

# QUARTERLY ACTIVITY REPORT

SYDNEY, AUSTRALIA 31 JANUARY 2023

Nº.

# HIGHLIGHTS OF THE QUARTER

Ending 31 December 2022

### **Cash position**

remains strong with a balance of \$75.9 million as at 31 December, 2022. Clarity's estimated R&D tax incentive claim for FY22 is approximately \$6 million. Together, with the current cash position, this provides an estimated \$82 million to fund the existing trial pipeline. Operating cash outflows for the December quarter were \$8.3 million.

### PROPELLER

Positive top-line results from Clarity's Phase I diagnostic <sup>64</sup>Cu SAR-bisPSMA prostate cancer trial, which met all primary and secondary objectives.

### BOP

Fifty percent recruitment milestone in the Phase II diagnostic <sup>64</sup>Cu SAR-Bombesin investigator-initiated trial for patients with prostate cancer, with 15 out of 30 participants enrolled and imaged.

### COBRA

Fifty percent recruitment milestone in the US-based Phase I/II diagnostic <sup>64</sup>Cu SAR-bisPSMA trial for patients with biochemical recurrence of prostate cancer following definitive therapy, with 25 out of 50 participants enrolled and imaged.

#### COMBAT

Approval of the Investigational New Drug application by the United States Food and Drug Administration to evaluate Clarity's <sup>64</sup>Cu/<sup>67</sup>Cu SAR-Bombesin product for identification and treatment of gastrin releasing peptide receptor expressing metastatic castrate-resistant prostate cancer in patients who are ineligible for therapy with <sup>177</sup>Lu-PSMA-617 in a Phase I/IIa US-based trial.

### SECuRE

First patient recruited and treated in the therapeutic phase of the US-based theranostic clinical trial investigating <sup>64</sup>Cu/<sup>67</sup>Cu SARbisPSMA in patients with PSMApositive metastatic castrateresistant prostate cancer.

### SABRE

First participant imaged in the US-based diagnostic <sup>64</sup>Cu SAR-Bombesin trial for patients with PSMA-negative prostate cancer. **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 quarter ending 31 December 2022.



Executive Chairman, Dr Alan Taylor said: "This second quarter of FY23 has concluded an extraordinary calendar year for Clarity, full of important achievements and exceptional headway in the development of our Targeted Copper Theranostics. With a cash balance of \$75.9 million at 31 December, 2022, or over \$80 million when taking into consideration an estimated R&D tax incentive claim of approximately \$6 million for FY22, we remain well financed to continue progressing our comprehensive pipeline of products and expanding our logistics and manufacturing footprint to support the clinical programs.

"Although the background of the global capital markets downturn remains a concern, Clarity continues to focus on its core mission, advancing the pipeline of Targeted Copper Theranostics with seven clinical trials actively progressing at the end of the quarter. Our strategy to position Clarity's products for first approvals in the US is well on track. We continue to differentiate our company from the many others in global biotechnology as we relentlessly generate meaningful clinical data to develop products for the patients that need us most and move these products towards approval in large markets globally." During the quarter, Clarity made significant progress developing its **SAR-bisPSMA** and **SAR-Bombesin** products in prostate cancer indications. The Company received its **fifth successful Investigational New Drug** (IND) application with the United States Food and Drug Administration (US FDA), opening up therapeutic applications for SAR-Bombesin in the theranostic Phase I/IIa COMBAT trial (<u>NCT05633160</u>)<sup>1</sup>. A total of **six products with both diagnostic and therapeutic applications** for SAR-Bombesin, SAR-bisPSMA and SARTATE are now under IND for US clinical trials.

Clarity's diagnostic Phase II trial with <sup>64</sup>Cu SAR-Bombesin in biochemical recurrence (BCR) of prostate cancer that is PSMA-negative, SABRE (<u>NCT05407311</u>)<sup>2</sup>, has seen its first participants imaged in the US in October 2022 and recruitment has continued to progress well through the quarter. A diagnostic investigator-initiated trial (IIT) with <sup>64</sup>Cu SAR-Bombesin led by Prof Louise Emmett at St Vincent's Hospital, Sydney, has also been recruiting quickly with fifty percent of participants enrolled and imaged in November 2022.

