

HIGHLIGHTS OF THE QUARTER

Ending 30 September 2023

Cash Position

Cash position remains strong with a balance of \$53.6 million as at 30 September 2023. Net operating cash outflows for the June quarter were \$11.7 million. This funding will provide cash runway into 2024 and take Clarity into registrational Phase III clinical trials.

SECuRE

Cohort 3 recruitment is ongoing in Clarity's theranostic ⁶⁴Cu/⁶⁷Cu-SAR-bisPSMA trial following the dosing of the first participant at the highest dose level of 12GBq of ⁶⁷Cu-SAR-bisPSMA and completion of cohort 1 and cohort 2 with no dose limiting toxicities. 100% of patients in cohort 2 showed a PSA decrease of 80% or greater from a single therapy cycle.

Phase III trial in prostate cancer (CLARIFY)

Start-up activities are well underway for the registrational CLARIFY trial. This 383-patient diagnostic study with ⁶⁴Cu-SAR-bisPSMA in participants with high risk prostate cancer prior to radical prostatectomy will examine the diagnostic potential of ⁶⁴Cu-SAR-bisPSMA to detect regional nodal metastasis. CLARIFY will look at the potential benefits of both same day and next day imaging, a feature currently unique to the SAR technology platform. Clarity will be commencing this registrational trial of the ⁶⁴Cu-SAR-bisPSMA product in late 2023.

PROPELLER

Clarity was awarded First Place in the Oncology, Clinical Therapy & Diagnosis category at the Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting 2023 for the poster presentation detailing the results from the completed Phase I diagnostic trial of ⁶⁴Cu-SAR-bisPSMA.

Pre-targeting

Clarity obtained a worldwide exclusive license from Memorial Sloan Kettering Cancer Center (MSK) for an antibody pre-targeting technology for the diagnosis and treatment of cancer.

COMBAT

Clarity treated the first participant in its theranostic ⁶⁴Cu/⁶⁷Cu-SAR-Bombesin Phase I/II trial in metastatic castrate resistant prostate cancer (mCRPC).

SABRE

Clarity reached the 50% recruitment milestone in its US-based diagnostic ⁶⁴Cu-SAR-Bombesin trial for patients with PSMA-negative prostate cancer with 25 out of 50 participants enrolled and imaged.

BOP

Initial results from the Phase II diagnostic investigatorinitiated trial (IIT) of ⁶⁴Cu-SAR-Bombesin in prostate cancer were presented at the European Association of Nuclear Medicine (EANM) 2023 Congress in Vienna, Austria.

CL04

Clarity advanced to cohort 4 and treated the first participant in this highest dose cohort of the theranostic trial investigating ⁶⁴Cu/⁶⁷Cu-SARTATE in neuroblastoma, an aggressive childhood 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 three months ending 30 September 2023.



Executive Chairperson's Letter

Dear fellow Shareholders,

I am delighted to present Clarity's report for the quarter ending 30 September 2023 as we continued reaching crucial milestones in the lead up to Phase III clinical programs. With a cash balance of \$53.6 million, we remain well financed to continue the development of our next-generation radiopharmaceutical products into late-stage trials.

We continue focusing on developing "best-in-class" products and this has resulted in our unique position in prostate cancer. Our SAR-bisPSMA therapy has continued to generate exciting data throughout the quarter, as this product was designed to distinguish Clarity from the rest of the radiopharmaceuticals field in prostate cancer and the initial results, even from a single dose, have been very impressive. Optimised with dual-targeting agents, SARbisPSMA shows higher uptake of product in the cancer lesions and increases the amount of time it is retained in the lesions. We believe these factors have been the major driver of the excellent results thus far and coupled with the higher therapeutic dose we can provide to patients due to the characteristics of copper-67 our confidence continues to grow in delivering a best-in-class product to address this very large market and deliver treatment benefits and continue to change the lives of these patients.

In our theranostic SECuRE trial with SAR-bisPSMA, we have successfully progressed to the highest dose cohort 3 and treated the first patient with 12GBq ⁶⁷Cu-SAR-bisPSMA as no dose limiting toxicities were reported in the lower dose cohorts. The data from cohort 2 is incredibly promising despite only a single dose being used and we look forward to progressing this trial to the multi-dose cohort where we anticipate an even stronger therapeutic response.

The diagnostic programs with SAR-bisPSMA are also generating a lot of excitement in the radiopharmaceutical field as Clarity is now progressing a registrational Phase III diagnostic trial for high-risk prostate cancer patients prior to radical prostatectomy. We engaged the United States Food and Drug Administration (US FDA) and received positive feedback at our successful end of phase meeting. We now look forward to opening recruitment into the CLARIFY trial before the end of the calendar year. The final study results from this pivotal trial are intended to provide sufficient evidence to support an application to the US FDA for approval of 64Cu-SARbisPSMA as a new diagnostic imaging agent in prostate cancer. The study design for the Phase III CLARIFY trial is based on our completed Phase I PROPELLER diagnostic trial, which showed that Clarity's optimised 64Cu-SARbisPSMA product was safe and effective for detecting PSMA expressing lesions in men with prostate cancer. Clarity was awarded First Place in the Oncology, Clinical Therapy & Diagnosis category for its poster presentation of the data from the PROPELLER trial at the world's most prestigious nuclear medicine conference, the Society of Nuclear Medicine and Molecular Imaging (SNMMI) 2023 Annual Meeting.

With our second product, SAR-Bombesin, we have also been exploring therapeutic and diagnostic benefits for prostate cancer patients, in particular those who have low or negative PSMA uptake. We successfully treated our first patient with ⁶⁷Cu-SAR-Bombesin in the theranostic Phase I/IIa trial, COMBAT, and look forward to progressing to the higher dose cohorts.

On the diagnostic front, Clarity reached a 50% milestone in the Phase II SABRE trial with ⁶⁴Cu-SAR-Bombesin in patients with PSMA-negative prostate cancer in the quarter ending 30 September and we are looking to close recruitment into the trial by the end of the calendar year. Subject to the data from the SABRE trial, we are planning to launch a pivotal Phase III trial with ⁶⁴Cu-SAR-Bombesin for first approvals in the US. In addition to the SABRE trial, SAR-Bombesin is being investigated in an investigator-initiated trial (IIT) led by Prof Louise Emmett at St Vincent's Hospital, Sydney and the exciting initial data was presented at one of the most prestigious nuclear medicine conferences in the world, European Association of Nuclear Medicine (EANM) 2023 Congress in Vienna, Austria.

