



QUARTERLY ACTIVITY REPORT

SYDNEY, AUSTRALIA
31 MARCH 2024



HIGHLIGHTS OF THE QUARTER

Ending 31 March 2024

Cash Position

The Company's cash position at the end of the March quarter was \$26.9 million, with a further \$10.1 million receivable for the FY23 research and development tax incentive (RDTI). The company commenced a capital raise in late March 2024 with the proceeds of \$115 million (net of the costs of the offer) received in April 2024. Collectively, these sources of funds provide the company with in-excess of \$150 million to fund the business into early 2026.

Capital Raise

On the 26th of March Clarity launched a fully underwritten equity raising of \$121 million (before costs), comprising an institutional placement and a 1 for 33 pro-rata accelerated non-renounceable entitlement offer to eligible Clarity shareholders at an issue price of \$2.55 per new share. The Company has successfully completed the Placement and Institutional Entitlement Offer component of the raise on the 28th of March, raising \$110 million in total. The Retail Entitlement Offer was launched on the 4th of April and has now completed.

SECURE

Clarity's theranostic trial, SECURE, is investigating ⁶⁴Cu/⁶⁷Cu-SAR-bisPSMA in metastatic castrate-resistant prostate cancer (mCRPC). In March, Clarity treated its first participant in the first multi-dose cohort of the trial, cohort 4. This cohort opened following the successful completion of cohort 3, where 6 participants were administered single doses of 12GBq of ⁶⁷Cu-SAR-bisPSMA with no dose limiting toxicities (DLTs).

COBRA

Clarity released data from its Phase I/II diagnostic trial, COBRA. Initial data confirmed ⁶⁴Cu-SAR-bisPSMA is safe and highly effective in detecting prostate cancer lesions in patients with biochemical recurrence (BCR). The data also confirmed advantages of next-day imaging and revealed that ⁶⁴Cu-SAR-bisPSMA was able to detect much smaller lesions than anticipated, including a lesion with a diameter of less than 2mm, which compares favourably against the current standard-of-care (SOC) prostate specific membrane antigen (PSMA) positron emission tomography (PET) imaging agents.

CLARIFY

During the quarter, Clarity continued recruitment into its first registrational Phase III trial, CLARIFY, along with the opening of new trial sites across the US. The aim of the CLARIFY trial is to assess the diagnostic performance of ⁶⁴Cu-SAR-bisPSMA PET to detect prostate cancer within the pelvic lymph nodes of patients 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).



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 March 2024.



Executive Chairperson's Letter

Dear fellow Shareholders,

I am delighted to present Clarity's report for the quarter ending 31 March 2024 as it lays the foundation for the exciting calendar year ahead with a number of crucial corporate and clinical milestones.

At Clarity, we have never found ourselves in a more extraordinary position, with a strong balance sheet that supports the development of our best-in-class platform of products in radiopharmaceuticals, one of the hottest sectors of the entire pharmaceutical industry.

The jewel in our crown of best-in-class products is our bisPSMA agent, and we now believe that this is the best prostate cancer targeting radiopharmaceutical. Our therapy data to date with ⁶⁷Cu-SAR-bisPSMA has been nothing short of sensational as we are observing responses in patients that have failed up to six lines of previous therapies and seeing these responses with just a single dose of the product. On top of this, to have the first patient we have ever dosed twice with what we believe to be a therapeutic dose of ⁶⁷Cu-SAR-bisPSMA have a complete response to treatment, sustained therapeutic benefit and high quality of life after failing so many lines of therapy is an amazing start to our program, especially as we now begin multi-dosing in our therapy trial, SECURE.

To further enhance this position, with the recent signing of our product supply agreement with NorthStar, we will be the only radiopharmaceutical company where therapeutic isotope and finished product are both centrally manufactured under one roof. This has been an incredible effort for those involved and uniquely positions Clarity as the major player to challenge the incumbent big pharmaceutical companies in the space.

As the radiopharmaceutical industry hits fever pitch, with three large transactions in a matter of months, we find ourselves with the most advanced proprietary radiopharmaceutical prostate focused clinical program in the industry with trials progressing at major treatment centres in the US.

Our competitor therapy-based radiopharmaceutical companies are now either progressing old generic products or unproven early-stage alpha-based therapies. At Clarity, we have a lot of experience with alpha therapies, with a number of our team members intimately involved in the commercialisation of the only alpha therapy on market. With the lack of clinical data, the destructive nature of alpha particles to both healthy tissue and cancer, and the massive manufacturing and waste handling challenges, it will be many years to bring these products to market, if at all.

The beta radiopharmaceutical market, where copper-67 (Cu-67) sits, has a number of precedents, including the latest commercial therapy utilising lutetium-177 (Lu-177). What we did at Clarity was focus on fixing the problems of beta-based prostate cancer therapies that suffer from lower uptake into the cancer cells, no dose optimisation and cumbersome supply chains.

Heading back to the benchtop, we re-engineered our bisPSMA agent to increase uptake into lesions, and have proceeded to a dose optimisation strategy, benefiting from the shorter half-life of Cu-67. It is extraordinary to see these patients treated with ⁶⁷Cu-SAR-bisPSMA, who have failed so many lines of therapy in the past, now respond to treatment with this product and with such a favourable safety profile. And now this product will be manufactured, from beginning to end, at one site in the US.

With a pipeline of products, both in the clinic and in pre-clinical development, we have the opportunity to roll out many number of products in many different diseases.

But our products are not just therapies. All of Clarity's products are also diagnostics, as we continue our phenomenal leadership position in the use of the perfect pairing of copper isotopes and proprietary SAR chelator.

In Clarity's most recent trial with ^{64}Cu -SAR-bisPSMA in biochemically recurrent (BCR) prostate cancer, COBRA, this diagnostic was not only found to be safe and highly effective in detecting prostate cancer in these patients, but it was also found to detect even the smallest lesions that current-generation radiopharmaceuticals fail to visualise, including a lesion smaller than 2mm in diameter. In addition, the COBRA trial data confirmed the advantages of next-day imaging, a benefit unique to ^{64}Cu -SAR-bisPSMA compared to the approved PSMA PET agents, with lesion uptake increasing by more than 80% and lesion contrast increasing almost 5 times when comparing same-day to next-day imaging.

Having high sensitivity and specificity of diagnostics is incredibly important when assessing the return of prostate cancer in BCR patients as this could be the difference between getting a suitable treatment that could put a patient's cancer into remission or unknowingly allow the prostate cancer to grow and progress to widespread metastatic disease.

Following ^{64}Cu -SAR-bisPSMA imaging, investigators in the trial indicated that they would change the treatment plan of approximately half of the patients. Of these, two-thirds proceeded to receive systemic and/or focal therapy.

It is equally important for patients at initial staging of their disease, when they are considering their first course of definitive therapy, in order to understand whether their prostate cancer has metastasised or not from the primary lesion prior to prostatectomy (removal of the prostate). This is an immediate unmet medical need, which we are addressing with our Phase III CLARIFY trial where recruitment is ongoing. Current standard-of-care (SOC) imaging fails to do this for a large percentage of men who eventually experience BCR of their prostate cancer. As such, there is an immediate opportunity for bisPSMA to address the entire market of PSMA imaging as we move closer to our ultimate goal of improving treatment outcomes of people with cancer.



These incredible results in both theranostic and diagnostic trials is testament to the good Australian science, our dedicated and hard-working team and collaborators across the US and Australia working tirelessly to ensure we are on track to developing best-in-class products with our proprietary technology. This has been a phenomenal achievement so far for an Australian biotechnology company and we are now very well positioned, both in terms of our clinical development and funding, to maximise the value of our Company in what has become one of the most exciting areas of the pharmaceutical industry, radiopharmaceuticals.