In addition to the numerous milestones achieved in the development of the SAR-Bombesin products, Clarity continued to deliver significant momentum in the development of its SAR-bisPSMA products. In October 2022, the first patient was treated in the therapeutic phase of the Phase I/IIa theranostic trial, SECuRE (NCT04868604)<sup>3</sup>, investigating <sup>64</sup>Cu/<sup>67</sup>Cu SAR-bisPSMA in metastatic castrate-resistant prostate cancer (mCRPC).

One of the most exciting milestones achieved in the last quarter is the release of the positive preliminary results from the PROPELLER (<u>NCT04839367</u>)<sup>4</sup> trial, a diagnostic Phase I trial of <sup>64</sup>Cu SAR-bisPSMA in participants with confirmed prostate cancer prior to undergoing radical prostatectomy. The trial met all primary and secondary objectives and was found to be safe, well tolerated and effective in detecting primary prostate cancer. Based on these positive results, Clarity has already commenced preparations for the definitive Phase III clinical trial scheduled to commence in 2023.

Clarity's US-based diagnostic trial of <sup>64</sup>Cu SAR-bisPSMA in participants with biochemical recurrence (BCR) of prostate cancer, COBRA (<u>NCT05249127</u>)<sup>5</sup> reached the fifty percent recruitment milestone in October 2022, with 25 out of 50 participants enrolled and imaged. Clarity expects to finish recruitment into the COBRA trial in the first quarter of CY2023 and, subject to the data generated, follow up with a definitive Phase III trial in this patient population.

### Dr Taylor said:

"We are very pleased with Clarity's clinical, preclinical, regulatory and operational progress and look forward to continuing to build on Clarity's story of success in this new year. Leveraging our strengths, being our team and collaborators, supportive and long term shareholder base and proprietary platform technology, we will continue to grow, excel and celebrate our achievements with our stakeholders as we move closer towards our ultimate goal of developing nextgeneration radiopharmaceuticals to improve treatment outcomes for children and adults with cancer."

# CLINICAL DEVELOPMENT OVERVIEW

As of 31 December 2022, Clarity's pipeline included the following cancer indications, products and clinical trials:

Product	5	SAR-bisPSMA SAR-Bombesin		SARTATE		
Indication	Prostate cancer		Neuroblastoma	NETs		
Application	Theranostic	Diagnostic	Theranostic	Diagnostic	Theranostic	Diagnostic
Trial	SECURE	PROPELLER COBRA X-Calibur	СОМВАТ	SABRE BOP	CL04	DISCO

At the end of December 2022, the company was actively progressing seven clinical trials with its three key products, SARTATE, SAR-bisPSMA and SAR-Bombesin. The trials are being conducted in three theranostic (therapeutic and diagnostic) and four diagnostic applications. In addition to these seven trials, sponsored by Clarity, there are also two investigator-initiated trials (IITs) with Clarity's products.

# **SARTATE**<sup>™</sup>

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

# SAR-bisPSMA

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

# **SAR-Bombesin**

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

# CLINICAL DEVELOPMENT OVERVIEW

# SARTATE™

### Theranostic

 CL04 – Phase I/IIa theranostic trial in paediatric patients with high-risk neuroblastoma using <sup>64</sup>Cu/<sup>67</sup>Cu SARTATE<sup>™</sup> in the US (NCT04023331)<sup>6</sup>

### Diagnostic

 DISCO – Phase II PET imaging trial of participants with known or suspected Neuroendocrine Tumours (NETs) using
<sup>64</sup>Cu SARTATE<sup>™</sup> in Australia (<u>NCT04438304</u>)<sup>7</sup>

