



QUARTERLY ACTIVITY REPORT

SYDNEY, AUSTRALIA
30 JUNE 2023



HIGHLIGHTS OF THE QUARTER

Ending 30 June 2023

Cash Position

Cash position remains strong with a balance of \$65.0 million as at 30 June 2023. Net operating cash outflows for the June quarter were \$2.1 million. FY22 R&D Tax Incentive Refund received in the quarter was \$6.7 million.

Phase III trial in prostate cancer (CLARIFY)

Clarity will be commencing a pivotal Phase III trial of its ⁶⁴Cu SAR-bisPSMA diagnostic in prostate cancer in late 2023, following a successful end of phase meeting with the US Food and Drug Administration (FDA).

PROPELLER¹

Results from Clarity's Phase I diagnostic ⁶⁴Cu SAR-bisPSMA prostate cancer trial were presented at two prestigious conferences, the American Society of Clinical Oncology (ASCO) Annual Meeting 2023 and the Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting 2023. Clarity was awarded First Place in the Oncology, Clinical Therapy & Diagnosis category at the SNMMI.

The PROPELLER trial showed that ⁶⁴Cu-SAR-bisPSMA was safe and well tolerated. ⁶⁴Cu-SAR-bisPSMA allowed brighter visualisation of cancerous lesions and detected more lesions than standard of care diagnostic imaging (using ⁶⁸Ga-PSMA-11; visualisation of lesions using Standardised Uptake Value).

SECURE²

Cohort 2 recruitment is ongoing in Clarity's theranostic ⁶⁴Cu/⁶⁷Cu SAR-bisPSMA trial following completion of cohort 1 in 6 participants with ⁶⁷Cu SAR-bisPSMA at the lowest dose level of 4GBq with no dose limiting toxicities.

Expanded Access Program (EAP) and Special Access Scheme (SAS)

⁶⁷Cu SAR-bisPSMA

⁶⁷Cu SAR-bisPSMA has been requested by clinicians under the US FDA EAP with early data indicating positive effects of the lowest 4GBq dose of ⁶⁷Cu SAR-bisPSMA on lesions with reduction in Prostate Specific Antigen (PSA) levels greater than 50%.

⁶⁴Cu SAR-bisPSMA

Four patients with prostate cancer and biochemical recurrence (BCR), who were negative on conventional PSMA-PET, received doses of ⁶⁴Cu SAR-bisPSMA under the Australian Therapeutic Goods Administration (TGA) SAS. ⁶⁴Cu SAR-bisPSMA PET/CT scans detected lesions in all four patients, with delayed imaging (24hrs post-dose), showing higher uptake of ⁶⁴Cu SAR-bisPSMA. Initial data in a disease other than prostate cancer (angiolioma) has also been published as "Image of The Month" in the European Journal of Nuclear Medicine and Molecular Imaging showing superiority of ⁶⁴Cu SAR-bisPSMA compared to ¹⁸F-DCFPyL due to late time point imaging.³



HIGHLIGHTS OF THE QUARTER CONT.

Ending 30 June 2023

COMBAT⁴

Clarity commenced its ⁶⁴Cu/⁶⁷Cu SAR-Bombesin theranostic Phase I/II trial in metastatic castrate resistant prostate cancer (mCRPC) in up to 38 participants.

BOP⁵

Recruitment completed for the Phase II investigator initiated diagnostic trial, evaluating Clarity's ⁶⁴Cu SAR-Bombesin product in 30 participants with prostate cancer. Study results have been accepted for poster presentation at the European Association of Nuclear Medicine (EANM) 2023 Congress.

Copper-67 supply

NorthStar Medical Radioisotopes is now routinely manufacturing Copper-67 on its electron accelerators exclusively for Clarity's therapy clinical programs.

⁶⁴Cu SAR-bisPSMA supply

Clarity expanded supply of ⁶⁴Cu SAR-bisPSMA for pivotal Phase III clinical trials by entering into a Master Service Agreement and a Clinical Supply Agreement with PETNET Solutions Inc.

US Center of Excellence

Clarity established a Center of Excellence at the Idaho Accelerator Center (IAC), a research facility operated by Idaho State University (ISU), for Targeted Copper Theranostics (TCTs).

Team

Othon Gervasio joined Clarity as a Senior Medical Director and Bryce Kanter joined as a Senior Director of Commercial Development.



Clarity Pharmaceuticals (ASX: CU6) (“Clarity” or the “Company”), a clinical stage radiopharmaceutical company with a mission to develop next-generation products that improve treatment outcomes for children and adults with cancer, is pleased to release its Quarterly Activity Report and Appendix 4C for the three months ending 30 June 2023.



Executive Chairperson's Letter

Dear fellow Shareholders,

In this second quarter of CY23 we continued to reach significant milestones in our therapeutic and diagnostic prostate cancer clinical programs as well as strengthening the supply and manufacturing in the lead up to Phase III trials. With a cash balance of more than \$65 million, we remain well financed to continue the development of our next-generation radiopharmaceutical products into late-stage trials.

We continue to differentiate ourselves from other first-generation radiopharmaceuticals and focus on “best-in-class” products. Most recently, Clarity has been awarded First Place in the Oncology, Clinical Therapy & Diagnosis category at the world’s most prestigious nuclear medicine conference, SNMMI 2023 Annual Meeting. The award relates to Clarity’s poster presentation detailing the results from the completed PROPELLER diagnostic trial, which showed that Clarity’s optimised ⁶⁴Cu SAR-bisPSMA product was safe and effective for detecting PSMA-expressing lesions in men with prostate cancer. The PROPELLER trial was our first opportunity to showcase the benefits of our optimised PSMA product that has two PSMA-targeting agents in comparison to the first-generation PSMA diagnostic products with only one PSMA-targeting agent. It is truly an honour to receive such prominent recognition of the quality and significance of our PROPELLER trial results.

Based on the compelling results from the PROPELLER trial, we designed a Phase III pivotal diagnostic trial called CLARIFY for the same patient population with high-risk prostate cancer prior to radical prostatectomy. Following a successful end of phase meeting with the US FDA, we plan to commence the prospective, non-randomised, single-arm, open-label, multi-centre clinical trial of ⁶⁴Cu SAR-bisPSMA in 383 participants in late 2023. As a pivotal trial, the final study results are intended to provide sufficient evidence to support an application to the US FDA for approval of ⁶⁴Cu SAR-bisPSMA as a new diagnostic imaging agent in prostate cancer.

In preparation for Phase III trials, we continue to fully leverage the advantages of TCTs. The longer shelf-life of ⁶⁴Cu SAR-bisPSMA (up to 48 hours) enables centralised manufacture and supply from just one facility, as opposed to the first-generation PSMA PET diagnostics that require an expensive and extensive network of cyclotrons, radioisotope generators and radiopharmacies due to the short half-life of gallium-68 and fluorine-18. As such, we have entered into a Master Service Agreement and a Clinical Supply Agreement covering Clarity’s ⁶⁴Cu SAR-bisPSMA with PETNET Solutions, Inc, the leading manufacturer of radiopharmaceuticals for PET imaging in the US. PETNET Solutions will provide a dependable and scalable supply of ⁶⁴Cu SAR-bisPSMA for the CLARIFY trial as well as our second planned Phase III trial that we hope to launch in 2024 based on the data from the COBRA trial in prostate cancer patients with biochemical recurrence (BCR).

The radio-diagnostic segment is rapidly expanding, offering blockbuster opportunities with the expected market size of US\$10 billion by 2031. As such, developing best-in-class imaging products and bringing them to market as quickly as possible remains a short-term priority for Clarity. Nevertheless, radio-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.

As such, our theranostic trial in prostate cancer, SECuRE, has been rapidly progressing during this quarter. We have completed cohort 1 in 6 patients at the lowest dose level of 4GBq ⁶⁷Cu SAR-bisPSMA with no dose limiting toxicities and progressed to cohort 2 where all the slots have been fully allocated at the dose level of 8GBq. Outside of the trial, clinicians whose patients responded well to the single dose of the product have requested additional therapy cycles of ⁶⁷Cu SAR-bisPSMA under the FDA EAP.

