CLARITY
PHARMACEUTICALS

QUARTERLY ACTIVITY REPORT

SYDNEY, AUSTRALIA
27 JULY 2022

HIGHLIGHTS OF THE QUARTER

Ending 30 June 2022

Cash position remains strong with a balance of $92.3 million as at 30 June 2022, funding the existing trial pipeline and providing cash runway into 2024.

Six active clinical trials advancing well, including four in prostate cancer.

Phase II diagnostic trial of SAR-Bombesin product in up to 50 PSMA-negative prostate cancer patients, SABRE, received US Food and Drug Administration (FDA) approval on June 6.

Data from SAR-Bombesin pilot study in breast cancer patients, C-BOBCAT, presented at the prestigious ASCO Annual Meeting in June 2022 by Prof Louise Emmett.

Two articles on the SAR-Bombesin product published in the *Pharmaceuticals* journal in June, the first one with findings from the C-BOBCAT pilot study and the second one with preclinical data supporting the development of SAR-Bombesin as a theranostic product.

First patient imaged in the US-based Phase I/II imaging trial in patients with biochemical recurrence of their prostate cancer, COBRA, on April 21.

Targeted nanobody platform IP and know-how acquired, bolstering Clarity's Discovery Program and team through the addition of leading nanotechnology researcher, Dr Kurt Gehlsen.

Three world leading oncology and nuclear medicine experts joined Clarity's Advisory Board, being Dr Andrei Iagaru, Dr Neal Shore and Prof Louise Emmett.

New Chief Financial Officer (CFO), Mr David Green, joined the Senior executive team with outgoing CFO, Mr Robert Vickery, continuing to serve as Company Secretary.

Clarity Pharmaceuticals (ASX: CU6) ("Clarity" or the "Company"), a clinical stage radiopharmaceutical company developing next-generation products to address the growing need for the use of radiopharmaceuticals in oncology, is pleased to release its Quarterly Activity Report for the quarter ending 30 June 2022.

Executive Chairman Dr Alan Taylor said*: "The final quarter of FY22 has continued the momentum of recent years as we head towards our ultimate goal of better treating children and adults with cancer. We have continued to achieve significant clinical development momentum for our Targeted Copper Theranostic (TCT) platform while bolstering our Discovery Program and intellectual property (IP), and strengthening our team and Advisory Board.*

"Importantly, Clarity is well funded with a cash balance of $92.3 million. This funding is sufficient to support our existing clinical trials and Discovery Program as well as to bring our diagnostic agents for imaging of prostate cancer to registrational Phase III trials in this large oncology indication with significant unmet clinical needs."

One of the key clinical development milestones this quarter has been the progress on Clarity's COBRA trial (NCT05249127)[1], the US-based diagnostic clinical trial of the **SAR-bisPSMA** agent in prostate cancer. Clarity successfully recruited and imaged the first patient in the COBRA trial in April 2022 with a number of patients imaged since then. This reflects swift progression from the commencement of the trial in March, shortly after receiving permission from the US FDA with an official "Study May Proceed" letter in February. This product is also supported by the Australian based PROPELLER clinical trial (NCT04839367)[2] in prostate cancer patients, which progressed recruitment and neared completion during the quarter.

Clarity has also reached exciting milestones in the development of its third product, **SAR-Bombesin**. In June 2022, Prof Louise Emmett, Principal Investigator in the diagnostic imaging trial of ^{64}Cu SAR-Bombesin (C-BOBCAT trial), presented her investigator-led trial data at the prestigious American Society of Clinical Oncology (ASCO) Annual Meeting in June 2022[3]. The results of the C-BOBCAT trial have now been published in the Pharmaceuticals Journal[4].

The clinical data from the C-BOBCAT trial supported Clarity's Investigational New Drug (IND) application to the US FDA for its US-based diagnostic trial of SAR-Bombesin in PSMA-negative prostate cancer, called SABRE (NCT05407311)[5]. Clarity received the "Study May Proceed" letter from the US FDA in June 2022 and is expecting to start imaging patients in the trial shortly.

SAR-Bombesin holds promise of addressing a significant segment of prostate cancer patients whose cancer either does not express PSMA, or cannot be detected by currently approved short half-life PSMA diagnostic agents or conventional imaging, such as CT and MRI, or treated with currently approved PSMA based therapy. The SABRE trial was developed in response to strong demand from clinicians who wanted to use SAR-Bombesin to image their PSMA-negative prostate cancer patients under a Special Access Scheme. Clarity will continue the development of SAR-Bombesin as a stand-alone diagnostic while also exploring various patient populations for therapy. The Company is preparing to lodge an IND with the US FDA for the theranostic trial this calendar year.

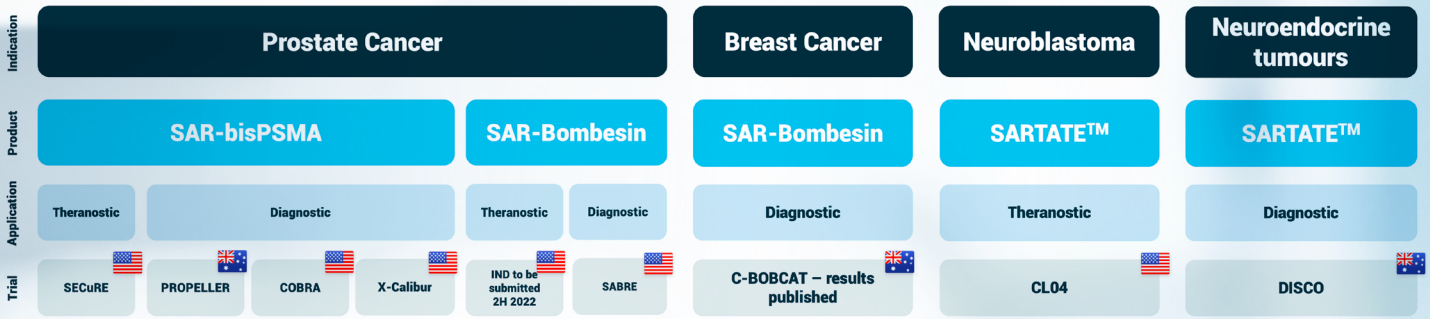
In addition to the progress achieved in the clinical development of Clarity's TCT platform, the Company also continues to reinforce its **intellectual property (IP)** and build the **Discovery Program** with the acquisition of a nanobody platform. Combined with Clarity's SAR Technology, nanobodies could be developed into new targeted radiopharmaceutical products potentially opening new opportunities to address unmet needs in oncology.