# SAR-bisPSMA

### Theranostic

**SECuRE –** Phase I/IIa theranostic trial for identification and treatment of PSMA-expressing metastatic castrate-resistant prostate cancer (mCRPC) using <sup>64</sup>Cu/<sup>67</sup>Cu SAR-bisPSMA in the US (<u>NCT04868604</u>)<sup>3</sup>

### Diagnostic

- 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>4</sup>
- 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>5</sup>
- X-Calibur Investigator Initiated Phase I/II PET imaging trial of participants with prostate cancer using <sup>64</sup>Cu SAR-bisPSMA led by Dr Luke Nordquist at the Urology Cancer Center and GU Research Network (GURN) in Omaha, Nebraska (NCT05286840)<sup>8</sup>

# **SAR-Bombesin**

### Diagnostic

- 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>1</sup>
- SABRE Phase II PET imaging trial of participants with PSMA-negative BCR of prostate cancer using <sup>64</sup>Cu SAR-Bombesin in the US (<u>NCT05407311</u>)<sup>2</sup>
- 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

Clarity is conducting multiple clinical trials for each of its three key products in order to explore both diagnostic and therapeutic modalities, as well as expand their potential applications in a range of cancers.

# PRODUCT UPDATES

For the quarter ending 31 December, 2022

# SAR-bisPSMA – Prostate Cancer

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

It is being developed for diagnosing, staging and subsequently treating cancers that express Prostate Specific Membrane Antigen (PSMA). The product uses either copper-64 (<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:

- pre-prostatectomy/pre-definitive treatment of patients with confirmed prostate cancer; and
- patients with suspected biochemical recurrence of prostate cancer.

# S E Cu R E

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

Clarity has recruited and treated its first participant in the therapeutic phase of the SAR-bisPSMA theranostic clinical trial SECuRE (<u>NCT04868604</u>)<sup>3</sup> in October 2022. Data from the initial dosimetry phase with <sup>64</sup>Cu SAR-bisPSMA was assessed by the Safety Review Committee which recommended to move to therapeutic applications with <sup>67</sup>Cu SAR-bisPSMA.

SECuRE, which derives from "SystEmic Cu theRanostics in prostatE cancer", is a US-based Phase I/IIa theranostic trial for identification and treatment of an advanced form of prostate cancer, mCRPC. Clarity's PSMA imaging product is used to visualise PSMA expressing cancers and select participants who are most likely to respond well to subsequent therapy with Clarity's PSMA therapy product. The initial imaging stage of the trial utilised Clarity's PSMA imaging product to determine where the product went in the body (biodistribution) and what dose of the product was received (dosimetry) in the participants.

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



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

Clarity has reached the fifty percent recruitment milestone, with 25 out of 50 participants with biochemical recurrence (BCR) of prostate cancer having been enrolled and imaged in the COBRA trial (<u>NCT05249127</u>)<sup>5</sup> in October 2022.

Clarity imaged its first participant in April, shortly after receiving a green light from the US FDA with an official Study May Proceed letter in February 2022.

**COBRA**, which derives from "<u>CO</u>pper-64 SAR-bisPSMA in <u>B</u>iochemically <u>R</u>ecurrent prost<u>A</u>te cancer", is a Phase I/II Positron Emission Tomography (PET) imaging trial of participants with BCR of prostate cancer following definitive therapy. This means the participants have indications their prostate cancer returned after a period of remission following initial therapy, but the location of their cancer is unknown. The primary objectives of the trial are to investigate the ability of <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 will investigate if delayed imaging allows better identification of very early disease or patients with low PSMA expression.

