



2024

# ANNUAL REPORT

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[www.claritypharmaceuticals.com](http://www.claritypharmaceuticals.com)

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# ABOUT CLARITY PHARMACEUTICALS

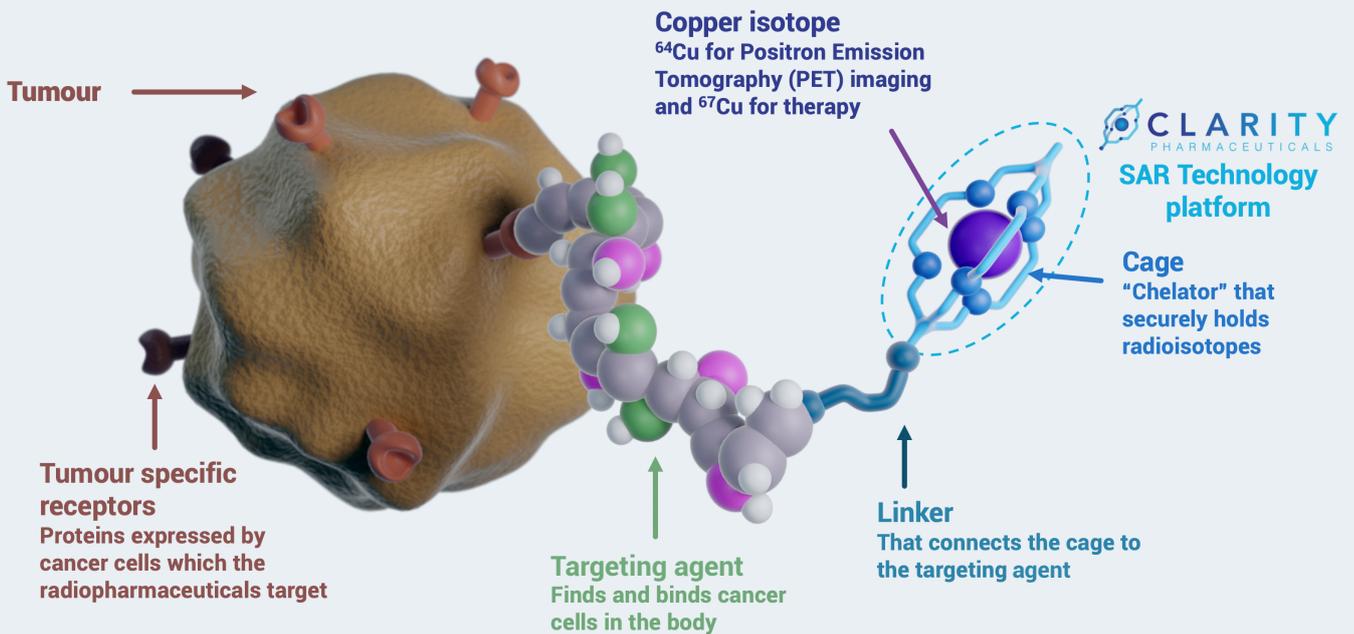
**Clarity is a clinical stage radiopharmaceutical company with a mission to develop next-generation products that improve treatment outcomes for children and adults with cancer.**

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 clinical stage products with the potential for best-in-class performance and a range of cutting edge pre-clinical assets at a time when radiopharmaceuticals are just beginning to revolutionise the treatment of cancer. The Company has a targeted clinical development strategy with the goal of commercialising diagnostic products in the United States (U.S.) with the Food and 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**

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Clarity's three core clinical stage theranostic (diagnostic and therapy) products, SAR-bisPSMA, SAR-Bombesin and SARTATE, each contain a different targeting agent that binds to specific receptors present on different cancer cells

The three theranostic products are in clinical development for both the diagnosis and treatment of various cancers addressing unmet clinical needs. In addition to these core products, Clarity's SAR Technology, as well as other proprietary platforms and know-how, are used in the Company's extensive Discovery Program, which explores a range of new products, thereby creating a pipeline of new radiopharmaceuticals to expand the existing portfolio.

### 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 2023-2024 (FY2023-2024).

For over a decade, every year without fail I have had the opportunity to share with our team and Shareholders that the last year has been our best year yet, and this past year has been no exception. Starting from very humble beginnings, the Company has now grown to become the Australian Securities Exchange (ASX)'s largest pharmaceutical biotechnology company by market capitalisation that has been solely grown from technology derived from the benchtop of Australian science. Reflective of this growth is Clarity's recent inclusion in the ASX300 and MSCI indexes with ASX200 on the horizon.

They say it takes a village to raise a child, and the translation of science from the laboratory to better treating patients around the world takes a village of exceptional people with the knowledge and know-how, and sheer guts and determination to run through the many obstacles that lie in the way. From the scientists at the benchtop and our long-term relationship with the University of Melbourne, to our extraordinary team and collaborators, and to our Shareholders, a lot of whom have been part of the story from the beginning,

or contributed to the funding rounds along the way, allowing us to do what we do best – develop products that improve treatment outcomes for children and adults with cancer.

It has been an exciting time for our Company as we now find ourselves progressing two diagnostic Phase III registrational trials with our lead product, <sup>64</sup>Cu-SAR-bisPSMA, in the pre-definitive therapy setting and in biochemical recurrence (BCR) of prostate cancer, supported by a Fast Track Designation granted by the U.S. Food and Drug Administration (FDA). Our therapeutic product, <sup>67</sup>Cu-SAR-bisPSMA, has also advanced incredibly well over the last year, and is now at the 12GBq dose level through cohort 4, the first multi-dose cohort in the SECuRE trial, where we have treated the first 3 patients with 2 doses of <sup>67</sup>Cu-SAR-bisPSMA and, following positive safety and early efficacy data, are now progressing with an additional 3 patients. We have seen incredible results in almost all patients we have treated with this product, despite most of them failing many previous lines of therapy. This year we have also reached a milestone every biotechnology company dreams of achieving, the first complete response to treatment, and it occurred the first time we treated a patient twice at what we considered an efficacious dose level. Most notably, this was in a patient with prostate cancer who had been heavily pre-treated and failed multiple lines of therapy prior to entering the study. He now has shown

complete molecular, anatomical and biochemical response to treatment after 2 doses with 8GBq of <sup>67</sup>Cu-SAR-bisPSMA, with his prostate specific antigen (PSA) undetectable for almost 8 months. We look forward to progressing the development of this exceptional product, replicating these fantastic results in the multi-dose cohorts of the SECuRE trial, and sharing more data as we advance its development in the coming months.

Dual-targeted 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 prostate-specific membrane antigen (PSMA) targeting products. It was optimised with two PSMA ligands, which increases not only the amount of product in the lesions, but also how long the product is retained in the lesions over time, making it an ideal candidate for diagnosis and therapy. The clinical data in both diagnostic and therapeutic indications that we are generating is remarkable, confirming these results that we initially saw in preclinical development. We are now exploring benefits of this unique product further, combining it with the alpha-particle emitter, actinium-225 (Ac-225 or <sup>225</sup>Ac), to complement our prostate cancer treatment paradigm in later-stage disease. We believe having both alpha- and beta-particle therapies in our portfolio puts Clarity in a strong position in the development of a range of radiopharmaceuticals and provides a powerful treatment approach to improve treatment outcomes for patients. We are extremely excited to progress the development of our bisPSMA based products, with a core focus on Targeted Copper Theranostics (TCTs) and a number of exciting milestones on the horizon.

SAR-bisPSMA is Clarity's lead product in clinical development, however, we have also been actively progressing two other products, SAR-Bombesin and SARTATE. SAR-Bombesin is a pan-cancer agent, which is currently being developed for prostate cancer as a stand-alone diagnostic in the Phase II SABRE trial, which closed recruitment and where we are now awaiting data, 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), with

the Phase II DISCO trial also closing recruitment in FY2023-2024. On the back of our clinical development, we had 14 abstracts accepted for presentation (including 6 oral presentations) at 6 leading international conferences, which is a testament to the high quality of the studies we run at Clarity and the data that they generate. We are very excited and encouraged by the positive preliminary data generated so far by these trials and look forward to providing further updates to the market in the future.

In addition to its strong roots in great Australian science with strong intellectual property (IP) and impressive data collected to date, Clarity also differentiates itself from its peers through our established supply chains for the production of TCTs in the United States (U.S.) via electron accelerators and cyclotrons, rather than nuclear reactors and generators. Our technology continues to pave the way for a scalable and dependable future for radiopharmaceuticals, unhindered by the quality and manufacturing issues currently plaguing the broader radiopharmaceuticals market. TCTs are ideally positioned to provide a sustainable solution for our field with minimal supply and logistical interruptions, unlike the current generation of products, in particular the therapeutic isotopes, including lutetium-177 and alpha-based therapies.

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 preferable 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. Our TCTs can be centrally manufactured and distributed broadly in the U.S. to every treatment or imaging centre with a positron emission tomography (PET) camera. This has the potential to reduce disparities in prostate cancer care and ensures that all patients, regardless of geographic location, can benefit from the latest advances in diagnostic imaging.

Clarity's mission is to improve treatment outcomes for children and adults with cancer. We are actively working with the EVAN Foundation, a U.S.-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. In the U.S., we are supporting the Children's Neuroblastoma Cancer Foundation and in Australia, The Kids Cancer Project, a charity organisation that funds vital scientific research to develop better treatments for all children with cancer. Outside of the oncology space, Clarity is supporting Story Factory, a not-for-profit creative writing centre for young people from under-resourced communities in our local area, and through this assistance is giving a voice to these young people.

Our team is at the core of Clarity's success, and we are excited to see it grow from 41 people as at 30 June 2023, to 61 team members today. I would like to welcome our new teammates and extend my utmost gratitude to all who have been instrumental in our Company's success over the years, changing the lives of people around the world with unwavering dedication and focus. With low employee turnover and an incredibly diverse group of people, we continue to build a culture of excellence and collaboration, united by our shared vision. Notably, almost a quarter of the current team were promoted based on their performance during financial year ending 30 June 2024. We are cognisant of the fact that we are not only developing unique skills and knowledge within Clarity, but are also creating a strong knowledge base for the STEM field and the translation of science in Australia for years to come.

Most recently, we made internal changes to the Senior Executive Team, with Michelle Parker promoted to Chief Clinical Officer, Dr Othon Gervasio promoted to Chief Medical Officer, and Dr Matt Harris stepping into the role of Chief Scientific Officer. Eva Lengyelova, VP of Clinical Development, also joined the Senior Executive Team. These changes reflect our dedication towards having a flat structure, being a true meritocracy, and creating efficiencies as we all work closely together during this most exciting period in the Company's history. 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 therapeutic platform. Clarity welcomed Michelle Parker to our Board of Directors as an Executive Director, replacing Rob Thomas who retired following the completion of his tenure on 23 August 2024. We thank Rob for his contribution and assistance at the Board level since Clarity's Initial Public Offering (IPO) on the ASX and wish him every success. Other changes at the Board level include Non-Executive Director, Dr Chris Roberts', appointment as Chair of the Audit and Risk Committee and joining the Nomination and Remuneration Committee. Thomas Ramdahl joined the Audit and Risk Committee, and fellow Non-Executive Director, Rosanne Robinson, moved to the role of Lead Independent Director.