Clarity also continues to strengthen its **team of employees, collaborators and advisors** to support the development of its TCT platform with world-class skills and expertise. This quarter, the Company has seen the addition of three leading oncology, nuclear medicine and theranostics experts to its Advisory Board, being Dr Andrei Iagaru, Dr Neal Shore and Prof Louise Emmett. Clarity also welcomed a new Chief Financial Officer, Mr David Green.

Dr Taylor said: ***"Our team and collaborators are pleased with the incredible progress we have achieved to date and the pace of the developments. We look forward to further growing our company, driven by our ultimate goal of developing next-generation radiopharmaceuticals to improve treatment outcomes for children and adults with cancer.***

CLINICAL DEVELOPMENT OVERVIEW

Clarity's pipeline includes the following cancer indications, products and clinical trials:



Clarity continues to generate strong results in the clinical development of our products in the TCT platform. At June 30, 2022, the company was actively progressing six clinical trials, being:

Theranostic trials

- **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)[6]
- **CL04** – Phase I/IIa theranostic trial in paediatric patients with high-risk neuroblastoma using ^{64}Cu/^{67}Cu SARTATE™ in the US (NCT04023331)[7]

Clarity is conducting multiple clinical trials for each product in order to explore both diagnostic and therapeutic modalities, as well as expand their potential applications in a range of diseases, address different patient groups, and open commercial opportunities when each product is approaching market authorisation.

Diagnostic trials

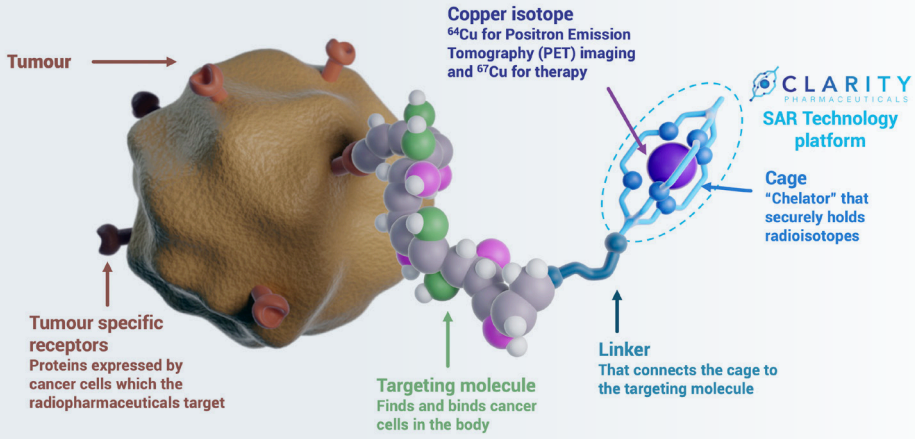
- **PROPELLER** – Phase I Positron Emission Tomography (PET) imaging trial of participants with confirmed prostate cancer using ^{64}Cu SAR-bisPSMA in Australia (NCT04839367)[2]
- **COBRA** – Phase I/II PET imaging trial of participants with biochemical recurrence (BCR) of prostate cancer following definitive therapy using ^{64}Cu SAR-bisPSMA in the US (NCT05249127)[1]
- **SABRE** – Phase II PET imaging trial of participants with PSMA-negative BCR of prostate cancer (NCT05407311)[5]
- **DISCO** – Phase II PET imaging trial of participants with known or suspected neuroendocrine tumours (NETs) using ^{64}Cu SARTATE™ in Australia (NCT04438304)[8]

TARGETED COPPER THERANOSTICS

What are Targeted Copper Theranostics?

Targeted Copper Theranostics (TCTs) are the next-generation disruptive platform in radiopharmaceuticals that employ the "perfect pairing" of isotopes, copper-64 (^{64}Cu) for diagnosis and copper-67 (^{67}Cu) for therapy.

TCTs deliver a compelling combination of high accuracy and high precision in the treatment of a range of cancers, as well as providing supply, logistical and environmental advantages over current theranostics. TCTs provide a highly efficacious, scalable, and cost-effective way to expand radiopharmaceuticals into the global oncology market.



The Perfect Pairing

The term "perfect pairing" relates to the unique characteristics of two of the isotopes of the one element, copper, utilising ^{64}Cu for diagnosis and ^{67}Cu for therapy.

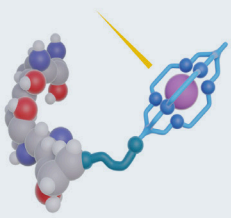
The pairing is well suited for precision medicine due to the unique physical characteristics of each isotope of copper as well as having the "ideal theranostic pair", meaning the same chemical composition of products are used for both diagnosis and therapy.