# **PR公PELLER**

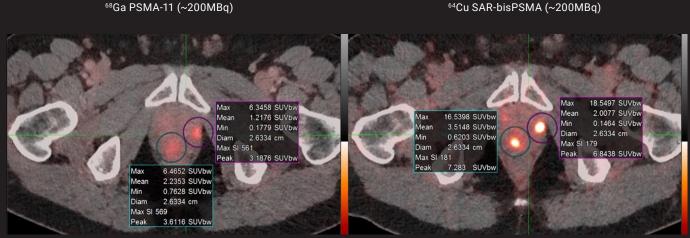
# **PROPELLER – a diagnostic 64Cu SAR-bisPSMA trial**

Clarity has announced positive topline results from the diagnostic Phase I trial of <sup>64</sup>Cu SAR-bisPSMA in prostate cancer, PROPELLER (<u>NCT04839367</u>)<sup>4</sup> in December 2022. The trial met 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. PROPELLER also met its secondary objective of determining the optimal dose for subsequent investigation of 64Cu SAR-bisPSMA. The selected optimal dose level of 200 MBg is currently applied in all ongoing trials.

Initial data on 64Cu SAR-bisPSMA will be released at the American Society of Clinical Oncology (ASCO) Genitourinary (GU) Symposium in February 2023.

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

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



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

68Ga PSMA-11 (~200MBg)

# P R 怂 P E L L E R

## **PROPELLER** cont.

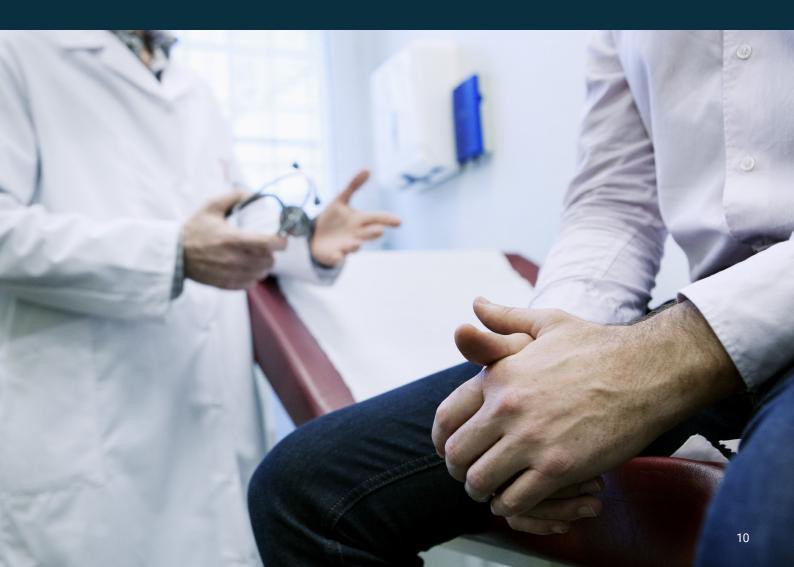
### **Primary objectives**

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

#### Secondary objectives

 Assessment of image quality at varying dose levels of <sup>64</sup>Cu SAR-bisPSMA for (100 MBq, 150 MBq and 200 MBq).

The initial 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. Clarity has commenced work towards the definitive diagnostic Phase III trials with <sup>64</sup>Cu SAR-bisPSMA and looks to engage with the US FDA in early 2023.



## SAR-Bombesin – Prostate Cancer

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

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

Approximately 20% of prostate cancers with BCR are PSMA-PET negative<sup>9-12</sup> and approximately 25% of mCRPC patients have low or no uptake of a PSMA-targeting tracer<sup>13</sup>. These patients are therefore unlikely to show uptake of PSMAtargeted 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.

Given the prostate cancer indication is one of the largest in oncology, there is a significant unmet medical need in this segment. The SAR-Bombesin product targets the GRPr found on prostate and many other cancers. As such, the product could offer valuable imaging and therapeutic options for not only PSMA negative patients, but also the large number of patients who have the target receptor on their cancers.

# C > M B A T

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

Clarity has received approval of its IND application by the US FDA to evaluate its SAR-Bombesin product for identification and treatment of mCRPC. This IND gives Clarity clearance to proceed with a US-based Phase I/IIa <sup>64</sup>Cu/<sup>67</sup>Cu SAR-Bombesin theranostic trial for identification and treatment of mCRPC that is expressing the GRPr, COMBAT (<u>NCT05633160</u>)<sup>1</sup>. It is Clarity's fifth successful IND application with the US FDA.