We remain committed to improving treatment outcomes for children with cancer with our theranostic ⁶⁴Cu/⁶⁷Cu-SARTATE trial for children with neuroblastoma, CL04. We have now successfully completed the first three cohorts and commenced the final dose-escalation cohort where the first patient was safely dosed at the highest dose level of 375MBq of ⁶⁷Cu-SARTATE per kilogram body weight. We look forward to building upon the promising data reported to date and progressing recruitment to the dose-expansion phase of the trial.

We are very excited and encouraged by the positive data so far generated by these theranostic and diagnostic trials with our three core products, SAR-bisPSMA, SAR-Bombesin and SARTATE, and look forward to providing further updates to the market in the future. As our SAR Technology allows us to explore new, exciting products for cancer management, we continue to seek opportunities to improve treatment outcomes in indications with high unmet needs. Most recently, Clarity acquired an exclusive worldwide license from Memorial Sloan Kettering Cancer Center (MSK) to intellectual property covering antibody pre-targeting technology. This cutting-edge technology harnesses the benefits of antibody targeting, amplifying uptake of radiopharmaceutical products in cancerous tissue, while reducing healthy tissue exposure to radiation that can arise due to the slow clearance of antibodies. We look forward to further exploring the benefits of pretargeting in combination with Clarity's proprietary SAR Technology.

On behalf of the entire team, I would like to thank all of our shareholders who have continued to support Clarity. We remain highly optimistic about our technology, team and strategy and look forward to continuing hitting important milestones in the development of the exciting pipeline of next-generation TCTs in a quickly developing radiopharmaceuticals market.

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

Clarity is a global leader in next-generation radiopharmaceuticals with its Targeted Copper Theranostic (TCT) platform of products. Clarity's products use the "perfect pairing" of copper isotopes, copper-64 (Cu-64 or ⁶⁴Cu) for imaging and copper-67 (Cu-67 or ⁶⁷Cu) for therapy, which deliver a compelling combination of high accuracy and high precision in the treatment of a range of cancers.

Clarity's three core products, SAR-bisPSMA, SAR-Bombesin and SARTATE, each contain a different targeting agent and bind to different receptors that are present on different cancer cells.

The three theranostic products are in clinical development for both diagnosis and treatment of various cancers and address unmet clinical needs. In addition to these core products, SAR Technology is used in Clarity's Discovery Program, which explores new targeting agents, thereby creating new TCTs to expand the existing platform.

SAR-bisPSMA

has been optimised with two targeting agents that bind to prostate specific membrane antigen (PSMA), which is present in the majority of prostate cancers.

SAR-Bombesin

targets the gastrin releasing peptide receptor (GRPr), a receptor present across a range of cancers, including breast and prostate cancers.

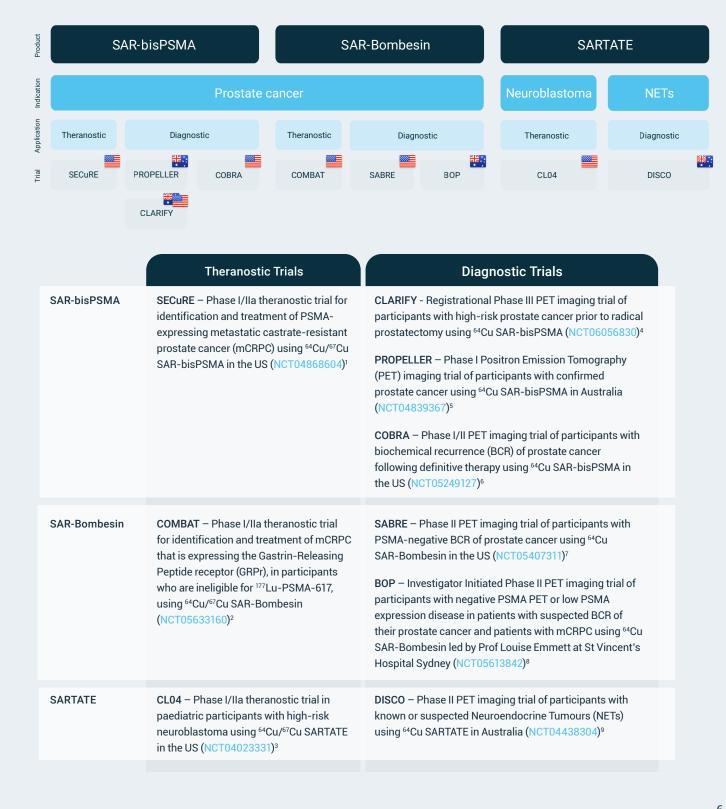
SARTATE

targets the somatostatin receptor 2 (SSTR2), which is present in an aggressive childhood cancer, neuroblastoma, as well as neuroendocrine tumours (NETs), among other cancers.

TCTs provide a scalable, dependable, cost-effective and environmentally friendly way to expand radiopharmaceuticals into the global oncology market.

CLINICAL DEVELOPMENT **OVERVIEW**

Clarity's three lead products, SAR-bisPSMA, SAR-Bombesin and SARTATE, are actively progressing through seven clinical trials with three theranostic and four diagnostic trials, including a Phase III registrational trial that is scheduled to open for recruitment shortly.



PRODUCT UPDATES

SAR-bisPSMA PROSTATE CANCER

SAR-bisPSMA is a next generation, theranostic radiopharmaceutical with optimised dual PSMAtargeting agents to improve uptake and retention of the product in tumours

SAR-bisPSMA

Prostate cancer

Theranostic

Diagnostic

PROPELLER

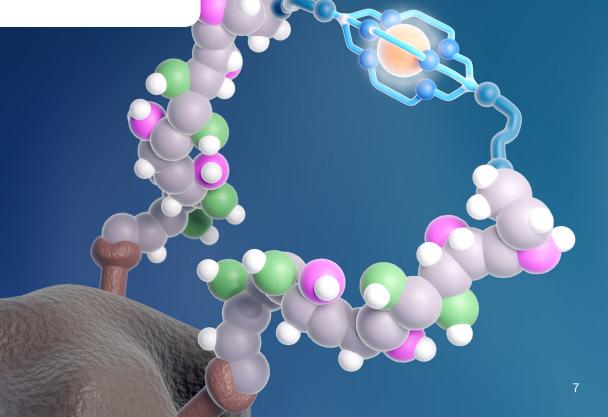
COBRA

CLARIFY

SAR-bisPSMA is being developed for diagnosing, staging and subsequently treating cancers that express PSMA. The product uses either copper-64 (⁶⁴Cu) for imaging (⁶⁴Cu-SAR-bisPSMA) or copper-67 (⁶⁷Cu) for therapy (⁶⁷Cu-SAR-bisPSMA).