On behalf of the entire team, I would like to thank all of our fellow shareholders who have continued to support Clarity. This support has brought us to this exciting chapter where the radiopharmaceutical field is becoming a beacon of hope in the oncology space, with big pharma on a hunt for next-generation products, and our TCTs continuously generating data to support their best-in-class potential in a number of indications. It has been an exciting journey from the benchtop of Australian science, and we are in a strong cash position to continue generating this outstanding data in the development of our exciting pipeline of next-generation radiopharmaceuticals within this highly acquisitive radiopharmaceuticals field.

We remain highly optimistic about our technology, team, and strategy as we enter FY2024-2025 and look forward to reporting our progress to you as we continue along this exciting phase of our journey.

Yours sincerely,



**Alan Taylor**  
Executive Chairperson, Clarity Pharmaceuticals



## CEO'S LETTER

Dear fellow Shareholders,

The FY2023-2024 has been a pivotal year for our team as we reached a number of exceptional milestones in the development of our three key products, SAR-bisPSMA, SAR-Bombesin and SARTATE in 7 clinical trials and one investigator-initiated trial (IIT), with excellent preliminary data generated to date. With a strong foundation of clinical data, we are now progressing Phase III trials and are closer than ever to our ultimate goal of improving treatment outcomes for children and adults with cancer.

On the theranostic front, during and since the reporting period, Clarity has successfully progressed through cohort 2 (8GBq dose level) and cohort 3 (12GBq dose level) of the SECURE trial with  $^{64/67}\text{Cu}$ -SAR-bisPSMA. We are now over halfway through a multi-dose cohort 4 (12GBq dose level), the last cohort in the dose escalation phase prior to entering the dose expansion phase of the trial. No dose-limiting toxicities (DLTs) have been reported in any of the cohorts to date and an overall safety review of cohorts 1, 2, 3 and 4 to date showed a favourable safety profile. The aim of the dose escalation phase is to assess the safety of the products; however, we are already seeing compelling data supporting efficacy of  $^{67}\text{Cu}$ -SAR-bisPSMA, even at single doses. Preliminary data from the first 3 cohorts has shown that despite

having high levels of PSA and having received multiple treatments before entering the study, 60% of participants across all cohorts (including the lowest dose cohort at 4GBq where we did not anticipate a therapeutic response) showed reductions in PSA levels of greater than 35% from a single therapy cycle of  $^{67}\text{Cu}$ -SAR-bisPSMA. PSA reductions of greater than 80% were seen in 27% of all trial participants. In cohorts 2 and 3, PSA reductions of greater than 35% were observed in 78% of participants and PSA was reduced by greater than 80% in almost half the participants so far from a single dose. We have seen similar results in cohort 4 of our multi-dose phase, and have already commenced recruitment for the final patients in this cohort. We look forward to sharing data from cohort 4 shortly.

In the reporting period, we commenced treating patients in cohort 1 of the theranostic  $^{64/67}\text{Cu}$ -SAR-Bombesin Phase I/IIa trial in metastatic castrate-resistant prostate cancer (mCRPC), COMBAT. Our CL04 trial in children with neuroblastoma is progressing through the dose-escalation and is currently at cohort 4 at the dose level of 375MBq/kg body weight of  $^{67}\text{Cu}$ -SARTATE, following successful completion of cohort 3 (275MBq/kg body weight) earlier in this reporting period. We look forward to progressing the CL04 trial in this important patient population and sharing more data once available.

**We will continue to progress our pipeline of products in clinical development, generate exciting data, strengthen our IP, grow our team, as well as expand our supply and manufacturing network throughout FY2024-2025**

The diagnostic trials have made significant progress as we are now actively recruiting into our first registrational Phase III trial, CLARIFY, that has built on the exciting data from the PROPELLER trial in pre-prostatectomy setting, and are actively planning a second Phase III trial in prostate cancer patients with BCR following successful completion and positive data from the COBRA trial. Based on the clinical evidence to date showing that  $^{64}\text{Cu}$ -SAR-bisPSMA may offer improved lesion detection compared to existing prostate cancer diagnostics, Clarity was granted Fast Track Designation by the U.S. FDA. The designation is intended to expedite the development and regulatory review of novel drugs addressing serious conditions with significant unmet medical needs and will allow Clarity to work closely with the FDA to facilitate the  $^{64}\text{Cu}$ -SAR-bisPSMA development process, potentially accelerating its approval and improving diagnosis and treatment planning for patients with this insidious disease sooner.

We have also successfully closed recruitment in our diagnostic Phase II trials, SABRE with  $^{64}\text{Cu}$ -SAR-Bombesin and DISCO with  $^{64}\text{Cu}$ -SARTATE. We are awaiting analysis of the trial data, which will guide further development with these products.

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 11).

Most recently, Clarity bolstered its Discovery Program by progressing the development of targeted alpha-particle therapy (TAT) with actinium-225 (Ac-225 or  $^{225}\text{Ac}$ ). We have been progressing preclinical studies for some months, exploring synergies of our bisPSMA targeting agent with the isotope of Ac-225 and aiming

to translate this work into clinical development to complement our beta-particle therapy product,  $^{67}\text{Cu}$ -SAR-bisPSMA. Our vision is for each product to offer treatment benefits for prostate cancer patients at different stages of disease progression and enable a more comprehensive treatment paradigm for people with prostate cancer.

Another important addition to Clarity's Discovery Program is the acquisition of an exclusive worldwide license from Memorial Sloan Kettering Cancer Center (MSKCC) to intellectual property covering antibody pre-targeting technology. Discover more about this exciting technology and the synergies of pre-targeting with Clarity's SAR Technology in the Discovery 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 the reporting period. In April 2024, Clarity has entered into a Clinical Supply Agreement with NorthStar Medical Isotopes, LLC (NorthStar), a global innovator in the development, production and commercialisation of therapeutic radiopharmaceuticals, for the production of  $^{67}\text{Cu}$ -SAR-bisPSMA drug product for Phase I/II and Phase III trials. This agreement uniquely provides large-scale manufacturing of both the therapeutic isotope, copper-67, and current good manufacturing practice (cGMP) radiopharmaceutical product in the U.S. under one roof and ready for shipment to clinical sites. This is a feature not available with any other radioligand therapies at present and can reduce logistical complexity and improve environmental considerations associated with shipment of the isotopes to manufacturing sites.

With regards to the supply of the diagnostic Cu-64 isotope, Clarity strengthened its supply by entering into a Supply Agreement with SpectronRx, a robust and established private supplier of Cu-64 in May 2024. The agreement for the production of Cu-64 complements our existing supply network as Clarity's products continue to progress swiftly through late-stage clinical trials.

To support our development of TAT as part of the Discovery Program, Clarity also signed a supply agreement with TerraPower Isotopes who have a unique Ac-225 manufacturing process in the US, and we will continue adding Ac-225 suppliers to our network in line with a strategy of developing sustainable, scalable and environmentally preferred solutions of next-generation radiopharmaceutical products.

As we look ahead to FY2024-2025, Clarity's future has never looked more promising. In anticipation of exciting data from a number of diagnostic and theranostic clinical trials and with exciting programs

in preclinical development, we look forward to further pursuing our ultimate goal of improving treatment outcomes for children and adults with cancer.

I would like to thank our rapidly growing team and collaborators. Thanks to their dedication and commitment to our shared mission, we are able to achieve something truly exceptional and build one of the most fascinating Australian success stories to date. I also thank the investigators, clinical trial participants, and their families for their commitment to supporting our programs. We cannot wait to progress this story further and share our successes with you as we enter this next exciting chapter.

Yours sincerely,



**Colin Biggin**  
CEO, Clarity Pharmaceuticals



# CORPORATE & FINANCE

**Clarity's cash position is strong with a balance of \$136.5 million as at 30 June 2024. This funding will provide cash runway into 2026 and help advance Clarity's clinical portfolio, including SAR-bisPSMA, SAR-Bombesin and SARTATE, enabling the Company to reach a number of crucial clinical milestones in their development.**

In April 2024, Clarity successfully completed a fully underwritten equity raising of \$121 million, comprising a pro rata accelerated non-renounceable entitlement offer and a placement to institutional investors at \$2.55 per share.

The placement to institutional investors raised \$110 million in total, and the retail entitlement offer approximately \$11 million.

## Environmental, Social & Governance

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

Clarity's Targeted Copper Theranostics (TCTs) offer a more sustainable approach to radiopharmaceuticals through a reliable and scalable supply chain, which is also environmentally preferable. The therapeutic radioisotope copper-67 is produced on electricity-powered electron accelerators, instead of nuclear reactors. Electron accelerator production is not fuelled by uranium, does not produce long-lived radioactive waste products and uses 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, avoids the inefficiencies of the current-generation diagnostic products, such as gallium-68 and fluorine-18, which utilise shorter half-life isotopes and require extensive, expensive 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, in Australia Clarity is also supporting The Kids Cancer Project, a charity organisation that funds vital scientific research to develop better treatments for all children with cancer. In the US, Clarity is working with 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 the Children's Neuroblastoma Cancer Foundation. Outside of the oncology sector, the Company is 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 & REGULATORY DEVELOPMENT

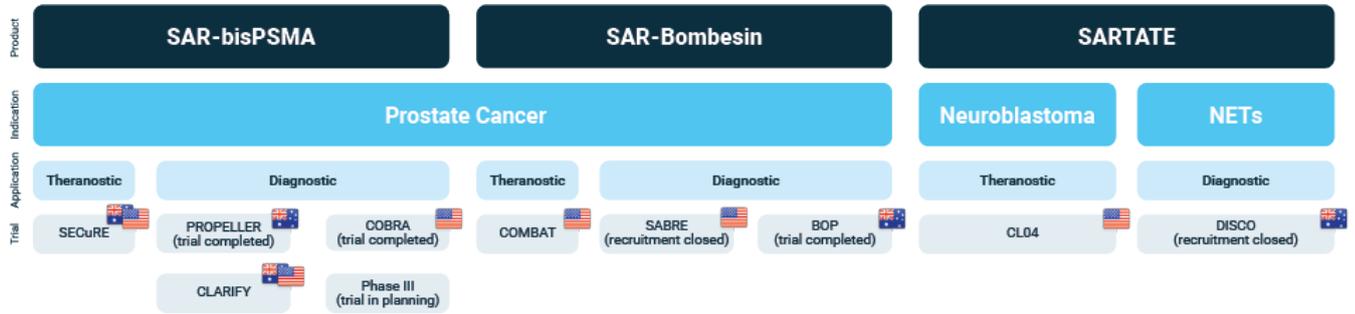
The FY2023-2024 has been significant for Clarity's clinical development, progressing the Company's diverse range of products through clinical trials, including a Phase III trial, addressing both large indications as well as rare and orphan indications of cancer.

During the FY2023-2024 Clarity's three key products, SAR-bisPSMA, SAR-Bombesin and SARTATE, have progressed in seven clinical trials, including three theranostic trials, four diagnostic trials and one investigator-initiated trial (IIT). Four clinical trials are actively recruiting participants, two trials are awaiting final data, results from the IIT were published in the prestigious Journal of Nuclear Medicine, and one trial successfully completed and resulted in a second Phase III registrational trial being designed based on the data.