**COMBAT** (**CO**pper-67 SAR Bo**MB**esin in metast**AT**ic castrate resistant prostate cancer) is a dose escalation study with a cohort expansion. The aim for the study is to determine the safety and efficacy of <sup>67</sup>Cu-SAR-Bombesin in participants with 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 - a diagnostic 64Cu SAR-Bombesin trial



Clarity has successfully imaged its first participant in the US-based diagnostic <sup>64</sup>Cu SAR-Bombesin trial for patients with PSMA-negative prostate cancer, SABRE (<u>NCT05407311</u>)<sup>2</sup>, in October 2022.

SABRE opened for recruitment in August 2022, following shortly after Clarity received approval of its IND application by the US FDA to evaluate the SAR-Bombesin product as an imaging agent in prostate cancer patients that are PSMA-negative.

**SABRE**, which derives from "Copper-64 **SA**R-**B**ombesin in Biochemical **RE**currence of Prostate Cancer trial", is a multi-center, single arm, non-randomised, openlabel trial in 50 PSMA-negative patients with suspected recurrence of their prostate cancer. The primary objectives of the trial are to investigate the safety and tolerability of <sup>64</sup>Cu SAR-Bombesin, as well as its ability to correctly detect the recurrence of prostate cancer. The SABRE trial was developed in response to the strong demand from clinicians with prostate cancer patients whose cancer was not visible when imaging with currently approved PSMA diagnostic agents or other conventional imaging modalities (such as CT and MRI). Their patients were successfully imaged with <sup>64</sup>Cu SAR Bombesin under Australia's Therapeutic Goods Administration Special Access Scheme (TGA SAS)<sup>14-15.</sup>

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.

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

The Phase II diagnostic <sup>64</sup>Cu SAR-Bombesin investigator-initiated trial (BOP) for patients with prostate cancer has reached the fifty percent recruitment milestone, with 15 out of 30 participants enrolled and imaged in November 2022.

The first participants were recruited and imaged in September 2022, shortly after the trial commenced in August 2022 at St Vincent's Hospital Sydney, led by Prof Louise Emmett.

**BOP**, which derives from Copper-64 SAR-<u>**BO**</u>mbesin in <u>P</u>SMA negative prostate cancer, is a Phase II IIT in up to 30 patients

The BOP trial is assessing the safety of <sup>64</sup>Cu-SAR-Bombesin as well as looking at the diagnostic potential for men with negative PSMA PET or low PSMA expression disease in patients with suspected biochemical recurrence (BCR) of their prostate cancer and patients with metastatic castrate resistant prostate cancer (mCRPC) who are not eligible for PSMA therapy. The trial participants will be imaged on the day of <sup>64</sup>Cu SAR-Bombesin administration as well as at later timepoints. Similar to the SABRE trial, the BOP trial builds on the data generated in PSMAnegative prostate cancer patients at St Vincent's Hospital imaged under TGA SAS<sup>14-15</sup> as well as from pilot diagnostic IIT of SAR-Bombesin in breast cancer patients, the C-BOBCAT trial<sup>16</sup>.

# FINANCIALS

Clarity's cash balance was \$75.9 million as at 31 December, 2022. The company's estimated R&D tax incentive claim for FY22 is around \$6 million, which would bring the cash position to approximately \$82 million.

Operating cash outflows for the December quarter were \$8.3 million, which is an increase on previous quarterly outflows of circa \$7.7 million, due to the annual renewal of insurance policies (including Directors & Officers Liability cover) of approximately \$0.7 million, together with increased activity on the Company's numerous clinical programs referred to in this Quarterly Activities Report. The increase in costs was partially offset by the increase in interest received on Term Deposits of \$0.3 million. In addition to clinical trial costs, operating cash outflows relate to payments for research and development, staff costs, administration, and general operating costs.

