CLARITY
PHARMACEUTICALS

QUARTERLY ACTIVITY REPORT

SYDNEY, AUSTRALIA
30 JUNE 2024

HIGHLIGHTS OF THE QUARTER

Ending 30 June 2024

Cash Position

The Company's cash position at the end of the June quarter was $136.5 million, including a $10 million Research and Development (R&D) Tax Incentive refund for FY23 received on the 24th of June. 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. These sources of funds are expected to provide the company with a cash runway through to 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 capital raise, which was significantly oversubscribed, successfully completed on 24th April.

Complete response with ^{67}Cu-SAR-bisPSMA

The first patient with metastatic castrate-resistant prostate cancer (mCRPC) to ever receive two cycles of Clarity's ^{67}Cu-SAR-bisPSMA at the 8GBq dose level achieved a complete response based on Response Evaluation Criteria In Solid Tumours (RECIST v1.1) assessment, undetectable levels of Prostate Specific Antigen (PSA) for almost 8 months and undetectable lesions using positron emission tomography (PET) imaging with ^{64}Cu-SAR-bisPSMA following the treatment.

Phase III registrational trial

Clarity is preparing for an End of Phase meeting with the US Food and Drug Administration (FDA) as the Company is planning its second registrational Phase III trial with ^{64}Cu-SAR-bisPSMA. The trial design is guided by the data collected from the Phase I/II diagnostic imaging study, COBRA, in participants with biochemical recurrence (BCR) of prostate cancer.

Data presented at 3 leading conferences

Clarity's most recent data was presented at the American Urological Association (AUA), American Society of Clinical Oncology (ASCO) and Society of Nuclear Medicine and Molecular Imaging (SNMMI) 2024 Annual Meetings, covering clinical results and trials in progress. The data showcases the extensive scope of Clarity's Targeted Copper Theranostic (TCT) platform in developing multiple products for imaging and treating cancer patients, with focus on prostate cancer.

SUPPLY AND MANUFACTURING

Clarity strengthened its supply and manufacturing with the signing of 2 agreements during the quarter. On the 30th of May the Company entered into a Supply Agreement with SpectronRx for the production of copper-64 isotope for Clarity's products which continue to progress through clinical trials, including a pivotal Phase III clinical trial. On the 4th of April Clarity signed a new Clinical Supply Agreement with NorthStar for the production of the ^{67}Cu-SAR-bisPSMA drug product, supporting late-stage therapy trials.

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 30 June 2024.

Executive Chairperson's Letter

Dear fellow Shareholders,

I am delighted to present Clarity's report for the quarter ending 30 June 2024 as we conclude the financial year and recap on the exciting clinical, corporate and operational milestones achieved in this quarter.

As the radiopharmaceutical sector continues to shine in the spotlight of the massive oncology market, attracting big pharma's attention and generating multi-billion-dollar mergers and acquisitions, Clarity continues to generate incredible results and delivers on its promise of developing next-generation radiopharmaceutical products that offer clinical, logistical and environmental advantages over currently available products.

Propelled by this powerful momentum, we have never found ourselves in a more extraordinary position. Having completed a $121 million capital raise and with the additional undiluted funding from the R&D Tax Incentive refund of almost $10 million, Clarity is well funded and on track towards our ultimate goal of improving treatment outcomes for children and adults with cancer.

At the core of our business is the proprietary SAR platform, enabling the development of a range of Targeted Copper Theranostics and clearly positioning us as the world leader in copper based theranostics. What this means is that we can continue to fully leverage our extensive Intellectual Property position and develop a broad range of novel radiopharmaceuticals that address a vast number of clinical indications with unmet needs, particularly as radiopharmaceuticals gather enormous traction in the oncology space.

One of the ultimate successes of this strategy is our most advanced product, SAR-bisPSMA, where the same targeting molecule can be used for diagnosis and therapy. We believe SAR-bisPSMA to be the best PSMA targeting molecule designed to date. What makes it truly unique is the dual targeting structure where we are using two agents attached to the cage holding the isotope instead of just one agent, in contrast to the other commonly used products, such as PSMA-617 (Pluvicto®), generic PSMA I&T and generic PSMA-11. This dual targeting results in increased uptake and retention in PSMA-expressing tumours, meaning more of the product is taken up in the tumours and stays there longer. And we are now observing these benefits through exceptional responses in patients with prostate cancer that have failed multiple lines of treatment, continuing to build on the large body of evidence so far obtained from in vitro and pre-clinical studies, and head-to-head comparator clinical trials in humans.

Most recently, we confirmed that our first ever patient to be dosed with two cycles of ^{67}Cu-SAR-bisPSMA at 8GBq achieved a complete response to treatment based on Response Evaluation Criteria In Solid Tumours (RECIST v1.1) assessment. The patient remains with undetectable levels of Prostate Specific Antigen (PSA) for almost 8 months, following the administration of the second dose of ^{67}Cu-SAR-bisPSMA and had no detectable lesions using positron emission tomography (PET) imaging with ^{64}Cu-SAR-bisPSMA following the treatment. It is important to note that this patient was heavily pre-treated and failed multiple lines of therapy, including androgen deprivation therapy (ADT), androgen receptor pathway inhibitors (ARPIs), chemotherapy and a poly (ADP-ribose) polymerase (PARP) inhibitor.

This outcome is remarkable, especially given the favourable safety profile of both ^{67}Cu-SAR-bisPSMA and ^{64}Cu-SAR-bisPSMA and the sustained response in a patient who had few treatment options available for his metastatic castration-resistant prostate cancer (mCRPC).