A reduction of greater than 50% in PSA levels was observed in one patient following the first administration of 4GBq of ⁶⁷Cu SAR-bisPSMA, and subsequently this patient has received three more doses, with their PSA levels continuing to fall. These results are incredibly promising given the initial low dose and we look forward to collecting more data from the SECuRE trial at higher doses and from additional EAP patients to progress the development of this important therapeutic radiopharmaceutical.

We already know that PSMA-based therapies hold promise of improving treatment outcomes for patients with prostate cancer. However, the first-generation of radiopharmaceuticals, such as Novartis' US FDA-approved Pluvicto™, experience significant supply and manufacturing challenges that have crippled the rollout of the product and added to the suffering of patients and their families, undermining the confidence of clinicians and their patients in radiopharmaceuticals.

Clarity's therapeutic products are based on copper-67, which is ideally suited to address large indications such as prostate cancer. The isotope is produced on electron accelerators, which are relatively inexpensive and infinitely more scalable in comparison to nuclear reactors. TCTs also do not require heating during the manufacturing process, minimising quality concerns and making it less costly to manufacture. Production of copper-67 also has favourable environmental characteristics in comparison to the current generation of therapeutics, with a smaller logistical footprint and minimal radioactive waste disposal issues.

Clarity's supplier of copper-67, NorthStar, now routinely produces large volume, high specific activity and high purity copper-67 and has supplied it for use in our clinical programs as part of an agreement for exclusive supply of copper-67 to Clarity. We are excited to continue progressing our clinical programs with best-in-class products that allow for a scalable global rollout of radiopharmaceuticals, offering the ability to completely control the radiopharmaceutical supply chain.

In addition to our optimised SAR-bisPSMA product, our second product in prostate cancer, SAR-Bombesin, has been progressing rapidly through three clinical trials. We have now commenced our third theranostic trial, COMBAT, and recruitment has closed for a diagnostic investigator-initiated trial called BOP. We believe that SAR-Bombesin holds promise of improving treatment outcomes for a large patient population with prostate cancers that are PSMA-negative or have low PSMA expression where, unfortunately, very few treatment options are currently available.

We are excited with the accelerated development in our prostate cancer program and are very pleased to see a lot of positive data coming out of our trials. Radiopharmaceuticals are a new, promising pillar in oncology, and we believe that our TCTs are the key to taking this sector from the small-scale cottage industry that it is today and into the world of big pharma with large-scale centralised manufacture and seamless supply chain, catering to large indications, such as prostate cancer.

Yours sincerely,

Dr Alan Taylor
Executive Chairperson
Clarity Pharmaceuticals Ltd

"We want to see the patients and their clinicians getting the best diagnostic imaging and treatment options in a timely manner, wherever they are in the world."

- Dr Alan Taylor

CLINICAL DEVELOPMENT OVERVIEW

SAR-bisPSMA

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









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-Bombesin

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

As of June 2023, the Company was actively progressing eight clinical trials with its three key products, SAR-bisPSMA, SAR-Bombesin and SARTATE. The trials are being conducted in three theranostic (therapeutic and diagnostic) and five 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), which closed recruitment during the quarter.

Product	SAR-bisPSMA	SAR-Bombesin	SARTATE
Indication	Prostate Cancer		Neuroblastoma
Application	Theranostic	Theranostic	Theranostic
Trial	Diagnostic SECURE  CLARIFY  COBRA 	Diagnostic COMBAT  SABRE  BOP (recruitment closed) 	Diagnostic CL04  DISCO 

CLINICAL DEVELOPMENT OVERVIEW

	Theranostic Trials	Diagnostic Trials
SAR-bisPSMA	<p>SECURE – Phase I/IIa theranostic trial for identification and treatment of PSMA-expressing metastatic castrate-resistant prostate cancer (mCRPC) using ⁶⁴Cu/⁶⁷Cu SAR-bisPSMA in the US (NCT04868604)²</p>	<p>PROPELLER – Phase I Positron Emission Tomography (PET) imaging trial of participants with confirmed prostate cancer using ⁶⁴Cu SAR-bisPSMA in Australia (NCT04839367)¹</p> <p>CLARIFY - Registrational Phase III PET imaging trial of participants with high-risk prostate cancer prior to radical prostatectomy using ⁶⁴Cu SAR-bisPSMA</p> <p>COBRA – Phase I/II PET imaging trial of participants with biochemical recurrence (BCR) of prostate cancer following definitive therapy using ⁶⁴Cu SAR-bisPSMA in the US (NCT05249127)⁶</p>
SAR-Bombesin	<p>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 ¹⁷⁷Lu-PSMA-617, using ⁶⁴Cu/⁶⁷Cu SAR-Bombesin (NCT05633160)⁴</p>	<p>SABRE – Phase II PET imaging trial of participants with PSMA-negative BCR of prostate cancer using ⁶⁴Cu SAR-Bombesin in the US (NCT05407311)⁷</p> <p>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 ⁶⁴Cu SAR-Bombesin led by Prof Louise Emmett at St Vincent’s Hospital Sydney (NCT05613842)⁵</p>
SARTATE	<p>CL04 – Phase I/IIa theranostic trial in paediatric participants with high-risk neuroblastoma using ⁶⁴Cu/⁶⁷Cu SARTATE in the US (NCT04023331)⁸</p>	<p>DISCO – Phase II PET imaging trial of participants with known or suspected Neuroendocrine Tumours (NETs) using ⁶⁴Cu SARTATE in Australia (NCT04438304)⁹</p>

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.