# **Use of Funds**

(Listing Rule 4.7C.2)				
	Prospectus dated 16 July 2021 \$ Million	% of Total Funds	Period* to 31 Dec 2022 \$ Million	% of Total Funds
Pre-Clinical	\$2.7	2.5%	\$1.6	4.2%
Clinical	\$84.0	76.6%	\$20.1	52.9%
Regulatory	\$5.7	5.2%	\$1.0	2.6%
Patents	\$1.4	1.3%	\$1.4	3.7%
Corporate	\$10.4	9.5%	\$7.3	19.2%
Costs associated with the Offer	\$5.4	4.9%	\$6.6	17.4%
Total uses	\$109.6	100.0%	\$38.0	100.0%

\* From date of admission 25 August 2021.

Costs associated with the offer exceed the amount set out in the "use of funds" in the Prospectus by \$1.2 million. This is due to (1) the additional fee to the Joint Lead Managers and costs relating to the preparation of, and (2) additional due diligence relating to, the Supplementary Prospectus dated 10 August 2021. The Company paid \$750,000 to the Joint Lead Managers as part of a potential \$920,000 Incentive Fee, payable entirely at the discretion of the Company. The Incentive Fee is described in 10.11.1 of the Prospectus.

As detailed in the Use of Funds table above, the expenditure for the period since admission to 31 December 2022, 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 \$370,000 for the quarter. This amount includes director fees and salaries paid in the December quarter.

### References

- 1. ClinicalTrials.gov Identifier: NCT05633160 clinicaltrials.gov/ct2/show/NCT05633160
- 2. ClinicalTrials.gov Identifier: NCT05407311 clinicaltrials.gov/ct2/show/NCT05407311
- 3. ClinicalTrials.gov Identifier: NCT04868604 clinicaltrials.gov/ct2/show/NCT04868604
- 4. ClinicalTrials.gov Identifier: NCT04839367 clinicaltrials.gov/ct2/show/NCT04839367
- 5. ClinicalTrials.gov Identifier: NCT05249127 clinicaltrials.gov/ct2/show/NCT05249127
- 6. ClinicalTrials.gov Identifier: NCT04023331 clinicaltrials.gov/ct2/show/NCT04023331
- 7. ClinicalTrials.gov Identifier: NCT04438304 clinicaltrials.gov/ct2/show/NCT04438304
- 8. ClinicalTrials.gov Identifier: NCT05286840 clinicaltrials.gov/ct2/show/NCT05286840
- Afshar-Oromieh A, Holland-Letz T, Giesel FL, et al. Diagnostic performance of <sup>68</sup>Ga-PSMA-11 (HBED-CC) PET/ CT in patients with recurrent prostate cancer: evaluation in 1007 patients. Eur J Nucl Med Mol Imaging. 2017 Aug;44(8):1258-1268.
- 10. Ferraro DA, Rüschoff JH, Muehlematter UJ, et al. Immunohistochemical PSMA expression patterns of primary prostate cancer tissue are associated with the detection rate of biochemical recurrence with <sup>68</sup>Ga-PSMA-11-PET. Theranostics. 2020;10(14):6082-6094.
- 11. Baratto L, Song H, Duan H, et al. PSMA- and GRPR-Targeted PET: Results from 50 Patients with Biochemically Recurrent Prostate Cancer. J Nucl Med. 2021;62(11):1545-1549.
- 12. Mapelli P, Ghezzo S, Samanes Gajate AM, et al. <sup>68</sup>Ga-PSMA and <sup>68</sup>Ga-DOTA-RM2 PET/MRI in Recurrent Prostate Cancer: Diagnostic Performance and Association with Clinical and Histopathological Data. Cancers (Basel). 2022;14(2):334.
- 13. Vlachostergios PJ, Niaz MJ, Sun M, et al. Prostate-Specific Membrane Antigen Uptake and Survival in Metastatic Castration-Resistant Prostate Cancer. Frontiers in oncology. 2021;11.
- Niketh J, Bao H, Emmett, L. <sup>64</sup>Cu-SAR-Bombesin PET-CT for the detection of biochemically recurrent PSMA-PET negative prostate cancer: a case series. 2022 ANZUP Annual Scientific Meeting. Program of Abstracts. Vol 18. Issue S1. P55. https://doi.org/10.1111/ajco.13827
- 15. Niketh J et al. [<sup>64</sup>Cu]Cu-SAR-Bombesin ([<sup>64</sup>Cu]Cu-SAR-BBN) PET-CT for the detection of biochemically recurrent PSMA-PET negative prostate cancer: a case series. Poster Abstracts – RANZCR ASM 2022. https://www.claritypharmaceuticals.com/wp-content/uploads/2022/08/Cu-BBN-Poster-RANZCR-ASM.pdf
- Wong K. <sup>64</sup>Cu-SAR-Bombesin PET-CT imaging in the staging of ER+/PR+/HER2- metastatic breast cancer: Safety, dosimetry, and feasibility in a phase I trial. 2022 ACSO Annual Meeting. https://meetings.asco.org/abstractspresentations/210783