But what is most extraordinary is that we were only in the midst of a single dose, dose escalation stage of our SECuRE trial at the time. Although our main focus has been safety data, which has been reported to shareholders after every safety review committee meeting at the completion of each cohort, the efficacy data has been exemplary, even in patients that have failed multiple lines of treatment, including other radiopharmaceutical treatments. In cohorts 2 and 3, at what we would consider therapeutic doses of 8GBq and 12GBq doses respectively, PSA reductions of greater than 35% were observed in almost 80% (78%, 7/9) of participants and PSA was reduced by over 80% in approximately 1 in every 2 patients (4/9), all from a single dose. These results were seen on the backdrop of a very favourable safety profile. Only two patients did not respond with a PSA drop below baseline in cohort 2 and 3, with both patients having previously failed five lines of therapy and their PSA in the hundreds.

Our team and collaborators are incredibly encouraged and excited with this outcome and we continue to work hard to progress our SECuRE trial with $^{64/67}$Cu-SAR-bisPSMA in this patient population, where we are now treating patients in the first multi-dose cohort at the dose level of 12GBq. An update to shareholders on this cohort will be provided immediately following the next safety review committee meeting.

We are also thrilled to continue building on the promising results from our diagnostic imaging Phase I/II study with ^{64}Cu-SAR-bisPSMA in biochemically recurrent (BCR) prostate cancer, COBRA, and are employing the data to inform trial design for a registrational Phase III study in this patient population. Our team is currently preparing for an End of Phase meeting with the US Food and Drug Administration (FDA), and we will provide an update to the market as the Phase III trial planning progresses. This will be Clarity's second Phase III trial with this diagnostic product. The first pivotal trial launched by Clarity, CLARIFY, is investigating the diagnostic performance of ^{64}Cu-SAR-bisPSMA to detect prostate cancer within the pelvic lymph nodes in participants prior to undergoing prostatectomy (removal of the prostate).

Reflecting the excitement and relevance of the data Clarity is generating with TCTs, we have recently presented at three leading world conferences, the American Urological Association (AUA), American Society of Clinical Oncology (ASCO) and Society of Nuclear Medicine and Molecular Imaging (SNMMI) 2024 Annual Meetings, covering clinical results and trials in progress. This included SECuRE, COBRA and CLARIFY trials for SAR-bisPSMA as well as COMBAT and SABRE trials for SAR-Bombesin. The data generated a lot of interest from the community and reassured Clarity's position as a next-generation radiopharmaceutical company with a pipeline of best-in-class products.

While strong clinical data and potential benefit to the patient are at the core of developing and commercialising successful products, delivering these products to patients and their treating professionals on time and at quantities needed for treatment are essential. We have seen from the Novartis' launch of Pluvicto® how an extremely promising product with high demand can fail to help patients in need due to logistical and manufacturing hurdles. With Novartis now controlling the vast majority of the lutetium-177 supply and openly admitting that the poor infrastructure, aging nuclear reactors and fragile

supply chains of the isotope are all major obstacles in the growth of the radiopharmaceutical sector[1], the future of current-generation radiopharmaceutical therapies is uncertain. While targeted alpha-particle therapies (TAT) have recently emerged and generated a lot of hype, these radiopharmaceuticals still have a number of unproven critical areas, such as safety and efficacy, due to the high energy of the alpha-emitting isotopes and the limitations of the currently used targeting molecules. Moreover, the manufacturing and sourcing of alpha-emitting isotopes pose a lot of challenges as we have seen from the recent shortage of actinium-225 (Ac-225 or ^{225}Ac) that has led to a delay in clinical recruitment into a number of TAT trials[2-3]. Clarity is now expanding into TAT, which we see as complementary to our TCT treatments that remain at the core of our strategy. With US-sourced Ac-225 and what we think is the best PSMA targeting molecule ever made, bisPSMA, Clarity is well positioned to address the current issues in the TAT field and fundamentally improve the arsenal of treatments available for oncologists and their patients through offering treatments for early stages of prostate cancer with ^{67}Cu-SAR-bisPSMA and later-stage treatment options with ^{225}Ac-bisPSMA.

However, TCTs remain our key focus. Clarity's unique position in TCTs and the inherent properties of copper-64 for imaging and copper-67 for therapy offer a scalable and dependable solution for expanding radiopharmaceuticals into the large oncology field, delivering the "big pharma" supply chain model with centralised manufacture under GMP and widespread distribution. We do not rely on the nuclear reactors and supply from countries like Russia that pose a number of geopolitical challenges at this time. Our copper-67 is made domestically in the US with our partners at the Idaho Accelerator Center (IAC) and NorthStar Medical Isotopes LLC (NorthStar) who supply this isotope exclusively to Clarity. It is made on electron accelerators that are relatively inexpensive and readily scalable in all geographies of the world. Further building on the benefits of copper, we have recently signed a finished drug product manufacturing agreement with NorthStar, becoming the only radiopharmaceutical company where therapeutic isotope and finished product are both centrally manufactured under one roof and uniquely positioning Clarity to provide a scalable solution to the future demands of the radiopharmaceutical space.

In the diagnostic field, we continue expanding our supply chain to ensure abundant availability of copper-64 for our trials as our products are swiftly progressing through clinical development, including Phase III trials.
Most recently, we added SpectronRx, our first private supplier, to Clarity's extensive and reliable network of copper-64 manufacturers. The unique properties of this isotope and its longer half-life enable production of this isotope in commercially relevant volumes daily, on centrally located cyclotrons.