In addition to the therapy program in metastatic castrate resistant prostate cancer (mCRPC) with ⁶⁴Cu-SAR-bisPSMA and ⁶⁷Cu-SAR-bisPSMA, Clarity is also running multiple diagnostic trials in line with advice received from the US FDA to address the two relevant patient populations for registration of ⁶⁴Cu-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

Clarity has successfully progressed the theranostic SECuRE trial (NCT04868604)¹ to cohort 3, dosing the first participant at the highest dose level of 12GBq of ⁶⁷Cu-SAR-bisPSMA in August 2023. All three participants in cohort 2 showed a PSA decrease of >80% from a single therapy cycle at the 8GBq dose level.

The 3 participants in the recently completed cohort 2 have been monitored by their physicians for safety and treatment response as per the trial protocol. All 3 participants have demonstrated a prostate specific antigen (PSA) reduction. PSA levels fell in all participants, with the first 2 showing reductions of greater than 95% and the last participant showing a drop of over 80% (Table 1). A 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.

In the trial, Clarity first uses its imaging product, ⁶⁴Cu-SAR-bisPSMA, to visualise PSMA expressing lesions and select participants who are most likely to respond well to subsequent therapy with ⁶⁷Cu-SAR-bisPSMA. PET/CT images collected before and after a single 8GBq therapy cycle of ⁶⁷Cu-SAR-bisPSMA demonstrated a reduction in the intensity of the diagnostic product at the lesion sites (Figure 1).

Table 1. SECuRE cohort 2 PSA responses

Cohort 2 (n=3)	PSA decrease following single therapy cycle
1	>95%
2	>99%
3	>80%

SECuRE is a US-based Phase I/IIa theranostic trial for identification and treatment of an advanced form of prostate cancer, mCRPC. It is a multi-centre, single arm, dose escalation study with a cohort expansion planned for up to 44 participants. 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.

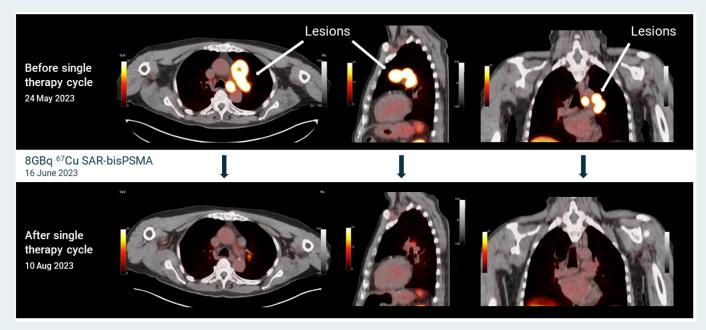
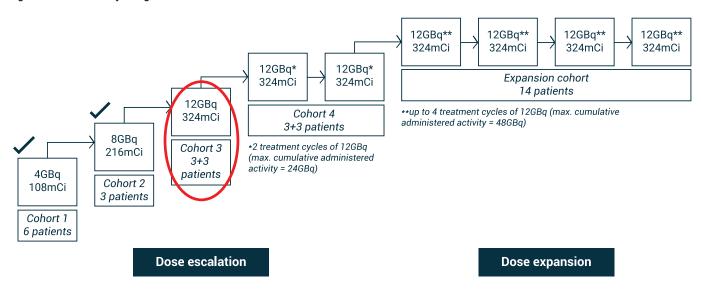


Figure 1. ⁶⁴Cu-SAR-bisPSMA PET/CT imaging before and after a single cycle of 8GBq ⁶⁷Cu-SAR-bisPSMA (cohort 2). White arrows guide to the lesions detected by ⁶⁴Cu-SAR-bisPSMA before therapy with ⁶⁷Cu-SAR-bisPSMA (top images) with considerable reduction in ⁶⁴Cu-SAR-bisPSMA uptake post-therapy (bottom images).



Figure 2. SECuRE study design



Cohort 3 is the last to assess single doses of ⁶⁷Cu-SAR-bisPSMA at the highest dose level of 12GBq and will be followed by a multi-dose cohort, pending safety evaluation (Figure 2).

Expanded Access Program Patient Case Study: Multiple 4GBq Cycles of 67Cu-SAR-bisPSMA

Outside of the trial, additional therapy cycles of ⁶⁷Cu-SARbisPSMA have also been requested by clinicians under the US Food and Drug Administration (FDA) Expanded Access Program (EAP) for participants in cohorts 1 and 2.

⁶⁷Cu-SAR-bisPSMA SPECT/CT images depicted on Figure 3 were collected 48 hours after the first and fourth administrations of 4GBq of ⁶⁷Cu-SAR-bisPSMA in a patient from cohort 1 who received additional cycles under the EAP. Images collected following the fourth therapy cycle demonstrate a reduction in the intensity of the therapeutic ⁶⁷Cu-SAR-bisPSMA product uptake at the lesion sites outlined in the images. A reduction of greater than 50% in PSA levels was observed in this participant following the first administration of 4GBq of therapeutic ⁶⁷Cu-SAR-bisPSMA and a drop of greater than 90% in PSA was observed after the fourth cycle of 4GBq of ⁶⁷Cu-SAR-bisPSMA.

The duration of response in PSA levels in this patient demonstrates the possibilities of sustained clinical benefits following multiple doses of ⁶⁷Cu-SAR-bisPSMA, which is currently being investigated in the SECuRE trial

⁶⁷Cu-SAR-bisPSMA SPECT-CT (Fixed Scaling)

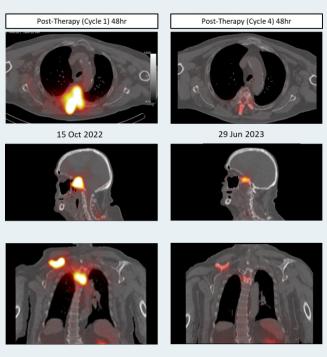


Figure 3. SPECT/CT imaging at 48 hrs following cycle 1 (Oct 2022) and cycle 4 (Jun 2023) of 4GBq ⁶⁷Cu-SAR-bisPSMA showing considerable reduction in uptake of the product.



