CLARITY
PHARMACEUTICALS

QUARTERLY ACTIVITY REPORT

SYDNEY, AUSTRALIA
28 APRIL 2023

HIGHLIGHTS OF THE QUARTER

Ending 31 March 2023

Cash Position
Cash position remains strong with a balance of $66.7 million as of 31 March 2023. Clarity's R&D tax incentive refund for FY22 was received in April and is $6.7 million. Combined, this provides an estimated $73.4 million to fund the existing trial pipeline. Operating cash outflows for the March quarter were $9.4 million.

PROPELLER[1]
Trial results from Clarity's Phase I diagnostic ^{64}Cu SAR-bisPSMA prostate cancer trial presented at the American Society of Clinical Oncology (ASCO) Genitourinary (GU) Symposium showed ^{64}Cu SAR-bisPSMA to be safe, well tolerated and efficacious in the detection of prostate cancer in the pre-prostatectomy/pre-definitive treatment setting.

COBRA[2]
Recruitment target was reached in the US-based Phase I/II diagnostic ^{64}Cu SAR-bisPSMA trial for patients with biochemical recurrence (BCR) of prostate cancer following definitive therapy.

DISCO[3]
Fifty percent recruitment milestone reached in the Phase II diagnostic ^{64}Cu SARTATE trial in up to 63 patients with gastroenteropancreatic neuroendocrine tumours (GEP-NETs).

Supply Chain
No supply interruptions to Clarity's ongoing clinical trial programs in light of Pluvicto™ supply disruptions.

Board of Directors
Cheryl Maley joined Clarity's Board of Directors as a Non-Executive Director.

Scientific Advisory Board
Jon Stoner joined Clarity's Scientific Advisory Board.

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 2023.

Executive Chairman's Letter

Dear fellow Shareholders,

On behalf of the entire team at Clarity Pharmaceuticals Ltd (Clarity), I am delighted to present Clarity's Quarterly Activity Report for the quarter ending 31 March 2023.

The first quarter of CY23 has laid a strong foundation for the year ahead as we continued to achieve important milestones in our clinical trials and progressed our Targeted Copper Theranostic platform of products towards commercialisation. With a cash balance of more than $73 million, we remain well financed to continue our important work and progress the development of our next-generation radiopharmaceutical products into late-stage diagnostic and therapy trials.

What differentiates Clarity from other radiopharmaceutical companies is our continued focus on "best-in-class" products for both diagnosis and therapy, and the need to only commercialise two isotopes of the one element, copper. Both isotopes, copper-64 for imaging and copper-67 for therapy, allow for centralised mass production and distribution of all products without the reliance on nuclear reactors or cumbersome supply chains. Our work during the quarter has continued to substantiate our differentiated offering of superior products that allow for a modular global rollout of radiopharmaceuticals. Targeted Copper Theranostics offer the ability to completely control the radiopharmaceutical supply chain.

Following the release of positive data in our diagnostic Phase I ^{64}Cu SAR-bisPSMA trial in prostate cancer in the pre-prostatectomy/pre-definitive treatment setting, PROPELLER, we are now progressing well with preparation for our first Phase III registrational trial in this patient population. We have started engagement with the US Food and Drug Administration and trial commencement is planned for this year. The Phase I trial data was presented at the prestigious ASCO GU Symposium in February and was very well received by physicians and the industry.

Our second SAR-bisPSMA diagnostic trial in prostate cancer patients with biochemical recurrence, COBRA, reached its recruitment target in February. We are now in the patient follow-up phase and the data collected will support our second definitive Phase III trial in this patient population with SAR-bisPSMA, planned to commence early next year. High level readouts from the trial are planned for release this year.

We are focused on continuing to reach these exciting milestones in our prostate cancer program as the radio-diagnostic market is rapidly expanding, offering blockbuster opportunities. Globally, this segment is expected to reach US$10 billion market size by 2031 with the PSMA diagnostics set to dominate this space with over US$1.6 billion annual sales in the US alone. Our copper-64 based radio-diagnostics offer significant opportunities for meeting this growing demand and offer convenient, reliable and sustainable products for oncology patients, including large indications, such as prostate cancer. We look forward to progressing our SAR-bisPSMA program as we continue to generate valuable data and move closer towards FDA marketing approval and commercialisation.

While developing best-in-class diagnostics and bringing them to market as quickly as possible remains a short-term priority, therapeutic products remain Clarity's key focus in the long run as this is where we can deliver the most significant improvements to the current treatment paradigm for people with cancer. Given the supply and manufacturing challenges the radio-therapeutic segment is facing today, we continue to focus on progressing the clinical development of our three theranostic programs

and gathering safety and efficacy data to support the roll-out of our Targeted Copper Theranostics. It is evident that employing copper-67 as a therapeutic isotope can help overcome supply and logistical challenges associated with current-generation theranostics, such as lutetium-177 based products, that are plaguing the radiopharmaceutical market. The most recent example is a supply disruption associated with the roll-out of Novartis' US FDA-approved Pluvicto™. Despite the significant demand from oncologists and the product's strong sales, with US$179 million in revenue achieved in the fourth quarter of 2022, Novartis is unable to meet the demand, leaving its patients and treating staff deprived of this important radio-therapeutic option. Novartis has stopped accepting new patients and is rescheduling treatments for existing patients due to recent supply issues with Pluvicto™. This was the second major supply disruption for Novartis, with the first being the suspension of production of Lutathera® and Pluvicto™ in May 2022 due to potential quality issues identified in its manufacturing processes. Given the recent challenges with Pluvicto™, the recruitment into Clarity's SECuRE trial and demand for ^{67}Cu SAR-bisPSMA therapy has accelerated in recent months.

A number of complications with nuclear reactor produced radiopharmaceuticals, such as the outage at the High Flux Reactor in Netherlands from January to March 2022, illustrate how fragile the supply chain of these therapeutic isotopes is, creating ripple effects in the field which ultimately leaves patients with no other options.