With a pipeline of best-in-class diagnostic and therapeutic products in clinic and a number of promising targets in pre-clinical development, supported by comprehensive IP, reliable supply chain and strong cash balance, Clarity is now well on track to propel radiopharmaceuticals into the new era.

It can then be manufactured into ready-to-use products with a shelf-life that is measured in days rather than hours and reliably supply any required number of doses to any zip code in the United States, removing the burden of the current supply issues with gallium-68 and fluorine-18 based products from practices and their patients.

With a pipeline of best-in-class diagnostic and therapeutic products in clinic and a number of promising targets in pre-clinical development, supported by comprehensive IP, reliable supply chain and strong cash balance, Clarity is now well on track to propel radiopharmaceuticals into the new era. We look forward to continuing progressing what has been an Australian success story, thanks to the great Australian science and a dedicated, hard-working team and collaborators across Australia and the US.

We thank our shareholders for their support and welcome our new shareholders to the Clarity story as we remain committed to maximising the value of our Company in one of the most exciting areas of the oncology field, radiopharmaceuticals. 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

KEY FINANCIALS

$121m
CAPITAL RAISE

Institutional Entitlement Offer of $110m and Retail Offer of ~$11m

$10m
R&D TAX INCENTIVE

RDTI contributed ~$10 million in non-dilutive cash funding

$136.5m
CASH BALANCE

Cash balance at 30 June. Well-funded with a cash runway into early 2026

In April, Clarity 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.

The offer price per new fully paid ordinary share in Clarity issued under the placement and entitlement offer was $2.55. The placement to institutional investors raised $110 million in total, and the retail entitlement offer approximately $11 million.

In June, Clarity also received a $10 million Research and Development Tax Incentive (RDTI) refund as part of the Australian Federal Government's RDTI program, recognising the R&D undertaken by the Company in the financial year ended 30 June 2023.

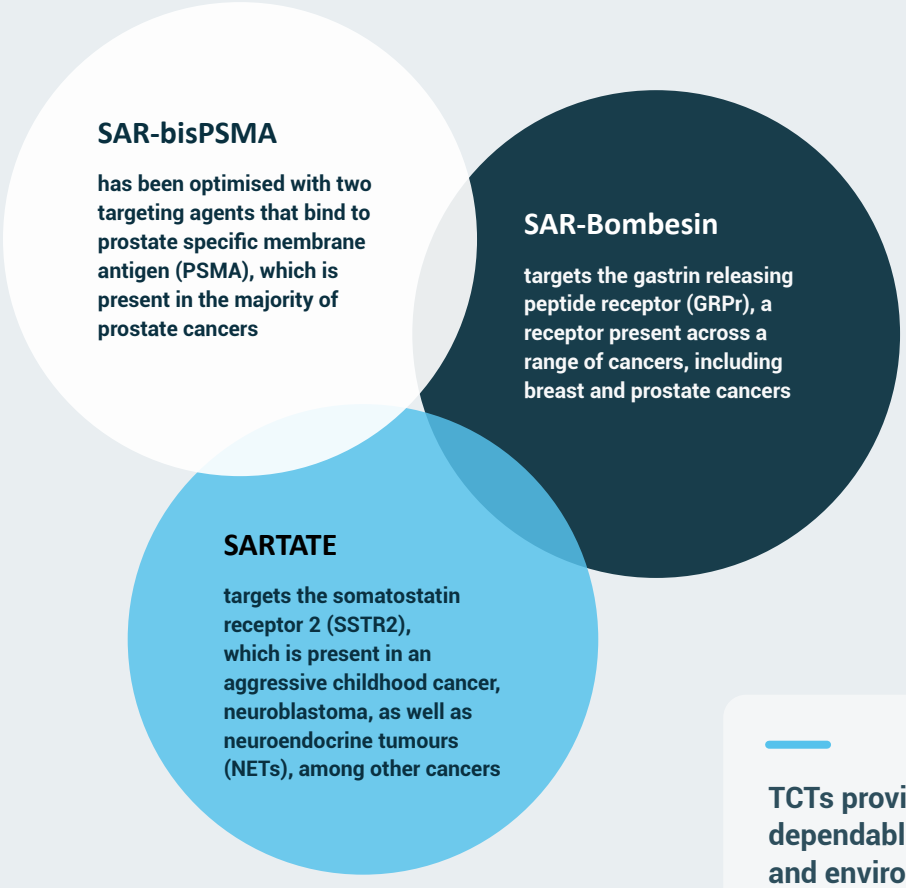
Proceeds from the equity raising and RDTI will be used to advance Clarity's clinical portfolio and strengthen the balance sheet. Clarity's clinical portfolio of products includes SAR-bisPSMA, SAR-Bombesin and SARTATE and the funding will enable the company to reach a number of crucial clinical milestones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

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.