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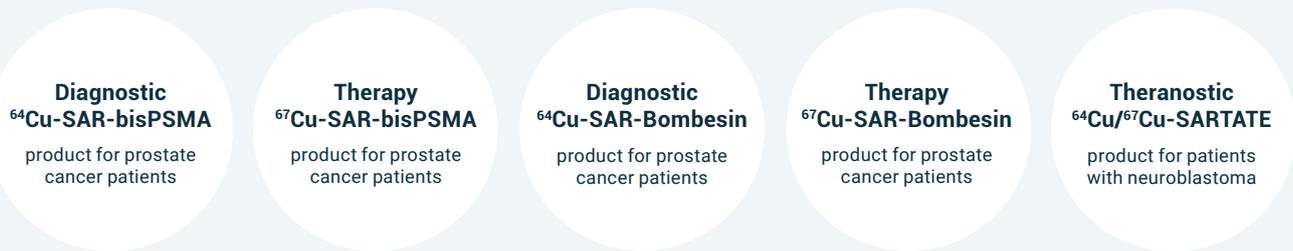
	Theranostic	Diagnostic
<b>SAR-bisPSMA</b>	<b>SECURE</b> – Phase I/IIa theranostic trial for identification and treatment of PSMA-expressing metastatic castrate-resistant prostate cancer (mCRPC) using <sup>64</sup> Cu/ <sup>67</sup> Cu-SAR-bisPSMA in the U.S. and Australia ( <a href="#">NCT04868604</a> ) <sup>1</sup>	<p><b>CLARIFY</b> – 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 U.S. and Australia (<a href="#">NCT06056830</a>)<sup>4</sup></p> <p><b>Phase III trial</b> – Registrational PET imaging trial of participants with biochemical recurrence (BCR) of prostate cancer following definitive therapy using <sup>64</sup>Cu-SAR-bisPSMA (in planning)</p> <p><b>COBRA</b> – Phase I/II PET imaging trial of participants with BCR of prostate cancer following definitive therapy using <sup>64</sup>Cu-SAR-bisPSMA in the U.S. (<a href="#">NCT05249127</a>)<sup>5</sup></p>
<b>SAR-Bombesin</b>	<b>COMBAT</b> – 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 U.S. ( <a href="#">NCT05633160</a> ) <sup>2</sup>	<p><b>SABRE</b> – Phase II PET imaging trial of participants with PSMA-negative BCR of prostate cancer using <sup>64</sup>Cu-SAR-Bombesin in the U.S. (<a href="#">NCT05407311</a>)<sup>6</sup></p> <p><b>BOP</b> – Investigator Initiated Phase II PET imaging trial of participants with negative PSMA PET or low PSMA expression disease in patients with suspected BCR of prostate cancer and patients with mCRPC using <sup>64</sup>Cu-SAR-Bombesin led by Prof Louise Emmett at St Vincent's Hospital Sydney (<a href="#">NCT05613842</a>)<sup>7</sup></p>
<b>SARTATE</b>	<b>CL04</b> – Phase I/IIa theranostic trial in paediatric participants with high-risk neuroblastoma using <sup>64</sup> Cu/ <sup>67</sup> Cu-SARTATE in the U.S. ( <a href="#">NCT04023331</a> ) <sup>3</sup>	<b>DISCO</b> – Phase II PET imaging trial of participants with known or suspected neuroendocrine tumours (NETs) using <sup>64</sup> Cu-SARTATE in Australia ( <a href="#">NCT04438304</a> ) <sup>8</sup>

Clarity is conducting multiple clinical trials for each of its 3 key products to explore both diagnostic and therapeutic opportunities, as well as expand their potential applications in a range of cancers.



## Five Open IND Applications

An open Investigational New Drug (IND) application allows Clarity to progress clinical trials of products in the U.S. Clarity received the U.S. Food and Drug Administration (FDA) clearance to proceed with the following trials:



## Fast Track Designation

The U.S. FDA granted Fast Track Designation for <sup>64</sup>Cu-SAR-bisPSMA for positron emission tomography (PET) imaging of prostate-specific membrane antigen (PSMA) positive prostate cancer lesions with suspected metastasis who are candidates for initial definitive therapy in August 2024.

The FDA's Fast Track Designation is designed to expedite the development and regulatory review of novel drugs addressing serious conditions with significant unmet medical needs. It is supported by the initial clinical evidence suggesting that <sup>64</sup>Cu-SAR-bisPSMA may offer improved lesion detection compared to existing prostate cancer diagnostics.

The designation paves the way for a potentially faster review process once Clarity submits its product approval application. Additionally, it enables more frequent communication with the FDA, allowing for

rapid resolution of queries during development. Furthermore, Clarity can submit completed sections of its application as they are ready, rather than waiting for the completion of the entire package before it can be lodged with the FDA. These benefits would reduce the review time needed to bring <sup>64</sup>Cu-SAR-bisPSMA to market, potentially improving the diagnosis and treatment planning for patients sooner and addressing the critical need for more accurate and accessible diagnostic tools in prostate cancer management.

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# CLARITY'S CLINICAL MILESTONES

During and since FY2023-2024

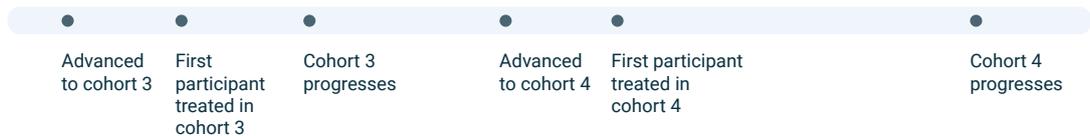
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Theranostic

Diagnostic

## SECURE

SAR-bisPSMA  
US



## COMBAT

SAR-Bombesin  
US



## CL04

SARTATE  
US



Q1 FY2023-24

Q2 FY2023-24

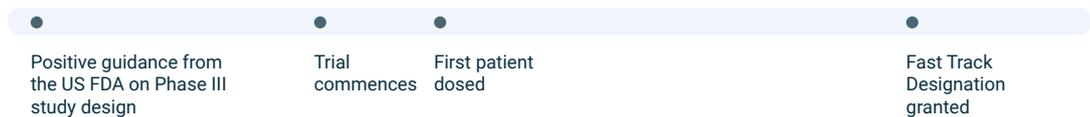
Q3 FY2023-24

Q4 FY2023-24

Q1 FY2024-25

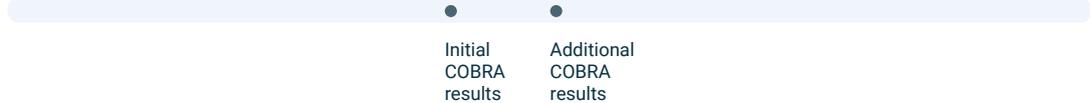
## CLARIFY

SAR-bisPSMA  
US



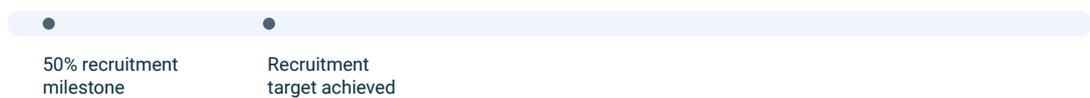
## COBRA/ Phase III

SAR-bisPSMA  
US



## SABRE

SAR-Bombesin  
US



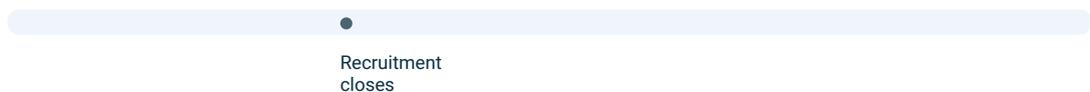
## BOP

SAR-Bombesin  
AU



## DISCO

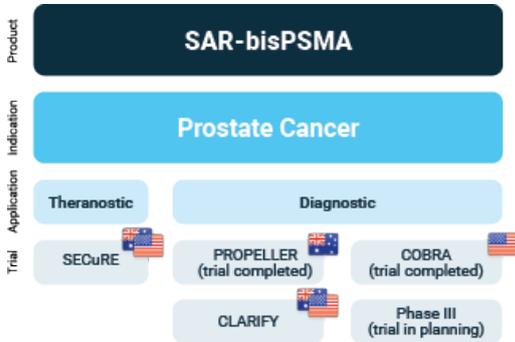
SARTATE AU



# PRODUCT UPDATES

## SAR-bisPSMA: Prostate Cancer

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

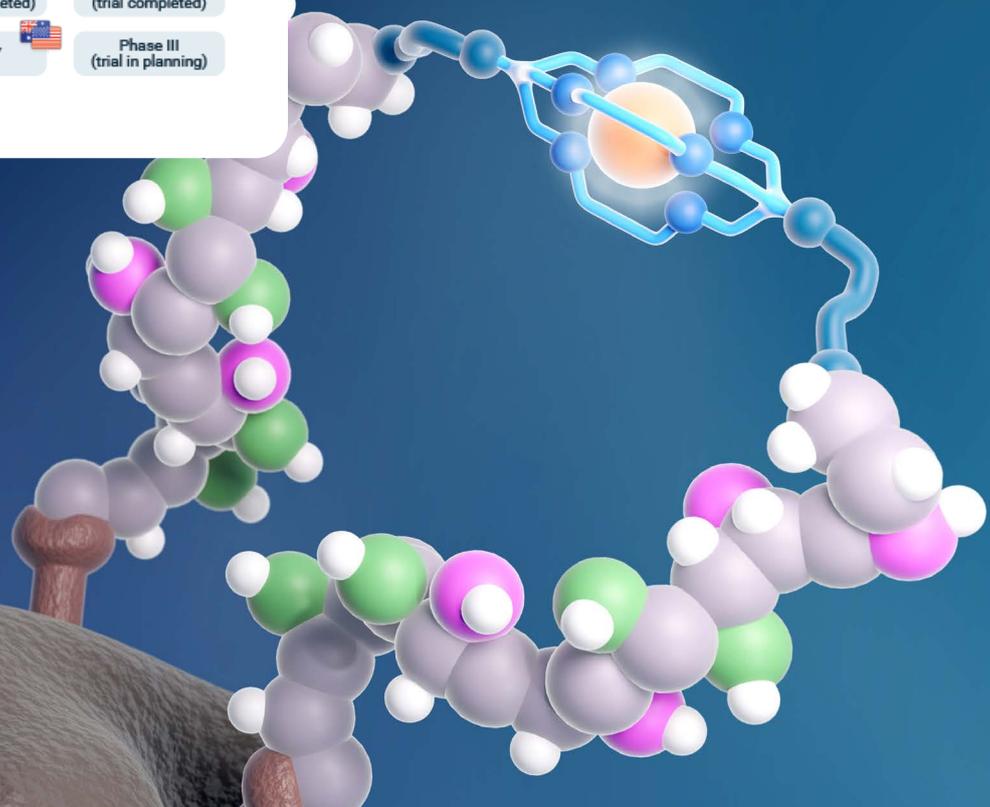


SAR-bisPSMA is being developed for diagnosing, staging and subsequently treating cancers that express PSMA. The product uses either copper-64 (<sup>64</sup>Cu) for imaging (<sup>64</sup>Cu-SAR-bisPSMA) or copper-67 (<sup>67</sup>Cu) for therapy (<sup>67</sup>Cu-SAR-bisPSMA).

