

# 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 <sup>64</sup>Cu SAR-bisPSMA diagnostic in prostate cancer in late 2023, following a successful end of phase meeting with the US Food and Drug Administration (FDA).

#### PROPELLER<sup>1</sup>

Results from Clarity's Phase I diagnostic <sup>64</sup>Cu 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 <sup>64</sup>Cu-SAR-bisPSMA was safe and well tolerated. <sup>64</sup>Cu-SAR-bisPSMA allowed brighter visualisation of cancerous lesions and detected more lesions than standard of care diagnostic imaging (using <sup>68</sup>Ga-PSMA-11; visualisation of lesions using Standardised Uptake Value).

#### SECuRE<sup>2</sup>

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

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

#### <sup>67</sup>Cu SAR-bisPSMA

<sup>67</sup>Cu SAR-bisPSMA has been requested by clinicians under the US FDA EAP with early data indicating positive effects of the lowest 4GBq dose of <sup>67</sup>Cu 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 <sup>64</sup>Cu SAR-bisPSMA under the Australian Therapeutic Goods Administration (TGA) SAS. <sup>64</sup>Cu SAR-bisPSMA PET/CT scans detected lesions in all four patients, with delayed imaging (24hrs post-dose), showing higher uptake of <sup>64</sup>Cu SAR-bisPSMA. Initial data in a disease other than prostate cancer (angiolipoma) has also been published as "Image of The Month" in the European Journal of Nuclear Medicine and Molecular Imaging showing superiority of <sup>64</sup>Cu SAR-bisPSMA compared to <sup>18</sup>F-DCFPyL due to late time point imaging.<sup>3</sup>



# HIGHLIGHTS OF THE QUARTER CONT.

Ending 30 June 2023

#### COMBAT<sup>4</sup>

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

#### BOP<sup>5</sup>

Recruitment completed for the Phase II investigator initiated diagnostic trial, evaluating Clarity's <sup>64</sup>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.

#### Copper-67 supply

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

#### <sup>64</sup>Cu SAR-bisPSMA supply

Clarity expanded supply of <sup>64</sup>Cu 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 firstgeneration radiopharmaceuticals and focus on "best-inclass" 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 PSMAexpressing 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 firstgeneration 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 <sup>64</sup>Cu 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 <sup>64</sup>Cu 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 <sup>64</sup>Cu 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 <sup>64</sup>Cu 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 <sup>67</sup>Cu 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 <sup>67</sup>Cu 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 4GBg 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.

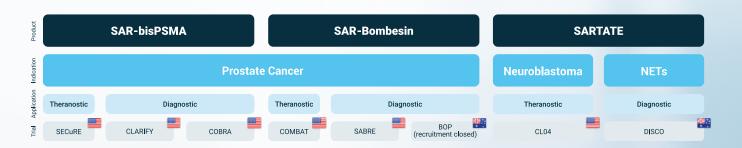
## **SARTATE**

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.



# CLINICAL DEVELOPMENT OVERVIEW

#### **Theranostic Trials**

#### **Diagnostic Trials**

#### SAR-bisPSMA

SECURE – Phase I/IIa theranostic trial for identification and treatment of PSMA-expressing metastatic castrate-resistant prostate cancer (mCRPC) using 64Cu/67Cu SAR-bisPSMA in the US (NCT04868604)<sup>2</sup>

PROPELLER – Phase I Positron Emission Tomography (PET) imaging trial of participants with confirmed prostate cancer using <sup>64</sup>Cu SAR-bisPSMA in Australia (NCT04839367)<sup>1</sup>

**CLARIFY** - Registrational Phase III PET imaging trial of participants with high-risk prostate cancer prior to radical prostatectomy using <sup>64</sup>Cu SAR-bisPSMA

COBRA – Phase I/II PET imaging trial of participants with biochemical recurrence (BCR) of prostate cancer following definitive therapy using <sup>64</sup>Cu SAR-bisPSMA in the US (NCT05249127)<sup>6</sup>

#### SAR-Bombesin

COMBAT – Phase I/IIa theranostic trial for identification and treatment of mCRPC that is expressing the Gastrin-Releasing Peptide receptor (GRPr), in participants who are ineligible for <sup>177</sup>Lu-PSMA-617, using <sup>64</sup>Cu/<sup>67</sup>Cu SAR-Bombesin (NCT05633160)<sup>4</sup>

 $\begin{tabular}{ll} SABRE - Phase II PET imaging trial of participants with PSMA-negative BCR of prostate cancer using $^{64}$Cu SAR-Bombesin in the US (NCT05407311)$^7 \\ \end{tabular}$ 

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 <sup>64</sup>Cu SAR-Bombesin led by Prof Louise Emmett at St Vincent's Hospital Sydney (NCT05613842)<sup>5</sup>

#### SARTATE

CL04 – Phase I/IIa theranostic trial in paediatric participants with high-risk neuroblastoma using <sup>64</sup>Cu/<sup>67</sup>Cu SARTATE in the US (NCT04023331)<sup>8</sup> DISCO – Phase II PET imaging trial of participants with known or suspected Neuroendocrine Tumours (NETs) using <sup>64</sup>Cu SARTATE in Australia (NCT04438304)<sup>9</sup>

# 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.

#### Therapy <sup>67</sup>Cu SAR-bisPSMA

product for prostate cancer patients

#### Therapy <sup>67</sup>Cu SAR-BBN

product for prostate cancer patients

## Diagnostic 64Cu SAR-bisPSMA

product for prostate cancer patients

#### Diagnostic 64Cu SAR-BBN

product for prostate cancer patients

## Theranostic 64Cu/67Cu SARTATE

product for patients with neuroblastoma

# PRODUCT UPDATES

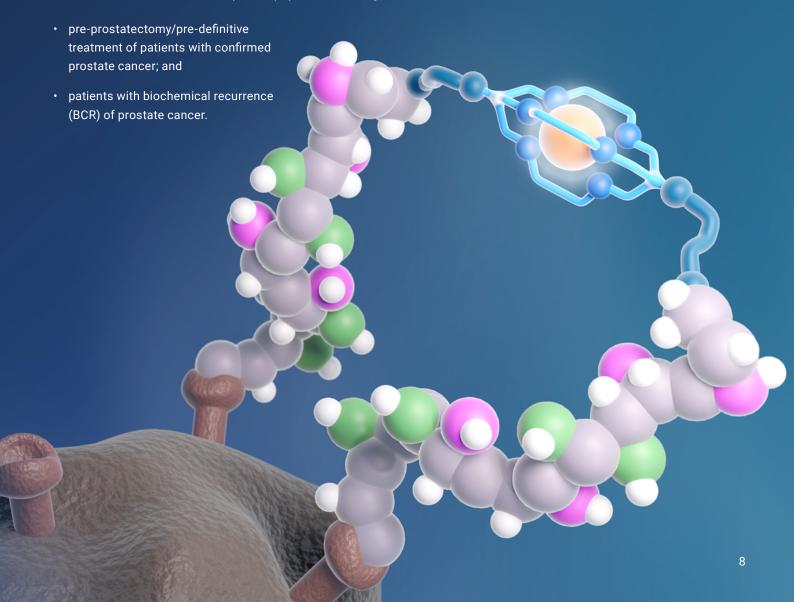
For the quarter ending 30 June, 2023

### 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 (<sup>64</sup>Cu) for imaging (<sup>64</sup>Cu SAR-bisPSMA) or copper-67 (<sup>67</sup>Cu) for therapy (<sup>67</sup>Cu SAR-bisPSMA).

In addition to the therapy program in metastatic castrate resistant prostate cancer (mCRPC) with <sup>67</sup>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 <sup>64</sup>Cu SAR-bisPSMA:





# SECuRE – a theranostic 64Cu/67Cu SAR-bisPSMA trial

The theranostic prostate cancer trial, SECuRE (NCT04868604)<sup>2</sup>, is evaluating <sup>64</sup>Cu/<sup>67</sup>Cu 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 <sup>67</sup>Cu SAR-bisPSMA and advanced to cohort 2, which is now fully allocated with all participants having received an 8GBq dose of <sup>67</sup>Cu 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 <sup>67</sup>Cu 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 "SystEmic Cu the Ranostics in prostat 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 <sup>64</sup>Cu-SAR-bisPSMA and <sup>67</sup>Cu SAR-bisPSMA as well as the efficacy of <sup>67</sup>Cu SAR-bisPSMA as a therapy.

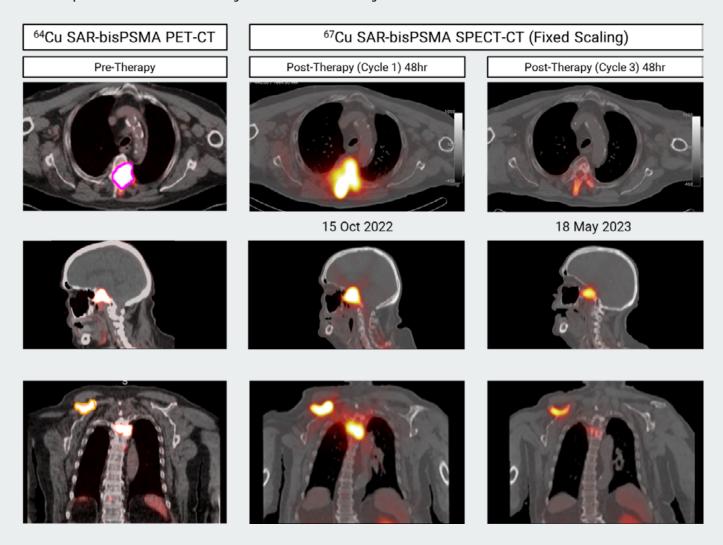
The initial imaging stage of the trial, which is now completed, utilised the copper-64 based imaging product to determine where the product went in the body (biodistribution) and what dose of the product was received (dosimetry) in the participants. The subsequent dosimetry phase with <sup>67</sup>Cu SAR-bisPSMA commenced the dose escalation phase of the study. In this stage, each subsequent cohort of participants will receive an increased dose of the therapeutic drug until the optimal therapeutic dose is determined (Maximum Tolerated Dose). In cohort 1, participants received a single administration of 4GBq of <sup>67</sup>Cu SAR-bisPSMA and in cohort 2 the dose was increased to 8GBq.

Outside of the trial, therapy cycles of <sup>67</sup>Cu 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 <sup>67</sup>Cu SAR-bisPSMA in a patient in the EAP. PET-CT images using <sup>64</sup>Cu 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 <sup>67</sup>Cu 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.



# **PR公PELLER**

# PROPELLER – a diagnostic <sup>64</sup>Cu SAR-bisPSMA trial

Clarity reported data from the diagnostic Phase I trial of <sup>64</sup>Cu SAR-bisPSMA in prostate cancer, PROPELLER (NCT04839367)<sup>1</sup>, 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 <sup>64</sup>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.

# PR必PELLER

### PROPELLER - cont.

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

**PROPELLER** derives from "PositRO 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 <sup>64</sup>Cu-SAR-bisPSMA was safe and well tolerated. <sup>64</sup>Cu-SAR-bisPSMA allowed brighter visualisation of cancerous lesions and detected more lesions than standard of care diagnostic imaging (using <sup>68</sup>Ga-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

<sup>1</sup> Clarity Pharmaceuticals, Sydney, Australia; <sup>2</sup> Nepean Hospital, Sydney, Australia; <sup>2</sup> GENESISCARE. Perth, Australia; <sup>4</sup> St. Vincent's Hospital, Sydney, Australia



# CLARIFY – diagnostic Phase III registrational <sup>64</sup>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 preprostatectomy/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 <sup>64</sup>Cu SAR-bisPSMA as a new diagnostic imaging agent in prostate cancer.

**CLARIFY** is derived from "Positron Emission Tomography using <sup>64</sup>**C**u SAR-bisPSMA in participants with high-risk prostate cancer prior to radical prostatectomy: A prospective, sing<u>l</u>e-<u>ar</u>m, mult<u>i</u>-centre, blinded-review, Phase III diagnostic per<u>f</u>ormance stud<u>y</u>."

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 <sup>64</sup>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 <sup>64</sup>Cu SAR bisPSMA trial

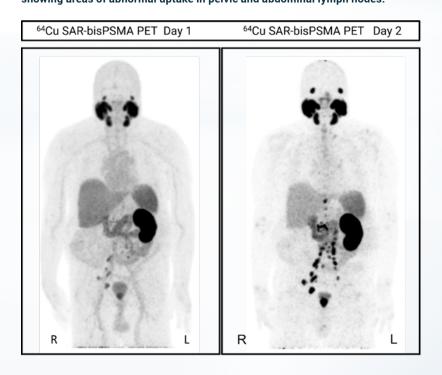
Clarity reached its recruitment target in the diagnostic <sup>64</sup>Cu SAR-bisPSMA trial, COBRA (NCT05249127)<sup>6</sup>, in February 2023. The patients from the COBRA trial are now in the follow up period. Central reads of the data from the trial are ongoing and data analysis is underway. Positive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

COBRA, which derives from "COpper-64 SAR-bisPSMA in Biochemically Recurrent prostAte 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 <sup>64</sup>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 (<sup>64</sup>Cu 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 (64Cu) for imaging (64Cu SAR-Bombesin) or copper-67 (67Cu) for therapy (67Cu SAR-Bombesin).

Approximately 20% of prostate cancers with BCR are PSMA-PET negative<sup>10-13</sup> and approximately 25% of mCRPC patients have low or no uptake of a PSMA-targeting tracer<sup>14</sup>. These patients are therefore unlikely to show meaningful uptake of PSMA-targeted products, such as <sup>68</sup>Ga-PSMA-11 for imaging or <sup>177</sup>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)<sup>4</sup> in patients with mCRPC;
- diagnostic Phase II trial in the US (SABRE)<sup>7</sup> in patients with BCR of prostate cancer;
   and
- investigator-initiated Phase II trial in Australia (BOP)<sup>5</sup> in patients with BCR of prostate cancer.



## COMBAT - theranostic 64Cu/67Cu SAR-Bombesin trial

Clarity commenced its <sup>64</sup>Cu/<sup>67</sup>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 Bomb esin in metastatic castrate resistant prostate cancer, NCT05633160)<sup>4</sup> 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 <sup>67</sup>Cu SAR-Bombesin in participants with gastrin-releasing peptide receptor (GRPr) expressing mCRPC in patients who are ineligible for therapy with <sup>177</sup>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 64Cu SAR-Bombesin trial

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

**SABRE**, which derives from "Copper-64 <u>SAR-Bombesin in Biochemical RE</u>currence of Prostate Cancer trial", is a multicenter, 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 <sup>64</sup>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.

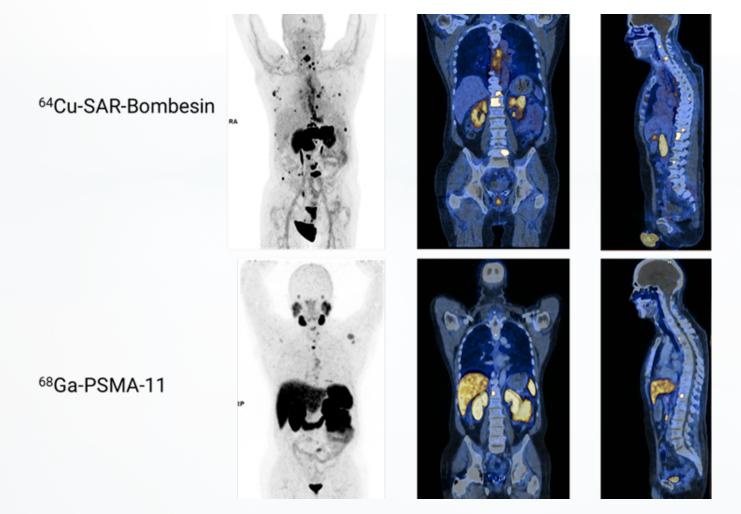
# **BOP – diagnostic <sup>64</sup>Cu SAR-Bombesin** investigator-initiated trial

Recruitment was completed for the Phase II investigator initiated diagnostic trial, BOP (NCT05613842)<sup>5</sup>, evaluating Clarity's <sup>64</sup>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 **Bo**mbesin in **P**rostate 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 <sup>64</sup>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. <sup>64</sup>Cu SAR-Bombesin and <sup>68</sup>Ga PSMA-11 images using PET (left) and PET/CT (middle/right) in a participant in the mCRPC cohort of the BOP trial. <sup>64</sup>Cu SAR-BBN scans (top) show discordant detection of disease and additional metastatic lesions compared to <sup>68</sup>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 theraputic 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 Center<sup>15</sup>

# 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 therapeutic 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 <sup>64</sup>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 <sup>64</sup>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 <sup>64</sup>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<sup>™</sup> 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%

<sup>\*</sup> 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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# For more information, please contact:

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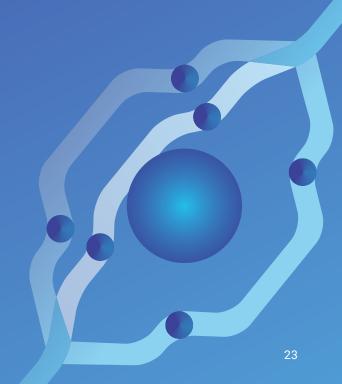
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# **About Clarity Pharmaceuticals**

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

36 143 005 341

Clarity Pharmaceuticals Ltd	
ABN	Quarter ended ("current quarter")

June 2023

Con	solidated 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	(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	-	-
	(I) other non-current assets	-	-

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Page 1

Cons	solidated 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)

ASX Listing Rules Appendix 4C (17/07/20) + See chapter 19 of the ASX Listing Rules for defined terms.

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (12 months) \$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 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	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

<sup>\*</sup> 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: I	Payments in 6.1 include director fees and salaries.	\

7.	Financing facilities  Note: the term "facility' includes all forms of financing arrangements available to the entity.  Add notes as necessary for an understanding of the sources of finance available to the entity.	Total facility amount at quarter end \$A'000	Amount drawn at quarter end \$A'000
7.1	Loan facilities	-	-
7.2	Credit standby arrangements	-	-
7.3	Other (please specify)	-	-
7.4	Total financing facilities	-	-
7.5	Unused financing facilities available at qu	arter end	-
7.6	Include in the box below a description of eac rate, maturity date and whether it is secured facilities have been entered into or are propo- include a note providing details of those facil	or unsecured. If any add osed to be entered into af	itional financing
***************************************			

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
	Note: if the entity has reported positive net operating cash flows in item 1.9, answer item figure for the estimated quarters of funding available must be included in item 8.5.	8.5 as "N/A". Otherwise, a

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

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**

- 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.

	31 July 2023
,	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".
- 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.