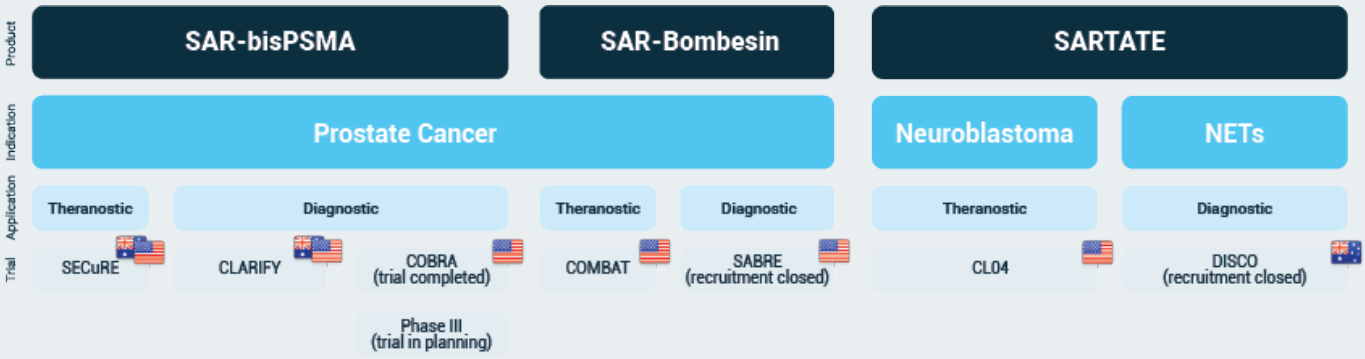
The three theranostic products are in clinical development for both the diagnosis and treatment of various cancers and address unmet clinical needs. In addition to these core products, SAR Technology is used in Clarity's Discovery Program, which explores new targeting agents, thereby creating new TCTs 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, three theranostic and four diagnostic trials, including a Phase III registrational trial, CLARIFY, and a second Phase III pivotal trial for the diagnostic SAR-bisPSMA product in biochemically recurrent prostate cancer that is currently being planned.

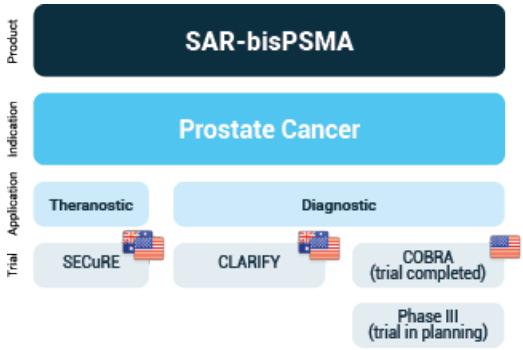


	Theranostic Trials	Diagnostic Trials
SAR-bisPSMA	**SECuRE** – Phase I/IIa theranostic trial for identification and treatment of PSMA-expressing metastatic castrate-resistant prostate cancer (mCRPC) using ^{64}Cu/^{67}Cu-SAR-bisPSMA (NCT04868604)[4]	**CLARIFY** - Registrational Phase III PET imaging trial of participants with high-risk prostate cancer prior to radical prostatectomy using ^{64}Cu-SAR-bisPSMA (NCT06056830)[7] **Phase III trial** – Registrational PET imaging trial of participants with biochemical recurrence (BCR) of prostate cancer following definitive therapy using ^{64}Cu-SAR-bisPSMA (in planning)
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)[5]	**SABRE** – Phase II PET imaging trial of participants with PSMA-negative BCR of prostate cancer using ^{64}Cu-SAR-Bombesin (NCT05407311)[8]
SARTATE	**CL04** – Phase I/IIa theranostic trial in paediatric participants with high-risk neuroblastoma using ^{64}Cu/^{67}Cu SARTATE (NCT04023331)[6]	**DISCO** – Phase II PET imaging trial of participants with known or suspected Neuroendocrine Tumours (NETs) using ^{64}Cu SARTATE (NCT04438304)[9]

PRODUCT UPDATES

SAR-bisPSMA – PROSTATE CANCER

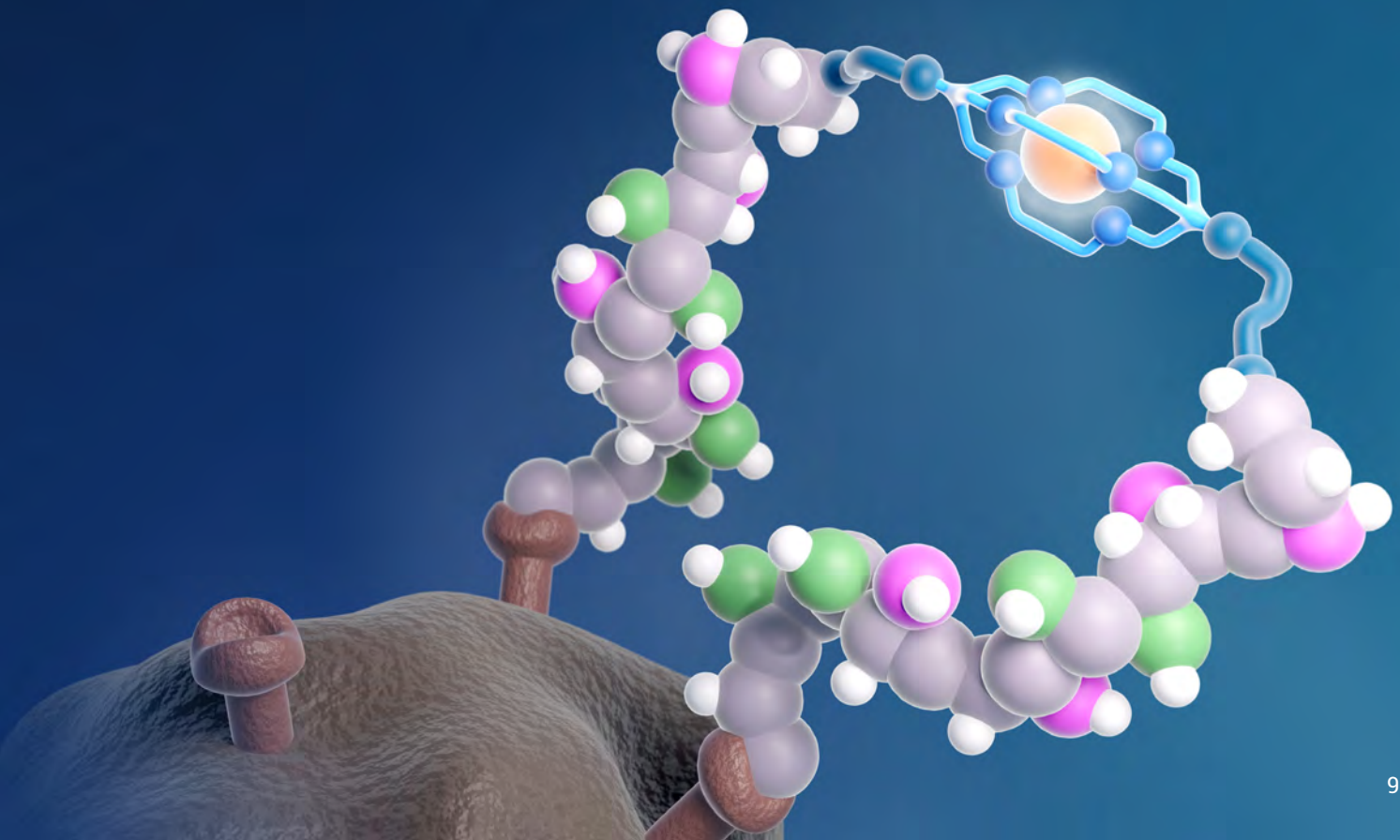
SAR-bisPSMA is a next generation, theranostic radiopharmaceutical with optimised dual PSMA-targeting agents to improve uptake and retention of the product in tumours