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 United States (U.S.) Food and Drug Administration (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.

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# SECURE: Theranostic <sup>64</sup>Cu/<sup>67</sup>Cu-SAR-bisPSMA trial

In September 2024, the Safety Review Committee (SRC) assessed early data from the first 3 participants in cohort 4 of the SECURE trial (NCT04868604)<sup>1</sup> who received 2 doses of <sup>67</sup>Cu-SAR-bisPSMA and recommended the trial progresses with the additional 3 participants. Cohort 4 is the last in the dose escalation phase of the trial and will be followed by a dose expansion phase that will explore the anti-cancer effects of multiple therapy cycles of <sup>67</sup>Cu-SAR-bisPSMA at the dose level of 12GBq.

The first 3 participants in cohort 4 who received 2 cycles of <sup>67</sup>Cu-SAR-bisPSMA have been treated since March 2024. During the reporting period, Clarity also successfully completed cohort 2 and cohort 3 of the SECURE trial. No dose-limiting toxicities (DLTs) have been reported in any of the cohorts to date and an overall safety review of cohorts 1, 2, 3 and 4 (4, 8 and 12GBq single dose and two doses of 12GBq respectively) showed a favourable safety profile, with no adverse events (AEs) related to <sup>64</sup>Cu-SAR-bisPSMA reported, and most AEs related to <sup>67</sup>Cu-SAR-bisPSMA being only mild-to-moderate.

SECURE is a 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. 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. Cohort 3 was the last to assess single doses of <sup>67</sup>Cu-SAR-bisPSMA at the highest dose level of 12GBq.

Based on the favourable safety profile observed in the first 3 cohorts of the SECURE trial, a change to the dosing schedule of cohort 4 from “2 doses” to “up to 4 doses” was approved by the SRC and implemented at the clinical sites (Figure 1). This allows patients who are benefiting from <sup>67</sup>Cu-SAR-bisPSMA to receive 2 additional doses under the SECURE trial in cohort 4 (up to 4 doses in total).

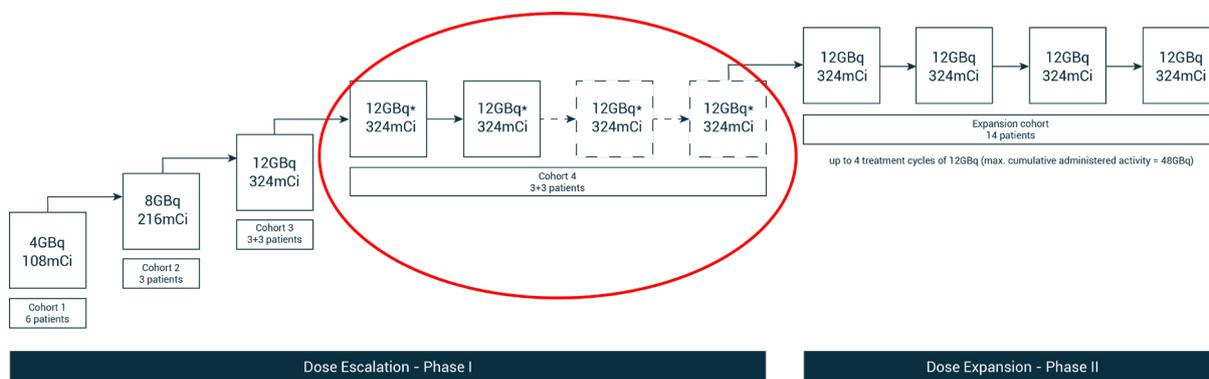


Figure 1. SECURE study design

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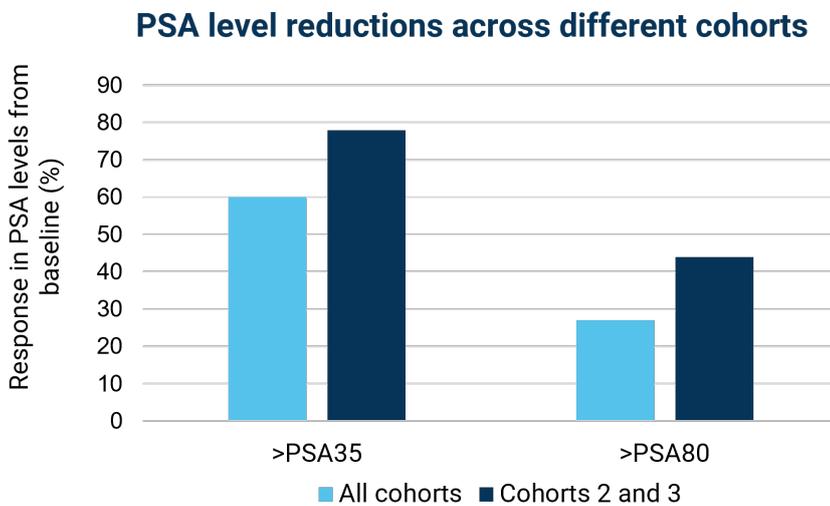
### Cohorts 1, 2 and 3 – Safety and Efficacy

The overall analysis of cohorts 1-3 to date suggests that <sup>67</sup>Cu-SAR-bisPSMA has a favourable safety profile. AEs were reported as related to <sup>67</sup>Cu-SAR-bisPSMA in 8 out of the 15 trial participants (all grades). No AEs were reported as related to <sup>64</sup>Cu-SAR-bisPSMA. Most AEs related to <sup>67</sup>Cu-SAR-bisPSMA were grade 1 or 2. The most common grade 3 AE was anaemia, reported in 2/15 participants (13%).

Preliminary efficacy analysis shows that despite having high levels of prostate specific antigen (PSA) and having received multiple treatments before entering the study, 60% (9/15) of participants across all cohorts (including the lowest dose cohort of <sup>67</sup>Cu-SAR-bisPSMA at 4GBq) showed reductions in PSA levels of greater than 35% from a single therapy cycle of <sup>67</sup>Cu-SAR-bisPSMA. PSA reductions of greater than 80% were seen in 27% of all trial

participants. In cohorts 2 and 3 (8 and 12GBq, respectively), PSA reductions of greater than 35% were observed in almost 80% (78%, 7/9) of participants and PSA was reduced by greater than 80% in 44% (4/9) of participants so far (**Figure 2**).

Participants in cohort 3 had the highest median baseline PSA and the highest median number of systemic therapies across all cohorts (median baseline PSA 122.6, 47.2 and 140.3 ng/ml; median lines of therapy 4, 3 and 5.5; cohorts 1, 2 and 3, respectively). Nevertheless, two-thirds (67%) of participants in this cohort so far have shown reductions in PSA greater than 35%. Importantly, a single dose of 12GBq of <sup>67</sup>Cu-SAR-bisPSMA was effective in reducing PSA levels in the majority of these patients despite receiving the most lines of prior therapy (**Figures 3 and 4**).

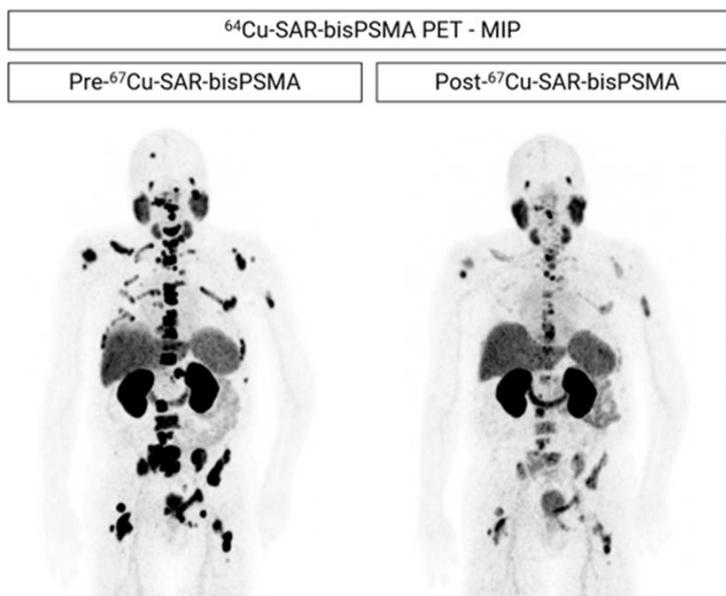


**Figure 2.** PSA reductions shown as the response observed post-single dose of <sup>67</sup>Cu-SAR-bisPSMA. PSA pre-dose value represents the most recent test result prior to the administration of <sup>67</sup>Cu-SAR-bisPSMA. At study entry, patients had median PSA of 117.1 ng/ml.

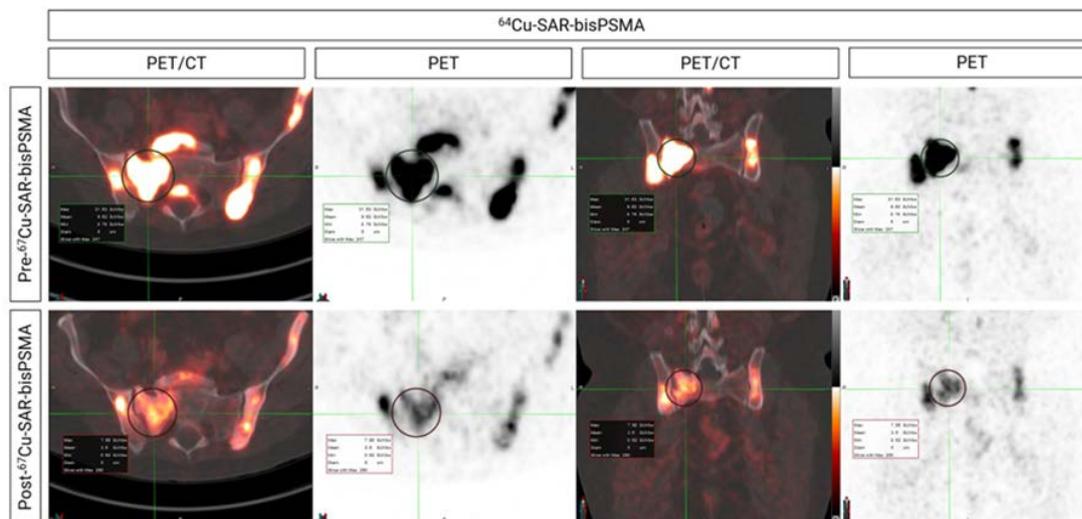
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**Figure 3.** Participant from cohort 3 showing reduction in uptake of <sup>64</sup>Cu-SAR-bisPSMA in prostate cancer lesions. The participant was treated with androgen deprivation therapy (ADT), androgen receptor pathway inhibitor (ARPI), chemotherapy and 2 investigational agents prior to enrolling in the SECURE study (PSA 270.9 ng/ml at study entry). The participant received a single dose of <sup>67</sup>Cu-SAR-bisPSMA (12GBq), which led to the reduction in uptake of <sup>64</sup>Cu-SAR-bisPSMA in the lesions. PSA reduction: 92.3%. Total body tumour reduction: Maximum standardised uptake values (SUVmax) from 51.7 to 19.0 (63.2% reduction) and tumour volume from 1,040.9 to 635.4 ml (39.0% reduction). MIP. maximum intensity projection.