CLARIFY – a diagnostic Phase III registrational ⁶⁴Cu-SAR-bisPSMA trial

Data generated from the first-in-human, Phase I trial, PROPELLER, was used to inform the study design of CLARIFY, a pivotal Phase III trial in patients with prostate cancer who are planned for prostatectomy.

Clarity has commenced activities on the CLARIFY (NCT06056830)⁴ 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 prostate cancer, with high-risk features, who are proceeding to radical prostatectomy with pelvic lymph node dissection.

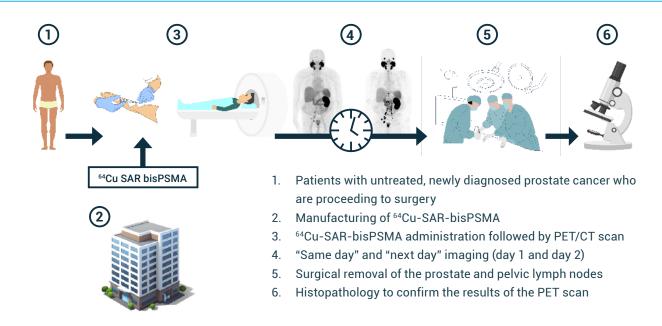
The aim of the Phase III trial is to assess the diagnostic performance of ⁶⁴Cu-SAR-bisPSMA PET to detect prostate cancer within the pelvic lymph nodes. Evaluation will be across two imaging timepoints, day 1 (1-4 hours post administration) and day 2 (approximately 24 hours post administration). Delayed imaging is not possible with current-generation radiopharmaceuticals due to the shorter half-life of the ⁶⁸Ga and ¹⁸F radioisotopes. ⁶⁴Cu has an optimal half-life that enables imaging up to 72 hours post administration. The CLARIFY study is investigating if delayed imaging allows for improved disease detection.

The longer half-life of ⁶⁴Cu may not only allow the detection of additional cancerous lesions on delayed imaging, but also provide timely supply of product covering a broad geographic area and flexibility for the scheduling of patients.

The final study results from the CLARIFY trial are intended to provide sufficient evidence to support an application to the FDA for approval of ⁶⁴Cu-SAR-bisPSMA as a new diagnostic imaging agent for preprostatectomy prostate cancer patients.

Currently approved diagnostic products have low sensitivity, meaning some lesions may remain undetected. Clarity's SAR-bisPSMA product was developed in response to this issue. The dual PSMA-targeting agent and delayed imaging feature have the potential to improve product uptake and retention in prostate cancer lesions.

Being able to accurately identify lesions outside of the prostate provides healthcare professionals with crucial information on disease progression and allows for better informed decisions in regard to the patients' treatment plan.





PROPELLER – a diagnostic ⁶⁴Cu-SAR-bisPSMA trial

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 (NCT04839367)⁵ at the SNMMI Annual Meeting 2023, the world's premier educational, scientific and research meeting in nuclear medicine and molecular imaging.

The PROPELLER data further validates ⁶⁴Cu-SAR-bisPSMA as a potential best-in-class PSMA agent for the diagnosis of prostate cancer.

PROPELLER 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 achieved its primary objectives and showed that ⁶⁴Cu-SAR-bisPSMA was safe, well tolerated and efficacious in detecting primary prostate cancer. ⁶⁴Cu-SAR-bisPSMA demonstrated higher uptake and detected more lesions than the standard of care ⁶⁸Ga-PSMA-11 product.

Table 2. 64Cu-SAR-bisPSMA showed statistically higher uptake than 68Ga-PSMA-11 in lesions detected by both products'

All Cohorts	Parameter	Imaging	N	Median	IQR	Min	Max	Median Difference	p-value
	CLIV/	⁶⁴ Cu	28	30.26	46.9	8	100	14.00	0 001
	SUVmax	⁶⁸ Ga	28	13.53	12.79	2.7	55.1	14.23	p < 0.001
Reader 1	SUVmean	⁶⁴ Cu	28	21.2	32.23	5.4	69.9	9.26	p < 0.001
Reader I	Sovillean	⁶⁸ Ga	28	9.12	8.71	1.8	37.6		
	TBR	⁶⁴ Cu	28	53.55	84.45	10.3	294.1	27.94	p < 0.001
		⁶⁸ Ga	28	24.29	36	9.6	134.4		
	SUVmax	⁶⁴ Cu	16	41.66	58.77	6.1	100	27.99	p < 0.001
	SUVIIIAX	⁶⁸ Ga	16	14.93	17.16	2.7	55.1	27.99	p < 0.001
Reader 2	SUVmean	⁶⁴ Cu	16	28.4	37.92	4.4	69.9	18.78	p < 0.001
neauer 2	Suvmean	⁶⁸ Ga	16	9.94	11.56	1.8	37.6	16.78	p < 0.001
	TBR	⁶⁴ Cu	16	78.37	98.97	6.7	243.9	46.93	n < 0.001
	IDK	⁶⁸ Ga	16	24.69	52.14	5	112.4	40.93	p < 0.001

*SUV: Standardised Uptake Value - measurement used to assess uptake of product in lesions or specific area

TBR: Tumor-to-Background Ratio

IQR: Interquartile Range

⁶⁴Cu-SAR-bisPSMA detected more lesions and showed statistically higher uptake when compared to ⁶⁸Ga-PSMA-11.

PR必PELLER

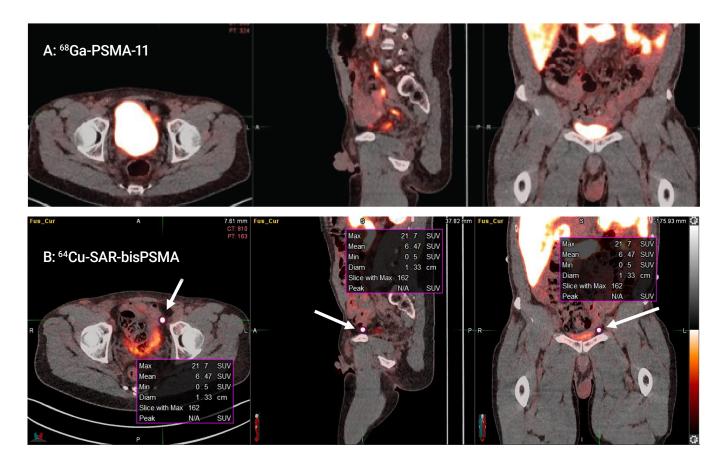


Figure 4. Readers did not detect uptake in pelvic lymph nodes on the ⁶⁸Ga-PSMA-11 PET/CT (top). PET/CT demonstrated uptake of ⁶⁴Cu-SAR-bisPSMA (bottom) in a left pelvic lymph node according to both central readers and PC was confirmed via histopathology. Arrows highlight the node detected on ⁶⁴Cu-SAR-bisPSMA PET/CT. Interval between serial imaging: 7 days.