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 Food and Drug Administration (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.

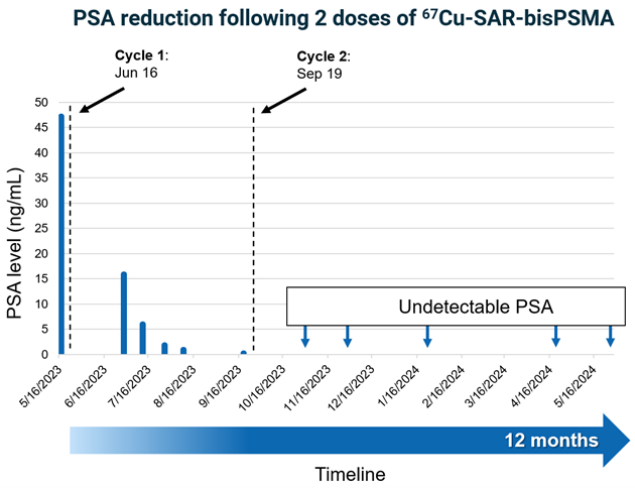


Complete response with ^{67}Cu-SAR-bisPSMA

The first patient ever to be dosed with two cycles of ^{67}Cu-SAR-bisPSMA at 8GBq achieved a complete response to treatment based on Response Evaluation Criteria In Solid Tumours (RECIST v1.1) criteria. The patient received the first cycle of ^{67}Cu-SAR-bisPSMA as part of cohort 2 of Clarity's theranostic trial, SECuRE (NCT04868604)[4], evaluating ^{64}Cu/^{67}Cu-SAR-bisPSMA in patients with mCRPC, and a second cycle under the US FDA Expanded Access Program (EAP), as requested by the patient's clinician. Prior to ^{67}Cu-SAR-bisPSMA, the patient had failed multiple lines of treatment, including hormone therapy, an investigational agent and chemotherapy.

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 ^{64}Cu-SAR-bisPSMA and ^{67}Cu-SAR-bisPSMA as well as the efficacy of ^{67}Cu-SAR-bisPSMA as a therapy. The study is continuing as planned with trial design data presented at the American Society of Clinical Oncology (ASCO) and the Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meetings 2024 in June.

Following the administration of the first cycle of ^{67}Cu-SAR-bisPSMA under the SECuRE trial, the patient showed a reduction of Prostate Specific Antigen (PSA) level of >99%. The patient then received a second cycle of ^{67}Cu-SAR-bisPSMA under the EAP, which resulted in further reduction of his PSA to undetectable levels (confirmed by two consecutive tests) (Graph 1). PSA is a well characterised marker of tumour burden and clinical response to treatment as well as an indicator of the recurrence of disease for prostate cancer[10-12]. Moreover, PSA decline is an independent prognostic indicator of improved overall survival following radioligand therapy[13-14].



Graph 1. PSA reduction following 2 doses of ^{67}Cu-SAR-bisPSMA (8GBq). A reduction of 99.4% in PSA was observed after the administration of the first cycle of ^{67}Cu-SAR-bisPSMA (from the baseline of 47.2 to 0.3 ng/ml). PSA reached undetectable levels following the administration of the second cycle of ^{67}Cu-SAR-bisPSMA. Dash lines: administration of ^{67}Cu-SAR-bisPSMA. "12 months" call-out in the timeline: time since the first dose of ^{67}Cu-SAR-bisPSMA to most recent follow-up. Almost 8 months of PSA at undetectable level. PSA level of detection: 0.05 ng/ml. Data cut off: 29 May 2024.

A complete response (absence of detectable cancer after treatment) was observed in all but one lesion assessed by computed tomography (CT) in November 2023 (one lesion showed a reduction in size from 27 mm to 12 mm, missing the complete response cut-off by only 2 mm based on RECIST assessment). No PSMA uptake was observed in any of the lesions using ^{64}Cu-SAR-bisPSMA following the second cycle of ^{67}Cu-SAR-bisPSMA (Figure 1).