**Figure 4.** Participant from cohort 3 showing reduction in uptake of <sup>64</sup>Cu-SAR-bisPSMA in pelvic bone lesions. mCRPC patient displaying the reduction in uptake of <sup>64</sup>Cu-SAR-bisPSMA in pelvic bone lesions after receiving a single dose of <sup>67</sup>Cu-SAR-bisPSMA (12GBq). The lesion highlighted in the circle shows a reduction in SUVmax from 31.6 to 8.0 (75% reduction, pre/post <sup>67</sup>Cu-SAR-bisPSMA cycle, respectively). Left images: axial view. Right images: coronal view.

The SECURE trial is continuing as planned and recruitment into cohort 4 is ongoing. The promising preliminary data is currently being used to inform the next stages of Clarity’s clinical development program, including the expanded cohort in the SECURE study and subsequently the Phase III clinical trial, exploring the potential use of <sup>67</sup>Cu-SAR-bisPSMA at earlier stages of the disease.

Trial design data for the study was presented at the American Society of Clinical Oncology Genitourinary Cancers Symposium (ASCO GU) in January 2024, as well as ASCO and the Society of Nuclear Medicine and Molecular Imaging (SNMMI) Annual Meetings 2024 in June.

## Cohort 4 – Safety and Efficacy

The SRC has reviewed the safety data of the first 3 participants of cohort 4 who have received 2 cycles of 12GBq of  $^{67}\text{Cu}$ -SAR-bisPSMA; no DLTs have been observed to date. Two participants have completed the DLT period, and 1 participant will complete the DLT period shortly. Almost all AEs were mild to moderate, with the majority having resolved or improved at the last assessment. In the final participant who is yet to complete the DLT period, the only AE reported to date was nausea, which has resolved.

Early preliminary efficacy assessment shows a reduction in PSA levels following treatment in both participants who have completed the DLT period. In

the weeks following the last therapy dose, these participants have already exhibited PSA drops of more than 60%. The largest drop in PSA to date in this cohort was a fall of 92.3% (from a baseline PSA of 157.4 ng/mL), and it continues to decline based on the latest assessment. This participant, who had failed several lines of therapy prior to receiving  $^{67}\text{Cu}$ -SAR-bisPSMA (i.e. ADT, ARPI and an investigational agent through a clinical trial), has already had a radiographic partial response based on Response Evaluation Criteria in Solid Tumours v1.1 (RECIST) assessment, with preliminary analysis showing a reduction of 60.6% in tumour volume evaluated by PSMA positron emission tomography (PET) imaging thus far (Figure 5).

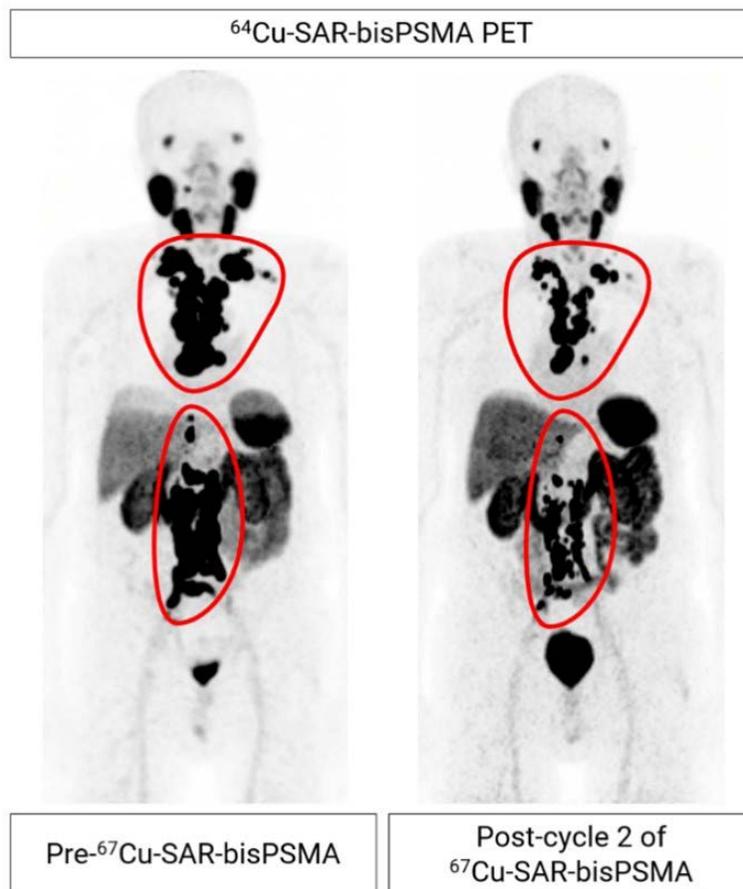


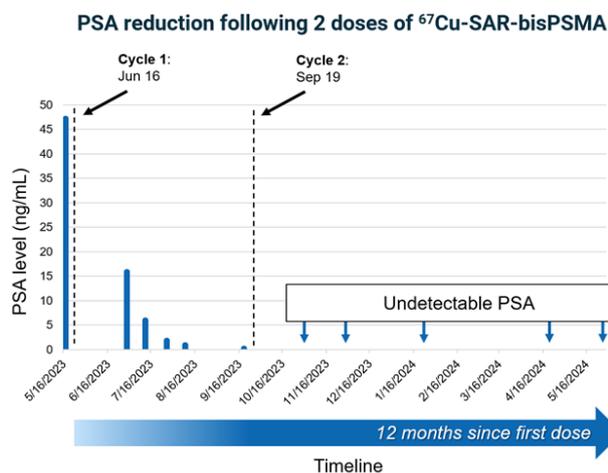
Figure 5. mCRPC patient from cohort 4 showing extensive metastasis of prostate cancer to the lymph nodes (regions highlighted by the red lines).  $^{64}\text{Cu}$ -SAR-bisPSMA images show reduction in tumour volume of 60.6% from pre- to post-treatment after two therapy cycles of 12GBq of  $^{67}\text{Cu}$ -SAR-bisPSMA to date. PSA reduction of 92.3% (from 157.4 to 12.1 ng/mL) to date. Post-cycle 2 scan ( $^{64}\text{Cu}$ -SAR-bisPSMA) performed approximately 8 weeks after the second dose of  $^{67}\text{Cu}$ -SAR-bisPSMA. Images shown as maximum intensity projections.

## Complete response with <sup>67</sup>Cu-SAR-bisPSMA

The first patient ever to be dosed with two cycles of <sup>67</sup>Cu-SAR-bisPSMA at 8GBq achieved a complete response to treatment based on RECIST v1.1 criteria. The patient received the first cycle of <sup>67</sup>Cu-SAR-bisPSMA as part of cohort 2 of the theranostic trial, SECuRE, and a second cycle under the U.S. FDA Expanded Access Program (EAP), as requested by the patient's clinician. Prior to <sup>67</sup>Cu-SAR-bisPSMA, the patient had failed multiple lines of treatment, including hormone therapy, an investigational agent and chemotherapy.

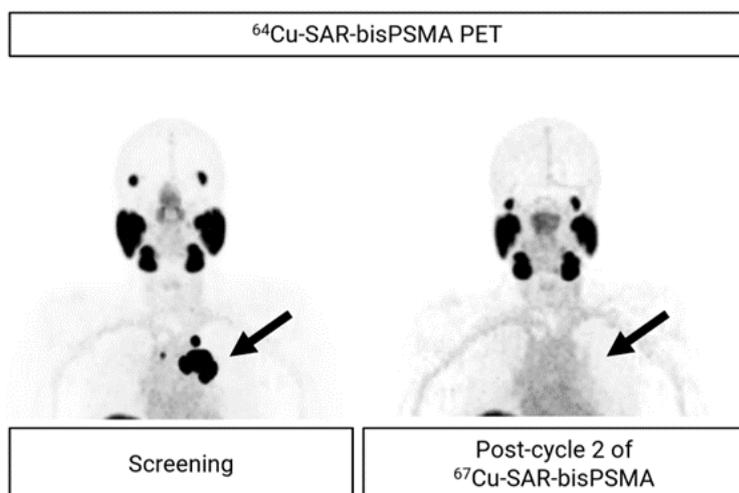
Following the administration of the first cycle of <sup>67</sup>Cu-SAR-bisPSMA under the SECuRE trial, the patient showed a reduction in PSA level of >99%. The patient then received a second cycle of <sup>67</sup>Cu-SAR-bisPSMA under the EAP, resulting in a further reduction of his PSA to undetectable levels (confirmed by two consecutive tests) (Figure 6). PSA is a well characterised marker of tumour burden and clinical response to treatment as well as an indicator of recurrence of disease for prostate cancer<sup>9-11</sup>. Moreover, PSA decline is an independent prognostic indicator of improved overall survival following radioligand therapy<sup>12-13</sup>.

No PSMA uptake was observed in any of the lesions using <sup>64</sup>Cu-SAR-bisPSMA following the second cycle of <sup>67</sup>Cu-SAR-bisPSMA (Figure 7). Complete response has also been confirmed by computed tomography (CT) (RECIST assessment).



**Figure 6. PSA reduction following 2 doses of <sup>67</sup>Cu-SAR-bisPSMA (8GBq).** A reduction of 99.4% in PSA was observed after administration of the first cycle of <sup>67</sup>Cu-SAR-bisPSMA (from the baseline of 47.2 to 0.3 ng/ml). PSA reached undetectable levels following the administration of the second cycle of <sup>67</sup>Cu-SAR-bisPSMA. Dash lines: administration of <sup>67</sup>Cu-SAR-bisPSMA. Almost 8 months of PSA at undetectable level. PSA level of detection: 0.05 ng/ml.

Data cut off: 29 May 2024.



**Figure 7. PET images showing uptake of <sup>64</sup>Cu-SAR-bisPSMA in prostate cancer lesions at screening (arrow, left image; SUVmax 140.1). Image post-treatment shows no <sup>64</sup>Cu-SAR-bisPSMA uptake (arrow, right image). Images shown as maximum intensity projection.**

No AEs were reported as related to <sup>64</sup>Cu-SAR-bisPSMA. All AEs related to <sup>67</sup>Cu-SAR-bisPSMA either improved or resolved over time. Those included dry mouth, altered taste, thrombocytopenia (all Grade 1, improved), fatigue (Grade 2, resolved) and anaemia (Grade 3, improved to Grade 2).

This case report was presented in a video abstract by Dr Luke Nordquist in February 2024 at the 34th Annual International Prostate Cancer Update (IPCU) in Vail, Colorado, during a session on advanced prostate cancer.