 * SUV: Standardised Uptake Value - measurement of product uptake in tissue normalised to a distribution volume

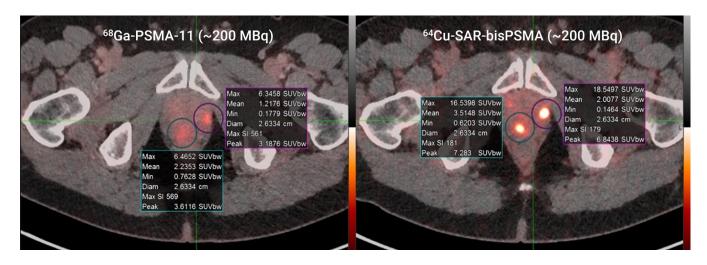


Figure 5. Comparison of ⁶⁸Ga-PSMA-11 (left image) to Clarity's ⁶⁴Cu-SAR-bisPSMA (right image) in the same patient. Concordant lesions on ⁶⁴Cu-SAR-bisPSMA and ⁶⁸Ga-PSMA-11 PET/CT consistently showed higher uptake with ⁶⁴Cu-SAR-bisPSMA. Standardised Uptake Value (SUVmax)' of the lesions were 16.5 and 18.5 for ⁶⁴Cu-SAR-bisPSMA and 6.5 and 6.3 for ⁶⁸Ga-PSMA-11 and. Interval between serial imaging: 8 days.

*SUV: Standardised Uptake Value - measurement of product uptake in tissue normalised to a distribution volume

SAR-BOMBESIN – PROSTATE CANCER

SAR-Bombesin is a highly targeted pancancer theranostic radiopharmaceutical

Prostate cancer

Theranostic

Diagnostic

COMBAT

SABRE

BOP

SAR-Bombesin is a highly targeted pancancer theranostic radiopharmaceutical. It is being developed for diagnosing, staging and subsequently treating 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 negative¹⁰⁻¹³ and approximately 25% of mCRPC patients have low or no uptake of a PSMA- targeting tracer¹⁴. These patients are unlikely to show meaningful uptake of PSMA-targeted products, such as ⁶⁸Ga-PSMA-11 for imaging, and therefore may not be eligible for a PSMA-targeted treatment, such as ¹⁷⁷Lu-PSMA-617. Currently these patients have few therapy options available to treat their cancer.

SAR-Bombesin is currently being investigated in two clinical trials in prostate cancer indications:

- theranostic Phase I/IIa trial in the US (COMBAT)² in patients with mCRPC;
- diagnostic Phase II trial in the US (SABRE)⁷ in patients with BCR of prostate cancer.

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.

C D M B A T

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

Clarity treated the first participant in its theranostic ⁶⁴Cu/⁶⁷Cu-SAR-Bombesin Phase I/IIa trial in mCRPC.

COMBAT (NCT05633160)² 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 ⁶⁷Cu-SAR-Bombesin as well as the safety of ⁶⁴Cu-SAR-Bombesin in participants with GRPr expressing mCRPC in patients who are ineligible for therapy with ¹⁷⁷Lu-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 reached the 50% recruitment milestone in its US-based diagnostic ⁶⁴Cu-SAR-Bombesin trial for patients with PSMA-negative prostate cancer, SABRE (NCT05407311)⁷ in July 2023.

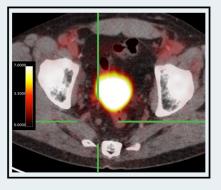
SABRE is a Phase II multi-center, single arm, non-randomised, open-label trial in 50 participants with suspected recurrence of their prostate cancer and who have negative or equivocal findings of prostate cancer on standard of care imaging, including approved PSMA agents.

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

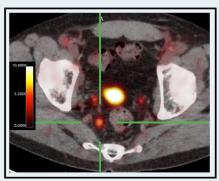
In the SABRE trial, participants are imaged on the day of administration (same day imaging) and 24 hours later (next day imaging). The study is investigating if delayed imaging allows better identification of very early disease or patients with low GRPr expression. In Figure 6, the images in the cross hairs on the day of administration of ⁶⁴Cu-SAR-Bombesin and on the next day following the administration clearly identify a pelvic lymph node, while there was no uptake with ¹⁸F-DCFPyL, an FDA-approved PSMA agent.

Subject to the outcome of the SABRE trial, Clarity is planning to launch a pivotal Phase III diagnostic trial with ⁶⁴Cu-SAR-Bombesin for first product approvals in the US.

¹⁸F-DCFPyL PET/CT



64Cu-SAR-Bombesin Same Day



64Cu-SAR-Bombesin Next Day

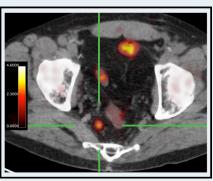


Figure 6. ⁶⁴Cu-SAR-Bombesin detected a positive lymph node on scans performed on two different days (same day and next day scans). No uptake was observed using ¹⁸F-DCFPyL PET/CT. A subsequent biopsy, performed and assessed locally by the study site, has confirmed prostate cancer.

⁶⁴Cu-SAR-Bombesin has the potential to identify areas of disease which have gone undetected with current standard of care modalities. Being able to visualise where the disease has reoccurred could lead to clinicians being able to better treat this group of patients who currently have limited treatment options

BOP – a diagnostic ⁶⁴Cu-SAR-Bombesin investigatorinitiated trial (IIT) in prostate cancer

The diagnostic BOP (NCT05613842)⁸ trial, evaluating ⁶⁴Cu-SAR-Bombesin, was completed in June 2023 with initial data presented at the European Association of Nuclear Medicine (EANM) 2023 Congress.