A complete response (no detectable cancer) has now been confirmed by CT at the last follow-up (April 2024, based on RECIST assessment). The patient's PSA remains undetectable for almost 8 months following the administration of the second cycle of ^{67}Cu-SAR-bisPSMA (Graph 1).

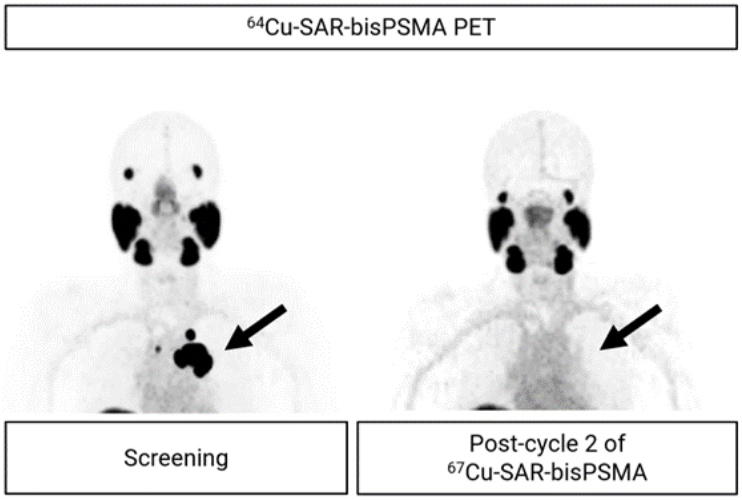


Figure 1. PET images showing uptake of ^{64}Cu-SAR-bisPSMA in prostate cancer lesions at screening (arrow, left image; maximum standardised uptake value [SUVmax] 140.1). Image post-treatment show no ^{64}Cu-SAR-bisPSMA uptake (arrow, right image). Images shown as maximum intensity projection.

No adverse events were reported as related to ^{64}Cu-SAR-bisPSMA. All adverse events related to ^{67}Cu-SAR-bisPSMA either improved or resolved over time. Those included dry mouth, altered taste, thrombocytopenia (all Grade 1, improved), fatigue (Grade 2, resolved) and anaemia (Grade 3, improved to Grade 2). No DLTs have been reported in the SECuRE trial in any of the patients dosed with ^{67}Cu-SAR-bisPSMA to date. Recruitment is ongoing into cohort 4, the first multi-dose cohort in the trial, at the dose level of 12GBq.

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 implemented at the clinical sites. This will allow patients who are benefiting from ^{67}Cu-SAR-bisPSMA to receive 2 additional doses under the SECuRE trial in cohort 4 (up to 4 doses in total).

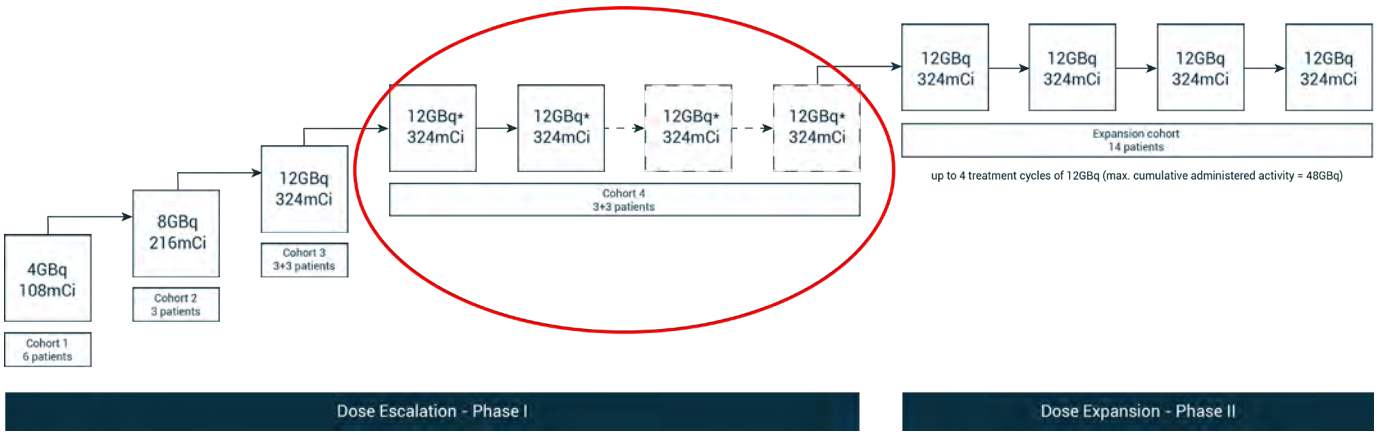


Figure 2. SECuRE Study Design.

Patients in cohort 4 will receive 2 doses of ^{67}Cu-SAR-bisPSMA (12GBq) and will be allowed to receive 2 additional doses of ^{67}Cu-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.

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

In May, CLARIFY was presented by one of the study's lead clinicians, Dr. Michael Gorin, at the American Urological Association (AUA) Annual Meeting 2024 in San Antonio. The presentation outlined the trial design, generating a lot of interest around next-day imaging, a feature unique to ^{64}Cu-SAR-bisPSMA and not feasible with approved PSMA PET agents.

Clarity also had the opportunity to present the CLARIFY trial design at the ASCO Annual Meeting in June, which was met with enthusiasm.

CLARIFY (NCT06056830)[7] 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). The study is continuing as planned with final results intended to provide sufficient evidence to support an application to the US FDA for approval of ^{64}Cu-SAR-bisPSMA as a new diagnostic imaging agent for newly diagnosed prostate cancer patients.

CLARIFY 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 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

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 Ga-68 and F-18 radioisotopes. Cu-64 has an optimal half-life that enables imaging up to 72 hours post administration.

