SAR-bisPSMA and, upon its completion, the trial will move to multi-dose cohorts.

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We have already had an early insight into what those multi-dose treatment benefits might look like with some patients receiving multiple doses of  $^{67}\text{Cu}$ -SAR-bisPSMA under the Expanded Access Program (EAP). In the most recent example, two cycles of 8GBq of  $^{67}\text{Cu}$ -SAR-bisPSMA were administered to a patient with metastatic castrate-resistant prostate cancer (mCRPC). The product delivered an outstanding outcome with a drop in Prostate Specific Antigen (PSA) to undetectable levels, undetectable disease using positron emission tomography (PET), and a near complete response to treatment as defined by the Response Evaluation Criteria In Solid Tumours (RECIST) at the time of imaging. The only adverse events the patient experienced were a mild dry mouth and altered taste, both having improved, and moderate fatigue, which resolved itself.

This is an extraordinary response, especially given the patient had been heavily pre-treated prior to receiving our therapy, having failed numerous therapies used in prostate cancer standard of care (SOC) and a clinical trial. Importantly, the patient is now experiencing an excellent quality of life following treatment. We look forward to progressing the SECuRE trial to multi-dose cohorts in hopes of emulating this result in many other patients with prostate cancer.

SAR-bisPSMA is also showing significant promise in our diagnostic programs. Our first Phase III registrational trial, CLARIFY, has progressed well and we are now actively recruiting participants with high-risk prostate cancer prior to radical prostatectomy (i.e. the complete removal of the prostate) into the trial.

We are also commencing planning for our second pivotal Phase III trial in participants with biochemically recurrent (BCR) prostate cancer following positive initial data from our Phase I/II COBRA trial in this patient population. The COBRA trial results show that  $^{64}\text{Cu}$ -SAR-bisPSMA is safe and highly effective in detecting prostate cancer lesions in up to 4 out of 5 (80%) of BCR patients, in whom SOC imaging was unable to detect any cancer. The number of lesions also almost doubled on next-day imaging using  $^{64}\text{Cu}$ -SAR-bisPSMA, compared to same-day imaging, a benefit not offered by the current PSMA agents.

With our second product, SAR-Bombesin, we have also been exploring therapeutic and diagnostic benefits for prostate cancer patients, in particular those who have low or no PSMA uptake on PET scans. We successfully dosed our first patient with  $^{67}\text{Cu}$ -SAR-Bombesin in the theranostic Phase I/IIa trial, COMBAT, and look forward to progressing to the higher dose cohorts. With the diagnostic  $^{64}\text{Cu}$ -SAR-Bombesin product, Clarity reached its recruitment target in the Phase II SABRE trial in patients with PSMA-negative prostate cancer. Subject to the data from the SABRE trial, we are planning to launch a pivotal Phase III trial with  $^{64}\text{Cu}$ -SAR-Bombesin for first approvals in the US.

We are also actively progressing our third product, SARTATE, in both diagnostic and theranostic indications. Clarity's main focus with this product is a very important patient population, children with an aggressive cancer called neuroblastoma. In our theranostic CL04 trial in this indication we completed cohort 3 and made significant headway in cohort 4 at the highest dose level of 375MBq/kg body weight. We look forward to completing this final dose escalation cohort and moving into multi-dose cohorts. On the diagnostic front, we successfully closed recruitment early for our DISCO trial in neuroendocrine tumours (NETs) and are now eagerly anticipating the comprehensive analysis from the trial.

We are incredibly excited about the progress with all three of our products in clinical development and the data we are generating in our trials. Thanks to the dedication and hard work of our team as well as the great Australian science underlying our proprietary advantage in copper theranostics, we are now in a unique position of having a strong platform of products in radiopharmaceuticals, a sector that is undergoing rapid consolidation and M&A activity.

We look forward to what this coming period has in store for our company, the biotech sector and, most importantly, our patients as we move closer to our ultimate goal of better treating children and adults with cancer.

Yours sincerely,

Dr Alan Taylor  
Executive Chairperson  
Clarity Pharmaceuticals Ltd

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# CLINICAL 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 three core products, SAR-bisPSMA, SAR-Bombesin and SARTATE, each contain a different targeting agent and bind to different receptors that are present on different cancer cells.

The three theranostic products are in clinical development for both diagnosis and treatment of various cancers and address unmet clinical needs. In addition to these core products, SAR Technology is used in Clarity's Discovery Program, which explores new targeting agents, thereby creating new TCTs to expand the existing platform.

## 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 breast and prostate cancers.

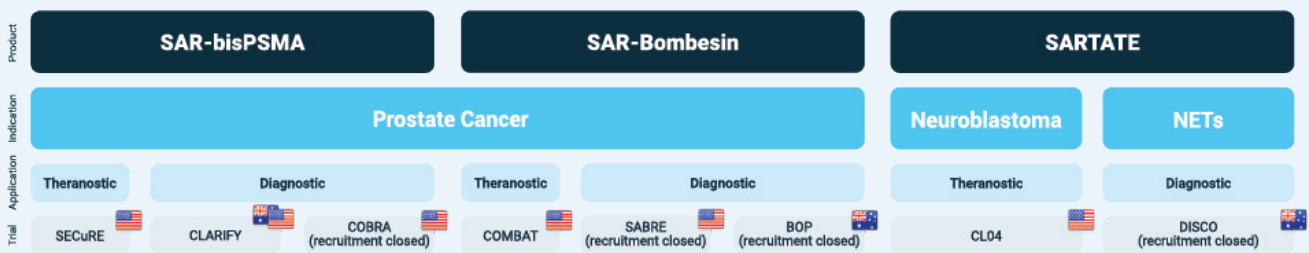
## SARTATE

targets the somatostatin receptor 2 (SSTR2), which is present in an aggressive childhood cancer, neuroblastoma, as well as neuroendocrine tumours (NETs), among other cancers.

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# CLINICAL DEVELOPMENT OVERVIEW

Clarity's three lead products, SAR-bisPSMA, SAR-Bombesin and SARTATE, are actively progressing through seven clinical trials with three theranostic and four diagnostic trials, including a Phase III registrational trial that recruited its first patient during the quarter.



## Theranostic Trials

## Diagnostic Trials

<b>SAR-bisPSMA</b>	SECuRE – 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 (NCT04868604) <sup>1</sup>	CLARIFY - 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 (NCT06056830) <sup>4</sup>  COBRA – Phase I/II PET imaging trial of participants with biochemical recurrence (BCR) of prostate cancer following definitive therapy using <sup>64</sup> Cu-SAR-bisPSMA in the US (NCT05249127) <sup>5</sup>
<b>SAR-Bombesin</b>	COMBAT – Phase I/IIa theranostic trial for identification and treatment of mCRPC that is expressing the GRPr, in participants who are ineligible for <sup>177</sup> Lu-PSMA-617, using <sup>64</sup> Cu/ <sup>67</sup> Cu-SAR-Bombesin in the US (NCT05633160) <sup>2</sup>	SABRE – Phase II PET imaging trial of participants with PSMA-negative BCR of prostate cancer using <sup>64</sup> Cu-SAR-Bombesin in the US (NCT05407311) <sup>6</sup>  BOP – Investigator Initiated Phase II PET imaging trial of participants with negative PSMA PET or low PSMA expression disease in patients with suspected BCR of their prostate cancer and patients with mCRPC using <sup>64</sup> Cu-SAR-Bombesin led by Prof Louise Emmett at St Vincent’s Hospital Sydney (NCT05613842) <sup>7</sup>
<b>SARTATE</b>	CL04 – Phase I/IIa theranostic trial in paediatric participants with high-risk neuroblastoma using <sup>64</sup> Cu/ <sup>67</sup> Cu-SARTATE in the US (NCT04023331) <sup>3</sup>	DISCO – Phase II PET imaging trial of participants with known or suspected NETs using <sup>64</sup> Cu-SARTATE in Australia (NCT04438304) <sup>8</sup>

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# CLARITY'S CLINICAL MILESTONES FROM 1 JULY 2023

2023

Jul 2023

**CLARIFY** positive guidance from the US FDA  
SAR-bisPSMA Dx US/Au

**SABRE** 50% recruitment SAR-BBN Dx US

**CL04** final cohort opens for recruitment SARTATE Tx US

Aug 2023

**Pre-targeting** IP licensed

**SECURE** advances to highest dose cohort  
SAR-bisPSMA Tx US

**SECURE** 1<sup>st</sup> participant treated at the highest  
dose level SAR-bisPSMA Tx US

**CL04** 1<sup>st</sup> participant treated at the highest dose  
level SARTATE Tx US

Sep 2023

**BOP** preliminary results presented SAR-BBN Dx Au IIT

Oct 2023

**COMBAT** 1<sup>st</sup> participant treated SAR-BBN Tx US

**CLARIFY** agreement with PSI CRO AG SAR-bisPSMA Dx US

Nov 2023

**SABRE** recruitment target achieved SAR-BBN Dx US

**SECURE** progresses at the highest dose level  
SAR-bisPSMA Tx US

**SAR-bisPSMA** 1<sup>st</sup> patient with mCRPC to receive 2 doses  
of <sup>67</sup>Cu-SAR-bisPSMA achieves undetectable PSA level

**CLARIFY** commences SAR-bisPSMA Dx US

Dec 2023

**DISCO** recruitment closes SARTATE Dx Au

**CLARIFY** 1<sup>st</sup> patient dosed SAR-bisPSMA Dx US

2024

Feb 2024

**COBRA** initial results SAR-bisPSMA Dx US

\* Tx = THERANOSTIC  
\*\* Dx = DIAGNOSTIC

# PRODUCT UPDATES

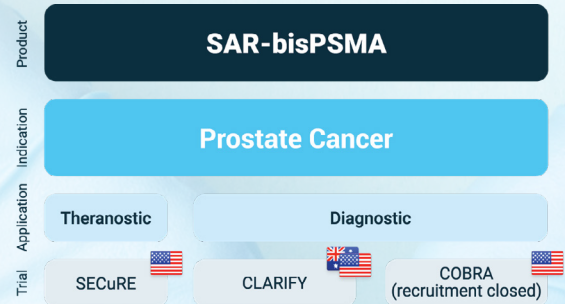
## SAR-bisPSMA PROSTATE CANCER

**SAR-bisPSMA is a next generation, theranostic radiopharmaceutical with optimised dual prostate specific membrane antigen (PSMA) targeting agents to improve uptake and retention of the product in tumours.**

SAR-bisPSMA is being developed for diagnosing, staging and subsequently treating cancers that express PSMA. The product uses either copper-64 (<sup>64</sup>Cu) for imaging (<sup>64</sup>Cu-SAR-bisPSMA) or copper-67 (<sup>67</sup>Cu) for therapy (<sup>67</sup>Cu-SAR-bisPSMA).

Clarity is running a therapy program in metastatic castrate-resistant prostate cancer (mCRPC) with <sup>64</sup>Cu-SAR-bisPSMA and <sup>67</sup>Cu-SAR-bisPSMA and multiple diagnostic trials in line with advice received from the United States Food and Drug Administration (US FDA) to address the two relevant patient populations for registration of <sup>64</sup>Cu-SAR-bisPSMA:

- pre-prostatectomy/pre-definitive treatment of patients with confirmed prostate cancer; and
- patients with biochemical recurrence (BCR) of prostate cancer.



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# SECuRE

## SECuRE – a theranostic <sup>64</sup>Cu/<sup>67</sup>Cu-SAR-bisPSMA trial

Clarity successfully completed cohort 2 at 8GBq dose level and progressed cohort 3 of the theranostic SECuRE trial (NCT04868604)<sup>1</sup>, where participants receive therapy with a single dose of <sup>67</sup>Cu-SAR-bisPSMA at the highest dose level of 12GBq.

SECuRE is a US-based 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 planned for up to 44 participants (Figure 1). 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 November, Clarity reported the initial 3 participants in cohort 3 of the SECuRE trial were enrolled and treated with 12GBq of <sup>67</sup>Cu-SAR-bisPSMA. All of the 3 participants were heavily pre-treated prior to entering the trial, having received multiple lines of therapy including other investigational products, radioligand therapy and chemotherapy. They continue to be monitored by their physicians for safety and treatment response as per the trial protocol. All 3 participants in cohort 3 remain on the trial following their administration of 12GBq of <sup>67</sup>Cu-SAR-bisPSMA.

Cohort 3 remains ongoing as planned. It is the last cohort to assess single doses of <sup>67</sup>Cu-SAR-bisPSMA and will be followed by a multi-dose cohort, pending safety evaluation. Cohort 4 will assess 2 therapy cycles of <sup>67</sup>Cu-SAR-bisPSMA in 6 participants in a 3+3 study design and is the final cohort of dose escalation before moving to the Phase II cohort expansion (Figure 1).

In cohort 2, where 3 participants received a single administration of 8GBq of <sup>67</sup>Cu-SAR-bisPSMA, no dose limiting toxicities (DLTs) have been reported and all 3 participants demonstrated a Prostate Specific Antigen (PSA) reduction, with the first 2 participants exhibiting a PSA reduction of greater than 95% and the last participant showing a drop of greater than 80%. A PSA decline of 50% or greater is one of the primary endpoints of the SECuRE trial and a commonly used surrogate endpoint for efficacy in this patient population. A participant in cohort 2 also had a significant tumour reduction as seen on positron emission tomography/computed tomography (PET/CT) imaging (Figure 2).