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## Patient Case Study: Durable response after multiple cycles of <sup>67</sup>Cu-SAR-bisPSMA

<sup>67</sup>Cu-SAR-bisPSMA single-photon emission computed tomography (SPECT)/CT images depicted below (Figure 8) were collected 48 hrs after the first and fourth administrations of 4GBq of <sup>67</sup>Cu-SAR-bisPSMA in a patient from cohort 1 who received 3 additional cycles under the U.S. FDA EAP. Images collected during 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.



Figure 8. SPECT/CT imaging at 48 hrs following cycle 1 (Oct 2022) and cycle 4 (Jun 2023) of 4GBq <sup>67</sup>Cu-SAR-bisPSMA.

A reduction of greater than 50% in PSA levels was observed in this participant following the first administration of 4GBq of <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 9). This patient has recently received a fifth dose of <sup>67</sup>Cu-SAR-bisPSMA, which led to a PSA reduction of >50% from baseline. It has been 2 years since he received the first dose of <sup>67</sup>Cu-SAR-bisPSMA, representing a remarkable outcome for a patient in the mCRPC setting with metastasis to the bones who had failed ADT and two ARPI treatments.

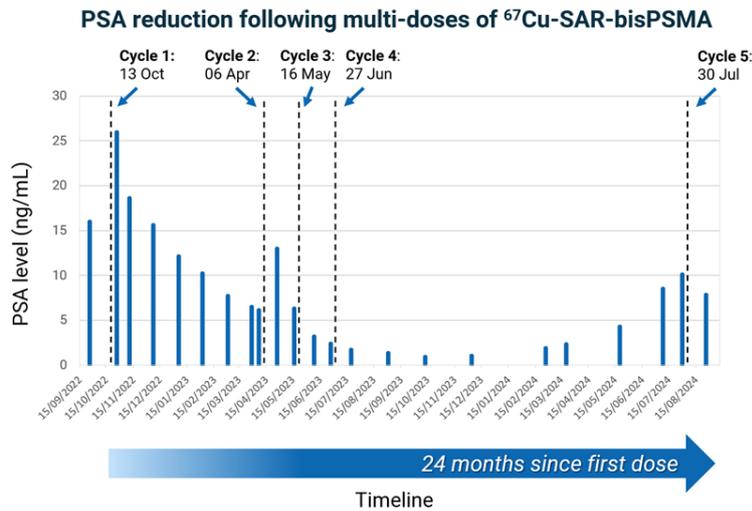


Figure 9. PSA reduction in mCRPC patient who received multiple cycles of <sup>67</sup>Cu-SAR-bisPSMA. Definitive radiation therapy in 2013. Previous treatments included ADT, abiraterone and enzalutamide. The patient received 4 cycles of <sup>67</sup>Cu-SAR-bisPSMA at 4GBq, which led to a reduction in PSA of 94% (baseline PSA 16, lowest value 0.9 ng/mL achieved 13 months after the first dose). The patient's PSA showed a gradual increase in recent months, which led to the administration of another cycle of <sup>67</sup>Cu-SAR-bisPSMA (8GBq). This resulted in a reduction in PSA, with the latest value still >50% lower than baseline. Data-cut off 26 Aug 2024.

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# CLARIFY: Diagnostic Phase III registrational <sup>64</sup>Cu-SAR-bisPSMA trial

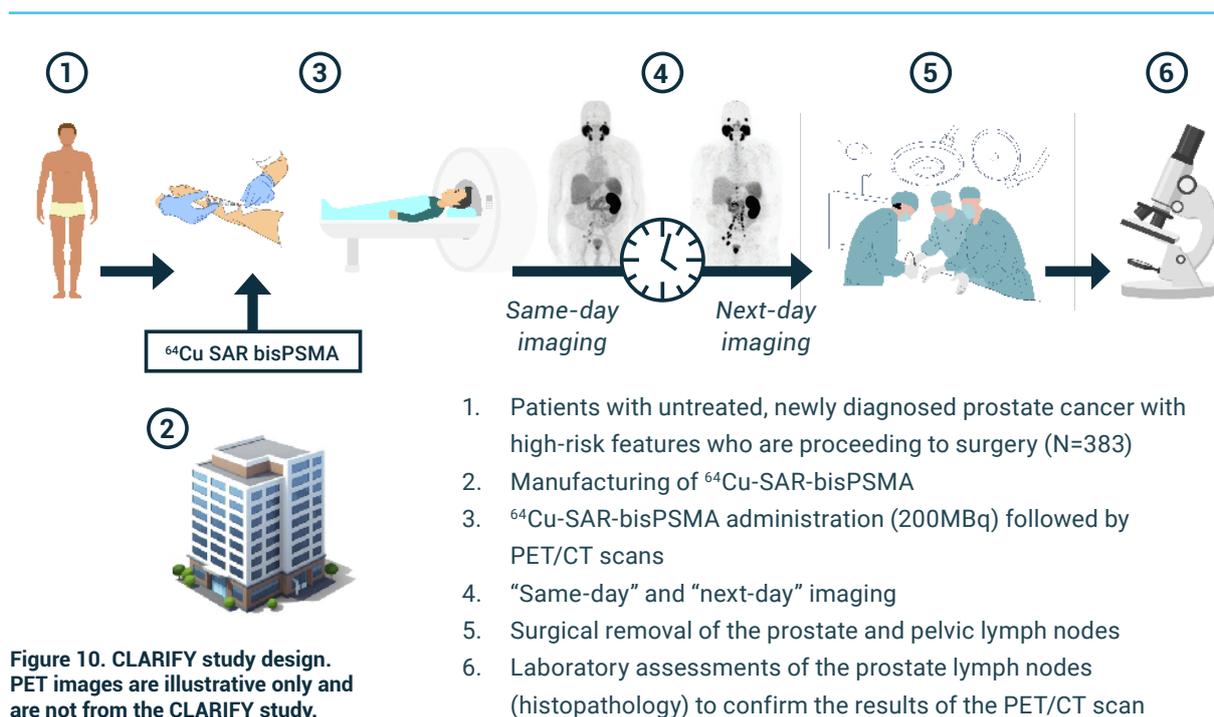
Clarity safely dosed its first participant with <sup>64</sup>Cu-SAR-bisPSMA in the diagnostic registrational Phase III trial, CLARIFY (NCT06056830)<sup>4</sup>, in December at Xcancer Omaha, NE. In May, CLARIFY was presented by one of the study’s lead clinicians, Dr. Michael Gorin, at the American Urological Association (AUA) Annual Meeting 2024 in San Antonio. The presentation outlined the trial design, generating a lot of interest around next-day imaging, a feature unique to <sup>64</sup>Cu-SAR-bisPSMA and not feasible with approved PSMA PET agents. Clarity also had the opportunity to present the CLARIFY trial design at the ASCO Annual Meeting 2024, which was met with enthusiasm.

CLARIFY is the first Phase III registrational trial for Clarity and the first trial to evaluate the benefits of next-day imaging in prostate cancer patients prior to undergoing radical prostatectomy (total removal of the prostate). The study is continuing as planned with final results intended to provide sufficient evidence to support an application to the U.S. FDA for approval of <sup>64</sup>Cu-SAR-bisPSMA as a new diagnostic imaging agent for newly diagnosed prostate cancer patients.

CLARIFY derives from “Positron Emission Tomography using <sup>64</sup>Cu-SAR-bisPSMA in participants with high-risk PC prior to radical prostatectomy: A prospective, single-arm, multi-centre, blinded-review, Phase III diagnostic performance study”.

It is a non-randomised, open-label clinical trial in 383 participants with confirmed prostate cancer who will be proceeding to radical prostatectomy and pelvic lymph node dissection (removal of lymph nodes from the pelvic region).

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 (1-4 hrs post administration, same-day imaging) and day 2 (approximately 24 hrs post administration, next-day imaging) (Figure 10).



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## COBRA: Diagnostic $^{64}\text{Cu}$ -SAR-bisPSMA trial

Initial data from Clarity's diagnostic Phase I/II trial, COBRA (NCT05249127)<sup>5</sup>, confirmed  $^{64}\text{Cu}$ -SAR-bisPSMA is safe and highly effective in detecting prostate cancer lesions in patients with BCR. Additional data from the trial also established that  $^{64}\text{Cu}$ -SAR-bisPSMA was able to detect much smaller lesions than anticipated, including a lesion with a diameter of less than 2 mm, which compares favourably against the current standard-of-care (SOC) PSMA imaging agents.

These data from the COBRA trial were presented at both ASCO and SNMMI Annual Meetings 2024, highlighting the advantages of  $^{64}\text{Cu}$ -SAR-bisPSMA and the value of next-day imaging.

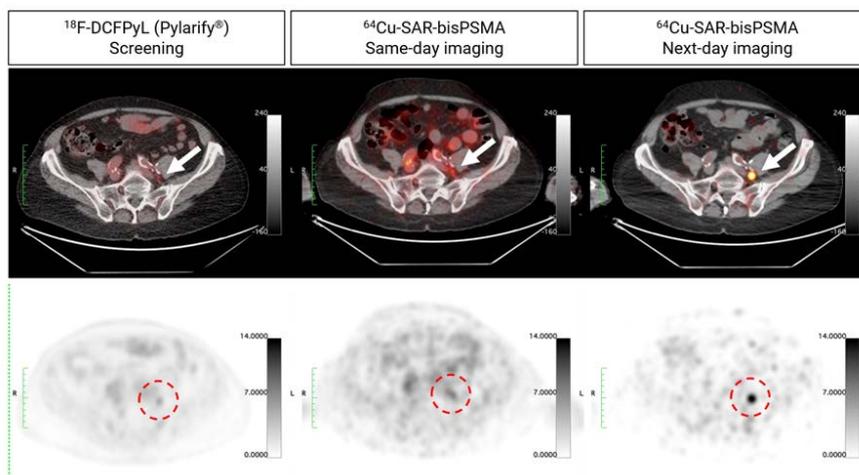
**COBRA** derives from "COpper-64 SAR-bisPSMA in Biochemically Recurrent prostate cancer". It was a multi-centre, single-arm, non-randomised, Phase I/II diagnostic imaging study of  $^{64}\text{Cu}$ -SAR-bisPSMA administered to participants with BCR of prostate cancer following definitive therapy and who had a negative or equivocal SOC scan at screening.

The primary objectives of the COBRA trial were to investigate the safety and tolerability of  $^{64}\text{Cu}$ -SAR-bisPSMA, as well as its ability to correctly detect recurrence of prostate cancer. Patients underwent PET/CT scans with  $^{64}\text{Cu}$ -SAR-bisPSMA on Day 0 and Day 1 (1-4 hrs and 24±6 hrs post-dose, same-day and next-day imaging, respectively), which were interpreted by three blinded central readers.

Fifty-two patients with negative or equivocal SOC scans were enrolled and imaged, of whom 42 were included in the calculation of the efficacy endpoints.

Results from COBRA showed for the first time that  $^{64}\text{Cu}$ -SAR-bisPSMA is safe and effective in detecting lesions in patients with BCR of prostate cancer who were negative or equivocal on SOC imaging (e.g. bone scan, CT or PET with approved PSMA imaging agents) at screening (**Figure 11**).