Phase III registrational trial – a diagnostic ^{64}Cu-SAR-bisPSMA in BCR of prostate cancer

Following the completion of the Phase I/II diagnostic imaging study of ^{64}Cu-SAR-bisPSMA in participants with BCR of prostate cancer, COBRA, Clarity has been utilising the data collected to inform the trial design for the pivotal study and prepare for an End of Phase meeting with the US FDA.

Initial data from Clarity's COBRA trial 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. These data were presented at both ASCO and SNMMI Annual Meetings 2024 this past quarter, highlighting the advantages of ^{64}Cu-SAR-bisPSMA and value of next-day imaging.

Clarity is currently preparing for an End of Phase meeting with the US FDA, scheduled for the quarter ending 30 September 2024. The purpose of an End of Phase meeting is to determine the safety of proceeding to Phase III, to evaluate the Phase III plan and protocols and the adequacy of current studies.

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 ^{64}Cu-SAR-bisPSMA as a new diagnostic imaging agent for patients with BCR of prostate cancer.

SUPPLY AND MANUFACTURING: THE GAME CHANGER FOR RADIOPHARMACEUTICALS

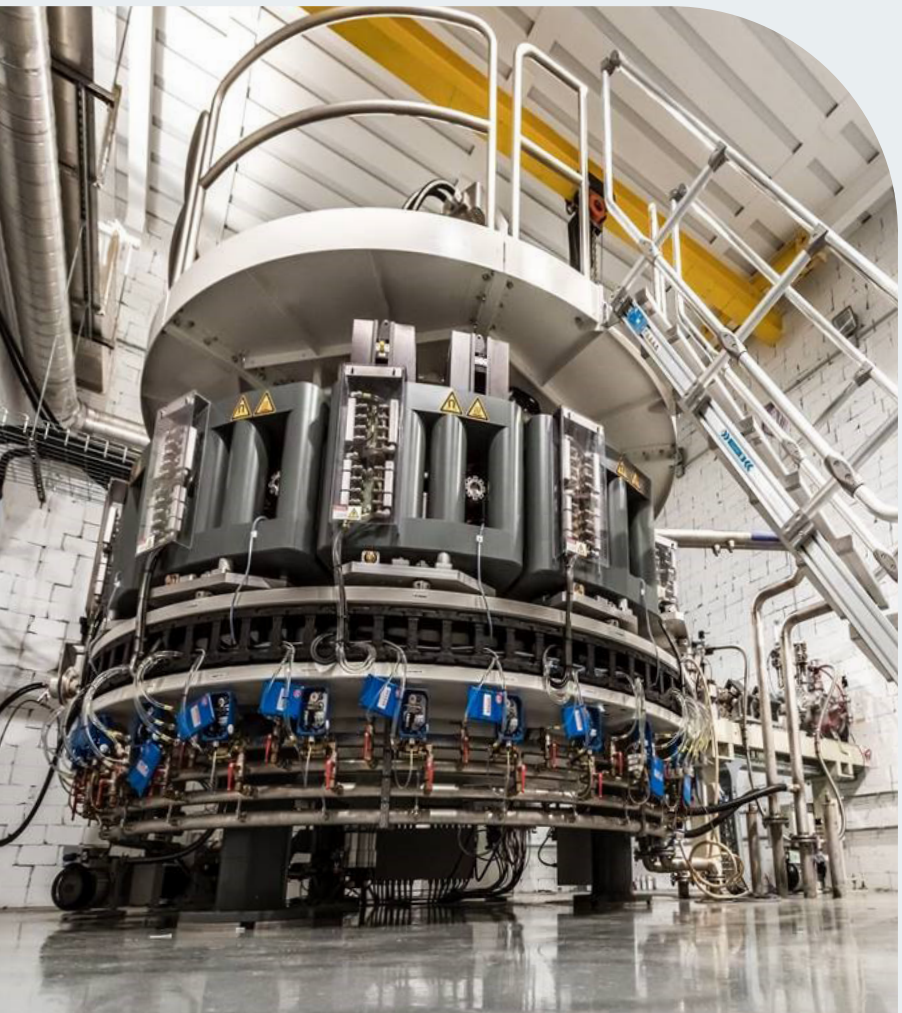
Targeted Copper Theranostics (TCTs) hold a number of competitive advantages, including clinical benefits, which Clarity is actively exploring through its clinical program.

However, the key differentiators, which hold promise of taking radiopharmaceuticals into the large oncology market, are the logistical, manufacturing and environmental advantages associated with the production of copper isotopes for diagnostic imaging (copper-64) and therapy (copper-67).

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

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

Clarity continued to expand its manufacturing and supply chain footprint, creating additional capacity and flexibility to supply products to any state in the US with new agreements made in the quarter ending 30 June 2024.



"We have patients on months long waiting lists when this may be all the time they have, and so it's been really disheartening to have to deal with these things,"

- Roby Thomas, MD, a medical oncologist, and hematologist at UPMC Hillman Cancer Center[15]

Copper-67

Copper-67 (Cu-67 or ^{67}Cu) is a therapeutic isotope that is produced on electron accelerators, which are relatively inexpensive and readily scalable in all geographies of the world, including the US, Europe and Asia.

Other commonly used therapeutic isotopes, such as lutetium-177 (Lu-177 or ^{177}Lu), are produced on a small number of aging nuclear reactors worldwide, many of which are approaching the end of their "useful life". This results in planned and unplanned shutdowns, causing shortages of therapeutic isotopes worldwide[16].

