CLARITY PHARMACEUTICALS

INTERIM REPORT

and Half-Year Financial Statements

Sydney, Australia
28 February 2023

ABN 36 143 005 341

CONTENTS

KEY OPERATIONAL HIGHLIGHTS

PROPELLER[1]
Trial results from Clarity's Phase I diagnostic ^{64}Cu SAR-bisPSMA prostate cancer trial presented at the American Society of Clinical Oncology (ASCO) Genitourinary (GU) Symposium showed ^{64}Cu SAR-bisPSMA to be safe, well tolerated and efficacious in the detection of prostate cancer in the pre-prostatectomy/pre-definitive treatment setting.

COBRA[2]
Recruitment target was reached in the US-based Phase I/II diagnostic ^{64}Cu SAR-bisPSMA trial for patients with biochemical recurrence of prostate cancer following definitive therapy.

COMBAT[3]
Approval of the Investigational New Drug (IND) application by the United States Food and Drug Administration (US FDA) to evaluate Clarity's ^{64}Cu/^{67}Cu SAR-Bombesin product. This US-based Phase I/IIa trial will investigate the identification and treatment of gastrin releasing peptide receptor (GRPr) expressing metastatic castrate-resistant prostate cancer (mCRPC) in patients who are ineligible for therapy with ^{177}Lu-PSMA-617.

BOP[4]
Fifty percent recruitment milestone reached in the Phase II diagnostic ^{64}Cu SAR-Bombesin investigator-initiated trial for patients with prostate cancer, with 15 out of 30 participants enrolled and imaged.

SECuRE[5]
First patient recruited and treated in the therapeutic phase of the US-based theranostic clinical trial investigating ^{64}Cu/^{67}Cu SAR-bisPSMA in patients with PSMA-positive metastatic castrate-resistant prostate cancer.

SABRE[6]
First patient imaged in the US-based diagnostic ^{64}Cu SAR-Bombesin trial for patients with PSMA-negative prostate cancer.

DISCO[7]
Fifty percent recruitment milestone reached in the Phase II diagnostic ^{64}Cu SARTATE trial in up to 63 patients with gastroenteropancreatic neuroendocrine tumours (GEP-NETs).

Intellectual Property
The patent application covering optimised Prostate Specific Membrane Antigen targeting agent, SAR-bisPSMA, was Granted in China.

Manufacturing
Clarity expanded the Targeted Copper Theranostics (TCTs) manufacturing agreement with Evergreen Theragnostics to include ^{67}Cu SAR-Bombesin for Clarity's COMBAT theranostic trial in the US.

Supply
Clarity signed a supply agreement with 3D Imaging, covering Clarity's diagnostic ^{64}Cu SAR-bisPSMA product.

Board of Directors
Cheryl Maley joined Clarity's Board of Directors as a Non-Executive Director.

Senior Executive Team
Dr Jeffrey Norenberg joined as Chief Scientific Officer.

KEY FINANCIALS

$75.9m
CASH BALANCE

Well-funded with a **cash balance of $75.9 million** at 31 December 2022 and an expected **FY22 R&D tax incentive of $6.7 million** in March 2023 to fund the existing trial pipeline.

$14.8m
R&D EXPENDITURE

R&D expenditure increased to $14.8 million in the half year, compared to $7.3m in the previous corresponding period, reflecting an increase in clinical trial activities.

$16.5m
NET OPERATING CASH OUTFLOWS

Net operating cash outflows of $16.5 million, up from $8.7 million in the previous corresponding period.

Clarity Pharmaceuticals Ltd (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 interim report and financial results for the half-year ended 31 December 2022.

Executive Chairperson, Dr Alan Taylor, said:

"On behalf of the entire team at Clarity, I am delighted to present Clarity's interim report and half-yearly financial statements.

"We would like to thank our strategic, institutional and retail investors for their support of the company; thanks to them, we remain well financed to continue progressing our Targeted Copper Theranostic (TCT) products and expanding our logistics and manufacturing footprint despite the challenging capital markets backdrop for the broader biotechnology industry. With a cash balance of $75.9 million at 31 December 2022, or over $80 million when taking into consideration the estimated R&D tax incentive claim of $6.7 million for FY22 , we are in a strong position to focus on advancing our business.

"As such, during the half-year we concentrated our efforts on leveraging Clarity's robust pipeline and the significant advantages of TCTs in the radiopharmaceuticals field. We have been actively progressing **seven clinical trials and an investigator-initiated trial** with our products. Clarity's strategy is to launch TCTs for first approvals in the US, the largest oncology market in the world, and we have made significant progress in implementing it. We now have **five open Investigational New Drug (IND) applications with the United States Food and Drug Administration (US FDA) for a total of six products** with both theranostic and diagnostic applications.

"Clarity has hit **significant milestones in all seven of its clinical trials** since 1 July 2022, demonstrating the unwavering dedication of our team and collaborators and bringing us closer to our mission to improve treatment outcomes for children and adults with cancer.

"Importantly, our Phase I PROPELLER trial of ^{64}Cu SAR-bisPSMA in prostate cancer met its primary and secondary objectives, confirming it was safe, well tolerated and efficacious in detecting primary 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 and has enabled us to commence work for our diagnostic Phase III trials with ^{64}Cu SAR-bisPSMA in the US.

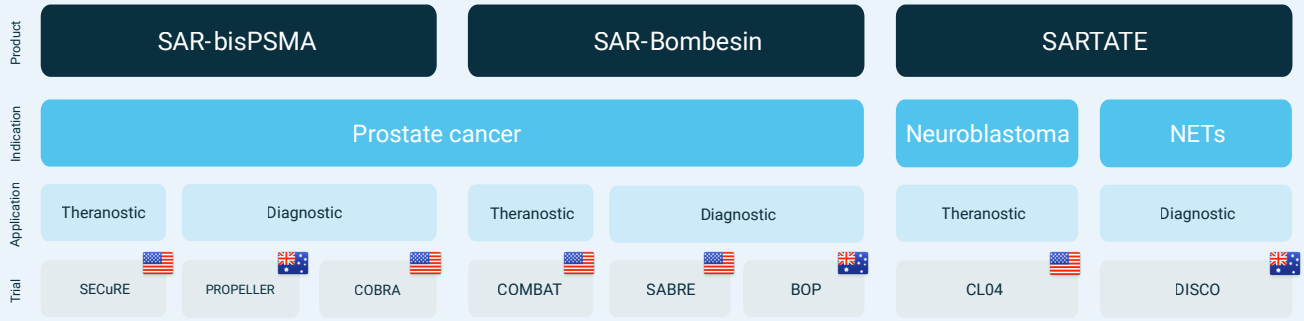
"We also **strengthened our manufacturing and supply chain** efforts in the half-year to support our existing studies as well as our planned Phase III trials, with two new agreements in the US. Clarity also continued strengthening our **patent portfolio** with a new patent granted in China for our SAR-bisPSMA product.

"The Clarity team has grown in the US and Australia by approximately 20% in the reporting period to ensure we continue to deliver the outstanding progress in clinical, preclinical, regulatory and operational developments and evolve to fulfill our ambitions. We continue to recognise and celebrate the efforts of our team and place a high value on diversity and high-performance in our culture. We welcomed a new Non-Executive Director, Ms Cheryl Maley, to our Board and a new Chief Scientific Officer, Dr Jeff Norenberg, to our Senior Executive Team.

"We look forward to updating you on Clarity's continued progress and the exciting milestones ahead."

CLINICAL & REGULATORY DEVELOPMENT OVERVIEW

Clarity is 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 is also an investigator-initiated trial (IIT) with Clarity's SAR-Bombesin product.



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-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.

	Theranostic	Diagnostic
SARTATE	**CL04** – Phase I/IIa theranostic trial in paediatric participants with high-risk neuroblastoma using $^{64}Cu/^{67}Cu$ SARTATE in the US (NCT04023331)[8]	**DISCO** – Phase II PET imaging trial of participants with known or suspected Neuroendocrine Tumours (NETs) using ^{64}Cu SARTATE in Australia (NCT04438304)[7]
SAR-bisPSMA	**SECuRE** – Phase I/IIa theranostic trial for identification and treatment of PSMA-expressing metastatic castrate-resistant prostate cancer (mCRPC) using $^{64}Cu/^{67}Cu$ SAR-bisPSMA in the US (NCT04868604)[5]	**PROPELLER** – Phase I Positron Emission Tomography (PET) imaging trial of participants with confirmed prostate cancer using ^{64}Cu SAR-bisPSMA in Australia (NCT04839367)[1] **COBRA** – Phase I/II PET imaging trial of participants with biochemical recurrence (BCR) of prostate cancer following definitive therapy using ^{64}Cu SAR-bisPSMA in the US (NCT05249127)[2]
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 ^{177}Lu-PSMA-617, using $^{64}Cu/^{67}Cu$ SAR-Bombesin (NCT05633160)[3]	**SABRE** – Phase II PET imaging trial of participants with PSMA-negative BCR of prostate cancer using ^{64}Cu SAR-Bombesin in the US (NCT05407311)[6] **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 ^{64}Cu SAR-Bombesin led by Prof Louise Emmett at St Vincent's Hospital Sydney (NCT05613842)[4].