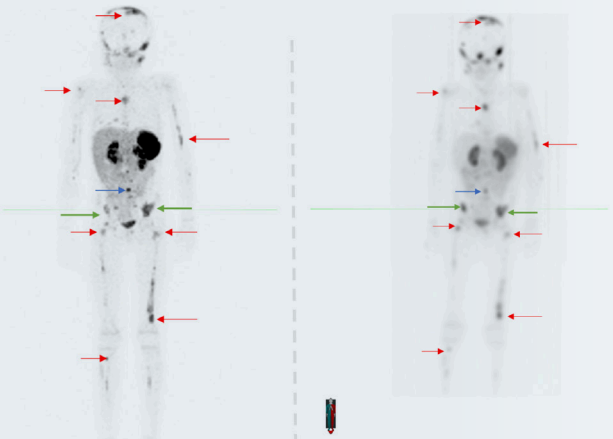
Until now, utilisation of copper isotopes has been hampered by the inability to hold the isotopes in a suitable cage and prevent their leakage from the radiopharmaceutical into the patient's body. Clarity's SAR Technology addressed this issue as it securely holds copper isotopes in the radiopharmaceutical when in the body, enabling better diagnostic and therapeutic outcomes.

Diagnostic

Positron emission from ^{64}Cu at the tumour site enables better diagnosis through PET imaging

^{64}Cu SARTATE™





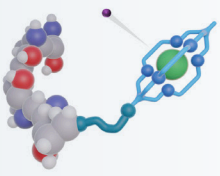
^{64}Cu SARTATE™
PET screening 4 hours

^{67}Cu SARTATE™
SPECT scan 24 hours

Therapeutic

Beta particle (β-) emission from ^{67}Cu delivers radiation directly to the cancer cells in order to kill them

^{67}Cu SARTATE™



Both diagnostics and therapeutics target the same cancer sites with high accuracy and precision, delivering a key platform advantage

Manufacturing and supply chain advantages

The manufacturing and supply chain are vitally important when considering the roll-out of radiopharmaceuticals in the large oncology market.

Two main characteristics underpin this, being the shelf-life of the products, determined by isotope half-life, and volume and consistency in producing the isotopes.

The shelf-life of the radiopharmaceutical product determines how long it remains useable after being manufactured and is a function of the isotopes used in the radiopharmaceutical product. The longer the radioactive half-life of the isotope, the longer the shelf-life of the radiopharmaceutical product can be. Isotopes must also be produced according to industry and quality standards, in a volume that can meet growing demand. It is imperative to avoid supply shortages and failures to deliver the products to physicians.

The supply and manufacturing of copper isotopes give Clarity an advantage in the commercialisation phase of its theranostic products. **The production of ^{64}Cu** occurs on existing cyclotrons, the infrastructure for which is already well established worldwide. The 12.7 hour half-life of ^{64}Cu permits central manufacturing and regional distribution whereas competing isotopes used for diagnostic imaging, like ^{68}Ga, are short lived, being approximately 1 hour, and therefore present logistical constraints for distribution. **The production of ^{67}Cu** employs electron accelerators. By contrast, the production of a commonly used therapeutic isotope, specifically ^{177}Lu, is reliant on a small number of ageing nuclear reactors globally, which can potentially present a challenge in meeting increased demand as the radiopharmaceutical field is growing into large oncology indications.

Environmental Benefits

Growing use of radiopharmaceuticals has raised awareness of their environmental impact, which has been generally neglected by the radiopharmaceutical industry.

The production of waste, particularly radioactive waste, as well as inefficient supply chains and the use of short-lived isotopes present significant environmental issues for the sector. In contrast, production of ^{64}Cu and ^{67}Cu has favourable environmental characteristics in comparison to the current generation of theranostics.

A recent presentation[9] at the Society of Nuclear Medicine and Imaging 2022 Annual Meeting in Vancouver covered some of the potential environmental aspects of TCTs, being:

- A relatively small infrastructure footprint
- Do not use nuclear reactors and enriched uranium
- Avoid the creation of long-lived radioactive impurities
- Lack significant radioactive waste disposal issues
- Use more readily available target material which do not employ rare-earth elements

These factors will significantly reduce the environmental impact compared to first generation ^{68}Ga- or ^{177}Lu-based theranostics. This is highly relevant considering the forecasted growth of theranostics over the next decade.

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).

Theranostic ^{64}Cu/^{67}Cu SAR-bisPSMA SECuRE trial

Clarity has completed recruitment for the imaging stage of the SECuRE (NCT04868604)[6] trial. The Company looks forward to progressing to the therapy stage at all seven clinical sites selected for the trial in the US.

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 called metastatic castrate-resistant prostate cancer (mCRPC). Clarity's PSMA imaging product is used to visualise PSMA expressing cancers and select participants who are most likely to respond well to subsequent therapy with Clarity's PSMA therapy product. The initial imaging stage of the trial utilised Clarity's PSMA imaging product to determine where the product went in the body (biodistribution) and what dose of the product was received (dosimetry) in the participants.

SECuRE is a multi-centre, single arm, dose escalation study with a cohort expansion planned for up to 44 patients. The aim of treatment for this trial is to determine the safety and efficacy of ^{67}Cu SAR-bisPSMA as a therapy.

Diagnostic ^{64}Cu SAR bisPSMA COBRA trial

Clarity successfully treated its first participant in the diagnostic US-based ^{64}Cu SAR-bisPSMA trial for patients with biochemical recurrence (BCR) of prostate cancer on the 21st of April, 2022. Clarity opened the COBRA trial (NCT05249127)[1] for recruitment on the 28th of March with the first trial site, Urology Cancer Center and GU Research Network (GURN) in Omaha, Nebraska, actively recruiting shortly after receiving a green light from the US FDA with an official Study May Proceed letter on the 7th of February.

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. This means the participants have indications their prostate cancer returned after a period of remission following initial therapy, but the location of their cancer is unknown.

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.

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. It builds on the encouraging preliminary results from the PROPELLER and SECuRE trials as well as the preclinical data. In the COBRA trial, participants are imaged on the day of administration and 24 hours later. The study will investigate if delayed imaging allows better identification of very early disease or patients with low PSMA expression.