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## **About Clarity Pharmaceuticals**

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

### claritypharmaceuticals.com/



### Appendix 4C

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

Name of entity				
Clarity Pharmaceuticals Ltd				
ABN	Quarter ended ("current quarter")			
36 143 005 341	December 2022			

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(6,614)	(13,070)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(24)	(45)
	(d) leased assets	-	-
	(e) staff costs	(456)	(1,236)
	(f) administration and corporate costs	(1,452)	(2,004)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	315	429
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	(58)	(58)
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-
1.9	Net cash from / (used in) operating activities	(8,289)	(15,984)
2.	Cash flows from investing activities		
2.1	Payments to acquire or for:		
	(g) entities	-	-
	(h) businesses	-	-
	(i) property, plant and equipment	(18)	(33)
	(j) investments	-	-
	(k) intellectual property	-	-
	(I) other non-current assets	-	-

Cons	solidated statement of cash flows	Current quarter \$A'000	Year to date (6 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	(18)	(33)
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	110	110
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(4)	(4)
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	106	106

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	84,687	92,336
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(8,289)	(15,984)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(18)	(33)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (6 months) \$A'000	
4.4	Net cash from / (used in) financing activities (item 3.10 above)	106	106	
4.5	Effect of movement in exchange rates on cash held	(598)	(537)	
4.6	Cash and cash equivalents at end of period	75,888	75,888	

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	57,888	55,336
5.2	Call deposits *	18,000	37,000
5.3	Bank overdrafts	-	-
5.4	Other (provide details)	-	-
5.5	Cash and cash equivalents at end of quarter (should equal item 4.6 above)	75,888	92,336
* Call d	leposits represents term deposit accounts with expiry dates r	more than 90 days after balan	ce date presented as

\* 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	370
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.	L

7.	<b>Financing facilities</b> 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	uarter 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.		itional financing

8.	Estim	ated cash available for future operating activities	\$A'000
8.1	Net ca	sh from / (used in) operating activities (item 1.9)	(8,289)
8.2	Cash a	and cash equivalents at quarter end (item 4.6)	75,888
8.3	Unused finance facilities available at quarter end (item 7.5)		-
8.4	Total a	available funding (item 8.2 + item 8.3)	75,888
8.5	Estima item 8	ated quarters of funding available (item 8.4 divided by .1)	9
		the entity has reported positive net operating cash flows in item 1.9, answer ite r the estimated quarters of funding available must be included in item 8.5.	m 8.5 as "N/A". Otherwise, a
8.6	If item	8.5 is less than 2 quarters, please provide answers to the follow	wing 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?		
	Answe	er:	
	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?		
	Answe	er:	
	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?		
	Answe	er:	
	Note: wl	here item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 abo	ve must be answered.

#### **Compliance statement**

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

31 January 2023 Date:

#### Board of Directors

Authorised by: (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.