As we are finding ourselves at the beginning of what we consider a radiopharmaceutical revolution with big pharmaceutical companies on the hunt for new clinical-stage radiopharmaceutical assets, we continue to differentiate from the current generation of products. What makes Clarity stand out from a myriad of other radiopharmaceuticals is not only the remarkable data on all three of our Targeted Copper Theranostic (TCT) products in clinical development to date, but also our strong intellectual property position and TCTs' ability to resolve the logistical and manufacturing limitations of the current generation of products and expand the field into the large oncology market. TCTs are scalable, sustainable and dependable, removing reliance on the antiquated fleet of nuclear reactors and short shelf life diagnostic products. With radiopharmaceuticals now rapidly growing into the large oncology market and the sector undergoing consolidation with accelerated M&A activity, our team is very excited about Clarity's future and the path ahead.

With the recently completed capital raising, it was great to see the incredible response from existing and new shareholders alike, and we thank you for your continued support in building Clarity into an Australian life sciences success story, being the only true Australian radiopharmaceutical company listed on the ASX that has developed our products at the benchtop of Australian science. These novel products are now well positioned to improve the treatment paradigm for cancer patients around the world. With a current cash funding of in-excess of \$150 million, we look forward to progressing our clinical trials and delivering exceptional data with all three of our products in clinical development.

Once again, we thank our shareholders for their support, and welcome our new shareholders to the Clarity story. We look forward to further updating our shareholders on the continued progress of our therapy and diagnostic programs as we head towards our ultimate goal of better treating children and adults with cancer.

Yours sincerely,

Dr Alan Taylor
Executive Chairperson
Clarity Pharmaceuticals Ltd

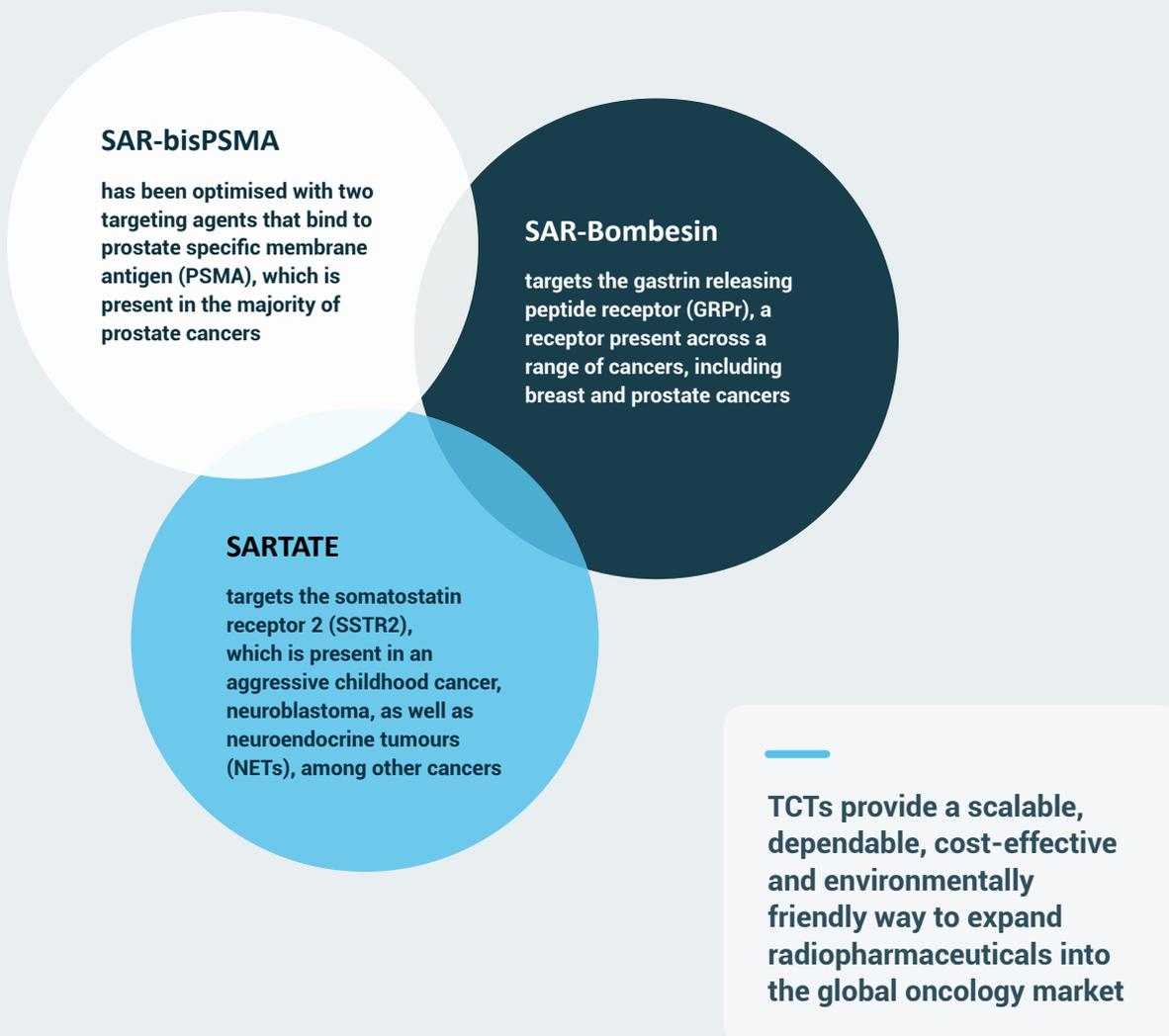


CLINICAL DEVELOPMENT OVERVIEW

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 ⁶⁴Cu) for imaging and copper-67 (Cu-67 or ⁶⁷Cu) 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.



CLINICAL DEVELOPMENT OVERVIEW

Clarity's three lead products, SAR-bisPSMA, SAR-Bombesin and SARTATE, are actively progressing through seven clinical trials, three theranostic and four diagnostic trials, including a Phase III registrational trial. Clarity is also currently planning its second Phase III pivotal trial for its diagnostic SAR-bisPSMA product in biochemically recurrent prostate cancer.



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

KEY FINANCIALS

\$121m
CAPITAL RAISE

Institutional Entitlement Offer and Retail Offer have been completed in April 2024