BOP is a Phase II IIT in 30 participants led by Prof Louise Emmett at St Vincent's Hospital, Sydney. This IIT is assessing the safety of ⁶⁴Cu-SAR-Bombesin as well as looking at the diagnostic potential across two different groups of men:

- Participants with BCR of their prostate cancer who have negative PSMA PET imaging scans or low PSMA expressing disease; and
- 2. Participants with mCRPC who are not suitable for PSMA-targeted therapy.

Study results from the cohort looking at BCR have been presented at the European Association of Nuclear Medicine (EANM) 2023 Congress in Vienna, Austria, one of the most prestigious conferences in the nuclear medicine field.

64Cu-SAR-Bombesin was found to be safe and able to detect prostate cancer lesions in over 30% of participants with negative or equivocal standard of care PSMA PET (8/25, 32% detection rate) in participants in the first cohort of the BOP trial.

No adverse events from ⁶⁴Cu-SAR-Bombesin administration were reported in participants in the first cohort of the BOP trial. They received the mean dose of 210MBq of ⁶⁴Cu-SAR-Bombesin and imaged with PET at 1, 3 and 24 hours post-administration of the product.

"This could be the difference between having an incorrect negative cancer diagnosis leading to cancer progression and now having an effective treatment plan that may lead to long term remission,"

- Dr Alan Taylor



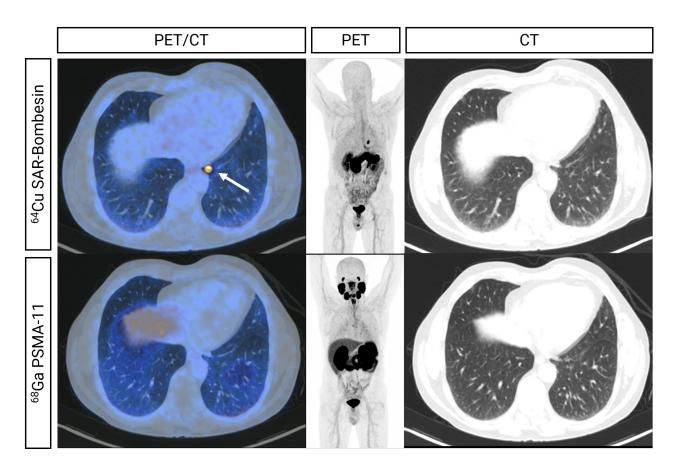


Figure 7. Fused, MIP (Maximum Intensity Projection) and CT (Computed Tomography) (left to right) images from ⁶⁴Cu-SAR-Bombesin (top) and ⁶⁸Ga-PSMA-11 (bottom) PET of a patient demonstrating a left subpleural lesion with ⁶⁴Cu-SAR-Bombesin uptake (arrow) without SOC PSMA uptake. This patient underwent a lobectomy with histopathology demonstrating metastatic prostate cancer.

Reproduced with permission from Prof Louise Emmett (St Vincent's Hospital, Sydney – Australia). EANM 2023.

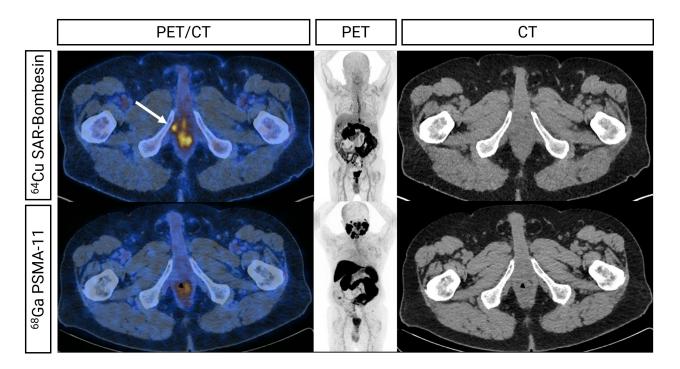
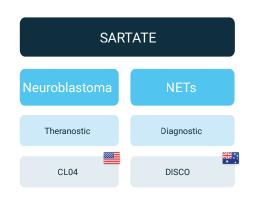


Figure 8. Fused, MIP and CT (left to right) images from ⁶⁴Cu-SAR-Bombesin (top) and ⁶⁸Ga-PSMA-11 (bottom) PET of a patient demonstrating uptake at the right urethral anastomosis on ⁶⁴Cu-SAR-Bombesin alone (arrow). This patient was managed with local radiotherapy with improvement in PSA post-treatment.

Reproduced with permission from Prof Louise Emmett (St Vincent's Hospital, Sydney - Australia). EANM 2023.

SARTATE - NEUROBLASTOMA AND NETS

SARTATE is a next generation, highly targeted theranostic radiopharmaceutical



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

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

- CL04 theranostic trial with an open IND in the US (NCT04023331)³
- DISCO diagnostic trial in Australia (NCT04438304)9.

In 2020, the US FDA awarded Clarity two Orphan Drug Designations (ODDs), one for ⁶⁴Cu-SARTATE as a diagnostic agent for the clinical management of neuroblastoma and one for ⁶⁷Cu-SARTATE as a therapy of neuroblastoma, as well as two Rare Paediatric Disease Designations (RPDDs) for these products. Should Clarity be successful in achieving marketing approval from the US FDA for these two products, RPDDs may allow the Company to access a total of two tradeable Priority Review Vouchers (PRVs) valued at ~\$100M USD each.¹⁵

CL04 – a theranostic 64Cu/67Cu-SARTATE neuroblastoma trial

Clarity successfully completed the first three cohorts of the CL04 theranostic trial (NCT04023331)³ in neuroblastoma patients. Final dose-escalation cohort opened for recruitment and the first participant was dosed at the highest dose level of 375MBq of ⁶⁷Cu-SARTATE per kilogram body weight in August 2023. Recruitment is ongoing at all clinical sites in the US.

CL04 is a multi-centre, dose-escalation, open label, non-randomised, theranostic clinical trial in paediatric patients with high-risk neuroblastoma. The trial is a Phase I/IIa with up to 34 participants where not only the safety and tolerability of both ⁶⁴Cu-SARTATE and ⁶⁷Cu-SARTATE are being assessed, but also the effectiveness of ⁶⁷Cu-SARTATE as a treatment for neuroblastoma. Participants who show uptake of ⁶⁴Cu-SARTATE in lesions will continue in the trial and will receive treatment with ⁶⁷Cu-SARTATE.