Diagnostic ^{64}Cu SAR-bisPSMA PROPELLER trial

Clarity is aiming to reach full recruitment in the PROPELLER trial (NCT04839367)[2] in Q3 of calendar year 2022.

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**ti-Centre, B**L**ind**E**d **R**eview, Dose Ranging Phase I study". The main goals of the trial are to:

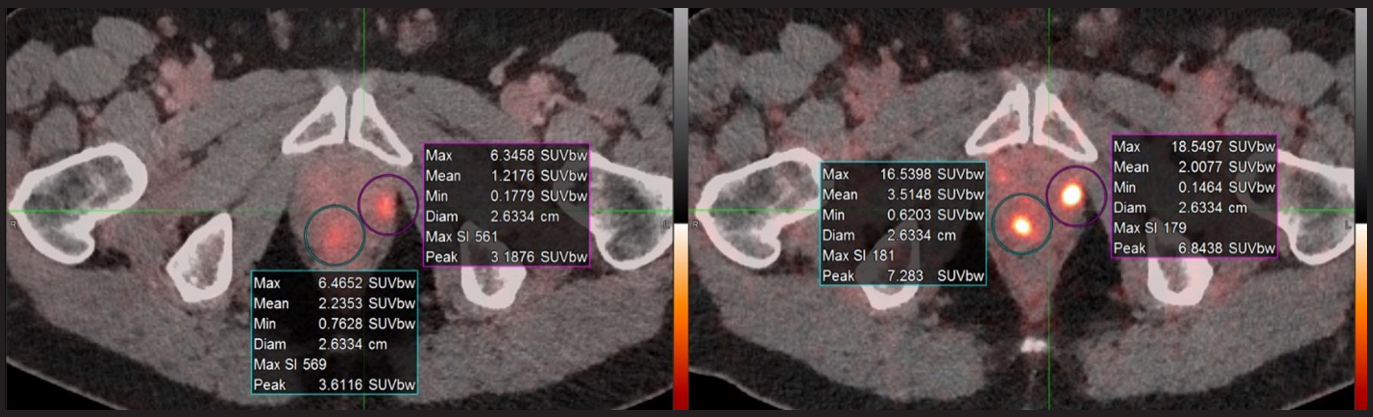
1. Determine the safety and tolerability of ^{64}Cu SAR-bisPSMA in participants with untreated, confirmed prostate cancer and planned for radical prostatectomy (radical prostatectomy means having the prostate gland removed with a surgery);
2. Examine ^{64}Cu SAR-bisPSMA at different dose levels;
3. Determine the ability of ^{64}Cu SAR-bisPSMA to detect primary prostate cancer.

The preliminary data from the patients imaged in the PROPELLER trial to date is encouraging and provides supporting evidence of the high uptake of ^{64}Cu SAR-bisPSMA in the tumours, which has previously been demonstrated in pre-clinical studies, and validates the development of this product as a diagnostic agent.

^{68}Ga PSMA-11 (~200MBq, left) vs. ^{64}Cu SAR-bisPSMA (~200MBq, right) in the same patient; time between serial imaging was 8 days. Standardised Uptake Value (SUVmax)⋆ of the lesions were 6.5 and 6.3 for ^{68}Ga PSMA-11 and 16.5 and 18.5 for ^{64}Cu SAR-bisPSMA

^{68}Ga PSMA-11 (~200MBq)

^{64}Cu SAR-bisPSMA (~200MBq)



⋆ SUV is a measurement of product uptake in tissue normalised to a distribution volume.

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™).

Theranostic ^{64}Cu/^{67}Cu SARTATE™ Neuroblastoma CL04 trial

Clarity successfully treated the first paediatric patient in cohort 2 of the SARTATE™ neuroblastoma therapy trial CL04 (NCT04023331)[7] on the 25th of February 2022 and continues to recruit in this trial.

Cohort 2 participants are treated with an increased product dose of 175 MBq of ^{67}Cu SARTATE™ per kilogram body weight. This builds on cohort 1 where 3 participants with neuroblastoma received an initial dose of the SARTATE™ therapy product (75MBq/kg body weight).

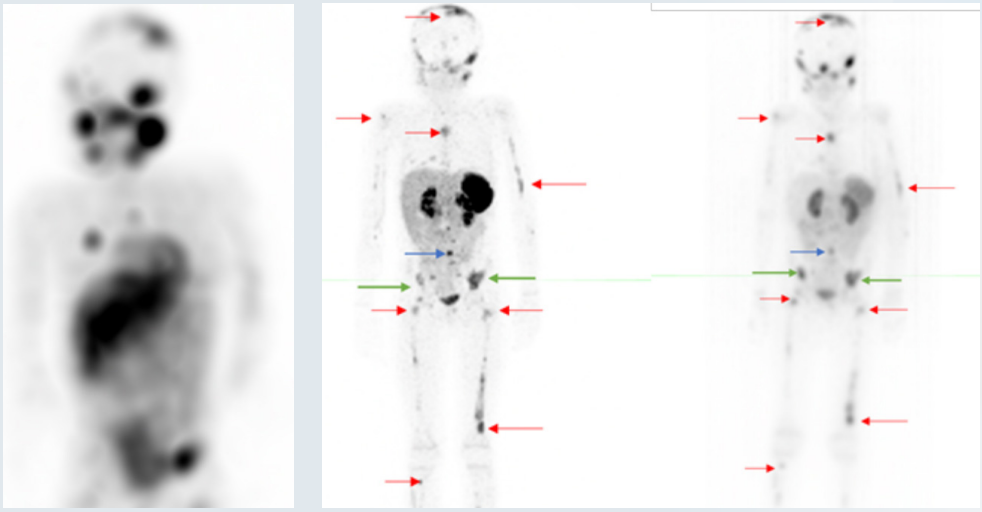
Each cohort will receive an increase in the therapeutic dose administered. Generally speaking, in the pharmaceutical field, higher therapeutic dose is usually associated with greater therapeutic response, up to a certain threshold where toxicity can occur. The CL04 trial is designed to gradually increase the dose of ^{67}Cu SARTATE™ administered to participants in each cohort until the Maximum Tolerated Dose (MTD) is reached.