\$10.1m
R&D TAX INCENTIVE

RDTI is expected to provide a further \$10.1 million in cash funding

\$26.9m
CASH BALANCE

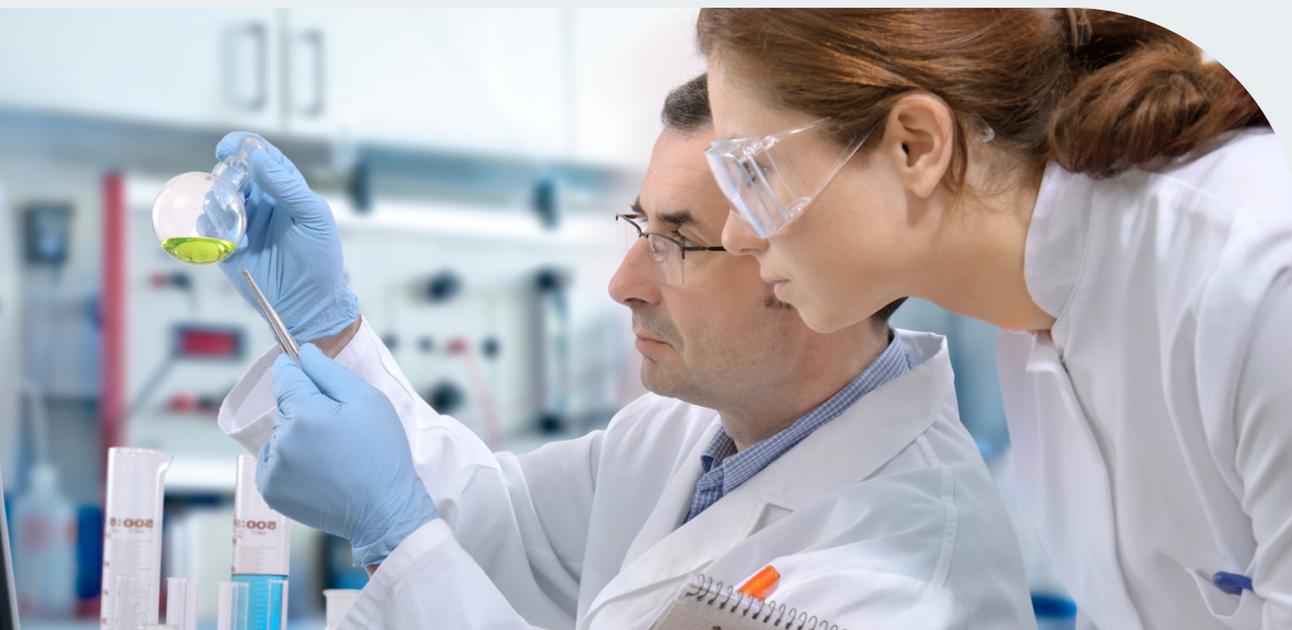
Cash balance at 31 March 2024

>\$150m
CASH FUNDING

Well-funded with a cash runway into early 2026

Clarity has successfully completed a fully underwritten equity raising of \$121 million comprising a pro rata accelerated non-renounceable entitlement offer and a placement to institutional investors which commenced on March 26th. The offer price per new fully paid ordinary share in Clarity issued under the placement and entitlement offer is \$2.55. The placement to institutional investors was successfully completed by the 28th of March, raising \$110 million in total, and the retail entitlement offer for approximately \$11 million opened on the 4th of April and has now completed.

Proceeds from the equity raising will be used to advance Clarity's clinical portfolio and strengthen the balance sheet. Clarity's clinical portfolio of products includes SAR-bisPSMA, SAR-Bombesin and SARTATE and the funding will enable the company to reach a number of crucial clinical milestones in their development.



PRODUCT UPDATES

SAR-bisPSMA PROSTATE CANCER

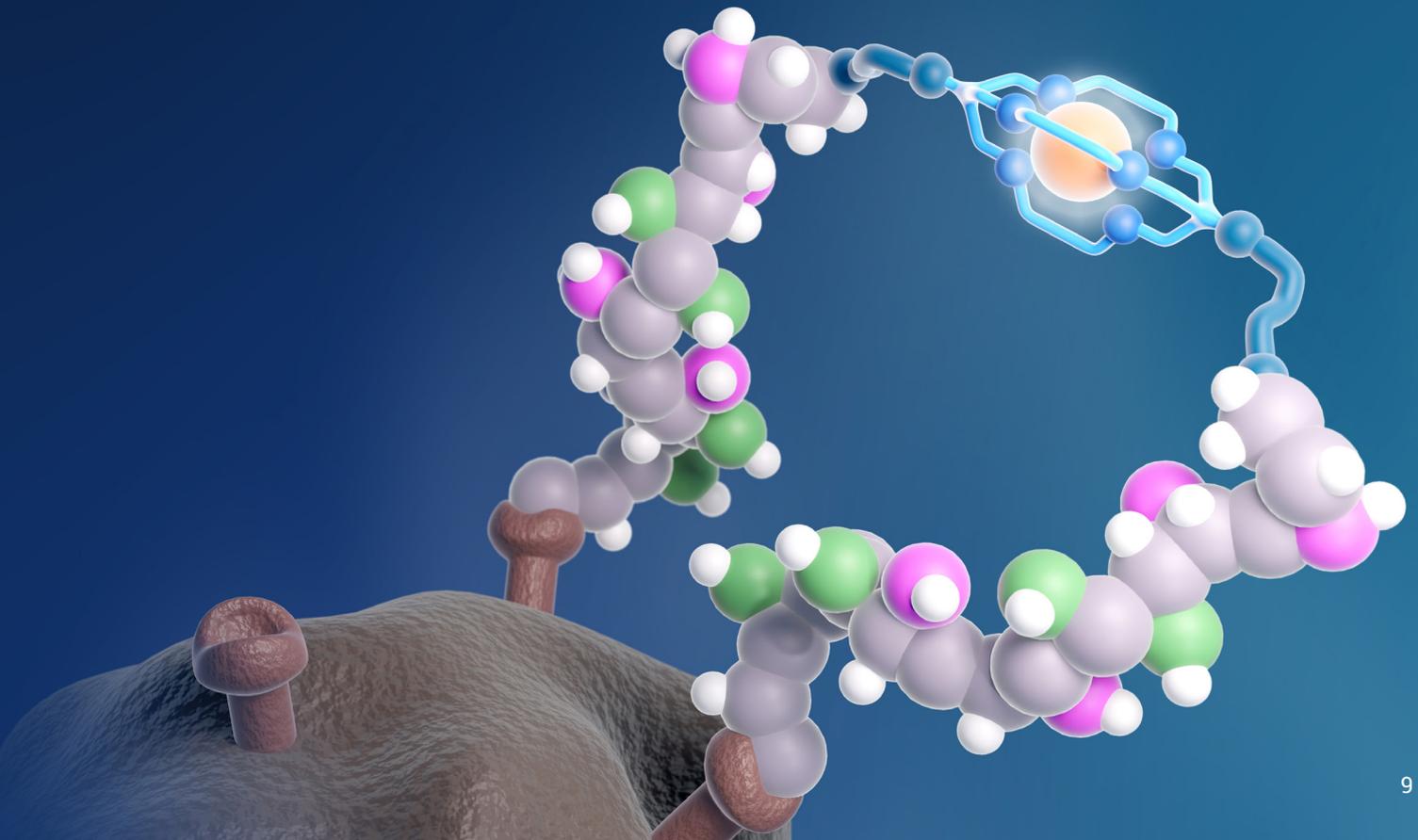
SAR-bisPSMA is a next generation, theranostic radiopharmaceutical with optimised dual PSMA-targeting agents to improve uptake and retention of the product in tumours

Product	SAR-bisPSMA		
Indication	Prostate Cancer		
Application	Theranostic	Diagnostic	
Trial	SECURE 	CLARIFY 	COBRA 

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 ⁶⁴Cu/⁶⁷Cu-SAR-bisPSMA trial

Clarity has successfully completed cohort 3 of the theranostic SECURE trial (NCT04868604)¹, enrolling and treating 6 participants who received a single therapy dose of ⁶⁷Cu-SAR-bisPSMA at the highest dose level of 12GBq with no dose limiting toxicities (DLTs) observed. Cohort 4, the first multi-dose cohort in the trial, is now progressing well with the first participant treated and all available patient slots allocated for the first part of the cohort.

SECURE is a Phase I/IIa theranostic trial for identification and treatment of an advanced form of prostate cancer, mCRPC. It is a multi-centre, single arm, dose escalation study with a cohort expansion planned for up to 44 participants. The aim of this trial is to determine the safety and tolerability of both ⁶⁴Cu-SAR-bisPSMA and ⁶⁷Cu-SAR-bisPSMA as well as the efficacy of ⁶⁷Cu-SAR-bisPSMA as a therapy.

Cohort 4 – first multi-dose cohort with 12GBq doses of ⁶⁷Cu-SAR-bisPSMA

Clarity treated its first participant in the first multi-dose cohort of the SECURE trial in March with the first of at least two cycles of 12GBq of ⁶⁷Cu-SAR-bisPSMA in cohort 4. This is the final cohort in the dose escalation phase of the SECURE trial, which will be followed by the dose expansion in 14 participants, pending safety evaluation.

Cohort 4 is designed as a “3+3” cohort, where the first 3 participants will receive 2 therapy cycles followed by a Safety Review Committee (SRC) meeting before commencing recruitment of the final 3 participants. Based on the favourable safety profile observed in the first 3 cohorts of the SECURE trial, a change to the dosing schedule of cohort 4 from “2 doses” to “up to 4 doses” has been approved by the SRC and will be implemented following the required regulatory approvals. This will allow patients who are benefiting from ⁶⁷Cu-SAR-bisPSMA to receive 2 additional doses under the SECURE trial in cohort 4 (up to 4 doses in total).