In the dose escalation phase of the trial, each subsequent cohort will receive an increase in the therapeutic dose administered. Generally speaking, higher therapeutic dose is usually associated with greater therapeutic response, up to a certain threshold where toxicity may occur. The CLO4 trial is designed to gradually increase the dose of ⁶⁷Cu-SARTATE administered to participants in each cohort, up to a maximum of 4 cohorts, until the Maximum Tolerated Dose (MTD) is reached.

Cohort 4 participants will be treated with a single dose of 375MBq of ⁶⁷Cu-SARTATE per kilogram body weight. This builds on the first 3 cohorts:

- Cohort 1 3 participants received an initial single dose of 75MBq/kg body weight ⁶⁷Cu-SARTATE
- Cohort 2 3 participants received an initial single dose of 175MBq/kg body weight ⁶⁷Cu-SARTATE
- Cohort 3 3 participants received an initial single dose of 275MBq/kg body weight ⁶⁷Cu-SARTATE

Once the MTD is established in the dose escalation phase, the trial will advance to the cohort expansion phase where an additional 10 participants will receive at least 2 therapy cycles of ⁶⁷Cu-SARTATE at the MTD, with up to 4 therapy cycles in total for those participants who demonstrate therapeutic benefit.

Some participants in the completed cohorts have received multiple therapy cycles of ⁶⁷Cu-SARTATE in addition to the single therapy cycle being assessed in the dose escalation phase of the CL04 trial. These subsequent therapy cycles are strictly contingent on the investigators' assessment that the participant is demonstrating therapeutic benefit after the first dose.

Clarity looks forward to building upon the promising data reported to date and progressing recruitment to the dose-expansion phase of the trial.



DISCOVERY PROGRAM

PRE-TARGETING

In addition to further progressing its key products that are already in clinical development, Clarity is expanding its product pipeline with a new generation of radiopharmaceuticals through its Discovery Program.

In August 2023, Clarity added a worldwide exclusive license from Memorial Sloan Kettering Cancer Center (MSK) to its IP. The license is to intellectual property that covers cutting-edge technology that enables antibody "pre-targeting" for the diagnosis and treatment of cancer, US Patent No. 11,135,320 (US16/203,513) Radioligands For Pretargeted PET Imaging And Methods Of Their Therapeutic Use (expiry 11 Oct 2035).

Pre-targeting is a radiopharmaceutical approach to diagnosing and treating cancer patients that harnesses the benefits of antibody targeting, amplifying uptake of radiopharmaceutical products in cancers, while reducing healthy tissue exposure to radiation that can arise due to the slow clearance of antibodies. This is achieved by tagging an antibody, designed specifically to target cancer cells, and then injecting it into the body. After several days, a chaser compound, which only attaches to the antibody tag, is injected. The chaser compound is initially radiolabelled with copper-64 to enable imaging with a Positron Emission Tomography (PET) camera which visualises the extent of cancer burden. Once the cancer is visualised, a second administration of the chaser is administered, this time radiolabelled with the therapeutic radionuclide copper-67, so that the cancer cells can be irradiated with the goal of killing the tumours.

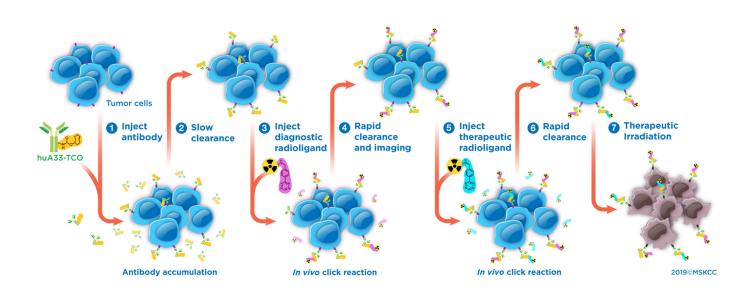


Figure 9. This pre-targeting therapy starts with an antibody 'tagged' with TCO. The antibody tagged-TCO is injected in the body and binds to cancer cells (1). The unbound antibody slowly clears the body (2) so that there is primarily binding to the cancer cells with limited background. After a few days, the radioligand (the chaser compound) is injected (3) in the body and via the "click" reaction, attaches to the TCO tag on the antibody. Unbound radioligand otherwise clears the body quickly (4). The bound antibodies, now radiolabeled, irradiate the cancer cells with a therapeutic dose (5).

TEAM AND COLLABORATORS

The team is at the heart of Clarity's success and is what drives the Company forward. Over the years, Clarity has assembled an exceptional team, including Board of Directors and Advisory Board, and continues to attract some of the best talent in the industry who deliver a unique range of skills and expertise together with extensive experience in the global radiopharmaceutical market.

This quarter, Clarity continued its efforts to build a team with worldclass expertise and was joined by Ms Kathryn Williams-Day as a VP of Regulatory Affairs and Quality and Ms Wendy Perez-Contreras as Senior Director, Clinical Operations.

Kathryn Williams-Day

Kathryn Williams is a highly accomplished professional with over two decades of experience in the fields of regulatory affairs, quality management and market access. She has worked as a senior leader across the Regulatory, Quality and Clinical departments at Pfizer, Genzyme (a Sanofi company), Sandoz, and Merck, as well as consulting for various biotech companies. Kathryn possesses a strategic mindset and has contributed significantly to the successful launch of various pharmaceutical and medical technology products in Australia and in the global markets. Her expertise extends to rare diseases, oncology and neurology. Kathryn has consistently demonstrated her proficiency in ensuring that products meet stringent regulatory and quality requirements while overseeing intricate and complex regulatory and reimbursement submissions for innovative products. Her career is marked by her deep commitment to making a positive impact on patients' lives and her ability to tackle complex market challenges with finesse.

Wendy Perez-Contreras

Wendy is an experienced leader with over 20 years of development operations experience. In the last 6 years she has been specialising in radioligand therapy (RLT) working with gallium, lutetium and actinium compounds for prostate cancer, NETs and other advanced solid tumour indications. Most recently, Wendy has been employed at Novartis in their Radiosensitive Cancers Team, working in early development of RLT compounds. Prior to this, she oversaw the VISION study, the Phase III registration trial of 177Lu-PSMA-617 in patients with prostate cancer that led to the approval of the Pluvicto® and Locametz® products. She was part of the integration of Endocyte Inc into Advanced Accelerated Applications S.A. and ultimately into Novartis RLT. Prior to Novartis, Wendy held various positions in Clinical Operations at Endocyte, working on folate receptor and PSMA targeted therapy; at Schering-Plough (now MERCK) and the Cardiovascular Research Foundation (a cardiac device CRO).