Recruitment into cohort 2 is currently open at five clinical sites in the US and is expected to close shortly following a review of data by the Safety Review Committee. It is also important to note that 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 stable disease in participants who came into this trial with disease progression.

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 show uptake of ^{64}Cu SARTATE™ in tumours will continue in the trial and will receive treatment with ^{67}Cu SARTATE™.

Clarity looks forward to building upon the promising data reported to date and progressing to higher cohorts.

Early imaging data from Clarity's CL-04 study showing ^{64}Cu SARTATE™ (diagnostic agent) and ^{67}Cu SARTATE™ (therapeutic agent) relative to diagnostic imaging with ^{123}I MIBG in the same patient as baseline. Arrows indicate the same lesions imaged with the diagnostic ^{64}Cu SARTATE™ and therapeutic ^{67}Cu SARTATE™.



^{123}I MIBG
Current Standard of Care

^{64}Cu SARTATE™
PET screening 4 hours

^{67}Cu SARTATE™
SPECT scan 24 hours

Diagnostic ^{64}Cu SARTATE™ NETs DISCO trial

Clarity's diagnostic imaging study of ^{64}Cu SARTATE™, DISCO (NCT04438304)[8], continues to recruit participants at four clinical sites in Australia.

The DISCO trial uses the product to image patients with known or suspected neuroendocrine tumours (NETs) and commenced in April 2021.

DISCO, which derives from "**D**iagnostic **I**maging **S**tudy of ^{64}**CO**pper-SARTATE™ Using PET on Patients With Known or Suspected Neuroendocrine Tumour", is assessing the performance of Clarity's SARTATE™ imaging product as a potential new way to help diagnose and manage NETs. It is a Phase II trial in up to 63 patients across four sites in Australia comparing the diagnostic performance of ^{64}Cu SARTATE™ at 4 and 20 hours post-administration to the current standard of care, ^{68}Ga DOTATATE, at one hour. The study looks to build on earlier studies with SARTATE™ (Hicks, R. et al)[10] which demonstrated delayed imaging may lead to better identification of disease.

SAR-Bombesin – Breast Cancer and 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).

Diagnostic ^{64}Cu SAR-Bombesin SABRE trial

Clarity received approval of its Investigational New Drug (IND) application by the United States Food and Drug Administration (US FDA) to evaluate its SAR-Bombesin product as an imaging agent in prostate cancer patients that are PSMA-negative on the 6th of June 2022.

The IND gives Clarity clearance to proceed with a US-based Phase II ^{64}Cu SAR-Bombesin PET imaging trial (NCT05407311)[5] in participants with PSMA-negative biochemical recurrence (BCR) of prostate cancer following definitive therapy (such as surgery or radiation).

SABRE, which derives from "Copper-64 **SA**R-Bombesin in **B**iochemical **RE**currence of Prostate Cancer trial", is a multi-center, single arm, non-randomised, open-label trial in 50 PSMA-negative patients with suspected recurrence of their prostate cancer. The primary objectives of the trial are to investigate the safety and tolerability of ^{64}Cu SAR-Bombesin, as well as its ability to correctly detect the recurrence of prostate cancer.

The SABRE trial was developed in response to the strong demand from clinicians with prostate cancer patients whose cancer was not visible when imaging with currently approved PSMA diagnostic agents or conventional imaging (such as CT and MRI). Their patients were successfully imaged with ^{64}Cu SAR-Bombesin under Australia's Therapeutic Goods Administration (TGA) Special Access Scheme.

Approximately 20% of prostate cancers with BCR are PSMA-PET negative[11-14]. The inability to localise the return of prostate cancer in these patients limits their treatments options. Given the prostate cancer indication is one of the largest in oncology, there is a significant unmet medical need in this segment.

The SAR-Bombesin product targets the Gastrin Releasing Peptide receptor (GRPr) found on prostate and many other cancers. As such, the product could offer valuable imaging and therapeutic options for not only PSMA negative patients, but also the large number of patients who have the target receptor on their cancers.

Clarity's team and collaborators look forward to further progressing the development of SAR-Bombesin and anticipate the first patient to be recruited and treated into the SABRE trial shortly. Building on the promising clinical and preclinical data reported to date, Clarity is also preparing an IND application for a theranostic trial in prostate cancer participants, using ^{67}Cu SAR-Bombesin therapy paired with the imaging agent, ^{64}Cu SAR-Bombesin.

Preclinical data supporting the development of SAR-Bombesin as a theranostic product was published in the *Pharmaceuticals* journal in June 2022. The article is entitled "Copper-67-Labeled Bombesin Peptide for Targeted Radionuclide Therapy of Prostate Cancer"[15]. The publication highlighted that the positive tumour inhibition reported demonstrate the suitability of this copper-based theranostic agent for clinical assessment in the treatment of cancers expressing GRPr.

Diagnostic ^{64}Cu SAR-Bombesin breast cancer

The diagnostic imaging trial of ^{64}Cu SAR-Bombesin (C-BOBCAT), led by Prof Louise Emmett at St Vincent's Hospital in Sydney, completed early in October 2021, having recruited seven participants with hormone positive metastatic breast cancer.

The study showed promising results in these patients and the data was recently presented at the prestigious American Society of Clinical Oncology (ASCO) Annual Meeting in June 2022[3].

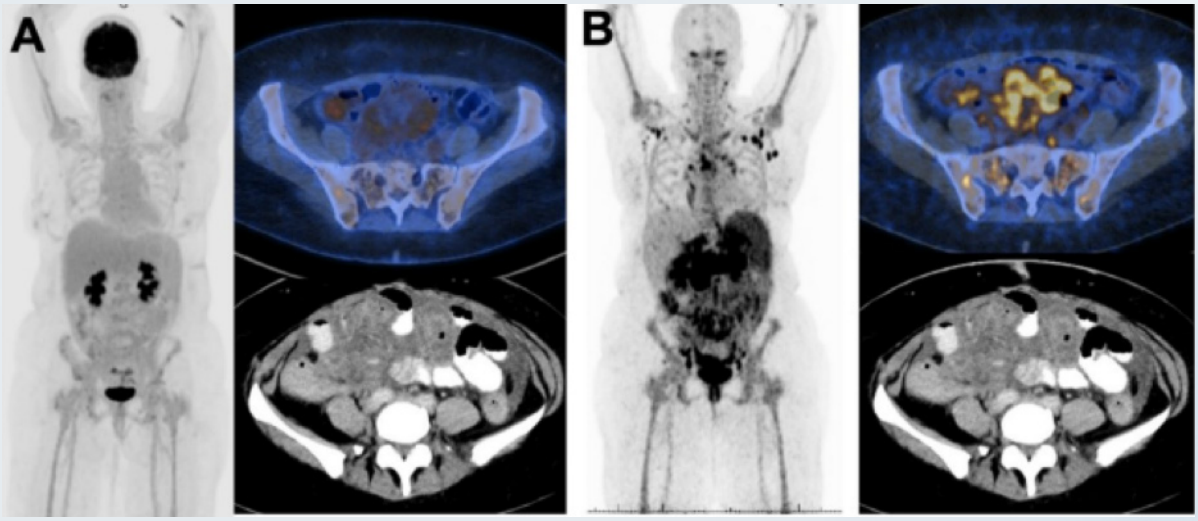
The findings from the C-BOBCAT trial have now been published in a paper in the *Pharmaceuticals* Journal[4] entitled '^{64}Cu-SAR-Bombesin PET-CT Imaging in the Staging of Estrogen/Progesterone Receptor Positive, HER2 Negative Metastatic Breast Cancer Patients: Safety, Dosimetry and Feasibility in a Phase I Trial'. The trial concluded that ^{64}Cu SAR-Bombesin appears safe and may have diagnostic value in metastatic hormone positive breast cancer, particularly the lobular subtype.

The C-BOBCAT trial was a pilot assessment of the diagnostic value of ^{64}Cu SAR-Bombesin PET/CT imaging for staging of hormone positive breast cancer patients with metastatic disease in comparison to standard of care imaging (CT, bone scan and ^{18}F FDG PET/CT).

The diagnostic program generated evidence of the utility and potential superiority in some patient subgroups compared to conventional imaging (e.g. ^{99m}Tc bone scan, ^{18}F FDG). The high uptake and strong product retention visualised by PET imaging of patients at 1, 3 and 24 hours after product administration suggests significant potential for therapy applications with ^{67}Cu SAR-Bombesin.

The clinical data from the C-BOBCAT trial was used for the IND Application filing with the US FDA for the diagnostic Phase II ^{64}Cu SAR-Bombesin SABRE trial and will also be utilised for the upcoming theranostic ^{67}Cu SAR-Bombesin IND submission.

Comparison of PET and cross-sectional PET-CT slices of the spine for [^{18}F]FDG (A) and [^{64}Cu]Cu-SAR-BBN (B) imaged at 1 hour following administration in a participant of the C-BOBCAT study. The image shows areas of disease in bone, lymph nodes and lining of the bowel seen on the [^{64}Cu]Cu-SAR-BBN scan but not on the [^{18}F]FDG scan (Wong et al 2022).[4]



^{18}F FDG images **^{64}Cu SAR-Bombesin images**

INTELLECTUAL PROPERTY AND DISCOVERY PROGRAM

Clarity has an extensive patent portfolio covering its SAR Technology platform and its existing radiopharmaceutical products, as well as its Discovery Program which is focused on developing new products.

The different patents and patent applications in the portfolio cover the various products (termed 'composition of matter' patents) as well as such aspects as manufacturing methods, formulations, and uses across the product mix. The Company's patent applications and granted patents are generally filed and prosecuted in multiple jurisdictions including the US, major countries in Europe, China and Japan.

The growing patent portfolio is testament to Clarity's aggressive patent strategy which allows the Company to achieve strong protection and to expand the product pipeline, gaining a sustainable competitive advantage in the radiopharmaceutical field.

Most recently, Clarity took assignment of a provisional patent application from leading nanotechnology researcher Dr Kurt Gehlsen. The application covers the development of a targeted nanobody platform to its Discovery Program.

Nanobodies are attractive targeting molecules which can be engineered to bind to a wide range of cancers. The nanobody platform allows the development of high affinity products suitable for targeting receptors specific to cancer cells. By only targeting cancer cells and not healthy cells, this approach aims to kill cancer cells while limiting the side effects elsewhere in the body, whilst also reducing the toxicity issues associated with the use of whole antibodies. The nanobody platform adds exciting new opportunities to Clarity's Discovery Program.

TEAM AND COLLABORATORS

At the core of Clarity's success is its people. Over the years, the Company has assembled an exceptional team, including Board of Directors and Scientific Advisory Board, who deliver a unique range of skills and expertise together with extensive experience in the global radiopharmaceutical market.

Clarity has continued to attract extraordinary talent and continued to build an exceptional team this quarter. Key additions include three leading oncology, nuclear medicine and theranostics experts joining the Advisory Board, namely, Dr Andrei Iagaru, Dr Neal Shore and Prof Louise Emmett.