PRODUCT UPDATES

For the quarter ending
30 June, 2023

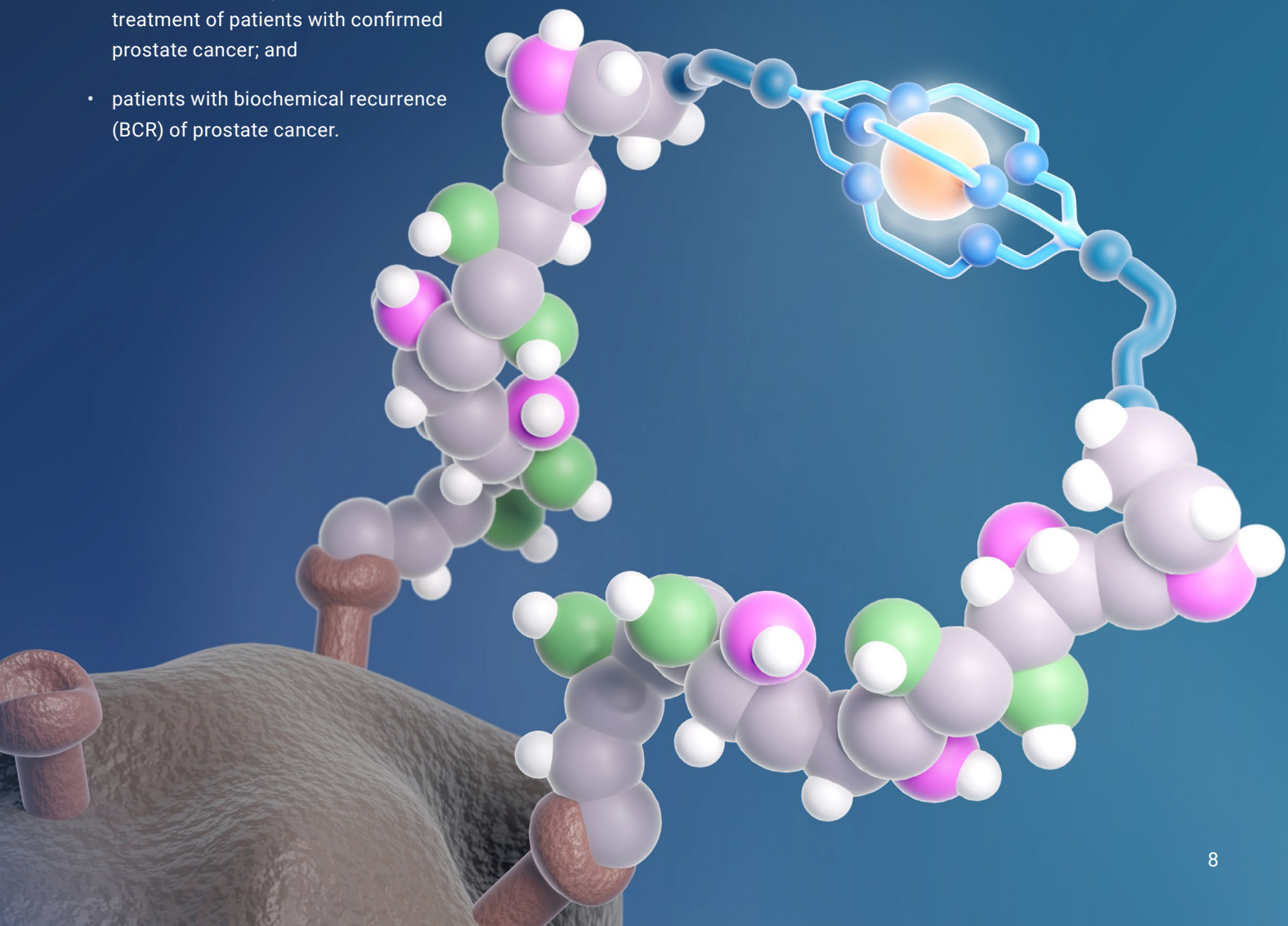
SAR-bisPSMA

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

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 biochemical recurrence (BCR) of prostate cancer.



SECURE – a theranostic ⁶⁴Cu/⁶⁷Cu SAR-bisPSMA trial

The theranostic prostate cancer trial, SECURE (NCT04868604)², is evaluating ⁶⁴Cu/⁶⁷Cu SAR-bisPSMA in patients with mCPRC and is now progressing through the therapeutic dose escalation phase. In this quarter, Clarity completed cohort 1 in 6 participants with no dose limiting toxicities at the dose level of 4GBq ⁶⁷Cu SAR-bisPSMA and advanced to cohort 2, which is now fully allocated with all participants having received an 8GBq dose of ⁶⁷Cu SAR-bisPSMA.

Current participants are undergoing safety follow up and the data will soon be reviewed by the safety review committee with the view to progress to Cohort 3. In cohort 3, the participants will receive ⁶⁷Cu SAR-bisPSMA at an increased dose level of 12GBq. There are up to 4 cohorts in the dose escalation phase of the SECURE trial.

SECURE, which derives from “**S**yst**E**mic **C**u 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, ⁶⁴Cu SAR-bisPSMA, to visualise PSMA expressing tumours and select participants who are most likely to respond well to subsequent therapy with ⁶⁷Cu 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 ⁶⁴Cu-SAR-bisPSMA and ⁶⁷Cu SAR-bisPSMA as well as the efficacy of ⁶⁷Cu SAR-bisPSMA as a therapy.

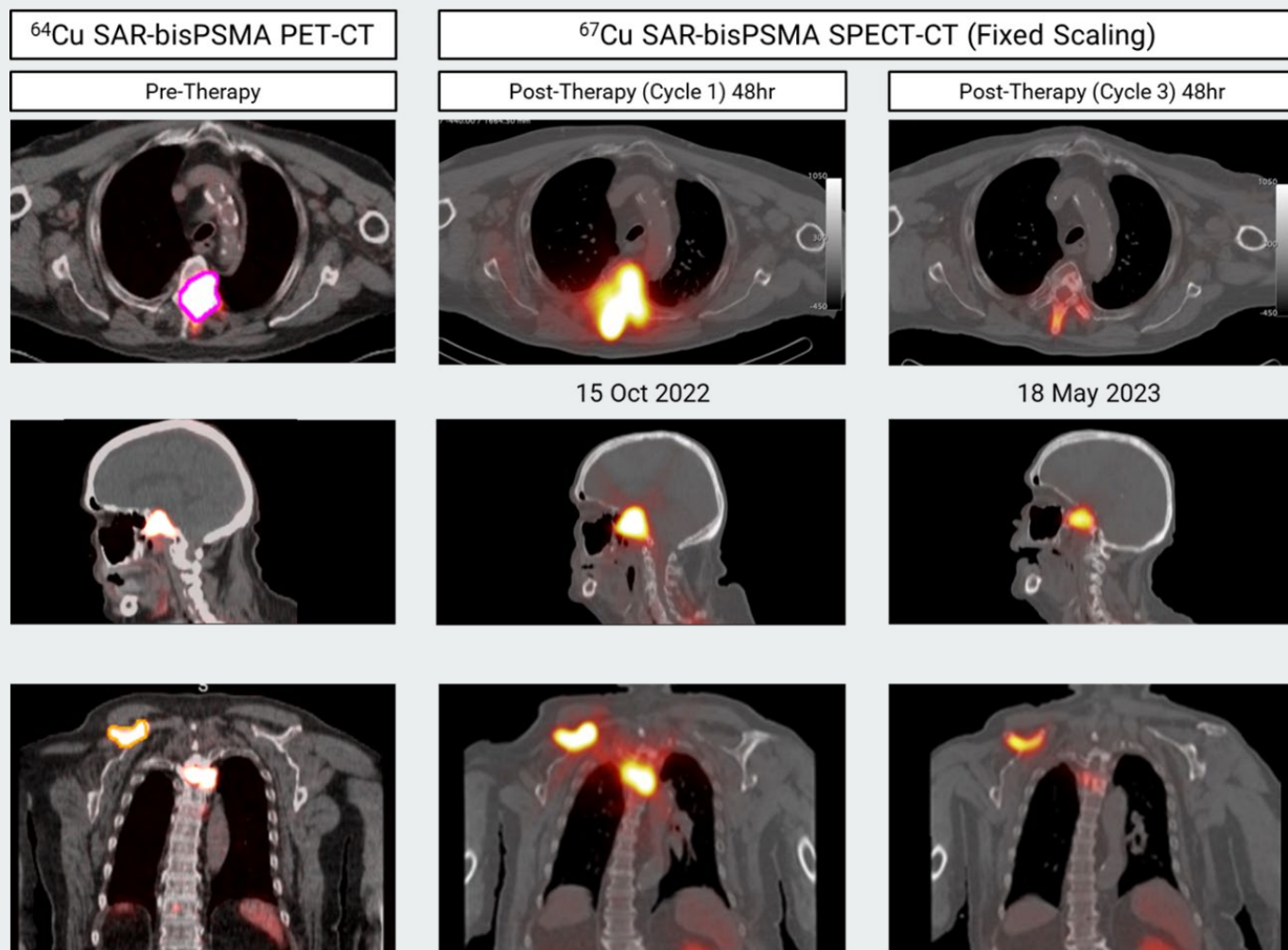
The initial imaging stage of the trial, which is now completed, utilised the copper-64 based imaging product to determine where the product went in the body (biodistribution) and what dose of the product was received (dosimetry) in the participants. The subsequent dosimetry phase with ⁶⁷Cu SAR-bisPSMA 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). In cohort 1, participants received a single administration of 4GBq of ⁶⁷Cu SAR-bisPSMA and in cohort 2 the dose was increased to 8GBq.

Outside of the trial, therapy cycles of ⁶⁷Cu SAR-bisPSMA have also been requested by clinicians under the US Food and Drug Administration (FDA) Expanded Access Program (EAP) for patients who participated in cohort 1, and data from the EAP continues to be generated.

SPECT-CT images depicted in Figure 1 below were collected 48 hours after the first and third administrations of ⁶⁷Cu SAR-bisPSMA in a patient in the EAP. PET-CT images using ⁶⁴Cu SAR-bisPSMA were collected prior to therapy. Images collected 48 hours following the third therapy cycle demonstrate a reduction in the intensity of product uptake at the tumour sites.

A reduction of >50% in PSA levels was observed in the patient in the EAP following the first administration of 4GBq of ⁶⁷Cu SAR-bisPSMA. PSA decline of 50% or greater is one of the primary endpoints of the SECURE trial and a commonly used surrogate endpoint for efficacy in this patient population.

Figure 1. Reduction in tumour intensity over time with multiple dosing of patient in lowest dose cohort 1. Patient experienced a reduction in PSA of greater than 50% after a single dose.



PROPELLER

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 two prestigious conferences, the American Society of Clinical Oncology (ASCO) Annual Meeting 2023 and the Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting 2023.

Clarity was awarded First Place in the Oncology, Clinical Therapy & Diagnosis category for the poster presentation detailing the results from the completed PROPELLER diagnostic trial at the SNMMI Annual Meeting 2023, the world's premier educational, scientific, research and networking meeting in nuclear medicine and molecular imaging.

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.

To view the full poster from ASCO 2023 online, [click here](#).

To view the full poster from SNMMI 2023 online, [click here](#).

PROPELLER – cont.

The PROPELLER data further substantiates the utility of ⁶⁴Cu 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 ⁶⁴Cu) and subsequent treatment (with ⁶⁷Cu) of prostate cancer.

PROPELLER derives from “PositROn Emission Tomography Imaging of Participants with Confirmed ProstatE Cancer Using ⁶⁴Cu-SAR-bisPSMA: A MuLtiCentre, BLindEd Review, Dose Ranging Phase I study”. It was a first-in-human trial administering Clarity’s optimised PSMA agent, ⁶⁴Cu SAR-bisPSMA, to 30 participants with confirmed prostate cancer prior to undergoing radical prostatectomy. The trial also compared the diagnostic properties of ⁶⁴Cu SAR-bisPSMA against ⁶⁸Ga PSMA-11, which is approved for prostate cancer imaging in Australia and the US.

The PROPELLER trial showed that ⁶⁴Cu-SAR-bisPSMA was safe and well tolerated. ⁶⁴Cu-SAR-bisPSMA allowed brighter visualisation of cancerous lesions and detected more lesions than standard of care diagnostic imaging (using ⁶⁸Ga-PSMA-11; visualisation of lesions using Standardised Uptake Value).

Figure 2. Poster presentation detailing the results from the completed PROPELLER diagnostic trial at the SNMMI Annual Meeting 2023.

PROPELLER - Comparison of PET/CT in Subjects with Confirmed Prostate Cancer Using ⁶⁴Cu-SAR-bisPSMA and ⁶⁸Ga-PSMA-11

Eva Lengyelova¹, Veronica Wong², Nat Leno³, Michelle Parker¹, Louise Emmett⁴
¹Clarity Pharmaceuticals, Sydney, Australia; ²Nepean Hospital, Sydney, Australia; ³GENESISCARE, Perth, Australia; ⁴St. Vincent’s Hospital, Sydney, Australia

Background:

Prostate-specific membrane antigen (PSMA) is a type II transmembrane glycoprotein that is overexpressed in prostate cancer (PC). PSMA targeting PET tracers using ⁶⁸Ga or ⁶⁴Cu have been approved by the FDA to detect PC with improvements in sensitivity and specificity compared to traditional imaging by frequently identifying sub-centimeter lesions. However, these products still exhibit a relatively low sensitivity for PC, potentially due to low tumor uptake and retention, or limitations of the short half-life of the isotopes being used.

⁶⁴Cu-SAR-bisPSMA is a next-generation PET product in development for the imaging of PSMA-expressing PC lesions. In contrast to the short half-lives of ⁶⁸Ga (t_{1/2}=1.1h) and ⁶⁷Zn (t_{1/2}=1.8h), the longer half-life of ⁶⁴Cu (t_{1/2}=12.7h) may offer significant advantages, including:

- better resolution of images and detection of lesions due to the ⁶⁴Cu positron range (0.56mm) and potential for delayed imaging (up to 72h post administration);
- universal access to products through large scale central manufacturing of ready-to-use ⁶⁴Cu-SAR-bisPSMA; and
- improved product shelf-life of up to 48h to simplify patient scheduling.

Beyond the benefits of ⁶⁴Cu-SAR-bisPSMA has two PSMA-targeting functional groups, compared to the current generation of PSMA targeting agents, which only have a single targeting group. This can lead to improved tumor uptake and retention and thus, detection of additional smaller lesions. This is highly relevant in patients with suspected metastatic disease or recurrence, as it can lead to a change in management.

PROPELLER (NCT04839367) was a prospective, Phase I, multi-center, blinded review, dose-ranging study evaluating safety and preliminary efficacy of ⁶⁴Cu-SAR-bisPSMA PET in patients with known primary PC.

The aims of PROPELLER were to:

- determine the safety and tolerability of ⁶⁴Cu-SAR-bisPSMA;
- determine the ability of ⁶⁴Cu-SAR-bisPSMA PET to detect primary PC at 200 MBq;
- assess image quality at 100 MBq, 150 MBq and 200 MBq dosages of ⁶⁴Cu-SAR-bisPSMA; and
- explore how ⁶⁴Cu-SAR-bisPSMA compares to ⁶⁸Ga-PSMA-11 PET, a standard-of-care (SOC) radiotracer for imaging of PSMA-positive lesions in PC.

Methods:

At screening, patients with untreated, histopathology proven primary PC with intermediate- to high-risk features completed a ⁶⁸Ga-PSMA-11 PET/CT between 45-60min post injection per standard of care (SOC) protocols. 30 patients with a median age of 64 years (range: 50-75) with (SUPT G2-5 and median PSA value of 8.21 ng/ml (range: 1.6-36) were enrolled.

Patients were dosed 1:1:3 with 100 MBq, 150 MBq and 200 MBq of ⁶⁴Cu-SAR-bisPSMA, followed by a PET/CT at 2-4h post injection, respectively. Safety was evaluated pre and post dose for up to 11 weeks via adverse event (AE) reporting, vital signs, electrocardiograms (ECGs), blood and urine analysis.

The ⁶⁸Ga-PSMA-11 and ⁶⁴Cu-SAR-bisPSMA PET/CT scans were evaluated by 2 independent, blinded central readers to determine image quality, primary PC detection, the number and location of lesions, intensity of tracer uptake in up to 5 concordant lesions using Standardized Uptake Values (SUV) and tumor-to-background ratios (TBR).

Patients then proceeded to prostatectomy with pelvic lymph node dissection.

Safety Results:

⁶⁴Cu-SAR-bisPSMA was well tolerated in all 30 patients with only a single related AE of Grade 1 dysgeusia (metallic taste) reported in the 200 MBq cohort. There were no clinically significant changes in any laboratory measures or ECGs at any dose level.

PROPELLER

⁶⁴Cu-SAR-bisPSMA - a next-generation diagnostic agent that is safe, efficacious, has a longer half-life with favourable logistics and improved lesion uptake compared to the SOC ⁶⁸Ga-PSMA-11 PET/CT.

Initiation of a Phase 3 registration trial is underway.

Table 1. Uptake of ⁶⁴Cu-SAR-bisPSMA and ⁶⁸Ga-PSMA-11 in concordant lesions

All Cohorts	Parameter	Imaging	N	Median	IQR	Min	Max	Median Difference	p-value*
Reader 1	SUV _{max}	⁶⁴ Cu	28	30.26	46.9	8	100	14.23	p < 0.001
		⁶⁸ Ga	28	13.53	12.79	2.7	55.1		
		⁶⁴ Cu	28	21.2	22.23	5.4	69.9		
	TBR	⁶⁴ Cu	28	9.12	8.71	1.8	37.6	9.26	p < 0.001
		⁶⁸ Ga	28	53.55	84.43	10.3	294.1		
		⁶⁴ Cu	28	24.29	36	9.6	134.4		
Reader 2	SUV _{max}	⁶⁴ Cu	16	41.66	58.77	6.1	100	27.99	p < 0.001
		⁶⁸ Ga	16	14.93	17.16	2.7	55.1		
		⁶⁴ Cu	16	28.4	37.92	4.4	69.9		
	TBR	⁶⁴ Cu	16	9.94	11.56	1.8	37.6	18.78	p < 0.001
		⁶⁸ Ga	16	78.37	98.97	6.7	243.9		
		⁶⁴ Cu	16	24.69	52.14	5	112.4		

*Comparison of imaging methods undertaken with two-sided Wilcoxon signed-rank test. Note: The lesions were averaged for each patient so that each patient contributes once to the summary statistics.

Table 2. Number of Lesions Detected on ⁶⁴Cu-SAR-bisPSMA vs ⁶⁸Ga-PSMA-11 per Reader per Participant Analysis

Reader	PET	Total # of Lesions Detected (all participants)	Mean Number of Lesions per Participant	Standard Deviation (SD)	Median Number of Lesions per Participant	Mean Difference	Median Difference	P-value*
Reader 1 (N=29)	⁶⁴ Cu	63	2.2	1.2	2	0.41	0.0	0.1005
	⁶⁸ Ga	51	1.8	1.3	1			
Reader 2 (N=17)	⁶⁴ Cu	34	2	1.4	1	0.52	0.0	0.0748
	⁶⁸ Ga	25	1.5	0.9	1			

200 MBq Cohort

Reader	PET	Mean	SD	Median	Mean Difference	Median Difference	P-value*	
Reader 1 (N=18)	⁶⁴ Cu	41	2.3	1.4	2	0.28	0.0	0.4427
	⁶⁸ Ga	36	2.0	1.4	1			
Reader 2 (N=14)	⁶⁴ Cu	31	2.2	1.5	2	0.64	0.0	0.0749
	⁶⁸ Ga	22	1.6	1.0	1			

*Comparison of imaging methods undertaken with two-sided Wilcoxon signed-rank test. Violation of normality assumption confirmed with Shapiro-Wilk Test for Normality (p<0.05). Only participants who had evaluable scans for both imaging modalities were included in the analysis. The difference between imaging modalities is the number of lesions detected with ⁶⁴Cu-SAR-bisPSMA PET/CT relative to ⁶⁸Ga-PSMA-11 PET/CT within a participant (ie. ⁶⁴Cu-SAR-bisPSMA PET/CT - ⁶⁸Ga-PSMA-11 PET/CT). A negative value indicates more lesions detected with ⁶⁸Ga-PSMA-11 PET/CT than ⁶⁴Cu-SAR-bisPSMA PET/CT. The trial was not powered to detect differences at an individual level.

Imaging Results:

- In the 200 MBq cohort, ⁶⁴Cu-SAR-bisPSMA and ⁶⁸Ga-PSMA-11 were able to detect primary PC in 100% and 77.8% of patients per Reader 1 and 85.7% and 83.3% of patients per Reader 2, respectively. The rest of the scans were indeterminate, no scan was deemed negative.
- For both readers, 200 MBq scans scored the highest in terms of image quality.
 - Reader 1 found 83%, 67% and 89% of scans to be acceptable at 100, 150 and 200 MBq respectively.
 - Reader 2 found 17%, 17% and 39% of scans to be acceptable at 100, 150 and 200 MBq respectively.
- Across all cohorts, both Readers identified more lesions with ⁶⁴Cu-SAR-bisPSMA than with ⁶⁸Ga-PSMA-11 PET/CT and more lesions were identified at the 200 MBq cohort (numerical difference which is not statistically significant; the trial was not powered to detect differences in the number of lesions) (Table 2, Figure 2). The interval between the ⁶⁸Ga-PSMA-11 and ⁶⁴Cu-SAR-bisPSMA scans was 2.50 days (median 20.5 days).
- Concordant lesions on ⁶⁴Cu-SAR-bisPSMA and ⁶⁸Ga-PSMA-11 PET/CT consistently showed higher SUV_{max}, SUV_{mean} and TBR with ⁶⁴Cu-SAR-bisPSMA compared to ⁶⁸Ga-PSMA-11 in all cohorts (statistically significant values for all parameters) (Table 1, Figure 3).

Figure 1. Comparison of ⁶⁴Cu-SAR-bisPSMA PET/CT and ⁶⁸Ga-PSMA-11 PET/CT by Reader in all cohorts

Figure 2. PET/CT demonstrated uptake of ⁶⁴Cu-SAR-bisPSMA at 200MBq (B) in a left pelvic lymph node according to both readers and PC was confirmed via histopathology. Readers did not detect uptake in pelvic lymph nodes on the ⁶⁸Ga-PSMA-11 PET/CT (A). Arrows highlight the additional node. Interval between serial imaging: 7 days

Figure 3. Intra-individual comparison of ⁶⁸Ga-PSMA-11 (A,C) and 200 MBq of ⁶⁴Cu-SAR-bisPSMA (B,D) PET/CT.

Figure 4. Interval between serial imaging: 8 days

Figure 5. Interval between serial imaging: 34 days

Conclusions

⁶⁴Cu-SAR-bisPSMA is shown to be safe and effective for detecting PSMA-expressing lesions

A 200 MBq dose of ⁶⁴Cu-SAR-bisPSMA was determined as optimal for future trials. ⁶⁴Cu-SAR-bisPSMA PET/CT showed a greater number of lesions and concordant lesions exhibited higher uptake on ⁶⁴Cu-SAR-bisPSMA compared to ⁶⁸Ga-PSMA-11 in all parameters in men with intermediate- to high-risk PC. Further trials to evaluate ⁶⁴Cu-SAR-bisPSMA as an imaging agent in patients with newly diagnosed and biochemical recurrence of PC using same-day and next-day imaging are underway.

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

CLARIFY is based on the data from the PROPELLER trial, which was used to design and initiate this pivotal Phase III trial for prostate cancer patients in the pre-prostatectomy/pre-definitive treatment setting.

This is a major milestone for Clarity as the Company moves forward with its first Phase III trial. The final study results from the CLARIFY trial are intended to provide sufficient evidence to support an application to the FDA for approval of ^{64}Cu SAR-bisPSMA as a new diagnostic imaging agent in prostate cancer.

CLARIFY is derived from “Positron Emission Tomography using ^{64}Cu SAR-bisPSMA in participants with high-risk prostate cancer prior to radical prostatectomy: A prospective, single-arm, multi-centre, blinded-review, Phase III diagnostic performance study.”

Clarity will be commencing the CLARIFY trial following a successful end of phase meeting with the US FDA and is expecting to begin patient recruitment in late 2023. The FDA is supportive of the trial in 383 participants with untreated, histopathology-confirmed PC, with high-risk features, who are proceeding to radical prostatectomy with pelvic lymph node dissection.

The aim of the Phase III trial is to assess the diagnostic performance of ^{64}Cu SAR-bisPSMA PET to detect PC within the pelvic lymph nodes. Evaluation will be across 2 imaging timepoints, Day 1 (day of administration) and Day 2 (approximately 24 hours post administration).



COBRA – a diagnostic ⁶⁴Cu SAR bisPSMA trial

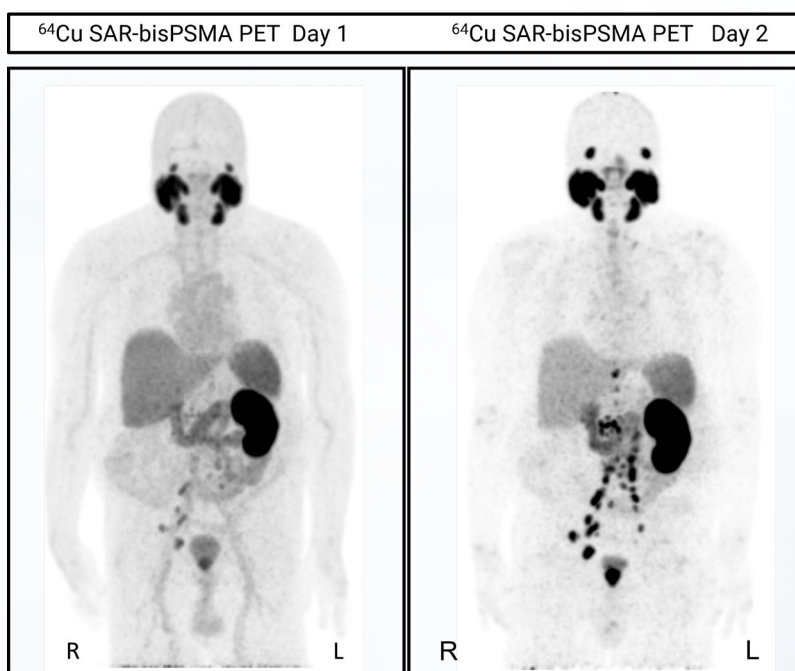
Clarity reached its recruitment target in the diagnostic ⁶⁴Cu SAR-bisPSMA trial, COBRA (NCT05249127)⁶, in February 2023. The patients from the COBRA trial are now in the follow up period. Central reads of the data from the trial are ongoing and data analysis is underway. Positive results from the COBRA trial will enable a Phase III trial in patients with BCR of their prostate cancer.

COBRA, which derives from “**C**opper-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.

The primary objectives of the trial are to investigate the ability of ⁶⁴Cu 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 (⁶⁴Cu SAR-bisPSMA) in 50 participants.

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 ⁶⁴Cu-SAR-bisPSMA (day 1). The image on the right shows the PET scan from the same patient imaged ~24 hours later (day 2). 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.

PRODUCT UPDATES

For the quarter ending
30 June, 2023

SAR-Bombesin

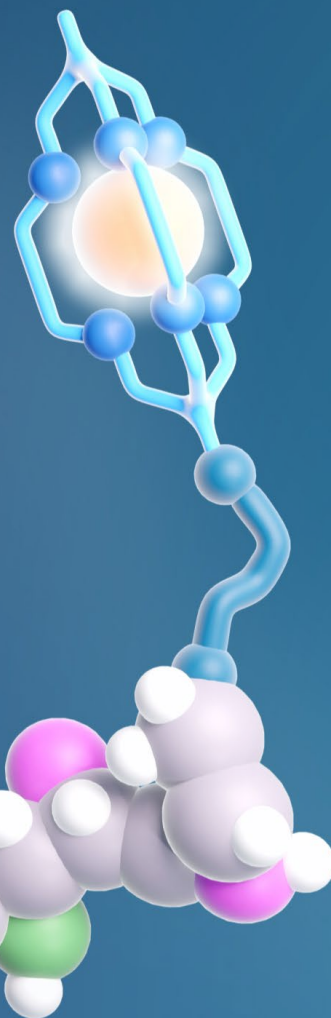
SAR-Bombesin is a next generation, highly targeted theranostic radiopharmaceutical.

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 prostate cancer and breast cancer. Like all Clarity products, the SAR-Bombesin product uses copper-64 (^{64}Cu) for imaging (^{64}Cu SAR-Bombesin) or copper-67 (^{67}Cu) for therapy (^{67}Cu SAR-Bombesin).

Approximately 20% of prostate cancers with BCR are PSMA-PET negative¹⁰⁻¹³ and approximately 25% of mCRPC patients have low or no uptake of a PSMA-targeting tracer¹⁴. 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.

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

- theranostic Phase I/IIa trial in the US (COMBAT)⁴ 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)⁵ in patients with BCR of prostate cancer.



COMBAT – theranostic $^{64}\text{Cu}/^{67}\text{Cu}$ SAR-Bombesin trial

Clarity commenced its $^{64}\text{Cu}/^{67}\text{Cu}$ SAR-Bombesin Phase I/II trial in mCRPC with the opening of the first site at BAMF Health, Inc. in Michigan.

COMBAT (Copper-67 SAR Bombesin in metastatic castrate resistant prostate cancer, NCT05633160)⁴ is a dose escalation and cohort expansion trial for up to 38 participants. The aim for the trial is to determine the safety and efficacy of ^{67}Cu SAR-Bombesin in participants with gastrin-releasing peptide receptor (GRPr) expressing mCRPC in patients who are ineligible for therapy with ^{177}Lu PSMA-617.

SAR-Bombesin is a pan-cancer product, and the open IND offers exciting opportunities for exploring new theranostic indications with this versatile product.



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

Clarity is actively recruiting in its US-based diagnostic ^{64}Cu SAR-Bombesin trial for patients with PSMA-negative prostate cancer, SABRE (NCT05407311)⁷.

SABRE, which derives from "Copper-64 SAR-Bombesin in Biochemical Recurrence of Prostate Cancer trial", is a multi-center, single arm, non-randomised, open label trial in 50 PSMA-negative patients with 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.

Subject to the outcome of the SABRE trial, Clarity is planning to launch a pivotal Phase III diagnostic trial for first product approvals in the US.

While the clinical development path for SAR-Bombesin is focused on prostate cancer with negative or low PSMA expression, there is a significant opportunity to expand its use into the broader group of prostate cancer patients who have both GRPr and PSMA expression on their cancers, as well as into other cancers that express GRPr.

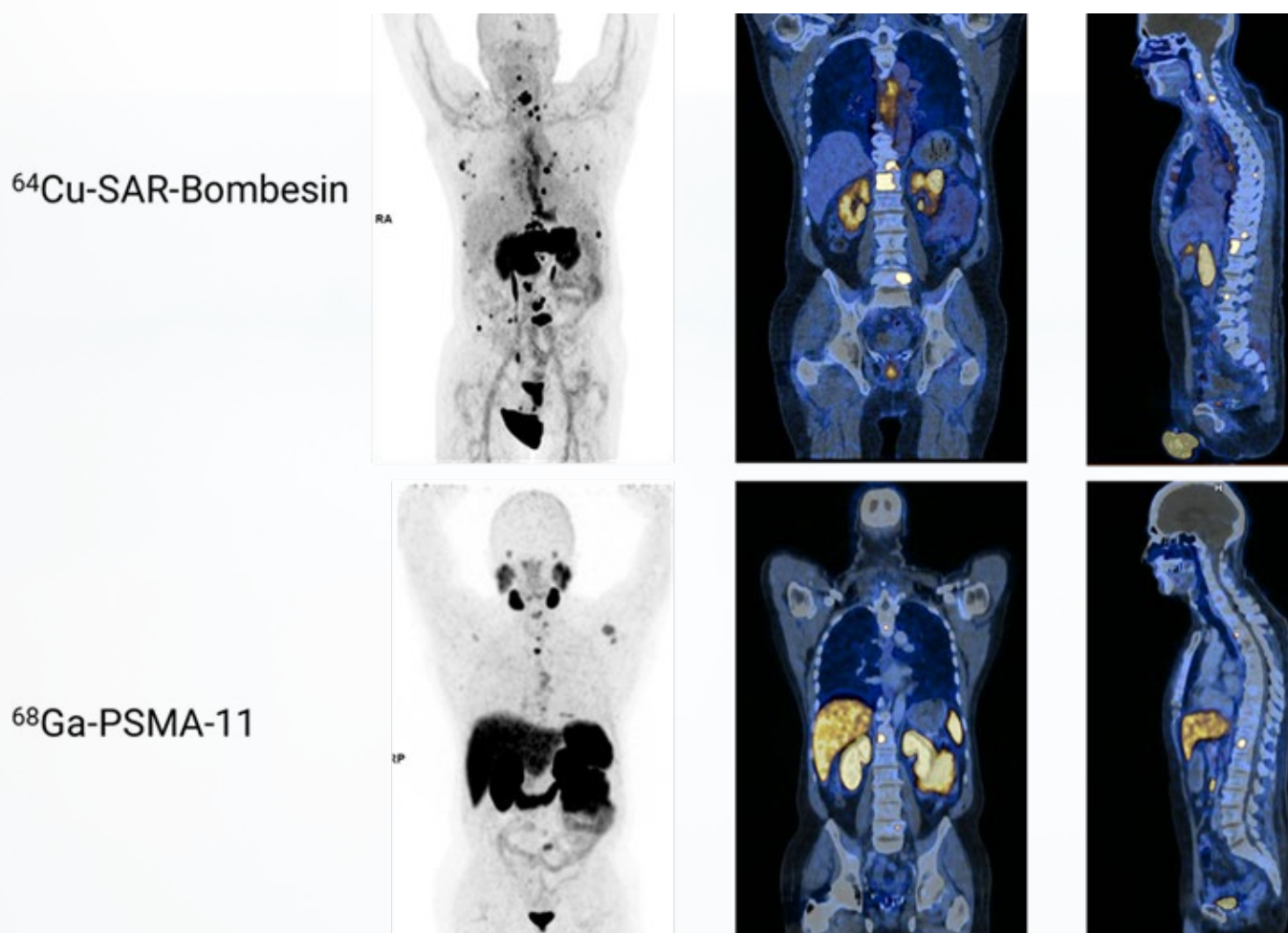
BOP – diagnostic ^{64}Cu SAR-Bombesin investigator-initiated trial

Recruitment was completed for the Phase II investigator initiated diagnostic trial, BOP (NCT05613842)⁵, evaluating Clarity's ^{64}Cu SAR-Bombesin product in 30 participants with prostate cancer. Study results have been accepted for poster presentation at the European Association of Nuclear Medicine (EANM) 2023 Congress.

BOP (Copper-64 SAR Bombesin in Prostate Specific Membrane Antigen (PSMA) negative Prostate Cancer) is led by Prof Louise Emmett at St Vincent's Hospital, Sydney, and is assessing the safety of ^{64}Cu SAR-Bombesin as well as looking at the diagnostic potential across two different groups of men:

1. Participants with BCR of their prostate cancer who have negative PSMA positron emission tomography (PET) imaging scans or low PSMA expression disease; and
2. Participants with mCRPC who are not suitable for PSMA therapy.

Figure 4. ^{64}Cu SAR-Bombesin and ^{68}Ga PSMA-11 images using PET (left) and PET/CT (middle/right) in a participant in the mCRPC cohort of the BOP trial. ^{64}Cu SAR-BBN scans (top) show discordant detection of disease and additional metastatic lesions compared to ^{68}Ga PSMA-11 (bottom).



TARGETED COPPER THERANOSTICS: THE GAME CHANGER FOR RADIOPHARMACEUTICALS

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

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

These differentiators are the reason TCTs are considered the next generation of radiopharmaceuticals as they enable Clarity to employ the big pharma model of centralised manufacturing of both diagnostic and therapeutic products under cGMP, something that the current generation of products is lacking.

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

Clarity continued to expand its manufacturing and supply chain footprint, creating additional capacity and flexibility to supply products to any ZIP-code in the US with new agreements and investments made in the quarter ending 30 June 2023.

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

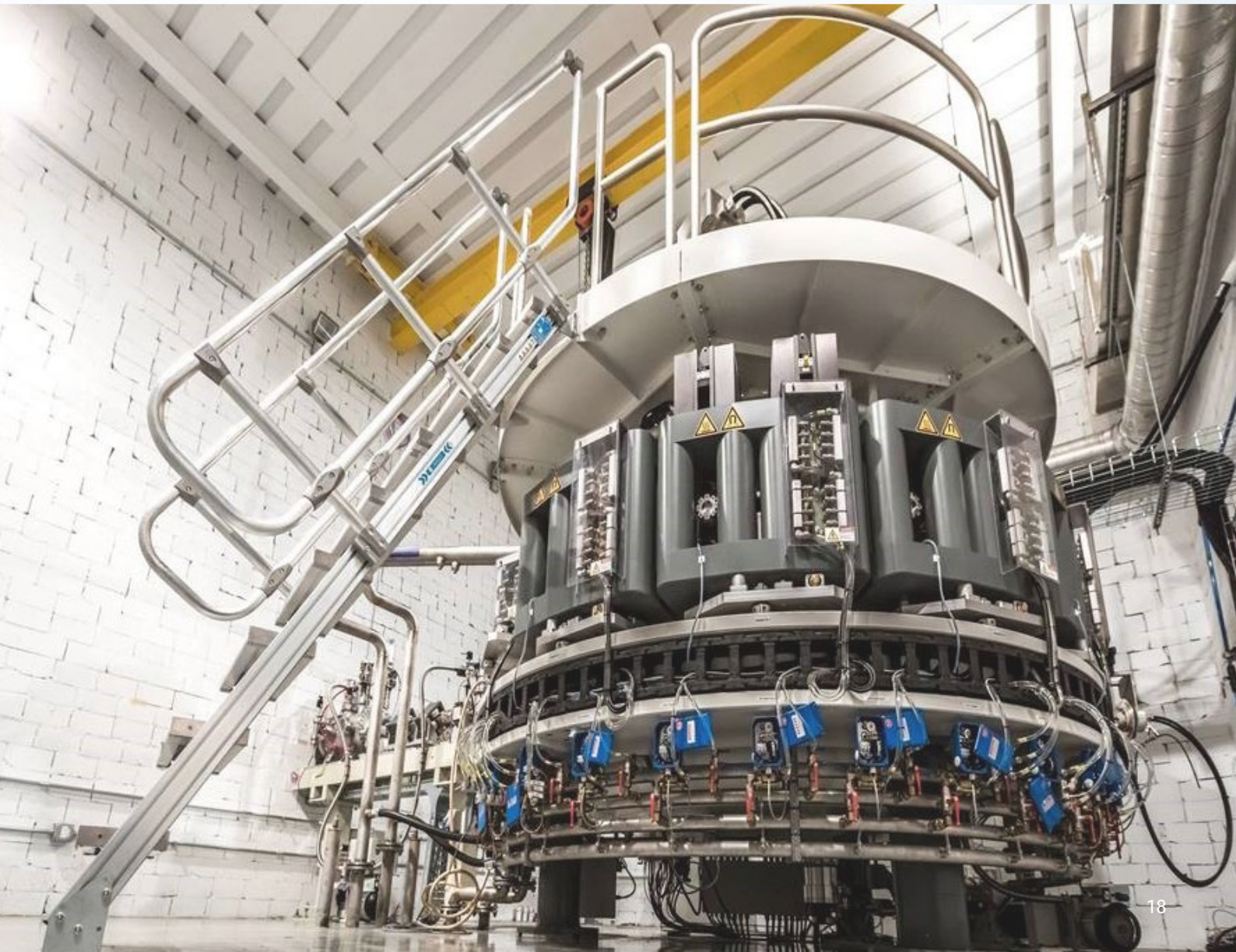
- Roby Thomas, MD, a medical oncologist, and hematologist at UPMC Hillman Cancer Center¹⁵

Copper-67

Copper-67 is a therapeutic isotope that is produced on electron accelerators, which are relatively inexpensive and infinitely scalable in all geographies of the world, including the US, Europe and Asia. Other commonly used therapeutic isotopes are produced on a small number of aging nuclear reactors worldwide. Outages at any of these reactors often cause shortages of therapeutic isotopes worldwide.

In May 2021, Clarity entered into a Master Supply Agreement to produce the therapeutic radioisotope Cu-67 with NorthStar, a global innovator in the development, production and commercialisation of radiopharmaceuticals used for therapeutic applications and medical imaging. Under the agreement, NorthStar will supply Cu-67 exclusively to Clarity to support Clarity's TCT programs, with three active theranostic trials currently underway in the US.

NorthStar is now routinely producing high activity, high specific activity and high purity Cu-67 at its state-of-the-art production accelerator facility in Wisconsin, US. The Cu-67 from Northstar has now been used as part of Clarity's clinical programs in the US. NorthStar is the first operational commercial-scale supplier of this important therapeutic radioisotope. Their large-scale production of Cu-67 uses a highly efficient, environmentally preferable electron accelerator technology.