FINANCIALS

Clarity's cash balance was \$53.6 million as at 30 September 2023.

Net operating cash outflows for the quarter were \$11.7 million which is higher than the previous quarter's outflow of \$9.5 million due to the increasing spend associated with the company's clinical trial programs together with the payment of FY23 bonuses. 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 September 2023 \$ Million	% of Total Funds
Pre-Clinical	\$2.7	2.5%	\$3.2	4.6%
Clinical	\$84.0	76.6%	\$43.5	63.2%
Regulatory	\$5.7	5.2%	\$2.1	3.0%
Patents	\$1.4	1.3%	\$2.5	3.6%
Corporate	\$10.4	9.5%	\$11.0	16.0%
Costs associated with the Offer	\$5.4	4.9%	\$6.6	9.6%
Total uses	\$109.6	100.0%	\$68.9	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 September 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 \$837,341 for the quarter. This amount includes director fees, salaries and bonuses paid in the September quarter.

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

REFERENCES

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- ClinicalTrials.gov Identifier: NCT05633160 clinicaltrials.gov/ct2/show/NCT05633160
- ClinicalTrials.gov Identifier: NCT04023331 clinicaltrials.gov/ct2/show/NCT04023331
- 4. ClinicalTrials.gov Identifier: NCT06056830 clinicaltrials.gov/ct2/show/NCT06056830
- ClinicalTrials.gov Identifier: NCT04839367 clinicaltrials.gov/ct2/show/NCT04839367
- ClinicalTrials.gov Identifier: NCT05249127 clinicaltrials.gov/ct2/show/NCT05249127
- ClinicalTrials.gov Identifier: NCT05407311
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- Sarepta Therapeutics. (2023, July 5). Sarepta Therapeutics Announces Sale of Priority Review Voucher for \$102 million [Press release]. https://investorrelations.sarepta. com/news-releases/news-release-details/ sarepta-therapeutics-announces-salepriority-review-voucher-102

For more information, please contact:

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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

30 September 2023

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
1.	Cash flows from operating activities		
1.1	Receipts from customers	-	-
1.2	Payments for		
	(a) research and development	(7,979)	(7,979)
	(b) product manufacturing and operating costs	-	-
	(c) advertising and marketing	(36)	(36)
	(d) leased assets	-	-
	(e) staff costs	(3,329)	(3,329)
	(f) administration and corporate costs	(899)	(899)
1.3	Dividends received (see note 3)	-	-
1.4	Interest received	540	540
1.5	Interest and other costs of finance paid	-	-
1.6	Income taxes paid	(14)	(14)
1.7	Government grants and tax incentives	-	-
1.8	Other (provide details if material)	-	-
1.9	Net cash from / (used in) operating activities	(11,717)	(11,717)

2.	Casl	h flows from investing activities		
2.1	Paym	nents to acquire or for:		
	(a) (entities	-	-
	(b) I	businesses	-	-
	(c) I	property, plant and equipment	(193)	(193)
	(d) i	investments	-	-
	(e) i	intellectual property		
	(f) (other non-current assets	-	-

Con	solidated statement of cash flows	Current quarter \$A'000	Year to date (3 months) \$A'000
2.2	Proceeds from disposal of:		
	(a) entities	-	-
	(b) businesses	-	-
	(c) property, plant and equipment	-	-
	(d) investments	-	-
	(e) intellectual property	-	-
	(f) other non-current assets	-	-
2.3	Cash flows from loans to other entities	-	=
2.4	Dividends received (see note 3)	-	-
2.5	Other (provide details if material)	-	-
2.6	Net cash from / (used in) investing activities	(193)	(193)

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	-	-
3.4	Transaction costs related to issues of equity securities or convertible debt securities	(3)	(3)
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	(3)	(3)

4.	Net increase / (decrease) in cash and cash equivalents for the period		
4.1	Cash and cash equivalents at beginning of period	65,015	65,015
4.2	Net cash from / (used in) operating activities (item 1.9 above)	(11,717)	(11,717)
4.3	Net cash from / (used in) investing activities (item 2.6 above)	(193)	(193)

Consolidated statement of cash flows		Current quarter \$A'000	Year to date (3 months) \$A'000
4.4	Net cash from / (used in) financing activities (item 3.10 above)	(3)	(3)
4.5	Effect of movement in exchange rates on cash held	489	489
4.6	Cash and cash equivalents at end of period	53,591	53,591

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	27,264	31,213
5.2	Call deposits	26,327	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)	53,591	65,015

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	837
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, salaries, and bonuses.	1

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	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.				

8.	Estimated cash available for future operating activities	\$A'000
8.1	Net cash from / (used in) operating activities (item 1.9)	(11,717)
8.2	Cash and cash equivalents at quarter end (item 4.6)	53,591
8.3	Unused finance facilities available at quarter end (item 7.5)	-
8.4	Total available funding (item 8.2 + item 8.3)	53,591
8.5	Estimated quarters of funding available (item 8.4 divided by item 8.1)	5
	Note: if the entity has reported positive net operating cash flows in item 1.9. answer item	8.5 as "N/A" Otherwise a

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

8.6 If item 8.5 is less than 2 quarters, please provide answers to the following questions:

8.6.1 Does the entity expect that it will continue to have the current level of net operating cash flows for the time being and, if not, why not?

Answer:			

8.6.2 Has the entity taken any steps, or does it propose to take any steps, to raise further cash to fund its operations and, if so, what are those steps and how likely does it believe that they will be successful?

Answer:			

8.6.3 Does the entity expect to be able to continue its operations and to meet its business objectives and, if so, on what basis?

objectives and, if so, on what	t basis?
Answer:	

Note: where item 8.5 is less than 2 quarters, all of questions 8.6.1, 8.6.2 and 8.6.3 above must be answered.

Compliance statement

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

Date:	31 October 2023
Authorised by:	Board of Directors
Additionsed 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 eg Audit and Risk Committee]". If it has been authorised for release to the market by a disclosure committee, you can insert here: "By the Disclosure Committee".
- 5. If this report has been authorised for release to the market by your board of directors and you wish to hold yourself out as complying with recommendation 4.2 of the ASX Corporate Governance Council's Corporate Governance Principles and Recommendations, the board should have received a declaration from its CEO and CFO that, in their opinion, the financial records of the entity have been properly maintained, that this report complies with the appropriate accounting standards and gives a true and fair view of the cash flows of the entity, and that their opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively.