

ASX MEDIA RELEASE

29 September 2023

### Annual Report - 30 June 2023

**Clarity Pharmaceuticals** (ASX: CU6) ("Clarity"), 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 announce, in accordance with requirements of ASX Listing Rules, the release of its Annual Report for the year ending 30 June 2023.

The Annual Report is attached to this release and has been authorised for release by the board of directors.

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#### **About Clarity Pharmaceuticals**

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

#### www.claritypharmaceuticals.com/



## 2023 ANNUAL REPORT

ABN 36 143 005 341 www.claritypharmaceuticals.com

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## ABOUT CLARITY PHARMACEUTICALS

Clarity is a clinical stage radiopharmaceutical company with a mission to develop nextgeneration products that improve treatment outcomes for children and adults with cancer.

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 <sup>64</sup>Cu) for imaging and copper-67 (Cu-67 or <sup>67</sup>Cu) for therapy, which deliver a compelling combination of high accuracy and high precision in the treatment of a range of cancers.

Clarity has used its Proprietary SAR Technology, a true platform technology, to develop three products with the potential for best-in-class performance. The Company has a targeted clinical development strategy with the goal of commercialising diagnostic products in the United States (US) with the Food an Drug Administration (FDA) first, generating revenue to fund late-stage therapeutic trials. Targeted Copper Theranostics offer significant supply, logistical and environmental advantages over the current generation of radiopharmaceutical products.

Tumour

**Copper isotope** <sup>64</sup>Cu for Positron Emission Tomography (PET) imaging and <sup>67</sup>Cu for therapy

CLARITY PHARMACEUTICALS SAR Technology platform

Cage "Chelator" that securely holds radioisotopes

Tumour specific receptors Proteins expressed by cancer cells which the radiopharmaceuticals target

Targeting agent Finds and binds cancer cells in the body Linker That connects the cage to the targeting agent



#### 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.



## EXECUTIVE CHAIRPERSON'S LETTER

#### Dear fellow Shareholders,

On behalf of the Directors of Clarity Pharmaceuticals Ltd (Clarity), I am delighted to present Clarity's annual report for the financial year 2022-2023 (FY2022-2023).

Clarity has had an outstanding year as we made significant headway in progressing our pipeline of products through clinical development and strengthening the supply and manufacturing in preparation for registrational trials. We would like to thank our Shareholders for their support of the company as their investment has ensured we are well-funded to continue our endeavours and address the growing demand for radiopharmaceuticals in oncology.

One of the most exciting developments over the last 12 months has been the results we are generating with our SAR-bisPSMA product. SAR-bisPSMA was developed at the bench top of the University of Melbourne in collaboration with Professor Paul Donnelly with the intent of overcoming the shortfalls of the current generation of PSMA-targeting products. SAR-bisPSMA was optimised with two PSMA-targeting agents, which not only increased the amount of product in the lesions but also increased how long the product was retained in the lesions over time, making it an ideal candidate for diagnosis and therapy. We are now generating encouraging data in our therapy trial in real time and the development of this product is evolving into a great Australian science story. With still 15 years of patent life for this agent, and Phase III trials for the diagnostic commencing this year and the therapy currently at the highest dose cohort, we are really excited to see the development of this agent over the next 12 months and beyond.

Clarity is a leader in the development of radiopharmaceuticals and is focused solely on TCTs. As a pure play, with all of our products relating to our TCT platform, we are leading this space globally as we fully leverage our innovative platform technology and continue to build a strong intellectual property position over our entire asset portfolio.

Clarity is further differentiated by our established supply chains for the production of TCTs in the US via electron accelerators and cyclotrons, rather than nuclear reactors and generators. Our technology lends itself to a scalable and dependable future for radiopharmaceuticals, unhindered by the quality and manufacturing issues currently plaguing the broader radiopharmaceuticals market.

Our TCT platform of products provides a reliable, scalable and cost-effective way to bolster radiopharmaceuticals in the global oncology market. With radiopharmaceuticals expanding into large oncology indications, such as prostate cancer, TCTs are ideally positioned to provide a sustainable future for our field with minimal supply and logistical interruptions, unlike the current generation of products, such as gallium-68 based diagnostics and lutetium-177 based therapies.

Clarity currently has three core product areas. Our first product area, SAR-bisPSMA, is an optimised dual PSMA-targeting agent for prostate cancer. It has been progressing through clinical development as the stand-alone diagnostic in three clinical trials this year, including an upcoming registrational Phase III trial, CLARIFY, as well as a theranostic product in the SECuRE trial, which has been advancing well with very promising early data. The second product area, SAR-Bombesin, is a pan-cancer agent which is currently being developed for prostate cancer as a stand-alone diagnostic as well as a theranostic product in the COMBAT trial. Our third product area, SARTATE, is in clinical trials as a theranostic for neuroblastoma, an aggressive childhood cancer, and as a stand-alone diagnostic for neuroendocrine tumours (NETs). We are very excited and encouraged by the positive data so far generated by these trials and look forward to providing further updates to the market in the future.

I would like to extend my utmost thanks to our incredibly dedicated fellow teammates whose unwavering dedication to the task at hand has single handedly built Clarity's success to date and changed the lives of a growing number of patients around the world. Thank you also to our Board of Directors, Advisory Board and collaborators, who are assisting us in skilfully implementing our strategic approach to advancing our diagnostic and therapy platform. Clarity welcomed Ms Cheryl Maley to our Board of Directors as a Non-Executive Director. Ms Maley is an experienced senior leader with over 25 years of experience in the pharmaceutical industry. We made a strong addition to our Scientific Advisory Board, welcoming Mr Jon Stoner, who is the director of the Idaho Accelerator Center (IAC), a research institute of Idaho State University (ISU), who pioneered a new process for therapeutic copper-67 production and has supplied all of our copper-67 until recently. We also welcomed a new VP of Regulatory Affairs and Quality, Ms Kathryn Williams-Day, Senior Medical Director, Dr Othon Gervasio, and Senior Director of Commercial Development, Mr Bryce Kanter, among other talented professionals who joined our team in the last financial year.

Clarity continues to progress our Environmental, Social and Governance (ESG) practices, driven by our desire to offer a more sustainable future for radiopharmaceuticals for the benefit of patients. We believe we will provide superior options for the diagnosis and treatment of cancer which are environmentally preferrable as they are non-uranium sourced and do not have long-lived radioactive waste products. Our products also avoid the inefficiencies of diagnostic products which utilise shorter half-life isotopes. All TCTs can be centrally manufactured and distributed in the US.

Clarity's mission is to improve treatment outcomes for children and adults with cancer. We are actively working with Neuroblastoma Australia, an Australian charity focused on raising awareness of this aggressive childhood cancer and funding leading research projects for the development of better, safer treatments for children with this insidious disease, as well as with EVAN Foundation, a US-based charity that is making a difference every day in the fight against neuroblastoma and other childhood cancers, whether in the laboratory, the clinic or the hospital room. We are also supporting Story Factory, a not-for-profit creative writing centre for young people from underresourced communities in our local area, and through this assistance giving a voice to these young people.

On behalf of the entire team, I would like to thank all of our shareholders who have continued to support Clarity. It has been an exciting journey from the bench top of Australian science and we remain in a strong cash position with sufficient funds to continue hitting crucial milestones in the development of the exciting pipeline of next-generation TCTs in a quickly developing radiopharmaceuticals market.

We remain highly optimistic about our technology, team and strategy as we enter FY2023-2024. We look forward to reporting our progress to you as we continue along this exciting phase of our journey.

Yours sincerely,

Ala Joy ( )

Alan Taylor Executive Chairperson, Clarity Pharmaceuticals



## CEO'S LETTER

Dear fellow Shareholders,

The financial year 2022-2023 (FY2022-2023) has been highly prolific for the Clarity team, with the Company achieving multiple major milestones in all active clinical trials and laying the foundations to commence registrational Phase III trials in the coming year.

During the year, our team advanced the development of our three core products, SAR-bisPSMA, SAR-Bombesin and SARTATE. We have achieved significant milestones in 9 clinical trials, with 2 of them now successfully completed, and are moving into Phase III clinical trials. On the theranostic front, Clarity has started its third theranostic trial with SAR-Bombesin for prostate cancer and rapidly progressed through 2 cohorts in the therapeutic phase of the SECuRE trial with SAR-bisPSMA in this reporting period. Furthermore, the first patient has already been dosed successfully at the highest dose level of 12GBg of 67Cu SAR-bisPSMA and we are actively recruiting into cohort 3. Our CL04 trial in children with neuroblastoma is also progressing well and the first participant in the highest dose escalation cohort has been treated. Recruitment into cohort 4 is ongoing.

The diagnostic trials have made significant progress as two prostate cancer trials, PROPELLER with SAR-bisPSMA and BOP with SAR-Bombesin, have been successfully completed with positive data being presented at some of the most prestigious conferences in the oncology and nuclear medicine fields. Clarity is now also initiating CLARIFY, a Phase III registrational trial with <sup>64</sup>Cu SAR-bisPSMA. The CLARIFY trial follows on from the earlier PROPELLER trial data and the Phase III study design has received positive guidance from the US FDA. Our second diagnostic trial with SAR-bisPSMA, COBRA, reached its recruitment target in February 2023 and trial participants have been followed up for 6 months as per the protocol. We are currently awaiting full trial data analysis to inform a second Phase III registrational trial to expand the use of the SARbisPSMA diagnostics to the broader patient population with prostate cancer. The SAR-Bombesin SABRE trial opened for recruitment in September 2022 and surpassed the 50% recruitment milestone in July 2023. We aim to complete recruitment in this trial in the coming year.

To learn more about our exciting pipeline of TCTs and the progress we made this year on each product, please read the Clinical and Regulatory Development section (page 9).

Clarity's SAR Technology allows us to explore new, exciting products for cancer indications with high unmet need beyond the three key products. We can achieve this by linking our proprietary chelator ("cage") that securely holds copper isotopes to various promising targeting agents to enable imaging and therapy. This ability constitutes the backbone of our Discovery Program. We will continue to progress our pipeline of products in clinical development, strengthen our intellectual property, grow our team as well as expand our supply and manufacturing network throughout FY2023-2024.

Most recently, Clarity bolstered the Discovery Program by acquiring an exclusive worldwide license from Memorial Sloan Kettering Cancer Center (MSK) to intellectual property covering antibody pretargeting technology. Discover more about this exciting technology and the synergies of pretargeting with Clarity's SAR Technology in the Discover Program section (page 33).

To ensure a strong supply, manufacturing and logistical foundation for our clinical trials and to fully exploit the benefits of copper theranostics, we executed a number of supply and manufacturing agreements during and since the reporting period. Our commercial-scale copper-67 supplier, NorthStar Medical Radioisotopes (NorthStar), is now routinely producing the radioisotope using their large-scale, highly efficient, environmentally preferable electron accelerator technology. NorthStar has now supplied copper-67 for clinical trial participants, with the first participant of the highest dose escalation cohort in the CL04 theranostic trial in neuroblastoma, an aggressive childhood cancer, receiving Northstar's copper-67. NorthStar complements our ongoing supply from the Idaho Accelerator Center, which has been supplying us copper-67 for all of our pre-clinical and clinical development over the last 8 years.

Clarity has also entered a Master Service Agreement and a Clinical Supply Agreement with PETNET Solutions Inc. to supply <sup>64</sup>Cu SAR-bisPSMA for Clarity's pivotal Phase III clinical trials. PETNET are a global positron emission tomography (PET) radiopharmaceutical network and the largest manufacturer of radiopharmaceuticals for PET imaging in the US. As Clarity commenced its third theranostic trial, COMBAT, in this financial year, we have also expanded our Targeted Copper Theranostic manufacturing agreement with Evergreen Theragnostics, Inc. to include <sup>67</sup>Cu SAR-Bombesin manufacture.

As we look ahead to FY2023-2024, there are multiple exciting milestones on the horizon. We will continue to progress our pipeline of products in clinical development, strengthen our intellectual property, grow our team as well as expand our supply and manufacturing network throughout FY2023-2024, while also advancing our business development efforts. Importantly, Clarity is well-funded to progress our existing trial program into registrational Phase III trials with a strong cash position of \$65.0 million that provides cash runway well into 2024.

I would like to thank the entire team for their hard work which has delivered considerable progress across our trials this year. I also thank the investigators, clinical trial participants and their families for their commitment to supporting our clinical trial programs in the pursuit of developing innovative and effective radiopharmaceutical therapies for better treating children and adults with cancer.

We look forward to reporting our progress to you as we enter this next exciting phase, driven by our ultimate goal of developing next-generation radiopharmaceuticals.

Yours sincerely,

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**Colin Biggin** CEO, Clarity Pharmaceuticals

## CORPORATE AND FINANCE

Clarity's cash position remains strong with a balance of \$65.0 million as at 30 June 2023. Inclusive of FY2022/2023 R&D Tax Incentive Refund of \$6.7 million, received in the June quarter, this funding will provide cash runway into 2024 and take Clarity into registrational Phase III clinical trials.

### ENVIRONMENTAL, SOCIAL AND GOVERNANCE

### During and since the reporting period, Clarity continued to progress its Environmental, Social and Governance (ESG) practices.

Clarity's Targeted Copper Theranostics (TCTs) offer a more sustainable future for radiopharmaceuticals through a reliable and scalable supply chain, which is also environmentally preferrable. The therapeutic radioisotope copper-67 is produced on electricitypowered electron accelerators, instead of nuclear reactors. Electron accelerator production is not fuelled by uranium, does not produce long-lived radioactive waste products and uses a readily available source material, unlike other nuclear reactor-based processes that are currently utilised to produce therapeutic radioisotopes, such as lutetium-177. The diagnostic radioisotope, copper-64, helps to avoid inefficiencies of currentgeneration diagnostic products, such gallium-68, which utilise shorter half-life isotopes and require extensive and complex manufacturing and supply chains.

Clarity's mission is to improve treatment outcomes for children and adults with cancer. While focusing on the development of next-generation radiopharmaceuticals to achieve this mission, Clarity is also actively working

with Neuroblastoma Australia, a charity focused on raising awareness of this aggressive childhood cancer and funding leading research projects for the development of better, safer treatments for children with this insidious disease. In FY2022-2023, Clarity was the Platinum Sponsor for the Run2Cure fun run organised by Neuroblastoma Australia. In the US, Clarity is supporting the Treats and Treasures Carts program by EVAN Foundation, a charity that is making a difference every day in the fight against neuroblastoma and other childhood cancers, whether in the laboratory, the clinic or the hospital. The program brings smiles to over 1,300 childhood cancer patients a week across 18 participating hospitals. Clarity is also supporting Story Factory, a not-for-profit creative writing centre for young people from under-resourced communities in Redfern, Clarity's local suburb. The contributions to Story Factory funded a partial salary for an Indigenous Storyteller to support and give voice to the local young Aboriginal and Torres Strait Islander people.



## CLINICAL AND REGULATORY DEVELOPMENT

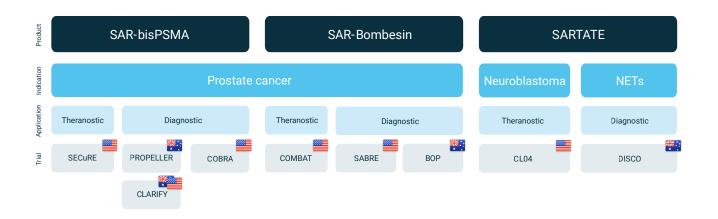
The FY2022/2023 has been momentous for Clarity's clinical and regulatory development, resulting in a diverse range of products in clinical trials which address both large indications as well as rare and orphan indications of cancer.

During and since FY2022/2023 Clarity's three key products, SAR-bisPSMA, SAR-Bombesin and SARTATE, have progressed in nine clinical trials, including three theranostic trials, five diagnostic trials and one investigatorinitiated trial (IIT). Five clinical trials are actively recruiting participants, with a Phase III registrational trial scheduled to open for recruitment in the current financial year.

	Theranostic	Diagnostic
SAR-bisPSMA	SECuRE – Phase I/IIa theranostic trial for identification and treatment of PSMA-expressing metastatic castrate- resistant prostate cancer (mCRPC) using <sup>64</sup> Cu/ <sup>67</sup> Cu SAR-bisPSMA in the US (NCT04868604) <sup>1</sup>	<ul> <li>PROPELLER – Phase I Positron Emission Tomography (PET) imaging trial of participants with confirmed prostate cancer using <sup>64</sup>Cu SAR-bisPSMA in Australia (NCT04839367)<sup>4</sup></li> <li>CLARIFY – Registrational Phase III PET imaging trial of participants with high-risk prostate cancer prior to radical prostatectomy using <sup>64</sup>Cu SAR-bisPSMA in the US and Australia (NCT06056830)<sup>18</sup></li> <li>COBRA – Phase I/II PET imaging trial of participants with biochemical recurrence (BCR) of prostate cancer following definitive therapy using <sup>64</sup>Cu SAR-bisPSMA in the US (NCT05249127)<sup>5</sup></li> </ul>
SAR-Bombesin	COMBAT – Phase I/IIa theranostic trial for identification and treatment of mCRPC that is expressing the Gastrin- Releasing Peptide receptor (GRPr), in participants who are ineligible for <sup>177</sup> Lu-PSMA-617, using <sup>64</sup> Cu/ <sup>67</sup> Cu SAR-Bombesin in the US (NCT05633160) <sup>2</sup>	<ul> <li>SABRE – Phase II PET imaging trial of participants with PSMA-negative BCR of prostate cancer in the US (NCT05407311)<sup>6</sup></li> <li>BOP – Investigator Initiated Phase II PET imaging trial of participants with negative PSMA PET or low PSMA expression disease in patients with suspected BCR of their prostate cancer and patients with mCRPC using <sup>64</sup>Cu SAR-Bombesin led by Prof Louise Emmett at St Vincent's Hospital Sydney (NCT05613842)<sup>7</sup></li> </ul>
SARTATE	<b>CL04</b> – Phase I/IIa theranostic trial in paediatric patients with high-risk neuroblastoma using <sup>64</sup> Cu/ <sup>67</sup> Cu SARTATE in the US (NCT04023331) <sup>3</sup>	DISCO – Phase II PET imaging trial of participants with known or suspected neuroendocrine tumours (NETs) using <sup>64</sup> Cu SARTATE in Australia (NCT04438304) <sup>8</sup>

## CLINICAL AND REGULATORY DEVELOPMENT CONT.

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



### FIVE OPEN INVESTIGATIONAL NEW DRUG (IND) APPLICATIONS WITH THE US FDA

An open IND allows Clarity to progress clinical trials of products in the US. Clarity received FDA clearance to proceed with the following trials:

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

product for prostate cancer patients Therapy <sup>67</sup>Cu SAR-bisPSMA

product for prostate cancer patients Diagnostic <sup>64</sup>Cu SAR-Bombesin

product for prostate cancer patients

Therapy <sup>67</sup>Cu SAR-Bombesin

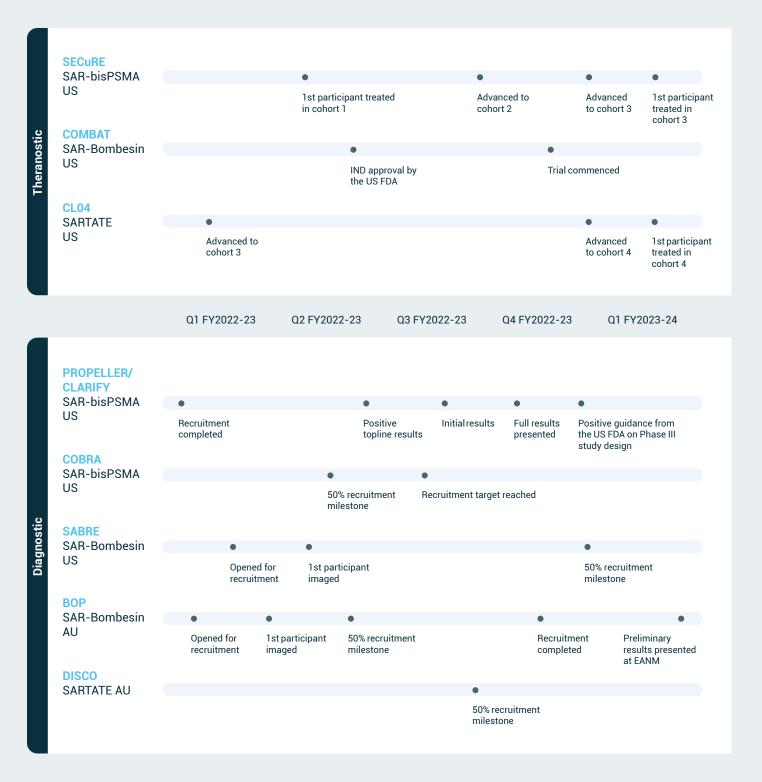
product for prostate cancer patients

#### Theranostic 64Cu/67Cu SARTATE

product for patients with neuroblastoma

## CLARITY'S CLINICAL MILESTONES

During and since FY2022-2023



## 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

PROPELLER

CLARIF

Diagnostic

COBRA

\*

Indication

pplication

Theranostic

SECuRE

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

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

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



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

Clarity treated the first participant with <sup>67</sup>Cu SAR-bisPSMA in the SECuRE trial (NCT04868604)<sup>1</sup> in October 2022 and since then successfully completed cohorts 1 and 2 of the dose escalation phase, progressing to cohort 3 and dosing the first participant at the highest dose level of 12GBq of <sup>67</sup>Cu SAR-bisPSMA in August 2023.

**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 <sup>64</sup>Cu SAR-bisPSMA and <sup>67</sup>Cu SAR-bisPSMA as well as the efficacy of <sup>67</sup>Cu SAR-bisPSMA as a therapy.

In this theranostic trial, Clarity first uses its imaging product, <sup>64</sup>Cu SAR-bisPSMA, to visualise PSMA expressing lesions and select participants who are most likely to respond well to subsequent therapy with <sup>67</sup>Cu SAR-bisPSMA.

In the dose escalation phase of this study, each subsequent cohort of participants receive an increased dose of the therapeutic drug until the optimal dose is determined (Maximum Tolerated Dose, MTD). In cohort 1, each participant received a single administration of 4GBq of <sup>67</sup>Cu SAR-bisPSMA and in cohort 2 the dose was increased to 8GBq. No dose limiting toxicities have been reported in any of the participants to date. Cohort 3 is the last to assess single doses of <sup>67</sup>Cu SAR-bisPSMA at the highest dose level of 12GBq and will be followed by a multi-dose cohort, pending safety evaluation.

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 approximately 70%. 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.

PET/CT images collected before and after a single 8GBq therapy cycle of <sup>67</sup>Cu SAR-bisPSMA demonstrated a reduction in the intensity of the diagnostic product at the lesion sites (Figure 1).