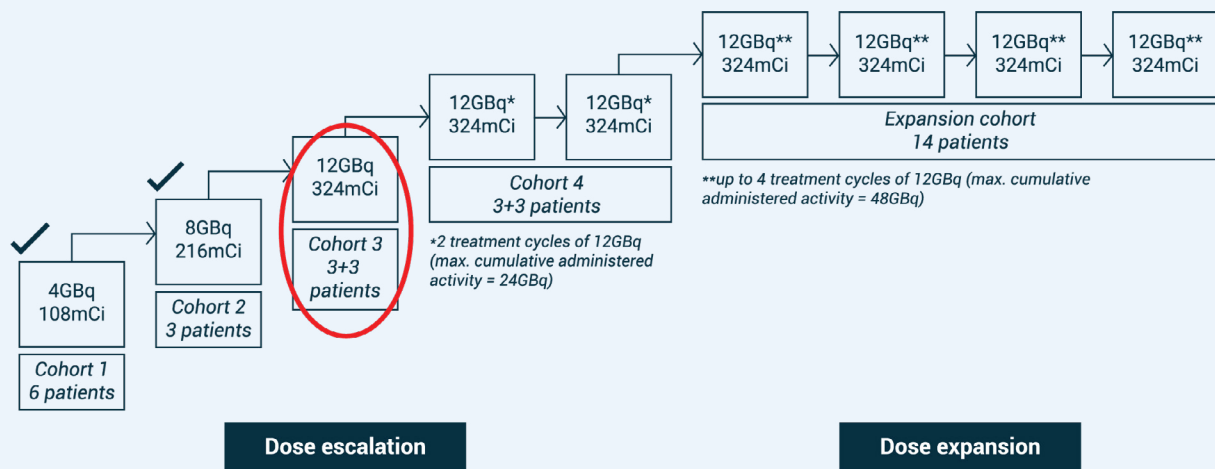
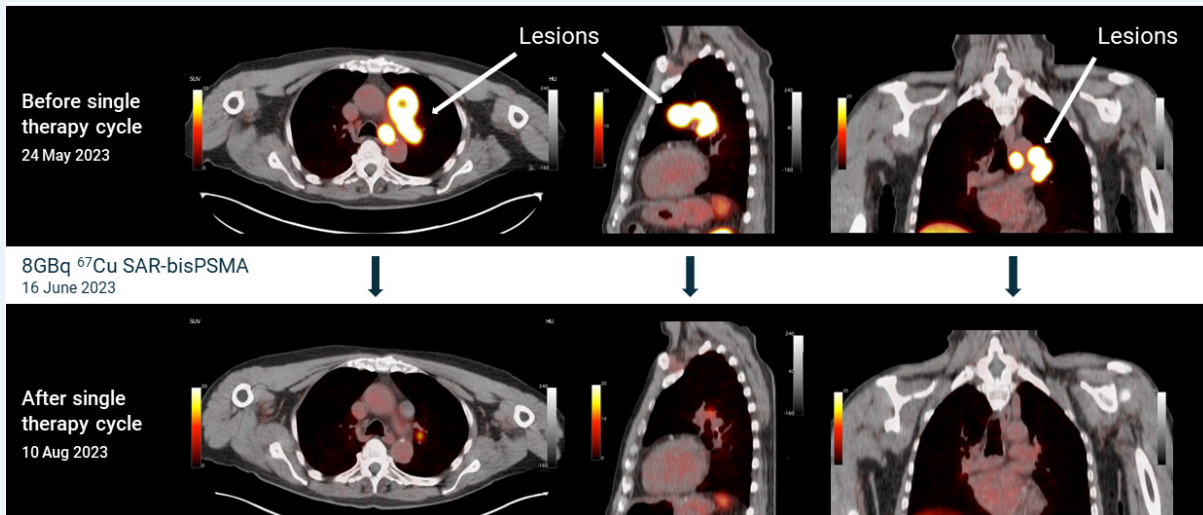


Figure 1. SECuRE Study Design

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# SECuRE



**Figure 2.**  $^{64}\text{Cu}$ -SAR-bisPSMA PET/CT imaging before (arrows) and after a single cycle of 8GBq  $^{67}\text{Cu}$ -SAR-bisPSMA in a cohort 2 participant. Images show considerable reduction in uptake of  $^{64}\text{Cu}$ -SAR-bisPSMA, as well as lesion size. Images: PET/CT fusion.

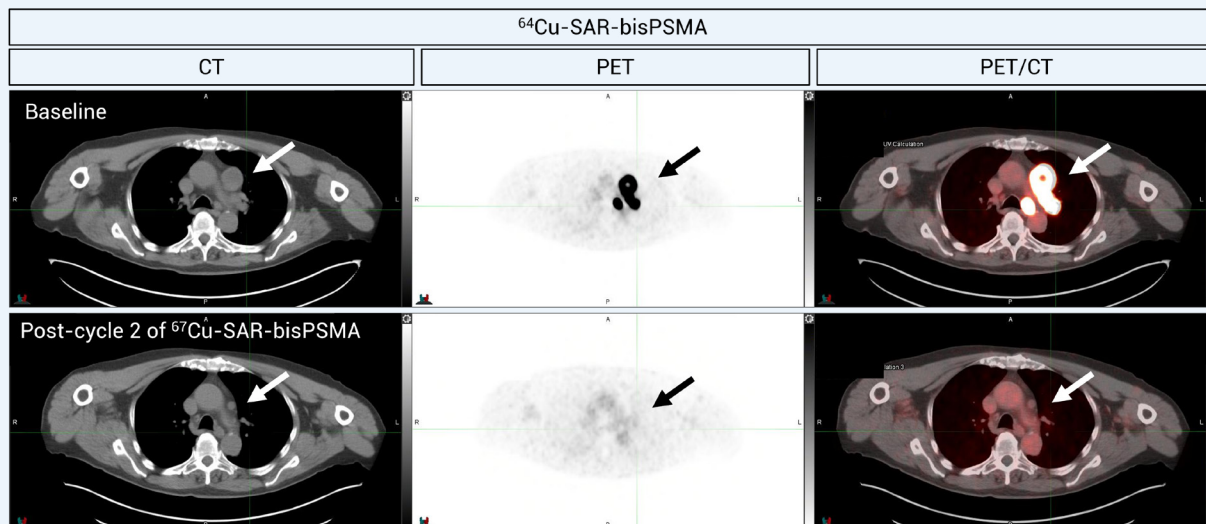
## Patient Case Study: Two Cycles of 8GBq of $^{67}\text{Cu}$ -SAR-bisPSMA

The first patient ever to be dosed with two cycles of 8GBq of  $^{67}\text{Cu}$ -SAR-bisPSMA has had a drop in PSA to undetectable levels, undetectable disease using PET and a near complete response to treatment as defined by Response Evaluation Criteria In Solid Tumours (RECIST) criteria.

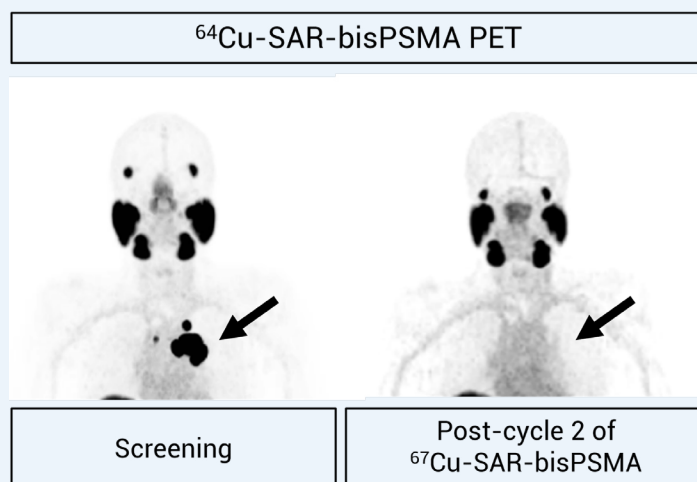
The patient received the first cycle as part of cohort 2 of Clarity's theranostic trial, SECuRE, and a second cycle under the US FDA Expanded Access Program (EAP), as requested by the patient's clinician. The patient experienced mild dry mouth and altered taste, both having improved, and moderate fatigue, which resolved itself.

Following the administration of two cycles of  $^{67}\text{Cu}$ -SAR-bisPSMA at the 8GBq dose level, the near complete response (absence of all detectable cancer after treatment) was reported following the RECIST assessment at the time of imaging – Figures 3 and 4. The complete response criteria was missed by only 2 mm in a lymph node (reduction in size post-therapy from 27 mm to 12 mm). The patient had already failed multiple lines of treatment, including hormone therapy, an investigational agent and chemotherapy prior to being treated with  $^{67}\text{Cu}$ -SAR-bisPSMA.





**Figure 3.** PET/CT images showing uptake of <sup>64</sup>Cu-SAR-bisPSMA at screening in a patient with mCRPC (top, arrows). The patient received 2 cycles of <sup>67</sup>Cu-SAR-bisPSMA at 8GBq. Images post-treatment show no <sup>64</sup>Cu-SAR-bisPSMA uptake (bottom, arrows).



**Figure 4.** PET images showing uptake of <sup>64</sup>Cu-SAR-bisPSMA at screening (arrow) in a patient with mCRPC (left; SUVmax 140.1. SUVmax: maximum standardised uptake value). The patient received 2 cycles of <sup>67</sup>Cu-SAR-bisPSMA at 8GBq. Images post-treatment show no <sup>64</sup>Cu-SAR-bisPSMA uptake (right, arrow).

The patient had a reduction in PSA levels from 47.2 ng/L at baseline to an undetectable level of less than 0.05 ng/ml (Figure 5). PSA is a well characterised marker of tumour burden, clinical response to treatment and an indicator of the recurrence of disease for prostate cancer. Moreover, PSA decline is an independent prognostic indicator of improved overall survival following radioligand therapy<sup>9,10</sup>.

**“As a clinician, there is nothing more rewarding than delivering the news to your patient that their cancer can no longer be detected, and with very few side effects following treatment, particularly for a patient that was heavily pre-treated with multiple lines of therapy. I believe <sup>67</sup>Cu-SAR-bisPSMA presents a new opportunity for cancer patients to have an effective result with few side effects.”**

- Dr Luke Nordquist, Xcancer, Omaha



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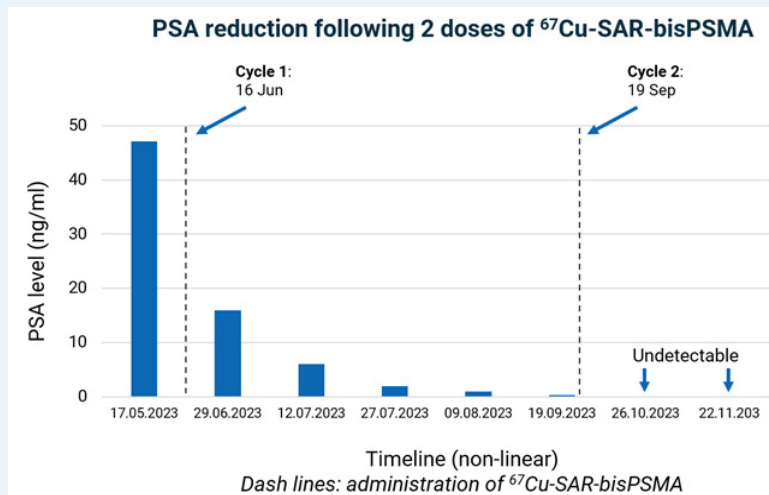


Figure 5. PSA dynamics over time. Series of PSA test results show baseline and decrease over time after the administration of one cycle of <sup>67</sup>Cu-SAR-bisPSMA. PSA level was undetectable in the last 2 measurements after the second cycle of <sup>67</sup>Cu-SAR-bisPSMA. Lower level of detection: 0.05 ng/ml.

## Patient Case Study: Four Cycles of 4GBq of <sup>67</sup>Cu-SAR-bisPSMA

<sup>67</sup>Cu-SAR-bisPSMA single-photon emission computed tomography (SPECT)/CT images depicted below were collected 48 hours after the first and fourth administrations of 4GBq of <sup>67</sup>Cu-SAR-bisPSMA in a patient from cohort 1 who received additional cycles under the US FDA EAP.

Images collected during the fourth therapy cycle demonstrate a reduction in the intensity of the therapeutic <sup>67</sup>Cu-SAR-bisPSMA product uptake at the lesion sites outlined in the images. A reduction of greater than 50% in PSA levels was observed in this participant following the first administration of 4GBq of therapeutic <sup>67</sup>Cu-SAR-bisPSMA and a drop of greater than 90% in PSA was observed after the fourth cycle of 4GBq of <sup>67</sup>Cu-SAR-bisPSMA.

### <sup>67</sup>Cu-SAR-bisPSMA SPECT-CT (Fixed Scaling)

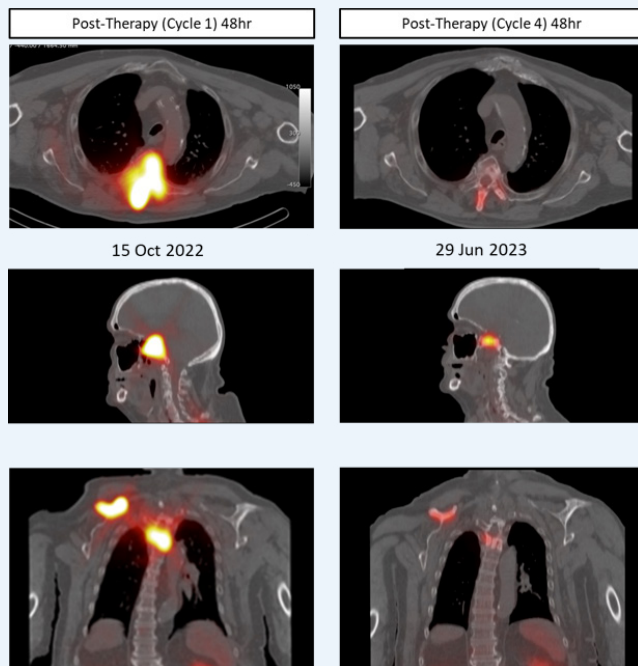


Figure 6. SPECT/CT imaging at 48 hrs following cycle 1 (Oct 2022) and cycle 4 (Jun 2023) of 4GBq <sup>67</sup>Cu-SAR-bisPSMA



# CLARIFY – a diagnostic <sup>64</sup>Cu-SAR-bisPSMA Phase III registrational trial

Clarity safely dosed its first participant with <sup>64</sup>Cu-SAR-bisPSMA in the diagnostic registrational Phase III trial, CLARIFY (NCT06056830)<sup>4</sup>, in December at XCancer Omaha, NE.

CLARIFY derives from "Positron Emission Tomography using <sup>64</sup>Cu-SAR-bisPSMA in participants with high-risk prostate cancer prior to radical prostatectomy: A prospective, single-arm, multi-centre, blinded-review, Phase III diagnostic performance study". It is a non-randomised, open-label clinical trial in 383 participants with confirmed prostate cancer who will be proceeding to radical prostatectomy (total removal of the prostate) 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 <sup>64</sup>Cu-SAR-bisPSMA PET to detect prostate cancer within the pelvic lymph nodes. Evaluation will be across two imaging timepoints, day 1 (1-4 hours post administration) and day 2 (approximately 24 hours post administration). Next-day imaging is not possible with current-generation radiopharmaceuticals due to the shorter half-life of the <sup>68</sup>Ga and <sup>18</sup>F radioisotopes. <sup>64</sup>Cu has an optimal half-life that enables imaging up to 72 hours post administration. The CLARIFY study is investigating if delayed imaging allows for improved disease detection.

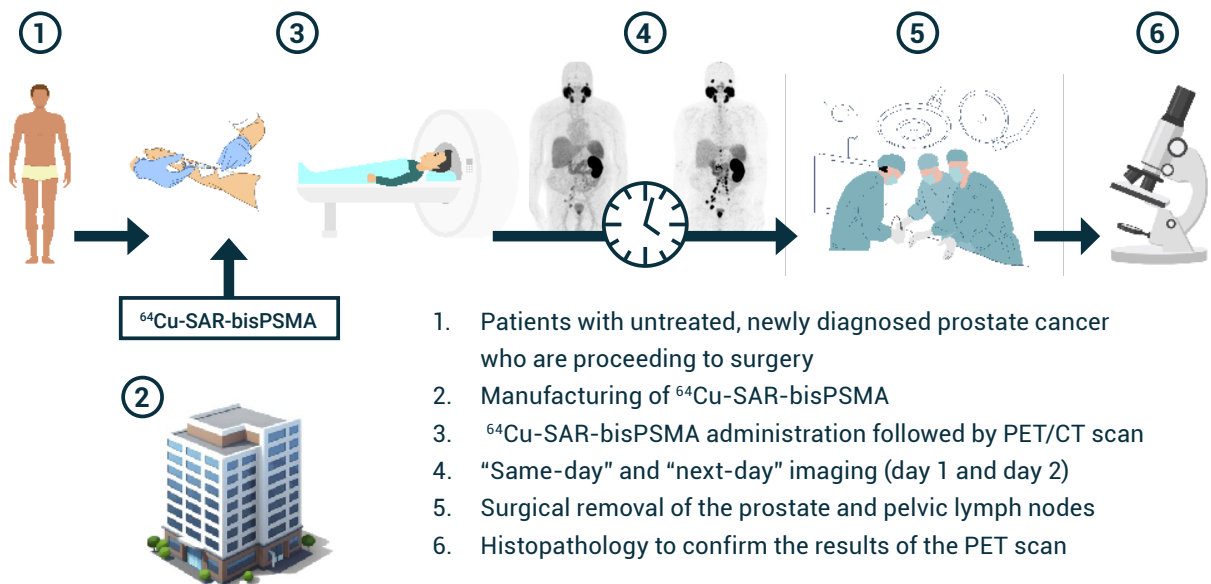
The longer half-life of <sup>64</sup>Cu may not only allow the detection of additional cancerous lesions on delayed imaging, but also provide timely supply of product covering a broad geographic area and flexibility for the scheduling of patients.

Currently approved diagnostic products have low sensitivity, meaning some lesions may remain undetected. Clarity's SAR-bisPSMA product was developed in response to this issue. The dual PSMA-targeting agent and delayed imaging feature have the potential to improve product uptake and retention in prostate cancer lesions. Being able to accurately identify lesions outside of the prostate provides healthcare professionals with crucial information on disease progression and allows for better informed decisions regarding the patients' treatment plan.

The final study results from the CLARIFY trial, along with the PROPELLER study results, are intended to provide sufficient evidence to support an application to the FDA for approval of <sup>64</sup>Cu-SAR-bisPSMA as a new diagnostic imaging agent for pre-prostatectomy prostate cancer patients.

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SAR-bisPSMA – PROSTATE CANCER





## COBRA – a diagnostic $^{64}\text{Cu}$ -SAR-bisPSMA trial

Initial results of Clarity's first trial in patients with BCR of prostate cancer (with negative or equivocal standard of care [SOC] imaging), COBRA (NCT05249127)<sup>5</sup>, showed that  $^{64}\text{Cu}$ -SAR-bisPSMA is safe and highly effective in detecting prostate cancer lesions.

The US-based COBRA study (Copper-64 SAR-bisPSMA in Biochemically Recurrent prostate cancer) was a first-in-human trial of  $^{64}\text{Cu}$ -SAR-bisPSMA in patients with BCR of prostate cancer. It was a multi-centre, single-arm, non-randomised, Phase I/II diagnostic imaging study of  $^{64}\text{Cu}$ -labelled SAR-bisPSMA ( $^{64}\text{Cu}$ -SAR-bisPSMA) administered to participants with BCR of prostate cancer following definitive therapy. The primary objectives of the trial were to investigate the safety and tolerability of  $^{64}\text{Cu}$ -SAR-bisPSMA as well as its ability to correctly detect recurrence of prostate cancer.

While SOC imaging was unable to identify the location of BCR of prostate cancer,  $^{64}\text{Cu}$ -SAR-bisPSMA identified prostate cancer in up to 80% of the patients (Figure 7). The number of lesions detected by  $^{64}\text{Cu}$ -SAR-bisPSMA almost doubled from same-day (up to 80) to next-day imaging (up to 153), demonstrating the benefits of delayed scans. Clinicians reported they would change their treatment plan in approximately 50% of patients due to  $^{64}\text{Cu}$ -SAR-bisPSMA scans, signaling a potential material improvement in patient care (Figures 8, 9 and 10).

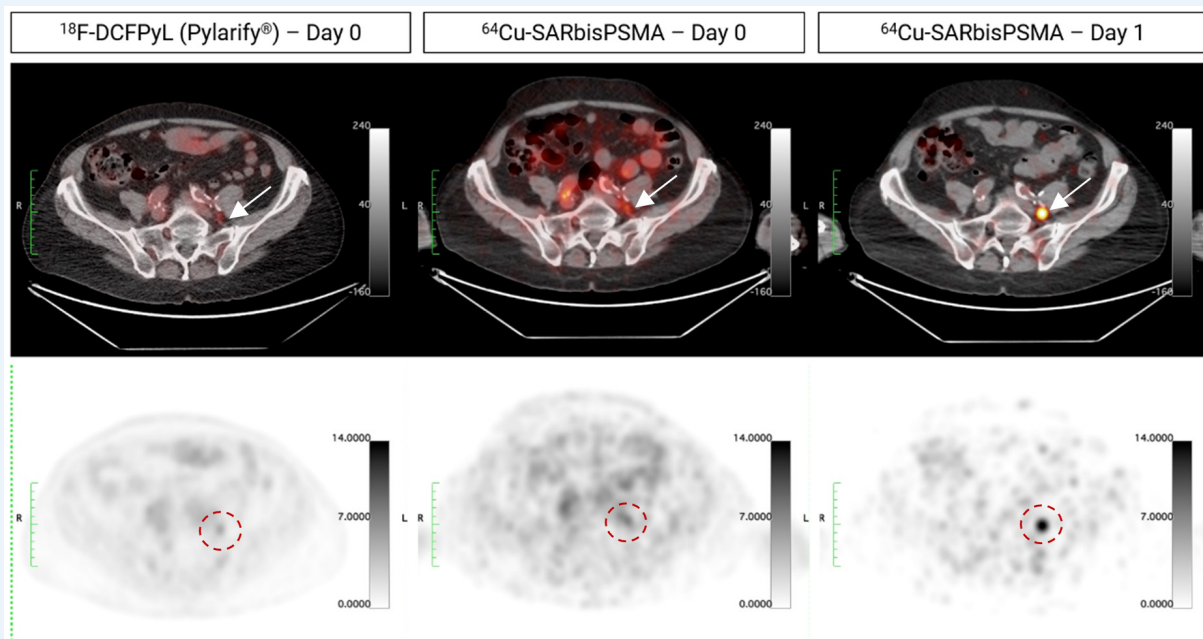


Figure 7. Identification of lesion in the pelvic region using  $^{64}\text{Cu}$ -SAR-bisPSMA on next-day imaging (right), negative on same-day imaging ( $^{64}\text{Cu}$ -SAR-bisPSMA; center) and equivocal on screening SOC imaging ( $^{18}\text{F}$ -DCFPyL, Pylarify®; left). SUVmax of the lesion across scans (arrows and red circles) was 2.3, 4.3 and 17.5 ( $^{18}\text{F}$ -DCFPyL, Pylarify®, Day 0 and Day 1  $^{64}\text{Cu}$ -SAR-bisPSMA, respectively). Top images: PET/CT fusion. Bottom images: PET.



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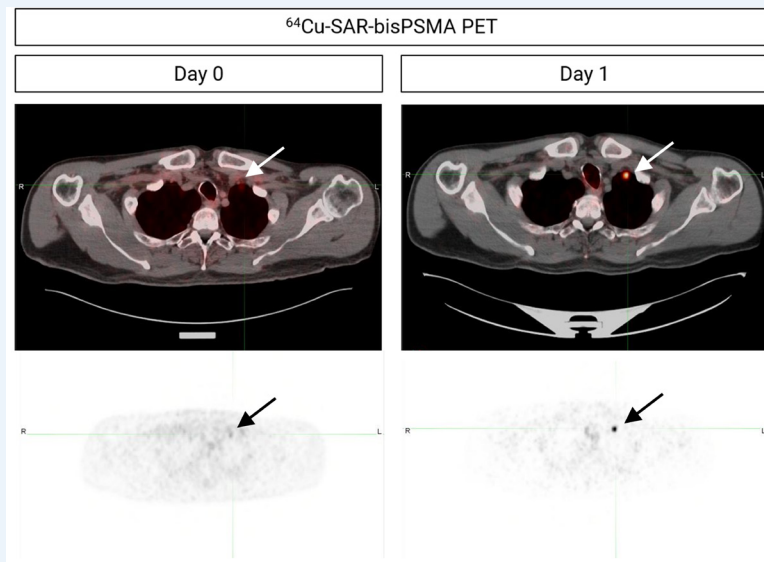


Figure 8. Extra-pelvic lesion identified on next-day imaging using <sup>64</sup>Cu-SAR-bisPSMA on Day 1 but not detected on Day 0 (arrows). Top images: PET/CT fusion. Bottom images: PET.

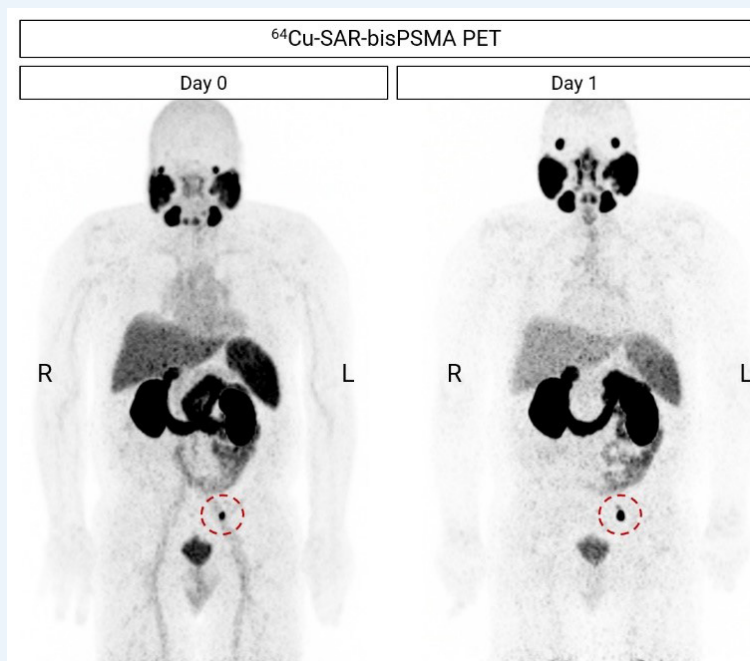
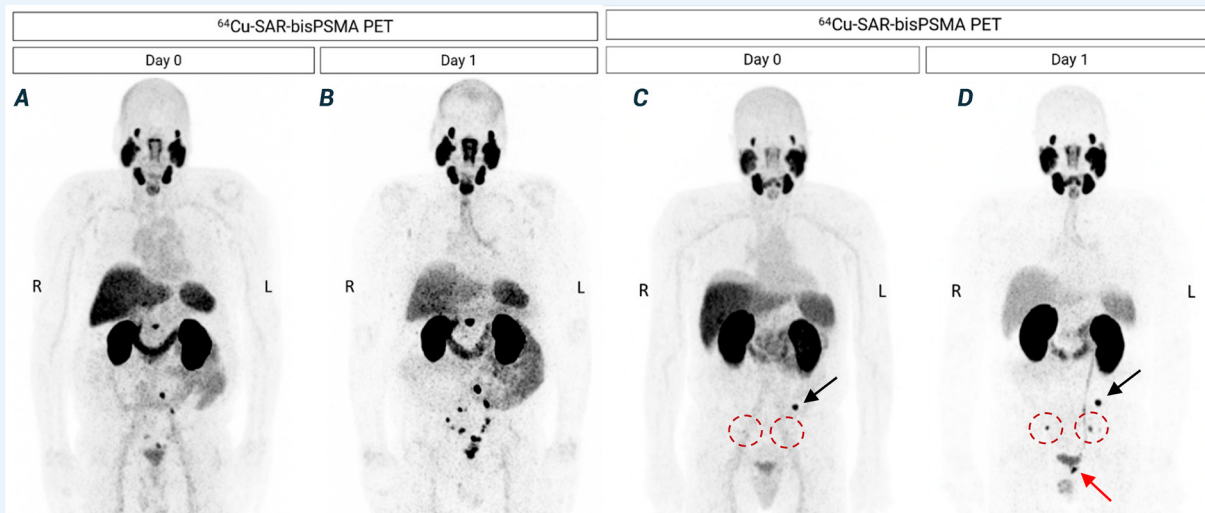


Figure 9. <sup>64</sup>Cu-SAR-bisPSMA PET showing a positive pelvic lymph node (LN; red circle, maximum intensity projection [MIP]). CT-guided needle biopsy of the lesion was performed and was negative for prostate cancer. This was followed by an excisional biopsy of the lesion, which confirmed the presence of prostate cancer by histopathology. Next-day imaging showed an increase of SUVmax of more than double compared to same-day imaging, from 20.8 on Day 0 to 50.4 on Day 1. All images are displayed at MIP.





**Figure 10. Next-day imaging identified additional lesions compared to same-day imaging. A, B – patient 1: <sup>64</sup>Cu-SAR-bisPSMA PET showing positive LNs in the pelvic and extra-pelvic (retroperitoneal) regions and lesions in the prostatic bed. C, D – patient 2: <sup>64</sup>Cu-SAR-bisPSMA PET showing a lesion in the pelvic bone (black arrow) on both days, pelvic LNs more clearly visualised on next-day image (red circles), and prostatic bed lesion only visualised on next-day imaging (red arrow). Average SUVmax for the bone and pelvic LN lesions increased from 9.8 on Day 0 to 20.0 on Day 1. Prostate cancer in the pelvic LNs was confirmed by histopathology in both patients. All images are displayed at MIP.**

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SAR-bisPSMA – PROSTATE CANCER

“The initial results from the COBRA study confirmed the advantages of <sup>64</sup>Cu-SAR-bisPSMA not only by detecting lesions in patients whose SOC scans were negative or equivocal at screening, but also by identifying more lesions on next-day imaging compared to same-day scans. As <sup>64</sup>Cu-SAR-bisPSMA may represent a new paradigm in diagnostic imaging, we have already commenced planning of the registrational Phase III study in the BCR of prostate cancer patients”.

- Dr Alan Taylor





# SAR-BOMBESIN PROSTATE CANCER

**SAR-Bombesin is a highly targeted pan-cancer theranostic radiopharmaceutical.**

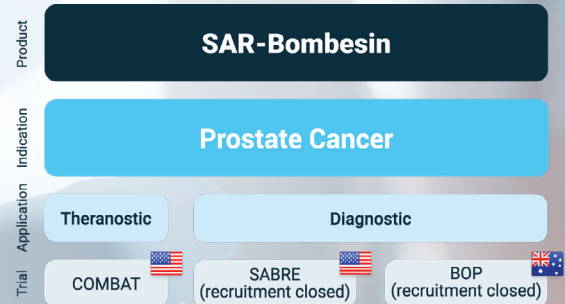
It is being developed for diagnosing, staging and subsequently treating cancers that express a specific receptor called the gastrin releasing peptide receptor (GRPr), including prostate and breast cancer. Like all Clarity products, the SAR-Bombesin product uses copper-64 (<sup>64</sup>Cu) for imaging (<sup>64</sup>Cu-SAR-Bombesin) or copper-67 (<sup>67</sup>Cu) for therapy (<sup>67</sup>Cu-SAR-Bombesin).

Approximately 20-25% of prostate cancer patients with BCR and approximately 25% of mCRPC patients have low or no uptake of PSMA-targeting tracer<sup>11-15</sup>. These patients are unlikely to show meaningful uptake of PSMA-targeted products, such as <sup>68</sup>Ga-PSMA-11 for imaging, and therefore may not be eligible for a PSMA-targeted treatment, such as <sup>177</sup>Lu-PSMA-617. Currently these patients have few therapy options available to treat their cancer.

SAR-Bombesin is currently being investigated in two clinical trials in prostate cancer indications:

- theranostic Phase I/IIa trial in the US (COMBAT)<sup>2</sup> in patients with mCRPC; and
- diagnostic Phase II trial in the US (SABRE)<sup>6</sup> in patients with BCR of prostate cancer.

While the clinical development path for SAR-Bombesin is focused on prostate cancer with negative or low PSMA expression, there is a significant opportunity to expand its use into the broader group of prostate cancer patients who have both GRPr and PSMA expression on their cancers, as well as into other malignancies that express GRPr, such as breast, lung and pancreatic cancers.



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# COMBAT

## COMBAT - a theranostic $^{64}\text{Cu}/^{67}\text{Cu}$ -SAR-Bombesin prostate cancer trial

Clarity treated the first participant in its theranostic  $^{64}\text{Cu}/^{67}\text{Cu}$ -SAR-Bombesin Phase I/IIa trial in mCRPC, COMBAT ([NCT05633160](#))<sup>2</sup>. Recruitment into the COMBAT trial is ongoing with additional sites soon joining the study.

COMBAT is a dose escalation and cohort expansion trial in up to 38 participants. The aim for the trial is to determine the safety and efficacy of  $^{67}\text{Cu}$ -SAR-Bombesin as well as the safety of  $^{64}\text{Cu}$ -SAR-Bombesin in participants with GRPr expressing mCRPC in patients who are ineligible for therapy with  $^{177}\text{Lu}$ -PSMA-617.

**SAR-Bombesin is a pan-cancer product and the open IND offers exciting opportunities for exploring new theranostic indications with this versatile agent.**



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## SABRE – a diagnostic $^{64}\text{Cu}$ -SAR-Bombesin prostate cancer trial

Clarity achieved its recruitment target for the US-based diagnostic  $^{64}\text{Cu}$ -SAR-Bombesin trial for patients with PSMA-negative prostate cancer, SABRE ([NCT05407311](#))<sup>6</sup> in November 2023. Fifty percent recruitment in the trial was achieved in July 2023.

SABRE is a Phase II multi-center, 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  $^{64}\text{Cu}$ -SAR-Bombesin, as well as its ability to correctly detect the recurrence of prostate cancer.

In the SABRE trial, 53 participants were imaged on the day of product administration (same-day imaging) and 24 hours later (next-day imaging). The trial is currently in the follow-up phase. The study is investigating if delayed imaging allows better identification of very early disease for patients with low PSMA expression.

In Figure 11, the images in the cross hairs on same-day and next-day scans following  $^{64}\text{Cu}$ -SAR-Bombesin administration clearly identify a pelvic lymph node with product uptake, while there was no uptake with  $^{18}\text{F}$ -DCFPyL, an FDA-approved PSMA agent.

Preclinical data, along with successful C-BOBCAT and BOP investigator-initiated clinical trials have already showed 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  $^{64}\text{Cu}$ -SAR-Bombesin product into a registrational Phase III trial for first approvals in the US.

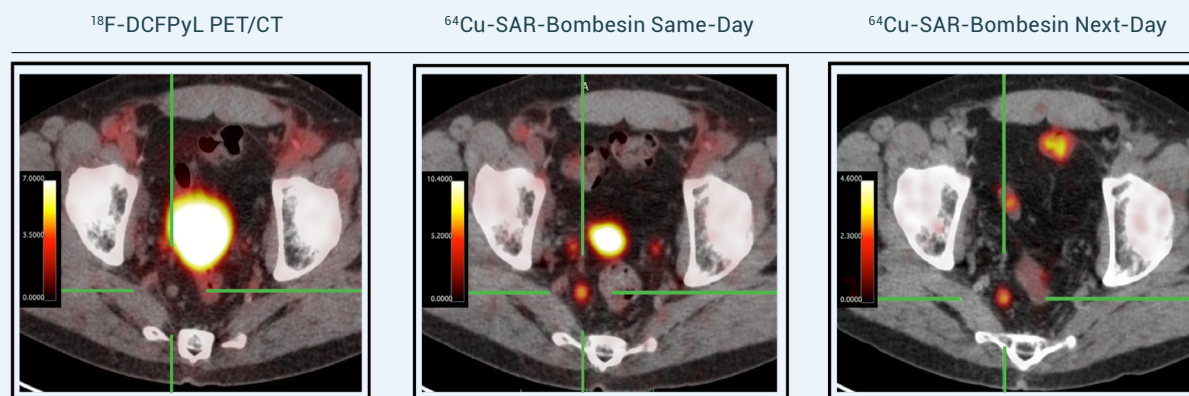


Figure 11.  $^{64}\text{Cu}$ -SAR-Bombesin detected a positive lymph node on scans performed on two different days (same-day and next-day scans). No uptake was observed using  $^{18}\text{F}$ -DCFPyL PET/CT. A subsequent biopsy, performed and assessed locally by the study site, has confirmed prostate cancer.

## BOP – a diagnostic <sup>64</sup>Cu-SAR-Bombesin investigator-initiated prostate cancer trial

Initial data from the diagnostic BOP (NCT05613842)<sup>7</sup> trial, evaluating <sup>64</sup>Cu-SAR-Bombesin, was presented at the European Association of Nuclear Medicine (EANM) 2023 Congress.

BOP is a Phase II investigator-initiated trial (IIT) in 30 participants led by Prof Louise Emmett at St Vincent's Hospital, Sydney. The IIT is assessing the safety of <sup>64</sup>Cu-SAR-Bombesin as well as looking at the diagnostic potential across two different groups of men:

1. Participants with BCR of their prostate cancer who have negative PSMA PET imaging scans or low PSMA expressing disease; and
2. Participants with mCRPC who are not suitable for PSMA-targeted therapy.

Study results from the first cohort (BCR) have been presented at the European Association of Nuclear Medicine (EANM) 2023 Congress in Vienna, Austria, one of the most prestigious conferences in the nuclear medicine field. A manuscript with full results from the study is currently being prepared for submission.

**<sup>64</sup>Cu-SAR-Bombesin was found to be safe and able to detect prostate cancer lesions in over a third of participants with negative or equivocal SOC PSMA PET in participants in the first cohort of the BOP trial.**

**No adverse events from <sup>64</sup>Cu-SAR-Bombesin administration were reported in participants in the first cohort of the BOP trial. They received the mean dose of 210MBq of <sup>64</sup>Cu-SAR-Bombesin and imaged with PET at 1, 3 and 24 hours post-administration of the product.**

**"This could be the difference between having an incorrect negative cancer diagnosis leading to cancer progression and now having an effective treatment plan that may lead to long term remission,"**

**- Dr Alan Taylor**



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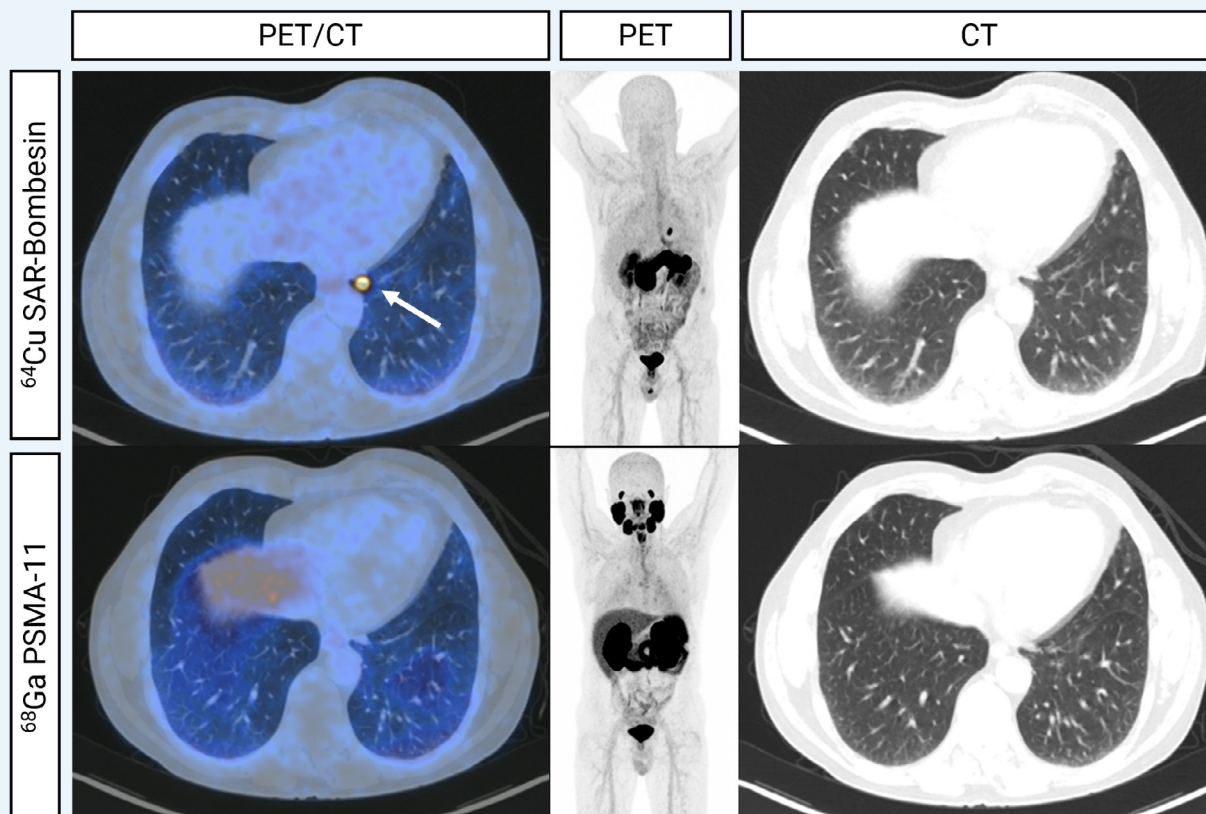


Figure 12. Fused, MIP and CT (left to right) images from <sup>64</sup>Cu-SAR-Bombesin (top) and <sup>68</sup>Ga-PSMA-11 (bottom) PET of a patient demonstrating a left subpleural lesion with <sup>64</sup>Cu-SAR-Bombesin uptake (arrow) without SOC PSMA uptake. This patient underwent a lobectomy with histopathology demonstrating metastatic prostate cancer.

Reproduced with permission from Prof Louise Emmett (St Vincent's Hospital, Sydney – Australia). EANM 2023.

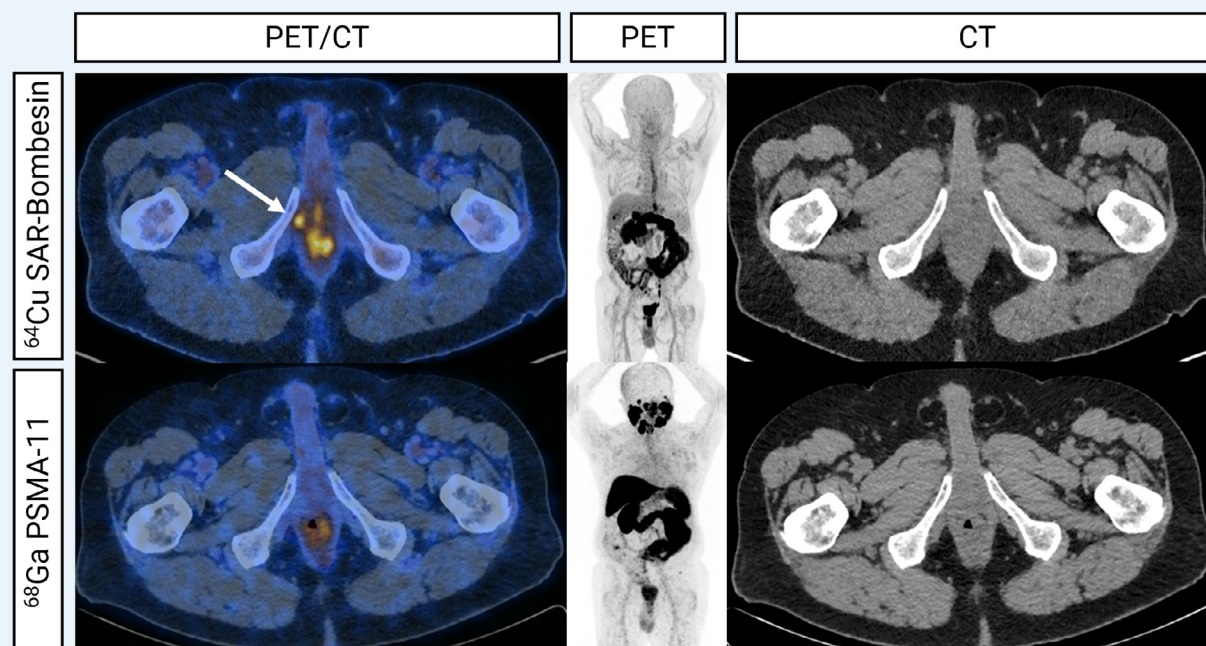


Figure 13. Fused, MIP and CT (left to right) images from <sup>64</sup>Cu-SAR-Bombesin (top) and <sup>68</sup>Ga-PSMA-11 (bottom) PET of a patient demonstrating uptake at the right urethral anastomosis on <sup>64</sup>Cu-SAR-Bombesin alone (arrow). This patient was managed with local radiotherapy with improvement in PSA post-treatment.

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# SARTATE NEUROBLASTOMA AND NETs

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

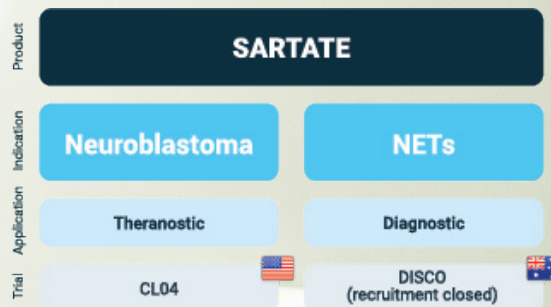
It is being developed for diagnosing, staging and subsequently treating cancers that express somatostatin receptor 2 (SSTR2), including neuroblastoma and neuroendocrine tumours (NETs). Like all Clarity products, SARTATE can be used with copper-64 ( $^{64}\text{Cu}$ ) for imaging ( $^{64}\text{Cu}$ -SARTATE) or copper-67 ( $^{67}\text{Cu}$ ) for therapy ( $^{67}\text{Cu}$ -SARTATE).

Clarity is progressing two trials with the SARTATE product, one theranostic trial in neuroblastoma and one diagnostic trial in NETs:

- **CL04** theranostic trial with an open Investigational New Drug (IND) application in the US (NCT04023331)<sup>3</sup>
- **DISCO** diagnostic trial in Australia (NCT04438304)<sup>8</sup>

Neuroblastoma, an aggressive childhood cancer, is Clarity's key focus with the SARTATE product. In 2020, the US FDA awarded Clarity two Orphan Drug Designations (ODDs) in this important indication, one for  $^{64}\text{Cu}$ -SARTATE as a diagnostic agent for the clinical management of neuroblastoma and one for  $^{67}\text{Cu}$ -SARTATE as a therapy of neuroblastoma, as well as two Rare Paediatric Disease Designations (RPDDs) for these products.

Should Clarity be successful in achieving marketing approval from the US FDA for these two products in neuroblastoma, RPDDs may allow the Company to access a total of two tradeable Priority Review Vouchers (PRVs) valued at ~\$100M USD each.<sup>16</sup>



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## CL04 – a theranostic $^{64}\text{Cu}/^{67}\text{Cu}$ -SARTATE trial in neuroblastoma

Clarity is progressing through the final dose-escalation cohort of the CL04 theranostic trial (NCT04023331)<sup>3</sup> in neuroblastoma patients and has successfully completed cohort 3 of the CL04 theranostic trial at the dose level of 275MBq/kg body weight in July. Recruitment is now progressing well in cohort 4 at the dose level of 375MBq/kg body weight of  $^{67}\text{Cu}$ -SARTATE, the highest dose level in the dose escalation phase of the trial.

CL04 is a multi-centre, dose-escalation, open label, non-randomised, theranostic clinical trial in paediatric patients with high-risk neuroblastoma. The trial is a Phase I/IIa with up to 34 participants where not only the safety and tolerability of both  $^{64}\text{Cu}$ -SARTATE and  $^{67}\text{Cu}$ -SARTATE are being assessed, but also the effectiveness of  $^{67}\text{Cu}$ -SARTATE as a treatment for neuroblastoma. Participants who show uptake of  $^{64}\text{Cu}$ -SARTATE in lesions will continue in the trial and will receive treatment with  $^{67}\text{Cu}$ -SARTATE.

In the dose escalation phase of the trial, each subsequent cohort will receive an increase in the therapeutic dose administered. Generally speaking, higher therapeutic dose is usually associated with greater therapeutic response, up to a certain threshold where toxicity may occur. The CL04 trial is designed to gradually increase the dose of  $^{67}\text{Cu}$ -SARTATE administered to participants in each cohort, up to a maximum of 4 cohorts, until the Maximum Tolerated Dose (MTD) is reached.

Cohort 4 participants are treated with a single dose of 375MBq of  $^{67}\text{Cu}$ -SARTATE per kilogram body weight. This builds on the first 3 cohorts:

- Cohort 1 – 3 participants received an initial single dose of 75MBq/kg body weight  $^{67}\text{Cu}$ -SARTATE
- Cohort 2 – 3 participants received an initial single dose of 175MBq/kg body weight  $^{67}\text{Cu}$ -SARTATE
- Cohort 3 – 3 participants received an initial single dose of 275MBq/kg body weight  $^{67}\text{Cu}$ -SARTATE

Once the MTD is established in the dose escalation phase, the trial will advance to the cohort expansion phase where an additional 10 participants will receive at least 2 therapy cycles of  $^{67}\text{Cu}$ -SARTATE at the MTD, with up to 4 therapy cycles in total for those participants who demonstrate therapeutic benefit.

Some participants in the completed cohorts have received multiple therapy cycles of  $^{67}\text{Cu}$ -SARTATE in addition to the single therapy cycle being assessed in the dose escalation phase of the CL04 trial. These subsequent therapy cycles are strictly contingent on the investigators' assessment that the patient's disease has not progressed after the first dose.

Clarity looks forward to building upon the promising data reported to date and progressing recruitment to the dose-expansion phase of the trial.



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## DISCO – a diagnostic $^{64}\text{Cu}$ -SARTATE NETs trial

Clarity successfully closed recruitment for the Phase II diagnostic  $^{64}\text{Cu}$ -SARTATE trial, DISCO ([NCT04438304](#))<sup>8</sup>. A total of 45 patients have been enrolled and imaged in the trial.

DISCO is assessing the performance of Clarity's SARTATE imaging product as a potential new way to help diagnose and manage NETs. It is a Phase II trial performed across four sites in Australia comparing the diagnostic performance of  $^{64}\text{Cu}$ -SARTATE at 4 and 20 hours post-administration to the current SOC,  $^{68}\text{Ga}$ -DOTATATE, at one hour. The study looks to build on earlier studies with SARTATE (Hicks, R. et al)<sup>17</sup> which demonstrated that delayed imaging may lead to better identification of disease.

The trial was originally planned for up to 63 patients based on an expected discordance level between imaging with Clarity's  $^{64}\text{Cu}$ -SARTATE and the current SOC,  $^{68}\text{Ga}$ -DOTATATE. The sample size was adjusted to 45 patients based on the pre-planned assessment of the images to generate sufficient evidence to plan for a Phase III trial in this indication, enabling recruitment to successfully close early.

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SARTATE - NETs



# DISCOVERY PROGRAM

**In addition to further 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.**

In August 2023, Clarity added a worldwide exclusive license from Memorial Sloan Kettering Cancer Center (MSK) to its intellectual property (IP). The license is to IP covering cutting-edge technology that enables antibody "pre-targeting" for the diagnosis and treatment of cancer, US Patent No. 11,135,320 (US16/203,513) Radioligands For Pretargeted PET Imaging And Methods Of Their Therapeutic Use (expiry 11 Oct 2035).

Pre-targeting is a radiopharmaceutical approach to diagnosing and treating cancer patients that harnesses the benefits of antibody targeting, amplifying uptake of radiopharmaceutical products in cancerous tissue, while reducing healthy tissue exposure to radiation that can arise due to the slow clearance of antibodies. This is achieved by tagging an antibody, designed specifically to target cancer cells, and then injecting it into the body. After several days, a chaser compound, which only attaches to the antibody tag, is injected. The chaser compound is initially radiolabelled with copper-64 to enable imaging with a PET camera which visualises the extent of cancer burden. Once the cancer is visualised, a second administration of the chaser is administered, this time radiolabelled with the therapeutic radionuclide copper-67, so that the cancer cells can be irradiated with the goal of killing the tumours.

A clinical trial using the MSK licensed technology is open for recruitment in patients with pancreatic cancer at MSK headed by Dr Pandit-Taskar ([NCT05737615](#))<sup>18</sup>.

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# MANUFACTURING AND SUPPLY CHAIN

## **Targeted Copper Theranostics (TCTs) offer key manufacturing, logistical, and environmental advantages compared to other radiopharmaceuticals in the market.**

Combined with clinical benefits, which Clarity is actively exploring through its clinical program, these differentiators are the reason TCTs are considered the next generation of radiopharmaceuticals. They enable Clarity to employ the big pharma model of centralised manufacturing of both diagnostic and therapeutic products under current Good Manufacturing Practice (cGMP), something that the current generation of products is lacking.

All TCT products are manufactured at room temperature, significantly lowering the risk of batch failures, which historically has been a challenge for current-generation radiopharmaceuticals that require heating the biological targeting agents to 90°C during manufacture.

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

Clarity continued to expand its manufacturing and supply chain footprint, creating additional capacity and flexibility to supply products to any ZIP-code in the US. During the reporting period, NorthStar Medical Radioisotopes (NorthStar), a commercial-stage nuclear medicine company focused on advancing patient care by providing diagnostic and therapeutic radioisotopes, started supplying copper-67 produced using their commercial scale manufacturing process exclusively to Clarity. NorthStar's copper-67 is manufactured using a scalable, efficient and environmentally preferable process based on electron accelerator technology. It has unique advantages compared to current-generation radiopharmaceuticals as they rely on aging nuclear reactors mainly outside the US.

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# REFERENCE LIST

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# FINANCIAL REPORT

OF CLARITY PHARMACEUTICALS LTD

FOR THE HALF YEAR ENDED

31 DECEMBER 2023

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## DIRECTORS' REPORT

FOR THE HALF-YEAR ENDED 31 DECEMBER 2023

The Directors of Clarity Pharmaceuticals Ltd (Clarity Pharmaceuticals) present their report together with the financial statements of the consolidated entity, being Clarity Pharmaceuticals (the Company) and its controlled entities (the Group) for the half-year ended 31 December 2023.

## DIRECTOR DETAILS

The following persons were Directors of Clarity Pharmaceuticals during or since the end of the half-year:

Dr Alan Taylor	Executive Chairperson
Dr Colin Biggin	Managing Director and Chief Executive Officer
Mr Rob Thomas	Lead Independent Director (resigned effective 23 August 2024)
Ms Rosanne Robinson	Non-Executive Director
Dr Christopher Roberts	Non-Executive Director
Dr Thomas Ramdahl	Non-Executive Director
Ms Cheryl Maley	Non-Executive Director (resigned effective 16 January 2024)

## RESULT

The loss for the half-year was \$17.2 million (2022: \$11.2 million loss). In the six months to December 2023, there was a significant increase in research and development expenditure, up \$4.9 million to \$19.7 million, reflecting an increase in clinical trial activities.

## STATEMENT OF FINANCIAL POSITION

The Group's financial position at 31 December 2023 compared to the prior year was as follows:

- Liquid assets of \$38.0 million (30 Jun 2023: \$65.0 million) comprising cash on hand of \$23.2 million (30 Jun 2023: \$31.2 million) and term deposits of \$14.8 million (30 Jun 2023: \$33.8 million).
- Net assets decreased to \$53.1 million from \$69.2 million at 30 June 2023.

The Board believes the Group is well placed to support its programs throughout 2024.



## REVIEW OF OPERATIONS

### CORPORATE OVERVIEW

The Company remains well funded with \$32.2 million as at the date of this report together with an expected R&D tax incentive of \$10.1 million. This puts Clarity Pharmaceuticals in a strong position to execute its clinical and operational objectives.

During the reporting period, management remained focussed on executing Clarity Pharmaceuticals' goal of developing the next generation of radiopharmaceutical products. The key highlights and significant events, until the date of this report, demonstrate the excellent progress made to date in achieving that objective.

### CLINICAL

Clarity is actively progressing a number of trials in its three key product areas, SAR-bisPSMA, SAR-Bombesin and SARTATE.

#### SAR-bisPSMA – Prostate Cancer

##### **SECURE - a theranostic $^{64}\text{Cu}/^{67}\text{Cu}$ -SAR-bisPSMA trial**

The SECURE theranostic trial is a Phase I/IIa trial for the treatment of PSMA-expressing metastatic castrate resistant prostate cancer (mCRPC) using  $^{64}\text{Cu}/^{67}\text{Cu}$ -SAR-bisPSMA. Clarity successfully completed cohort 2 of the SECURE trial at the 8GBq dose level and treated the first participant in cohort 3 at 12GBq, the highest dose level in the dose escalation phase of the trial, in August. Cohort 3 remains ongoing as planned.

##### **Patient Case Study: Two Cycles of 8GBq of $^{67}\text{Cu}$ -SAR-bisPSMA**

In November, the first mCRPC patient to ever receive 2 cycles of 8GBq of  $^{67}\text{Cu}$ -SAR-bisPSMA (one dose from the SECURE trial and one from the US Expanded Access Program [EAP]) exhibited a Prostate Specific Antigen (PSA) reduction to undetectable levels post-treatment, with favourable safety profile. The patient also had undetectable lesions using positron emission tomography (PET) imaging post-treatment. This case was presented at the Annual International Prostate Cancer Update conference.

##### **Patient Case Study: Four Cycles of 4GBq of $^{67}\text{Cu}$ -SAR-bisPSMA**

In August, a patient from cohort 1 of the SECURE trial who received a total of four cycles of 4GBq of  $^{67}\text{Cu}$ -SAR-bisPSMA (one dose from the SECURE trial and three from the US Expanded Access Program (EAP)) exhibited a significant reduction in the intensity of the therapeutic  $^{67}\text{Cu}$ -SAR-bisPSMA product uptake at the lesion sites. A reduction of greater than 90% in PSA was observed after the fourth cycle of 4GBq of  $^{67}\text{Cu}$ -SAR-bisPSMA.

##### **CLARIFY – a diagnostic $^{64}\text{Cu}$ -SAR-bisPSMA Phase III registrational trial**

The CLARIFY diagnostic trial is a 383-patient registrational Phase III trial of participants with high-risk prostate cancer prior to radical prostatectomy. It opened enrolment and recruited its first participant in December 2023. The trial will examine the diagnostic potential of  $^{64}\text{Cu}$ -SAR-bisPSMA to detect regional nodal metastasis. In addition to investigating the benefits of Clarity's optimised bisPSMA product in this patient population, CLARIFY will look at the potential benefits of both same-day and next-day imaging, a benefit currently unique to the SAR technology platform.

Other milestones in relation to the CLARIFY trial in the reporting period include a successful end-of-phase (EOP) meeting with the US FDA in July, partnering with PSI CRO AG, a global contract research organisation committed

to on-time enrolment in radiopharmaceutical clinical trials, in October 2023, and initiating the first clinical site at Xcancer Omaha, NE, in November.

#### **COBRA – a diagnostic $^{64}\text{Cu}$ -SAR-bisPSMA trial**

The COBRA diagnostic trial was a US-based Phase I/II trial of  $^{64}\text{Cu}$ -SAR-bisPSMA. Initial results of the trial in patients with biochemical recurrence (BCR) of prostate cancer (with negative or equivocal standard of care [SOC] imaging) showed that  $^{64}\text{Cu}$ -SAR-bisPSMA is safe and highly effective in detecting prostate cancer lesions. In this patient group in whom SOC imaging was unable to identify the location of the cancer,  $^{64}\text{Cu}$ -SAR-bisPSMA identified prostate cancer in up to 80% of patients. The number of lesions detected by  $^{64}\text{Cu}$ -SAR-bisPSMA almost doubled from same-day (up to 80) to next-day imaging (up to 153), demonstrating the benefits of delayed scans. Next-day imaging is a feature with important clinical relevance and it is not offered by currently approved PSMA agents. Clinicians reported they would change their treatment plan in approximately 50% of patients due to  $^{64}\text{Cu}$ -SAR-bisPSMA scans, signalling a potential material improvement in patient care.

#### SAR-Bombesin – Prostate Cancer

#### **COMBAT – a theranostic $^{64}\text{Cu}/^{67}\text{Cu}$ -SAR-Bombesin prostate cancer trial**

The COMBAT theranostic trial is a US-based Phase I/IIa trial for identification and treatment of mCRPC that is expressing the Gastrin-Releasing Peptide receptor (GRPr) using  $^{64}\text{Cu}/^{67}\text{Cu}$ -SAR-Bombesin in participants who are ineligible for therapy with  $^{177}\text{Lu}$ -PSMA-617. Clarity treated the first participant in the COMBAT trial in October. The aim for the trial is to determine the safety and efficacy of  $^{67}\text{Cu}$ -SAR-Bombesin in this patient group.

#### **SABRE – a diagnostic $^{64}\text{Cu}$ -SAR-Bombesin prostate cancer trial**

The SABRE diagnostic trial was a US-based Phase II trial in participants with suspected recurrence of their prostate cancer and who have negative or equivocal findings of prostate cancer on standard of care imaging, including approved prostate specific membrane antigen (PSMA) agents. Clarity achieved its recruitment target for the SABRE trial in November where 53 patients have been imaged with  $^{64}\text{Cu}$ -SAR-Bombesin on the day of product administration (same-day imaging) and 24 hours later (next-day imaging). Preceding this milestone was the achievement of the 50% recruitment target in July. The primary objectives of the SABRE trial were to investigate the safety and tolerability of the product as well as its ability to correctly detect recurrence of prostate cancer. Results from the SABRE trial have guided the design of the registrational Phase III study in this patient population. The trial is currently in the follow-up phase.

#### **BOP – a diagnostic $^{64}\text{Cu}$ -SAR-Bombesin investigator-initiated prostate cancer trial**

The BOP diagnostic trial was an Australia-based investigator-initiated Phase II PET imaging trial of participants with negative PSMA PET or low PSMA expression disease in patients with suspected biochemical recurrence (BCR) of their prostate cancer and participants with mCRPC using  $^{64}\text{Cu}$ -SAR-Bombesin. The trial was led by Prof Louise Emmett at St Vincent's Hospital Sydney. Initial data from the BOP trial was presented at the European Association of Nuclear Medicine (EANM) 2023 Congress.  $^{64}\text{Cu}$ -SAR-Bombesin was found to be safe and able to detect prostate cancer lesions in over a third of participants with negative or equivocal standard of care PSMA PET who were in the first cohort of the BOP trial with BCR of prostate cancer.

## SARTATE – Neuroblastoma and NETs

### **CL04 – a theranostic <sup>64</sup>Cu/<sup>67</sup>Cu-SARTATE neuroblastoma trial**

The CL04 theranostic trial is a US-based Phase I/IIa trial in paediatric participants with high-risk neuroblastoma using <sup>64</sup>Cu/<sup>67</sup>Cu-SARTATE. In July, Clarity successfully completed cohort 3 of the trial at the dose level of 275MBq/kg body weight and treated the first participant in cohort 4 at 375MBq/kg body weight, the highest dose level in the dose escalation phase of the trial, in August. Recruitment is ongoing into cohort 4 of the trial.

### **DISCO – a diagnostic <sup>64</sup>Cu-SARTATE NET trial**

The DISCO diagnostic trial was an Australia-based Phase II trial of participants with known or suspected Neuroendocrine Tumours (NETs) using <sup>64</sup>Cu-SARTATE. Recruitment was successfully completed in December with a total of 45 patients enrolled and imaged. DISCO aims to build on earlier work with SARTATE which demonstrated that imaging at later time points, enabled by the longer half-life of <sup>64</sup>Cu in comparison to <sup>68</sup>Ga, may lead to better identification of disease and the results will guide the study design for a Phase III trial in the NET indication.

### **DISCOVERY PLATFORM**

Clarity is expanding its product pipeline with a new generation of radiopharmaceuticals through its Discovery Program.

In August 2023, Clarity added a worldwide exclusive license from Memorial Sloan Kettering Cancer Center (MSK) to its IP. The license is to intellectual property that covers cutting-edge technology that enables antibody “pre-targeting” for the diagnosis and treatment of cancer.

### **MANUFACTURING AND SUPPLY CHAIN**

Targeted Copper Theranostics' (TCTs) key differentiators are their logistical, manufacturing and environmental advantages associated with the perfect pairing of copper isotopes for diagnostic imaging (copper-64) and therapy (copper-67). Clarity continued to expand its manufacturing and supply chain footprint, creating additional capacity and flexibility to supply products to any ZIP-code in the US.

During the reporting period, NorthStar Medical Radioisotopes (NorthStar) successfully validated large scale Rhodotron production of the therapeutic radionuclide copper-67 (Cu-67 or <sup>67</sup>Cu). NorthStar-produced <sup>67</sup>Cu is now in routine use across Clarity's therapeutic clinical programs.