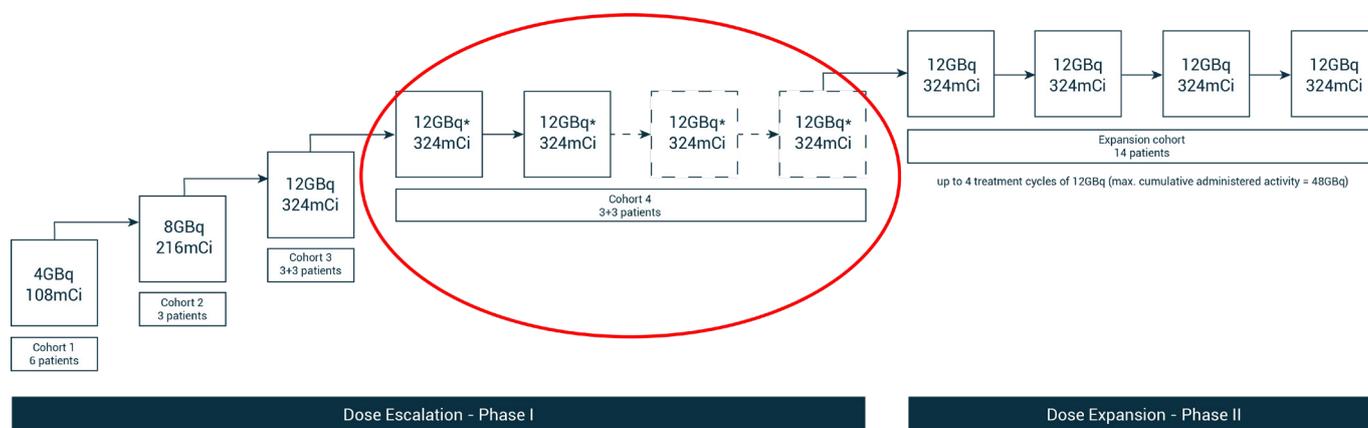


Figure 1. SECURE Study Design

*Patients in cohort 4 will receive 2 doses of ⁶⁷Cu-SAR-bisPSMA (12GBq) according to the current study protocol. A protocol amendment is underway to allow 2 additional doses of ⁶⁷Cu-SAR-bisPSMA in cohort 4. An SRC meeting will take place after participants receive their 2 doses, with a period of 6 weeks for safety follow-up.

Cohort 3 – single 12GBq dose of ⁶⁷Cu-SAR-bisPSMA

Cohort 3 of the dose escalation phase of the trial, where 6 participants received a single administration of 12GBq of ⁶⁷Cu-SAR-bisPSMA, has been successfully completed in March with no DLTs reported in any of the participants treated in this cohort.

Participants in cohort 3 had the highest median baseline prostate specific antigen (PSA) level and the highest median number of systemic therapies received prior to the treatment in the SECURE trial across all cohorts (median baseline PSA 122.6, 47.2 and 140.3 ng/ml; median lines of therapy 4, 3 and 5.5; cohorts 1, 2 and 3, respectively). Nevertheless, two-thirds (67%) of participants in this cohort so far have shown reductions in PSA greater than 35%. Importantly, a single dose of 12GBq of ⁶⁷Cu-SAR-bisPSMA was effective in reducing PSA levels and reducing the uptake of ⁶⁴Cu-SAR-bisPSMA in the lesions in the majority of these patients despite receiving the most lines of prior therapy (Figures 2 and 3).

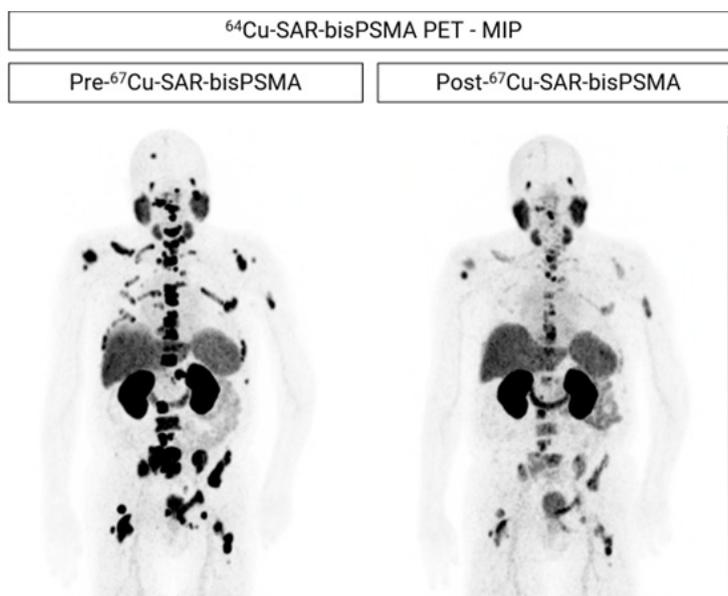


Figure 2. Participant from cohort 3 showing reduction in uptake of ⁶⁴Cu-SAR-bisPSMA in prostate cancer lesions. The participant was treated with androgen deprivation therapy (ADT), androgen receptor pathway inhibition (ARPI) therapy and 4 investigational agents prior to enrolling in the SECURE study (PSA 270.9 ng/ml at study entry). The participant received a single dose of ⁶⁷Cu-SAR-bisPSMA (12GBq), which led to the reduction in uptake of ⁶⁴Cu-SAR-bisPSMA in the lesions. PSA reduction: 92.3%. Total body tumour reduction: Maximum standardised uptake values (SUVmax) from 51.7 to 19.0 (63.2% reduction) and tumour volume from 1,040.9 to 635.4 ml (39.0% reduction). MIP: maximum intensity projection.

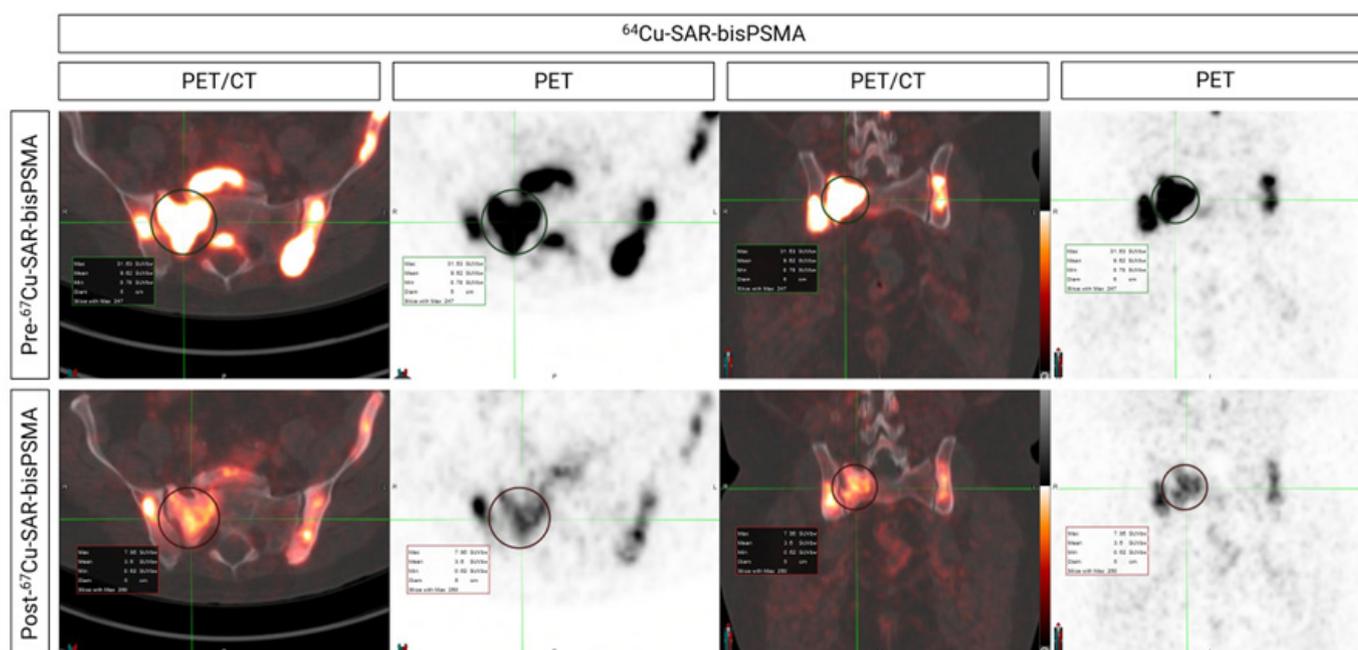


Figure 3. Participant from cohort 3 showing reduction in uptake of ⁶⁴Cu-SAR-bisPSMA in pelvic bone lesions after receiving a single dose of ⁶⁷Cu-SAR-bisPSMA (12GBq). The lesion highlighted in the circle shows a reduction in SUVmax from 31.6 to 8.0 (75% reduction, pre/post ⁶⁷Cu-SAR-bisPSMA cycle, respectively). Left images: axial view. Right images: coronal view.

Serial imaging using single-photon emission computed tomography (SPECT) at various timepoints following ⁶⁷Cu-SAR-bisPSMA injection show high uptake and retention of ⁶⁷Cu-SAR-bisPSMA in lesions and good clearance from organs (Figure 4), supporting the administration of multiple doses of ⁶⁷Cu-SAR-bisPSMA at the highest dose level (12GBq).

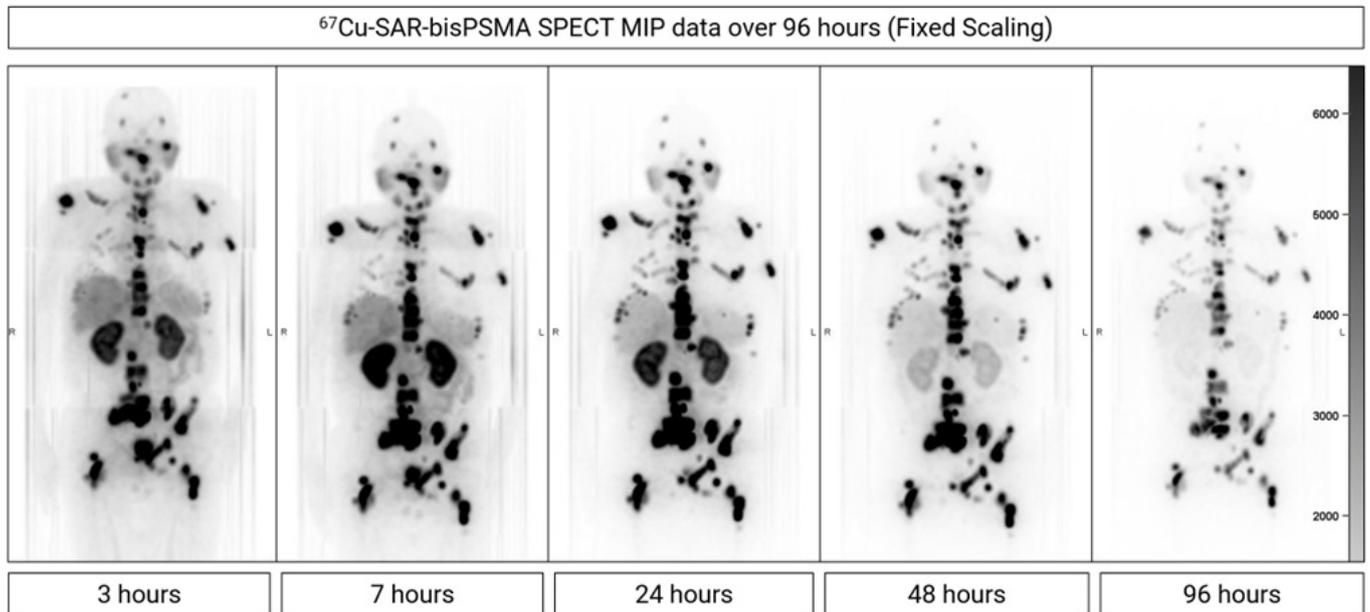


Figure 4. Serial imaging in a participant from cohort 3 (12GBq). SPECT was performed at different timepoints (3, 7, 24, 48 and 96 hours post-injection of ⁶⁷Cu-SAR-bisPSMA). Images show fast clearance from the kidneys, compared to prolonged retention of ⁶⁷Cu-SAR-bisPSMA in lesions. MIP: maximum intensity projection.



"The data to date continues to reinforce our strong belief that we have a best-in-class radiopharmaceutical therapy, with dramatic responses obtained in patients that had failed multiple treatments, including other radiopharmaceutical therapies, as well as all other standard of care therapies and products in development."

- Dr Alan Taylor,
Executive Chairperson

COBRA – a diagnostic ^{64}Cu -SAR-bisPSMA Phase I/II trial

Initial data from Clarity's diagnostic Phase I/II trial, COBRA, confirmed ^{64}Cu -SAR-bisPSMA is safe and highly effective in detecting prostate cancer lesions in patients with BCR. Additional data from the trial also confirmed that ^{64}Cu -SAR-bisPSMA was able to detect much smaller lesions than anticipated, including a lesion with a diameter of less than 2mm, which compares favourably against the current standard-of-care (SOC) PSMA imaging agents.

COBRA (NCT05249127)⁵ derives from COpper-64 SAR-bisPSMA in Biochemically Recurrent prostate cancer. It was a multi-centre, single-arm, non-randomised, Phase I/II diagnostic imaging study of ^{64}Cu -SAR-bisPSMA administered to participants with BCR of prostate cancer following definitive therapy and who had a negative or equivocal SOC scan at screening.

The primary objectives of the COBRA trial were to investigate the safety and tolerability of ^{64}Cu -SAR-bisPSMA as well as its ability to correctly detect recurrence of prostate cancer. Patients underwent positron emission tomography (PET) / computed tomography (CT) scans with ^{64}Cu -SAR-bisPSMA on Day 0 and Day 1 (1-4h and 24±6h post-dose, respectively), which were interpreted by three blinded central readers.

To determine the efficacy of ^{64}Cu -SAR-bisPSMA imaging, the Day 0 and Day 1 PET/CT results of the central readers were assessed against a composite reference standard that was determined by an independent, blinded, central expert panel. The reference standard consisted of histopathology, follow-up SOC imaging and/or confirmed PSA response to focal therapy.

Fifty-two patients with negative or equivocal SOC scans were enrolled and imaged, of whom 42 were included in the calculation of the efficacy endpoints. Results from COBRA showed for the first time that ^{64}Cu -SAR-bisPSMA is safe and effective in detecting lesions in patients with BCR of prostate cancer who were negative or equivocal on SOC imaging (e.g. bone scan, CT or PET with approved PSMA imaging agents) at screening (Figure 5).