Geopolitical considerations are also vital as Russia remains the predominant supplier of stable isotopes used in the production of a variety of isotopes. Clarity remains unaffected by supply disruptions of both Lu-177 and Ac-225 due to its strategy of developing sustainable, scalable and environmentally preferred solutions to radionuclide sourcing with all of the Cu-67 supply coming from the US.

In April 2024, Clarity has entered into Clinical Supply Agreement with NorthStar Medical Isotopes, LLC (NorthStar) for the production of ^{67}Cu-SAR-bisPSMA drug product for Phase I/II and Phase III trials. NorthStar is a global innovator in the development, production and commercialisation of therapeutic radiopharmaceuticals. This agreement builds on the existing copper-67 supply agreement with NorthStar, signed in 2021, and uniquely provides large-scale manufacturing of both therapeutic isotope, copper-67, and cGMP radiopharmaceutical product in the US under one roof and ready for shipment to clinical sites.

Integrated manufacturing offers significant logistical, manufacturing and environmental advantages, including simplified logistics with minimal shipping requirements, efficient utilisation of the radioisotope and reduced carbon footprint.

Copper-64

Copper-64 (Cu-64 or ^{64}Cu) is a diagnostic imaging isotope with an ideal half-life of 12.7 hours that facilitates a significantly longer product shelf-life (up to 48 hours) than most commonly used radio-diagnostics on the market. This helps to overcome the acute supply restraints of current-generation radiodiagnostics based on gallium-68 (Ga-68 or ^{68}Ga) with a half-life of ~1 hour and fluorine-18 (F-18 or ^{18}F) with a half-life of ~2 hours.

The longer shelf-life of Cu-64 based diagnostics enables centralised manufacture, opposed to the current-generation PSMA PET diagnostics that require an expensive and extensive network of cyclotrons, radioisotope generators and radiopharmacies due to the shorter half-life of Ga-68 and F-18. Cu-64 is produced on cyclotrons with a single cyclotron able to supply the entire Phase III diagnostic clinical program.

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

In May, Clarity has entered into a Supply Agreement with SpectronRx for the production of Cu-64, strengthening the Company's supply network and ensuring seamless supply of the diagnostic isotope for Clarity's products which continue to progress through clinical trials, including the ongoing pivotal Phase III clinical trial, CLARIFY. SpectronRx is a robust and established private supplier of Cu-64 that will support Clarity as it progresses towards a commercial launch of its TCT products. The agreement compliments and expands Clarity's existing network of Cu-64 suppliers across the US and Australia.

FINANCIALS

Clarity's cash balance at 30 June 2024 was $136.5 million.

Net operating cash outflows for the June quarter were $4 million which is lower than the previous quarters net outflow of $12.2 million, due to the receipt of the RDTI of $10 million in late June. Net operating cash outflows, before the RDTI, were $14 million which is higher than the previous quarter due to increased spend on the company's clinical trial programmes. Operating cash outflows relate to payments for research and development, staff costs, administration, and general operating costs.

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

Use of Funds

(Listing Rule 4.7C.2)

Uses of funds	Institutional Placement & Rights Issue Offer dated 26 March 2024 $ million	% of Total Funds	Period* to 30 June 2024 $ million	% of Total Funds
Pre-Clinical	$8.5	5.3%	$0.8	3.6%
Clinical	$111.0	69.7%	$10.4	47.1%
Regulatory	$7.1	4.5%	$0.5	2.3%
Patents	$1.8	1.2%	$0.2	0.9%
Corporate	$10.2	6.4%	$0.2	0.9%
Working Capital** and Costs of the Offer	$20.6	12.9%	$10.0	45.2%
Total uses	**159.2**	**100%**	**$22.1**	**100.0%**

* From 25 March 2024

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

As detailed in the Use of Funds table above, the expenditure for the period to 30 June 2024, is in accordance with the Use of Funds outlined in the Company's Offer document for the Institutional Placement and Rights Issue dated 26 March 2024 and there are no material variances against the estimated use of funds disclosed to-date.

Related Party Transactions

(Listing Rule 4.7C.3)

Payments to related parties of the entity and their associates (6.1 of the Appendix 4C) totalled $389,035 for the quarter. This amount includes director fees and salaries paid in the June quarter.

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

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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	30 June 2024

Consolidated statement of cash flows		**Current quarter $A'000**	**Year to date (12 months) $A'000**
1.	**Cash flows from operating activities**		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(10,181)	(38,493)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(64)	(250)
	(d) leased assets	-	-
	(e) staff costs	(2,627)	(10,958)
	(f) administration and corporate costs	(1,582)	(4,633)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	457	2,096
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	25	(76)
1.7	Government grants and tax incentives	9,952	9,952
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(4,020)**	**(42,362)**

2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	(72)	(504)
	(d) investments	-	-
	(e) intellectual property		
	(f) other non-current assets	-	-

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 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**	**(72)**	**(504)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	120,982	120,982
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	271	878
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(6,635)	(6,647)
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**	**114,618**	**115,213**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	26,920	65,015
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(4,020)	(42,362)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(72)	(504)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	114,618	115,213

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
4.5	Effect of movement in exchange rates on cash held	(940)	(856)
4.6	**Cash and cash equivalents at end of period**	**136,506**	**136,506**

5.	Reconciliation of cash and cash equivalents at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	Current quarter $A'000	Previous quarter $A'000
5.1	Bank balances	47,901	24,920
5.2	Call deposits	88,605	2,000
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)**	**136,506**	**26,920**

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	389
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)	(4,020)
8.2	Cash and cash equivalents at quarter end (item 4.6)	136,506
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	**136,506**
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	34

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 July 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.