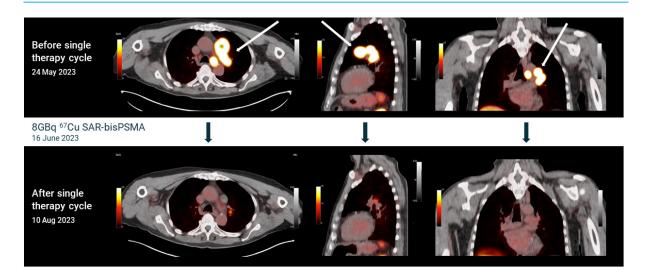


Figure 1. <sup>64</sup>Cu SAR-bisPSMA PET/CT imaging before and after a single cycle of 8GBq <sup>67</sup>Cu SAR-bisPSMA (cohort 2). White arrows show increased uptake of <sup>64</sup>Cu SAR-bisPSMA before therapy with <sup>67</sup>Cu SAR-bisPSMA (top images) with considerable reduction in <sup>64</sup>Cu SAR-bisPSMA uptake post-therapy (bottom images).

#### Expanded Access Program Patient Case Study: Multiple 4GBq Cycles of <sup>67</sup>Cu SAR-bisPSMA

Outside of the trial, additional therapy cycles of <sup>67</sup>Cu SAR-bisPSMA have also been requested by clinicians under the US Food and Drug Administration (FDA) Expanded Access Program (EAP) for participants in cohorts 1 and 2. <sup>67</sup>Cu SAR-bisPSMA SPECT/CT images depicted on Figure 2 were collected 48 hours after the first and fourth administrations of 4GBq of <sup>67</sup>Cu SARbisPSMA 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 <sup>67</sup>Cu 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 <sup>67</sup>Cu-SAR-bisPSMA and a drop of greater than 90% in PSA was observed after the fourth cycle of 4GBq of <sup>67</sup>Cu-SAR-bisPSMA.

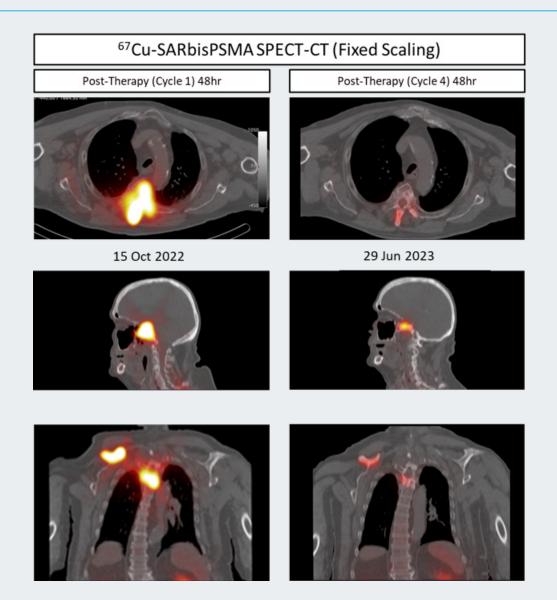


Figure 2. SPECT/CT imaging at 48 hrs following cycle 1 (Oct 2022) and cycle 4 (Jun 2023) of 4GBq <sup>67</sup>Cu SAR-bisPSMA

### P R 🕸 P E L L E R

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

Clarity reached full recruitment in the PROPELLER trial (NCT04839367)<sup>4</sup> in July 2022 and since then presented positive results as <sup>64</sup>Cu SAR-bisPSMA was found to be safe, well tolerated and efficacious in detecting prostate cancer. The results have been presented at three prestigious conferences, the American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU), American Society of Clinical Oncology (ASCO) and the Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meeting in 2023.

**PROPELLER** was the first-in-human trial administering Clarity's optimised PSMA agent, <sup>64</sup>Cu SAR-bisPSMA, to 30 participants with confirmed prostate cancer prior to undergoing radical prostatectomy. The trial also compared the diagnostic properties of <sup>64</sup>Cu SAR-bisPSMA against <sup>68</sup>Ga PSMA-11, which is approved for prostate cancer imaging in Australia and the US.

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

To view the full poster from ASCO 2023 online, click here. To view the full poster from SNMMI 2023 online, click here. The PROPELLER trial achieved its primary objectives and showed that <sup>64</sup>Cu SAR-bisPSMA was safe, well tolerated and efficacious in detecting primary prostate cancer. <sup>64</sup>Cu SAR-bisPSMA demonstrated brighter uptake and detected more lesions than the standard of care <sup>68</sup>Ga PSMA-11 product.

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

All Cohorts	Parameter	Imaging	N	Median	IQR	Min	Мах	Median Difference	p-value
	0111/1	<sup>64</sup> Cu	28	30.26	46.9	8	100	14.00	14.23 p < 0.001
	SUVmax	68Ga	28	13.53	12.79	2.7	55.1	14.23	
Reader 1	SUVmean	<sup>64</sup> Cu	28	21.2	32.23	5.4	69.9	9.26	p < 0.001
neauer 1	Sovinean	68Ga	28	9.12	8.71	1.8	37.6		
	TBR	<sup>64</sup> Cu	28	53.55	84.45	10.3	294.1	27.94	p < 0.001
	1 Bit	68Ga	28	24.29	36	9.6	134.4	27171	p 0.001
	SUVmax	<sup>64</sup> Cu	16	41.66	58.77	6.1	100	27.99	p < 0.001
	SOVINAX	68Ga	16	14.93	17.16	2.7	55.1	27.99	μ < 0.001
Reader 2	SUVmean	<sup>64</sup> Cu	16	28.4	37.92	4.4	69.9	18.78	p < 0.001
header 2	Sovinean	68Ga	16	9.94	11.56	1.8	37.6		μ < 0.001
	TBR	<sup>64</sup> Cu	16	78.37	98.97	6.7	243.9	46.93	p < 0.001
	IDK	68Ga	16	24.69	52.14	5	112.4		p < 0.001

Table 1. 64Cu SAR-bisPSMA showed statistically higher uptake than 68Ga PSMA-11 in lesions detected by both products.

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

<sup>•</sup>SUV: Standardised Uptake Value - measurement used to assess uptake of product in lesions or specific area TBR: Tumor-to-Background Ratio IQR: Interquartile Range

### P R 😃 P E L L E R

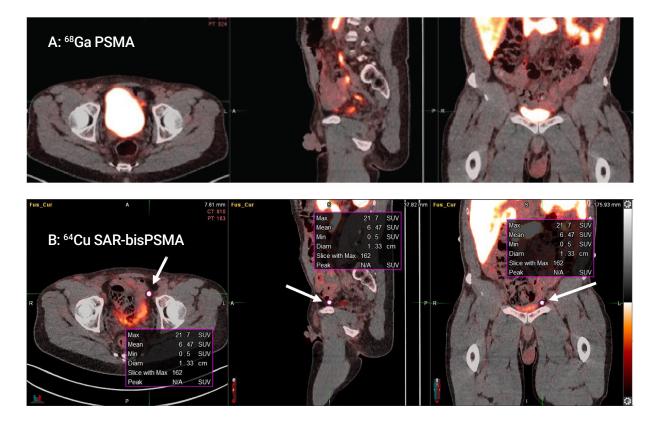


Figure 3. PET/CT demonstrated uptake of <sup>64</sup>Cu SAR-bisPSMA (B) in a left pelvic lymph node (white arrows) according to both readers and prostate cancer was confirmed via histopathology. Readers did not detect uptake in the pelvic lymph node on the <sup>68</sup>Ga PSMA-11 PET/CT (A). Time between serial imaging was 7 days.

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



Figure 4. Comparison of 68Ga PSMA-11 (left image) to Clarity's 64Cu SAR-bisPSMA (right image) in the same patient.

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

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

### CLARIFY,

#### CLARIFY – diagnostic Phase III registrational <sup>64</sup>Cu SAR-bisPSMA trial

Data generated from the PROPELLER trial 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 will be commencing the CLARIFY (NCT06056830)<sup>18</sup> trial following a successful end-ofphase meeting with the US FDA in July 2023 and is expecting to begin patient recruitment in late 2023. The FDA is supportive of the trial in 383 participants with untreated, histopathology-confirmed PC, with high-risk features, who are proceeding to radical prostatectomy with pelvic lymph node dissection.

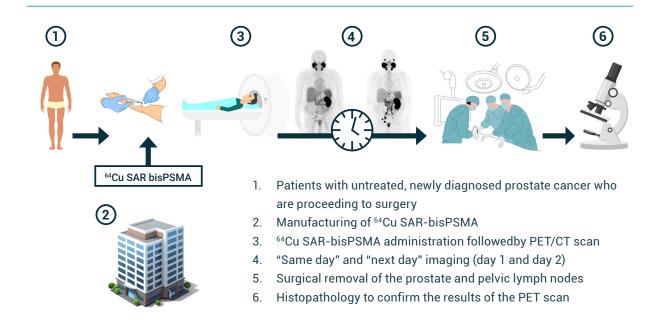
The aim of the Phase III trial is to assess the diagnostic performance of <sup>64</sup>Cu SAR-bisPSMA PET to detect prostate cancer within the pelvic lymph nodes. Evaluation will be across two imaging timepoints, day 1 (day of administration) and day 2 (approximately 24 hours post administration). Delayed imaging is not possible with current-generation radiopharmaceuticals due to the shorter half-life of the <sup>68</sup>Ga and <sup>18</sup>F radioisotopes. <sup>64</sup>Cu 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 final study results from the CLARIFY trial are intended to provide sufficient evidence to support an application to the FDA for approval of <sup>64</sup>Cu SAR-bisPSMA as a new diagnostic imaging agent 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 PSMAtargeting 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 regards to the patients' treatment plan.





#### COBRA – diagnostic 64Cu SAR-bisPSMA trial

Clarity reached its recruitment target in the diagnostic <sup>64</sup>Cu SAR-bisPSMA trial, COBRA (NCT05249127)<sup>5</sup>, in February 2023. All participants have completed the trial and the data is being prepared for analysis of results. Positive results from the COBRA trial will enable a Phase III trial in patients with BCR of their prostate cancer.

COBRA is a Phase I/II Positron Emission Tomography (PET) imaging trial of participants with BCR of prostate cancer following definitive therapy. In this study, participants have an increase of prostate specific antigen (PSA), a blood measurement indicating their prostate cancer has returned or spread following initial therapy, but the location of their cancer is unknown.

COBRA is a multi-centre, single arm, non-randomised, open-label trial of Clarity's PSMA imaging product (<sup>64</sup>Cu SAR-bisPSMA) in 50 participants. The primary objectives of the trial are to investigate the ability of <sup>64</sup>Cu SAR-bisPSMA to correctly detect recurrence of prostate cancer as well as assess its safety and tolerability. In the COBRA trial, participants are imaged on the day of administration and 24 hours later. The study is investigating if delayed imaging allows for improved disease detection and the potential to change the treatment plan for these patients.

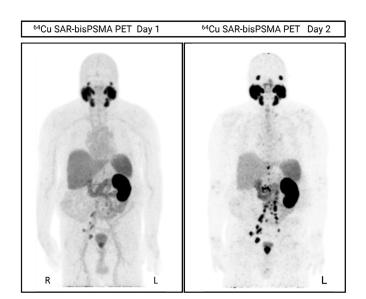


Figure 5. Serial Maximum Intensity Projection (MIP) PET scans over 24hrs showing areas of abnormal uptake in pelvic and abdominal lymph nodes.

The above image shows the PET scan from a patient with known recurrence of their disease from the COBRA trial after administration of <sup>64</sup>Cu SAR-bisPSMA. The image on the right shows the PET scan from the same patient imaged ~24 hours later. The COBRA trial is investigating whether imaging at later time points is able to detect additional disease that is not visible when images are only collected shortly after administration of the product. As a diagnostic tool, this is highly relevant in patients with suspected BCR which is where these PSMA PET products have significant utility. Being able to detect disease only visible at later time points, something not possible with <sup>18</sup>F- or <sup>68</sup>Ga-based products, could lead to a significant change in treatment management of these patients.

### SAR-BOMBESIN – PROSTATE CANCER

SAR-Bombesin is a highly targeted pancancer theranostic radiopharmaceutical.

SAR-Bombesin		
Prostate cancer		
Theranostic	Diagno	ostic
COMBAT	SABRE	BOP

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

Approximately 20% of prostate cancers with BCR are PSMA-PET negative<sup>9-12</sup> and approximately 25% of mCRPC patients have low or no uptake of a PSMAtargeting tracer<sup>13</sup>. These patients are unlikely to show meaningful uptake of PSMA-targeted products, such as <sup>68</sup>Ga-PSMA-11 for imaging, and therefore may not be eligible for a PSMA-targeted treatment, such as <sup>177</sup>Lu 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)<sup>2</sup> in patients with mCRPC;
- diagnostic Phase II trial in the US (SABRE)<sup>6</sup> 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 🔊 M B A T

#### COMBAT – theranostic <sup>67</sup>Cu SAR-Bombesin prostate cancer trial

Clarity commenced its theranostic <sup>64</sup>Cu/<sup>67</sup>Cu SAR-Bombesin Phase I/IIa trial in mCRPC with the opening of the first site at BAMF Health, Inc. in Michigan in June 2023, following IND approval from the US FDA in November 2022.

COMBAT (NCT05633160)<sup>2</sup> is a dose escalation and cohort expansion trial for up to 38 participants. The aim for the trial is to determine the safety and efficacy of <sup>67</sup>Cu SAR-Bombesin as well as the safety of <sup>64</sup>Cu SAR-Bombesin in participants with GRPr expressing mCRPC in patients who are ineligible for therapy with <sup>177</sup>Lu PSMA-617.

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



# SABRE

#### SABRE – diagnostic <sup>64</sup>Cu SAR-Bombesin prostate cancer trial

Clarity is actively recruiting in its US-based diagnostic <sup>64</sup>Cu SAR-Bombesin trial for patients with PSMA-negative prostate cancer, SABRE (NCT05407311)<sup>6</sup>, under an open IND from the US FDA. Clarity hit the 50% recruitment milestone in July 2023. Recruitment into the trial opened in September 2022 with the first participant imaged shortly after.

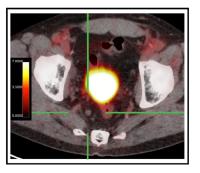
**SABRE** is a Phase II multi-center, single arm, nonrandomised, open-label trial in 50 participants with suspected recurrence of their prostate cancer and who have negative or equivocal findings of prostate cancer on standard of care imaging, including approved PSMA agents.

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

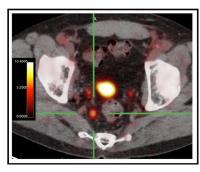
In the SABRE trial, participants are imaged on the day of administration (same day imaging) and 24 hours later (next day imaging). The study is investigating if delayed imaging allows better identification of very early disease or patients with low GRPr expression. Subject to the outcome of the SABRE trial, Clarity is planning to launch a pivotal Phase III diagnostic trial with <sup>64</sup>Cu SAR-Bombesin for first product approvals in the US.

On Figure 6, the images in the cross hairs on day 1 and day 2 following <sup>64</sup>Cu SAR-Bombesin administration clearly identify a pelvic lymph node, while there was no uptake with <sup>18</sup>F DCFPyL, an FDA-approved PSMA agent.

#### <sup>18</sup>F DCFPyL PET/CT



<sup>64</sup>Cu SAR-Bombesin Same Day



<sup>64</sup>Cu SAR-Bombesin Next Day

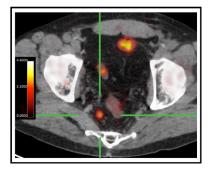


Figure 6. <sup>64</sup>Cu SAR-Bombesin detected a positive lymph node on both scans (same day and next day imaging scans). No uptake was observed using <sup>18</sup>F DCFPyL PET/CT. A subsequent biopsy, performed and assessed locally by the study site, has confirmed prostate cancer.

<sup>64</sup>Cu-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 with GRPr expression of BCR prostate cancer.

#### BOP – diagnostic <sup>64</sup>Cu SAR-Bombesin investigator-initiated trial (IIT) in prostate cancer

The diagnostic BOP (NCT05613842)<sup>7</sup> trial, evaluating <sup>64</sup>Cu SAR-Bombesin, was completed in June 2023 with initial data presented at the European Association of Nuclear Medicine (EANM) 2023 Congress. The trial opened for recruitment in August 2022 and quickly progressed through recruitment milestones throughout the financial year.

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

- 1. Participants with BCR of their prostate cancer who have negative PSMA 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 first cohort (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.

<sup>64</sup>Cu 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. "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

No adverse events from <sup>64</sup>Cu-SAR-Bombesin administration were reported in participants in the first cohort of the BOP trial. They received the mean dose of 210 MBq of <sup>64</sup>Cu SAR-Bombesin and imaged with PET at 1, 3 and 24 hours post-administration of the product. Prostate Specific Antigen (PSA) doubling time of 4.2 months (range 2.8 – 7.5; PSA mean 0.69 ng/ml, range 0.28 – 2.45) prior to entering the study. PSA is a blood test where high levels of PSA may indicate the presence of prostate cancer.



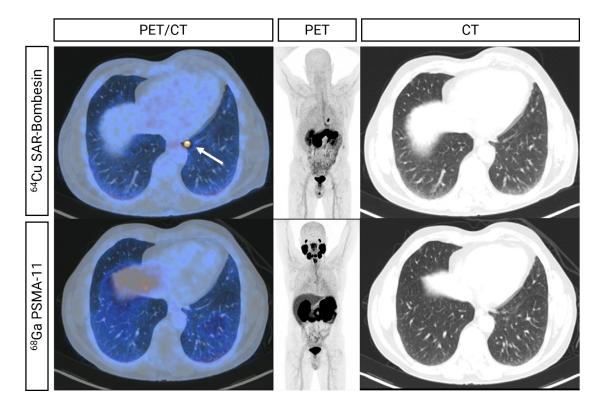


Figure 7. Fused, MIP (Maximum Intensity Projection) and CT (Computed Tomography) (left to right) images from <sup>64</sup>Cu SAR-Bombesin (top) and PSMA (bottom) PET of a patient demonstrating a left subpleural lesion with <sup>64</sup>Cu SAR-Bombesin uptake (arrow) without SOC PSMA uptake. This patient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

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

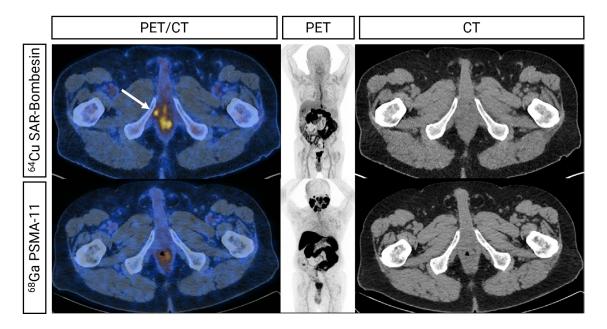


Figure 8. Fused, MIP and CT (left to right) images from <sup>64</sup>Cu SAR-Bombesin (top) and PSMA (bottom) PET of a patient demonstrating uptake at the right urethral anastomosis on <sup>64</sup>Cu SAR-Bombesin alone (arrow). This patient was managed with local radiotherapy with improvement in PSA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

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## SARTATE -NEUROBLASTOMA AND NETS

SARTATE is a next generation, highly targeted theranostic radiopharmaceutical.

SARTA	ATE
Neuroblastoma	NETs
Theranostic	Diagnostic
CL04	DISCO

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 (<sup>64</sup>Cu) for imaging (<sup>64</sup>Cu SARTATE) or copper-67 (<sup>67</sup>Cu) for therapy (<sup>67</sup>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)<sup>3</sup>
- DISCO diagnostic trial in Australia (NCT04438304)<sup>8</sup>.

In 2020, the US FDA awarded Clarity two Orphan Drug Designations (ODDs), one for <sup>64</sup>Cu SARTATE as a diagnostic agent for the clinical management of neuroblastoma and one for <sup>67</sup>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 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.<sup>19</sup>

# CL04 – theranostic <sup>64</sup>Cu/<sup>67</sup>Cu SARTATE neuroblastoma trial

Clarity successfully completed the first three cohorts of the CL04 theranostic trial (NCT04023331)<sup>3</sup> in neuroblastoma patients. Final dose-escalation cohort opened for recruitment and the first participant was dosed at the highest dose level of 375MBq of <sup>67</sup>Cu 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 <sup>64</sup>Cu SARTATE and <sup>67</sup>Cu SARTATE are being assessed, but also the effectiveness of <sup>67</sup>Cu SARTATE as a treatment for neuroblastoma. Participants who show uptake of <sup>64</sup>Cu SARTATE in lesions will continue in the trial and will receive treatment with <sup>67</sup>Cu 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 CL04 trial is designed to gradually increase the dose of <sup>67</sup>Cu 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 are being treated with a single dose of 375MBq of <sup>67</sup>Cu 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 <sup>67</sup>Cu SARTATE
- Cohort 2 3 participants received an initial single dose of 175MBq/kg body weight <sup>67</sup>Cu SARTATE
- Cohort 3 3 participants received an initial single dose of 275MBq/kg body weight <sup>67</sup>Cu 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 <sup>67</sup>Cu 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 additional therapy cycles of <sup>67</sup>Cu SARTATE in addition to the single therapy cycle administered under 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.





#### DISCO – diagnostic <sup>64</sup>Cu SARTATE NETs trial

Clarity's diagnostic imaging study of <sup>64</sup>Cu SARTATE in participants with known or suspected neuroendocrine tumours (NETs), DISCO (NCT04438304)<sup>8</sup>, continues to recruit participants in Australia following the 50% recruitment milestone achieved in February 2023.

**DISCO** 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 trial in up to 63 participants across four sites in Australia comparing the diagnostic performance of <sup>64</sup>Cu SARTATE at 4 and 20 hours post-administration to the current standard of care, <sup>68</sup>Ga DOTATATE, at one hour. The study looks to build on earlier studies with SARTATE (Hicks, R. et al)<sup>14</sup> which demonstrated that delayed imaging may lead to better identification of disease.



## MANUFACTURING AND SUPPLY: THE GAME CHANGER IN RADIOPHARMACEUTICALS

Targeted Copper Theranostics' (TCTs) key differentiators are their logistical, manufacturing and environmental advantages associated with the perfect pairing of copper isotopes for diagnostic imaging (copper-64) and therapy (copper-67).

Combined with clinical benefits, which Clarity is actively exploring through its clinical program, these differentiators are the reason TCTs are considered the next generation of radiopharmaceuticals. They enable Clarity to employ the big pharma model of centralised manufacturing of both diagnostic and therapeutic products under current Good Manufacturing Practice (cGMP), something that the current generation of products is lacking.

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

Clarity continued to expand its manufacturing and supply chain footprint, creating additional capacity and flexibility to supply products to any ZIP-code in the US with new agreements and investments made in the FY2022-2023.

## COPPER-67

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

In May 2021, Clarity entered into a Master Supply Agreement to produce the therapeutic radioisotope copper-67 with NorthStar Medical Radioisotopes (NorthStar), a global innovator in the development, production and commercialisation of radiopharmaceuticals used for therapeutic applications and medical imaging. Under the agreement, NorthStar will supply copper-67 exclusively to Clarity to support Clarity's TCT programs, with three active theranostic trials currently underway in the US. NorthStar is now routinely producing Cu-67 at its state-of-the art production accelerator facility in Wisconsin, US. The Cu-67 from Northstar has been used as part of Clarity's clinical programs in the US. It is the first operational commercial-scale supplier of this important therapeutic radioisotope. Their large-scale production of Cu-67 uses a highly efficient, environmentally preferable electron accelerator technology.



### **COPPER-64**

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

Copper-64 is produced in large volumes on cyclotrons and, due to the longer half-life of the isotope, the finished products can be made centrally with a significantly longer shelf life compared to current-generation PET diagnostics.

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

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

### TCT MANUFACTURING

TCTs can be produced on-demand in a centralised cGMP facility, thus allowing the finished radiopharmaceutical product to be delivered directly to hospitals and clinics for patient dose administration. All TCT products are manufactured at room temperature, significantly lowering the risk of batch failures, which historically has been a challenge for current-generation radiopharmaceuticals that require heating the biological targeting agents to 90°C during manufacture.

In August 2022, Clarity expanded its relationship with Evergreen Theranostics, Inc. ("Evergreen"), a radiopharmaceutical contract development and manufacturing organisation, to include manufacturing of <sup>67</sup>Cu SAR-Bombesin. Evergreen is now centrally manufacturing and distributing the following products from its state-of-the-art facility in Springfield, New Jersey, USA:

- <sup>67</sup>Cu and <sup>64</sup>Cu SAR-Bombesin for Clarity's theranostic trial in PSMA-negative GRPr-positive prostate cancer in the US;
- <sup>64</sup>Cu SAR-Bombesin for Clarity's stand-alone diagnostic trial in PSMA-negative GRPr-positive prostate cancer in the US;
- <sup>67</sup>Cu SARTATE for Clarity's theranostic neuroblastoma trial which is currently underway at multiple sites across the US.

### US CENTRE OF EXCELLENCE FOR TCTs

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

Clarity has worked with the IAC and its Director, Jon Stoner, for over 8 years and their role in bringing copper-67 based therapies to patients cannot be overstated.

The Centre of Excellence enables Clarity to efficiently execute several strategically important projects, supporting commercial readiness of products currently in clinical development and enabling the expansion of TCTs as a platform uniquely positioned to take the radiopharmaceutical sector into large global markets. In a field with unforeseen product outages, Clarity is building a reliable supply network with additional capacity and flexibility to supply products to any zip-code in the US.



## **ENVIRONMENTAL BENEFITS OF TCTs**

As the radiopharmaceutical industry is expected to grow exponentially over the next decade, the environmental impact of producing and commercially distributing these diagnostics and therapies is a critical element to consider. Inefficient supply chains, the use of short-lived radioisotopes as well as the production of waste, particularly radioactive waste, associated with current-generation radiopharmaceuticals, present significant environmental issues for the sector.

Production of <sup>64</sup>Cu and <sup>67</sup>Cu has favourable environmental characteristics in comparison to the current generation of theranostics. Some of the environmental aspects of TCTs in comparison to the current generation of radiopharmaceuticals potentially are<sup>16</sup>:

#### Copper-67

- <sup>67</sup>Cu production uses a readily available transition metal, zinc, as its source material, in comparison to <sup>177</sup>Lu that uses rare earth elements, lutetium or ytterbium.
- <sup>67</sup>Cu production is driven by an electricitypowered electron accelerator with no longlived radioactive waste products, unlike the uranium-powered nuclear reactors used to produce <sup>177</sup>Lu and the significant long-lived radioactive waste associated with the production and the use of nuclear reactors.
- <sup>67</sup>Cu eliminates the reliance on an aging fleet of nuclear reactors, which are primarily located outside of the US and dependent upon subsidies from the governments to operate.
- Regional production of <sup>67</sup>Cu using electron accelerators will also greatly reduce the carbon footprint from an international supply chain and allow for start-to-finish production of <sup>67</sup>Cu-based therapeutics to occur entirely in the US, the largest oncology market.
- <sup>67</sup>Cu-based products are manufactured at room temperature, significantly lowering the risk of batch failures, in contrast to currentgeneration radiopharmaceuticals, including <sup>177</sup>Lu-based products, some of which require heating the biological targeting agents to 90°C during manufacture. Batch failures lead to an unnecessary environmental footprint, while creating additional waste that needs to be disposed of.

#### Copper-64

The shelf-life of 64Cu-based products means:

- The products can be centrally manufactured and shipped from a single cGMP facility, alleviating the need for cyclotrons, generators or nuclear pharmacies near the site of administration.
- There is less risk of product expiring before being administered to patients, reducing waste from unused, expired products.
- Broader geographical range that diagnostic products can be distributed to, which increases patient access and decreases patient travel time to the site of administration.
- The ability to provide patient doses in the morning, which are viable for administration all day, removes the need for couriers to travel between radiopharmacies throughout the day due to the limited shelf-life of current-generation PET diagnostics, reducing the carbon footprint of the supply chain.
- The ability to run a single cyclotron to produce a commercial quantity of <sup>64</sup>Cu, as opposed to 50+ cyclotrons around the US.

These factors will significantly reduce the environmental impact compared to first-generation theranostics. This is highly relevant considering the forecasted growth of theranostics over the next decades.

## **INTELLECTUAL PROPERTY**

### Clarity continues to build its extensive patent portfolio covering the SAR Technology platform and its existing radiopharmaceutical products.

The different patents and patent applications in Clarity's IP portfolio span its products as well as manufacturing methods, formulations, and uses across the product range. Clarity's patent applications and granted patents are generally filed and prosecuted across multiple jurisdictions including the US, major countries in Europe, China and Japan.

During and since the reporting period, Clarity strengthened patent protection of its optimised PSMA agent, SAR-bisPSMA. In August 2022, the patent application covering SAR-bisPSMA was granted in China. The patent had been previously granted in the US, Australia and Mexico. This enabled Clarity to enhance protection of SAR-bisPSMA which is one of Clarity's key products and has been rapidly progressing through multiple clinical trials in prostate cancer during FY2022/2023.



## **DISCOVERY PROGRAM**

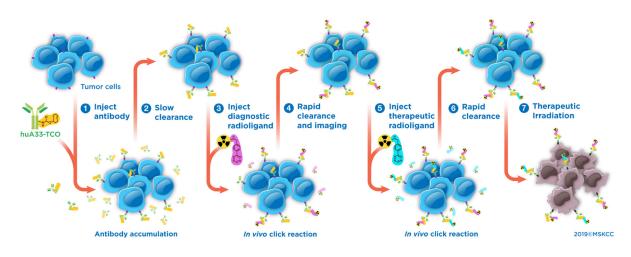
In addition to further progressing its key products that are already in clinical development, Clarity is expanding its product pipeline with a new generation of radiopharmaceuticals through its Discovery Program.

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 cancerous tissue, 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.

A clinical trial using the MSK licensed technology is open for recruitment in patients with pancreatic cancer at MSK headed by Dr Pandit-Taskar (NCT05737615)<sup>17</sup>. The trial is titled: "PET Imaging Using <sup>64</sup>Cu-Tz-SarAr and hu5B1-TCO in People With Pancreatic Cancer". It is a first-in-human diagnostic trial, utilising copper-64 and a sarcophagine chelator, core to Clarity's SAR Technology. The antibody (hu5B1-TCO) being used targets pancreatic cancer.

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.

During and since the FY2022-2023, Clarity has continued its efforts to build a team with world-class expertise and knowledge in radiopharmaceutical development and commercialisation, supporting rapid growth of the Company and its pipeline of products in development.

A key addition to Clarity's Board of Directors is Ms Cheryl Maley joining as a Non-Executive Director in February and replacing Dr Gillies O'Bryan-Tear who has resigned from the Board effective 15 May, 2023. Ms Maley is an experienced senior leader with over 25 years in the pharmaceutical industry. Her 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. Clarity's Advisory Board has seen an addition of a world leading expert in copper-67 isotope production, Mr Jon Stoner. He is the director of the Idaho Accelerator Center (IAC), a research institute of Idaho State University (ISU) and has been researching isotope production using linear accelerators for 14 years, pioneering a new process and mechanism for therapeutic copper-67 production that enables it to be manufactured in the quantities and quality required for clinical development.

Clarity's Senior Executive Team welcomed Ms Kathryn Williams-Day as a VP of Regulatory Affairs and Quality. Dr Othon Gervasio also joined as a Senior Medical Director, and Bryce Kanter, as a Senior Director of Commercial Development.

The increased support of the Company from world class experts in the oncology and the nuclear medicine fields is reflective of the excitement about TCTs and their ability to deliver clinical, logistical and environmental benefits in comparison to the current generation of radiopharmaceuticals, a field that is rapidly growing in the large oncology market.



# AT THE CORE OF CLARITY'S SUCCESS IS ITS PEOPLE

## Clarity has succeeded in building an extraordinary team, united and driven by the goal of improving treatment outcomes for children and adults with cancer.

Despite its relatively small size of around 40 employees in the US and Australia, Clarity's team is currently involved in progressing 7 clinical trials with its TCT products whilst continuing to expand the R&D pipeline and Discovery Program through the development of further novel modalities as well as to further develop a seamless supply chain to fully leverage the logistical and environmental benefits of the copper radioisotopes. This is an exceptional achievement in the industry for a company of Clarity's size.



Clarity hires staff based on talent, ability and commitment to the team effort and recognises that these attributes do not recognise ethnicity, gender identity, sex and sexual preference, family or carer responsibilities, or other identifiers. To support and promote the contribution of diverse skills and talent, the Company offers flexible work conditions and provides flexible return to work arrangements for staff who take parental or carer leave. Through this philosophy the team comprises people representing a broad range of backgrounds, recognising the positive outcomes that can be achieved through a diverse workforce.



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- 3. ClinicalTrials.gov Identifier: NCT04023331 clinicaltrials.gov/ct2/show/NCT04023331
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- 5. ClinicalTrials.gov Identifier: NCT05249127 clinicaltrials.gov/ct2/show/NCT05249127
- ClinicalTrials.gov Identifier: NCT05407311 clinicaltrials.gov/ct2/show/NCT05407311
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# **DIRECTORS' REPORT** FOR THE YEAR ENDED 30 JUNE 2023

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 year ended 30 June 2023.

### **DIRECTOR DETAILS**

The following persons were Directors of Clarity Pharmaceuticals during or since the end of the financial 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
Ms Cheryl Maley	Non-Executive Director (appointed 1 February 2023)
Dr Charles Gillies O'Bryan-Tear	Non-Executive Director (resigned 15 May 2023)

### COMPANY SECRETARY

The Company Secretary during the financial year was Mr Robert Vickery, who remains Company Secretary at the date of this report.

### PRINCIPAL ACTIVITIES

The principal activities of the Group involve research and development (R&D) and clinical stage evaluation of its portfolio of novel radiopharmaceuticals products.

### RESULT

The loss for the year was \$24.6 million (2022: \$23.8 million loss). In the year ended 30 June 2022, 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 year ended 30 June 2023, there was a significant increase in research and development expenditure, up \$12.6 million to \$31.5 million, reflecting an increase in clinical trial activities.

### STATEMENT OF FINANCIAL POSITION

The Group's financial position compared to the prior year was as follows:

- Liquid assets of \$65.0 million (2022: \$92.3 million) comprising cash on hand of \$31.2 million (2022: \$55.3 million) and term deposits of \$33.8 million (2022: \$37.0 million).
- Net assets decreased to \$69.2 million from \$92.2 million at 30 June 2022.

The Board believes the Group is well placed to support its programs throughout 2024.

### **REVIEW OF OPERATIONS**

#### **Corporate Overview**

The financial year ended 30 June 2023 has been an extremely rewarding period for the Company, with significant progress made across its many clinical programs. The goal remains to develop the next generation of radiopharmaceutical products across a diverse range of indications including larger markets, such as prostate cancer, as well as rare and orphan indications such as neuroblastoma in children. To that end, the Company has met a number of significant clinical milestones since 1 July 2022 and, at the same time, continued to strengthen its manufacturing and supply chain efforts to support both the current clinical trial demands together with anticipated future commercialisation needs.

The significant achievements made over the past 12 months continue to accelerate the Company along the path to executing its strategy of launching Targeted Copper Theranostics (TCTs) for first approvals in the US, the largest oncology market in the world, with 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.

#### **Clinical and Regulatory**

Clarity Pharmaceuticals is actively progressing seven clinical trials with its three key products, SARTATE, SARbisPSMA and SAR-Bombesin. The trials are being conducted in three theranostic (therapeutic and diagnostic) and five diagnostic applications (inclusive of the BOP Investigator Initiated Trial).

Progress made and key milestones met since 1 July 2022 are set out below:

#### 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 <sup>64</sup>Cu SAR-bisPSMA and <sup>67</sup>Cu SAR-bisPSMA in the US. Six participants were recruited in Cohort 1 for the therapeutic phase of the trial receiving a single administration of 4GBq of <sup>67</sup>Cu SAR-bisPSMA, with no dose limiting toxicities (DLTs) reported. Following the Safety Review Committee's recommendation to continue the trial Cohort 2, opened in May 2023, at 5 clinical sites in the US at an increased dose of 8GBq. To date 3 patients have been treated with no DLTs reported in any patients dosed.

The PROPELLER diagnostic trial was a Phase I Positron Emission Tomography (PET) imaging trial of participants with confirmed prostate cancer using <sup>64</sup>Cu SAR-bisPSMA in Australia. Recruitment into the PROPELLER trial was completed in July 2022. The Company 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. The trial results were also presented at the American Society of Clinical Oncology (ASCO) and the Society of Nuclear Medicine and Molecular Imaging (SNMMI) in June 2023.

Following the positive conclusion of the PROPELLER study, the Company had a successful end of phase meeting with the US Food & Drug Administration (US FDA), to commence a pivotal diagnostic Phase III trial (CLARIFY), with <sup>64</sup>Cu SAR-bisPSMA in patients in the pre-prostatectomy/pre-definitive treatment setting. The trial is a prospective, non-randomised, single-arm, open-label, multi-centre, diagnostic clinical trial of <sup>64</sup>Cu SAR-bisPSMA PET in 383 participants with untreated, histopathology-confirmed prostate cancer with high-risk features, who are proceeding to radical prostatectomy with pelvic lymph node dissection. In this pivotal trial, the final study results are intended to provide sufficient evidence to support an application to the US FDA for approval of <sup>64</sup>Cu SAR-bisPSMA as a new diagnostic imaging agent in prostate cancer. The aim of the Phase III trial is to assess the diagnostic performance of <sup>64</sup>Cu SAR-bisPSMA PET to detect PC within the pelvic lymph nodes. Evaluation will be across 2 imaging timepoints, Day 1 (day of administration) and Day 2 (approximately 24 hours post administration).

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 <sup>64</sup>Cu SAR-bisPSMA in the US. The recruitment target of 50 patients 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.

During the period the Company was approached under an Expanded Access Program (EAP) and Special Access Scheme (SAS) for

- Additional doses of <sup>67</sup>Cu SAR-bisPSMA requested by clinicians under the US FDA EAP for participants in the SECuRE study. Early data indicated positive effects at the low 4GBq dose level with a decrease in intensity of uptake on subsequent cycles and evidence of a reduction in Prostate Specific Antigen (PSA) levels greater than 50% from the initial cycle.
- <sup>64</sup>Cu SAR-bisPSMA requested under a SAS for 4 patients with prostate cancer and biochemical recurrence (BCR) who were negative on conventional PSMA-PET but lesions were detected with delayed imaging using <sup>64</sup>Cu SAR-bisPSMA.

#### SAR-Bombesin - Prostate Cancer

The Company has three trials in progress with its SAR-Bombesin product, including one Investigator Initiated Trial (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 <sup>64</sup>Cu SAR-Bombesin and <sup>67</sup>Cu SAR-Bombesin in participants who are ineligible for therapy with <sup>177</sup>Lu-PSMA-617 in the US. The US Food & Drug Administration (US FDA) approved the Company's Investigational New Drug (IND) application in November 2022 with trial opening for enrolment, of up to 38 participants, in June 2023.

The SABRE diagnostic trial is a Phase II PET imaging trial of participants with PSMA-negative BCR of prostate cancer using <sup>64</sup>Cu SAR-Bombesin in the US. SABRE opened for recruitment in September 2022 with 50% recruitment achieved in July 2023. Recruitment is ongoing and the Company anticipates 100% recruitment before the end of calendar 2023.

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 participants with suspected BCR of their prostate cancer and participants with mCRPC using <sup>64</sup>Cu SAR-Bombesin. The trial is led by Prof Louise Emmett at St Vincent's Hospital Sydney. The BOP trial reached its recruitment target of 30 participants in June 2023. As at the date of this report the final study report is in the process of being prepared.

#### 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 <sup>64</sup>Cu/<sup>67</sup>Cu SARTATE<sup>™</sup> in the US. Following successful completion of the first 3 dose escalation cohort in July 2023, the trial has progressed to the final cohort, cohort 4, at a dose of 375MBq per kilogram body weight. Recruitment into cohort 4 is ongoing.

The DISCO diagnostic trial is a Phase II trial of participants with known or suspected Neuroendocrine Tumours (NETs) using <sup>64</sup>Cu SARTATE<sup>™</sup> in Australia. In February 2023, the Company reached the 50% recruitment milestone enrolled and imaged. Recruitment into the DISCO trial is ongoing.

#### **Manufacturing and Supply Chain**

A key competitive advantage of Clarity Pharmaceuticals is the ability of its TCTs to overcome a number of logistics and supply chain limitations that have hindered the broader expansion of radiopharmaceuticals into the large oncology market.

Management have continued to actively build, strengthen and expand Clarity Pharmaceuticals' 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. The robustness of Clarity Pharmaceuticals' supply chain was evidenced by smooth and uninterrupted supply during the year despite production disruptions experienced by other producers of radiopharmaceuticals in the period due to their dependency on a limited number of nuclear reactors, most based outside the US. <sup>64</sup>Cu is produced on cyclotrons and <sup>67</sup>Cu on electron accelerators based domestically in the US, with both isotopes having characteristics that favour centralised manufacture and distribution.

During reporting period, the Company entered into a number of manufacturing and supply agreements, including:

- Expansion of the agreement with Evergreen Theragnostics to include manufacturing and supply of therapeutic <sup>67</sup>Cu SAR-Bombesin for COMBAT, Clarity Pharmaceuticals' theranostic trial in the US.
- Expansion of supply of <sup>64</sup>Cu SAR-bisPSMA for the pivotal Phase III clinical trials by entering into a Master Service Agreement and a Clinical Supply Agreement with PETNET Solutions Inc.
- NorthStar commencement of routine high activity manufacture of copper-67 on its electron accelerators exclusively for Clarity Pharmaceuticals' clinical therapy programs in Q4 of the financial year.
- Establishment of a Centre of Excellence with Idaho Accelerator Centre (IAC), operated by Idaho State University, for TCTs. This follows a long and fruitful relationship with the IAC as one of its first suppliers of copper-67.

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 Pharmaceuticals, distinguishing it from many of the current generation of products in the radiopharmaceuticals field.

#### **Intellectual Property**

Clarity Pharmaceuticals 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 Pharmaceuticals focused on strengthening protection of its optimised PSMA targeting agent, SAR-bis-PSMA, with the granting of a 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.

In July, the Company also announced an exclusive license and IP agreement with Memorial Sloan Kettering Cancer Centre (MSK) that covers cutting-edge technology that enables antibody pre-targeting for the diagnosis and treatment of cancers. A clinical trial using the MSK licensed technology is open for recruitment in patients with pancreatic cancer at MSK headed by Dr Pandit-Taskar (NCT05737615)<sup>3</sup>. The trial is titled: "PET Imaging Using <sup>64</sup>Cu-Tz-SarAr and hu5B1-TCO in People with Pancreatic Cancer". It is a first-in-human diagnostic trial, using copper-64 and a sarcophagine chelator, core to Clarity Pharmaceuticals' SAR Technology. The antibody (hu5B1-TCO) being used targets pancreatic cancer.

#### 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 keeping with this increase in the clinical, regulatory, and operational footprint, the Company continues to grow the team in the US and Australia. Some additions during the period include the following appointments:

- Ms Cheryl Maley joined the Board of Clarity Pharmaceuticals as a Non-Executive Director. Ms Maley, an
  experienced senior leader with over 25 years of experience in the pharmaceutical industry joined the
  Board in February 2023. Ms Maley brings strong strategic and commercial skills to the Board and has a
  proven track record in product launches and timely patient access to innovative medicines.
- In March, the Company's Scientific Advisory Board (SAB) was further strengthened with the appointment of Jon Stoner, director of the Idaho Accelerator Center, and a leading expert in pioneering new processes and mechanisms for producing isotopes, particularly copper-67.
- Dr Othon Gervasio joined the Senior Executive Team as Clarity Pharmaceuticals' Senior Medical Director. Dr Gervasio has over 20 years' experience in medical affairs and research & development. Formerly with Novartis, he brings a wealth of experience in oncology product launches, medical affairs strategy together with pre- and post-market authorisations.
- Mr Bryce Kanter became Senior Director of Commercial Development with 10 years' experience in the biotech and pharmaceuticals industry. Mr Kanter was formerly at Novartis where he was marketing lead for the launches of Pluvicto and Locametz.

### SIGNIFICANT CHANGES IN THE STATE OF AFFAIRS

There have been no significant changes in the state of affairs of the Group during the financial year.

### EVENTS ARISING SINCE THE END OF THE REPORTING PERIOD

There are no 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.

### LIKELY DEVELOPMENTS

The operations of the Group in subsequent financial years will continue to focus on the research and development of radiopharmaceuticals.

### DIVIDENDS

No dividends were paid, and the Directors did not recommend a dividend to be paid.