Dr Andrei Iagaru

Dr Andrei Iagaru joined Clarity's Advisory Board in April 2022. Dr Iagaru is a Professor of Radiology – Nuclear Medicine and the Chief of the Division of Nuclear Medicine and Molecular Imaging at Stanford University. His research focus includes PET/MRI and PET/CT imaging for early cancer detection as well as peptide-based diagnostic imaging and therapy. Dr Iagaru is also passionate about clinical translation of novel PET radiopharmaceuticals.

Since joining the faculty at Stanford in 2007, Dr Iagaru has received several awards including the Society of Nuclear Medicine (SNM) 2009 Image of the Year Award; AuntMinnie 2016 Best Radiology Image, American College of Nuclear Medicine (ACNM) Mid-Winter Conference 2010 Best Essay Award; 2009, 2014 and 2015 Western Regional SNM Scientist Award; 2011 SNM Nuclear Oncology Council Young Investigator Award; and the 2020 Sanjiv Sam Gambhir Distinguished Scientist Award, Western Regional SNM. Dr. Iagaru published more than 200 papers in peer-reviewed journals, as well as 7 book chapters and 1 book.

Dr Neal Shore

Dr Neal Shore joined Clarity's Advisory Board in May 2022. Dr Shore MD, FACS is a world renowned prostate cancer expert with over 30 years of urologic oncology expertise. He is the Chief Medical Officer of Urology/ Surgical Oncology at GenesisCare, US and the Medical Director of Carolina Urologic Research Centre. He has conducted more than 400 clinical trials with a particular focus on genitourinary (GU) oncology indications and is an internationally recognised expert and researcher in systemic therapies for patients with advanced urologic cancers, such as prostate, kidney and bladder cancers.

Dr Shore is Principal Investigator of Clarity's COBRA trial of SAR-bisPSMA product for imaging of participants with biochemical recurrence (BCR) of prostate cancer in the US.

TEAM AND COLLABORATORS (CONT.)

Prof Louise Emmett

Prof Louise Emmett joined Clarity's Advisory Board in June 2022. Prof Emmett is the Director of Theranostics and Nuclear Medicine at St Vincent's Hospital Sydney, a conjoint professor of medicine at the University of New South Wales and clinical research leader at the Garvan Institute of Medical Research. Since joining the Nuclear Medicine and Positron Emission Tomography (PET) department at St Vincent's Hospital in 2012, Prof Emmett has been instrumental in developing the theranostics initiative at the St Vincent's Campus, introducing new radiopharmaceuticals for clinical and research evaluation of cancer as well as setting up radiopharmacy production of a number of imaging and therapy tracers.

Prof Emmett has been deeply involved and influential in progressing Clarity's SAR-Bombesin and SAR-bisPSMA products and presented data from the pilot diagnostic trial of SAR-Bombesin in breast cancer at the prestigious ASCO 2022 Annual Meeting earlier in June. Prof Emmett has also successfully imaged a number of prostate cancer patients who are PSMA-negative under a Special Access Scheme in Australia, laying groundwork for Clarity's recently approved US-based Phase II trial with SAR-Bombesin in this indication. Prof Emmett is also Lead Principal Investigator of Clarity's PROPELLER trial of SAR-bisPSMA in participants with untreated, confirmed prostate cancer in Australia.

Mr David Green

Dr Kurt Gehlsen

Clarity also welcomed a new Chief Financial Officer, **Mr David Green**, and leading nanotechnology researcher, **Dr Kurt Gehlsen**, who will work with the R&D team to further develop the recently acquired nanobody platform and advance it from the lab, through preclinical studies and into clinical development.

The increased support of the Company from world class experts in the oncology and the nuclear medicine fields is reflective of the excitement about TCTs and their ability to deliver clinical, logistical and environmental benefits in comparison to the current generation of radiopharmaceuticals, a field that is rapidly growing in the large oncology market.

FINANCIALS

The Group cash balance was $92.3 million as at 30 June 2022. Operating cash outflows for the June quarter were just under $4.0 million, which is line with previous quarter outflow of $3.9 million and the average quarterly gross operating cash outflows (ignoring receipts from the R&D Tax Incentive) over the twelve months to 30 June 2022. 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)

	Prospectus dated 16 July 2021 $ Million	% of Total Funds	Period* to 30 June 2022 $ Million	% of Total Funds
Pre-Clinical	$2.7	2.5%	$0.8	3.8%
Clinical	$84.0	76.6%	$9.1	43.2%
Regulatory	$5.7	5.2%	$0.6	2.8%
Patents	$1.4	1.3%	$0.6	2.8%
Corporate	$10.4	9.5%	$3.4	16.1%
Costs associated with the Offer	$5.4	4.9%	$6.6	31.3%
Total uses	**$109.6**	**100.0%**	**$21.1**	**100.0%**

* From date of admission 25 August 2021.

Costs associated with the offer exceed the amount set out in the "use of funds" in the Prospectus by $1.2 million. This is explained mainly by the additional fee to the Joint Lead Managers and costs relating to the preparation of, and 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.

Aside from the above, the expenditure for the twelve-month period ended 30 June 2022 as set out in the table above 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.

Related Party Transactions

(Listing Rule 4.7C.3)

Payments to related parties of the entity and their associates (6.1 of the Appendix 4C) totaled $241,000 for the quarter. This amount included director fees and salaries and consulting fees to a non-executive director for clinical development services.