### **TEAM AND COLLABORATORS**

The Company has built a diverse and high-performing team, including its Board of Directors, Advisory Board and collaborators, who deliver a unique range of skills, expertise, extensive experience in the global radiopharmaceutical market and outstanding performance.

In the reporting period, Clarity Pharmaceuticals' Senior Executive Team welcomed Kathryn Williams Day as Vice President, Regulatory Affairs and Quality.

## EVENTS ARISING SINCE THE END OF THE REPORTING PERIOD

Ms Cheryl Maley resigned from the Board of Directors, effective 16 January 2024. On that same date Mr Rob Thomas announced his intention to resign from the Board, effective 23 August 2024.

As noted in the Review of Operations, Clarity announced on 15 February 2024 that the results of its COBRA trial indicated SAR-bisPSMA is safe and highly effective in detecting tumours in prostate cancer patients.

There are no other matters or circumstances that have arisen since the end of the year that have significantly affected or may significantly affect either:

- the entity's operations in future financial years
- the results of those operations in future financial years; or
- the entity's state of affairs in future financial years.

## AUDITOR INDEPENDENCE DECLARATION

A statement of independence has been provided by the Group's auditor, Grant Thornton, and is attached to this report.

Signed in accordance with a resolution of the Board of Directors.



Dr Alan Taylor  
Chairperson

Date: 29 February 2024



## Auditor's Independence Declaration

### To the Directors of Clarity Pharmaceuticals Ltd

In accordance with the requirements of section 307C of the *Corporations Act 2001*, as lead auditor for the review of Clarity Pharmaceuticals Ltd for the half-year ended 31 December 2023, I declare that, to the best of my knowledge and belief, there have been:

- a no contraventions of the auditor independence requirements of the *Corporations Act 2001* in relation to the review; and
- b no contraventions of any applicable code of professional conduct in relation to the review.

*Grant Thornton*

Grant Thornton Audit Pty Ltd  
Chartered Accountants

*L M Worsley*

L M Worsley  
Partner – Audit & Assurance

Sydney, 29 February 2024

# CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

FOR THE HALF-YEAR ENDED 31 DECEMBER 2023

	Note	December 2023 \$	December 2022 \$
Finance income	5	1,099,718	649,171
Research and Development Tax Incentive	5	5,418,247	5,732,620
<b>Income</b>		<b>6,517,965</b>	<b>6,381,791</b>
Corporate and administration expenses	6	(3,910,302)	(2,773,450)
Research and development expenses	7	(19,705,623)	(14,793,099)
<b>Loss before income tax</b>		<b>(17,097,960)</b>	<b>(11,184,758)</b>
Income tax expense		(104,758)	(57,897)
<b>Loss for the year from continuing operations</b>		<b>(17,202,718)</b>	<b>(11,242,655)</b>
<b>Loss for the year</b>		<b>(17,202,718)</b>	<b>(11,242,655)</b>
<b>Other comprehensive (loss) income</b>			
Exchange differences on translating foreign entity		(6,291)	1,604
<b>Total comprehensive loss for the period</b>		<b>(17,209,009)</b>	<b>(11,241,051)</b>

		December 2023 Cents	December 2022 Cents
<b>Earnings per Share</b>			
Basic, loss for the year attributable to ordinary equity holders	8	(6.6)	(4.3)
Diluted, loss for the year attributable to ordinary equity holders	8	(6.6)	(4.3)

The accompanying notes form part of these financial statements

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# CONSOLIDATED STATEMENT OF FINANCIAL POSITION

AS AT 31 DECEMBER 2023

	Notes	December 2023 \$	June 2023 \$
<b>Assets</b>			
<b>Current</b>			
Cash and cash equivalents	9	23,176,134	31,213,092
Financial assets	10	14,806,671	33,801,828
Research & development tax incentive receivable	11	14,887,852	9,469,604
Other receivables	11	498,852	532,608
Prepayments	12	4,194,827	1,660,789
<b>Total current assets</b>		<b>57,564,336</b>	<b>76,677,921</b>
<b>Non-current</b>			
Plant & equipment	13	594,677	206,142
Other financial assets	10	13,026	12,343
<b>Total non-current assets</b>		<b>607,703</b>	<b>218,485</b>
<b>Total assets</b>		<b>58,172,039</b>	<b>76,896,406</b>
<b>Liabilities</b>			
<b>Current</b>			
Trade and other payables	14	3,982,720	6,739,431
Employee entitlements	15	911,361	802,609
<b>Total current liabilities</b>		<b>4,894,081</b>	<b>7,542,040</b>
<b>Non-current</b>			
Employee entitlements	15	217,650	178,698
<b>Total non-current liabilities</b>		<b>217,650</b>	<b>178,698</b>
<b>Total liabilities</b>		<b>5,111,731</b>	<b>7,720,738</b>
<b>Net assets</b>		<b>53,060,308</b>	<b>69,175,668</b>
<b>Equity</b>			
Share capital	16	133,589,860	132,820,320
Share option reserve	17	7,047,749	6,723,640
Accumulated losses		(87,576,987)	(70,374,269)
Foreign currency translation reserve		(314)	5,977
<b>Total equity</b>		<b>53,060,308</b>	<b>69,175,668</b>

The accompanying notes form part of these financial statements

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## CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

FOR THE HALF-YEAR ENDED 31 DECEMBER 2023

	Share Option Reserve \$	Foreign Currency Reserve \$	Share Capital \$	Accumulated Losses \$	Total \$
<b>Half-year ended 31 December 2022</b>					
Balance at 1 July 2022	5,898,745	18,049	132,115,430	(45,795,690)	92,236,534
Loss for the period	-	-	-	(11,242,655)	(11,242,655)
Foreign currency translation	-	1,604	-	-	1,604
<b>Total Comprehensive Loss</b>	-	<b>1,604</b>	-	<b>(11,242,655)</b>	<b>(11,241,051)</b>
Transfer to share capital for options exercised	(250,836)	-	250,836	-	-
Ordinary shares issued on exercise of options	-	-	242,001	-	242,001
Transfer to retained earnings for options expired	(57,106)	-	-	57,106	-
Capital raising costs	-	-	(6,132)	-	(6,132)
Share-based options	552,849	-	-	-	552,849
<b>Balance at 31 December 2022</b>	<b>6,143,652</b>	<b>19,653</b>	<b>132,602,135</b>	<b>(56,981,239)</b>	<b>81,784,201</b>
<b>Half-year ended 31 December 2023</b>					
Balance at 1 July 2023	6,723,640	5,977	132,820,320	(70,374,269)	69,175,668
Loss for the period	-	-	-	(17,202,718)	(17,202,718)
Foreign currency translation	-	(6,291)	-	-	(6,291)
<b>Total Comprehensive Loss</b>	-	<b>(6,291)</b>	-	<b>(17,202,718)</b>	<b>(17,209,009)</b>
Transfer to share capital for options exercised	(591,371)	-	591,371	-	-
Ordinary shares issued on exercise of options	-	-	182,000	-	182,000
Capital raising costs	-	-	(3,831)	-	(3,831)
Share-based options	915,480	-	-	-	915,480
<b>Balance at 31 December 2023</b>	<b>7,047,749</b>	<b>(314)</b>	<b>133,589,860</b>	<b>(87,576,987)</b>	<b>53,060,308</b>

The accompanying notes form part of these financial statements



## CONSOLIDATED STATEMENT OF CASHFLOWS

FOR THE HALF-YEAR ENDED 31 DECEMBER 2023

Notes	December 2023 \$	December 2022 \$
<b>Cash Flows from Operating Activities</b>		
Interest received	1,110,651	442,510
Payments to suppliers and employees	(27,705,850)	(16,920,822)
Income taxes paid	(104,758)	(57,897)
<b>Net operating cash flows</b>	<b>(26,699,957)</b>	<b>(16,536,209)</b>
<b>Cash Flows from Investing Activities</b>		
Transfer from other financial assets	18,994,474	18,999,402
Purchase of plant & equipment	(441,248)	(19,501)
<b>Net investing cash flows</b>	<b>18,553,226</b>	<b>18,979,901</b>
<b>Cash Flows from Financing Activities</b>		
Exercise of options	121,000	110,000
Cost of capital raisings – complete and incomplete	(3,831)	(6,132)
<b>Net financing cash flows</b>	<b>117,169</b>	<b>103,868</b>
<b>Net (decrease)/increase in cash held</b>	<b>(8,029,562)</b>	<b>2,547,560</b>
Cash at the beginning of the financial year	31,213,092	55,336,328
Effect of exchange rate changes on cash and cash equivalents	(7,396)	4,394
<b>Closing cash at the end of the half-year</b>	<b>23,176,134</b>	<b>57,888,282</b>

The accompanying notes form part of these financial statements

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# NOTES TO THE FINANCIAL STATEMENTS

FOR THE HALF-YEAR ENDED 31 DECEMBER 2023

## 1. General information and statement of compliance

The financial report includes the consolidated financial statements and notes of Clarity Pharmaceuticals Ltd and Controlled Entities (Consolidated Group).

These interim financial statements are general purpose financial statements that have been prepared on an accruals basis in accordance with Australian Accounting Standards AASB 134 *Interim Financial Reporting* and the Corporations Act 2001. They have been prepared under the assumption that the Group operates on a going concern basis. Clarity Pharmaceuticals Ltd is a for-profit entity for the purpose of preparing the financial statements.

The consolidated financial statements for the half-year ended 31 December 2023 were approved and authorised for issue by the Board of Directors on 29 February 2024. The consolidated financial statements for the half-year can be amended by the Board of Directors after issue.

### Going Concern

The financial statements have been prepared on a going concern basis, which contemplates continuity of normal business activities and the realisation of assets and settlement of liabilities in the normal course of business. The Group incurred a loss before tax of \$17.1 million and expects to incur additional losses to continue its research and commercialisation of its portfolio of assets.

The ability of the Group to continue as a going concern and therefore to be able to pay its debts as and when they fall due is contingent upon periodic capital raising to support research and development activities.

The need to raise additional capital gives rise to uncertainty over the Group's ability to continue as a going concern. The Board is assessing capital sources with advisors and the Directors believe that the Group will raise capital as required based on the exciting progress of the Group's clinical trials, the current significant interest from investors in the Group, the broader excitement in the radio pharmaceuticals sector generally including a number of recent strategic acquisitions, together with the success of previous capital raises undertaken by the Group and the management team. As at the date of this report the Group has \$32.2 million cash and \$10.1 million in RDTI receivable due in the coming months. These combined funds of \$42.3 million, together with management's ability to reduce cash burn, provide the Group with flexibility in terms of both the timing and quantum of a capital raise.

Accordingly, at the date of this report the Directors believe there will be sufficient working capital for the Group to meet its expenditure commitments and pay its debts as and when they fall due for the next 12 months.

## 2. Changes in accounting policies

The accounting policies adopted in the preparation of the consolidated financial statements are consistent with those followed in the preparation of the Group's previous annual consolidated financial statements for the year ended 30 June 2023.

During the year there have been no new or revised accounting standards issued by the Australian Accounting Standards Board (AASB) that are mandatorily effective for the accounting period that begins on or after 1 July 2023.

## 3. Operating segments

Clarity Pharmaceuticals Ltd and its subsidiaries, Clarity Personnel Inc. and Clarity Pharmaceuticals Europe S.A., operate in only one business segment – Development of Radiopharmaceuticals. The activities of the group principally take place in Australia and the United States. The Group does not have any sales revenue hence is not able to report revenue by segment. Accordingly, it also does not have any customers. All assets and liabilities of the Group are attributable to the single segment.

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#### 4. Interests in subsidiaries

Set out below details of the subsidiary held directly by the Group:

Name of the Subsidiary	Country of Incorporation and principal place of business	Principal Activity	Proportion of ownership interests held by the group	
			31 Dec 2023	31 Dec 2022
Clarity Pharmaceuticals Europe SA	Belgium	Scientific Research & Development	100%	100%
Clarity Personnel Inc.	U. S. A	Provision of US Personnel to the Group	100%	100%

#### 5. Other Income

The Group has derived no commercial revenue during the year. Other Income comprises:

	Dec 2023 \$	Dec 2022 \$
Finance income	1,099,718	649,171
Research and Development Tax Incentive	5,418,247	5,732,620

#### 6. Corporate and administration expenses

	Dec 2023 \$	Dec 2022 \$
Corporate and administration employment costs	(1,711,313)	(978,148)
Depreciation	(51,159)	(47,480)
Insurance, professional fees, rent and other	(2,147,830)	(1,747,822)
	<b>(3,910,302)</b>	<b>(2,773,450)</b>

#### 7. Research and development expenses

	Dec 2023 \$	Dec 2022 \$
Clinical trials and supporting activities	(13,787,643)	(10,859,779)
Research and development employment costs	(5,114,181)	(3,252,814)
Patents and related costs	(803,799)	(680,506)
	<b>(19,705,623)</b>	<b>(14,793,099)</b>

**8. Earnings per share**

	Dec 2023 Cents	Dec 2022 Cents
Basic earnings (loss) per share	(6.6)	(4.3)
Diluted earnings (loss) per share	(6.6)	(4.3)

Income and share data used in calculations of basic and diluted earnings per share:

	\$	\$
Net (Loss)	(17,202,718)	(11,242,655)

	Number	Number
Weighted average number of Ordinary shares on issue in the calculation of basic earnings per share	261,939,839	259,017,482
Effect of dilutive securities <sup>1</sup>	-	-
Adjusted weighted average number of Ordinary shares used in the calculation of diluted earnings per share	261,939,839	259,017,482

1. At 31 December 2023 there were 27,397,811 (June 2023: 25,192,250) share options on issue which have not been taken into account when calculating the diluted loss per share due to their anti-dilutive nature.