Clarity's Targeted Copper Theranostics overcome these challenges as copper-67 is produced domestically in the US on relatively low-cost electron accelerators with high purity and high specific activity. Other therapeutic isotopes, such as lutetium-177, are mainly produced outside of the US on a limited, ageing fleet of nuclear reactors where outages and interruptions are common. Clarity's production method enables a cleaner, more sustainable approach. Importantly, Targeted Copper Theranostics' room-temperature product manufacturing process lowers the risks of batch failures, whereas lutetium-177 based product manufacturing typically requires heating them to high temperatures, which may result in frequent quality control failures.

Regardless of the challenges, there is no doubt that radiopharmaceuticals represent a new, exciting diagnostic and treatment pillar in oncology. We believe that Clarity's Targeted Copper Theranostics are poised to resolve the current supply issues and build on the undeniable treatment benefits to patients. We look forward to continuing to build on Clarity's story of success, leveraging our strengths and generating data to get us closer to our ultimate goal of commercialising next-generation radiopharmaceuticals to improve treatment outcomes for children and adults with cancer.

Yours sincerely,

Dr Alan Taylor
Executive Chairman
Clarity Pharmaceuticals Ltd

CLINICAL DEVELOPMENT OVERVIEW

SARTATE

targets the Somatostatin Receptor 2 (SSTR2), which is present in an aggressive childhood cancer, neuroblastoma, as well as Neuroendocrine Tumours (NETs), among other cancers.

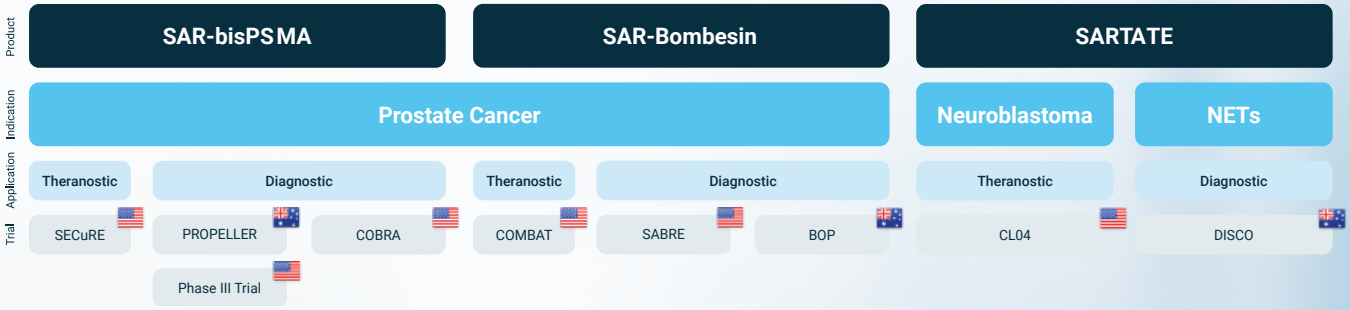
SAR-bisPSMA

targets the Prostate Specific Membrane Antigen (PSMA), present in the majority of prostate cancers.

SAR-Bombesin

targets the Gastrin Releasing Peptide receptor (GRPr), which is present in a number of cancers, including breast and prostate cancers.

As of March 2023, the Company was actively progressing seven clinical trials with its three key products, SARTATE, SAR-bisPSMA and SAR-Bombesin. The trials are being conducted in three theranostic (therapeutic and diagnostic) and four diagnostic applications. In addition to these seven trials, sponsored by Clarity, there is an investigator-initiated trial (IIT) with Clarity's SAR-Bombesin diagnostic product (BOP).



CLINICAL DEVELOPMENT OVERVIEW

	Theranostic Trials	Diagnostic Trials
SARTATE	**CL04** – Phase I/IIa theranostic trial in paediatric participants with high-risk neuroblastoma using $^{64}Cu/^{67}Cu$ SARTATE in the US (NCT04023331)[4]	**DISCO** – Phase II PET imaging trial of participants with known or suspected Neuroendocrine Tumours (NETs) using ^{64}Cu SARTATE in Australia (NCT04438304)[3]
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)[5]	**PROPELLER** – Phase I Positron Emission Tomography (PET) imaging trial of participants with confirmed prostate cancer using ^{64}Cu SAR-bisPSMA in Australia (NCT04839367)[1] **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)[2]
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)[6]	**SABRE** – Phase II PET imaging trial of participants with PSMA-negative BCR of prostate cancer using ^{64}Cu SAR-Bombesin in the US (NCT05407311)[7] **BOP** – Investigator Initiated Phase II PET imaging trial of participants with negative PSMA PET or low PSMA expression disease in patients with suspected BCR of their prostate cancer and patients with mCRPC using ^{64}Cu SAR-Bombesin led by Prof Louise Emmett at St Vincent's Hospital Sydney (NCT05613842)[8]

FIVE OPEN INVESTIGATIONAL NEW DRUG (IND) APPLICATIONS WITH THE US FDA

Clarity's strategy is to progress its TCT products for first approvals in the US, the largest oncology market in the world. An open IND enables the Company to progress clinical trials of products in the US and allows for valuable FDA feedback on early phase trial design, which supports the late-stage development and should facilitate efficient regulatory engagements for registrational trials.

Theranostic
$^{64}Cu/^{67}Cu$ SARTATE
product for patients with neuroblastoma

Therapy
^{67}Cu SAR-bisPSMA
product for prostate cancer patients

Therapy
^{67}Cu SAR-Bombesin
product for prostate cancer patients

Diagnostic
^{64}Cu SAR-bisPSMA
product for prostate cancer patients

Diagnostic
^{64}Cu SAR-Bombesin
product for prostate cancer patients

PRODUCT UPDATES

For the quarter ending
31 March, 2023

SAR-bisPSMA – Prostate Cancer

SAR-bisPSMA is a next generation, highly targeted theranostic radiopharmaceutical.