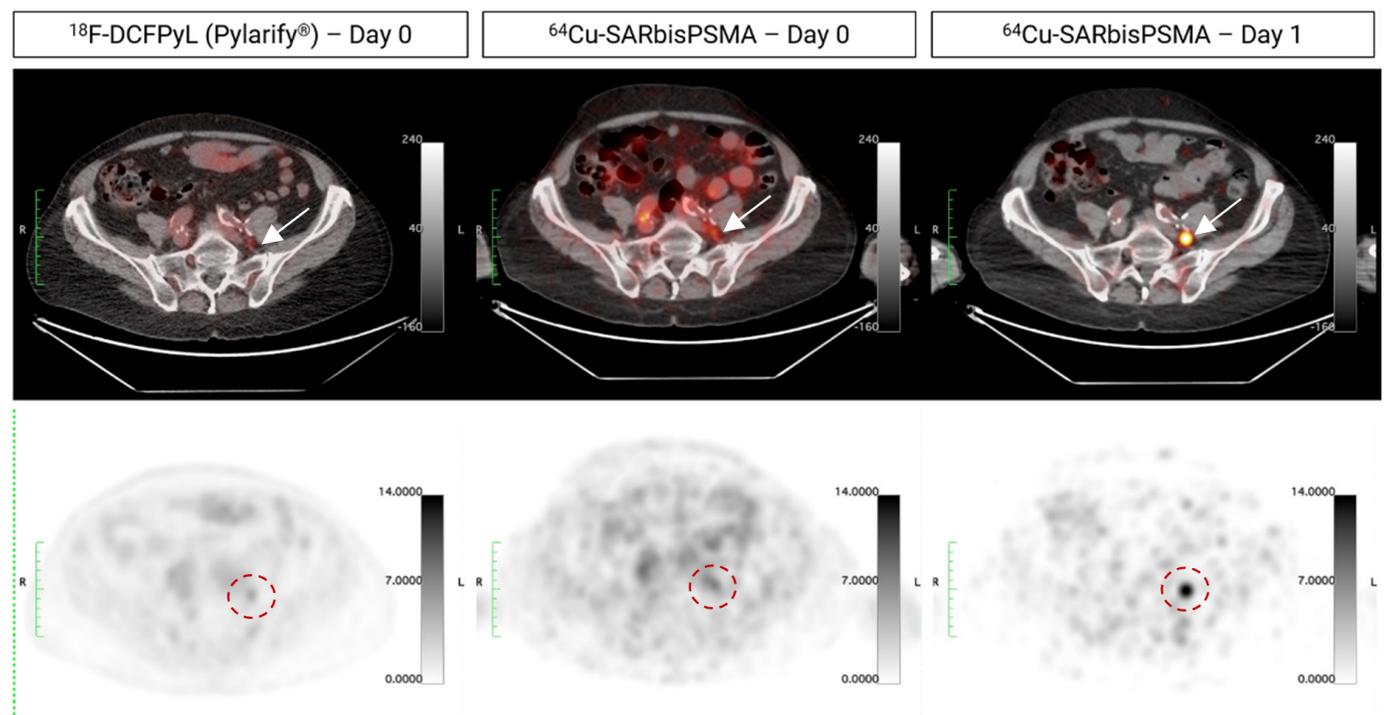
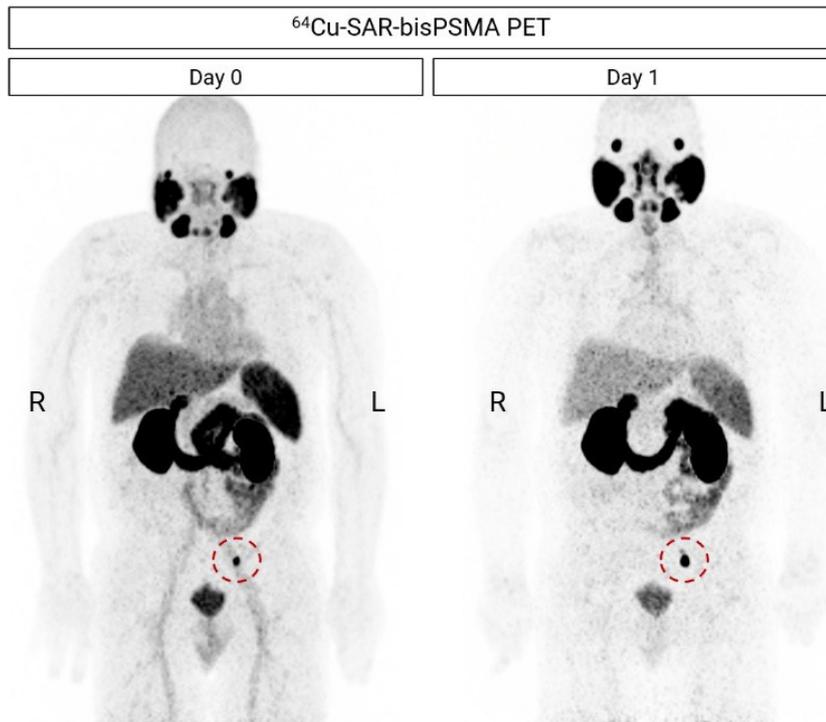


Figure 5. Identification of lesion in the pelvic region using ^{64}Cu -SAR-bisPSMA on next-day imaging (right), negative on same-day imaging (^{64}Cu -SAR-bisPSMA; center) and equivocal on screening SOC imaging (^{18}F -DCFPyL, Pylarify®; left). Maximum standardised uptake values (SUVmax) of the lesion across scans (arrows and red circles) was 2.3, 4.3 and 17.5 (^{18}F -DCFPyL, Pylarify®, Day 0 and Day 1 ^{64}Cu -SAR-bisPSMA, respectively). Top images: PET/CT fusion. Bottom images: PET.

Only one adverse event was related to ^{64}Cu -SAR-bisPSMA (Grade 2 worsening of type II diabetes, resolved) among all 52 patients who received the product (Safety Analysis Set). ^{64}Cu -SAR-bisPSMA identified lesions in up to approximately 60% of patients on same-day imaging, and up to 80% on next-day imaging, with high specificity on both days (Figure 6).



Following ^{64}Cu -SAR-bisPSMA PET imaging, investigators indicated that they would change the treatment plan of approximately half of the patients (48%). Of these patients, two-thirds (67%) proceeded to receive systemic and/or focal therapy

Figure 6. ^{64}Cu -SAR-bisPSMA PET showing a positive pelvic lymph node (LN; red circle, maximum intensity projection). 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. MIP: maximum intensity projection.

Next-day imaging – a key advantage over currently approved PSMA PET agents

The possibility of performing next-day imaging is a feature not available to currently approved PSMA-targeted PET products. This is due to 3 key features: firstly, the optimal half-life of ^{64}Cu (12.7 h), which is longer than that of the isotopes used in currently approved PSMA PET agents, such as gallium-68 (^{68}Ga) and fluorine-18 (^{18}F) (<2 h); secondly, the ability of the SAR Technology to prevent leakage of copper isotopes from the radiopharmaceutical in-vivo; and thirdly, the bivalent structure of bisPSMA. The COBRA trial confirmed the benefits of delayed imaging in this patient group as more lesions and more patients with a positive scan were identified on next-day imaging.

^{64}Cu -SAR-bisPSMA was able to identify approximately 91% more lesions (median increase) on next-day imaging compared to same-day imaging (ranges across the readers for the total number of lesions: 53–80 on Day 0 vs. 82–153 on Day 1). The number of lesions in the pelvic LN region more than doubled on next-day imaging compared to same-day imaging (median increase of 108.3% across all readers comparing Day 0 vs. Day 1) (Figure 7). The ranges of correct detection rate (CDR, defined as the proportion of true positive participants out of all scanned participants who had at least one evaluable reference standard datapoint) and patient-level detection rate (DR, defined as the proportion of participants with a positive ^{64}Cu -SAR-bisPSMA PET/CT scan out of all scanned participants) were both higher on Day 1 compared to Day 0. The DR range on Day 0 was 44–58% (95% confidence interval (CI) 30–71.8), increasing on Day 1 to 58–80% (95% CI 43.2–90).

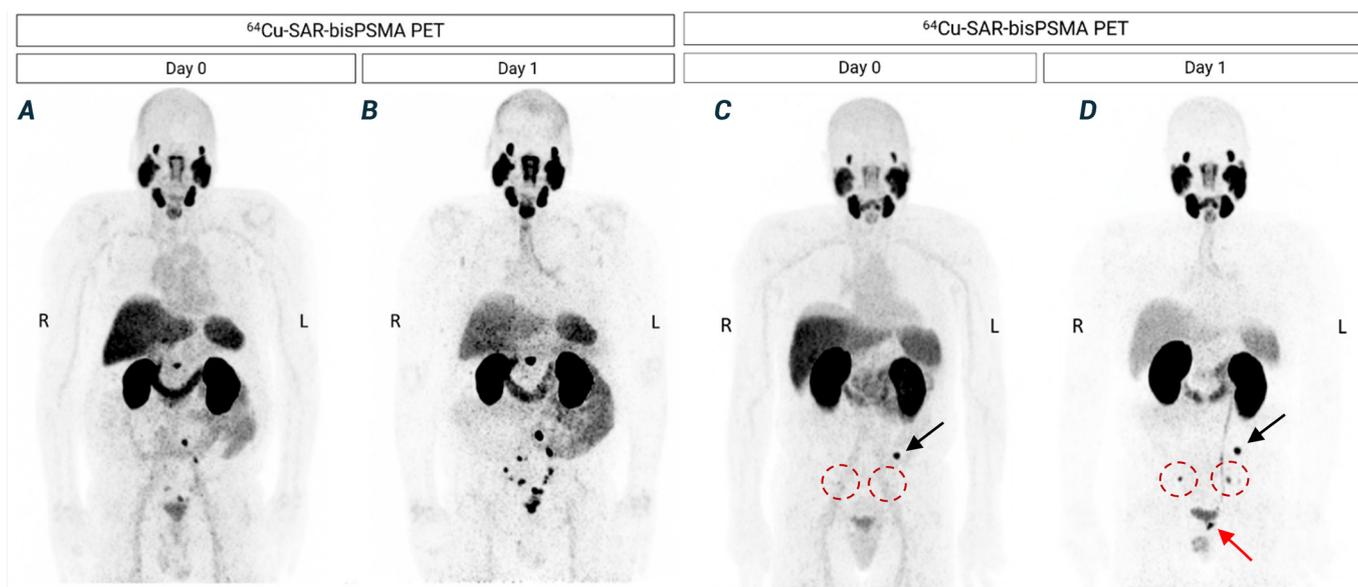


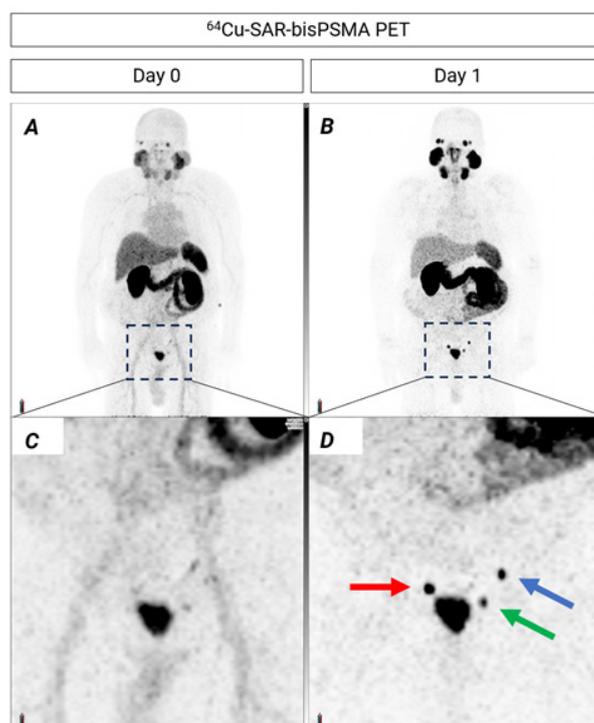
Figure 7. Next-day imaging identified additional lesions compared to same-day imaging. **A, B** – patient 1: ⁶⁴Cu-SAR-bisPSMA PET showing positive LNs in the pelvic and extra-pelvic (retroperitoneal) regions and lesions in the prostatic bed. **C, D** – patient 2: ⁶⁴Cu-SAR-bisPSMA PET showing a lesion in the pelvic bone (black arrow) on both days, pelvic LNs more clearly visualised on next-day imaging (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. MIP: maximum intensity projection.

Detection of smaller lesions

⁶⁴Cu-SAR-bisPSMA was able to detect much smaller lesions than anticipated, including a lesion with a diameter of less than 2 mm. This compares favourably against the current SOC PSMA PET imaging agents, including PYLARIFY® and the generic product ⁶⁸Ga-PSMA-11, with which the detection of lesions smaller than 5 mm is challenging. Sensitivity is a known challenge for the existing PSMA PET agents, particularly for lesions <5 mm⁸⁻¹¹. This suggests that lesions are missed by current SOC imaging, which can have significant implications on accurate staging and subsequent treatment decisions. For those undergoing initial staging of their disease, missing lesions may lead to unnecessary surgery resulting in long-lasting side effects (e.g. impotence and/or incontinence following the removal of the prostate)¹². In patients with BCR of prostate cancer, it is also crucial to identify their cancer early in order to intervene with appropriate treatment that could put a patient's cancer into remission and avoid uncontrollable disease progression from lesions that are missed, which could lead to widespread metastatic disease¹³.

The size of the prostate cancer lesions detected by ⁶⁴Cu-SAR-bisPSMA was recorded on the same-day (Day 0) and next-day (Day 1) imaging. Lesions with less than 5 mm in size were identified across readers among 14% (7/50) of patients (Figure 8). These lesions were located in the bone, pelvic and extra-pelvic lymph node regions. The smallest lesion (pelvic lymph node) identified in the study was 2.6 x 1.9 mm (Figure 9).

Figure 8. Pelvic lymph nodes showing uptake of ⁶⁴Cu-SAR-bisPSMA on Day 1 (arrows). Blue arrow: lesion size 3.8 mm x 4.4 mm, SUVmean 20.6, SUVmax 22.1 and TBR 130.1. Green arrow: lesion size also 3.8 mm x 4.4 mm, SUVmean 11.9, SUVmax 12.8 and TBR 75.3. Red arrow: lymph node showing ⁶⁴Cu-SAR-bisPSMA uptake (>5 mm). **A, B, C, D:** Maximum Intensity Projection. Inset in top images displays pelvic region (bottom images).