**9. Cash and cash equivalents**

Cash and cash equivalents consist of the following:

	Dec 2023 \$	Jun 2023 \$
Cash at bank – Australian dollars	2,035,234	5,189,905
Cash at bank – US dollars	1,443,666	617,810
Cash at bank – Euros	161,781	167,106
Term deposits – cash equivalents – Australian dollars	10,032,529	2,105,774
Term deposits – cash equivalents – US dollars	9,502,924	23,132,497
	<b>23,176,134</b>	<b>31,213,092</b>

Term deposits with a maturity of less than 90 days from the date of acquisition are presented as cash equivalents.



**10. Other financial assets**

	Dec 2023 \$	Jun 2023 \$
<b>Current</b>		
Term deposits	14,806,671	33,801,828
	<b>14,806,671</b>	<b>33,801,828</b>

Term deposits with a maturity of greater than 90 days from the date of acquisition are presented as other financial assets. Term deposits are measured at face value, with interest recognised as income on an accruals basis.

**Non-current**

Security deposit	13,026	12,343
	<b>13,026</b>	<b>12,343</b>

This security deposit represents one month's rental fees for the business premises. The landlord may deduct from the security deposit amounts owing to them in connection with the rental agreement. The security deposit will be returned to Clarity Pharmaceuticals within one month after the later of the termination of the agreement and Clarity Pharmaceuticals complying to the reasonable satisfaction of the landlord with all its obligations under the agreement.

**11. Other receivables**

	Dec 2023 \$	Jun 2023 \$
Research & development incentive receivable	14,887,852	9,469,604
Consumption taxes receivable	198,239	221,061
Interest receivable	300,613	311,547
	<b>498,852</b>	<b>532,608</b>

R&D Tax Incentive receivable at 31 December 2023 comprises \$10,082,973 in respect of the year ended 30 June 2023 and \$4,804,878 for the period July to December 2023 which is anticipated to be receivable as part of the Group's application for the year ending 30 June 2024. The receivable is an estimate and is conditional on the 2024 application being successful. The Group considers it has sufficient R&D claim history to be able to reliably estimate the R&D tax refund at this interim period.

All amounts are short-term.

**12. Prepayments**

	Dec 2023 \$	Jun 2023 \$
Clinical trials and supporting activities	3,462,811	1,102,336
Corporate activities	567,091	265,624
Patents and related costs	164,925	99,831
Equipment	-	192,998
	<b>4,194,827</b>	<b>1,660,789</b>

All amounts are short term. Prepayments for clinical trials includes upfront payments to clinical research organisations which will be recouped on completion of the clinical trial contract.

**13. Plant & equipment**

	Dec 2023 \$	Jun 2023 \$
Equipment	875,452	435,885
Less accumulated depreciation	(280,775)	(229,743)
	<b>594,677</b>	<b>206,142</b>
Balance as at 1 July	206,142	260,092
Additions	441,248	46,562
Disposals	(1,554)	-
Depreciation	(51,159)	(100,512)
<b>Balance as at end of period</b>	<b>594,677</b>	<b>206,142</b>

**14. Trade & other payables**

Trade and other payables recognised consist of the following:

	Dec 2023 \$	Jun 2023 \$
<b>Current:</b>		
Trade creditors	555,767	2,846,510
Sundry creditors	3,100,710	2,769,069
Payroll liabilities	134,872	910,749
Superannuation payable	109,147	129,775
Other liabilities	82,224	83,328
	<b>3,982,720</b>	<b>6,739,431</b>

All amounts are short-term. The carrying values of trade payables are a reasonable approximation of fair value.

Sundry creditors include expenses incurred but not yet paid for clinical trials of \$1,208,188 (Jun 2023: \$1,355,035) and operational costs of \$1,599,055 (Jun 2023: \$1,021,851).

Other liabilities at 31 December 2023 arise from unexpended amounts under a now-completed grant received by Clarity Pharmaceuticals Europe SA (from the Walloon Government, Belgium) supporting the Group's research and development programs. The Grant has concluded and the Group believes that the balance of the grant, which remains unearned, will be refunded to the Walloon Government.

**15. Employee entitlements**

	Dec 2023 \$	Jun 2023 \$
<b>Current</b>		
Annual leave liability	887,270	782,764
Long service leave liability	24,091	19,845
	<b>911,361</b>	<b>802,609</b>
<b>Non-Current</b>		
Long service leave liability	<b>217,650</b>	<b>178,698</b>

The current liability represents the Group's obligations to which employees have a current legal entitlement. It arises from accrued annual leave and long service leave entitlement at the reporting date. The non-current liability represents obligations to which employees will have a legal entitlement upon completion of a requisite service period, more than 12 months beyond the end of the year.

**16. Equity**

	Dec 2023 \$	Jun 2023 \$
Ordinary shares issued and fully paid	139,899,137	139,125,766
Cost of capital raising	(6,309,277)	(6,305,446)
<b>Total contributed equity at period end</b>	<b>133,589,860</b>	<b>132,820,320</b>
	\$	Number
Movement in ordinary shares on issue:		
As at 1 July 2023	132,820,320	260,662,670
Issue on exercise of share options	773,370	1,577,119
Transaction costs	(3,830)	-
<b>As at 31 December 2023</b>	<b>133,589,860</b>	<b>262,239,789</b>

**17. Share option reserve**

	Dec 2023 \$	Jun 2023 \$
Balance at beginning of period	6,723,640	5,898,745
Share options expensed – employees & consultants	915,480	1,251,068
Options exercised	(591,371)	(402,306)
Options expired	-	(23,867)
<b>Balance at end of period</b>	<b>7,047,749</b>	<b>6,723,640</b>

The share option reserve represents the cumulative total expense attributed to vested options and expense to date for options that have not yet vested as the expense is spread over the vesting period. The expense is determined using a Black-Scholes valuation of the options.

**18. Related party transactions**

During the period, non-executive directors' fees totalled \$196,570. Executive directors' salaries and superannuation totalled \$562,750, and executive bonuses of \$117,615 were accrued for the period but unpaid at 31 Dec 2023. The Company's subsidiary, Clarity Personnel Inc., charged Clarity Pharmaceuticals Ltd \$3,260,578 in management fees to fund its operations.

**19. Commitment & contingencies**

The Company has intellectual property that is either licensed or assigned from the University of Melbourne, Australian Nuclear Science and Technology Organisation, Dr Kurt Gehlsen, University of Southern California, Memorial Sloan Kettering Cancer Center and University of Antwerp representing contingent liabilities totalling \$10,650,546 (Jun 2023 \$7,256,880). These contingent liabilities are intellectual property licence and assignment milestones payments which are dependent upon the success of the Group's clinical research, as well as future decisions regarding the clinical focus of the Company and are therefore not recognised in the statement of financial position. Milestones for each intellectual property agreement are for various clinical milestones, from filing regulatory applications to conducting clinical trials to entering Phase III trials, along with commencement of sales of radiopharmaceutical agents. It is anticipated that no further milestones will be reached in the year ending 30 June 2024 which will result in payments to licensors.

**20. Post-reporting date events**

Ms Cheryl Maley resigned from the Board of Directors, effective 16 January 2024. Mr Rob Thomas announced his intention to resign from the Board, effective 23 August 2024.

Clarity announced on 15 February 2024 that the results of its COBRA trial indicated SAR-bisPSMA is safe and highly effective in detecting tumours in prostate cancer patients.

There are no matters or circumstances that have arisen since the end of the half-year that have significantly affected or may significantly affect:

- the operation of the Group;
- the results of those operations; or
- the state of affairs of the Group;

in future financial years.



# DIRECTORS' DECLARATION

## FOR THE HALF-YEAR ENDED 31 DECEMBER 2023

In the Directors' opinion:

- the consolidated financial statements for the half-year and notes of Clarity Pharmaceuticals Ltd are in accordance with the Corporations Act 2001, the Accounting Standards, the Corporations Regulations 2001 and other mandatory professional reporting requirements, including
  - Giving a true and fair view of its financial position as at 31 December 2023 and of its performance for the half-year ended on that date; and
  - Complying with Australian Accounting Standards as issued by the Australian Accounting Standards (including the Australian Accounting Interpretations) and Corporations Regulations 2001; and
- there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.

Signed in accordance with a resolution of the Directors.

On behalf of the Directors

A handwritten signature in blue ink, appearing to read "Alan Taylor", is written over a light blue rectangular background.

Dr Alan Taylor  
Chairperson

Dated this 29 day of February 2024

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# Independent Auditor's Review Report

To the Members of Clarity Pharmaceuticals Ltd

Report on the half-year financial report

Grant Thornton Audit Pty Ltd

Level 17

383 Kent Street

Sydney NSW 2000

Locked Bag Q800

Queen Victoria Building NSW

1230

T +61 2 8297 2400

## Conclusion

We have reviewed the accompanying half-year financial report of Clarity Pharmaceuticals Ltd (the Company) and its subsidiaries (the Group), which comprises the consolidated statement of financial position as at 31 December 2023, and the consolidated statement of profit or loss and other comprehensive income, consolidated statement of changes in equity and consolidated statement of cash flows for the half-year ended on that date, a summary of accounting policies, other selected explanatory notes, and the Directors' declaration.

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the accompanying half-year financial report of Clarity Pharmaceuticals Ltd does not comply with the *Corporations Act 2001* including:

- a giving a true and fair view of the Group's financial position as at 31 December 2023 and of its performance for the half-year ended on that date; and
- b complying with Accounting Standard AASB 134 *Interim Financial Reporting and the Corporations Regulations 2001*.

## Basis for Conclusion

We conducted our review in accordance with ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity*. Our responsibilities are further described in the Auditor's responsibilities for the review of the half year Financial Report section of our report. We are independent of the Group in accordance with the auditor independence requirements of the *Corporations Act 2001* and the ethical requirements of the Accounting Professional and Ethical Standards Board's APES 110 *Code of Ethics for Professional Accountants (including Independence Standards)* (the Code) that are relevant to our audit of the annual financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

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### Material uncertainty related to going concern

We draw attention to Note 1 in the half-year financial report, which indicates that the Group incurred a net loss before tax of \$17,097,960 during the half-year ended 31 December 2023 and will require additional funding to support its research activities. As stated in Note 1, these events or conditions, along with other matters as set forth in Note 1, indicate that a material uncertainty exists that may cast significant doubt on the Group's ability to continue as a going concern. Our conclusion is not modified in respect of this matter.

### Directors' responsibility for the half-year financial report

The Directors of the Company are responsible for the preparation of the half-year financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001* and for such internal control as the Directors determine is necessary to enable the preparation of the half-year financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

### Auditor's responsibility

Our responsibility is to express a conclusion on the half-year financial report based on our review. We conducted our review in accordance with Auditing Standard on Review Engagements ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity*, in order to state whether, on the basis of the procedures described, we have become aware of any matter that makes us believe that the half-year financial report is not in accordance with the *Corporations Act 2001* including giving a true and fair view of the Group's financial position as at 31 December 2023 and its performance for the half-year ended on that date, and complying with Accounting Standard AASB 134 *Interim Financial Reporting and the Corporations Regulations 2001*.

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.



Grant Thornton Audit Pty Ltd  
Chartered Accountants



L M Worsley  
Partner – Audit & Assurance

Sydney, 29 February 2024

# CORPORATE DIRECTORY

## **Directors**

Dr Alan Taylor  
Executive Chairman

Dr Colin Biggin  
Managing Director and  
Chief Executive Officer

Mr Robert Thomas  
Lead Independent Director  
Non-Executive Director

Ms Rosanne Robinson  
Non-Executive Director

Dr Chris Roberts  
Non-Executive Director

Dr Thomas Ramdahl  
Non-Executive Director

## **Company Secretary**

Mr Robert Vickery

## **Chief Financial Officer**

Mr David Green

## **Principal Place of Business**

National Innovation Centre  
4 Cornwallis Street  
Eveleigh NSW 2015  
Australia

## **Registered Office**

Clarity Pharmaceuticals Ltd  
C/- Company Matters Pty Limited  
Level 12, 680 George Street Sydney  
NSW 2000 Australia

**ABN** 36 143 005 341

## **Contact Information**

+61 (0)2 9209 4037  
investor@claritypharmaceuticals.com

## **Website**

[www.claritypharmaceuticals.com](http://www.claritypharmaceuticals.com)

## **Securities Exchange Listing**

Australian Securities Exchange  
ASX: CU6

## **Independent Auditor**

Grant Thornton Audit Pty Ltd  
Level 17, 383 Kent Street  
Sydney NSW 2000

## **Share Registry**

Link Market Services Limited  
Level 12, 680 George Street  
Sydney NSW 2000  
1300 554 474  
[registrars@linkmarketservices.com.au](mailto:registrars@linkmarketservices.com.au)

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