It is being developed for diagnosing, staging and subsequently treating cancers that express Prostate Specific Membrane Antigen (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 ^{67}Cu SAR-bisPSMA, Clarity is also running a diagnostic program 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 suspected biochemical recurrence (BCR) of prostate cancer.

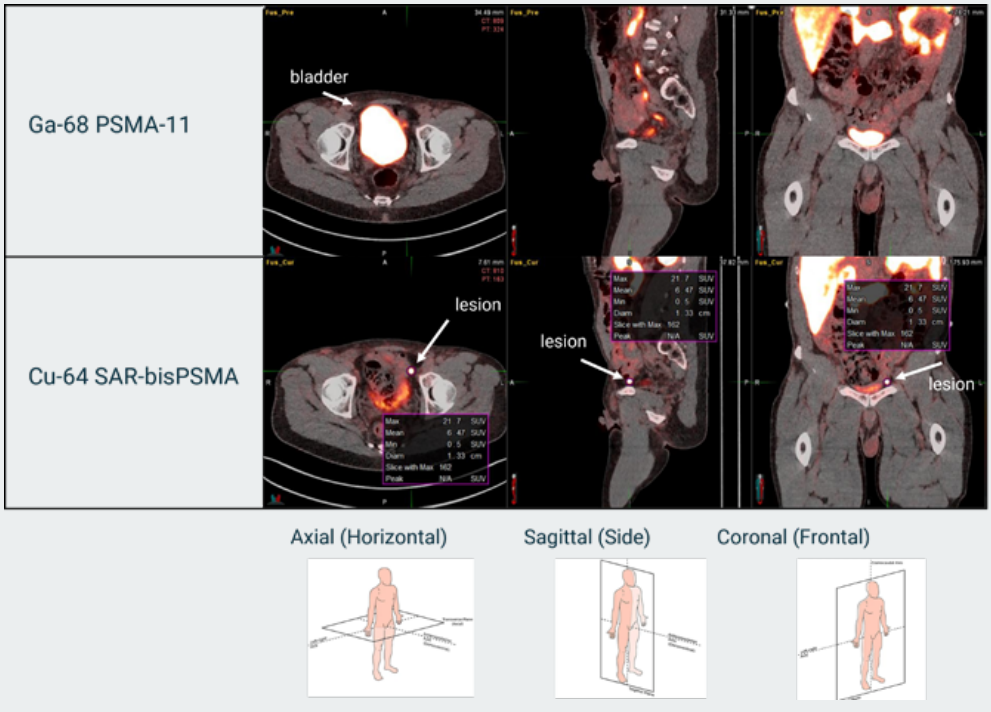
PROPELLER – a diagnostic ^{64}Cu SAR-bisPSMA trial

Clarity reported data from the diagnostic Phase I trial of ^{64}Cu SAR-bisPSMA in prostate cancer, PROPELLER (NCT04839367)[1] at the ASCO GU Symposium in February 2023, following the announcement of positive top line results from the trial in December 2022. The data from the PROPELLER trial is being used to design and initiate a Phase III trial for prostate cancer patients in the pre-prostatectomy/pre-definitive treatment setting. Clarity has commenced engagement with the US FDA to facilitate the Phase III trial.

The PROPELLER trial achieved its primary objectives and the ^{64}Cu SAR-bisPSMA product was found to be safe, well tolerated and efficacious in detecting primary prostate cancer. PROPELLER also achieved its secondary objective of determining the optimal dose for subsequent investigation of ^{64}Cu SAR-bisPSMA. The selected optimal dose level of 200 MBq is currently applied in all ongoing trials.

PROPELLER derives from "**P**osit**RO**n Emission Tomography Imaging of **P**articipants with Confirmed Prostat**E** Cancer Using ^{64}Cu-SAR-bisPSMA: A Mu**L**tiCentre, B**L**ind**E**d **R**eview, Dose Ranging Phase I study". It was a first-in-human trial administering Clarity's optimised PSMA agent, ^{64}Cu SAR-bisPSMA, to 30 participants with confirmed prostate cancer prior to undergoing radical prostatectomy. The trial also compared the diagnostic properties of ^{64}Cu SAR-bisPSMA against ^{68}Ga PSMA-11, which is approved for prostate cancer imaging in Australia and the US.

Figure 1. PET-CT images (through three different planes of the pelvis) from the PROPELLER study. Time between serial imaging was 7 days.



The independent blinded readers did not observe uptake in pelvic lymph nodes on the ^{68}Ga-PSMA-11 PET-CT in this patient. However, both readers observed a left pelvic lymph node (shown by the white arrows) when the same patient was imaged after administration of ^{64}Cu-SAR-bisPSMA. The pelvic lymph node was biopsied and confirmed to be prostate cancer via histopathology in accordance with both readers.

PROPELLER cont.

Primary objectives

- Safety and tolerability of ^{64}Cu-SAR-bisPSMA using the National Cancer Institute Common Terminology Criteria for Adverse Events version 5.0.
- Efficacy of ^{64}Cu-SAR-bisPSMA in the detection of primary prostate cancer compared to histopathology.

Secondary objectives

- Assessment of image quality at varying dose levels of ^{64}Cu SAR-bisPSMA for (100 MBq, 150 MBq and 200 MBq).

Figure 1 illustrates that imaging with Clarity's ^{64}Cu SAR-bisPSMA helped to identify a cancer lesion in the lymph node of this patient with prostate cancer. The spread of their cancer from the prostate into the lymph node went undetected when imaged with ^{68}Ga-PSMA-11, per the central reads, which means that this patient would have had their cancer incorrectly staged (categorised) as only present within the prostate gland. Receiving an accurate diagnosis can have a tremendous impact as it can lead to changes in the entire treatment paradigm for these patients such as guiding surgeons to all areas of disease to be removed or choosing a different treatment plan altogether.

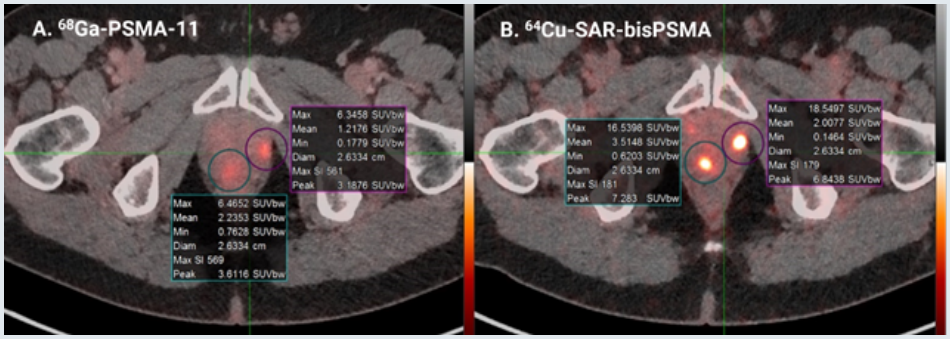
On Figure 2, ^{64}Cu-SAR-bisPSMA PET-CT imaging shows clearer delineation of lesions and greater uptake (SUVmax) than ^{68}Ga-PSMA-11, making it easier to identify the tumours in both patients.

To view the full poster from ASCO GU online, **click here**.

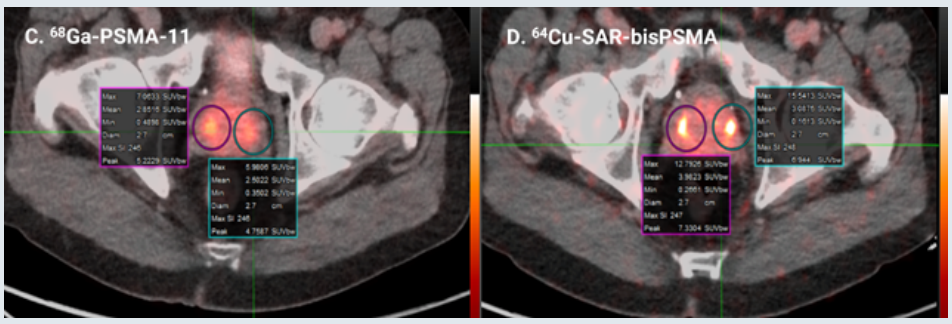
The PROPELLER data further substantiates the utility of ^{64}Cu SAR-bisPSMA in the diagnosis of prostate cancer. Combined with the clinical and pre-clinical trial data to date, this validates SAR-bisPSMA as a potential best-in-class PSMA agent for the diagnosis (with ^{64}Cu) and subsequent treatment (with ^{67}Cu) of prostate cancer.

Figure 2. Comparison of ^{68}Ga-PSMA-11 (A,C) and 200 MBq of ^{64}Cu-SAR-bisPSMA (B,D) PET-CT.

Patient 1 - Interval between serial imaging: 8 days



Patient 2 - Interval between serial imaging: 34 days



PET-CT images of two patients from the PROPELLER study who were imaged firstly with ^{68}Ga-PSMA-11 (boxes A and C) and subsequently with 200MBq of ^{64}Cu-SAR-bisPSMA (boxes B and D). The images collected with ^{64}Cu-SAR-bisPSMA have SUVmax values (a measurement indicating the maximum amount of product reaching the tumours) which are 2 to 3 times higher than the ^{68}Ga-PSMA-11 Standard of Care scan.

COBRA – a diagnostic ^{64}Cu SAR bisPSMA trial

Clarity reached its recruitment target in the diagnostic ^{64}Cu SAR-bisPSMA trial, COBRA (NCT05249127)[2], in February 2023, shortly after achieving the fifty percent recruitment milestone in the trial in October 2022. The patients from the COBRA trial are now in the follow up period, central reads of the data from the COBRA trial are ongoing and data analysis is underway. Positive results from the COBRA trial will enable a Phase III trial in patients with BCR of their prostate cancer.

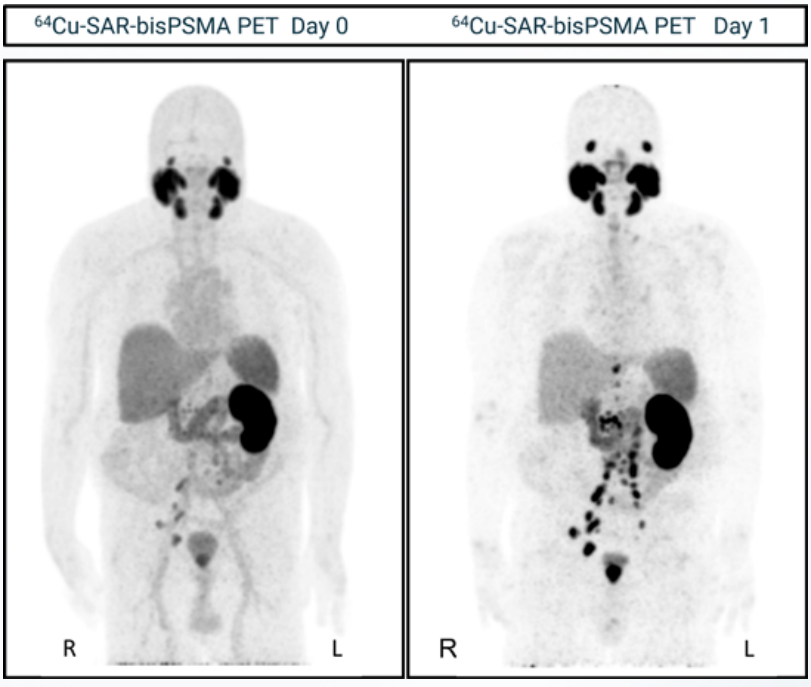
COBRA, which derives from "**CO**pper-64 SAR-bisPSMA in **B**iochemically **R**ecurrent prost**A**te cancer", is a Phase I/II Positron Emission Tomography (PET) imaging trial of participants with BCR of prostate cancer following definitive therapy. In this study, participants have an increase of prostate specific antigen (PSA), a blood measurement indicating their prostate cancer has returned or spread following initial therapy, but the location of their cancer is unknown.