Only 1 AE was related to  $^{64}\text{Cu}$ -SAR-bisPSMA (Grade 2 worsening of type II diabetes, resolved) among all 52 patients who received the product (Safety Analysis Set).  $^{64}\text{Cu}$ -SAR-bisPSMA identified lesions in up to approximately 60% of patients on same-day imaging, and up to 80% on next-day imaging, with high specificity on both days.



Following  $^{64}\text{Cu}$ -SAR-bisPSMA PET imaging, investigators indicated that they would change the treatment plan of approximately half of the patients (48%).

**Figure 11.** Identification of lesion in the pelvic region using  $^{64}\text{Cu}$ -SAR-bisPSMA on next-day imaging (right), negative on same-day imaging ( $^{64}\text{Cu}$ -SAR-bisPSMA; centre) and equivocal on screening SOC imaging ( $^{18}\text{F}$ -DCFPyL, Pylarify®; left). SUVmax of the lesion across scans (arrows and red circles) was 2.3, 4.3 and 17.5 ( $^{18}\text{F}$ -DCFPyL, Pylarify®, Day 0 and Day 1  $^{64}\text{Cu}$ -SAR-bisPSMA, respectively). Top images: PET/CT fusion. Bottom images: PET.



## Next-day imaging – a key advantage over currently approved PSMA PET agents

The COBRA trial confirmed the benefits of delayed imaging in patients with BCR of prostate cancer as more lesions and more patients with a positive scan were identified on next-day imaging.

$^{64}\text{Cu}$ -SAR-bisPSMA was able to identify 82% more lesions (average increase across all readers) on next-day imaging compared to same-day imaging (ranges across the readers for the total number of lesions: 53–80 on Day 0 vs. 82–153 on Day 1) (Figure 12). The ranges of correct detection rate (CDR, defined as the proportion of true positive participants out of all scanned participants who had at least one evaluable reference standard datapoint) and patient-level detection rate (DR, defined as the proportion of participants with a positive  $^{64}\text{Cu}$ -SAR-bisPSMA PET/CT scan out of all scanned participants) were both higher on next-day imaging compared to same-day imaging. The DR range on same-day imaging was 44–58% (95% confidence interval (CI) 30–71.8), increasing on next-day imaging to 58–80% (95% CI 43.2–90).

### Detection of smaller lesions

$^{64}\text{Cu}$ -SAR-bisPSMA was able to detect much smaller lesions than anticipated, including a lesion with a diameter of less than 2 mm. This compares favourably against the current SOC PSMA PET imaging agents, including PYLARIFY® and the generic product  $^{68}\text{Ga}$ -PSMA-11, with which the detection of lesions smaller than 5 mm is challenging. Sensitivity is a known challenge for the existing PSMA PET agents, particularly for lesions  $<5$  mm<sup>14-17</sup>. This suggests that lesions are missed by current SOC imaging, which can have significant implications on accurate staging and subsequent treatment decisions.

The size of the prostate cancer lesions detected by  $^{64}\text{Cu}$ -SAR-bisPSMA was recorded on same-day (Day 0) and next-day (Day 1) imaging. Lesions less than 5 mm in size were identified across readers among 14% (7/50) of patients (Figure 13). These lesions were located in the bone, pelvic and extra-pelvic lymph node regions. The smallest lesion (pelvic lymph node) identified in the study was 2.6 x 1.9 mm.

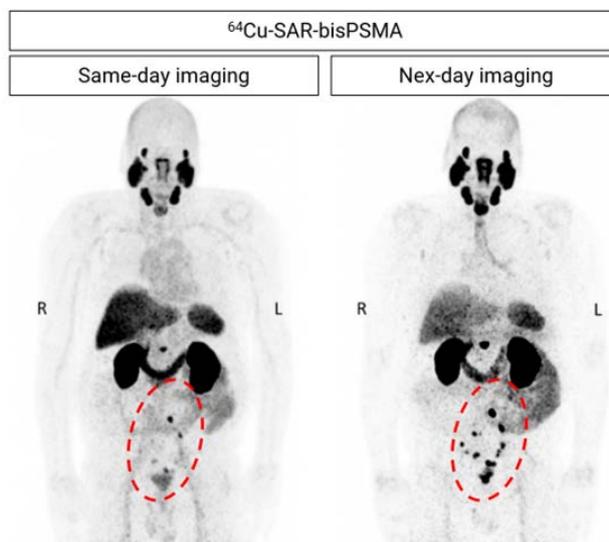
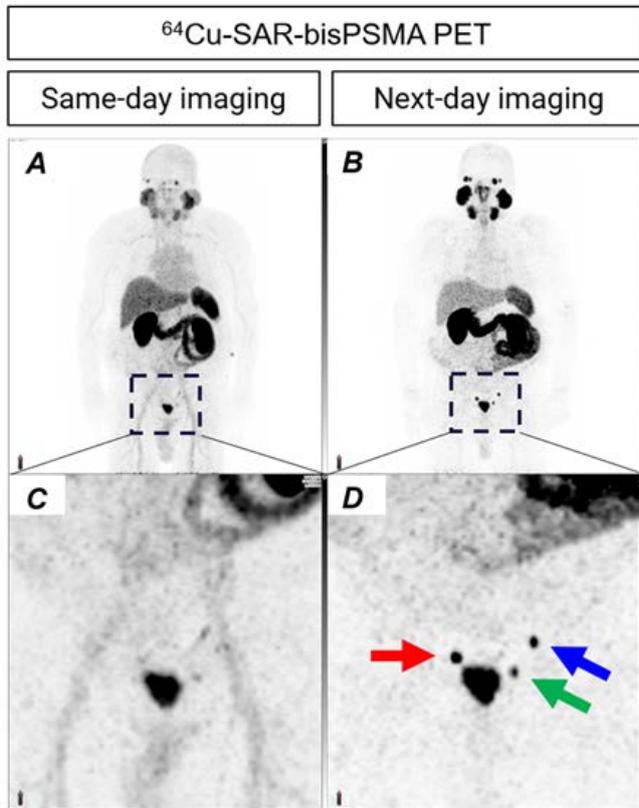


Figure 12. Next-day imaging identified additional lesions compared to same-day imaging.  $^{64}\text{Cu}$ -SAR-bisPSMA PET showing positive lymph nodes (LNs) in the pelvic and extra-pelvic (retroperitoneal) regions and lesions in the prostatic bed. Prostate cancer in the pelvic LNs was confirmed by histopathology. MIP: maximum intensity projection.

The ability of  $^{64}\text{Cu}$ -SAR-bisPSMA to detect lesions less than 5 mm is a result of multiple factors unique to the product that also enable next-day imaging. First, Clarity's proprietary SAR technology employs a cage, or chelator, that securely holds isotopes of copper and prevents their leakage in vivo. In addition, pre-clinical and clinical evidence to date has demonstrated that the optimised dual targeting molecule connected to the cage, bisPSMA, ensures increased targeting and retention of the product in prostate cancer tumours compared to its single targeting molecule counterpart and approved PSMA agents<sup>18-19</sup>. Both of these features, combined with the longer half-life of Cu-64, enabled  $^{64}\text{Cu}$ -SAR-bisPSMA to be imaged at 24 hrs post-administration of the product in the COBRA trial and resulted in the identification of additional lesions in BCR patients with negative or equivocal SOC scan.



“The cornerstone of better therapy is better diagnosis, and we are incredibly excited about the substantial degree of improvement in detection of lesions with our bisPSMA product compared to SOC imaging,”

- Dr Alan Taylor

Figure 13. Pelvic lymph nodes showing uptake of <sup>64</sup>Cu-SAR-bisPSMA on Day 1 (arrows). Blue arrow: lesion size 3.8 mm x 4.4 mm, SUVmean 20.6, SUVmax 22.1 and TBR 130.1. Green arrow: lesion size also 3.8 mm x 4.4 mm, SUVmean 11.9, SUVmax 12.8 and TBR 75.3. Red arrow: lymph node showing <sup>64</sup>Cu-SAR-bisPSMA uptake (>5 mm). A, B, C, D: Maximum Intensity Projection. Inset in top images displays pelvic region (bottom images).

### <sup>64</sup>Cu-SAR-bisPSMA identifies lesions months before currently approved PSMA PET agents

Twenty participants in the COBRA study (40%) underwent follow-up SOC PSMA PET, performed up to 6 months after the <sup>64</sup>Cu-SAR-bisPSMA scans. Both the number of patients with a positive scan and the number of lesions identified by <sup>64</sup>Cu-SAR-bisPSMA were higher than those detected by SOC PSMA agents, even when those follow-up scans were performed several months after the <sup>64</sup>Cu-SAR-bisPSMA PET (Figure 14).

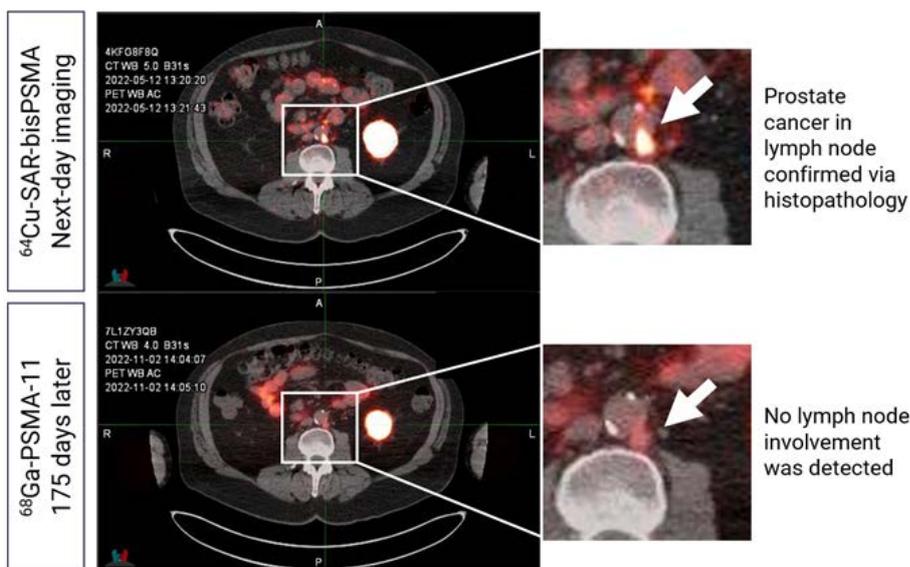


Figure 14. Retroperitoneal lesion detected by <sup>64</sup>Cu-SAR-bisPSMA on next-day imaging. <sup>68</sup>Ga-PSMA-11 scan performed 176 days post-Day 0 (175 days post-Day 1) did not show uptake of tracer. PET/CT fusion. Prostate cancer in lymph node confirmed via histopathology.

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## Diagnostic Phase III registrational $^{64}\text{Cu}$ -SAR-bisPSMA trial in BCR of prostate cancer

**Based on the results from the COBRA study to date, Clarity commenced planning of a registrational Phase III imaging trial in patients with BCR of prostate cancer.**

The data has been guiding trial design for the pivotal study and helping to prepare for an End of Phase meeting with the U.S. FDA. The purpose of an End of Phase meeting is to determine the safety of proceeding to Phase III, to evaluate the Phase III plan and protocols, and the adequacy of current studies.