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.

The Company has previously received clearance to proceed to clinical trials from the FDA for the following products and trials:

Theranostic
$^{64}Cu/^{67}Cu$ SARTATE
product for patients with neuroblastoma
CL04 trial[8]

Therapy
^{67}Cu SAR-bisPSMA
product for prostate cancer patients
SECuRE trial[5]

Therapy
^{67}Cu SAR-Bombesin
product for prostate cancer patients
COMBAT trial[3]

Diagnostic
^{64}Cu SAR-bisPSMA
product for prostate cancer patients
COBRA trial[2]

Diagnostic
^{64}Cu SAR-Bombesin
product for prostate cancer patients
SABRE trial[6]

Clarity received its fifth successful IND application with the US FDA in the reporting period for a theranostic trial of SAR-Bombesin in prostate cancer patients, COMBAT (NCT05633160)[3].

CLARITY'S CLINICAL AND REGULATORY MILESTONES FROM 1 JULY 2022

2022

Jul 2022

PROPELLER recruitment complete SAR-bisPSMA Dx Au

Aug 2022

BOP opened for recruitment SAR-BBN Dx Au

CL04 advanced to cohort 3 SARTATE Tx US

Sep 2022

SABRE recruitment opened SAR-BBN Dx US

BOP first patients imaged SAR-BBN Dx Au

Oct 2022

SABRE first patient imaged SAR-BBN Dx US

SECuRE first patient treated in the therapeutic phase SAR-bisPSMA Tx US

COBRA 50% recruitment milestone SAR-bisPSMA Dx US

Nov 2022

BOP 50% recruitment milestone SAR-BBN Dx Au

COMBAT approval of the IND by the US FDA SAR-BBN Tx US

Dec 2022

PROPELLER Positive top-line results SAR-bisPSMA Dx Au

2023

Feb 2023

COBRA reached recruitment target SAR-bisPSMA Dx US

PROPELLER trial results presented at ASCO GU SAR-bisPSMA Dx Au

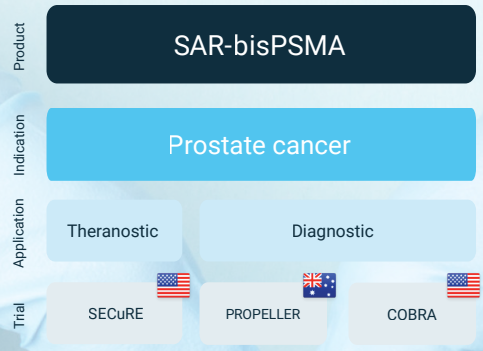
DISCO 50% recruitment milestone SARTATE NETs Dx Au

* Tx = THERANOSTIC
** Dx = DIAGNOSTIC

PRODUCT UPDATES

SAR-bisPSMA – PROSTATE CANCER

SAR-bisPSMA is a next generation, highly targeted theranostic radiopharmaceutical. It is being developed for diagnosing, staging and subsequently treating cancers that express Prostate Specific Membrane Antigen (PSMA).



The product uses either copper-64 (^{64}Cu) for imaging (^{64}Cu SAR-bisPSMA) or copper-67 (^{67}Cu) for therapy (^{67}Cu SAR-bisPSMA). In addition to the therapy program in metastatic castrate resistant prostate cancer (mCRPC) with ^{67}Cu SAR-bisPSMA, Clarity is also running a diagnostic program in line with advice received from the US FDA to address the two relevant patient populations for registration of ^{64}Cu SAR-bisPSMA:

- pre-prostatectomy/pre-definitive treatment of patients with confirmed prostate cancer
- patients with biochemical recurrence of prostate cancer

SECuRE

SECuRE – a theranostic ^{64}Cu/^{67}Cu SAR-bisPSMA trial

Clarity is progressing recruitment in the therapy phase of the SAR-bisPSMA theranostic clinical trial SECuRE (NCT04868604)[5]. Data from the initial dosimetry phase with ^{64}Cu SAR-bisPSMA was assessed by the Safety Review Committee which recommended to move to therapeutic applications with ^{67}Cu SAR-bisPSMA. The Company recruited and treated patients in the 1st cohort of the therapy phase in October 2022.

SECuRE, which derives from "**S**yst**E**mic **Cu** the**R**anostics in prostat**E** cancer", is a US-based Phase I/IIa theranostic trial for identification and treatment of an advanced form of prostate cancer, mCRPC. Clarity's PSMA imaging product is used to visualise PSMA expressing cancers and select patients 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 patients.

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

COBRA

COBRA – a diagnostic ^{64}Cu SAR-bisPSMA trial

Clarity reached its recruitment target in the diagnostic ^{64}Cu SAR-bisPSMA trial, COBRA (NCT05249127)[2], in February 2023, shortly after reaching the fifty percent recruitment milestone in the trial in October 2022.

COBRA, which derives from "**CO**pper-64 SAR-bisPSMA in **B**iochemically **R**ecurrent prost**A**te cancer", is a Phase I/II Positron Emission Tomography (PET) imaging trial of patients with BCR of prostate cancer following definitive therapy. In this study, patients have an increase of PSA (a blood level) 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 ^{64}Cu SAR-bisPSMA to correctly detect recurrence of prostate cancer, as well as assess its safety and tolerability. COBRA is a multi-centre, single arm, non-randomised, open-label trial of Clarity's PSMA imaging product (^{64}Cu SAR-bisPSMA) in 50 patients. 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.

PROPELLER

PROPELLER – a diagnostic ^{64}Cu SAR-bisPSMA trial

Clarity reported data from the diagnostic Phase I trial of ^{64}Cu SAR-bisPSMA in prostate cancer, PROPELLER (NCT04839367)[1] at the ASCO GU Symposium in February 2023, following the announcement of positive top line results from the trial in December 2022. Recruitment into the PROPELLER trial was completed in July 2022.

PROPELLER derives from "**P**osit**RO**n Emission Tomography Imaging of **P**articipants with Confirmed Prostat**E** Cancer Using ^{64}Cu-SAR-bisPSMA: A Mu**L**tiCentre, B**L**ind**E**d Review, Dose **R**anging Phase I study". It was a first-in-human trial administering Clarity's optimised PSMA agent, ^{64}Cu SAR-bisPSMA, to 30 patients with confirmed prostate cancer prior to undergoing radical prostatectomy. The trial also compared the diagnostic properties of ^{64}Cu SAR-bisPSMA against ^{68}Ga PSMA-11, which is approved for prostate cancer imaging in Australia and the US.

Primary objectives

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

Secondary objectives

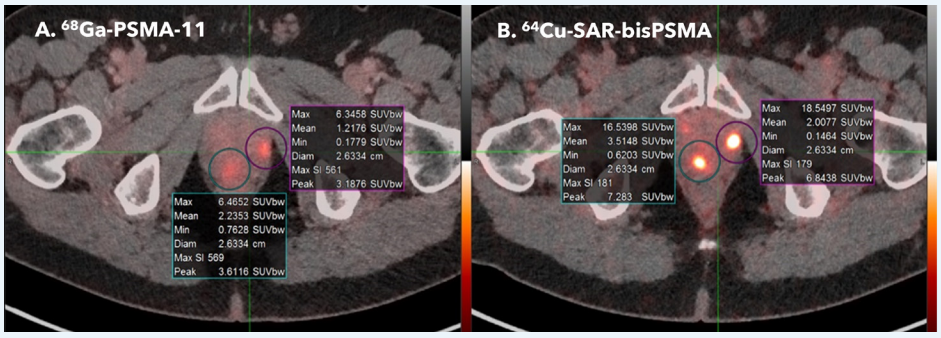
- Assessment of image quality at varying dose levels of ^{64}Cu SAR-bisPSMA for (100 MBq, 150 MBq and 200 MBq).

The PROPELLER data further substantiates the utility of ^{64}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 ^{64}Cu) and subsequent treatment (with ^{67}Cu) of prostate cancer. Clarity has commenced preparations for a diagnostic Phase III trial with ^{64}Cu SAR-bisPSMA in patients in the pre-prostatectomy/pre-definitive treatment setting and looks to engage with the US FDA later in 2023.

PROPELLER

Figure 1. Scans from two patients, comparing ^{68}Ga PSMA-11 (images A and C to the right) to ^{64}Cu SAR-bisPSMA (images B and D to the left). In both patients, the ^{64}Cu SAR-bisPSMA had higher uptake, leading to brighter lesions.

Patient 1 – Interval between the ^{68}Ga PSMA-11 and ^{64}Cu SAR-bisPSMA scan was 8 days



Patient 2 – Interval between the ^{68}Ga PSMA-11 and ^{64}Cu SAR-bisPSMA scan was 34 days

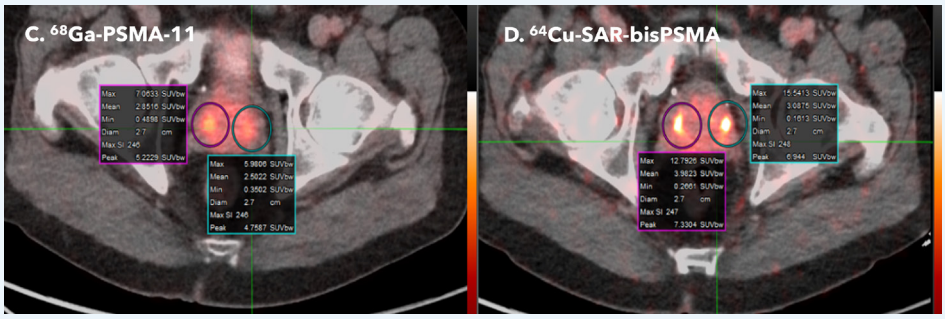
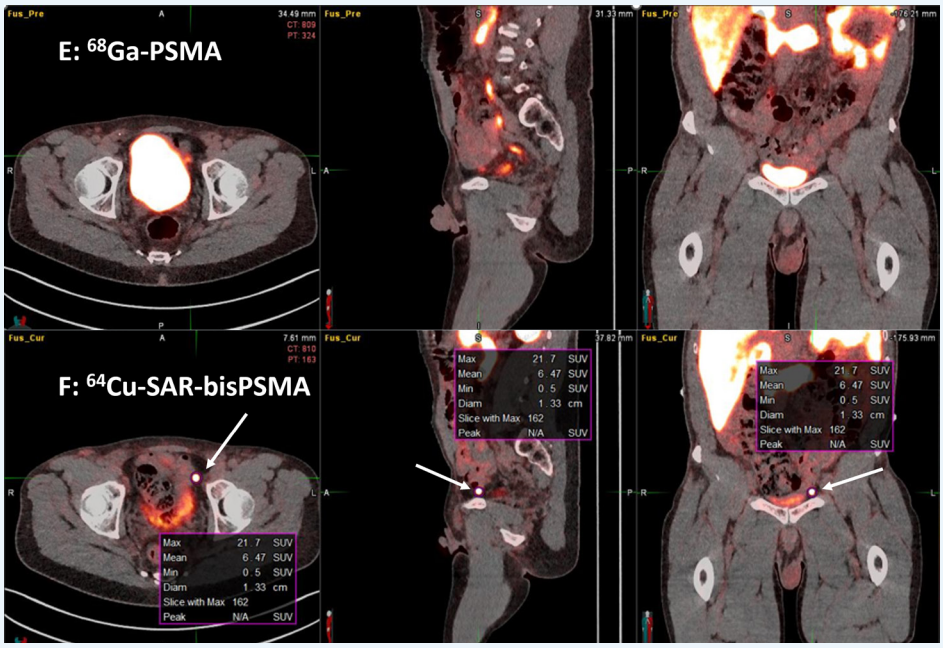
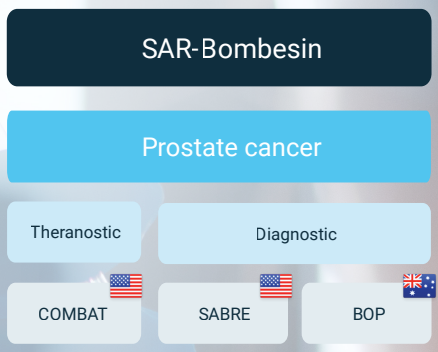


Figure 2. Scans from a third patient show uptake of ^{64}Cu SAR-bisPSMA in a pelvic lymph node (image F in the bottom row), outside of the prostate. This lesion was not detected by the readers on the ^{68}Ga PSMA-11 scan (image E in the top row).

Patient 3 – Interval between the ^{68}Ga PSMA-11 and ^{64}Cu SAR-bisPSMA scan was 7 days



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 (^{64}Cu) for imaging (^{64}Cu SAR-Bombesin) or copper-67 (^{67}Cu) for therapy (^{67}Cu SAR-Bombesin).

Approximately 20% of prostate cancers with BCR are PSMA-PET negative[9-12] and approximately 25% of mCRPC patients have low or no uptake of a PSMA-targeting tracer[13]. These patients are therefore unlikely to show uptake of PSMA-targeted products, such as ^{68}Ga-PSMA-11 for imaging or ^{177}Lu-PSMA-617 for therapy, and currently have few radiopharmaceutical treatment options available to them. Given the prostate cancer indication is one of the largest in oncology, there is a significant unmet medical need in this area. 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.

COMBAT

COMBAT - a theranostic ^{64}Cu/^{67}Cu SAR-Bombesin trial

Clarity has received approval of its IND application by the US FDA, giving Clarity clearance to proceed with a US-based Phase I/IIa ^{64}Cu/^{67}Cu SAR-Bombesin theranostic trial, COMBAT (NCT05633160)[3]. 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 ^{67}Cu-SAR-Bombesin in patients with GRPr-expressing mCRPC who are ineligible for therapy with ^{177}Lu-PSMA-617. Clarity anticipates opening this study for recruitment in Q2 2023.

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

SABRE

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

Clarity has successfully imaged its first patient in the US-based diagnostic ^{64}Cu SAR-Bombesin trial for patients with PSMA-negative prostate cancer, SABRE (NCT05407311)[6], in October 2022.

SABRE opened for recruitment in September 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, open-label trial in 50 PSMA-negative patients with biochemical recurrence of their prostate cancer. The primary objectives of the trial are to investigate the safety and tolerability of ^{64}Cu SAR-Bombesin, as well as its ability to correctly detect the recurrence of prostate cancer. The SABRE trial was developed in response to the strong demand from clinicians with prostate cancer patients whose cancer was not deemed 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 ^{64}Cu SAR Bombesin under Australia's Therapeutic Goods Administration Special Access Scheme (TGA SAS)[14-15].

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 ^{64}Cu SAR-Bombesin investigator-initiated trial

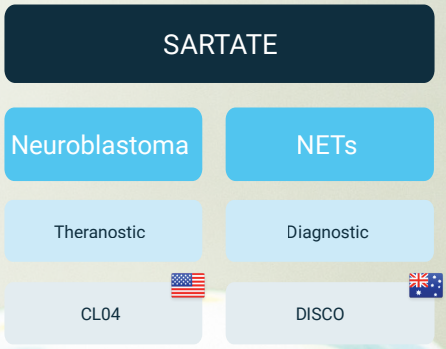
The Phase II diagnostic ^{64}Cu SAR-Bombesin investigator-initiated trial (BOP, NCT05613842[4]) for patients with prostate cancer has reached the fifty percent recruitment milestone, with 15 out of 30 patients enrolled and imaged in November 2022.

The first patients 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 **BO**mbesin in **P**SMA negative prostate cancer, is a Phase II IIT in up to 30 patients. The BOP trial will be assessing the safety of ^{64}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 ^{64}Cu SAR-Bombesin administration as well as at later timepoints.

Similar to the SABRE trial, the BOP trial builds on the data generated in PSMA-negative prostate cancer patients at St Vincent's Hospital imaged under TGA SAS[14-15] as well as from pilot diagnostic IIT of SAR-Bombesin in breast cancer patients, the C-BOBCAT trial[16].

SARTATE – NEUROBLASTOMA AND NETs



SARTATE is a next generation, highly targeted theranostic radiopharmaceutical.

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

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)[8]
- **DISCO** diagnostic trial in Australia (NCT04438304)[7]

In 2020, the US FDA awarded Clarity two Orphan Drug Designations (ODDs), one for ^{64}Cu SARTATE as a diagnostic agent for the clinical management of neuroblastoma and one for ^{67}Cu 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 US FDA for these two products, RPDDs may allow the Company to access a total of two tradeable Priority Review Vouchers (PRVs) which most recently traded at USD95M per voucher.[17]

CL04 – a theranostic ^{64}Cu/^{67}Cu SARTATE trial in neuroblastoma

Clarity has advanced to cohort 3 in the theranostic ^{64}Cu/^{67}Cu SARTATE trial in neuroblastoma patients, CL04 (NCT04023331)[8], having successfully completed the first two cohorts.

In line with the recommendations from the independent Safety Review Committee, the trial continues with the dose escalation phase as planned, increasing the ^{67}Cu SARTATE dose from 175MBq/kg body weight in cohort 2 to 275MBq/kg body weight in cohort 3. Generally speaking, higher therapeutic dose is usually associated with greater therapeutic response, up to a certain threshold where toxicity can occur. The CL04 trial is designed to gradually increase the dose of ^{67}Cu SARTATE administered to patients in each cohort, with the maximum of 4 cohorts, until the Maximum Tolerated Dose (MTD) is reached.

Recruitment into cohort 3 is currently underway in the US, with additional US clinical sites opening for recruitment in the coming months. Importantly, additional therapy cycles of ^{67}Cu SARTATE have been requested by clinicians for patietns in cohort 1 and cohort 2. Subsequent therapy cycles are contingent on the Investigators' assessment that the patient is demonstrating therapeutic benefit.

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

DISCO – a diagnostic ^{64}Cu SARTATE NETs trial

Clarity's diagnostic imaging study of ^{64}Cu SARTATE, DISCO (NCT04438304)[7], reached the fifty percent recruitment milestone, with 32 out of 63 patients with known or suspected NETs enrolled and imaged in February 2023.

DISCO, which derives from "**D**iagnostic **I**maging **S**tudy of ^{64}**Co**pper-SARTATE Using PET on Patients With Known or Suspected Neuroendocrine Tumours", is assessing the performance of Clarity's SARTATE imaging product as a potential new way to help diagnose and manage NETs. It is a Phase II study in up to 63 patients with Gastroenteropancreatic NETs (GEP-NETs) across four sites in Australia, comparing the diagnostic performance of ^{64}Cu SARTATE at 4 and 20 hours post-administration to the current standard of care, ^{68}Ga DOTATATE, at one hour.

NETs traditionally have been considered uncommon; however, the incidence has been increasing as a worldwide phenomenon[18]. This increase is thought to be mostly related to improvements in the way NETs are diagnosed, including better imaging tests and endoscopy, and increased awareness of these tumours. Overall, it is estimated that more than 12,000 people in the United States are diagnosed with a NET each year, and approximately 175,000 people are living with this diagnosis[19]. Patients with GEP-NETs present with subtle clinical symptoms, which can lead to a delay in diagnosis of up to 5–7 years, or result in inappropriate management[20]. As such, about 30-75% of NET patients have distant metastases at the time of diagnosis[21]. A 10-year relative survival rate for patients with metastatic GEP-NETs is 3–36%[22].

There is a clear unmet need in the NET indication and Clarity continues to build on the promising first-in-human data with SARTATE (Hicks, R. et al)[23], which demonstrated that imaging at later time points, enabled by a longer half-life of ^{64}Cu isotope in comparison to ^{68}Ga, may lead to better identification of disease, and indicated the safety and potential effectiveness of the product as a new way to detect NETs.

MANUFACTURING AND SUPPLY CHAIN

One of Clarity's key competitive advantages is the ability of TCTs to overcome a number of supply chain limitations that have been preventing radiopharmaceuticals from further expanding into the large oncology market.

CURRENT CHALLENGES

The two key limitations for the current generation of radiopharmaceuticals are:

- Short shelf-life of diagnostic products presents logistical constraints for manufacturing and distribution
- Volume and consistency in producing therapeutic isotopes required to manufacture the products to meet growing demand is limited by a small number of ageing nuclear reactors

ADVANTAGES OF TCTs

TCTs are next-generation radiopharmaceuticals that employ copper-64 (^{64}Cu or Cu-64) for diagnosis and copper-67 (^{67}Cu or Cu-67) for therapy. In addition to clinical benefits of high accuracy and high precision in treating cancer, the copper pairing provides significant supply and manufacturing advantages:

- Diagnostic products based on ^{64}Cu and utilising SAR technology have a longer shelf-life, allowing central manufacture and regional distribution, potentially reaching more treatment centres and patients
- Diagnostic ^{64}Cu is produced on cyclotrons with a single cyclotron able to supply the entire Phase III diagnostic clinical program
- Therapeutic ^{67}Cu is produced on electron accelerators, which are relatively inexpensive and infinitely scalable in comparison to nuclear reactor produced isotopes

CLARITY'S SUPPLY CHAIN

Clarity has been actively building, strengthening and expanding a dependable and sustainable manufacturing base and supply chain to take full advantage of the TCT benefits ahead of Phase III trials and product commercialisation stage. In the reporting period, the Company entered into two agreements:

- Expansion of the agreement with Evergreen Theragnostics to include manufacturing and supply of therapeutic ^{67}Cu SAR-Bombesin for Clarity's theranostic trial in the US, COMBAT^{3}
- Supply agreement with 3D Imaging for ^{64}Cu and ^{64}Cu SAR-bisPSMA for diagnostic Phase III clinical trials

Clarity is building a reliable and accessible supply chain consistent with the "big pharma" model with an aspiration to launch the radiopharmaceutical field into the large oncology market. This is a key differentiator for Clarity, distinguishing it from the current generation of products in the radiopharmaceuticals field.

INTELLECTUAL PROPERTY

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

In the reporting period Clarity focused on strengthening protection of its optimised PSMA targeting agent, SAR-bisPSMA, with granting of China patent that has an expiry date of 5 June 2038. This follows corresponding patents previously approved in the USA, Australia and Mexico. The patent application remains under review in other major jurisdictions, including Europe and Japan.

The prostate cancer market is a key focus for Clarity as the company continues to hit key milestones in the development of SAR-bisPSMA in three clinical trials:

- SECuRE (NCT04868604)[5] theranostic US-based trial– recruitment in the therapeutic phase of the trial ongoing
- PROPELLER (NCT04839367)[1] diagnostic Australia-based trial– initial data presented at ASCO GU, Phase III trial planning ongoing
- COBRA (NCT05249127)[2] diagnostic US-based trial – recruitment target reached

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

TEAM AND COLLABORATORS

Clarity is very proud of the exceptional, diverse and high-performing team it has built over the years, including its Board of Directors, Advisory Board and collaborators, who deliver a unique range of skills, expertise, extensive experience in the global radiopharmaceutical market and outstanding performance.

In the reporting period, the Company continued to build a team with world-class expertise and knowledge in the radiopharmaceutical field, supporting rapid growth of the Company and clinical development of its products.

Clarity's Senior Executive Team has welcomed a new Chief Scientific Officer (CSO), Dr Jeffrey Norenberg. Dr Norenberg is a globally recognised industry expert in the design and development of novel targeted radioligands for molecular imaging and therapy. Outgoing CSO, Dr Matt Harris, is now serving in a newly created role of Director of Technology.

A key addition to Clarity's Board of Directors is Ms Cheryl Maley, an experienced senior leader with over 25 years of experience in the pharmaceutical industry. Ms Maley's most recent role was the General Manger, Novartis Oncology, Australia and New Zealand. She has a strong strategic, commercial background with a proven track record in product launch excellence and timely patient access to innovative medicines. She has worked in the US, Philippines and Australia with local, regional and global responsibilities.

The addition of Ms Maley is in line with Clarity's goal of strengthening the Board's skills, knowledge and experience while also supports the Company's commitment to gender balance at Board level, made in the ESG report in November 2022.

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2. ClinicalTrials.gov Identifier: NCT05249127 clinicaltrials.gov/ct2/show/NCT05249127
3. ClinicalTrials.gov Identifier: NCT05633160 clinicaltrials.gov/ct2/show/NCT05633160
4. ClinicalTrials.gov Identifier: NCT05613842 clinicaltrials.gov/ct2/show/ NCT05613842
5. ClinicalTrials.gov Identifier: NCT04868604 clinicaltrials.gov/ct2/show/NCT04868604
6. ClinicalTrials.gov Identifier: NCT05407311 clinicaltrials.gov/ct2/show/NCT05407311
7. ClinicalTrials.gov Identifier: NCT04438304 clinicaltrials.gov/ct2/show/NCT04438304
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FINANCIAL REPORT

OF CLARITY PHARMACEUTICALS LTD

FOR THE HALF YEAR ENDED

31 DECEMBER 2022

DIRECTORS' REPORT

FOR THE HALF-YEAR ENDED 31 DECEMBER 2022

The Directors of Clarity Pharmaceuticals Ltd (Clarity Pharmaceuticals) present their report together with the financial statements of the consolidated entity, being Clarity Pharmaceuticals (the Company) and its controlled entities (the Group) for the half-year ended 31 December 2022.

DIRECTOR DETAILS

The following persons were Directors of Clarity Pharmaceuticals during or since the end of the half-year:

Dr Alan Taylor	Executive Chairperson
Dr Colin Biggin	Managing Director and Chief Executive Officer
Mr Rob Thomas	Lead Independent Director
Ms Rosanne Robinson	Non-Executive Director
Dr Christopher Roberts	Non-Executive Director
Dr Thomas Ramdahl	Non-Executive Director
Dr Charles Gillies O'Bryan-Tear	Non-Executive Director (resigned effective 15 May 2023)
Ms Cheryl Maley	Non-Executive Director (appointed 1 February 2023)

RESULT

The loss for the half-year was $11.2 million (2021: $13.7 million loss). In December 2021, the loss was in part due to a one-off share-based expense of $6.8 million for options granted to China Grand Pharmaceutical and Healthcare Holdings Limited in July 2021. In the six months to December 2022, there was a significant increase in research and development expenditure, up $7.5 million to $14.8 million, reflecting an increase in clinical trial activities.

STATEMENT OF FINANCIAL POSITION

The Group's financial position at 31 December 2022 compared to the prior year was as follows:

- Liquid assets of $75.9 million (30 Jun 2022: $92.3 million) comprising cash on hand of $57.9 million (30 Jun 2022: $55.3 million) and term deposits of $18.0 million (30 Jun 2022: $37.0 million).
- Net assets decreased to $81.8 million from $92.2 million at 30 June 2022.

The Board believes the Group is well placed to support its programs throughout 2023.

REVIEW OF OPERATIONS

Corporate Overview

The Company remains well funded with $70.7 mil as at the date of this report together with an imminent R&D tax incentive of $6.7 mil expected in the coming months. This puts Clarity Pharmaceuticals in a strong position to execute its clinical and operational objectives.

During the reporting period management remained focussed on executing Clarity Pharmaceuticals' goal of developing the next generation of radiopharmaceutical products. The key highlights and significant events, until the date of this report, demonstrate the excellent progress made to-date in achieving that objective.

The Company has hit significant milestones in all seven clinical trials and an investigator-initiated trial (IIT) with its products since 1 July 2022 and at the same time strengthened its manufacturing and supply chain efforts to support this rapid clinical trial development. Clarity Pharmaceuticals remains committed to its strategy of launching Targeted Copper Theranostics (TCTs) for first approvals in the US, the largest oncology market in the world, and now have five Investigational New Drug (IND) applications with the United States Food and Drug Administration (US FDA) for a total of six products with both theranostic and diagnostic applications.

In keeping with this increase in clinical, regulatory and operational footprint, the Company continues to grow the team in the US and Australia, which increased by ~ 20% since July 1, 2022.

Clinical and Regulatory

Clarity Pharmaceuticals is 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.

SAR-bisPSMA – Prostate Cancer

Clarity Pharmaceuticals has made progress in three clinical trials using its optimised PSMA product:

The SECuRE theranostic trial is a Phase I/IIa trial for the treatment of PSMA-expressing metastatic castrate resistant prostate cancer (mCRPC) using ^{64}Cu/^{67}Cu SAR-bisPSMA in the US. The first participant in the therapeutic phase of the trial was recruited and treated in October 2022 and recruitment in the therapeutic phase remains ongoing.

The PROPELLER diagnostic trial was a Phase I Positron Emission Tomography (PET) imaging trial of participants with confirmed prostate cancer using ^{64}Cu SAR-bisPSMA in Australia. Clarity Pharmaceuticals reported data from the trial at the American Society of Clinical Oncology Genitourinary Symposium (ASCO GU) in February 2023, following the announcement of positive top line results from the trial in December 2022. Recruitment into the PROPELLER trial was completed in July 2022. The Company has commenced preparations for a diagnostic Phase III trial with ^{64}Cu SAR-bisPSMA in patients in the pre-prostatectomy/pre-definitive treatment setting.

The COBRA diagnostic trial is a Phase I/II PET imaging trial of participants with biochemical recurrence (BCR) of prostate cancer following definitive therapy using ^{64}Cu SAR-bisPSMA in the US. The recruitment target in the trial was reached in February 2023, shortly after achieving fifty percent recruitment in October 2022. The Company is currently collecting the data from the study for analysis.

SAR-Bombesin – Prostate Cancer

The Company has three trials in progress with its SAR-Bombesin product, including one IIT:

The COMBAT theranostic trial is a Phase I/IIa trial for identification and treatment of mCRPC that is expressing the Gastrin-Releasing Peptide receptor (GRPr) using ^{64}Cu/^{67}Cu SAR-Bombesin in participants who are ineligible for therapy with ^{177}Lu-PSMA-617 in the US. Clarity Pharmaceuticals received approval of the IND application by the US FDA to proceed with the trial received in November 2022.

The SABRE diagnostic trial is a Phase II PET imaging trial of participants with PSMA-negative BCR of prostate cancer using ^{64}Cu SAR-Bombesin in the US. SABRE opened for recruitment in September 2022 with the first participant in the trial successfully imaged in October 2022. Recruitment is ongoing.

The BOP diagnostic trial is an 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 ^{64}Cu SAR-Bombesin. The trial is led by Prof Louise Emmett at St Vincent's Hospital Sydney. The BOP trial reached fifty percent recruitment in November 2022, with 15 out of 30 participants enrolled and imaged. The first participant in the trial was imaged in September 2022, shortly after the trial opened for recruitment in August 2022. Recruitment in this trial is ongoing.

SARTATE – Neuroblastoma and NETs

The Company has two trials in progress using its SARTATE product:

The CL04 theranostic trial is a Phase I/IIa trial in paediatric participants with high-risk neuroblastoma using ^{64}Cu/^{67}Cu SARTATE™ in the US. The trial has progressed to cohort 3, having successfully completed the first two cohorts, in August 2022. Recruitment into cohort 3 is ongoing.

The DISCO diagnostic trial is a Phase II trial of participants with known or suspected Neuroendocrine Tumours (NETs) using ^{64}Cu SARTATE™ in Australia. In February 2023, the Company achieved fifty percent recruitment, with 32 out of 63 participants with known or suspected NETs enrolled and imaged. Recruitment into the DISCO trial is ongoing.

Manufacturing and Supply Chain

One of Clarity Pharmaceuticals' key competitive advantages is the ability of TCTs to overcome a number of logistics and supply chain limitations that have hindered radiopharmaceuticals expansion further into the large oncology market.

Clarity Pharmaceuticals has been actively building, strengthening and expanding a dependable and sustainable manufacturing base and supply chain to take full advantage of the TCT benefits ahead of Phase III trials and eventual product commercialisation. In the reporting period, the Company entered into two agreements:

- Expansion of the agreement with Evergreen Theragnostics to include manufacturing and supply of therapeutic ^{67}Cu SAR-Bombesin for COMBAT, Clarity Pharmaceuticals' theranostic trial in the US
- Supply agreement with 3D Imaging for ^{64}Cu and ^{64}Cu SAR-bisPSMA for Phase III diagnostic clinical trials.

The Company remains focussed on building a reliable, scalable, sustainable and accessible supply chain consistent with the "big pharma" model with products available on demand in the required volumes, without delays and supply interruptions. This is a key differentiator for Clarity, distinguishing it from many of the current generation of products in the radiopharmaceuticals field.

Intellectual Property

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

In the reporting period Clarity focused on strengthening protection of its optimised PSMA targeting agent, SAR-bis-PSMA, with granting of China patent that has an expiry date of 5 June 2038. This follows corresponding patents previously approved in the USA, Australia and Mexico. The patent application remains under review in other major jurisdictions, including Europe and Japan.

Team and collaborators

The Company is very proud of the exceptional, diverse and high-performing team it has built over the years, including its Board of Directors, Advisory Board and collaborators, who deliver a unique range of skills, expertise, extensive experience in the global radiopharmaceutical market and outstanding performance.

In the reporting period, Clarity Pharmaceuticals' Senior Executive Team welcomed a new Chief Scientific Officer (CSO), Dr Jeffrey Norenberg. Dr Norenberg is a globally recognised industry expert in the design and development of novel targeted radioligands for molecular imaging and therapy. Outgoing CSO, Dr Matt Harris, is now serving in a newly created role of Director of Technology.

A key addition to Clarity Pharmaceuticals' Board of Directors is Ms Cheryl Maley, an experienced senior leader with over 25 years of experience in the pharmaceutical industry who joined the Board in February 2023.

EVENTS ARISING SINCE THE END OF THE REPORTING PERIOD

On 1 February 2023, Cheryl Maley joined the board of the Clarity as a Non-Executive Director. On that same date, Dr Gillies O'Bryan-Tear tendered his resignation from the Clarity board of directors, with an effective date of 15 May 2023.

As noted in the Review of Operations Clarity achieved a number of significant clinical milestones following the period end, including:

- On 9 February 2023, Clarity's diagnostic ^{64}Cu SAR-bisPSMA trial, COBRA, for patients with prostate cancer, reached its recruitment target.
- On 14 February 2023, Clarity announced favourable imaging data from its Phase I diagnostic trial of ^{64}Cu SAR-bisPSMA in prostate cancer, PROPELLER, which was found to be safe, well tolerated and efficacious in the detection of prostate cancer.
- On 16 February 2023, Clarity reached 50% recruitment for its DISCO neuroendocrine tumour diagnostic Phase II trial of ^{64}Cu SARTATE.

There are no other matters or circumstances that have arisen since the end of the year that have significantly affected or may significantly affect either:

- the entity's operations in future financial years
- the results of those operations in future financial years; or
- the entity's state of affairs in future financial years.

AUDITOR INDEPENDENCE DECLARATION

A statement of independence has been provided by the Group's auditor, Grant Thornton, and is attached to this report.

Signed in accordance with a resolution of the Board of Directors.

Dr Alan Taylor
Chairperson
Date: 28 February 2023

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Auditor's Independence Declaration

To the Directors of Clarity Pharmaceuticals Ltd

In accordance with the requirements of section 307C of the *Corporations Act 2001*, as lead auditor for the review of Clarity Pharmaceuticals Ltd for the half-year ended 31 December 2022, I declare that, to the best of my knowledge and belief, there have been:

a no contraventions of the auditor independence requirements of the *Corporations Act 2001* in relation to the review; and

b no contraventions of any applicable code of professional conduct in relation to the review.

Grant Thornton Audit Pty Ltd
Chartered Accountants

Louise Worsley
Partner – Audit & Assurance

Sydney, 28 February 2023

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

FOR THE HALF-YEAR ENDED 31 DECEMBER 2022

	Note	December 2022 $	December 2021 $
Finance income	5	649,171	26,183
Research and Development Tax Incentive	5	5,732,620	2,807,272
Income		**6,381,791**	**2,833,455**
Corporate and administration	6	(2,773,450)	(9,198,126)
Research and development	7	(14,793,099)	(7,342,263)
Loss before income tax		**(11,184,758)**	**(13,706,934)**
Income tax expense		(57,897)	(5,465)
Loss for the year from continuing operations		**(11,242,655)**	**(13,712,399)**
Loss for the year		**(11,242,655)**	**(13,712,399)**
Other comprehensive income			
Exchange differences on translating foreign entity		1,604	1,967
Total comprehensive income for the period		**(11,241,051)**	**(13,710,432)**

Earnings per Share		December 2022 Cents	December 2021 Cents
Basic, loss for the year attributable to ordinary equity holders	8	(4.3)	(5.7)
Diluted, loss for the year attributable to ordinary equity holders	8	(4.3)	(5.7)

The accompanying notes form part of these financial statements

CONSOLIDATED STATEMENT OF FINANCIAL POSITION
AS AT 31 DECEMBER 2022

	Notes	December 2022 $	June 2022 $
Assets			
Current			
Cash and cash equivalents	9	57,888,282	55,336,328
Financial assets	10	18,000,000	37,000,000
Research & development tax incentive receivable	11	12,128,567	6,395,947
Other receivables	11	560,544	261,626
Prepayments		874,105	556,205
Total current assets		**89,451,498**	**99,550,106**
Non-current			
Plant & equipment	12	232,113	260,092
Other financial assets	10	12,343	11,745
Total non-current assets		244,456	**271,837**
Total assets		**89,695,954**	**99,821,943**
Liabilities			
Current			
Trade and other payables	13	6,951,042	6,792,254
Employee entitlements	14	859,491	713,929
Total current liabilities		**7,810,533**	**7,506,183**
Non-current			
Employee entitlements	14	101,220	79,226
Total non-current liabilities		101,220	**79,226**
Total liabilities		**7,911,753**	**7,585,409**
Net assets		**81,784,201**	**92,236,534**
Equity			
Share capital	15	132,602,135	132,115,430
Share option reserve	16	6,143,652	5,898,745
Accumulated losses		(56,981,239)	(45,795,690)
Foreign currency translation reserve		19,653	18,049
Total equity		**81,784,201**	**92,236,534**

The accompanying notes form part of these financial statements

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

FOR THE HALF-YEAR ENDED 31 DECEMBER 2022

	Share Option Reserve $	Foreign Currency Reserve $	Share Capital $	Accumulated Losses $	Total $
Half-year ended 31 December 2021					
Balance at 1 July 2021	**4,205,714**	**17,926**	**44,903,522**	**(28,849,604)**	**20,277,558**
Loss for the period	-	-	-	(13,712,399)	(13,712,399)
Foreign currency translation	-	1,967	-	-	1,967
Total Comprehensive Income	**-**	**1,967**	**-**	**(13,712,399)**	**(13,710,432)**
Transfer to share capital for options exercised	(60,775)	-	60,775	-	-
Ordinary shares issued on exercise of options	-	-	119,000	-	119,000
Issue of share capital	-	-	92,000,000	-	92,000,000
Capital raising costs	-	-	(5,496,537)	-	(5,496,537)
Share-based options	7,958,835	-	-	-	7,958,835
Balance at 31 December 2021	**12,103,774**	**19,893**	**131,586,760**	**(42,562,003)**	**101,148,424**
Half-year ended 31 December 2022					
Balance at 1 July 2022	**5,898,745**	**18,049**	**132,115,430**	**(45,795,690)**	**92,236,534**
Loss for the period	-	-	-	(11,242,655)	(11,242,655)
Foreign currency translation	-	1,604	-	-	1,604
Total Comprehensive Income	**-**	**1,604**	**-**	**(11,242,655)**	**(11,241,051)**
Transfer to share capital for options exercised	(250,836)	-	250,836	-	-
Ordinary shares issued on exercise of options	-	-	242,001	-	242,001
Transfer to retained earnings for options expired	(57,106)	-	-	57,106	-
Capital raising costs		-	(6,132)	-	(6,132)
Share-based options	552,849	-	-	-	552,849
Balance at 31 December 2022	**6,143,652**	**19,653**	**132,602,135**	**(56,981,239)**	**81,784,201**

The accompanying notes form part of these financial statements

CONSOLIDATED STATEMENT OF CASHFLOWS

FOR THE HALF-YEAR ENDED 31 DECEMBER 2022

	Notes	December 2022 $	December 2021 $
Cash Flows from Operating Activities			
Interest received		442,510	16,257
Payments to suppliers and employees		(16,920,822)	(8,752,972)
Income taxes paid		(57,897)	(5,465)
Net cash (used in) operating activities		**(16,536,209)**	**(8,742,180)**
Cash Flows from Investing Activities			
Investment in Term Deposits		18,999,402	(38,000,365)
Purchase of plant & equipment		(19,501)	(3,273)
Net cash (used in) investing activities		**18,979,901**	**(38,003,638)**
Cash Flows from Financing Activities			
Proceeds from issue of share capital		-	92,000,000
Exercise of options		110,000	69,000
Cost of capital raisings – complete and incomplete		(6,132)	(5,598,667)
Net cash provided by financing activities		**103,868**	**86,470,333**
Net increase in cash held			
Cash at the beginning of the financial year		55,336,328	8,439,068
Effect of exchange rate changes on cash and cash equivalents		4,394	826
Closing cash at the end of the half-year		**57,888,282**	**48,164,409**

The accompanying notes form part of these financial statements

NOTES TO THE FINANCIAL STATEMENTS

FOR THE HALF-YEAR ENDED 31 DECEMBER 2022

1. General information and statement of compliance

The financial report includes the consolidated financial statements and notes of Clarity Pharmaceuticals Ltd and Controlled Entities (Consolidated Group).

These interim financial statements are general purpose financial statements that have been prepared on an accruals basis in accordance with Australian Accounting Standards AASB 134 *Interim Financial Reporting* and the Corporations Act 2001. They have been prepared under the assumption that the Group operates on a going concern basis. Clarity Pharmaceuticals Ltd is a for-profit entity for the purpose of preparing the financial statements.

The consolidated financial statements for the half-year ended 31 December 2022 were approved and authorised for issue by the Board of Directors on 28 February 2023. The consolidated financial statements for the half-year can be amended by the Board of Directors after issue.

Going Concern

The directors believe the Group will be able to continue as a going concern. The Group has a history of losses. The ability of the Group to continue as a going concern and be able to pay its debts as and when they fall due is contingent upon periodic capital raising to support research and development activities.

The Group had cash and financial assets of $70.7 million at 28 February 2023.

Accordingly, at the date of this report the directors believe that the cash and financial assets on hand will provide sufficient working capital for the Group to meet its foreseeable expenditure commitments and pay its debts as and when they fall due for the next 12 months.

2. Changes in accounting policies

The accounting policies adopted in the preparation of the consolidated financial statements are consistent with those followed in the preparation of the Group's previous annual consolidated financial statements for the year ended 30 June 2022.

During the year there have been no new or revised accounting standards issued by the Australian Accounting Standards Board (AASB) that are mandatorily effective for the accounting period that begins on or after 1 July 2022.

3. Operating segments

Clarity Pharmaceuticals Ltd and its subsidiaries, Clarity Personnel Inc. and Clarity Pharmaceuticals Europe S.A., operate in only one business segment – Development of Radiopharmaceuticals. The activities of the group principally take place in Australia and the United States. The Group does not have any sales revenue hence is not able to report revenue by segment. Accordingly, it also does not have any customers. All assets and liabilities of the Group are attributable to the single segment.

4. Interests in subsidiaries

Set out below details of the subsidiary held directly by the Group:

Name of the Subsidiary	Country of Incorporation and principal place of business	Principal Activity	Proportion of ownership interests held by the group	
			31 Dec 22	31 Dec 21
Clarity Pharmaceuticals Europe SA	Belgium	Scientific Research & Development	100%	100%
Clarity Personnel Inc.	U. S. A	Provision of US Personnel to the Group	100%	100%

5. Other Income

The Group has derived no commercial revenue during the year. Other Income comprises:

	Dec 2022 $	Dec 2021 $
Finance income	649,171	26,183
Research and Development Tax Incentive	5,732,620	2,807,272

6. Corporate and administration

	Dec 2022 $	Dec 2021 $
Corporate and administration employment costs	(978,148)	(1,160,314)
Depreciation	(47,480)	(12,510)
Share-based payments to third parties	-	(6,784,556)
IPO-related costs	-	(656,489)
Insurance, professional fees, rent and other	(1,747,822)	(584,257)
	(2,773,450)	**(9,198,126)**

Details of share-based payments to third parties in Dec 2021 can be found in note 16.

IPO-related costs in Dec 2021 include costs associated with preparation of the IPO not deducted from equity, including legal fees ($293,820) and listing fees ($307,810).

7. Research and development

	Dec 2022 $	Dec 2021 $
Clinical trials and supporting activities	(10,859,779)	(4,669,303)
Research and development employment costs	(3,252,814)	(2,347,597)
Patents and related costs	(680,506)	(325,363)
	(14,793,099)	**(7,342,263)**

8. Earnings per share

	Dec 2022 Cents	Dec 2021 Cents
Basic earnings (loss) per share	(4.3)	(5.7)
Diluted earnings (loss) per share	(4.3)	(5.7)

Income and share data used in calculations of basic and diluted earnings per share:		
Net (Loss)	(11,242,655)	(13,712,399)

	Number	Number
Weighted average number of Ordinary shares on issue in the calculation of basic earnings per share		
Effect of dilutive securities[1]	259,017,482	238,508,914
Adjusted weighted average number of Ordinary shares used in the calculation of diluted earnings per share	259,017,482	238,508,914

1. At 31 December 2022 there are 26,789,221 (June 2022 - 23,844,900) share options on issue which have not been taken into account when calculating the diluted loss per share due to their anti-dilutive nature.

9. Cash and cash equivalents

Cash and cash equivalents consist of the following:

	Dec 2022 $	Jun 2022 $
Cash at bank		
Australian dollars	5,735,354	27,798,528
US dollars	157,015	2,380,731
Euros	160,444	157,069
Term deposits – cash equivalents		
Australian dollars	29,652,591	25,000,000
US dollars	22,182,878	-
	57,888,282	**55,336,328**

Term deposits with a maturity of less than 90 days from the date of acquisition are presented as cash equivalents.

10. Other financial assets

	Dec 2022 $	Jun 2022 $
Current		
Term deposits	18,000,000	37,000,000
	18,000,000	**37,000,000**

Term deposits with a maturity of less than 90 days from the date of acquisition are presented as cash equivalents. Term deposits are measured at face value, with interest recognised as income on an accruals basis.

Non-current		
Security deposit	12,343	11,745
	12,343	**11,745**

This security deposit represents one month's rental fees for the business premises. The landlord may deduct from the security deposit amounts owing to them in connection with the rental agreement. The security deposit will be returned to Clarity Pharmaceuticals within one month after the later of the termination of the agreement and Clarity Pharmaceuticals complying to the reasonable satisfaction of the landlord with all its obligations under the agreement.

11. Other receivables

	Dec 2022 $	Jun 2022 $
Research & development incentive receivable	12,128,567	6,395,947
Consumption taxes receivable	326,515	234,258
Interest receivable	234,029	27,368
	560,544	**261,626**

R&D Tax Incentive receivable at 31 December 2022 comprises $6,726,900 in respect of the year ended 30 June 2022 (following adjustments on finalisation of tax return) and $5,401,667 for the period July to December 2022 which is anticipated to be receivable as part of the Group's application for the year ending 30 June 2023. The receivable relating to the period July to December 2022 is an estimate and is conditional on the 2023 application being successful. The Group considers it has sufficient R&D claim history to be able to reliably estimate the R&D tax refund at this interim period.

All amounts are short-term.

12. Plant & equipment

	Dec 2022 $	Jun 2022 $
Equipment	408,823	389,322
Less accumulated depreciation	(176,710)	(129,230)
	232,113	**260,092**

Balance as at 1 July	260,092	93,193
Additions	19,501	213,148
Disposals	-	-
Depreciation	(47,480)	(46,249)
Balance as at period end	**232,113**	**260,092**

13. Trade & other payables

Trade and other payables recognised consist of the following:

	Dec 2022 $	Jun 2022 $
Current:		
Trade creditors	2,310,106	2,849,747
Sundry creditors	4,216,638	3,146,719
Payroll liabilities	234,826	631,775
Superannuation payable	109,546	86,882
Other liabilities	79,926	77,131
	6,951,042	**6,792,254**

All amounts are short-term. The carrying values of trade payables are a reasonable approximation of fair value.

Sundry creditors include expenses incurred but not yet paid for clinical trials of $2,839,967 (Jun 2022 - $2,675,473) and operational costs of $999,441 (Jun 2022 - $56,168).

Other liabilities at 31 December 2022 arise from unexpended amounts under a now-completed grant received by Clarity Pharmaceuticals Europe SA (from the Walloon Government, Belgium) supporting the Group's research and development programs.

14. Employee entitlements

	Dec 2022 $	Jun 2022 $
Current		
Annual leave liability	659,818	548,802
Long service leave liability	199,673	165,127
	859,491	**713,929**
Non-Current		
Long service leave liability	**101,220**	**79,226**

The current liability represents the Group's obligations to which employees have a current legal entitlement. It arises from accrued annual leave and long service leave entitlement at reporting date. The non-current liability represents obligations to which employees will have a legal entitlement upon completion of a requisite service period, more than 12 months beyond the end of the year.

15. Equity

	Dec 2022 $	Jun 2022 $
Ordinary shares issued and fully paid	138,900,962	138,408,125
Cost of capital raising	(6,298,827)	(6,292,695)
Total contributed equity at period end	**132,602,135**	**132,115,430**

	$	Number
Movement in ordinary shares on issue:		
As at 1 July 2022	132,115,430	257,938,769
Issue on exercise of share options	492,837	1,723,747
Transaction costs	(6,132)	-
As at 31 December 2022	**132,602,135**	**259,662,516**

16. Share option reserve

	Dec 2022 $	Jun 2022 $
Balance as at 1 July	5,898,745	4,205,714
Share options expensed – employees & consultants	552,849	1,980,899
Share options expensed – China Grand	-	6,784,556
Options exercised	(250,836)	(263,927)
Options expired	(57,106)	(6,808,497)
Balance as at period end	**6,143,652**	**5,898,745**

The share option reserve represents the cumulative total expense attributed to vested options and expense to date for options that have not yet vested as the expense is spread over the vesting period. The expense is determined using a Black-Scholes valuation of the options.

In the prior period, in connection with an exclusive licensing negotiation, Clarity granted China Grand Pharmaceutical and Healthcare Holdings Limited a total of 25,543,912 options at an exercise price of $1.75 per option. Having successfully completed listing on the ASX, the expiry date of the options was 25 February 2022, subject to no change of control or insolvency events as described in the Prospectus. The options would vest only on the condition that:

i. the Company is admitted to the Official List and its shares are quoted on the ASX; and

ii. that the Company and China Grand validly execute a binding licence agreement on terms that are acceptable to both parties.

These options were independently valued using the Black and Scholes method, using a share price of $1.40, share volatility of 84% (based on comparable ASX-listed companies) and a risk-free rate of 0.06%. The quantum of the option expense is not impacted by the probability of reaching a binding licence agreement, as this is considered a non-vesting condition as prescribed by Accounting Standard AASB 2 “Share Based Payment”. The options expired on 25 February 2022, without vesting. As such, the share option reserve total was reduced by $6,784,556 on 25 February 2022 and transferred to retained earnings.

17. Related party transactions

During the period, non-executive directors’ fees totalled $185,640. Executive directors’ salaries and superannuation totalled $481,500, and executive bonuses of $96,300 were accrued for the period but unpaid at 31 Dec 2022. The Company’s subsidiary, Clarity Personnel Inc., charged Clarity Pharmaceuticals Ltd $1,193,689 in management fees to fund its operations.

18. Commitment & contingencies

The Company has intellectual property that is either licensed or assigned from the University of Melbourne, Australian Nuclear Science and Technology Organisation or Dr Kurt Gehlsen representing contingent liabilities totalling $6,395,000 (Jun 2022 - $8,940,000). These contingent liabilities are intellectual property licence and assignment milestones payments which are dependent upon the success of the Group’s clinical research, as well as future decisions regarding the clinical focus of the Company and are therefore not recognised in the statement of financial position. Milestones for each intellectual property agreement are for various clinical milestones, from filing regulatory applications to conduct clinical trials to entering Phase III trials, along with commencement of sales of a radiopharmaceutical agent. It is not anticipated that any further milestones will be reached in the year ending 30 June 2023 that will result in payments to licensors (Jun 2022 - $140,000).

19. Post-reporting date events

On 1 February 2023, Cheryl Maley joined the board of directors of the Company as a Non-Executive Director. On that same date, Dr Charles Gillies O'Bryan-Tear tendered his resignation from the Clarity board of directors, with an effective date of 15 May 2023.

Clarity also achieved a number of significant clinical milestones following the period end, including:

- On 9 February 2023, Clarity's diagnostic 64Cu SAR-bisPSMA trial COBRA for patients with prostate cancer has reached its recruitment target.
- On 14 February 2023, Clarity announced favourable imaging data from its Phase I diagnostic trial of 64Cu SAR-bisPSMA in prostate cancer, PROPELLER, which was found to be safe, well tolerated and efficacious in the detection of prostate cancer.
- On 16 February 2023, Clarity reached 50% recruitment milestone for DISCO neuroendocrine tumour diagnostic Phase II trial of 64Cu SARTATE.

There are no matters or circumstances that have arisen since the end of the half-year that have significantly affected or may significantly affect:

- the operation of the Group;
- the results of those operations; or
- the state of affairs of the Group;

in future financial years.

DIRECTORS' DECLARATION

FOR THE HALF-YEAR ENDED 31 DECEMBER 2022

In the Directors' opinion:

- the consolidated financial statements for the half-year and notes of Clarity Pharmaceuticals Ltd are in accordance with the Corporations Act 2001, the Accounting Standards, the Corporations Regulations 2001 and other mandatory professional reporting requirements, including
    - Giving a true and fair view of its financial position as at 31 December 2022 and of its performance for the half-year ended on that date; and
    - Complying with Australian Accounting Standards as issued by the Australian Accounting Standards (including the Australian Accounting Interpretations) and Corporations Regulations 2001; and
- there are reasonable grounds to believe that the Company will be able to pay its debts as and when they become due and payable.

Signed in accordance with a resolution of the Directors.

On behalf of the Directors

Dr Alan Taylor
Chairperson
Dated this 28 day of February 2023

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Independent Auditor's Review Report

To the Members of Clarity Pharmaceuticals Ltd

Report on the half-year financial report

Conclusion

We have reviewed the accompanying half-year financial report of Clarity Pharmaceuticals Ltd (the Company) and its subsidiaries (the Group), which comprises the consolidated statement of financial position as at 31 December 2022, and the consolidated statement of profit or loss and other comprehensive income, consolidated statement of changes in equity and consolidated statement of cash flows for the half-year ended on that date, a description of accounting policies, other selected explanatory notes, and the directors' declaration.

Based on our review, which is not an audit, we have not become aware of any matter that makes us believe that the accompanying half-year financial report of Clarity Pharmaceuticals Ltd does not comply with the *Corporations Act 2001* including:

a giving a true and fair view of the Group's financial position as at 31 December 2022 and of its performance for the half year ended on that date; and

b complying with Accounting Standard AASB 134 *Interim Financial Reporting and the Corporations Regulations 2001*.

Basis for Conclusion

We conducted our review in accordance with ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity*. Our responsibilities are further described in the Auditor's Responsibilities for the Review of the Financial Report section of our report. We are independent of the Company in accordance with the auditor independence requirements of the *Corporations Act 2001* and the ethical requirements of the Accounting Professional and Ethical Standards Board's APES *110 Code of Ethics for Professional Accountants (including Independence Standards)* (the Code) that are relevant to our audit of the annual financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

Directors' responsibility for the half-year financial report

The Directors of the Company are responsible for the preparation of the half-year financial report that gives a true and fair view in accordance with Australian Accounting Standards and the *Corporations Act 2001* and for such internal control as the Directors determine is necessary to enable the preparation of the half-year financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

Auditor's responsibility

Our responsibility is to express a conclusion on the half-year financial report based on our review. We conducted our review in accordance with Auditing Standard on Review Engagements ASRE 2410 *Review of a Financial Report Performed by the Independent Auditor of the Entity*, in order to state whether, on the basis of the procedures described, we have become aware of any matter that makes us believe that the half-year financial report is not in accordance with the *Corporations Act 2001* including giving a true and fair view of the Group's financial position as at 31 December 2022 and its performance for the half-year ended on that date, and complying with Accounting Standard AASB 134 *Interim Financial Reporting and the Corporations Regulations 2001*.

A review of a half-year financial report consists of making enquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with Australian Auditing Standards and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Grant Thornton

Grant Thornton Audit Pty Ltd
Chartered Accountants

LWorsley.

Louise Worsley
Partner – Audit & Assurance

Sydney, 28th February 2023

CORPORATE DIRECTORY

Directors

Dr Alan Taylor
Executive Chairman

Dr Colin Biggin
Managing Director and
Chief Executive Officer

Mr Robert Thomas
Lead Independent Director
Non-Executive Director

Ms Rosanne Robinson
Non-Executive Director

Dr Chris Roberts
Non-Executive Director

Dr Thomas Ramdahl
Non-Executive Director

Ms Cheryl Maley
Non-Executive Director

Dr Gillies O'Bryan-Tear
Non-Executive Director

Company Secretary

Mr Robert Vickery

Chief Financial Officer

Mr David Green

Principal Place of Business

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CLARITY
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