COBRA is a multi-centre, single arm, non-randomised, open-label trial of Clarity's PSMA imaging product (^{64}Cu SAR-bisPSMA) in 50 participants.

The primary objectives of the trial are to investigate the ability of ^{64}Cu SAR-bisPSMA to correctly detect recurrence of prostate cancer, as well as assess its safety and tolerability.

In the COBRA trial, participants are imaged on the day of administration and 24 hours later. The study is investigating the utility of delayed imaging in BCR disease.

Figure 3. Serial Maximum Intensity Projection (MIP) PET scans over 24hrs showing areas of abnormal uptake in pelvic and abdominal lymph nodes.



The image on the left shows the PET scan from a patient with known recurrence of their disease from the COBRA trial after administration of ^{64}Cu-SAR-bisPSMA (day 0). The image on the right shows the PET scan from the same patient imaged ~24 hours later (day 1). The COBRA trial is investigating whether imaging at later time points is able to detect additional disease that is not visible when images are only collected shortly after administration of the product. As a diagnostic tool, this is highly relevant in patients with suspected biochemical recurrence which is where these PSMA PET products have significant utility. Being able to detect cancerous lesions only visible at later time points, something not possible with F-18 or Ga-68 based products, could lead to a significant change in management for these patients.

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

Clarity is actively progressing the dose escalation phase of the SAR-bisPSMA theranostic clinical trial, SECuRE (NCT04868604)[5] and remains unaffected by the supply chain issues Novartis is seeing with Pluvicto™.

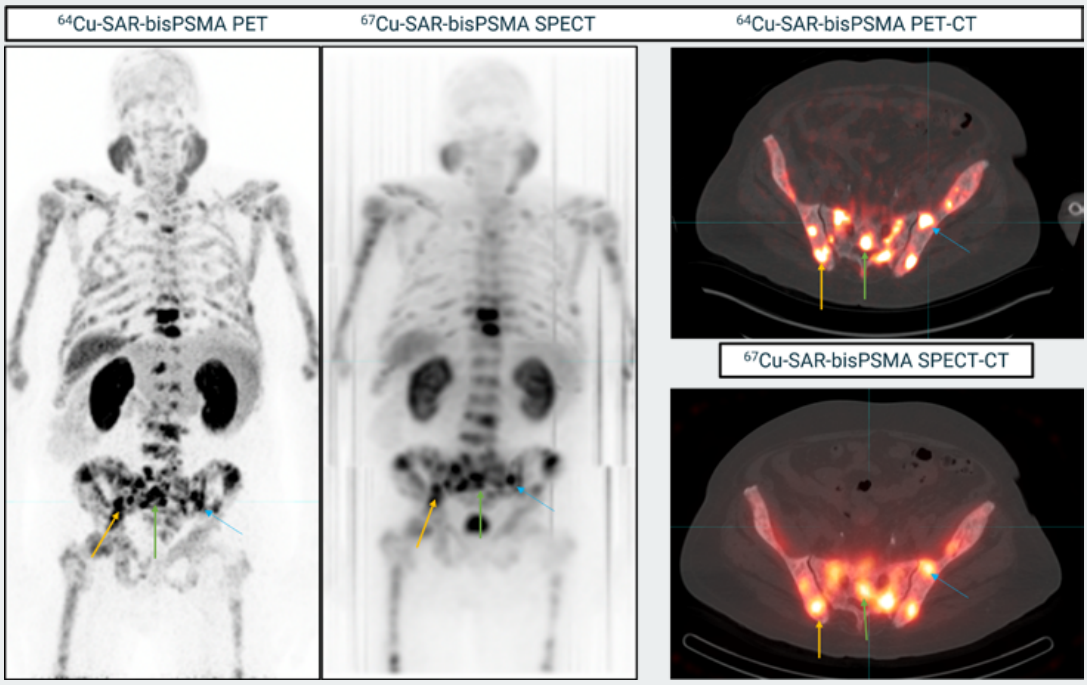
SECuRE, which derives from "**S**yst**E**mic **Cu** the**R**anostics in prostat**E** cancer", is a US-based Phase I/IIa theranostic trial for identification and treatment of an advanced form of prostate cancer, mCRPC. In this trial, Clarity first uses its imaging product, ^{64}Cu SAR-bisPSMA, to visualise PSMA expressing tumours and select participants who are most likely to respond well to subsequent therapy with ^{67}Cu SAR-bisPSMA.

SECuRE is a multi-centre, single arm, dose escalation study with a cohort expansion planned for up to 44 patients. 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 initial imaging stage of the trial, which is now completed, utilised the copper-64 based imaging product to determine where the product went in the body (biodistribution) and what dose of the product was received (dosimetry) in the participants. The subsequent dosimetry phase with ^{67}Cu SAR-bisPSMA commenced the dose escalation phase of the study. In this stage, each subsequent cohort of participants will receive an increased dose of the therapeutic drug until the optimal therapeutic dose is determined (Maximum Tolerated Dose).

Cohort 1 in the SECuRE trial is now fully allocated with no participant slots available. Current participants are undergoing safety follow up, the data will soon be reviewed by the safety review committee with the view to progress to Cohort 2.

