CLARITY
PHARMACEUTICALS

QUARTERLY ACTIVITY REPORT

SYDNEY, AUSTRALIA
31 DECEMBER 2023

HIGHLIGHTS OF THE QUARTER

Ending 31 December 2023

Cash Position

Cash position remains strong with a balance of $37.9 million as at 31 December 2023. Net operating cash outflows for the December quarter were $14.4 million. In addition, the company's RDTI, which is due shortly, is expected to provide in excess of a further ~$10 million in cash funding. This funding will provide cash runway into late 2024.

CLARIFY

Clarity's first Phase III clinical trial opened enrolment in November and recruited its first participant in December 2023. CLARIFY is a 383-patient diagnostic registrational study with ^{64}Cu-SAR-bisPSMA in participants with high-risk prostate cancer prior to radical prostatectomy. The trial will examine the diagnostic potential of ^{64}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.

SECuRE

Clarity's theranostic trial, SECuRE, is investigating ^{64}Cu/^{67}Cu-SAR-bisPSMA in metastatic castrate-resistant prostate cancer (mCRPC). Throughout the quarter, 3 participants were enrolled and each treated with a single dose of ^{67}Cu-SAR-bisPSMA at the highest dose level of 12GBq. No dose limiting toxicities (DLTs) have been reported to date and the Safety Review Committee (SRC) has recommended that the trial continues with the additional 3 participants as planned in cohort 3.

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

The first mCRPC patient to ever receive 2 cycles of 8GBq of ^{67}Cu-SAR-bisPSMA (1 dose from the SECuRE trial and one from the US Expanded Access Program (EAP)) exhibited undetectable levels of Prostate Specific Antigen (PSA) post-treatment. The patient also had undetectable lesions using PET imaging post-treatment.

COMBAT

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

SABRE

Clarity achieved its recruitment target for the diagnostic ^{64}Cu-SAR-Bombesin Phase II trial in participants with PSMA-negative biochemical recurrence (BCR) of prostate cancer following definitive therapy. 53 patients have been imaged with ^{64}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.

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}Cu in comparison to ^{68}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.

Clarity Pharmaceuticals (ASX: CU6) ("Clarity" or the "Company"), a clinical stage radiopharmaceutical company with a mission to develop next-generation products that improve treatment outcomes for children and adults with cancer, is pleased to release its Quarterly Activity Report and Appendix 4C for the three months ending 31 December 2023.

Executive Chairperson's Letter

Dear fellow Shareholders,

I am delighted to present Clarity's report for the quarter ending 31 December 2023 as it culminated an exceptional calendar year, reaching crucial milestones and laying a strong foundation for the year ahead. With all our trials progressing as planned, we are generating remarkable data in what is a very exciting sector of the global pharmaceutical market. With a cash balance of $37.9 million together with the large RDTI receivable of ~$10 million, we remain well financed to continue the development of our next-generation radiopharmaceutical products with a number of imminent data readouts in a sector which is quickly consolidating.

Our unique position in prostate cancer continues to help us generate exciting data to confirm the "best-in-class" potential of our products. Most impressively, our theranostic SAR-bisPSMA product delivered an unprecedented outcome when two cycles of 8GBq of ^{67}Cu-SAR-bisPSMA were first administered to a patient with metastatic castrate-resistant prostate cancer (mCRPC).

Following the treatment, the patient had 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 many number of therapies used in prostate cancer standard of care. Importantly, the patient is now experiencing an excellent quality of life following treatment. Although we have now treated a number of patients in the trial with great results so far, this outcome in the first patient to be double dosed with what we believe to be a therapeutic dose is an incredible result we are looking to emulate in many other patients in our clinical trials and beyond with this product. As such, our team is working tirelessly to continue the development of this promising product to bring its benefits to a larger number of men who live with this insidious disease. We successfully enrolled and treated the first 3 participants in cohort 3 of the SECuRE trial during the last quarter, the highest dose cohort in this study. All 3 participants had been heavily pre-treated and failed a number of commercial and investigational therapies prior to treatment in the trial. Despite this, 2 of the 3 participants so far have shown a reduction in PSA levels within weeks after a single cycle of 12GBq ^{67}Cu-SAR-bisPSMA. No Dose Limiting Toxicities (DLTs) have been reported in the study to date, and the Safety Review Committee (SRC) has recommended that the trial continues with the additional 3 participants as planned in cohort 3. We look forward to progressing this trial to multi-dose cohorts shortly as we continue to receive these impressive preliminary results throughout the trial and under the US Food and Drug Administration (FDA) Expanded Access Program (EAP).

In addition to the theranostic programs, SAR-bisPSMA continues to provide impressive data for improving diagnosis of prostate cancer and this quarter we commenced our registrational trial, CLARIFY, imaging its first participant with high-risk prostate cancer prior to radical prostatectomy (i.e. the complete removal of the prostate). We expect that final results from this pivotal trial will provide sufficient evidence to support an application to the FDA for the approval of the ^{64}Cu-SAR-bisPSMA product in patients that are pre-definitive therapy. We are also eagerly anticipating initial results from our COBRA trial with ^{64}Cu-SAR-bisPSMA to guide study design for our second pivotal Phase III trial with this product in patients with biochemical recurrence (BCR) of prostate cancer.

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}Cu-SAR-Bombesin in the theranostic Phase I/IIa trial, COMBAT, and look forward to progressing to the higher dose cohorts. With our diagnostic ^{64}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}Cu-SAR-Bombesin for first approvals in the US.

We also reached an important milestone with our third product, SARTATE, in our Phase II diagnostic trial of neuroendocrine tumours (NETs), DISCO, closing recruitment after imaging 45 patients. Although our key priority with SARTATE is treatment and management of children with an aggressive cancer, neuroblastoma, this product could potentially improve the diagnosis of NETs and we look forward to the final results to guide a registrational Phase III trial and expanding the market for this product. Our CL04 study in children with high-risk neuroblastoma continues to recruit for its cohort at the highest planned dose of ^{67}Cu-SARTATE.

This is a very exciting time for our Company, as the dedication and commitment of our team over the last decade has produced incredible results for patients. In a sector of the market that has quickly consolidated in recent times, we are inspired and encouraged by our progress and unique position of diagnostics and therapies, enabled by our proprietary advantage in the perfect pairing of copper isotopes, which provides an unmatched platform in radiopharmaceuticals. Our team is looking forward to the undoubtedly exciting year ahead as we continue to generate strong data and tread closer every day to our ultimate goal of improving treatment outcomes for children and adults with cancer.

Yours sincerely,

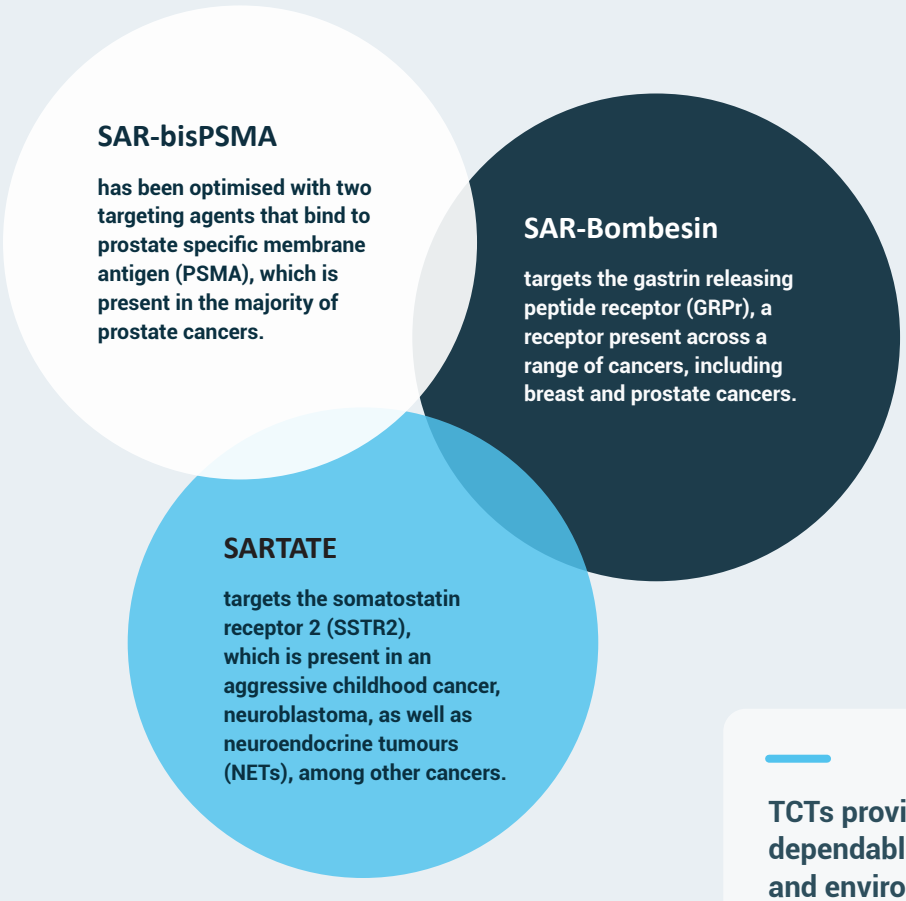
Dr Alan Taylor
Executive Chairperson
Clarity Pharmaceuticals Ltd

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}Cu) for imaging and copper-67 (Cu-67 or ^{67}Cu) for therapy, which deliver a compelling combination of high accuracy and high precision in the treatment of a range of cancers.

Clarity's three core 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.

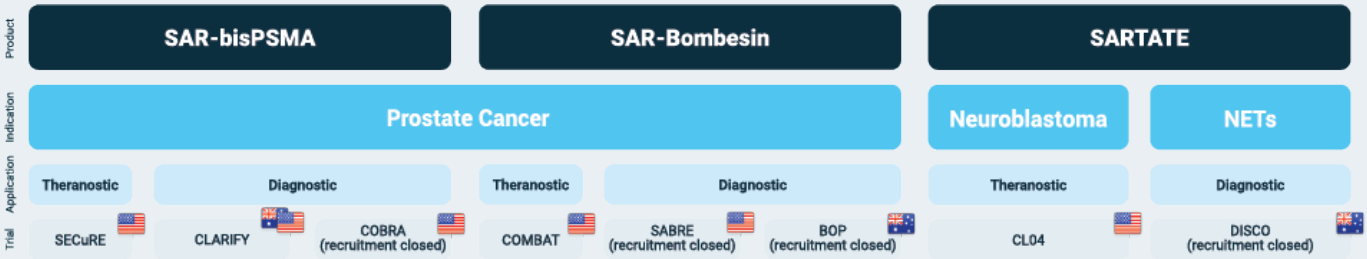
The three theranostic products are in clinical development for both diagnosis and treatment of various cancers and address unmet clinical needs. In addition to these core products, SAR Technology is used in Clarity's Discovery Program, which explores new targeting agents, thereby creating new TCTs to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



TCTs provide a scalable, dependable, cost-effective and environmentally friendly way to expand radiopharmaceuticals into the global oncology market.

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.

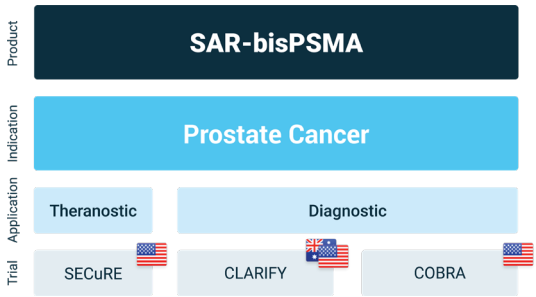


	Theranostic Trials	Diagnostic Trials
SAR-bisPSMA	**SECuRE** – Phase I/IIa theranostic trial for identification and treatment of PSMA-expressing metastatic castrate-resistant prostate cancer (mCRPC) using ^{64}Cu/^{67}Cu SAR-bisPSMA in the US (NCT04868604)[1]	**CLARIFY** - Registrational Phase III PET imaging trial of participants with high-risk prostate cancer prior to radical prostatectomy using ^{64}Cu SAR-bisPSMA (NCT06056830)[4] **COBRA** – Phase I/II PET imaging trial of participants with biochemical recurrence (BCR) of prostate cancer following definitive therapy using ^{64}Cu SAR-bisPSMA in the US (NCT05249127)[5]
SAR-Bombesin	**COMBAT** – Phase I/IIa theranostic trial for identification and treatment of mCRPC that is expressing the Gastrin-Releasing Peptide receptor (GRPr), in participants who are ineligible for ^{177}Lu-PSMA-617, using ^{64}Cu/^{67}Cu SAR-Bombesin (NCT05633160)[2]	**SABRE** – Phase II PET imaging trial of participants with PSMA-negative BCR of prostate cancer using ^{64}Cu SAR-Bombesin in the US (NCT05407311)[6]
SARTATE	**CL04** – Phase I/IIa theranostic trial in paediatric participants with high-risk neuroblastoma using ^{64}Cu/^{67}Cu SARTATE in the US (NCT04023331)[3]	**DISCO** – Phase II PET imaging trial of participants with known or suspected Neuroendocrine Tumours (NETs) using ^{64}Cu SARTATE in Australia (NCT04438304)[7]

PRODUCT UPDATES

SAR-bisPSMA
PROSTATE CANCER

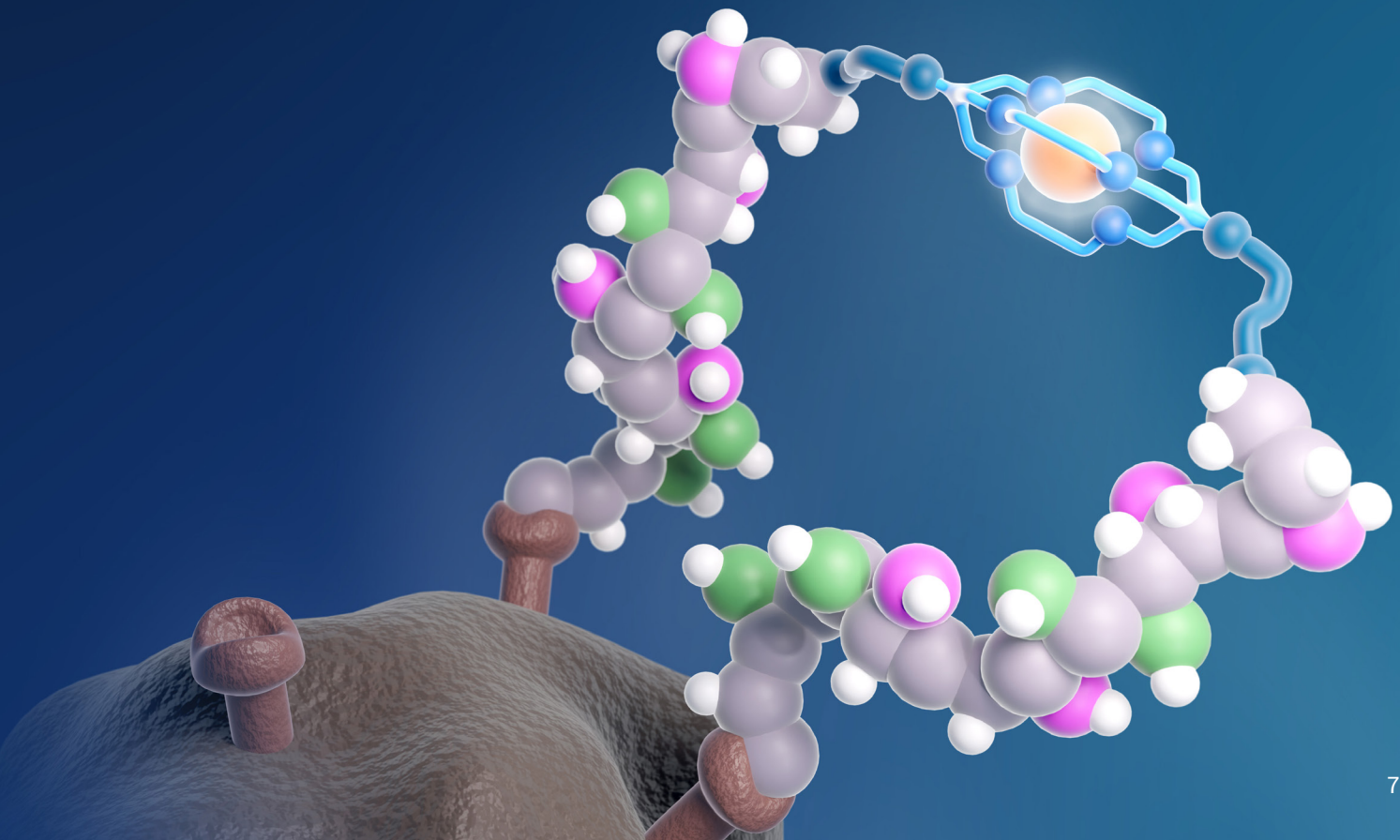
SAR-bisPSMA is a next generation, theranostic radiopharmaceutical with optimised dual PSMA-targeting agents to improve uptake and retention of the product in tumours



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

In addition to the therapy program in metastatic castrate resistant prostate cancer (mCRPC) with ^{64}Cu-SAR-bisPSMA and ^{67}Cu-SAR-bisPSMA, Clarity is also running multiple diagnostic trials in line with advice received from the US FDA to address the two relevant patient populations for registration of ^{64}Cu-SAR-bisPSMA:

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



SECuRE – a theranostic ^{64}Cu/^{67}Cu-SAR-bisPSMA trial

Clarity has successfully progressed cohort 3 of the theranostic SECuRE trial (NCT04868604)[1] enrolling and treating 3 participants who received therapy with ^{67}Cu-SAR-bisPSMA at the highest dose level of 12GBq.

No adverse events (side effects) were reported in relation to ^{64}Cu-SAR-bisPSMA. Only 1 adverse event was reported and related to the 12GBq cycle of ^{67}Cu-SAR-bisPSMA in 1 of the 3 participants, which was a grade 1 decrease in neutrophil count. This patient has fully recovered. No ongoing adverse events and no DLTs have been reported and the SRC has recommended the trial progresses with the 3 additional participants as planned in cohort 3.

The initial 3 participants in cohort 3 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 recent administration of 12GBq of ^{67}Cu-SAR-bisPSMA, with 2 demonstrating a PSA reduction within weeks of dosing, one of which is greater than 90% reduction and the second approximately 40% reduction to date.

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. The aim of this trial is to determine the safety and tolerability of both ^{64}Cu-SAR-bisPSMA and ^{67}Cu-SAR-bisPSMA as well as the efficacy of ^{67}Cu-SAR-bisPSMA as a therapy.

Cohort 3 is the last to assess single doses of ^{67}Cu-SAR-bisPSMA at the highest dose level of 12GBq and will be followed by a multi-dose cohort, pending safety evaluation (Figure 1).

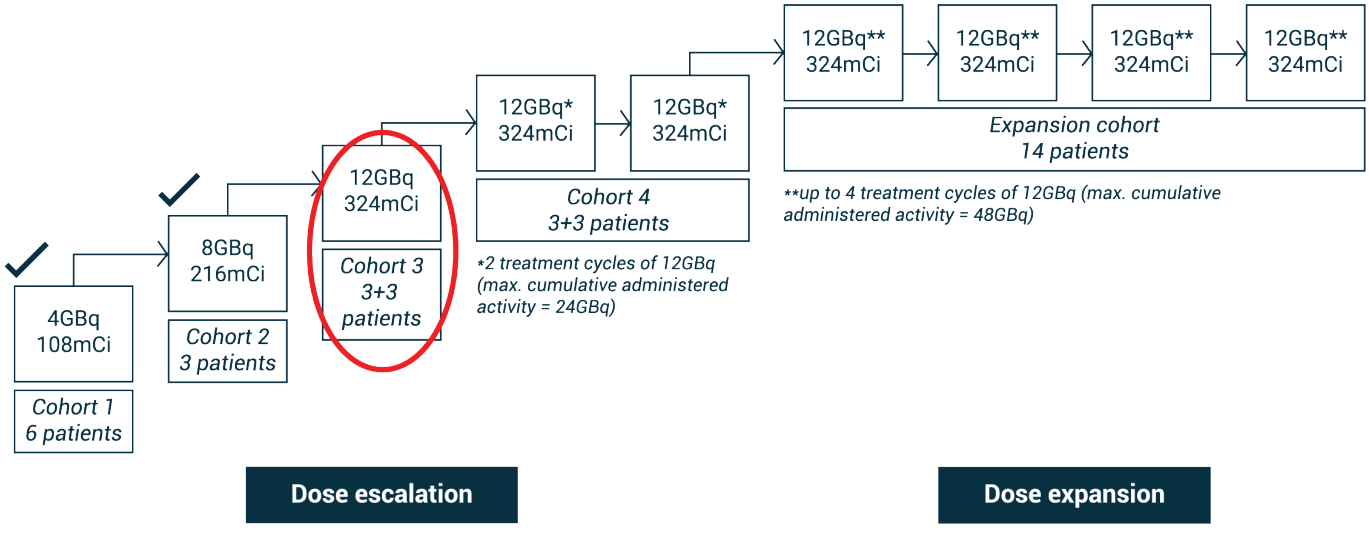


Figure 1. SECuRE Study Design

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

The first patient ever to be dosed with two cycles of 8GBq of ^{67}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 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 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}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 2 and 3. The patient had already failed multiple lines of treatment, including hormone therapy, an investigational agent and chemotherapy prior to being treated with ^{67}Cu-SAR-bisPSMA.

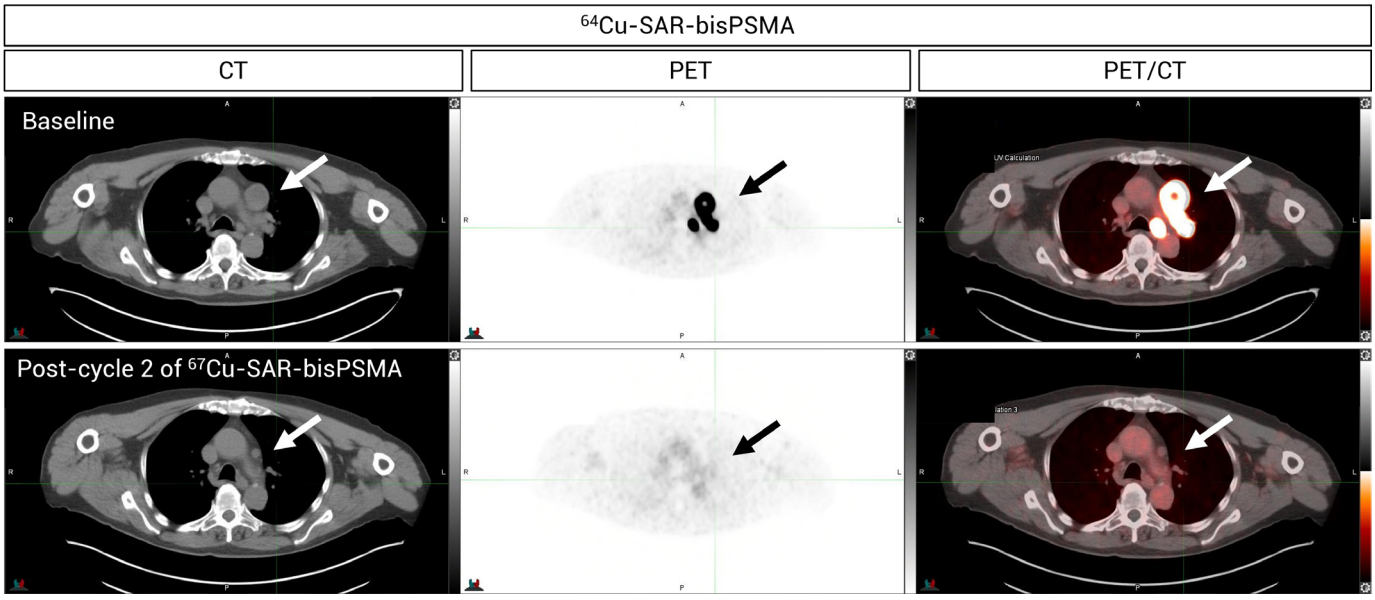


Figure 2. PET/CT images showing uptake of ^{64}Cu-SAR-bisPSMA at screening in a patient with mCRPC (top). The patient received 2 cycles of ^{67}Cu-SAR-bisPSMA at 8GBq. Images post-treatment show no ^{64}Cu-SAR-bisPSMA uptake (bottom).

Patient Case Study: Two Cycles of 8GBq of ^{67}Cu-SAR-bisPSMA cont.

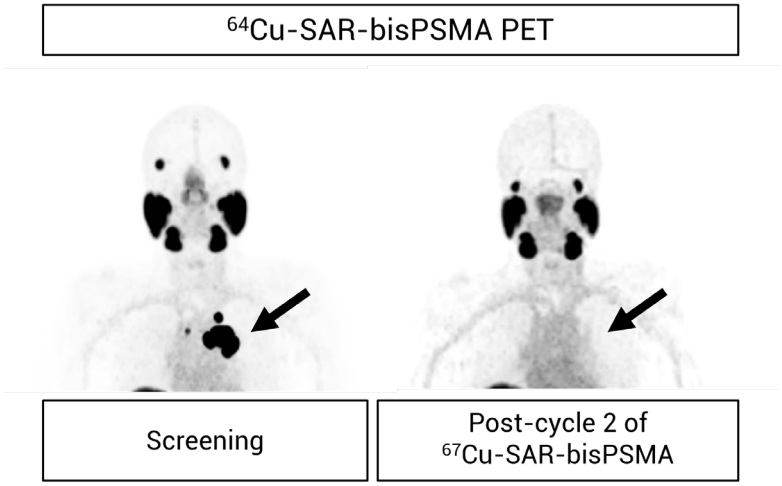


Figure 3. PET images showing uptake of ^{64}Cu-SAR-bisPSMA at screening in a patient with mCRPC (left; SUVmax 140.1. SUV: standardised uptake value). The patient received 2 cycles of ^{67}Cu-SAR-bisPSMA at 8GBq. Images post-treatment show no ^{64}Cu-SAR-bisPSMA uptake (right).

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 4. 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[8,9].

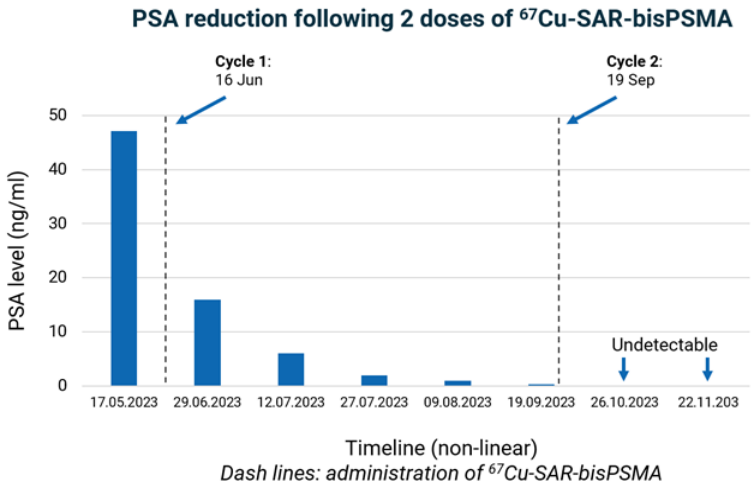


Figure 4. PSA dynamics over time. Series of PSA test results show baseline and decrease over time after the administration of one cycle of ^{67}Cu-SAR-bisPSMA. PSA level was undetectable in the last 2 measurements after the second cycle of ^{67}Cu-SAR-bisPSMA. Lower level of detection: 0.05 ng/ml.

"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 ^{67}Cu-SAR-bisPSMA presents a new opportunity for cancer patients to have an effective result with few side effects."

- Dr Luke Nordquist, XCancer, Omaha

CLARIFY – a diagnostic ^{64}Cu-SAR-bisPSMA Phase III registrational trial

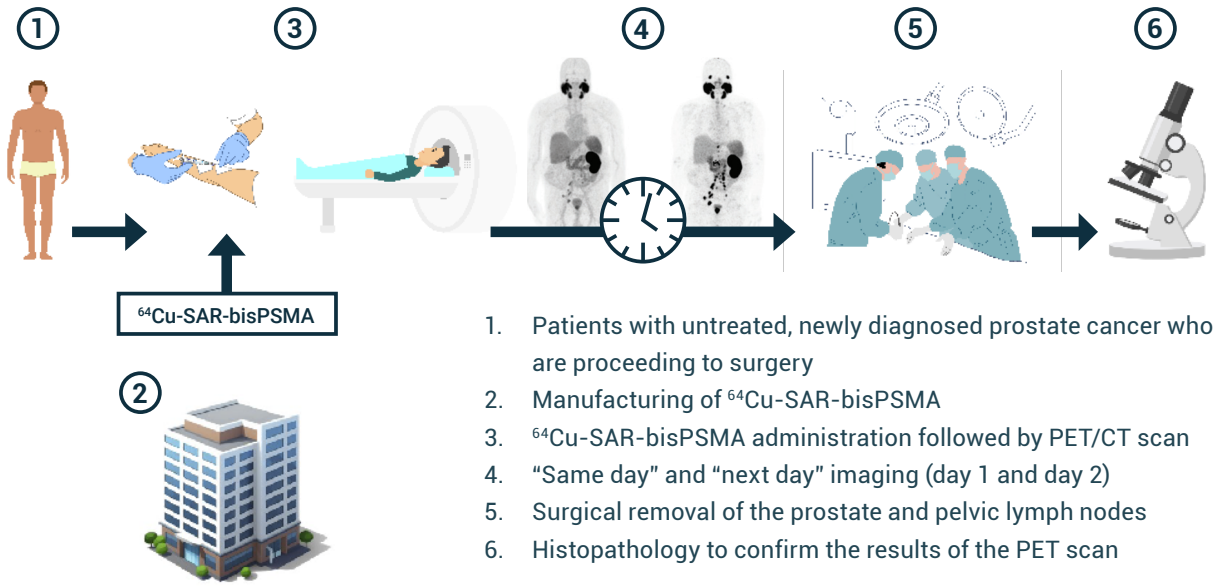
Clarity opened the first site for the diagnostic registrational Phase III trial, CLARIFY, and safely dosed its first participant with ^{64}Cu-SAR-bisPSMA.

CLARIFY (NCT06056830)[4] derives from "Positron Emission Tomography using ^{64}Cu-SAR-bisPSMA in participants with high-risk PC 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.

The aim of the Phase III trial is to assess the diagnostic performance of ^{64}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 ^{68}Ga and ^{18}F radioisotopes. ^{64}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 ^{64}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.

The final study results from the CLARIFY trial are intended to provide sufficient evidence to support an application to the FDA for approval of ^{64}Cu-SAR-bisPSMA as a new diagnostic imaging agent for pre-prostatectomy prostate cancer 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 in regard to the patients' treatment plan.



1. Patients with untreated, newly diagnosed prostate cancer who are proceeding to surgery
2. Manufacturing of ^{64}Cu-SAR-bisPSMA
3. ^{64}Cu-SAR-bisPSMA administration followed by PET/CT scan
4. "Same day" and "next day" imaging (day 1 and day 2)
5. Surgical removal of the prostate and pelvic lymph nodes
6. Histopathology to confirm the results of the PET scan

SAR-BOMBESIN – PROSTATE CANCER

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

SAR-Bombesin

Prostate cancer

Theranostic

Diagnostic

COMBAT

SABRE

BOP

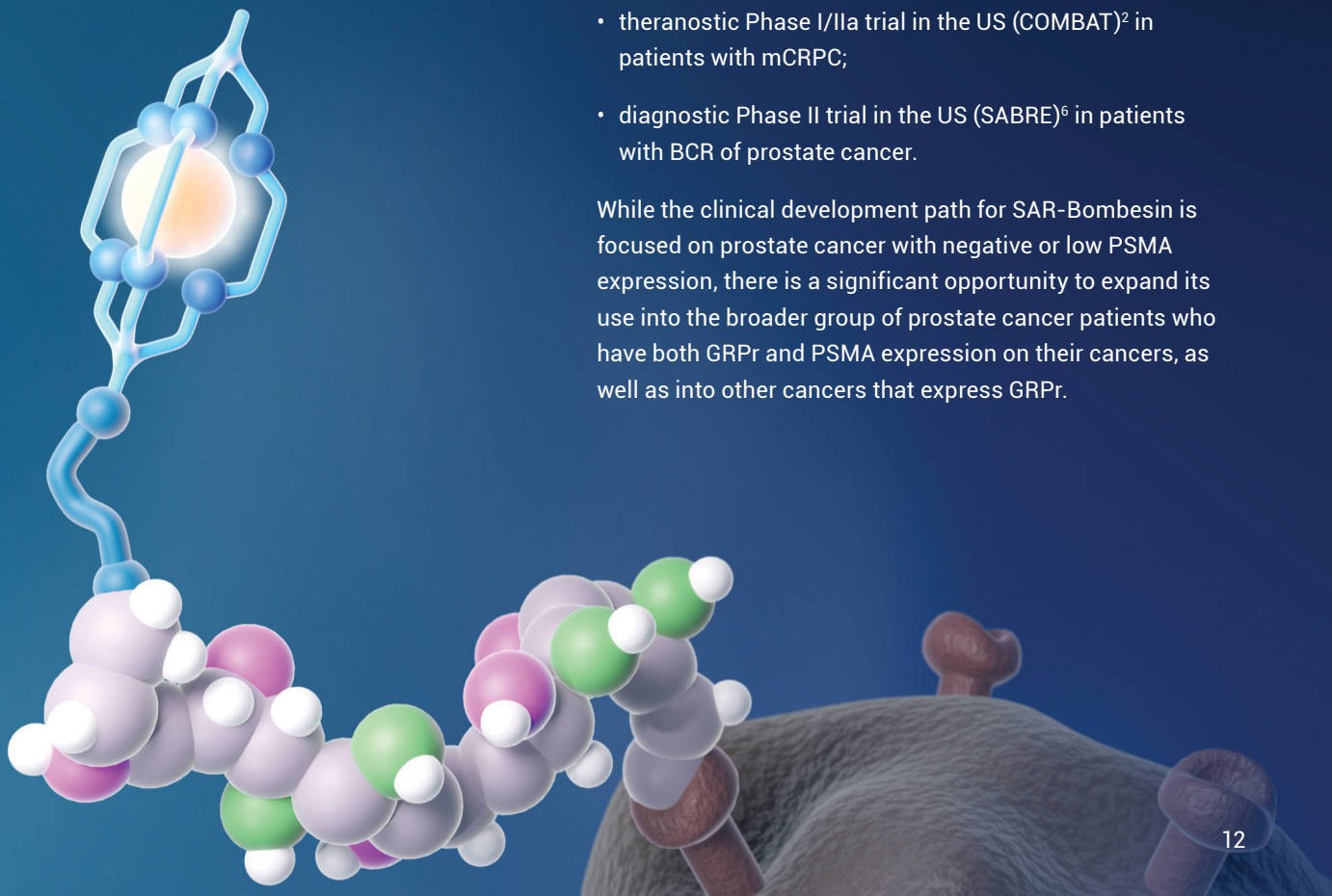
SAR-Bombesin is a highly targeted pan-cancer theranostic radiopharmaceutical. It is being developed for diagnosing, staging and subsequently treating cancers that express a specific receptor called the gastrin releasing peptide receptor (GRPr), including prostate cancer and breast cancer. Like all Clarity products, the SAR-Bombesin product uses copper-64 (^{64}Cu) for imaging (^{64}Cu-SAR-Bombesin) or copper-67 (^{67}Cu) for therapy (^{67}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[10-14]. These patients are unlikely to show meaningful uptake of PSMA-targeted products, such as ^{68}Ga-PSMA-11 for imaging, and therefore may not be eligible for a PSMA-targeted treatment, such as ^{177}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)[2] in patients with mCRPC;
- diagnostic Phase II trial in the US (SABRE)[6] 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 cancers that express GRPr.



COMBAT – a theranostic ^{64}Cu/^{67}Cu-SAR-Bombesin prostate cancer trial

Clarity treated the first participant in its theranostic ^{64}Cu/^{67}Cu-SAR-Bombesin Phase I/IIa trial in mCRPC. Recruitment into the COMBAT trial is ongoing.

COMBAT (NCT05633160)[2] is a dose escalation and cohort expansion trial for up to 38 participants. The aim for the trial is to determine the safety and efficacy of ^{67}Cu-SAR-Bombesin as well as the safety of ^{64}Cu-SAR-Bombesin in participants with GRPr expressing mCRPC in patients who are ineligible for therapy with ^{177}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 product.

SABRE – a diagnostic ^{64}Cu-SAR-Bombesin prostate cancer trial

Clarity achieved its recruitment target for the US-based diagnostic ^{64}Cu-SAR-Bombesin trial for patients with PSMA-negative prostate cancer, SABRE (NCT05407311)[6].

SABRE is a Phase II multi-center, single arm, non-randomised, open-label trial in 50 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 PSMA agents.

The primary objectives of the trial are to investigate the safety and tolerability of ^{64}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 study is investigating if delayed imaging allows better identification of very early disease or patients with low GRPr expression. In Figure 5, the images in the cross hairs on day 1 and day 2 following ^{64}Cu-SAR-Bombesin administration clearly identify a pelvic lymph node with product uptake, which was biopsied and confirmed as prostate cancer, while there was no uptake with ^{18}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}Cu-SAR-Bombesin product into a registrational Phase III trial for first approvals in the US.

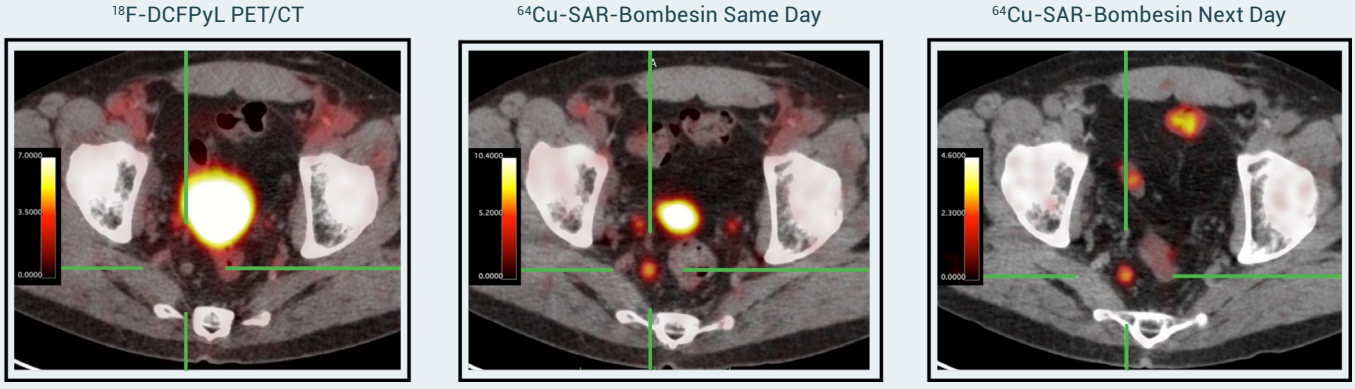


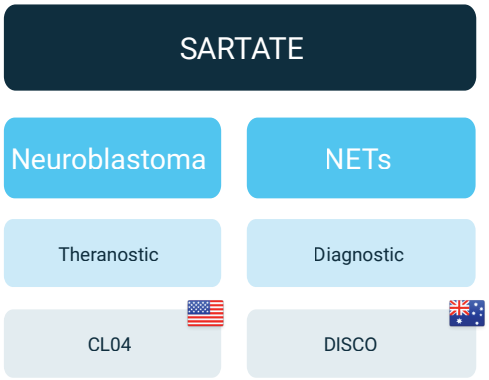
Figure 5. ^{64}Cu-SAR-Bombesin detected a positive lymph node on scans performed on two different days (same day and next day scans). No uptake was observed using ^{18}F-DCFPyL PET/CT. A subsequent biopsy, performed and assessed locally by the study site, has confirmed prostate cancer.

SAR-Bombesin holds significant potential for improving the diagnosis and treatment of prostate cancer, giving hope to clinicians and patients who have no other suitable diagnostic options available. Being able to now visualise the GRPr expressing lesions with SAR-Bombesin has the potential to change the entire treatment paradigm for patients. With more tools to detect prostate cancer that may not be visible with other imaging agents, we may be able to better diagnose and offer more effective treatment for their disease.

- Andrei Iagaru, MD

SARTATE - NEUROBLASTOMA AND NETs

SARTATE is a next generation, highly targeted theranostic radiopharmaceutical



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

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

- **CL04** theranostic trial with an open IND in the US (NCT04023331)[3]
- **DISCO** diagnostic trial in Australia (NCT04438304)[7].

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}Cu-SARTATE as a diagnostic agent for the clinical management of neuroblastoma and one for ^{67}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.[15]

DISCO – a diagnostic ^{64}Cu SARTATE NETs trial

Clarity successfully closed recruitment for the Phase II diagnostic ^{64}Cu-SARTATE trial, DISCO (NCT04438304)[7]. A total of 45 participants 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}Cu-SARTATE at 4 and 20 hours post-administration to the current standard of care, ^{68}Ga-DOTATATE, at one hour. The study looks to build on earlier studies with SARTATE (Hicks, R. et al)[16] which demonstrated that delayed imaging may lead to better identification of disease.

The trial was originally planned for up to 63 participants based on an expected discordance level between imaging with Clarity's ^{64}Cu-SARTATE and the current standard of care, ^{68}Ga-DOTATATE. The sample size was adjusted to 45 participants 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.

CL04 – a theranostic ^{64}Cu/^{67}Cu-SARTATE neuroblastoma trial

Clarity is progressing the final dose-escalation cohort following the successful completion of the first three cohorts of the CL04 theranostic trial (NCT04023331)[3] in neuroblastoma patients. During the reporting period, 3 participants were treated at the highest dose level of 375MBq of ^{67}Cu-SARTATE per kilogram body weight. Recruitment is ongoing at all clinical sites in the US.

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}Cu-SARTATE and ^{67}Cu-SARTATE are being assessed, but also the effectiveness of ^{67}Cu-SARTATE as a treatment for neuroblastoma. Participants who show uptake of ^{64}Cu-SARTATE in lesions will continue in the trial and will receive treatment with ^{67}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}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}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}Cu-SARTATE
- Cohort 2 – 3 participants received an initial single dose of 175MBq/kg body weight ^{67}Cu-SARTATE
- Cohort 3 – 3 participants received an initial single dose of 275MBq/kg body weight ^{67}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}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}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.

FINANCIALS

Clarity's cash balance was $37.9 million as at 31 December 2023.

Net operating cash outflows for the quarter were $14.4 million which is higher than the previous quarters outflow of $11.7 million due to the increasing spend associated with the company's clinical trial programs together with annual insurance premiums, particularly D&O Insurance, due in the December quarter. Operating cash outflows relate to payments for research and development, staff costs, administration, and general operating costs.

Use of Funds

(Listing Rule 4.7C.2)

Uses of funds	Prospectus dated 16 July 2021 $ Million	% of Total Funds	Period* to 31 Dec 2023 $ Million	% of Total Funds
Pre-Clinical	$2.7	2.5%	$3.5	4.1%
Clinical	$84.0	76.6%	$55.2	64.9%
Regulatory	$5.7	5.2%	$2.4	2.8%
Patents	$1.4	1.3%	$2.8	3.3%
Corporate	$10.4	9.5%	$14.6	17.2%
Costs associated with the Offer	$5.4	4.9%	$6.6	7.7%
Total uses	**$109.6**	**100.0%**	**$85.1**	**100.0%**

* From date of admission 25 August 2021

Costs associated with the offer exceed the amount set out in the "use of funds" in the Prospectus by $1.2 million. This is due to (1) the additional fee to the Joint Lead Managers and costs relating to the preparation of, and (2) additional due diligence relating to the Supplementary Prospectus dated 10 August 2021. The Company paid $750,000 to the Joint Lead Managers as part of a potential $920,000 Incentive Fee, payable entirely at the discretion of the Company. The Incentive Fee is described in 10.11.1 of the Prospectus.

As detailed in the Use of Funds table above, the expenditure for the period since admission to 31 December 2023, is in accordance with the Use of Funds outlined in the Company's prospectus dated 16 July 2021 and there are no material variances against the estimated use of funds except for the Incentive Fee noted in the previous paragraph.

Related Party Transactions

(Listing Rule 4.7C.3)

Payments to related parties of the entity and their associates (6.1 of the Appendix 4C) totalled $432,054 for the quarter. This amount includes director fees and salaries paid in the December quarter.

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

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15. Sarepta Therapeutics. (2023, July 5). Sarepta Therapeutics Announces Sale of Priority Review Voucher for $102 million [Press release]. https://investorrelations.sarepta.com/news-releases/news-release-details/sarepta-therapeutics-announces-sale-priority-review-voucher-102
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About Clarity Pharmaceuticals

Clarity is a clinical stage radiopharmaceutical company focused on the treatment of serious disease. The Company is a leader in innovative radiopharmaceuticals, developing targeted copper theranostics based on its SAR Technology Platform for the treatment of cancer in children and adults.

claritypharmaceuticals.com/

CLARITY
PHARMACEUTICALS

Appendix 4C

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

Name of entity	
Clarity Pharmaceuticals Ltd	
ABN	**Quarter ended ("current quarter")**
36 143 005 341	31 December 2023

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (6 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(10,942)	(18,921)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(41)	(77)
	(d) leased assets	-	-
	(e) staff costs	(2,528)	(5,857)
	(f) administration and corporate costs	(1,395)	(2,294)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	571	1,111
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	(87)	(101)
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	(14,422)	(26,139)

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(233)	(426)
	(d) investments	-	-
	(e) intellectual property		
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	**Net cash from / (used in) investing activities**	**(233)**	**(426)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	-
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	121	121
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(2)	(5)
3.5	Proceeds from borrowings	-	-
3.6	Repayment of borrowings	-	-
3.7	Transaction costs related to loans and borrowings	-	-
3.8	Dividends paid	-	-
3.9	Other (provide details if material)	-	-
3.10	**Net cash from / (used in) financing activities**	**119**	**116**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	53,591	65,015
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(14,422)	(26,139)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(233)	(426)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	119	116

Consolidated statement of cash flows		Current quarter $A'000	Year to date (6 months) $A'000
4.5	Effect of movement in exchange rates on cash held	(1,072)	(583)
4.6	**Cash and cash equivalents at end of period**	**37,983**	**37,983**

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter $A'000	Previous quarter $A'000
5.1	Bank balances	23,176	27,264
5.2	Call deposits	14,807	26,327
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	**Cash and cash equivalents at end of quarter (should equal item 4.6 above)**	**37,983**	**53,591**

6.	Payments to related parties of the entity and their associates	Current quarter $A'000
6.1	Aggregate amount of payments to related parties and their associates included in item 1	432
6.2	Aggregate amount of payments to related parties and their associates included in item 2	-

Note: Payments in 6.1 include Director fees and salaries.

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

7.5	**Unused financing facilities available at quarter end**	
7.6	Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.	

8.	**Estimated cash available for future operating activities**	**$A'000**
8.1	Net cash from / (used in) operating activities (item 1.9)	(14,422)
8.2	Cash and cash equivalents at quarter end (item 4.6)	37,983
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	37,983
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	3

Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer:

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer:

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

Answer:

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.

2 This statement gives a true and fair view of the matters disclosed.

Date: 31 Jan 2024 .....

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

Notes

1. This quarterly cash flow report and the accompanying activity report provide a basis for informing the market about the entity's activities for the past quarter, how they have been financed and the effect this has had on its cash position. An entity that wishes to disclose additional information over and above the minimum required under the Listing Rules is encouraged to do so.

2. If this quarterly cash flow report has been prepared in accordance with Australian Accounting Standards, the definitions in, and provisions of, *AASB 107: Statement of Cash Flows* apply to this report. If this quarterly cash flow report has been prepared in accordance with other accounting standards agreed by ASX pursuant to Listing Rule 19.11A, the corresponding equivalent standard applies to this report.

3. Dividends received may be classified either as cash flows from operating activities or cash flows from investing activities, depending on the accounting policy of the entity.

4. If this report has been authorised for release to the market by your board of directors, you can insert here: "By the board". If it has been authorised for release to the market by a committee of your board of directors, you can insert here: "By the [*name of board committee – eg Audit and Risk Committee*]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".

5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's *Corporate Governance Principles and Recommendations*, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.