### UNISSUED SHARES UNDER OPTION

Unissued ordinary shares of Clarity Pharmaceuticals Ltd under option at the date of this report:

Grant Date	Date of Expiry	Exercise Price <sup>1</sup>	Number under Option <sup>1</sup>
3 December 2018	3 December 2023	\$0.605	200,000
10 December 2018	10 December 2023	\$0.605	200,000
21 March 2019	21 March 2024	\$0.605	800,000
1 July 2019	5 August 2024	\$0.605	2,100,000
22 July 2019	5 August 2024	\$0.605	100,000
1 October 2019	1 October 2024	\$0.605	1,000,000
21 October 2019	21 October 2024	\$0.605	100,000
1 December 2019	1 December 2024	\$0.605	200,000
1 March 2020	1 March 2025	\$0.938	200,000
2 March 2020	2 March 2025	\$0.938	400,000
1 June 2020	1 June 2025	\$0.938	100,000
1 July 2020	1 July 2025	\$0.938	3,560,000
26 August 2020	26 August 2025	\$0.938	100,000
15 December 2020	15 December 2023	\$1.125	918,220
4 May 2021	4 May 2026	\$0.938	200,000
10 May 2021	10 May 2026	\$0.938	1,000,000
17 June 2021	18 December 2024	\$0.825	6,650,000
26 May 2022	26 May 2027	\$1.400	400,000
1 July 2022	1 July 2027	\$0.508	2,774,865
12 October 2022	12 September 2027	\$0.725	350,000
25 November 2022	25 November 2027	\$0.508	1,921,081
13 December 2022	14 November 2027	\$1.060	161,771
6 March 2023	6 March 2028	\$0.970	60,000
1 May 2023	1 May 2028	\$0.845	96,313
1 July 2023	1 July 2028	\$0.790	2,726,506
10 July 2023	10 July 2028	\$0.840	60,276
			26,379,032

1. For options issued prior to 13 July 2021, the number under option and exercise price have been re-stated for the effect of the 1:20 share split completed on 13 July 2021 (891,411 in pre-split terms re-stated as 17,828,220).

Options were issued under various conditions to both employees and non-employees of the Group. Vesting conditions are described in Note 18 to the Financial Statements. These options do not entitle the holder to participate in any share issue of the Company.

#### Shares issued during or since the end of the year because of exercise

During or since the end of the financial year, the Group issued ordinary shares because of the exercise of options as follows (there were no amounts unpaid on the shares issued):

Date shares granted	Issue price of shares	Number of shares issued
1 July 2022	0.220	914,358
12 October 2022	0.220	100,000
15 November 2022	0.220	309,389
13 December 2022	0.220	400,000
1 February 2023	0.220	50,000
16 February 2023	0.220	591,289
27 March 2023	0.220	75,000
16 June 2023	0.220	142,618
26 June 2023	0.220	141,247
1 July 2023	0.220	1,196,563
		3,920,464

### **REGULATORY AND ENVIRONMENTAL MATTERS**

The Group's activities include working with radiopharmaceutical products that use radioactive materials, which generate medical and other regulated wastes. It is required to carry out its activities in accordance with applicable environment and human safety regulations in each of the jurisdictions it undertakes operations. The Group is not aware of any matter that requires disclosure with respect to any significant regulations in respect of its operating activities, and there have been no issues of non-compliance during the year.

### MEETINGS OF DIRECTORS

During the reporting period, 6 meetings of Directors were held. Attendances by each Director during the year were as follows:

	Meetings eligible to attend	Meetings attended
Dr Alan Taylor	6	6
Dr Colin Biggin	6	6
Mr Rob Thomas	6	6
Ms Rosanne Robinson	6	6
Dr Christopher Roberts	6	6
Dr Thomas Ramdahl	6	6
Dr Charles Gillies O'Bryan-Tear	5	4
Ms Cheryl Maley	2	2

### AUDIT AND RISK COMMITTEE

During the period, four meetings of the Audit and Risk Committee were held.

Attendance by each member during the period were as follows:

	Meetings eligible to attend	Meetings attended
Mr Rob Thomas (Committee Chair)	4	4
Ms Rosanne Robinson	4	4
Dr Christopher Roberts	4	4

The role of the Audit and Risk Committee is to assist the Board in fulfilling its accounting, auditing and financial reporting responsibilities, including oversight of:

- the integrity of the Company's financial reporting systems, internal and external financial reporting and financial statements;
- the appointment, remuneration, independence and competence of the Company's external auditors;
- the performance of the external audit functions and review of their audits;
- the effectiveness of the Company's system of risk management and internal controls; and
- the Company's systems and procedures for compliance with applicable legal and regulatory requirements.

The Audit and Risk Committee comprises Mr Rob Thomas (Chair), Ms Rosanne Robinson and Dr Christopher Roberts.

### NOMINATION AND REMUNERATION COMMITTEE MEETINGS

During the period, seven meetings of the Remuneration and Nomination Committee were held.

Attendance by each member during the period were as follows:

	Meetings eligible to attend	Meetings attended
Ms Rosanne Robinson (Committee Chair)	7	7
Dr Thomas Ramdahl	7	7
Mr Rob Thomas	7	7
Dr Charles Gillies O'Bryan Tear (resigned 27 February 2023)	6	5
Ms Cheryl Maley (appointed 27 February 2023)	2	2

The Role of the Nomination and Remuneration Committee is to assist and advise the Board on:

- Board succession planning generally;
- induction and continuing professional development programs for Directors;
- the development and implementation of a process for evaluating the performance of the Board, its committees and Directors;

- the process for recruiting a new Director, including evaluating the balance of skills, knowledge, experience, independence and diversity on the Board and, in the light of this evaluation, preparing a description of the role and capabilities required for a particular appointment;
- the appointment and re-election of Directors;
- ensuring there are plans in place to manage the succession of the CEO and other senior executives of the Company;
- to ensure that the Board is of a size and composition conducive to making appropriate decisions, with the benefit of a variety of perspectives and skills and in the best interests of the Group as a whole.

The Nomination and Remuneration Committee comprises Ms Rosanne Robinson (Chair), Dr Thomas Ramdahl, Mr Rob Thomas and Ms Cheryl Maley.

### DIRECTORS' QUALIFICATIONS AND EXPERIENCE

#### Dr Alan Taylor, PhD – Executive Chairperson

Dr Taylor joined the Board in November 2013 as Executive Chairperson. Dr Taylor has been instrumental in the growth of the Company and has been heavily involved in all areas of the Company's business.

Dr Taylor has approximately 15 years of investment banking experience focused predominantly on the life sciences sector, and has significant expertise in capital raisings, mergers and acquisitions, and general corporate advisory. Prior to joining Clarity Pharmaceuticals, Dr Taylor was an Executive Director of Inteq Limited, a boutique Australian investment bank.

After receiving the University Medal for his undergraduate degree in Applied Science at the University of Sydney, Dr Taylor completed his PhD in Medicine at the Garvan Institute of Medical Research. Dr Taylor has also completed a Graduate Diploma in Applied Finance at the Securities Institute of Australia.

Other Current Listed Directorships:	Interest in Issued Shares:
Nil	14,066,660
Previous Listed Directorships (last 3 years):	Interest in Issued Options:

#### Dr Colin Biggin, PhD – Managing Director and CEO

Dr Biggin joined the Board in October 2019 as Managing Director and CEO after playing an instrumental role in enhancing and designing the Company's product development and clinical programs since he first joined the Company in January 2017.

Dr Biggin has over 15 years of radiopharmaceutical development and commercialisation experience. Dr Biggin previously served with Algeta ASA during the development and commercialisation of its product Xofigo® (radium-223 dichloride) for metastatic prostate cancer, which was approved by the US FDA in 2013. Prior to joining the Company, Dr Biggin also consulted to a range of biotech and large pharmaceutical companies developing radiopharmaceuticals.

Dr Biggin holds a Bachelor of Science (Honours) and a PhD from the University of Glasgow.

Other Current Listed Directorships:	Interest in Issued Shares:
Nil	1,801,304
Previous Listed Directorships (last 3 years):	Interest in Issued Options:

#### Mr Rob Thomas - Lead Independent Director

Mr Thomas joined the Board as a Non-Executive Director on 25 August 2021.

Mr Thomas has a strong background in financial services and capital markets and has considerable expertise in mergers & acquisitions and capital markets including advising on the IPOs of the Commonwealth Bank of Australia and Qantas. Mr Thomas is the former CEO of County NatWest Securities and the former CEO (and then Chairman) of Citi Corporate and Investment Bank Australasia. Mr Thomas has also held the position of Chairman at Australian Wealth Management Ltd (ultimately IOOF Ltd), TAL (Australia's largest life insurance company) and the previously ASX-listed company HeartWare® International Inc. Mr Thomas is the Chairman of AusBio Ltd, Grahger Retail Securities Pty Ltd and ASX-listed Starpharma Holdings Limited and is a non-executive director of Biotron Limited and O'Connell Street Associates. He is a past non-executive director of Reva Medical Inc. and Virgin Australia.

Mr Thomas holds a Bachelor of Economics from Monash University and a Diploma of Business (Accounting) from Swinburne. He is a Fellow of the Securities Institute of Australia, Fellow of the Australian Institute of Company Directors and a Fellow of the Royal Society of New South Wales. He is also Co-Chair of the State Library of New South Wales Foundation.

Other Current Listed Directorships:	Interest in Issued Shares:
Starpharma Holdings Ltd	1,125,000
Biotron Ltd	
Previous Listed Directorships (last 3 years):	Interest in Issued Options:
Nil	Nil

#### Ms Rosanne Robinson - Non-Executive Director

Ms Robinson joined the Board in October 2010 as a Non-Executive Director.

Ms Robinson brings extensive experience in the nuclear field and a range of commercial and operational expertise to the Group. She has over 25 years of experience in senior leadership and governance roles in public and private companies and government. Ms Robinson is the Chief Operating Officer of Cyclotek (Aust) Pty Ltd and previously General Manager Business Development at Australian Nuclear Science and Technology Organisation for over 13 years. Ms Robinson's in-depth knowledge of the nuclear medicine industry provides the Group with a clear vision across the dynamics of a rapidly evolving segment of the healthcare industry.

Ms Robinson holds a Bachelor of Business (Accounting), a Graduate Diploma of Accounting (CA) and is a Graduate of the Australian Institute of Company Directors.

Other Current Listed Directorships:	Interest in Issued Shares:
Nil	Nil
Previous Listed Directorships (last 3 years):	Interest in Issued Options:

#### Dr Christopher Roberts, PhD - Non-Executive Director

Dr Roberts joined the Board in March 2016 as a Non-Executive Director.

Dr Roberts has over 40 years of experience in the medical innovation space and has served on the boards of a number of ASX-listed companies during his career. Dr Roberts was previously the CEO of ASX-listed company Cochlear Limited and Chairman of ASX-listed company Sirtex Medical Ltd. Dr Roberts was also Executive Vice-President and a director of the dual-listed (ASX and NYSE) company ResMed Inc., a global sleep disorder treatment company. Dr Roberts is a non-executive director of ASX listed HealthCo Heath and Wellness REIT.

Dr Roberts holds a Bachelor of Engineering (Honours) in Chemical Engineering from the University of New South Wales, an MBA from Macquarie University and a PhD from the University of New South Wales. He has also been awarded Honorary Doctor of Science degrees from Macquarie University and the University of New South Wales.

Other Current Listed Directorships:	Interest in Issued Shares:
HealthCo Healthcare and Wellness REIT	17,911,280
Previous Listed Directorships (last 3 years):	Interest in Issued Options:

#### Dr Thomas Ramdahl, PhD - Non-Executive Director

Dr Ramdahl joined the Board in March 2019 as a Non-Executive Director.

Dr Ramdahl is a pharmaceutical executive with over 20 years of clinical and development experience. In 2001, he became President and the first CEO of Algeta ASA. When Dr Ramdahl joined Algeta, he was one of six employees and he played an instrumental role in its success, including the approval of the alpha particle emitting radiopharmaceutical Xofigo, serving in several senior positions within the company through to and post the acquisition of Algeta by Bayer AG in 2014 for US\$2.9 billion. Dr Ramdahl has authored more than 40 publications and is a co-inventor of several patents. Dr Ramdahl currently serves as a non-executive director of Precirix (Belgium).

Dr Ramdahl gained his PhD in Environmental Chemistry from the University of Oslo and holds a Master of Science in Organic Chemistry from the Norwegian Institute of Technology.

Other Current Listed Directorships:	Interest in Issued Shares:
Nil	120,000
Previous Listed Directorships (last 3 years):	Interact in leaved Options:
Previous Listeu Directorsnips (last 5 years).	Interest in Issued Options:

#### Ms Cheryl Maley - Non-Executive Director

Ms Maley joined the Board in February 2023 as a Non-Executive Director.

Ms Maley is an experienced commercial leader and strategic advisor with over 25 years' working in the pharmaceutical industry, healthcare sector and more recently as a Non-Executive Director in the biotech sector. She has extensive experience in product commercialisation, portfolio optimisation, pipeline evaluation, and the assessment of multiple markets for launch readiness. Her experience also includes multiple organisation transformations and a track record of successfully building high performing teams in highly specialised therapeutic areas. She has led numerous complex transformation initiatives and she has lived and worked in Australia, Asia, and the USA, including roles with global and APAC regional responsibilities.

Ms Maley has a Bachelor of Science Degree, a Diploma of Education, a Master of Business Administration and is a Graduate of the Australian Institute of Company Directors. She has a passion for innovation and has completed formal innovation training both in Australia and USA. She is also a graduate of an Executive Female Leadership Program from Novartis (Switzerland).

Other Current Listed Directorships:	Interest in Issued Shares:			
Nil	Nil			
Previous Listed Directorships (last 3 years):	Interest in Issued Options:			
MedLab Clinical Ltd (Ceased February 2023)	Nil			

#### Dr Charles Gillies O'Bryan-Tear, MBBS FRCrcP - Non-Executive Director

Dr O'Bryan-Tear served on the Board from April 2019 to May 2023 as a Non-Executive Director.

Dr O'Bryan-Tear has over 30 years of experience in the pharmaceutical industry in clinical development, medical management and commercial roles. He has held senior leadership roles in large and small pharmaceutical and biotech companies in the US and Europe and has been involved in multiple product approvals. He was previously the Chief Medical Officer of Algeta ASA. Dr O'Bryan-Tear has been an adviser to several US and European biotech companies and is a member of the Scientific Advisory Board of Fusion Pharmaceuticals Inc. (Canada).

Dr O'Bryan-Tear obtained his Doctor of Medicine degree from the Universities of Cambridge and London and trained in internal medicine and oncology in the United Kingdom.

Other Current Listed Directorships:	Interest in Issued Shares:			
Nil	120,000			
Previous Listed Directorships (last 3 years):	Interest in Issued Options:			

### **REMUNERATION REPORT – AUDITED**

This Remuneration Report for the year ended 30 June 2023 outlines the remuneration arrangements of Clarity Pharmaceuticals Limited (Clarity Pharmaceuticals) and its controlled entities (the Group) in accordance with the requirements of the Corporations Act 2001 (Cth) and its regulations. This information has been audited as required by section 308(3C) of the Corporations Act 2001 (Cth).

The Remuneration Report details the remuneration arrangements for key management personnel (KMP) who are defined as those persons having authority and responsibility for planning, directing and controlling the major activities of the Group, directly or indirectly, including any Director, whether executive or otherwise.

For the purposes of this report, the term 'Director' refers to Non-Executive Directors (NEDs) only. 'KMP' refers to Executive Directors and other key management personnel.

The names and details of the Directors and KMP of the Group in office during the financial year and until the date of this report are detailed below. Apart from Ms Maley and Dr O'Bryan-Tear, all Directors and KMP listed are in office at the date of this report and held the position for the full financial year.

#### **Non-Executive directors**

Mr Rob Thomas	Non-Executive and Lead Independent Director
Ms Rosanne Robinson	Non-Executive Director
Dr Christopher Roberts	Non-Executive Director
Dr Thomas Ramdahl	Non-Executive Director
Ms Cheryl Maley	Non-Executive Director (Appointed 1 Feb 2023)
Dr Charles Gillies O'Bryan-Tear	Non-Executive Director (Resigned 15 May 2023)
Executive directors	
Dr Alan Taylor	Executive Chairperson
Dr Colin Biggin	Managing Director
Other key management personnel	
Mr David Green	Chief Financial Officer

#### **Overall Remuneration Strategy**

The Group aims to ensure that its remuneration strategy aligns the interests of its executives and employees with those of its shareholders. In framing its remuneration strategy, the Board's determinations have been influenced by several key factors:

- Headcount continues to grow in line with the Company's expanding clinical and operational footprint.
- The Group operates across Australia and the US, each with different remuneration environments.
- The radiopharmaceuticals sector is highly specialised, competitive, and rapidly growing.
- There is often a premium required to attract experienced executives with demonstrated experience in this niche sector.
- With a global team of 41 employees, the Group is currently progressing seven clinical trials and supporting one investigator-initiated trial with its products whilst continuing to expand its R&D pipeline and discovery program through the development of further novel modalities. This is an exceptional achievement in the industry for a Company of the Group's size.

These factors have influenced the Board to keep its remuneration structure simple, to acknowledge that some differences between the US and Australian payment structures will occur. As such, its remuneration structure contains a mixture of the following elements:

- 1. fixed remuneration;
- 2. short-term incentives (STIs) in cash or participation in equity incentives; and
- 3. time-based long-term incentives (LTIs) to ensure employee retention.

The remuneration structure is based on Key Performance Indicators (KPIs) which are designed to align with the interests of shareholders and to reward performance across value-adding milestones. It also recognises that retaining a stable team is critical given the duration of the Group's comprehensive clinical trial programs. The Board will continue to refine the Group's remuneration structure as the Group's activities mature. To this end, the Group engaged with Godfrey Remuneration Group Pty Ltd to help develop a remuneration strategy for the Company's medium to long term development.

The Board retains discretion to take account of events and circumstances not envisaged, given the dynamic nature of the radiopharmaceuticals market.

#### People and Culture

The Group operates in an industry which requires a specialised and skilled workforce and where employee retention is crucial given the long-term nature of clinical development programs. Its people are a key asset and, having significantly grown its team in recent years, it strives to maintain an environment that nurtures and rewards its staff. The Group seeks to achieve this through the following principles:

- 1. **Competitive remuneration** including a significant equity component to allow staff to participate in potential success of the group.
- 2. Commitment to the Group's shared Core Values:
  - a. Innovation
  - b. Thought leadership
  - c. Collaboration
  - d. Reliability and trust
  - e. Honesty and integrity
  - f. Environment

3. Diversity – The Group hires staff based on talent, ability and commitment to the team effort. Through this philosophy the Group team comprises people representing a broad range of backgrounds, recognising the positive outcomes that can be achieved through a diverse workforce. The Group recognises and utilises the diverse skills and talent of its directors, officers, employees, contractors and consultants. Gender diversity within the Group is set out in the following table.

	20	023	20	22
	No.	%	No.	%
Total Women employed	24	75%	17	56%
Women in non-board senior executive roles	2	29%	2	33%
Women in board positions	2	29%	1	17%

- 4. Flexible work conditions the Group recognises that flexible arrangements can be desirable for both professional and personal reasons. It seeks to accommodate work from home and flexible working hours by arrangement with employees to ensure it retains its talent and diversity in the team as their personal and professional responsibilities require. This flexibility recognises the geographical spread of the team and commitments which require staff attention outside of regular work hours. The Group also seeks to be proactive in retaining staff who take parental or carer leave by supporting flexible return to work arrangements.
- 5. Community The Group organises regular in-person and remote events for its team and enables volunteering opportunities with selected organisations that share the Group's values and goals, to ensure development of a strong team culture, notwithstanding that many staff work from home on a regular basis.

The Group's Senior Executive Team promotes these principles and aspires to foster positive culture in the workplace environment. This is achieved through onboarding, team meetings and briefings. They are also supported by the Company's written policies and are embedded into its performance management system.

#### Remuneration Governance

The Nomination and Remuneration Committee, consisting of four non-executive directors, advises the Board on remuneration policies and practices. It provides an independent and objective perspective on the value and structure of remuneration and other terms of employment for non-executive directors, executives, and other employees. In meeting these objectives, it may also seek external remuneration advice from time to time.

Specifically, the Board approves the remuneration arrangements of the Executive Chairman and Managing Director, including awards made under the Short-Term Incentive (STI) and Long-Term Incentive (LTI) plans, following recommendations from the Nomination and Remuneration Committee. The Board also reviews, having regard to recommendations made by the Executive Chairman and Managing Director to the Nomination and Remuneration Committee, the level of remuneration, including STI and LTI awards, for other executives and employees. The Board also sets the aggregate fee pool for non-executive directors (which is subject to shareholder approval) and non-executive director fee levels.

#### **Benchmarking**

Central to remuneration governance is bi-annual remuneration benchmarking for executive and non-executive positions. The Group benchmarks fixed and total remuneration by market capitalisation and to industry peers, using employment positions of comparable specialisation, size, and responsibility. Fixed remuneration may be

supplemented by providing incentives (variable remuneration) to reward superior performance. Where remuneration consultants are engaged to provide remuneration recommendations, as defined in section 9B of the Corporations Act 2001, they are engaged by, and report directly to, the Nomination and Remuneration Committee.

In April 2023, the Nomination and Remuneration Committee (NRC) engaged Godfrey Remuneration Group (GRG), an Australian based remuneration consultant to provide remuneration recommendations and related advice, including:

- Review of the remuneration quantum and structure, including benchmarking the market competitiveness of remuneration practices for the Executive Chairperson, CEO, KMP and other executive leadership members.
- Formulating recommendations with a view to ensuring that remuneration quantum and structure was reasonable, market competitive and appropriate to the Company's circumstances.
- Recommending Non-Executive Director remuneration quantum and structure.
- Review of the remuneration framework and recommendations on short-term variable remuneration and long-term variable remuneration design and implementation, including a specific reference to the different remuneration practices between Australia and the USA where Clarity operates, understanding that we operate in a globally competitive marketplace for talent.

At the time of issue of this report, the GRG Report had been received in draft form and the recommendations were under consideration. The Board is satisfied that the remuneration recommendations received from GRG were free from undue influence from those to whom the recommendations related.

#### Performance Reviews

The Group employs a performance management system for assessing employee performance. Key performance indicators (KPIs) are set for all staff at the beginning of a performance period. Performance against KPIs is assessed and the results are used in the salary review process. Performance reviews also consider behavioural and cultural aspects of performance, as well as professional and personal development.

During the year a performance review of all staff took place in accordance with this process. As part of the process, each employee's performance was assessed against their pre-agreed individual KPIs and Company KPIs. From this assessment, and subject to business considerations, a determination was made on whether an incentive award was payable, and if so, at what level.

The overriding objective of the salary review process is to ensure that all employees are appropriately and competitively remunerated based on market conditions, performance, and in recognition of the employees' skills and responsibilities.

#### Voting at the Company's 2022 Annual General Meeting (AGM)

Of the votes cast on the Company's remuneration report for the 2022 financial year, over 99% were in favour of the non-binding resolution. As part of the Group's commitment to continuous improvement, the Nomination and Remuneration Committee and the Board considered carefully the comments made by shareholders and proxy advisers in respect of remuneration related issues. Members of the Nomination and Remuneration Committee routinely engage with proxy advisors to discuss a range of governance and remuneration matters.

#### **Remuneration Structure**

The Group's remuneration structure aims to:

- Attract and retain exceptional people to lead and manage the Group and to support internal development of executive talent, recognising that the Group is operating in the competitive global pharmaceutical industry.
- Drive sustainable growth to shareholders, certain executives are set both short-term and long-term performance targets which are linked to the core activities necessary to build competitive advantage and shareholder value.
- Motivate and reward superior performance by the executive team whilst aligning performance elements/KPIs to the interests of shareholders.
- **Create a respectful, positive workplace culture** reflecting Company values through appropriately structured employee performance reviews.

#### **Remuneration Framework**

To compete with better resourced global pharmaceutical companies, the Group's remuneration framework includes equity-based incentive arrangements to assist in the attraction, motivation, and retention of employees. Equity-based incentives also assist the Group in aligning shareholder expectations and employee interests.

The remuneration framework comprises:

Fixed Remuneration	<ul><li>Base Salary</li><li>Superannuation / Pension Fund contributions</li></ul>
Short-Term Incentives (STIs)	<ul><li>Performance based cash bonuses</li><li>Equity Incentive Plan</li></ul>
Long-Term Incentives (LTIs)	Equity Incentive Plan

The Nomination and Remuneration Committee is responsible for developing, reviewing, and advising the Board on the remuneration arrangements for directors and executives.

Non-Executive Directors Remuneration Policy

The Board seeks to set non-executive directors' fees at a level which provides the group with the ability to attract and retain non-executive directors of the highest calibre with relevant professional expertise. The fees seek to balance the demands and responsibilities placed on the non-executive directors, with a cost which is acceptable to shareholders.

Non-executive directors' fees and the aggregate fee pool are reviewed annually by the Nomination and Remuneration Committee against fees paid to non-executive directors in comparable peer companies in the biotechnology sector and relevant companies in the broader ASX-listed market.

The Board is responsible for approving any changes to non-executive director fees, upon consideration of recommendations put forward by the Nomination and Remuneration Committee. The Group's constitution and the ASX listing rules specify that the non-executive directors' maximum aggregate fee pool shall be determined from time to time by a general meeting of shareholders. The latest determination was an aggregate fee pool of \$500,000 (including superannuation payments).

#### Non-Executive Directors Fees

Non-executive directors' fees consist of base fees and committee fees. The payment of committee fees recognises the additional time, responsibility and commitment required by non-executive directors who serve on board committees.

The aggregate directors' fees paid to non-executive directors for the year ended 30 June 2023 was \$375,503 excluding share-based payments expense of \$35,220 (2022 - \$292,228 excluding share-based payments expense of \$219,778)

From 1 July 2022, base fees for non-executive directors was \$60,000 plus superannuation. Non-executive directors received a fee of \$8,000 plus superannuation for chairing a committee and committee members received a fee of \$4,000 plus superannuation. Directors based outside Australia received additional fees in lieu of superannuation. In addition to Board fees, non-executive directors may receive share-based incentives as part of their overall remuneration. This is subject to shareholder approval at the Company's AGM.

#### Executive Remuneration Policy

The Group aims to reward executives with a level and mix of remuneration appropriate to their position, skills, experience, and responsibilities, by being market competitive and structuring awards appropriately to meet the Company's short- and long-term objectives. The Nomination and Remuneration Committee also considers the Group's growth and the number of clinical trial programs in development, also being cognisant of the Group's operational expansion into the US market.

The Nomination and Remuneration Committee, together with the Board, reviews the Group's remuneration structure, and benchmarks packages against relevant industry comparators to ensure the policy objectives are met and are in line with good corporate practice for the Group's size, industry, and stage of development.

Remuneration levels are determined annually through the remuneration review, which considers industry benchmarks and the performance of the Group and the individual. Other factors considered in determining remuneration structure include a demonstrated record of performance and the Group's ability to pay.

#### Executive Directors

Employment contracts have been executed with the Executive Chairman and Managing Director of the Group. Remuneration comprises fixed remuneration in the form of salary and superannuation contributions, short- and long-term variable remuneration in the form of cash bonus and participation in the Equity Incentive Plan. Performance based variable remuneration is based on a prescribed scorecard of agreed Company and individual KPIs which is assessed by the Nomination and Remuneration Committee. All remuneration paid to Executive Directors is valued at the cost to the Group and expensed.

#### Other Key Management Personnel

Employment contracts are in place for all Key Management Personnel (KMP) of the Group. Remuneration for KMP during the financial year consists of fixed remuneration in the form of salary and superannuation contributions; and variable remuneration in the form of options and, in some cases, a cash bonus based on a prescribed scorecard based on agreed Company and individual KPIs within a framework approved by the Board. All remuneration paid to KMP is valued at the cost to the Group and expensed.

#### **Fixed Remuneration**

#### **Base Salary**

The Group seeks to offer salaries at a level which is attractive in a competitive global marketplace but also recognises that it is not always able to compete with much larger employers seeking the same talent. The Group seeks to complement salary offers with equity-based remuneration.

#### Superannuation / Pension Fund Contributions

Australian-based staff are paid the statutory superannuation guarantee amount. Staff have the option to increase the contribution to their superannuation by salary sacrifice arrangements. US staff are entitled to contribute a portion of their salary to an employer-sponsored, defined-contribution, personal pension account, as defined in subsection 401(k) of the U.S. Internal Revenue Code, with contributions up to 4% of the employee's base salary matched by the Company.

#### Performance-based remuneration

The Group is still in its development stage and does not earn commercial revenue. This development phase involves developing a body of clinical data and supporting regulatory, research and manufacturing programs that are essential to bring the Group's products to regulatory approval and commercialisation. This pre-revenue growth phase necessarily generates financial losses and accordingly, it is not considered appropriate to feature financial metrics as part of KMP performance indicators.

#### Short-term Cash-based bonuses

The Board may approve short-term cash bonus arrangements for Executive Directors and other members of management. Participants will have an opportunity to receive a cash bonus payment calculated as a percentage of their fixed annual remuneration, conditional on a prescribed scorecard aligned with and adapted from the Group's key performance indicators, which is used to measure performance.

The performance measures are based on achievement of key milestones in relation to clinical, regulatory, research and manufacturing programs. These are the key areas which will deliver value to stakeholders in the short-tomedium term. The measures will be tailored and weighted to a participant's role and assessed in respect of the Group's financial year (or such other period as set by the Board).

The Nomination and Remuneration Committee is responsible for assessing the extent to which performance milestones have been achieved and approving the amount of the bonus which is payable.

The Board may set certain performance conditions that must be met prior to participants receiving any payment and, if met, will be used to determine the quantum of the payment.

#### Equity Incentive Plan

The Board considers equity-based remuneration, with service period-related vesting conditions, to be a critical component of the remuneration mix and a strategic tool to align the interests of directors and employees with those of the Group and its stakeholders. The Plan is used not only as a retention tool, but in certain limited cases, may also be used as a sign-on incentive to attract talent. The Plan provides participants the opportunity to share in the growth of the business at a potentially greater trajectory than available in larger groups, encourages a high-performance culture and promotes longer periods of service, which are crucial given the long-term nature of the clinical development programs and the importance of having a stable team during that time. This provides an important tool for the Group when competing with larger companies for workforce talent.

Under the Equity Incentive Plan, options, performance rights and restricted shares may be granted to eligible participants which includes directors, employees, and consultants, however only options have been issued to date.

The Board may also consider the future use of equity-based remuneration to reward, motivate, and retain management including the use of equity as a means of deferring STIs.

From July 2022, option grants for each employee are determined based on a scorecard which considers:

- (1) Achievements of the Group's objectives for the year;
- (2) Achievement of individual KPIs for the year; and
- (3) Management assessment of the employee, in recognition that, due to the dynamic nature of the business, Group and individual achievements during the year often arise in areas not contemplated in goal setting 12 months earlier.

The cap on an individual option allocation is set at a fixed percentage of the employee's base salary but can be increased by the Nomination and Remunerations Committee based on the Executive Directors recommendation.

The Group grants options to its employees annually. In 2021, ahead of the August 2021 IPO, options were granted earlier than usual, in June 2021. As a result, two rounds of options were granted to employees in the year ending 30 June 2021 and none in the year ending 30 June 2022. The Group may also grant options to directors subject to approval at the Company's Annual General Meeting.

#### Grant terms

The Board adopted the Equity Incentive Plan in July 2021, prior to its IPO, to facilitate the grant of equity to management and employees after listing, in circumstances in which the Board determines a grant of equity is appropriate. The Plan was updated slightly in May 2023 to accommodate new ESS provisions under the *Corporations Act (2001)*. The key terms of the Equity Incentive Plan are outlined in the table below:

Eligibility	Directors, employees, contractors or consultants of the Group or any other person who the Board determines, at its discretion, to be eligible to participate in the Equity Incentive Plan and who is invited to participate in the Plan.
Types of securities	The Equity Incentive Plan provides flexibility for the Board to grant one or more of the following securities subject to the terms of the individual invitation at the relevant time:
	Options – Options are an entitlement to receive a share upon the satisfaction of specified conditions and payment of a specified exercise price;
	Performance Rights – Performance Rights are an entitlement to receive a share for nil consideration upon the satisfaction of specified conditions; and
	Restricted shares – Restricted Shares are shares subject to specified disposal restrictions.
	The Board has the discretion to settle options or performance rights with a cash equivalent payment or determine that a participant may use a cashless exercise facility.
Invitations to participate	The Board may invite an eligible person to participate in the Equity Incentive Plan and grant an eligible person Options, Performance Rights and/or Restricted Shares in its discretion.
	The Board has the discretion to set the terms and conditions on which it will grant Options, Performance Rights and Restricted Shares in the individual invitations.

Consideration payable for grant of Options, Performance Rights and/or Restricted Shares	No consideration is payable by a participant in respect of the grant of Options, Performance Rights or Restricted Shares under the Equity Incentive Plan, unless the Board determines otherwise.				
Performance conditions	Securities granted under the Equity Incentive Plan will vest subject to the satisfaction of performance conditions determined by the Board from time to time and set out in the individual invitations.				
	Generally, the performance conditions must be satisfied for the securities to vest or otherwise cease to be subject to restrictions.				
	Performance hurdles set are time-based service conditions designed to retain employees whose expertise and experience are deemed vital to Clarity Pharmaceuticals' operational success.				
Rights associated with	Options and Performance Rights will not carry any voting rights or right to dividends.				
Options and Performance Rights	Shares issued or transferred to participants on conversion of a Performance Right or exercise of an Option (as applicable) will have the same rights and entitlements as other issued Shares, including voting and dividend rights.				
Rights associated with Restricted Shares	Restricted Shares will have the same rights and entitlements as other issued Shares, including voting and dividend rights.				
Vesting	Vesting of Options, Performance Rights and Restricted Shares under the Equity Incentive Plan is subject to any vesting or performance conditions determined by the Board and specified in the individual invitations.				
Restrictions on dealing	Participants must not sell, transfer, encumber, hedge, or otherwise deal with securities granted under the Equity Incentive Plan.				
	Following vesting of the applicable security and issue or transfer of a Share (as applicable), the participant will be free to deal with the Shares delivered, subject to the requirements of the Company's Securities Trading Policy.				
Bonus issues, pro-rata issues and capital reorganisations and reconstructions	The Equity Incentive Plan provides for adjustments to be made to the number of Shares which a participant would be entitled to receive on the vesting and/or exercise of Performance Rights and/or Options (as applicable) in the event of a bonus issue or pro-rata issue to holders of Shares or a reorganisation of capital, subject to the ASX Listing Rules and all applicable laws.				
	If the capital of the Company is reconstructed, the number of securities held by each participant under the Equity Incentive Plan may, in the discretion of the Board, be adjusted such that the value of the securities held prior to any reorganisation is restored.				
Cessation of employment	If a participant is considered a "good leaver", a pro-rata portion of any unvested securities granted under the Equity Incentive Plan will remain on foot and will be tested at the end of the relevant Performance Period against the applicable performance conditions.				

	A "good leaver" includes a participant who ceases employment with the Group by reason of retirement, genuine redundancy, death, invalidity, or any other reason as determined by the Board.
	Generally, any unvested securities granted under the Equity Incentive Plan will forfeit or lapse where the participant ceases employment with the Group for any reason other than as a "good leaver."
Clawback of equity	The Board has the discretion to claw back unvested securities from participants in certain circumstances, including in the case of fraud, gross misconduct, or material misstatement of the Company's financial statements.
Change of control	The Board has the discretion to determine whether, and the extent to which, securities granted under the Equity Incentive Plan vest or cease to be subject to restrictions upon a change of control.
Source of Restricted Shares and Shares	The Board has the discretion to issue or procure the transfer of any Restricted Shares or Shares delivered under the Equity Incentive Plan, including on the vesting and/or exercise of Performance Rights and/or Options (as applicable).
Trustee	The Company may appoint a trustee to acquire and hold Restricted Shares and Shares on behalf of participants or for the transfer to future participants or otherwise for the purposes of the Equity Incentive Plan.
Amendments to Equity Incentive Plan	Subject to the ASX Listing Rules, the Board may, in its absolute discretion, amend the Equity Incentive Plan rules or waive or modify the application of the Plan rules, except in certain circumstances.
Exercise Price	The Exercise Price is set at a 10% premium to the 5-day Volume Weighted Average Price (VWAP) at the time of grant.
Term	Generally, options have a term of 5 years from the grant date.

The Group measures cost of equity-settled share-based payments at Fair Value (FV) of the Share Options at grant date using the Black-Scholes valuation methodology considering the terms & conditions upon which the instruments were granted. Inputs into the Black-Scholes valuation model require a level of estimation and judgement. For options issued prior to the Group listing on the ASX on 25 August 2021, judgement was required to determine the share price input for the Black-Scholes valuation. It was typically the price of the most recent successful capital raising or the indicative share price where there was sufficient interest from investors to begin a new capital raising.

On 13 July 2021, every share on issue in Clarity Pharmaceuticals Ltd was split into twenty shares. Options were also split 1:20 with an exercise price of one-twentieth of their original issue. Unless otherwise stated, all share and option details are presented in this report in post-split terms.

#### Consequences of performance on Shareholder Wealth:

	2023	2022	2021	2020	2019
EPS (cents)	(0.0944)	(0.0921)	(0.0538)	(0.0446)	(0.0258)
Dividends	Nil	Nil	Nil	Nil	Nil
Net loss (\$,000)	(24,615)	(23,754)	(10,221)	(6,953)	(3,676)
Share price (\$) <sup>1</sup>	0.7213	0.5176	0.7500	0.7500	0.4825

1. Share prices from 2019 to 2021 were determined by the Board of Directors. No active market existed for the shares.

Performance-based remuneration is apportioned as follow:

#### Performance-based remuneration for the year ended 30 June 2023

		<u>Related to</u> performance Non-salary		Not related to performance			<u>Total</u>
	Position Held as of 30 June 2023	Cash- based Incentives %	Options / Rights %	Options/ Rights <sup>3</sup> %	Fixed Salary/ Fees %	Consulting Fees %	%
Dr A Taylor	Executive Chairperson	24	-	25	51	-	100
Dr C Biggin	Managing Director	23	-	27	50	-	100
Ms R Robinson	Non-Executive Director	-	-	12	88	-	100
Dr C Roberts	Non-Executive Director	-	-	13	87	-	100
Dr T Ramdahl	Non-Executive Director	-	-	13	87	-	100
Dr C G O'Bryan- Tear <sup>1</sup>	Non-Executive Director	-	-	3	97	-	100
Mr R Thomas	Non-Executive Director	-	-	-	100	-	100
Ms Cheryl Maley <sup>2</sup>	Non-Executive Director	-	-	-	100	-	100
Mr D Green	Chief Financial Officer	-	-	10	90		100

1. Dr O'Bryan-Tear resigned from the Board on 25 May 2023

2. Ms Maley was appointed to the Board on 1 February 2023

3. Options are granted based on time-based service conditions rather than milestone-based

		<u>Related to</u> <u>performance</u> Non-salary		Not related to performance			<u>Total</u>
	Position Held as of 30 June 2022	Cash- based Incentives	Options / Rights %	Options/ Rights <sup>4</sup> %	Fixed Salary/ Fees %	Consulting Fees %	%
Dr A Taylor	Executive Chairperson	18	-	27	55	-	100
Dr C Biggin	Managing Director	15	-	39	46	-	100
Ms R Robinson	Non-Executive Director	-	-	41	59	-	100
Dr C Roberts	Non-Executive Director	-	-	41	59	-	100
Dr T Ramdahl	Non-Executive Director	-	-	53	47	-	100
Dr C G O'Bryan- Tear	Non-Executive Director	-	-	40	36	24	100
Mr R Thomas <sup>1</sup>	Non-Executive Director	-	-	-	100	-	100
Mr D Green <sup>2</sup>	Chief Financial Officer	-	-	-	100	-	100
Mr R Vickery <sup>3</sup>	Chief Financial Officer	-	-	39	61	-	100

#### Performance-based remuneration for the year ended 30 June 2022

1. Mr Thomas was appointed to the Board on 25 August 2021

2. Mr Green commenced as Deputy CFO on 17 January 2022 and was appointed as Chief Financial Officer on 4 April 2022

3. Mr Vickery resigned as Chief Financial Officer on 4 April 2022 and retained the Company Secretarial role

4. Options are granted based on time-based service conditions rather than milestone based

	<u>Shor</u> Directors	t-term benefits	<u>5</u>	<u>Post</u> <u>Employ-</u> <u>ment</u>	<u>Termin-</u> <u>ation</u> <u>Benefits</u> Termin-	<u>Share-</u> <u>based</u> Payment	<u>Total</u>
	fees & Salary \$	Bonus \$	Other <sup>1</sup> \$	Superann -uation \$	ation Benefits \$	Options \$	\$
Non-Executive Di	rectors						
Ms R Robinson	72,000	-	-	7,560	-	11,029	90,589
Dr C Roberts	70,720	-	-	-	-	11,029	81,749
Dr T Ramdahl	70,720	-	-	-	-	11,029	81,749
Dr C G O'Bryan- Tear <sup>1</sup>	60,596	-	-	-	-	2,133	62,729
Mr R Thomas	72,000	-	-	7,560	-	-	79,560
Ms C Maley <sup>2</sup>	29,467	-	-	-	-	-	29,467
Executive Directo	Executive Directors						
Dr A Taylor <sup>3</sup>	550,564	271,500	-	25,292	-	282,975	1,130,331
Dr C Biggin <sup>3</sup>	444,091	210,000	-	25,292	-	250,318	929,701
Total	1,370,158	481,500	-	65,704	-	568,513	2,485,875

#### Director Remuneration for the year ended 30 June 2023

1. Dr O'Bryan-Tear resigned from the Board 25 May 2023

2. Ms Maley was appointed to the Board 1 February 2023

3. The salary of Executive directors includes the movement in annual leave and long service leave obligations

	<u>Shoi</u> Directors	t-term benefit	<u>s</u>	<u>Post</u> <u>Employ-</u> <u>ment</u>	<u>Termin-</u> <u>ation</u> <u>Benefits</u> Termin-	<u>Share-</u> <u>based</u> Payment	<u>Total</u>
	fees & Salary \$	Bonus \$	Other <sup>1</sup> \$	Superann -uation \$	ation Benefits \$	Options \$	\$
Non-Executive Dir	ectors						
Ms R Robinson	54,750	-	-	5,475	-	42,238	102,463
Dr C Roberts	60,225	-	-	-	-	42,238	102,463
Dr T Ramdahl	60,225	-	-	-	-	67,651	127,876
Dr C G O'Bryan- Tear <sup>1</sup>	60,225	-	41,095	-	-	67,651	168,971
Mr R Thomas <sup>2</sup>	46,662	-	-	4,666	-	-	51,328
Executive Directors							
Dr A Taylor <sup>3</sup>	495,083	171,000	-	24,761	-	253,429	944,273
Dr C Biggin <sup>3</sup>	346,506	122,400	-	23,568	-	318,529	811,003
Total	1,123,676	293,400	41,095	58,470	-	791,736	2,308,377

#### Director Remuneration for the year ended 30 June 2022

1. Dr O'Bryan-Tear received a consulting fee of \$41,095 (US\$30,000) in relation to Clinical Development advisory services.

2. Mr Thomas was appointed to the Board 25 August 2021

3. The salary of Executive directors includes the movement in annual leave and long service leave obligations

#### **Group Key Management Personnel**

Remuneration for Key Management Personnel (KMP) is set out below:

#### Details of KMP Remuneration for the year ended 30 June 2023 (not including KMP who are also Directors)

	Short-term Benefits		Post Employ- ment	Termination Benefits	Share-based Payment	Total		
	Salary <sup>2</sup> \$	Bonus \$	Superan- nuation \$	\$	Options \$	\$		
Key Management P	Key Management Personnel							
Mr D Green 1	215,729	-	22,073	-	27,684	265,486		
Total	215,729	-	22,073	-	27,684	265,486		

1. Mr Green's role was changed from 0.8FTE to 1.0FTE on 1 March 2023

2. The salary of KMPs includes the movement in their annual leave and long service leave obligations

#### Information relating to KMP Bonuses for the Year Ending 30 June 2023

	Grant Date	Nature of compen- sation	Service and performance criteria	% Paid	% Forfeited	Minimum/ Maximum possible grant for 2022/2023
Dr A Taylor	July 2022	Cash	Clinical & regulatory milestones <sup>1</sup>	100	-	\$0/\$271,500
Dr C Biggin	July 2022	Cash	Clinical & regulatory milestones <sup>1</sup>	100	-	\$0/\$210,000

1. Bonuses approved in June 2023 were paid in July 2023 and were for KPIs set for the period July 2022 to June 2023. The KPIs consisted of strategic clinical and regulatory milestones, each with a specific weighting. Clinical and regulatory performance was measured against these milestones and bonuses were proportionally awarded based on the progress towards their completion. The achievement of each milestone represents a considerable step in the execution of the Company's strategy presented to the market at the IPO including critical advancement within clinical trial programs, the expansion of products into new indications and securing regulatory approvals.

	Short-term Benefits		Post Employ- ment	Termination Benefits	Share-based Payment	Total
	Salary <sup>3</sup> \$	Bonus \$	Superan- nuation \$	\$	Options \$	\$
Key Management P	ersonnel					
Mr D Green 1	101,207	-	9,199	-	-	110,406
Mr R Vickery <sup>2</sup>	148,749	-	14,350	-	105,595	268,694
Total	249,956	-	23,549	-	105,595	379,100

#### Details of KMP Remuneration for the year ended 30 June 2022 (not including KMP who are also Directors)

1. Mr Green was appointed as Chief Financial Officer on 4 April 2022, on a part time basis (0.8FTE)

2. Mr Vickery resigned as Chief Financial Officer on 4 April 2022

3. The salary of KMPs includes the movement in their annual leave and long service leave obligations

#### Information relating to KMP Bonuses for the Year Ending 30 June 2022

	Grant Date	Nature of compen- sation	Service and performance criteria	% Paid	% Forfeited	Minimum/ Maximum possible grant for 2021/2022
Dr A Taylor	July 2021	Cash	Clinical, regulatory & corporate milestones	90%	10%	\$0/\$190,000
Dr C Biggin	July 2021	Cash	Clinical, regulatory & corporate milestones	90%	10%	\$0/\$136,000

#### KMP contractual arrangements

Remuneration and other terms of employment for KMP are formalised in Employment Agreements. The major provisions of the agreements relating to remuneration from 1 July 2023 are set out below:

Name	Base salary <sup>1</sup> \$	Term of agreement	Notice period
Dr A Taylor <sup>1</sup>	543,000	Unspecified	6 months
Dr C Biggin <sup>1</sup>	420,000	Unspecified	6 months
Mr D Green	302,399	Unspecified	6 months

1. Base salaries are presented inclusive of super

#### Loans to KMP

The Group does not have any facilities in place to establish loans to KMP. There are no loans to KMP at 30 June 2023 (2022: nil).

#### **Performance rights**

#### 2023

No performance rights were issued to Directors or KMP.

#### 2022

No performance rights were issued to Directors or KMP.

#### Terms and conditions of options issued as remuneration to Directors and KMP in 2023

	Grant date	Vesting and exercisable date	Expiry date	Exercise price \$	Value per option \$	Vesting condition achieved <sup>1</sup>	% Vested
Dr C Biggin	1 Oct 19	1 Oct 22	1 Oct 24	0.605	0.3255	100%	100%
Dr A Taylor	17 Jun 21	13 Apr 23	18 Dec 24	0.825	0.4114	100%	100%
Dr A Taylor	17 Jun 21	13 Apr 24	18 Dec 24	0.825	0.4114	0%	0%
Dr C Biggin	17 Jun 21	13 Apr 23	18 Dec 24	0.825	0.4114	100%	100%
Dr C Biggin	17 Jun 21	13 Apr 24	18 Dec 24	0.825	0.4114	0%	0%
Dr C Roberts	17 Jun 21	13 Apr 23	18 Dec 24	0.825	0.4114	100%	100%
Dr C Roberts	17 Jun 21	13 Apr 24	18 Dec 24	0.825	0.4114	0%	0%
Dr T Ramdahl	17 Jun 21	13 Apr 23	18 Dec 24	0.825	0.4114	100%	100%
Dr T Ramdahl	17 Jun 21	13 Apr 24	18 Dec 24	0.825	0.4114	0%	0%
Dr C G O'Bryan-Tear	17 Jun 21	13 Apr 23	18 Dec 24	0.825	0.4114	100%	100%
Dr C G O'Bryan-Tear	17 Jun 21	13 Apr 24	18 Dec 24	0.825	0.4114	0%	0%
Ms R Robinson	17 Jun 21	13 Apr 23	18 Dec 24	0.825	0.4114	100%	100%
Ms R Robinson	17 Jun 21	13 Apr 24	18 Dec 24	0.825	0.4114	0%	0%
D Green	1 Jul 22	1 Jul 23	1 Jul 27	0.508	0.3306	0%	0%
D Green	1 Jul 22	1 Jul 24	1 Jul 27	0.508	0.3306	0%	0%
D Green	1 Jul 22	1 Jul 25	1 Jul 27	0.508	0.3306	0%	0%
Dr A Taylor	25 Nov 22	25 Nov 23	24 Nov 27	0.508	0.8044	0%	0%
Dr A Taylor	25 Nov 22	25 Nov 24	24 Nov 27	0.508	0.8044	0%	0%
Dr A Taylor	25 Nov 22	25 Nov 25	24 Nov 27	0.508	0.8044	0%	0%
Dr C Biggin	25 Nov 22	25 Nov 23	24 Nov 27	0.508	0.8044	0%	0%
Dr C Biggin	25 Nov 22	25 Nov 24	24 Nov 27	0.508	0.8044	0%	0%
Dr C Biggin	25 Nov 22	25 Nov 25	24 Nov 27	0.508	0.8044	0%	0%

1. All vesting conditions are met when the grantee remains in service to the Company up to the vesting date.

#### Options and rights converted to shares

During the year ended 30 June 2023 the following current and former directors and KMP exercised options:

	N Number cas		Exercise price
Dr C Biggin	600,000	112,792	\$0.22

During the year ended 30 June 2022 the following current and former directors and KMP exercised options:

	Number	Number used in cashless exercise	Exercise price
Dr C Biggin	200,000	-	\$0.22

During the year ended 30 June 2023, no current or former directors and KMP received shares following conversion of performance rights.

During the year ended 30 June 2022, no current or former directors and KMP received shares following conversion of performance rights.

#### Options lapsed during the year

#### 2023

During the year ended 30 June 2023, the following director and KMP options lapsed:

	Number
Dr C G O'Bryan-Tear	50,000

#### 2022

No options lapsed during the year.

#### Directors and KMP relevant interests in securities

Relevant interest in securities during the year ended 30 June 2023 are as follows:

#### (a) Ordinary shares

	Opening balance	Shares acquired	Shares disposed	Closing balance
Dr C Roberts				
Cabbit Pty Ltd ATF Robwill Trust <sup>1</sup>	17,911,280	-	-	17,911,280
Dr A Taylor				
A.C.N. 136 437 913 Pty Ltd ATF Taylor Family Trust <sup>2</sup>	13,266,660	-	-	13,266,660
Ms Sally Taylor <sup>3</sup>	800,000	-	-	800,000
Dr C Biggin	619,100	487,208	-	1,106,308
Mr Rob Thomas	550,000	-	-	550,000
Stornaway Nominees Pty Ltd ATF R. Thomas Penson Fund 4	300,000	-	-	300,000
Murtoa Flour Mills Pty Ltd <sup>5</sup>	250,000	-	-	250,000
The Tony McCullough Foundation <sup>6</sup>	25,000	-	-	25,000
Dr C G O'Bryan-Tear	120,000	-	-	120,000
Dr T Ramdahl	120,000	-	-	120,000
	33,962,040	487,208	-	34,449,248

1. Dr Roberts is a beneficiary of the Robwill Trust

2. Dr Taylor is a beneficiary of the Taylor Family Trust

3. Ms Taylor is the spouse of Dr Taylor

4. Mr Thomas is a beneficiary of the R. Thomas Pension Fund

5. Mr Thomas is a shareholder of Murtoa Flour Mills Pty Ltd

6. Mr Thomas is Trustee of the Tony McCullough Foundation, a registered charity

(b) Offisier	Opening balance	Issued during the year	Exercised during the year	Expired/ assigned	Movement on resignation of Director	Closing balance	Vested and exercisable at 30 June	Vested and unexercisable at 30 June
Ms R Robinson	200,000	-	-	-	-	200,000	150,000	-
Dr C Roberts	200,000	-	-	-	-	200,000	150,000	-
Dr T Ramdahl	600,000	-	-	-	-	600,000	550,000	-
Dr C G O'Bryan- Tear <sup>1</sup>	900,000	-	-	(50,000)	(850,000)	-	-	-
Dr A Taylor	2,800,000	1,083,226	-	-		3,883,226	2,500,000	-
Dr C Biggin	5,400,000	837,855	(600,000)	-		5,637,855	4,500,000	-
Mr D Green	-	200,000	-	-		200,000	-	-
	10,100,000	2,121,081	(600,000)	(50,000)	(850,000)	10,721,081	7,850,000	-

# (b) Unlisted Options

1. Dr O'Bryan-Tear resigned from the Board on 25 May 2023.

All options vest on the fulfilment of a service period.

# END OF AUDITED REMUNERATION REPORT

# INDEMNIFYING OFFICERS AND AUDITORS

During the financial year the Group paid a premium of \$594,851 (2022: \$831,964) to insure the directors of the Company and the key management personnel of the Group. The liabilities insured are legal costs that may be incurred in defending civil or criminal proceedings that may be brought against the officers in their capacity as officers of the Group, and any other payments arising from liabilities incurred by the officers in connection with such proceedings. This does not include such liabilities that arise from conduct involving a wilful breach of duty by the officers or the improper use by the officers of their position or of information to gain advantage for themselves or someone else or to cause detriment to the Group. The Group has not otherwise, during or since the end of the financial year, except to the extent permitted by law, indemnified or agreed to indemnify any current or former officer or auditor of the Group against a liability incurred as such by an officer or auditor.

# AUDITOR INDEPENDENCE AND NON-AUDIT SERVICES

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

During the year the Group's auditor performed non-audit services being tax advice and preparation of an investigating accountants' report in preparation for listing. The Directors are satisfied that the provision of non-audit services during the year by the auditors (or by another person of firm on the auditors' behalf) is compatible with the general standard of independence for auditors imposed by the Corporations Act 2001. The details of the services provided, and their costs are as follows:

	2023 \$	2022 \$
Tax compliance & advisory services	88,843	87,706
Investigating accountants' report	-	11,000
	88,843	98,706

# PROCEEDINGS ON BEHALF OF THE COMPANY

No person has applied to the Court under section 237 of the Corporations Act 2001 for leave to bring proceedings on behalf of the Company, or to intervene in any proceedings to which the Company is a party, for the purpose of taking responsibility on behalf of the Company for all or part of those proceedings.

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

la /ay (or

Dr Alan Taylor Chairperson Date: 24 August 2023



Grant Thornton Audit Pty Ltd Level 17 383 Kent Street Sydney NSW 2000 Locked Bag Q800 Queen Victoria Building NSW 1230 T +61 2 8297 2400

# 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 audit of Clarity Pharmaceuticals Ltd for the year ended 30 June 2023, 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 audit; and
- b no contraventions of any applicable code of professional conduct in relation to the audit.

Cirant Thernton

Grant Thornton Audit Pty Ltd Chartered Accountants

Dorsley

L M Worsley Partner – Audit & Assurance

Sydney, 24 August 2023

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FINANCIAL STATEMENTS

# CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

FOR THE YEAR ENDED 30 JUNE 2023

	Note	2023 \$	2022 \$
Finance income	6	1,864,260	95,093
Research and Development Tax Incentive	6	9,800,556	6,458,925
Income		11,664,816	6,554,018
Corporate and administration expenses	7	(4,705,417)	(11,391,637)
Research and development expenses	8	(31,458,645)	(18,899,332)
Loss before income tax		(24,499,246)	(23,736,951)
Income tax expense	19	(103,200)	(17,632)
Loss for the year from continuing operations		(24,602,446)	(23,754,583)
Loss for the year		(24,602,446)	(23,754,583)
Other comprehensive (loss) income			
Exchange differences on translating foreign entity		(12,072)	123
Total comprehensive loss for the period		(24,614,518)	(23,754,460)

Earnings per Share	Note	2023 cents	2022 cents
Basic, loss for the year attributable to ordinary equity holders	10	(9.5)	(9.6)
Diluted, loss for the year attributable to ordinary equity holders	10	(9.5)	(9.6)

# CONSOLIDATED STATEMENT OF FINANCIAL POSITION

AS AT 30 JUNE 2023

	Notes	2023 \$	2022 \$
Assets			
Current			
Cash and cash equivalents	11	31,213,092	55,336,328
Financial assets	12	33,801,828	37,000,000
Research & development tax incentive receivable	13	9,469,604	6,395,947
Other receivables	13	532,608	261,626
Prepayments		1,660,789	556,205
Total current assets		76,677,921	99,550,106
Non-current			
Plant & equipment	14	206,142	260,092
Other financial assets	12	12,343	11,745
Total non-current assets		218,485	271,837
Total assets		76,896,406	99,821,943
Liabilities			
Current			
Trade and other payables	15	6,739,431	6,792,254
Employee entitlements	16	802,609	713,929
Total current liabilities		7,542,040	7,506,183
Non-current			
Employee entitlements	16	178,698	79,226
Total non-current liabilities		178,698	79,226
Total liabilities		7,720,738	7,585,409
Net assets		69,175,668	92,236,534
Equity			
Share capital	17	132,820,320	132,115,430
Share option reserve	18	6,723,640	5,898,745
Accumulated losses		(70,374,269)	(45,795,690)
Foreign currency translation reserve		5,977	18,049
Total equity		69,175,668	92,236,534

# CONSOLIDATED STATEMENT OF CHANGES IN EQUITY FOR THE YEAR ENDED 30 JUNE 2023

	Share Option Reserve \$	Foreign Currency Reserve \$	Share Capital \$	Accumulated Losses \$	Total \$
Year ended 30 June 2022					
Balance at 30 June 2021	4,205,714	17,926	44,903,522	(28,849,604)	20,277,558
Loss for the year	-	-	-	(23,754,583)	(23,754,583)
Foreign currency translation	-	123	-	-	123
Total Comprehensive Loss	-	123	-	(23,754,583)	(23,754,460)
Transactions with owners in their c	apacity as owne	ers:			
Transfer to share capital for options exercised	(263,927)	-	263,927	-	-
Ordinary shares issued on exercise of options	-	-	449,000	-	449,000
Transfer to retained earnings for options expired	(6,808,497)	-	-	6,808,497	-
Issue of share capital	-	-	92,000,000	-	92,000,000
Capital raising costs	-	-	(5,501,019)	-	(5,501,019)
Share-based options	8,765,455	-	-	-	8,765,455
Balance at 30 June 2022	5,898,745	18,049	132,115,430	(45,795,690)	92,236,534
Year ended 30 June 2023					
Loss for the year	-	-	-	(24,602,446)	(24,602,446)
Foreign currency translation	-	(12,072)	-	-	(12,072)
Total Comprehensive Loss	-	(12,072)	-	(24,602,446)	(24,614,518)
Transactions with owners in their o	apacity as owne	ers:			
Transfer to share capital for options exercised	(402,306)	-	402,306	-	-
Ordinary shares issued on exercise of options	-	-	315,335	-	315,335
Transfer to retained earnings for options expired	(23,867)	-	-	23,867	-
Capital raising costs	-	-	(12,750)	-	(12,750)
Share-based options	1,251,067	-	-	-	1,251,067
Balance at 30 June 2023	6,723,640	5,977	132,820,320	(70,374,269)	69,175,668

# CONSOLIDATED STATEMENT OF CASHFLOWS

FOR THE YEAR ENDED 30 JUNE 2023

	Notes	2023 \$	2022 \$
Cash Flows from Operating Activities			
Interest received		1,580,082	75,624
Research and development incentive received		6,726,900	3,262,862
Payments to suppliers and employees		(35,703,739)	(16,634,772)
Income taxes paid		(103,200)	(17,632)
Net operating cash flows	21	(27,499,957)	(13,313,918)
Cash Flows from Investing Activities			
Investment in Term Deposits		3,197,574	(26,500,365
Purchase of plant & equipment		(46,562)	(213,148)
Net investing cash flows		3,151,012	(26,713,513)
Cash Flows from Financing Activities			
Proceeds from issue of share capital		-	92,000,000
Proceeds from unissued share capital		61,000	132,000
Exercise of options		183,335	399,000
Cost of capital raising	17	(12,750)	(5,603,149)
Net financing cash flows		231,584	86,927,851
Net (decrease)/increase in cash held		(24,117,361)	46,900,420
Cash at the beginning of the financial year		55,336,328	8,439,068
Effect of exchange rate changes on cash and ca equivalents	sh	(5,875)	(3,160
Cash at the end of the financial year	11	31,213,092	55,336,328

# NOTES TO THE FINANCIAL STATEMENTS

FOR THE YEAR ENDED 30 JUNE 2023

## 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 financial statements are general purpose financial statements that have been prepared on an accruals basis in accordance with the Corporations Act 2001, Australian Accounting Standards and other authoritative pronouncements of the Australian Accounting Standards Board (AASB) and International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB). They have been prepared under the assumption that the Group operates on a going concern basis. Clarity Pharmaceuticals Ltd is a forprofit entity for the purpose of preparing the financial statements.

The consolidated financial statements for the year ended 30 June 2023 were approved and authorised for issue by the Board of Directors on 24 August 2023. The consolidated financial statements 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. To that end, the Group monitors cashflow closely against a detailed cashflow forecast which is periodically updated in line with actuals and changes in anticipated future spend to ensure the Group operates as a going concern. The combined cash position and forecast is reviewed by the directors who continue to assess the funding requirements of the Group, including the potential to raise capital, if required.

The Group had cash and financial assets of \$58.5 million at 23 August 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 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. These are not expected to have a significant impact on the Group's consolidated financial statements.

# 3. Summary of accounting policies

## (a) Overall considerations

The consolidated financial statements have been prepared using the significant accounting policies and measurement bases summarised below. Clarity Pharmaceuticals Ltd is an Australian for-profit company, located in Eveleigh NSW, Australia. The registered office address is Company Matters Pty Limited, Level 12, 680 George Street, Sydney, NSW 2000. The principal activities of the Group involve research and development (R&D) and clinical stage evaluation of its portfolio of novel radiopharmaceuticals products.

#### (b) Basis of consolidation

The Group financial statements consolidate those of the Parent Company and its subsidiaries as of 30 June 2023. The parent controls a subsidiary if it is exposed, or has rights, to variable returns from its involvement with the subsidiary and can affect those returns through its power over the subsidiary. One subsidiary, Clarity Personnel Inc., has a reporting date of 30 June 2023. The other subsidiary, Clarity Pharmaceuticals Europe SA (CPEU), has a reporting date of 31 December 2022. The balance date of CPEU has not been changed to 30 June due to (i) the immaterial nature of its operations and (ii) the expected short duration of its incorporation i.e., it is a special purpose entity specifically incorporated to execute a European grant and is to be wound up on finalisation of that purpose.

All transactions and balances between Group companies are eliminated on consolidation as at 30 June 2023, including unrealised gains and losses on transactions between Group companies. Where unrealised losses on intra-Group asset sales are reversed on consolidation, the underlying asset is also tested for impairment from a Group perspective. Amounts reported in the financial statements of subsidiaries have been adjusted where necessary to ensure consistency with the accounting policies adopted by the Group.

#### (c) Functional currency translation

The consolidated financial statements are presented in Australian dollars (\$AUD), which is also the functional currency of the Parent Company. Foreign currency transactions are translated into the functional currency of the respective Group entity, using the exchange rates prevailing at the dates of the transactions (spot exchange rate). Foreign exchange gains and losses resulting from the settlement of such transactions and from the re-measurement of monetary items at year end exchange rates are recognised in profit or loss.

Non-monetary items are not translated at year-end and are measured at historical cost (translated using the exchange rates at the date of the transaction), except for non-monetary items measured at fair value which are translated using the exchange rates at the date when fair value was determined. In the Group's financial statements, all assets, liabilities and transactions of Group entities with a functional currency other than the \$AUD are translated into \$AUD upon consolidation. The functional currency of the entities in the Group has remained unchanged during the reporting period. On consolidation, assets and liabilities have been translated into \$AUD at the closing rate at the reporting date. Goodwill and fair value adjustments arising on the acquisition of a foreign entity have been treated as assets and liabilities of the foreign entity and translated into \$AUD at the closing rate. Income and expenses have been translated into \$AUD at the average rate over the reporting period. Exchange differences are charged and/or credited to other comprehensive income and recognised in the currency translation reserve in equity.

# (d) Other income

The following recognition criteria must be met before other income is recognised.

*Grant Income* - Grant Income is recognised when the expenditure related to the grant is recognised. Grant monies that have been received or are receivable but are not yet used for the purpose specified in the grant agreement, are recognised as deferred income liabilities. Grant incomes received but unearned and refundable, are recognised as an other liability.

*Finance Income* – Finance Income relates to interest from bank and term deposits and is recognised on an accruals basis.

*Research & Development Tax Incentive* - Research & Development Tax Incentive is recognised as income when a reliable estimate can be made of the amount receivable and when there is reasonable assurance that the entity will comply with the conditions attached and the amount will be received. The Research & Development Tax Incentive for the year ended 30 June 2023 has been recognised as income for the said year.

#### (e) Income tax

The charge for current income tax expense is based on the profit for the period adjusted for any nonassessable or disallowed items. It is calculated using tax rates that have been enacted or are substantively enacted by the statement of financial position date. The amount of current tax payable or receivable is the best estimate of the tax amount expected to be paid or received that reflects uncertainty related to income taxes. It is measured using tax rates enacted or substantively enacted at the reporting date.

Deferred tax is accounted for using the statement of financial position liability method in respect of temporary differences arising between the tax bases of the assets and liability and their carrying amounts in the financial statements. No deferred income tax will be recognised from the initial recognition of an asset or liability, excluding a business combination, where there is no effect on accounting or taxable profit or loss.

Deferred tax assets are recognised to the extent that it is probable that sufficient taxable amounts will be available against which deductible temporary differences or unused tax losses and tax offsets can be utilised and reflects uncertainty related to income taxes. They are measured at their expected value, using tax rates enacted or substantively enacted at the reporting date. Deferred tax assets would be offset only if the Group had a legally enforceable right to set off current tax assets against current tax liabilities and the deferred tax assets and deferred tax liabilities related to income taxes levied by the same taxation authority on the same entity or group.

# (f) Goods and services tax (GST)

Revenues, expenses and assets are recognised net of the amount of GST except where the amount of GST incurred is not recoverable from the Australian Tax Office (ATO). In these circumstances the GST is recognised as part of the cost of acquisition of the asset or as part of an item of the expense.

Receivables and payables in the statement of financial position are shown inclusive of GST. The net amount of GST recoverable from, or payable to, the ATO is included as part of receivables or payables in the statement of financial position.

Cash flows are included in the statement of cash flows on a gross basis and the GST component of cash flows arising from investing and financing activities, which is recoverable from, or payable to, the ATO are classified as operating cash flows.

Commitments and contingencies are disclosed net of the GST recoverable from, or payable to, the ATO.

## (g) Cash and cash equivalents

Cash and cash equivalents include cash on hand and short-term deposits with banks or financial institutions, with an original maturity of 90 days or less. For the statement of cash flows, cash and cash equivalents consist of cash and cash equivalents as defined above, net of outstanding bank overdrafts.

## (h) Impairment of assets

At each reporting date, the Group reviews the carrying values of its tangible assets to determine whether there is any indication that those assets have been impaired. If such an indication exists, the recoverable amount of the asset, being the higher of the asset's fair value less costs to sell and value in use, is compared to the asset's carrying value. Where the asset does not generate cash flows that are independent from other assets, the Group estimates the recoverable amount of the cash generating unit to which it belongs. Any excess of the asset's carrying value over its recoverable amount is expensed to the statement of profit or loss and other comprehensive income.

## (i) Plant and equipment

Plant and equipment are measured at cost less depreciation and impairment losses. Subsequent costs are included in the asset's carrying amount or recognised as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Group and the cost of the item can be measured reliably. All other repairs and maintenance are charged to the statement of profit or loss and other comprehensive income during the financial period in which they are incurred.

# (j) Depreciation

The depreciable amount of all fixed assets is depreciated on a diminishing value basis over their useful lives to the Group commencing from the time the asset is held ready for use. Diminishing value basis has been chosen as it most accurately reflects the pattern of economic benefits consumed. The depreciation rates used for each class of depreciable assets are:

<u>Class of Fixed Asset</u> <u>Depreciation Rate</u>

Plant and Equipment 25 - 40%

The assets residual values and useful lives are reviewed, and adjusted if appropriate, at each reporting period.

An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount. Gains and losses on disposals are determined by comparing proceeds with the carrying amount. These gains or losses are included in the statement of profit or loss and other comprehensive income.

### (k) Financial instruments

#### Financial assets at amortised cost

Financial assets are measured at amortised cost if the assets meet the following conditions (and are not designated as FVTPL):

- they are held within a business model whose objective is to hold the financial assets and collect its contractual cash flows
- the contractual terms of the financial assets give rise to cash flows that are solely payments of principal and interest on the principal amount outstanding

After initial recognition, these are measured at amortised cost using the effective interest method. Discounting is omitted where the effect of discounting is immaterial. The Group's cash and cash equivalents fall into this category of financial instruments.

# Financial assets at fair value through profit or loss (FVTPL)

Financial assets that are held within a different business model other than 'hold to collect' or 'hold to collect and sell' are categorised at fair value through profit and loss. Further, irrespective of business model financial assets whose contractual cash flows are not solely payments of principal and interest are accounted for at FVTPL.

#### Fair value

Fair value is determined based on current bid prices for all quoted investments. Valuation techniques are applied to determine fair value for all unlisted securities, including recent arm's length transactions, references to similar instruments and option pricing models.

# (I) Employee benefits

Provision is made for the Group's liability for employee benefits arising from services rendered by employees to the end of the reporting period. Employee benefits that are expected to be settled within one year have been measured at the amounts expected to be paid when the liability is settled.

Employee benefits payable later than one year have been measured at the present value of the estimated future cash outflows to be made for those benefits. In determining the liability, consideration is given to employee wage increases and the probability that the employee may satisfy vesting requirements. Those cash flows are discounted using market yields on national government bonds with terms to maturity that match the expected timing of cash flows.

# (m) Intangible Assets

#### Research and Development

The dominant purpose of the Group is the development of diagnostic and therapeutic radiopharmaceuticals. The development of such products is preceded by many years of research through clinical trials and other activities. Expenditure on the research phase of projects is recognised as an expense as incurred.

Costs that are directly attributable to a project's development phase are recognised as intangible assets, provided they meet all of the following recognition requirements:

- the development costs can be measured reliably
- the project is technically and commercially feasible
- the Group intends to and has sufficient resources to execute a commercial outcome from the project
- the Group has the ability to derive income from the project, and
- the radiopharmaceuticals will generate probable future economic benefits.

Development costs not meeting these criteria for capitalisation are expensed as incurred. Directly attributable costs include employee costs incurred on development along with an appropriate portion of relevant overheads and borrowing costs.

# Patents

All patent costs incurred in acquiring and extending patents are expensed as incurred except to the extent such costs relate to projects which satisfy the above requirements for capitalisation.

# (n) Share Based Payments

The Group operates equity-settled share-based remuneration plans for its employees and offers share-based payments to consultants and as part of licensing arrangements. None of the Group's plans are cash-settled. All goods and services received in exchange for the grant of any share-based payment are measured at their fair values.

Where employees and other eligible participants are compensated using share-based payments, the fair value of employees' services is determined indirectly by reference to the fair value of the equity instruments granted. This fair value is appraised at the grant date and excludes the impact of non-market vesting conditions.

All share-based remuneration is ultimately recognised as an expense in profit or loss with a corresponding credit to the Share Options Reserve. If vesting periods or other vesting conditions apply, the expense is allocated over the vesting period, based on the best available estimate of the number of share options expected to vest.

Non-market vesting conditions are included in assumptions about the number of options that are expected to become exercisable. Estimates are subsequently revised if there is any indication that the number of share options expected to vest differs from previous estimates. Any adjustment to cumulative share-based compensation resulting from a revision is recognised in the current period. The number of vested options ultimately exercised by holders does not impact the expense recorded in any period.

Upon exercise of share options, the proceeds received, net of any directly attributable transaction costs, are allocated to share capital up to the nominal (or par) value of the shares issued with any excess being recorded as share premium.

# (o) Leases

Payments associated with short-term leases of office premises are recognised on a straight-line basis as an expense in the profit or loss. Short-term leases are leases with a lease term of 12 months or less.

# (p) Segments

The Group is a radiopharmaceutical development group with operations in Australia and the United States. As it has no commercial products it does not derive any commercial revenue. The Group does not currently consider that the risks and returns of the Group are affected by differences in its products or services, the geographical areas in which it operates, or its customers.

Group financial performance is evaluated by the Board of Directors (being the 'Chief Operating Decision Makers (CODM)') based on profit or loss before tax and cash flow for the group as a whole. As such the Group currently operates as one segment – Development of Radiopharmaceuticals.

#### (q) Critical accounting estimates and judgements

The directors evaluate estimates and judgements incorporated into the financial report based on historical knowledge and best available current information. Estimates assume a reasonable expectation of future events and are based on current trends and economic data, obtained both externally and within the Group. The directors have considered the impact of the COVID-19 pandemic on the accounting estimates and judgements and concluded that none of the estimates and judgements described here have been significantly impacted by the pandemic. Accordingly, no adjustment was required relative to the approach taken in the prior year.

*Key estimate – Research and Development Tax Incentive –* The Group assesses its Australian federal Government Research and Development Tax Incentive receivable at each reporting date, by tracking its eligible research and development expenditure, applying the Research and Development Tax Incentive refundable tax offset rate and applying applicable clawback provisions to its related grant expenditure.

Key estimates – Impairment of Assets – Assets are tested for impairment annually or whenever events or changes in circumstances indicate their full carrying amount might not be recoverable. The Group uses judgement in assessing the carrying value of assets, including assessing whether there are any indications that an asset may be impaired. Impairment indicators include evidence of obsolescence, permanent diminution in value or physical damage. Where impairment indicators exist, the asset is written down to the lower of its recoverable amount and value in use.

Key estimates – Share Based Payments – The Group measures cost of equity settled share-based payments at Fair Value (FV) of the Share Options at grant date using the Black-Scholes valuation methodology considering the terms & conditions upon which the instruments were granted. Inputs into the Black-Scholes valuation model require a level of estimation and judgement. Share based payments generally contain vesting conditions that must be met before such instruments can be exercised. Judgement must be exercised in assessing the probability of vesting conditions being met and in cases where the agreement is silent on the vesting condition, the quantum of non-vesting conditions included in FV calculations. As the Group was not trading publicly in the period between 1 July 2021 and 25 August 2021, judgement was also required to determine the share price input for the Black-Scholes valuation for options issued between those dates. The Company determined the share price as the proposed price of the Initial Public Offering.

*Critical accounting estimate – share price pre-public trading –* Prior to listing, the Company determined the share price, for the purposes of share-based payments, as the price of the most recent successful capital raising, or the share price where there was sufficient interest from investors to begin capital raising.

# 4. Operating segments

Clarity Pharmaceuticals Ltd and its subsidiaries, Clarity Pharmaceuticals Europe S.A. and Clarity Personnel Inc., 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.

# 5. Interests in subsidiaries

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

Country of Incorporation and principal place of			Proportion of ownership interests held by the group	
Name of the Subsidiary	business	Principal Activity	30 Jun 2023	30 Jun 2022
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%

# 6. Other Income

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

	2023 \$	2022 \$
Finance income	1,864,260	95,093
Research and Development Tax Incentive	9,800,556	6,458,925

# 7. Corporate and administration expenses

	2023 \$	2022 \$
Corporate and administration employment costs	(2,025,226)	(2,284,391)
Depreciation	(100,513)	(46,249)
Share-based payments to third parties		
China Grand	-	(6,784,556)
IPO-related costs	-	(656,489)
Insurance, professional fees, rent and other	(2,579,678)	(1,619,952)
	(4,705,417)	(11,391,637)

Details of share-based payments to China Grand in 2022 can be found in note 18.

IPO-related costs in 2022 include costs associated with preparation of the IPO not deducted from equity, including legal fees (\$293,820) and listing fees (\$307,810).

# 8. Research and development expenses

	2023 \$	2022 \$
Clinical trials and supporting activities	(21,965,377)	(13,476,835)
Research and development employment costs	(8,297,119)	(4,812,282)
Patents and related costs	(1,196,149)	(610,215)
	(31,458,645)	(18,899,332)

# 9. Leases

	2023 \$	2022 \$
Short-term leases	(151,384)	(140,939)

The Group has elected to account for short-term leases using the practical expedients. Short-term leases relates to office premises. Instead of recognising a right-of-use asset and lease liability, the payments in relation to these are recognised as an expense in profit or loss on a straight-line basis over the lease term.

# 10. Earnings per share

	2023 Cents	2022 Cents
Basic earnings (loss) per share	(9.5)	(9.6)
Diluted earnings (loss) per share	(9.5)	(9.6)

Income and share data used in calculations of basic and diluted earnings per share:

	\$	\$
Net (Loss)	(24,602,446)	(23,754,583)

	Number	Number
Weighted average number of Ordinary shares on issue in the calculation of basic earnings per share	259,604,114	247,695,819
Effect of dilutive securities <sup>1</sup>	-	-
Adjusted weighted average number of Ordinary shares used in the calculation of diluted earnings per share	259,604,114	247,695,819

1. At 30 June 2023 there were 25,192,250 (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.

# 11. Cash and cash equivalents

Cash and cash equivalents consist of the following:

	2023 \$	2022 \$
Cash at bank – Australian Dollars	5,189,905	27,798,528
Cash at bank – US Dollars	617,810	2,380,731
Cash at bank – Euro	167,106	157,069
Term deposits – cash equivalents – Australian Dollars	2,105,774	25,000,000
Term deposits – cash equivalents – US Dollars	23,132,497	-
	31,213,092	55,336,328

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

# 12. Other financial assets

	2023 \$	2022 \$
Current		
Term deposits	33,801,828	37,000,000
	33,801,828	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. Term deposits held have a maturity of 91 days with interest rates between 4.16% and 4.26% (2022: 91 days to 181 days with interest rates between 0.27% and 1.75%).

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.

# 13. Other receivables

	2023 \$	2022 \$
Research & development incentive receivable	9,469,604	6,395,947
Consumption taxes receivable	221,061	234,258
Interest receivable	311,547	27,368
	532,608	261,626

All amounts are short-term.

# 14. Plant & equipment

	2023 \$	2022 \$
Equipment	435,885	389,322
Less accumulated depreciation	(229,743)	(129,230)
	206,142	260,092
Balance as at 1 July	260,092	93,193
Additions	46,562	213,148
Depreciation	(100,513)	(46,249)
Balance as at 30 June	206,142	260,092

# 15. Trade & other payables

Trade and other payables recognised consist of the following:

	2023 \$	2022 \$
Current:		
Trade creditors	2,846,510	2,849,747
Sundry creditors	2,769,069	3,146,719
Payroll liabilities	910,749	631,775
Superannuation payable	129,775	86,882
Other liabilities	83,329	77,131
	6,739,431	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 \$1,355,035 (2022: \$2,675,473) and operations of \$1,021,851 (2022: \$56,168).

Other liabilities at 30 June 2023 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. The Grant has concluded and the Group believes that the balance of the grant, which remains unearned, will be refunded to the Walloon Government.

# 16. Employee entitlements

	2023 \$	2022 \$
Current		
Annual leave liability	782,764	548,802
Long service leave liability	19,845	165,127
	802,609	713,929

#### Non-Current

Long service leave liability	178,698	79,226
Movement in Total Employee Entitlement Provisions:		
Balance as at 1 July	793,155	448,772
Arisen during year	454,179	404,986
Utilised and reversed	(181,942)	( 60,603)
Probability revaluation <sup>1</sup>	(84,085)	-
Balance as at 30 June	981,307	793,155

1. In the current year, the Group has revalued the current and non-current long service leave liability in relation to the probability of employees satisfying vesting requirements.

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.

# 17. Equity

	2023 \$	2022 \$
Ordinary shares issued and fully paid	139,125,766	138,408,125
Cost of capital raising	(6,305,446)	(6,292,695)
Total contributed equity at 30 June	132,820,320	132,115,430
	\$	Number
Movement in ordinary shares on issue:		
Balance as at 1 July 2022	132,115,430	257,938,769
Issue on exercise of share options	717,640	2,723,901
Transaction costs	(12,750)	-
Balance as at 30 June 2023	132,820,320	260,662,670

# 17. Equity continued

#### Ordinary shares

Ordinary shares participate in dividends and the proceeds on winding up of the parent entity in proportion to the number of shares held. At the shareholders meetings each ordinary share is entitled to one vote when a poll is called, otherwise each shareholder has one vote on a show of hands. The Group does not have a limited amount of authorised capital and issued shares do not have a par value.

At an Extraordinary General Meeting (EGM) of shareholders held on 13 July 2021, it was resolved that all shares in Clarity Pharmaceuticals Ltd be split on the basis that every share on issue be split into twenty shares. Following the split, the number of issued shares increased from 9,520,913 to 190,418,260.

## Capital management

The Group's objective is to ensure it continues as a going concern as well as to maintain optimal returns to shareholders and benefits for other stakeholders. It also seeks to maintain the lowest cost of capital to which it is available. The Group does not currently make use of debt financing and as such, capital consists of shareholder equity finance together with other sources of non-dilutive funding such as grants and the Australian Federal Government Research and Development Tax Incentive.

The Group may, based on its circumstances and prevailing market conditions, adjust the capital structure; change the amount of dividends to be paid to shareholders; return capital to shareholders; or issue new shares as appropriate. No dividends were paid in the current financial period (2022: nil).

#### 18. Share option reserve

	2023 \$	2022 \$
Balance as at 1 July	5,898,745	4,205,714
Share options expensed – employees & consultants	1,251,067	1,980,899
Share options expensed – China Grand	-	6,784,556
Options exercised	(402,306)	(263,927)
Options lapsed	(23,867)	(6,808,497)
Balance as at 30 June	6,723,640	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 (see note 3(q)).

Share options held by employees and consultants issued under Clarity Pharmaceuticals' Equity Incentive Plan vest based on conditions regarding service provided to the Company. Options vest at the end of the stated service period or when another service-related milestone is reached. Options expire 5 years after their grant date.

In the prior period, in connection with an exclusive licensing negotiation, Clarity Pharmaceuticals 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-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%. As the purpose of the option agreement was to secure an exclusivity period for negotiations, this was treated as a non-vesting condition and therefore included into the fair value of the options granted. The options expired on 25 February 2022, without vesting. As such, the share option reserve total was reduced by the expired China Grand options, totalling \$6,784,556, on 25 February 2022 and transferred to retained earnings.

# 18. Share option reserve continued

For options granted during the year, the valuation model inputs used to determine the fair value at the grant date are as follows:

Grant Date	1 July 2022	12 October 2022	14 November 2022
Share Price	\$0.462	\$0.660	\$0.965
Exercise Price	\$0.508	\$0.725	\$1.060
Volatility Rate	93.8%	92.2%	93.4%
Options Life	5 years	5 years	5 years
Risk-free interest rate	3.24%	3.66%	3.44%
Grant Date	25 November 2022	6 March 2023	1 May 2023
Share Price	\$0.990	\$0.881	\$0.768
Exercise Price	\$0.508	\$0.970	\$0.845
Volatility Rate	93.2%	90.4%	94.0%
Options Life	5 years	5 years	5 years
Risk-free interest rate	3.38%	3.55%	3.09%

# 18. Share option reserve continued

Options on issue at 30 June 2023 comprise:

Expiry Date	Balance 1 July 22	Weighted Average Exercise Price	Granted during year	Lapsed during year	Exercised during year	Balance 30 June 2023	Vested and exercisable	Weighted Average Exercise Price	Weighted Average Remaining Life (years)
1 Jul 22	1,400,000	\$0.220	-	(200,000)	(1,200,000)	-	-	-	-
1 Nov 22	100,000	\$0.220	-	-	(100,000)	-	-	-	-
1 Jan 23	400,000	\$0.220	-	-	(400,000)	-	-	-	-
16 Feb 23	1,066,680	\$0.220	-	-	(1,066,680)	-	-	-	-
1 Jul 23	2,200,000	\$0.220	-	-	(600,000)	1,600,000	1,600,000	\$0.220	-
3 Dec 23	200,000	\$0.605	-	-	-	200,000	200,000	\$0.605	0.40
10 Dec 23	200,000	\$0.605	-	-	-	200,000	200,000	\$0.605	0.40
15 Dec 23	918,220	\$1.125	-	-	-	918,220	918,220	\$1.125	0.50
21 Mar 24	800,000	\$0.605	-	-	-	800,000	800,000	\$0.605	0.70
5 Aug 24	2,200,000	\$0.605	-	-	-	2,200,000	2,200,000	\$0.605	1.10
1 Oct 24	1,000,000	\$0.605	-	-	-	1,000,000	1,000,000	\$0.605	1.30
21 Oct 24	100,000	\$0.605	-	-	-	100,000	100,000	\$0.605	1.30
1 Dec 24	200,000	\$0.605	-	-	-	200,000	200,000	\$0.605	1.40
18 Dec 24	7,100,000	\$0.825	-	(450,000)	-	6,650,000	5,125,000	\$0.825	1.50
1 Mar 25	200,000	\$0.938	-	-	-	200,000	-	\$0.938	1.70
2 Mar 25	400,000	\$0.938	-	-	-	400,000	400,000	\$0.938	1.70
1 Jun 25	100,000	\$0.938	-	-	-	100,000	100,000	\$0.938	1.90
1 Jul 25	3,560,000	\$0.938	-	-	-	3,560,000	3,560,000	\$0.938	2.00
26 Aug 25	100,000	\$0.938	-	-	-	100,000	100,000	\$0.938	2.20
4 May 26	200,000	\$0.938	-	-	-	200,000	200,000	\$0.938	2.80
10 May 26	1,000,000	\$0.938	-	-	-	1,000,000	1,000,000	\$0.938	2.90
26 May 27	400,000	\$1.400	-	-	-	400,000	-	\$1.400	3.90
1 Jul 27	-	-	3,061,469	(286,604)	-	2,774,865	-	\$0.508	4.00
12 Sep 27	-	-	350,000	-	-	350,000	-	\$0.725	4.20
25 Nov 27	-	-	1,921,081	-	-	1,921,081	-	\$0.508	4.40
14 Nov 27	-	-	161,771	-	-	161,771	-	\$1.060	4.40
6 Mar 28	-	-	60,000	-	-	60,000	-	\$0.970	4.70
1 May 28	-	-	96,313	-	-	96,313	-	\$0.845	4.80
	23,844,900	\$0.698	5,650,634	(936,604)	(3,366,680)	25,192,250	17,703,220	\$0.732	2.04

The weighted average share price on exercise of options was as follows: expiring 1 Jul 22, \$0.462; expiring 1 Nov 22, \$0.615; expiring 1 Jan 23, \$0.940; expiring 16 Feb 23, 400,000 \$0.971, 666,680 \$0.780; expiring 1 Jul 23, 50,000 \$0.780, 75,000 \$0.780, 75,000 \$0.762, 200,000 \$0.767, 200,000 \$0.749.

# 19. Income tax

The aggregate amount of income tax attributable to the financial year differs from the amount prima facie payable on the operating profit. The difference is reconciled as follows:

	2023 \$	2022 \$
Result before income tax	(24,499,246)	(23,736,951)
Prima facie tax payable on (loss) before income tax at 30% (2022: 25%)	(7,349,774)	(5,934,238)
Add: Tax effect of:		
Non-deductible research and development expense subject to R&D tax incentive	5,857,487	3,675,832
Non-deductible share-based payment	375,320	2,191,364
Less: Tax effect of:		
Research & development incentive recognised	(2,840,881)	(6,395,948)
Adjustment to prior year research & development incentive	(99,286)	(62,977)
Other differences	(379,575)	109,486
Tax effect of losses not brought to account	4,539,909	6,416,481
Income tax expense attributable to loss before income tax	103,200	17,632
Unused tax losses for which no tax loss has been recognised as a deferred tax asset:	30,872,187	16,166,876
Tax effect:		
Australia (30%) (2022: 25%)	9,261,656	4,029,219
Europe (20%)	27,201	26,473
U. S. A. (25.55%)	-	-

Unused tax losses for Clarity Pharmaceuticals Ltd at 30 June 2022 has been re-stated from prior year following lodgement of the tax return for that year.

The benefit from tax losses will only be obtained if:

- (i) Clarity Pharmaceuticals Ltd derives future assessable income of a nature and of an amount sufficient to enable the benefit from the deductions for the losses to be realised;
- (ii) No changes in the tax legislation adversely affect the Group in realising the benefit from the deductions for the losses.

# 19. Income tax continued

	10,894,763	3,820,740
Unused tax losses	9,261,656	3,600,731
Provisions	333,325	220,009
Blackhole deduction	1,299,783	-
Deferred tax asset		
	2023 \$	2022 \$

No deferred tax asset was recognised in the year ended June 2023 due to the uncertainty of its recoverability.

# 20. Employee remuneration

# (a) Employee benefits expense

Expenses recognised for employee benefits are analysed below:

	2023 \$	2022 \$
Wages, salaries	7,281,434	3,918,756
Superannuation costs	457,213	303,424
Share-based payments	1,240,369	1,912,780
Other employee expenses	952,706	669,485
Employee benefits expense	9,931,722	6,804,445

# (b) Share-based employee remuneration

As at 30 June 2023, the Group maintained a share-based payment scheme for employee remuneration. This program is settled in equity.

Options under this program will vest if the participant remains employed for the agreed vesting period. Upon vesting, each option allows the holder to purchase one ordinary share at a discount to the market price determined at grant date. The fair value of options granted were determined using the Black-Scholes valuation method. In total \$1,240,369 (2022: \$1,912,780) of employee remuneration expense (all of which related to equity-settled share-based payment transactions) has been included in profit or loss and credited to share option reserve.

# 21. Cash flow statement reconciliation

	2023 \$	2022 \$
Reconciliation of net loss after tax to net cash flows from operation	ons	
Loss from ordinary activities after Income Tax	(24,602,446)	(23,754,583)
Non-Cash items in Total Comprehensive Income:		
Depreciation expense	100,513	46,249
Share option expense	1,251,067	8,765,455
Changes in Assets and Liabilities:		
Unrealised currency (gain)/loss	5,875	3,160
(Increase) in Trade and Other Receivables	(3,344,639)	(3,285,655)
Decrease/(Increase) in Prepayments	(1,104,584)	(358,897)
(Decrease)/Increase in Trade and Other Payables <sup>1</sup>	18,177	5,006,264
(Decrease)/Increase in Deferred Income	-	(80,419)
Increase in Provisions	188,152	344,383
Currency differences on translating a foreign entity	(12,072)	123
Cash Flow from Operations	(27,499,957)	(13,313,918)

1. Excluding \$70,000 in equity related items which are non-operating (2022: \$20,130).

# 22. Financial instruments

# (a) Assets

	2023 \$	2022 \$
Current assets		
Financial assets:		
Cash at bank	31,213,092	55,336,328
Term deposits	33,801,828	37,000,000
Total financial assets	65,014,920	92,336,328
Non-current assets		
Financial assets:		
Other financial assets	12,343	11,745
Total financial assets	12,343	11,745

# 22. Financial instruments continued

	2023 \$	2022 \$
Financial assets maturity analysis		
Less than 30 days	8,080,595	55,336,328
31 – 60 days	10,824,714	-
61 – 90 days	12,307,783	-
More than 90 days	33,814,171	37,011,745
More than 1 year	-	-
Balance at 30 June	65,027,263	92,348,073

# Fair value and credit risk

The Group expects equity raises and operating activities will generate sufficient cash flows for any future cash commitments. It holds sufficient financial assets that are readily available to meet liquidity needs.

# (b) Current liabilities

	2023 \$	2022 \$
Financial liabilities:		
Trade & other payables	5,615,578	5,996,466
Total financial liabilities	5,615,578	5,996,466

#### **Financial liabilities maturity analysis**

Less than 1 year	5,615,578	5,996,466
Balance at 30 June	5,615,578	5,996,466

# Fair Value and Credit Risk

Carrying value approximates fair value due to the short-term nature of these payables. These payables are due and expected to be paid in less than 12 months.

# (c) Credit risk

Credit risk is the risk that a counterparty fails to discharge an obligation to the Group. Given the absence of loan and trade receivables, the Group's exposure to credit risk is from financial assets including cash and cash equivalents held at bank.

The credit risk in respect of cash balances held with banks and deposits with banks is managed via diversification of bank deposits and only using banks with a Standard and Poor's Local Short-Term Credit Rating of A-1 or higher and only APRA regulated Authorised Deposit Taking Institutions (ADIs).

The maximum exposure to credit risk, excluding the value of any collateral or other security, at balance date to recognised financial assets, is the carrying amount, net of any provisions for impairment of those assets, as disclosed in the Statement of Financial Position and Notes to the Financial Statements.

# (d) Price risk

The Group is not exposed to any price risk from its operations of radiopharmaceuticals.

# 22. Financial instruments continued

# (e) Foreign currency risk

The Group is exposed to foreign currency risk, with several contracts denominated in US Dollars (USD) and Euro (EUR). The Group accepts the foreign currency risk attached to such contracts, however non-AUD cash flow exposures are monitored and the exposure to foreign exchange movement is factored into projected costs. No foreign exchange hedging takes place. To assist in risk management, the Group holds a portion of its forecast USD cash flow in USD.

# (f) Liquidity risk

The Group manages liquidity risk by monitoring cash flows and ensuring that adequate cash reserves are maintained.

# (g) Interest rate risk

The Group's exposure to interest rate risk, which is the risk that a financial instrument's value will fluctuate as a result of changes in market interest rates and the effective weighted average interest rates on classes of financial assets and financial liabilities, is as follows:

	Floating	Fixed Less than 1 Year	Non-interest bearing
	2023 \$	2023 \$	2023 \$
Financial assets:			
Cash and cash equivalents	4,662,135	25,238,271	1,312,687
Financial assets	-	33,801,828	-
Security deposits	-	-	12,343
Total financial assets	4,662,135	59,040,099	1,325,030
Financial liabilities:			
Trade and other payables	-	-	5,615,578
Total financial liabilities	-	-	5,615,578

# 22. Financial instruments continued

# (h) Sensitivity analysis

The Group has performed a sensitivity analysis relating to its exposure to changes in interest and foreign exchange rates at balance date. This sensitivity analysis demonstrates the effect on current year results and equity which could result from a change in these risks.

		2023 \$	2022 \$
Increase or decrease in interest rate by 1% - change in profit and equity	+/-	650,149	923,363
Increase or decrease in USD/AUD foreign exchange rate by 5 cents - change in profit and equity	+/-	(700,292)	35,541

The above sensitivity analysis has been performed on the assumption that all other variables remain unchanged.

# 23. Related party transactions

#### (a) Parent Entity

The Group is controlled by the following entity:

Name:	<u>Type:</u>	Place of business/incorporation:
Clarity Pharmaceuticals Limited	Ultimate Australian parent entity	Australia

## (b) Subsidiaries

Interests in subsidiaries is set out in note 5.

# (c) Key Management Personnel

Key management personnel received remuneration in the form of wages and salaries, bonuses, employment benefits including superannuation and options, as follows:

# Year ending 30 June 2023

	Salary <sup>1</sup> \$	Bonus \$	Superan- nuation \$	Options \$	Total \$	Unpaid at 30 Jun 2023 \$
Key Managemer	nt Personnel					
Dr A Taylor	550,564	271,500	25,292	282,975	1,130,331	277,823
Dr C Biggin	444,091	210,000	25,292	250,318	929,701	216,323
Mr D Green	215,729	-	22,073	27,684	265,486	6,323
Total	1,210,384	481,500	72,657	560,977	2,325,518	500,469

1. Salary includes movements in annual and long service leave

# 23. Related party transactions continued

Year ending 30 June 2022

			Superan-			Unpaid at 30 Jun
	Salary <sup>1</sup> \$	Bonus \$	nuation \$	Options \$	Total \$	2022 \$
Key Managemen	t Personnel					
Dr A Taylor	495,083	171,000	24,761	253,429	944,273	210,253
Dr C Biggin	346,506	122,400	23,568	318,529	811,003	150,733
Mr D Green	101,207	-	9,199	-	110,406	18,333
Mr R Vickery	148,749	-	14,350	105,595	268,694	7,517
Total	1,091,545	293,400	71,878	677,553	2,134,376	386,836

1. Salary includes movements in annual and long service leave

# (d) Transactions With Related Parties

# Transactions with subsidiaries

Clarity Pharmaceuticals Ltd paid management fees to its subsidiary, Clarity Personnel Inc., under an intercompany services agreement. In the year ended 30 June 2023, Clarity Personnel Inc. invoiced Clarity Pharmaceuticals Ltd \$3,889,863, of which \$535,316 was unpaid at 30 June 2023 (2022: \$721,967 invoiced, of which \$154,130 was unpaid at balance date).

# Share transactions of directors

In the year ended 30 June 2023, Dr Biggin exercised 200,000 in cash and 400,000 using a cashless exercise mechanism at a price of \$0.22 per option, resulting in the issue of 487,208 shares.

In the year ended 30 June 2022, Dr Biggin exercised 200,000 options at a price of \$0.22 per option resulting in the issue of 200,000 shares; Dr O'Bryan-Tear purchased 120,000 shares at market price; Dr Ramdahl purchased 120,000 at market price and parties related to Mr Thomas purchased 195,000 shares (Murtoa Flour Mills Pty Ltd (170,000); The Tony McCullough Foundation (25,000) at market price.

# Other transactions with directors

Directors receive a fixed director's fee and options. If any directors perform additional services for the Group they are paid a fee based on normal commercial terms. Transactions with directors in the year ended 30 June 2023 are as follows:

	Directors' fees \$	Options \$	U Total \$	Inpaid at 30 Jun 2023 \$
Non-executive directors				
Ms R Robinson <sup>1</sup>	79,560	11,029	90,589	1,890
Dr C Roberts	70,720	11,029	81,749	-
Dr T Ramdahl	70,720	11,029	81,749	-
Dr C G O'Bryan-Tear	60,596	2,133	62,729	-
Ms C Maley	29,467	-	29,467	19,448
Mr R Thomas <sup>1</sup>	79,560	-	79,560	1,890
Total	390,623	35,220	425,843	23,228

1. Directors' fees for Ms Robinson and Mr Thomas includes superannuation payable.

# 23. Related party transactions continued

	Directors' fees¹ \$	Other <sup>2</sup> \$	Options \$	Total \$	Unpaid at 30 Jun 2022 \$
Non-executive directed	ors				
Ms R Robinson	65,796	-	42,238	108,043	5,571
Dr C Roberts	60,225	-	42,238	102,463	-
Dr T Ramdahl	60,225	-	67,651	127,876	225
Dr C G O'Bryan-Tear	60,225	41,095	67,651	168,971	-
Mr R Thomas	57,022	-	-	57,022	5,694
Total	303,493	41,095	219,778	564,366	11,490

Transactions with directors in the year ended 30 June 2022 are as follows:

1. Directors' fees for Ms Robinson and Mr Thomas includes superannuation payable.

2. Dr O'Bryan-Tear received a consulting service fee on normal commercial terms.

# Transactions with directors of subsidiaries

Randall Pratt is a director of Clarity Personnel Inc. which was incorporated in May 2021. He is also a Partner of Life Science Legal LLC, which provides legal services to the Group. During the year Life Science Legal received fees from the Group totalling \$106,206 (2022: \$70,457). All fees were charged on normal commercial terms. Mr Pratt did not receive any payment for his services as director of Clarity Personnel Inc.

# 24. Auditors' remuneration

	2023 \$	2022 \$
Audit of financial report	113,820	107,448

The Group's auditors Grant Thornton received fees for the following non-audit services:

	88,843	98,706
Corporate advisory services	-	11,000
Tax compliance and advisory services	88,843	87,706

# 25. Commitment & contingencies

The Company has intellectual property that is either licensed or assigned from the University of Melbourne, Australian Nuclear Science and Technology Organisation, Dr Kurt Gehlsen, University of Southern California and University of Antwerp representing contingent liabilities totalling \$7,256,880 (2022: \$8,940,500). 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 radiopharmaceutical agents. It is anticipated that no further milestones will be reached in the year ending 30 June 2024 which will result in payments to licensors (June 2022: \$140,000).

# 26. Parent entity information

Information relating to Clarity Pharmaceuticals Ltd (the Parent Entity):

The Parent Entity has not entered a deed of cross guarantee. Contingent liabilities for the Parent Entity are the same as those for the Group, noted in Note 25. The Parent Entity uses the same accounting policies as the Group.

	2023 \$	2022 \$
Statement of financial position		
Current assets	75,322,836	99,061,615
Total assets	77,037,965	99,515,793
Current liabilities	(3,840,005)	(3,770,474)
Total liabilities	(8,130,275)	(7,355,094)
Net assets	68,907,690	92,160,699
Issued capital	139,543,960	132,115,431
Share option reserve	(52,526,964)	5,898,745
Retained losses	(18,109,306)	(45,853,477)
Total equity	68,907,690	92,160,699

# Statement of profit or loss and other comprehensive income

Total comprehensive income	(24,806,660)	(23,863,978)
Loss for the year	24,806,660	23,863,978

# 27. Post-reporting date events

There are no matters or circumstances that have arisen since the end of the financial 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 YEAR ENDED 30 JUNE 2023

In the Directors' opinion:

- the attached financial statements 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;
- the attached financial statements comply with Australian Accounting Standards as issued by the Australian Accounting Standards Board as described in Note 1 to the financial statements;
- the attached financial statements and notes give a true and fair view of its financial position as at 30 June 2023 and of its performance for the financial year ended on that date; 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.

The Directors have been given the declarations required by section 295A of the Corporations Act 2001.

Signed in accordance with a resolution of the Directors made pursuant to section 295(5)(a) of the Corporations Act 2001.

On behalf of the Directors

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Dr Alan Taylor Chairperson Dated this 24<sup>th</sup> day of August 2023



# Independent Auditor's Report

To the Members of Clarity Pharmaceuticals Ltd

Grant Thornton Audit Pty Ltd Level 17 383 Kent Street Sydney NSW 2000 Locked Bag Q800 Queen Victoria Building NSW 1230 + 61 2 8297 2400

Report on the audit of the financial report

#### Opinion

We have audited the financial report of Clarity Pharmaceuticals Ltd (the Company) and its subsidiaries (the Group), which comprises the consolidated statement of financial position as at 30 June 2023, 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 year then ended, and notes to the consolidated financial statements, including a summary of significant accounting policies, and the Directors' declaration.

In our opinion, the accompanying financial report of the Group is in accordance with the *Corporations Act* 2001, including:

- a giving a true and fair view of the Group's financial position as at 30 June 2023 and of its performance for the year ended on that date; and
- b complying with Australian Accounting Standards and the Corporations Regulations 2001.

#### **Basis for opinion**

We conducted our audit in accordance with Australian Auditing Standards. Our responsibilities under those standards are further described in the *Auditor's Responsibilities for the Audit of the Financial Report* section of our report. We are independent of the Group 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 financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

#### Key audit matters

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the financial report of the current period. These matters were addressed in the context of our audit of the financial report as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

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Research and Development Tax Incentive (Note 6 & Note 13)	
The Group receives a research and development (R&D) refundable tax offset from the Australian government, which represents the Group's corporate tax rate (30%) plus 18.5 cents in each dollar of eligible annual R&D expenditure if its turnover is less than \$20 million per annum. Registration of R&D Activities Application is filed with AusIndustry in the following financial year and, based on this filing, the Group receives the	<ul> <li>Our procedures included, amongst others:</li> <li>Performing procedures to understand the design and implementation of controls;</li> <li>Utilising an internal R&amp;D tax specialist to:</li> </ul>
	<ul> <li>review the expenditure methodology employed by management for consistency with the R&amp;D tax offset rules; and</li> </ul>
incentive in cash. Management reviewed the Group's total R&D expenditure to estimate the refundable tax offset receivable under the R&D tax incentive legislation.	<ul> <li>consider the nature of the expenses against the eligibility criteria of the R&amp;D tax incentive scheme to form a view about whether the expenses included in the estimate were likely to meet the eligibility criteria;</li> </ul>
This area is a key audit matter due to the degree of judgment and interpretation of the R&D tax legislation required by management to assess the eligibility of the R&D expenditure under the	<ul> <li>selecting a sample of R&amp;D expenditure and agreeing to supporting documentation to ensure the validity of the claimed amount and eligibility against the R&amp;D tax incentive scheme criteria; and</li> </ul>
scheme.	assessing the appropriateness of the financial

How our audit addressed the key audit matter

#### Information other than the financial report and auditor's report thereon

Key audit matter

The Directors are responsible for the other information. The other information comprises the information included in the Group's annual report for the year ended 30 June 2023, but does not include the financial report and our auditor's report thereon.

statement disclosures.

Our opinion on the financial report does not cover the other information and we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial report, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial report or our knowledge obtained in the audit or otherwise appears to be materially misstated.

If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

#### Responsibilities of the Directors for the financial report

The Directors of the Company are responsible for the preparation of the 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 financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error.

In preparing the financial report, the Directors are responsible for assessing the Group's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the Directors either intend to liquidate the Group or to cease operations, or have no realistic alternative but to do so.

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#### Auditor's responsibilities for the audit of the financial report

Our objectives are to obtain reasonable assurance about whether the financial report as a whole is free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with the Australian Auditing Standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of this financial report.

A further description of our responsibilities for the audit of the financial report is located at the Auditing and Assurance Standards Board website at: <u>http://www.auasb.gov.au/auditors\_responsibilities/ar1\_2020.pdf</u>.This description forms part of our auditor's report.

#### Report on the remuneration report

#### Opinion on the remuneration report

We have audited the Remuneration Report included in pages 17 to 36 of the Directors' report for the year ended 30 June 2023.

In our opinion, the Remuneration Report of Clarity Pharmaceutical Ltd, for the year ended 30 June 2023 complies with section 300A of the *Corporations Act 2001*.

#### Responsibilities

The Directors of the Company are responsible for the preparation and presentation of the Remuneration Report in accordance with section 300A of the *Corporations Act 2001*. Our responsibility is to express an opinion on the Remuneration Report, based on our audit conducted in accordance with Australian Auditing Standards.

Cirant Thernton

Grant Thornton Audit Pty Ltd Chartered Accountants

Worsley

L M Worsley Partner – Audit & Assurance Sydney, 24 August 2023

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Additional information required by the Australian Securities Exchange (ASX) and not disclosed elsewhere in the Annual Report is set out below. The shareholder information below is correct as at 20 September 2023.

# Substantial shareholders of ordinary shares (as reported to the ASX)

Name	Number of Shares Held	%
TM VENTURES PTY LTD	18,788,460	7.18
CABBIT PTY LTD ATF ROBWILL TRUST	17,911,280	6.84
A.C.N. 136 437 913 PTY LTD ATF THE TAYLOR FAMILY A/C	13,266,660	5.07

# Distribution of shareholders and shareholdings - ordinary shares

There are 261,859,233 ordinary shares on issue held by 2,011 shareholders.

Range	Ordinary Shares	%	No. of holders	%
1 to 1,000	247,831	0.09	385	19.14
1,001 to 5,000	1,622,444	0.62	594	29.54
5,001 to 10,000	2,226,373	0.85	284	14.12
10,001 to 100,000	19,105,778	7.30	550	27.35
100,001 and Over	238,656,807	91.14	198	9.85
Total	261,859,233	100.00	2,011	100.00

# Distribution of option holders and holdings - options (unlisted)

There are 26,337,909 unlisted options on issue held by 56 option holders. Of these 25,419,689 were issued under an employee share plan to 55 option holders.

Range	Options	%	No. of holders	%
1 to 1,000	-	-	-	-
1,001 to 5,000	-	-	-	-
5,001 to 10,000	-	-	-	-
10,001 to 100,000	1,282,968	4.87	20	35.71
100,001 and Over	25,054,941	95.13	36	64.29
Total	26,337,909	100.00	56	100.00

# **Unmarketable parcels**

The number of shareholders holding less than a marketable parcel of ordinary shares is 90, based on the Company's closing share price of \$1.22 on 20 September 2023.

# Twenty largest shareholders

Rank	Name	No. Shares	ç
1	TM VENTURES PTY LTD	18,788,460	7.1
2	CABBIT PTY LTD ATF ROBWILL TRUST	17,911,280	6.8
3	NATIONAL NOMINEES LIMITED	16,737,583	6.3
4	A.C.N. 136 437 913 PTY LTD ATF THE TAYLOR FAMILY A/C	13,266,660	5.0
5	BNP PARIBAS NOMS PTY LTD	10,077,537	3.8
6	ARGO INVESTMENTS LIMITED	9,247,447	3.5
7	UBS NOMINEES PTY LTD	8,176,111	3.1
8	YARRAWAH PTY LTD ATF PETER HENDERSON P/L S/F A/C	7,803,450	2.9
9	VANTRES PTY LTD ATF ASTEN SUPERANNUATION FUND	7,487,340	2.8
10	CHARLES WAITE MORGAN	6,900,041	2.6
11	BOORRIS PTY LTD ATF BOORRIS TRUST	6,065,800	2.3
12	MOORE FAMILY NOMINEE PTY LTD ATF MOORE FAMILY SUPER FUND	5,800,000	2.2
13	CITICORP NOMINEES PTY LIMITED	5,725,451	2.1
14	SMARTER CAPITAL PTY LTD	5,004,543	1.9
15	KYLACO PTY LTD	3,896,280	1.4
16	AUSTRALIAN NUCLEAR SCIENCE AND TECHNOLOGY ORGANISATION	3,599,920	1.3
17	PACIFIC CUSTODIANS PTY LIMITED	3,201,408	1.2
18	WYARGINE HOLDINGS PTY LTD ATF SHELLCOVE SUPER FUND	3,116,000	1.1
19	UM COMMERCIALISATION PTY LTD	2,946,500	1.1
20	EIGHT PAGODAS PTY LTD ATF EIGHT PAGODAS SUPERANNUATION FUND	2,768,320	1.0
	Total	158,520,131	60.5
	Balance of register	103,339,102	39.4
	Grand total	261,859,233	100.0

#### **On-Market Buy Back**

There is no current on-market buy back.

# Voting rights

The voting rights attached to ordinary shares are set out below:

On a show of hands every member present at a meeting in person or by proxy shall have one vote, and upon a poll, one vote for each fully paid share held.

Holders of options do not have voting rights on the options held by them.

# **Escrow Securities**

The Company has no securities under escrow, following the release of 78,742,707 securities from escrow on 25 August 2023.

#### Stock Exchange Listing

The Company's securities are only listed on the ASX.

# **Use of Funds Post Admission**

Clarity has used the cash and assets in the form readily convertible to cash at admission in a manner consistent with its business activities between the time of admission and the end of the reporting period.

# CORPORATE GOVERNANCE STATEMENT

The board of directors is responsible for the overall corporate governance of the Company, including adopting appropriate policies and procedures designed to ensure that the Clarity Pharmaceuticals is properly managed to protect and enhance shareholder interests.

Details of the Company's key governance policies and the charters for the board and each of its committees are available on the Company's website at <a href="https://www.claritypharmaceuticals.com/investor-center/">https://www.claritypharmaceuticals.com/investor-center/</a>.

The Corporate Governance Statement reports against the 4th edition of the ASX Corporate Governance Council's Principles and Recommendations (**ASX Principles**) and the practices detailed in the Corporate Governance Statement are current as at 29 September 2023. It has been approved by the board and is available on the Company's website under Investors at <u>https://www.claritypharmaceuticals.com/investor-center/</u>.

# 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

# **Company Secretary**

Mr Robert Vickery

**Chief Financial Officer** 

Mr David Green

Principal Place of Business National Innovation Centre 4 Cornwallis Street Eveleigh NSW 2015 Australia

# **Registered Office**

Clarity Pharmaceuticals Ltd C/- Company Matters Pty Limited Level 12, 680 George Street Sydney NSW 2000 Australia

ABN 36 143 005 341

Contact Information +61 (0)2 9209 4037 investor@claritypharmaceuticals.com

Website www.claritypharmaceuticals.com

Securities Exchange Listing Australian Securities Exchange ASX: CU6

# **Independent Auditor**

Grant Thornton Audit Pty Ltd Level 17, 383 Kent Street Sydney NSW 2000

# Share Registry

Link Market Services Limited Level 12, 680 George Street Sydney NSW 2000 1300 554 474 registrars@linkmarketservices.com.au