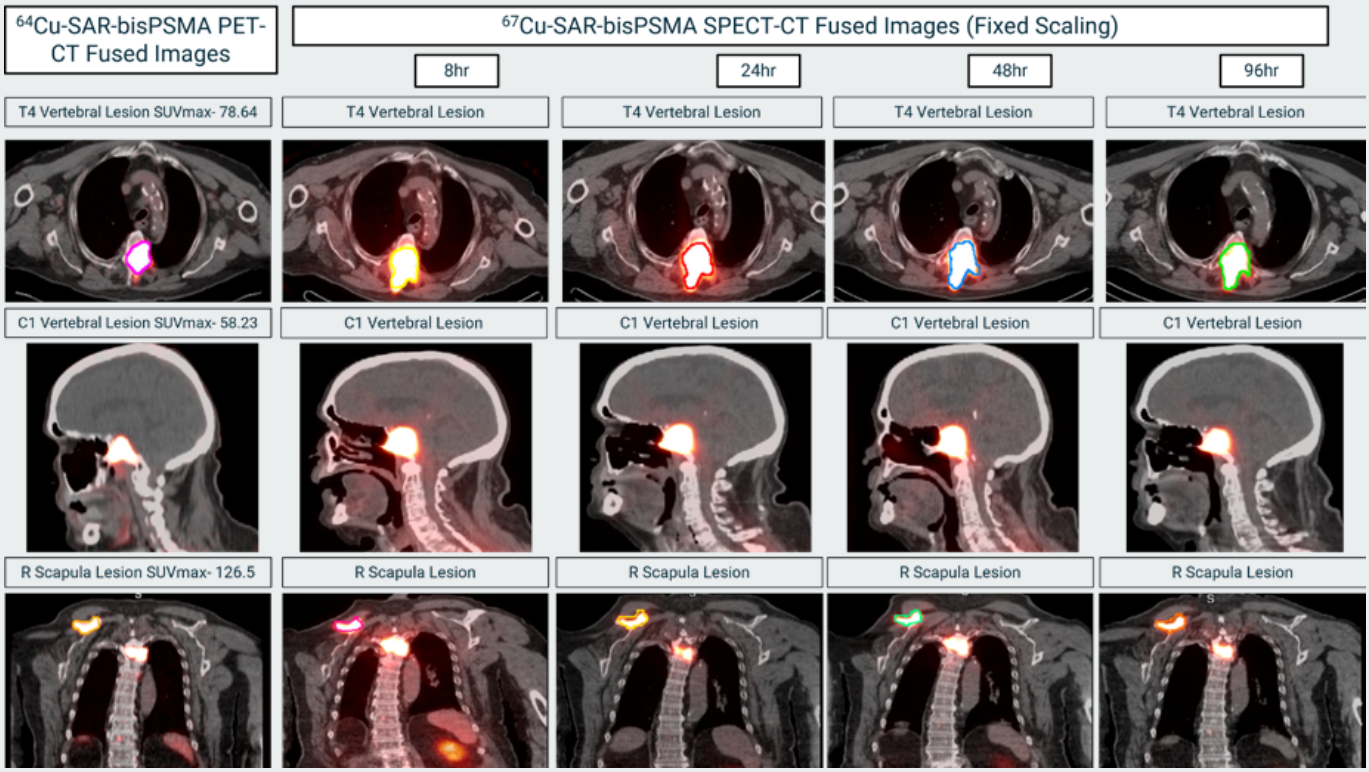
Figure 4. Comparison of ^{64}Cu SAR-bisPSMA and ^{67}Cu SAR-bisPSMA imaging. PET, SPECT, PET-CT and SPECT-CT images of the same patient administered with the diagnostic agent (^{64}Cu-SAR bisPSMA) followed by the therapeutic agent (^{67}Cu SAR-bisPSMA). The coloured arrows show examples of the same areas of disease being targeted by both the diagnostic and therapeutic agents.



SECuRE cont.

TCTs are a true theranostic platform where the same chemical entity is labelled with copper-64 for diagnosis or copper-67 for therapy. Being the same chemical entity, SAR-bisPSMA, the diagnostic and therapy target the same areas of disease. Other theranostics in development and on the market use different chemical structures and radionuclide elements for diagnosis and therapy, which can cause changes in the uptake of the products in the disease.

Figure 5. Comparison of ^{64}Cu SAR-bisPSMA and ^{67}Cu SAR-bisPSMA imaging. The ^{64}Cu-SAR-bisPSMA PET-CT images show high uptake of the diagnostic product in the patient's cancer. The corresponding serial SPECT-CT images collected from 8 to 96 hours after the administration of the ^{67}Cu-SAR-bisPSMA therapy show that (a) the same areas of disease are targeted with both the diagnostic and the therapy and (b) that the therapeutic agent is retained in the tumours over time to provide irradiation of the tumours with the beta emitting ^{67}Cu, a critical aspect of radiopharmaceutical therapy.



SARTATE - Neuroblastoma and NETs

SARTATE is a next generation, highly targeted theranostic radiopharmaceutical

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

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

- CL04 theranostic trial with an open IND in the US (NCT04023331)[4]
- DISCO diagnostic trial in Australia (NCT04438304)[3]

In 2020, the US FDA awarded Clarity two Orphan Drug Designations (ODDs), one for ^{64}Cu SARTATE as a diagnostic agent for the clinical management of neuroblastoma and one for ^{67}Cu SARTATE as a therapy of neuroblastoma, as well as two Rare Paediatric Disease Designations (RPDDs) for these products. Should Clarity be successful in achieving marketing approval from US FDA for these two products, RPDDs may allow the Company to access a total of two tradeable Priority Review Vouchers (PRVs) which most recently traded at USD95M per voucher.[9]

CL04 – a theranostic $^{64}Cu/^{67}Cu$ SARTATE Neuroblastoma trial

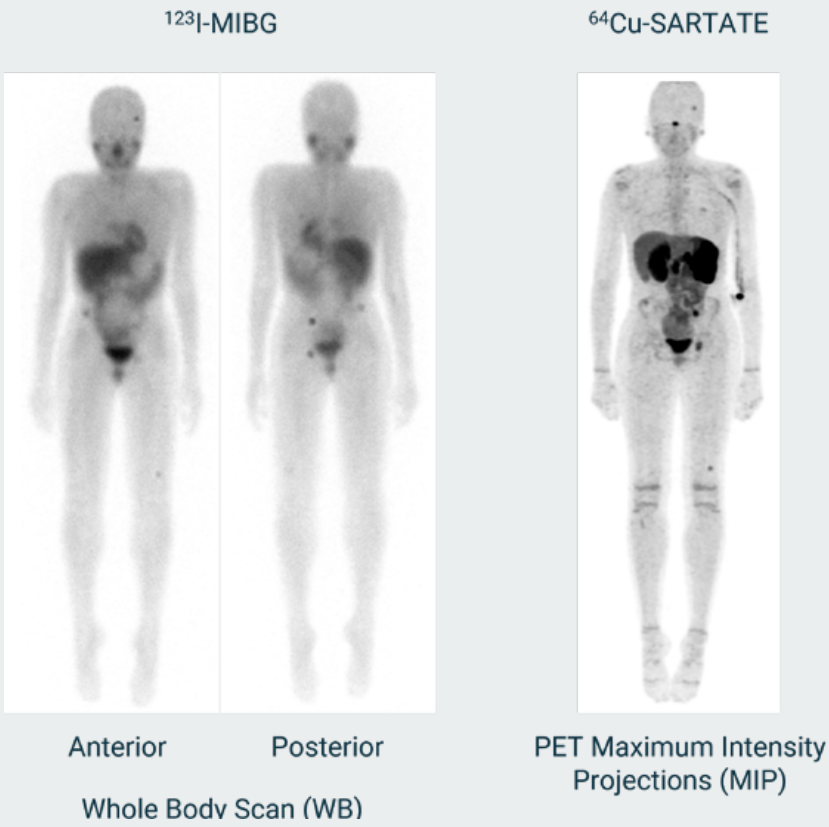
Clarity is actively progressing recruitment in cohort 3 in the theranostic $^{64}Cu/^{67}Cu$ SARTATE trial in neuroblastoma patients, CL04 (NCT04023331)[4], and has recently opened additional US clinical sites for participation.

Importantly, additional therapy cycles of ^{67}Cu SARTATE have been requested by clinicians for participants in cohort 1 and cohort 2. Subsequent therapy cycles are contingent on the Investigators' assessment that the participant is demonstrating therapeutic benefit.

The dose level of ^{67}Cu SARTATE administered in cohort 3 is 275MBq/kg body weight. The CL04 trial is designed to gradually increase the dose of ^{67}Cu SARTATE administered to participants in each cohort, with the maximum of 4 cohorts, until the Maximum Tolerated Dose (MTD) is reached.

CL04 is a multi-centre, dose-escalation, open label, non-randomised, theranostic clinical trial in paediatric patients with high-risk neuroblastoma. The trial is a Phase I/IIa with up to 34 patients where not only the safety of both ^{64}Cu SARTATE and ^{67}Cu SARTATE are assessed, but also the effectiveness of ^{67}Cu SARTATE as a treatment for neuroblastoma. Patients who meet all eligibility criteria, including showing uptake of ^{64}Cu SARTATE in tumours, will enter the trial and receive treatment with ^{67}Cu SARTATE.

Figure 6. The two images on the left depict the Whole Body Standard of Care ^{123}I-MIBG scans with the image on the right being the pre-treatment ^{64}Cu-SARTATE scan. This CL04 (Cohort 3) participant subsequently received 275MBq/kg of ^{67}Cu SARTATE.



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

Clarity's diagnostic imaging study of ^{64}Cu SARTATE, DISCO (NCT04438304)[3], reached the fifty percent recruitment milestone, with 32 out of 63 patients with known or suspected NETs enrolled and imaged in February 2023.

DISCO, which derives from "**D**iagnostic **I**maging **S**tudy of ^{64}**Co**pper-SARTATE Using PET in Patients With Known or Suspected Neuroendocrine Tumours", is assessing the performance of Clarity's SARTATE imaging product as a potential new way to help diagnose and manage NETs. It is a Phase II study in up to 63 patients with Gastroenteropancreatic NETs (GEP-NETs) across four sites in Australia, comparing the diagnostic performance of ^{64}Cu SARTATE at 4 and 20 hours post-administration to the current Standard of Care, ^{68}Ga DOTATATE, at one hour.

NETs traditionally have been considered uncommon; however, the incidence has been increasing as a worldwide phenomenon[10]. This increase is thought to be mostly related to improvements in the way NETs are diagnosed, including better imaging tests and endoscopy, and increased awareness of these tumours. Overall, it is estimated that more than 12,000 people in the United States are diagnosed with a NET each year, and approximately 175,000 people are living with this diagnosis[11]. Patients with GEP-NETs present with subtle clinical symptoms, which can lead to a delay in diagnosis of up to 5–7 years, or result in inappropriate management[12].

As such, about 30-75% of NET patients have distant metastases at the time of diagnosis[13]. A 10-year relative survival rate for patients with metastatic GEP-NETs is 3–36%[14]. There is a clear unmet need in the NET indication and Clarity continues to build on the promising first-in-human data with SARTATE (Hicks, R. et al)[15], which demonstrated that imaging at later time points, enabled by a longer half-life of ^{64}Cu isotope in comparison to ^{68}Ga, may lead to better identification of disease, and indicated the safety and potential effectiveness of the product as a new way to detect NETs.

SAR-Bombesin – Prostate Cancer

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

It is being developed for identifying and selecting patients for subsequent treatment of cancers that express a specific receptor called the gastrin releasing peptide receptor (GRPr), including breast cancer and prostate cancer. Like all Clarity products, the SAR-Bombesin product uses copper-64 (^{64}Cu) for imaging (^{64}Cu SAR-Bombesin) or copper-67 (^{67}Cu) for therapy (^{67}Cu SAR-Bombesin).