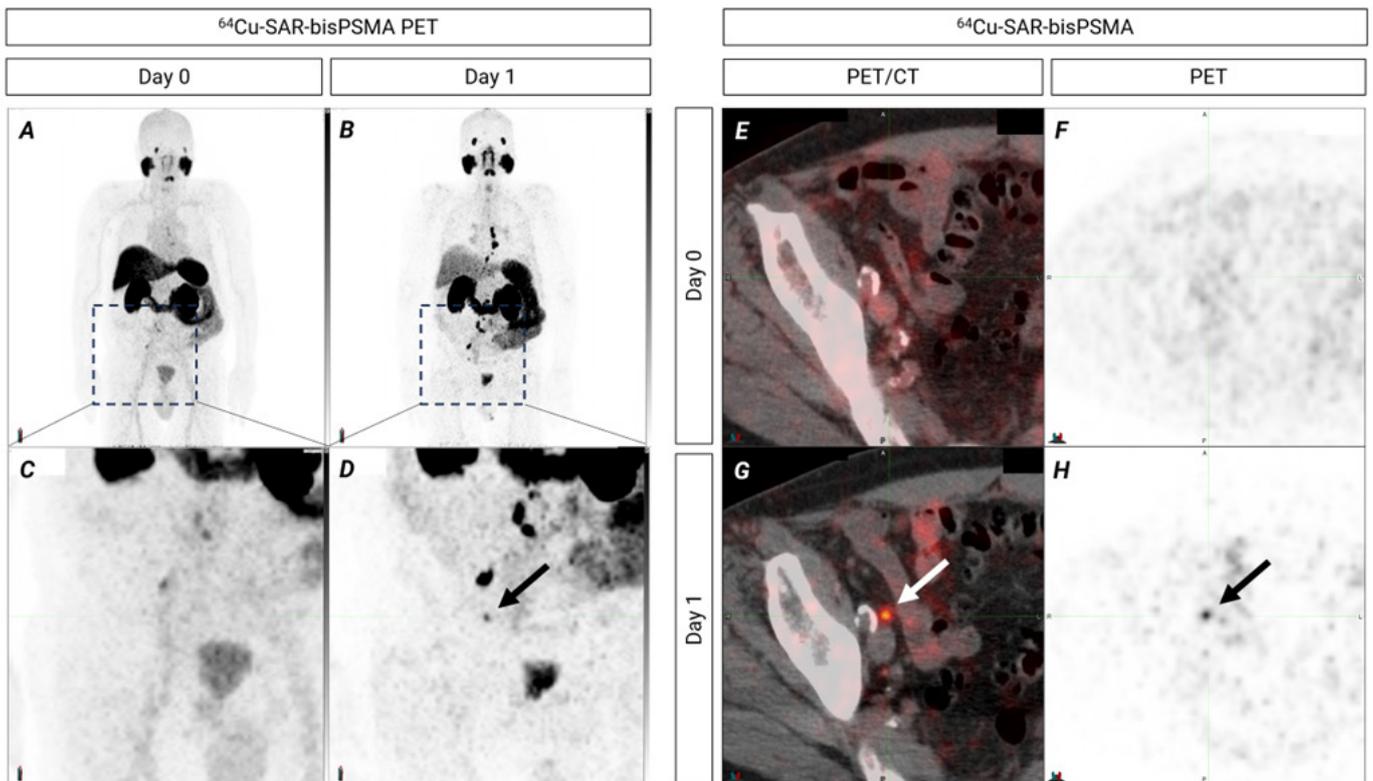


Figure 9. PET images showing lymph nodes with uptake of ⁶⁴Cu-SAR-bisPSMA better visualised on Day 1 (pelvic and extra-pelvic regions – retroperitoneal and supradiaphragmatic). Right pelvic lymph node showing uptake of ⁶⁴Cu-SAR-bisPSMA on Day 1 (arrows, bottom images). Lesion size: 1.9 mm x 2.6 mm. SUVmean 8.0, SUVmax 8.2 and TBR 67.9. A, B, C, D: Maximum Intensity Projection. Inset in top images displays pelvic and extra-pelvic regions (bottom images). E, F, G, H: axial view of pelvic region showing the same lymph node as on image D (arrow).

The ability of ⁶⁴Cu-SAR-bisPSMA to detect lesions less than 5 mm is a result of a few factors unique to the product that also enable next-day imaging. First, Clarity's proprietary SAR technology employs a cage, or chelator, that securely holds isotopes of copper and prevents their leakage in vivo. In addition, pre-clinical and clinical evidence to date has demonstrated that the optimised dual targeting molecule connected to the cage, bisPSMA, ensures increased targeting and retention of the product in prostate cancer tumours compared to its single targeting molecule counterpart and approved PSMA agents¹⁴⁻¹⁵. Both of these features, combined with the longer half-life of Cu-64, enabled ⁶⁴Cu-SAR-bisPSMA to be imaged at 24 hrs post-administration of the product in the COBRA trial and resulted in the identification of additional lesions in BCR patients with negative or equivocal SOC scan.

Based on the results from the COBRA study to date, Clarity has now commenced planning of a registrational Phase III trial in this patient population. Final study results from the pivotal trial will be intended to provide sufficient evidence to support a New Drug Application to the FDA for approval of ⁶⁴Cu-SAR-bisPSMA as a new diagnostic imaging agent for patients with BCR of prostate cancer.

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

During the quarter, Clarity continued recruitment into the pivotal CLARIFY trial and progressed the selection and activation of clinical trial sites in the US and Australia. CLARIFY is the first Phase III registrational trial for Clarity and the first trial to evaluate the benefits of next-day imaging in prostate cancer patients prior to undergoing prostatectomy (removal of the prostate). Next-day imaging is a feature unique to ^{64}Cu -SAR-bisPSMA and not feasible with approved PSMA PET agents.

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 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 ^{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).

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

Next-day imaging is not possible with current-generation radiopharmaceuticals due to the shorter half-life of the Ga-68 and F-18 radioisotopes. Cu-64 has an optimal half-life that enables imaging up to 72 hours post administration.



FINANCIALS

Clarity's cash balance was \$26.9 million as at 31 March 2024.

Net operating cash outflows for the quarter were \$12.2 million which is lower than the previous quarters outflow of \$14.4 million due to timing and execution of clinical trial costs together with the absence of 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.

The following Use of Funds table reflects the use of funds raised as part of the Company's IPO in August 2021. This table will be updated in future Appendix 4C's to reflect the use of funds received in April 2024 from the company's most recent capital raise.

Use of Funds

(Listing Rule 4.7C.2)

Uses of funds	Prospectus dated 16 July 2021 \$ Million	% of Total Funds	Period* to 31 March 2024 \$ Million	% of Total Funds
Pre-Clinical	\$2.7	2.5%	\$3.7	3.8%
Clinical	\$84.0	76.6%	\$65.6	67.5%
Regulatory	\$5.7	5.2%	\$2.8	2.9%
Patents	\$1.4	1.3%	\$2.9	3.0%
Corporate	\$10.4	9.5%	\$15.6	16.0%
Costs associated with the Offer	\$5.4	4.9%	\$6.6	6.8%
Total uses	\$109.6	100.0%	\$97.2	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 March 2024, 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 \$437,878 for the quarter. This amount includes director fees and salaries paid in the March quarter.

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

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1. ClinicalTrials.gov Identifier: NCT04868604
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3. ClinicalTrials.gov Identifier: NCT04023331
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4. ClinicalTrials.gov Identifier: NCT06056830
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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



Appendix 4C

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

Name of entity

Clarity Pharmaceuticals Ltd

ABN

36 143 005 341

Quarter ended ("current quarter")

31 March 2024

Consolidated statement of cash flows	Current quarter \$A'000	Year to date (9 months) \$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(9,391)	(28,312)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(109)	(186)
(d) leased assets	-	-
(e) staff costs	(2,474)	(8,331)
(f) administration and corporate costs	(757)	(3,051)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	528	1,639
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	-	(101)
1.7 Government grants and tax incentives	-	-
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(12,203)	(38,342)

2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(a) entities	-	-
(b) businesses	-	-
(c) property, plant and equipment	(6)	(432)
(d) investments	-	-
(e) intellectual property	-	-
(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	-
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	Net cash from / (used in) investing activities	(6)	(432)

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	486	607
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(7)	(12)
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	479	595

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	37,983	65,015
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(12,203)	(38,342)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(6)	(432)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	479	595

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

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (9 months) \$A'000
4.5	Effect of movement in exchange rates on cash held	667	84
4.6	Cash and cash equivalents at end of period	26,920	26,920

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	24,920	23,176
5.2	Call deposits	2,000	14,807
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)	26,920	37,983

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	438
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	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
<i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i>		
<i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>		
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 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)	(12,203)
8.2 Cash and cash equivalents at quarter end (item 4.6)	26,920
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	26,920
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	2
<i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i>	
8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?	
Answer: Yes, the Company will continue to execute its clinical development programs and experience similar levels of net operating cash flows moving forward.	
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: Yes, the Company commenced a capital raising process in late March 2024 involving an institutional placement and accelerated non-renounceable rights issue. The company expects proceeds from the capital raise, to be received in April 2024, of circa \$115 million net of capital raising costs.	

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: Yes, the Company will use the proceeds from the capital raise to fund its future business operations and to meet its business objectives.

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: 30 April 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.