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

References

1. ClinicalTrials.gov Identifier: NCT05249127 clinicaltrials.gov/ct2/show/NCT05249127
2. ClinicalTrials.gov Identifier: NCT04839367 clinicaltrials.gov/ct2/show/NCT04839367
3. Wong K. ^{64}Cu-SAR-Bombesin PET-CT imaging in the staging of ER+/PR+/HER2- metastatic breast cancer: Safety, dosimetry, and feasibility in a phase I trial. 2022 ACSO Annual Meeting. meetings.asco.org/abstracts-presentations/210783
4. Wong K, Sheehan-Dare G, Nguyen A, Ho B, Liu V, Lee J, Brown L, Dear R, Chan L, Sharma S, Malaroda A, Smith I, Lim E, Emmett L. ^{64}Cu-SAR-Bombesin PET-CT Imaging in the Staging of Estrogen/Progesterone Receptor Positive, HER2 Negative Metastatic Breast Cancer Patients: Safety, Dosimetry and Feasibility in a Phase I Trial. *Pharmaceuticals*. 2022; 15(7):772. doi.org/10.3390/ph15070772
5. ClinicalTrials.gov Identifier: NCT05407311 clinicaltrials.gov/ct2/show/NCT05407311
6. ClinicalTrials.gov Identifier: NCT04868604 clinicaltrials.gov/ct2/show/NCT04868604
7. ClinicalTrials.gov Identifier: NCT04023331 clinicaltrials.gov/ct2/show/NCT04023331
8. ClinicalTrials.gov Identifier: NCT04438304 clinicaltrials.gov/ct2/show/NCT04438304
9. Norenberg et al. Environmental Considerations Resulting from the Increased Use of Theranostics: Advantages of Targeted Copper Theranostics. SNMMI 2022. Abstract ID: 1338. Publication (Program ID): 2655. Vancouver, BC Canda
10. Hicks R et al. First-in-human trial of ^{64}Cu-SARTATE PET imaging of patients with neuroendocrine tumours demonstrates high tumor uptake and retention, potentially allowing prospective dosimetry for peptide receptor radionuclide therapy. *The Journal of Nuclear Medicine. 2018.* jnm.snmjournals.org/content/early/2018/11/14/jnumed.118.217745
11. Afshar-Oromieh A, Holland-Letz T, Giesel FL, et al. Diagnostic performance of ^{68}Ga-PSMA-11 (HBED-CC) PET/CT in patients with recurrent prostate cancer: evaluation in 1007 patients. Eur J Nucl Med Mol Imaging. 2017 Aug;44(8):1258-1268
12. Ferraro DA, Rüschoff JH, Muehlematter UJ, et al. Immunohistochemical PSMA expression patterns of primary prostate cancer tissue are associated with the detection rate of biochemical recurrence with ^{68}Ga-PSMA-11-PET. Theranostics. 2020;10(14):6082-6094
13. Baratto L, Song H, Duan H, et al. PSMA- and GRPR-Targeted PET: Results from 50 Patients with Biochemically Recurrent Prostate Cancer. J Nucl Med. 2021;62(11):1545-1549
14. Mapelli P, Ghezzo S, Samanes Gajate AM, et al. ^{68}Ga-PSMA and ^{68}Ga-DOTA-RM2 PET/MRI in Recurrent Prostate Cancer: Diagnostic Performance and Association with Clinical and Histopathological Data. Cancers (Basel). 2022;14(2):334
15. Huynh, T.T.; van Dam, E.M.; Sreekumar, S.; Mpoy, C.; Blyth, B.J.; Muntz, F.; Harris, M.J.; Rogers, B.E. Copper-67-Labeled Bombesin Peptide for Targeted Radionuclide Therapy of Prostate Cancer. Pharmaceuticals 2022, 15, 728. doi.org/10.3390/ph15060728

For more information, please contact:

Clarity Pharmaceuticals

Dr Alan Taylor
Executive Chairman
ataylor@claritypharm.com

Citadel-MAGNUS

Catherine Strong
Investor/Media Relations
cstrong@citadelmagnus.com | 0406 759 268

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	June 2022

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	(3,293)	(12,290)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(17)	(67)
	(d) leased assets	-	-
	(e) staff costs	(252)	(1,287)
	(f) administration and corporate costs	(436)	(2,405)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	37	76
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	(5)	(10)
1.7	Government grants and tax incentives	-	3,263
1.8	Other (provide details if material)	-	-
1.9	**Net cash from / (used in) operating activities**	**(3,966)**	**(12,720)**
2.	**Cash flows from investing activities**		
2.1	Payments to acquire or for:		
	(g) entities	-	-
	(h) businesses	-	-
	(i) property, plant and equipment	(193)	(210)
	(j) investments	-	-
	(k) intellectual property	-	-
	(l) 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**	**(193)**	**(210)**

3.	**Cash flows from financing activities**		
3.1	Proceeds from issues of equity securities (excluding convertible debt securities)	-	92,000
3.2	Proceeds from issue of convertible debt securities	-	-
3.3	Proceeds from exercise of options	462	531
3.4	Transaction costs related to issues of equity securities or convertible debt securities*	(3)	(6,327)
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**	**459**	**86,204**

** Transaction costs related to issues of equity securities includes all costs related to Clarity Pharmaceuticals Ltd's Initial Public Offering, including $750,000 classed as "payments to suppliers and employees" in the Consolidated Statement of Cash Flows in the Company's December 2021 Half Year Accounts and option exercises.*

4.	**Net increase / (decrease) in cash and cash equivalents for the period**		
4.1	Cash and cash equivalents at beginning of period	95,890	18,939
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(3,966)	(12,720)

Consolidated statement of cash flows		Current quarter $A'000	Year to date (12 months) $A'000
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(193)	(210)
4.4	Net cash from / (used in) financing activities (item 3.10 above)	459	86,204
4.5	Effect of movement in exchange rates on cash held	146	123
4.6	**Cash and cash equivalents at end of period**	**92,336**	**92,336**

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	30,336	45,890
5.2	Call deposits *	62,000	50,000
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)**	**92,336**	**95,890**

** Call deposits represents term deposit accounts with expiry dates more than 3 months 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	241
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 and consulting fees to a non-executive director for clinical development services.

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)	(3,966)
8.2	Cash and cash equivalents at quarter end (item 4.6)	92,336
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	92,336
8.5	**Estimated quarters of funding available (item 8.4 divided by item 8.1)**	23

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: *27 July 2022*
.....

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.