Approximately 20% of prostate cancers with BCR are PSMA-PET negative[16-19] and approximately 25% of mCRPC patients have low or no uptake of a PSMA-targeting tracer[20]. These patients are therefore unlikely to show meaningful uptake of PSMA-targeted products, such as ^{68}Ga-PSMA-11 for imaging or ^{177}Lu-PSMA-617 for therapy, and currently have few radiopharmaceutical treatment options available to them. Given the prostate cancer indication is one of the largest in oncology, there is a significant unmet medical need in this area. The SAR-Bombesin product targets the GRPr found on prostate and many other cancers. Although the clinical development path is focused on prostate cancer with low or no uptake of PSMA, there is a significant opportunity to widen the use of SAR-Bombesin into the broader group of prostate cancer patients who have the GRPr expression on their cancers.

Clarity is currently progressing three trials with SAR-Bombesin in prostate cancer indications:

- theranostic Phase I/IIa trial in the US (COMBAT)[6] in in patients with mCRPC;
- diagnostic Phase II trial in the US (SABRE)[7] in patients with BCR of prostate cancer; and
- investigator-initiated Phase II trial in Australia (BOP)[8] in patients with BCR of prostate cancer.

The BOP and SABRE trials are actively recruiting patients. The COMBAT trial, which received approval to proceed in late November, is anticipating the first sites opening for recruitment shortly.

TEAM AND COLLABORATORS

Clarity continues placing high importance on its team, including its Board of Directors, Advisory Board and collaborators. The highly diverse, inclusive and high-performance environment the Company has built over the years is one of the key pillars of Clarity's success. In the reporting period, the Company continued to grow the team with world-class expertise and knowledge in the radiopharmaceutical field.

Clarity's Board of Directors welcomed Ms Cheryl Maley, an experienced senior leader with over 25 years of experience in the pharmaceutical industry. Ms Maley's most recent role was the General Manger, Novartis Oncology, Australia and New Zealand. She has a strong strategic, commercial background with a proven track record in product launch excellence and timely patient access to innovative medicines. She has worked in the US, Philippines and Australia with local, regional and global responsibilities.

The addition of Ms Maley is in line with Clarity's goal of strengthening the Board's skills, knowledge and experience while also supporting the Company's commitment to gender balance at Board level.

Clarity also welcomed Jon Stoner to its Scientific Advisory Board. Mr Stoner is the Director of the Idaho Accelerator Center (IAC), a research institute of Idaho State University (ISU). He has been researching isotope production using linear accelerators for 14 years and pioneered a new process and mechanism for producing therapeutic copper-67 that enables it to be manufactured in the quantities and quality required for clinical development. He has 10 years of experience in production of the copper-67 isotope, and under his leadership the IAC has been shipping copper-67 commercially since 2014, supporting Clarity's TCT programs from preclinical through to the clinic where there are now three therapy products in clinical development.

FINANCIALS

Clarity's cash balance was $66.7 million as at 31 March 2023. The company's R&D tax incentive claim for FY22 was received in April and was $6.7 million, which brings the cash position to approximately $73 million.

Operating cash outflows for the March quarter were $9.4 million, which is an increase on previous quarterly outflows of $8.3 million, due to the increased activity on the Company's numerous clinical programs referred to in this Quarterly Activities Report.

The increase in costs was partially offset by the increase in interest received on Term Deposits of $0.4 million. In addition to clinical trial costs, operating cash outflows relate to payments for research and development, staff costs, administration, and general operating costs.

Use of Funds

(Listing Rule 4.7C.2)

Uses of funds	Prospectus dated 16 July 2021 $ Million	% of Total Funds	Period* to 31 March 2023 $ Million	% of Total Funds
Pre-Clinical	$2.7	2.5%	$2.1	4.4%
Clinical	$84.0	76.6%	$28.0	58.8%
Regulatory	$5.7	5.2%	$1.2	2.5%
Patents	$1.4	1.3%	$1.5	3.1%
Corporate	$10.4	9.5%	$8.3	17.4%
Costs associated with the Offer	$5.4	4.9%	$6.6	13.8%
Total uses	**$109.6**	**100.0%**	**$47.7**	**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 2023, is in accordance with the Use of Funds outlined in the Company's prospectus dated 16 July 2021 and there are no material variances against the estimated use of funds except for the Incentive Fee noted in the previous paragraph.

Related Party Transactions

(Listing Rule 4.7C.3)

Payments to related parties of the entity and their associates (6.1 of the Appendix 4C) totalled $368,110 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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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	**Quarter ended ("current quarter")**
36 143 005 341	March 2023

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	(8,679)	(21,749)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(28)	(73)
	(d) leased assets	-	-
	(e) staff costs	(685)	(1,921)
	(f) administration and corporate costs	(423)	(2,427)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	443	873
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	-	(58)
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(9,372)**	**(25,356)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(g) entities	-	-
	(h) businesses	-	-
	(i) property, plant and equipment	(15)	(48)
	(j) investments	-	-
	(k) intellectual property	-	-
	(l) 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**	**(15)**	**(48)**

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	73	183
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(4)	(8)
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**	**69**	**175**

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	75,888	92,336
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(9,372)	(25,356)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(15)	(48)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (9 months) $A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	69	175
4.5	Effect of movement in exchange rates on cash held	173	(364)
4.6	**Cash and cash equivalents at end of period**	**66,743**	**66,743**

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	66,743	57,888
5.2	Call deposits *	-	18,000
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)**	**66,743**	**75,888**

** Call deposits represents term deposit accounts with expiry dates more than 90 days after balance date, presented as "financial assets" in the audited financial statements.*

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	368
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)	(9,372)
8.2	Cash and cash equivalents at quarter end (item 4.6)	66,743
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	66,743

8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	7

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: *28 April 2023*
.....

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 – e.g.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.