Copper-64

Copper-64 is a diagnostic imaging isotope that facilitates a significantly longer product shelf-life than most commonly used radio-diagnostics on the market, allowing for central manufacture and regional distribution, potentially reaching more treatment centres and patients.

Copper-64 is produced on cyclotrons with a single cyclotron able to supply the entire Phase III diagnostic clinical program.

In preparation for the upcoming Phase III programs, Clarity has entered into a Master Service Agreement and a Clinical Supply Agreement covering the ^{64}Cu SAR-bisPSMA product with PETNET Solutions Inc, a Siemens Healthineers Company – a global PET radiopharmaceutical network and the leading manufacturer of radiopharmaceuticals for PET imaging in the US. Under the Clinical Supply Agreement, PETNET Solutions will provide a dependable and scalable supply of ^{64}Cu SAR-bisPSMA, allowing two stand-alone diagnostic Phase III clinical trials to proceed at a large number of clinical sites across the US.

The longer shelf-life of ^{64}Cu SAR-bisPSMA (up to 48 hours) enables centralised manufacture and supply for Clarity's both planned Phase III trials, as opposed to the first-generation PSMA PET diagnostics that require an expensive and extensive network of cyclotrons, radioisotope generators and radiopharmacies due to the shorter half-life of gallium-68 and fluorine-18.

US Center of Excellence for TCTs

To advance research and development of TCTs close to a source of copper-67 production, Clarity established a Center of Excellence at the Idaho Accelerator Center (IAC), a research facility operated by Idaho State University (ISU).

Clarity has worked with the IAC and its Director, Jon Stoner, for over 7 years and their role in bringing copper-67 based therapies to patients cannot be overstated.

The Center of Excellence will enable Clarity to efficiently execute several strategically important projects, support commercial readiness of products currently in clinical development and enable the expansion of TCTs as a platform uniquely positioned to take the radiopharmaceutical sector into large global markets.



TEAM AND COLLABORATORS

Clarity's extraordinary team is at the heart of the Company's success and is what drives the Company forward. With the core mission of improving treatment outcomes for children and adults with cancer, Clarity continues fostering its high-performance, diverse and inclusive environment, attracting some of the best talent in the industry.

This quarter, Clarity was joined by Dr Othon Gervasio as a Senior Medical Director, and Bryce Kanter, as a Senior Director of Commercial Development.



Dr Othon Gervasio

Dr Gervasio is an experienced leader with over 20 years in Research and Development (academic and clinical research) as well as Medical Affairs. Dr Gervasio joins us from Novartis, where he developed his extensive expertise in oncology product launch, medical affairs strategy, as well as pre- and post-market authorisation.

Dr Gervasio's addition to the team will be instrumental in reaching Clarity's ultimate goal of developing next-generation radiopharmaceuticals that will improve treatment outcomes for children and adults with cancer.



Bryce Kanter

Bryce Kanter is an experienced US commercial leader with over 10 years of experience in the biotech and pharmaceutical industry. Bryce also has an extensive background in the prostate cancer market and the radiopharmaceutical industry, and he joins Clarity from Novartis, where he was the marketing lead for the launches of Pluvicto™ and Locametz®. At Novartis, Bryce was responsible for developing the launch strategies for both brands and leading the launch cross-functional team from planning through execution. Bryce holds an MBA in Marketing and MS in Biomedical Sciences from Rutgers University.

FINANCIALS

Clarity's cash balance was \$65.0 million as at 30 June 2023.

Operating cash outflows for the June quarter were \$9.5 million. Net operating cash outflows however were only \$2.1 million, inclusive of the RDTI received of \$6.7 million and interest income received of \$0.7 million. The overall spend in the quarter of \$9.5 million, is in line with the previous quarterly outflows and reflects the Company's ongoing clinical programs referred to in this Quarterly Activities Report.

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 30 June 2023 \$ Million	% of Total Funds
Pre-Clinical	\$2.7	2.5%	\$2.7	4.7%
Clinical	\$84.0	76.6%	\$34.9	61.4%
Regulatory	\$5.7	5.2%	\$1.6	2.8%
Patents	\$1.4	1.3%	\$1.9	3.3%
Corporate	\$10.4	9.5%	\$9.2	16.2%
Costs associated with the Offer	\$5.4	4.9%	\$6.6	11.6%
Total uses	\$109.6	100.0%	\$56.9	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 30 June 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 \$366,798 for the quarter. This amount includes director fees and salaries paid in the June quarter.

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

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About Clarity Pharmaceuticals

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

claritypharmaceuticals.com/



Appendix 4C

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

Name of entity

Clarity Pharmaceuticals Ltd

ABN

36 143 005 341

Quarter ended ("current quarter")

June 2023

Consolidated statement of cash flows	Current quarter	Year to date (12 months)
	\$A'000	\$A'000
1. Cash flows from operating activities		
1.1 Receipts from customers	-	-
1.2 Payments for		
(a) research and development	(8,401)	(30,151)
(b) product manufacturing and operating costs	-	-
(c) advertising and marketing	(6)	(79)
(d) leased assets	-	-
(e) staff costs	(415)	(2,336)
(f) administration and corporate costs	(627)	(3,054)
1.3 Dividends received (see note 3)	-	-
1.4 Interest received	660	1,533
1.5 Interest and other costs of finance paid	-	-
1.6 Income taxes paid	(45)	(103)
1.7 Government grants and tax incentives	6,727	6,727
1.8 Other (provide details if material)	-	-
1.9 Net cash from / (used in) operating activities	(2,107)	(27,463)
2. Cash flows from investing activities		
2.1 Payments to acquire or for:		
(g) entities	-	-
(h) businesses	-	-
(i) property, plant and equipment	-	(48)
(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	-	(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	61	244
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(1)	(9)
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	60	235
4. Net increase / (decrease) in cash and cash equivalents for the period			
4.1	Cash and cash equivalents at beginning of period	66,743	92,336
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(2,107)	(27,463)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	-	(48)

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

Consolidated statement of cash flows		Current quarter	Year to date (12 months)
		\$A'000	\$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	60	235
4.5	Effect of movement in exchange rates on cash held	319	(45)
4.6	Cash and cash equivalents at end of period	65,015	65,015

5.	Reconciliation of cash and cash equivalents	Current quarter	Previous quarter
	at the end of the quarter (as shown in the consolidated statement of cash flows) to the related items in the accounts	\$A'000	\$A'000
5.1	Bank balances	31,213	66,743
5.2	Call deposits *	33,802	-
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)	65,015	66,743

* 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	367
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.

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

7. Financing facilities	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
<i>Note: the term "facility" includes all forms of financing arrangements available to the entity.</i>		
<i>Add notes as necessary for an understanding of the sources of finance available to the entity.</i>		
7.1 Loan facilities	-	-
7.2 Credit standby arrangements	-	-
7.3 Other (please specify)	-	-
7.4 Total financing facilities	-	-
7.5 Unused financing facilities available at quarter end		-
7.6 Include in the box below a description of each facility above, including the lender, interest rate, maturity date and whether it is secured or unsecured. If any additional financing facilities have been entered into or are proposed to be entered into after quarter end, include a note providing details of those facilities as well.		

8. Estimated cash available for future operating activities	\$A'000
8.1 Net cash from / (used in) operating activities (item 1.9)	(2,107)
8.2 Cash and cash equivalents at quarter end (item 4.6)	65,015
8.3 Unused finance facilities available at quarter end (item 7.5)	-
8.4 Total available funding (item 8.2 + item 8.3)	65,015
8.5 Estimated quarters of funding available (item 8.4 divided by item 8.1)	31
<i>Note: if the entity has reported positive net operating cash flows in item 1.9, answer item 8.5 as "N/A". Otherwise, a figure for the estimated quarters of funding available must be included in item 8.5.</i>	
8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:	
8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?	
Answer:	
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:	
<i>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.</i>	

Compliance statement

- 1 This statement has been prepared in accordance with accounting standards and policies which comply with Listing Rule 19.11A.
- 2 This statement gives a true and fair view of the matters disclosed.

Date: 31 July 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.