Final study results from the pivotal trial will be intended to provide sufficient evidence to support a New Drug Application (NDA) to the FDA for approval of  $^{64}\text{Cu}$ -SAR-bisPSMA as a new diagnostic imaging agent for patients with BCR of prostate cancer.



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# SAR-Bombesin: Prostate Cancer

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

Product	SAR-Bombesin		
Indication	Prostate Cancer		
Application	Theranostic	Diagnostic	
Trial	COMBAT 	SABRE (recruitment closed) 	BOP (trial completed) 

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 20-25% of prostate cancer patients with BCR and approximately 25% of mCRPC patients have low or no uptake of PSMA-targeting tracer<sup>20-24</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 Pluvicto®. 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 U.S. (COMBAT)<sup>2</sup> in patients with mCRPC;
- diagnostic Phase II trial in the U.S. (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 a 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, such as breast, lung and pancreatic cancers.





## COMBAT: Theranostic $^{67}\text{Cu}$ -SAR-Bombesin prostate cancer trial

Clarity treated the first participant in its theranostic  $^{64}\text{Cu}/^{67}\text{Cu}$ -SAR-Bombesin Phase I/IIa trial in mCRPC, COMBAT ([NCT05633160](#))<sup>2</sup>. Recruitment into the COMBAT trial is ongoing with additional sites soon joining the study. The COMBAT trial was presented at the SNMMI 2024 Annual Meeting and ASCO GU meeting 2024.

COMBAT is a theranostic trial for identification and treatment of mCRPC that is expressing the GRPr using  $^{64}\text{Cu}/^{67}\text{Cu}$ -SAR-Bombesin in participants who are ineligible for therapy with  $^{177}\text{Lu}$ -PSMA-617. The aim for the trial is to determine the safety and efficacy of  $^{67}\text{Cu}$ -SAR-Bombesin in this patient group.

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

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## SABRE: Diagnostic $^{64}\text{Cu}$ -SAR-Bombesin prostate cancer trial

Clarity achieved its recruitment target for the U.S.-based diagnostic  $^{64}\text{Cu}$ -SAR-Bombesin trial for patients with PSMA-negative prostate cancer, SABRE (NCT05407311)<sup>6</sup>, in November 2023 with data review and analysis ongoing. The SABRE trial was presented at the SNMMI Annual Meeting and ASCO GU meeting in 2024, generating significant interest.

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

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

In the SABRE trial, 53 participants were imaged on the day of product administration (same-day imaging) and 24 hrs later (next-day imaging). The study is investigating if delayed imaging allows better identification of very early disease or patients with low PSMA expression.

In Figure 15, the images in the cross hairs on same-day and next-day scans following  $^{64}\text{Cu}$ -SAR-Bombesin administration clearly identify a pelvic lymph node, while there was no uptake with  $^{18}\text{F}$ -DCFPyL, (Pylarify®) an FDA-approved PSMA PET agent.

Preclinical data, along with successful C-BOBCAT and BOP investigator-initiated clinical trials, have already shown the utility of SAR-Bombesin and its potential to identify disease in some patient subgroups where conventional diagnostic imaging has failed. Clarity looks forward to reporting data from the SABRE trial and, subject to these results, progressing the  $^{64}\text{Cu}$ -SAR-Bombesin product into a registrational Phase III trial for first approvals in the U.S.

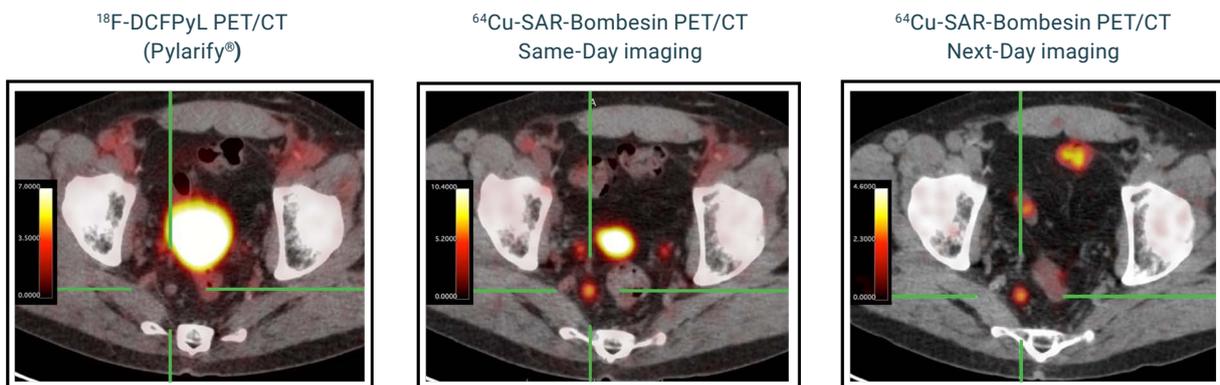


Figure 15.  $^{64}\text{Cu}$  SAR-Bombesin detected a positive lymph node on scans performed on two different days (same-day and next-day scans). No uptake was observed using  $^{18}\text{F}$ -DCFPyL (Pylarify®) PET/CT. A subsequent biopsy, performed and assessed locally by the study site, has confirmed prostate cancer.

$^{64}\text{Cu}$ -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 $^{64}\text{Cu}$ -SAR-Bombesin investigator-initiated trial (IIT) in prostate cancer

Initial data from the diagnostic BOP (NCT05613842)<sup>7</sup> trial in patients with BCR of prostate cancer, evaluating  $^{64}\text{Cu}$ -SAR-Bombesin, was presented at the European Association of Nuclear Medicine (EANM) 2023 Congress. Full manuscript was published in the Journal of Nuclear Medicine in August 2024<sup>25</sup>.

BOP was a Phase II IIT in 30 participants led by Prof Louise Emmett at St Vincent's Hospital, Sydney. The IIT assessed the safety of  $^{64}\text{Cu}$ -SAR-Bombesin as well as the diagnostic performance across two different groups of men with prostate cancer:

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

Participants received 200MBq of  $^{64}\text{Cu}$ -SAR-Bombesin and PET imaging was performed at 1 and 3 hrs after injection and at an optional 24 hrs time point after injection. Results from the BCR cohort showed PSA doubling time of 4.2 months (range 2.8 – 7.5; PSA median 0.69 ng/ml, range 0.28 – 2.45) prior to entering the study.

**“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 AEs from  $^{64}\text{Cu}$ -SAR-Bombesin administration were reported.

$^{64}\text{Cu}$ -SAR-Bombesin was found to be safe and able to detect prostate cancer in 44% (11/25) of patients with BCR of prostate cancer who had a negative or equivocal standard of care PSMA PET.

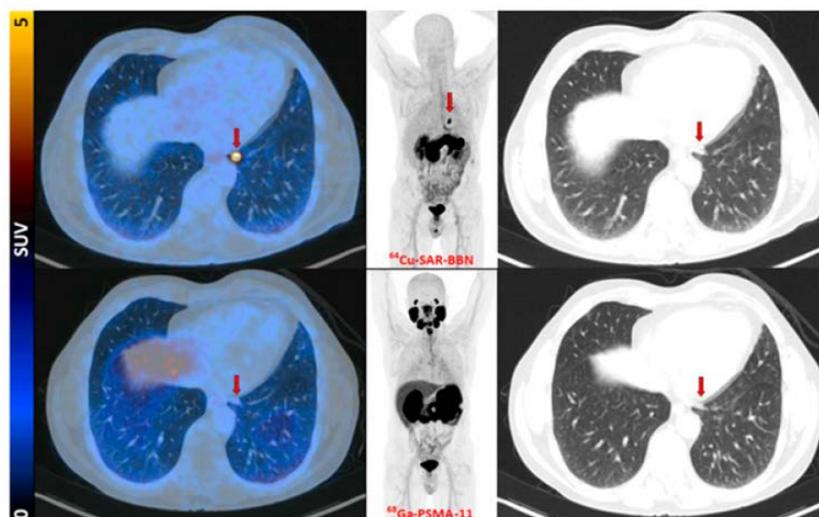


Figure 16. Fused PET/CT, maximum-intensity projection PET, and lung-windowed CT images (from left to right) from  $^{64}\text{Cu}$ -SAR-BBN (top row) and  $^{68}\text{Ga}$ -PSMA-11 (bottom row) PET/CT study of patient demonstrating left subpleural lesion (arrows, SUVmax of 10 at 1 hr) that showed  $^{64}\text{Cu}$ -SAR-BBN uptake but no  $^{68}\text{Ga}$ -PSMA-11 uptake. PSA was 1.84 ng/mL at time of imaging. This patient underwent lobectomy, with histopathology demonstrating metastatic prostate cancer.

Reproduced with permission from Prof Louise Emmett (St Vincent's Hospital, Sydney – Australia). J Nucl Med. 42024; 00:1–5.

# SARTATE: Neuroblastoma and NETs

**SARTATE is a next generation, highly targeted theranostic radiopharmaceutical**

Product	SARTATE	
Indication	Neuroblastoma	NETs
Application	Theranostic	Diagnostic
Trial	CL04 	DISCO (recruitment closed) 

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 ( $^{64}\text{Cu}$ ) for imaging ( $^{64}\text{Cu}$ -SARTATE) or copper-67 ( $^{67}\text{Cu}$ ) for therapy ( $^{67}\text{Cu}$ -SARTATE).

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

- **CL04** theranostic trial with an open IND in the U.S. ([NCT04023331](#))<sup>3</sup>
- **DISCO** diagnostic trial in Australia ([NCT04438304](#))<sup>8</sup>.

Neuroblastoma, an aggressive childhood cancer, is Clarity's key focus with SARTATE. In 2020, the U.S. FDA awarded Clarity two Orphan Drug Designations (ODDs) in this important indication, one for  $^{64}\text{Cu}$ -SARTATE as a diagnostic agent for the clinical management of neuroblastoma and one for  $^{67}\text{Cu}$ -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 U.S. FDA for these two products in neuroblastoma, RPDDs may allow the Company to access a total of two tradeable Priority Review Vouchers (PRVs) currently valued at around USD158 million each.<sup>26</sup>

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## CL04: Theranostic $^{64}\text{Cu}/^{67}\text{Cu}$ -SARTATE neuroblastoma trial

Clarity is progressing through cohort 4 of the dose-escalation phase of the CL04 theranostic trial ([NCT04023331](#))<sup>3</sup> in neuroblastoma patients and has successfully completed cohort 3 of the CL04 theranostic trial at the dose level of 275MBq/kg body weight in July 2023.

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 where not only the safety and tolerability of both  $^{64}\text{Cu}$ -SARTATE and  $^{67}\text{Cu}$ -SARTATE are being assessed, but also the effectiveness of  $^{67}\text{Cu}$ -SARTATE as a treatment for neuroblastoma. Participants who show uptake of  $^{64}\text{Cu}$ -SARTATE in lesions will continue in the trial and will receive treatment with  $^{67}\text{Cu}$ -SARTATE.

In the dose escalation phase of the trial, each subsequent cohort will receive an increase in the therapeutic dose administered. Generally speaking, a 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  $^{67}\text{Cu}$ -SARTATE administered to participants in each cohort, until the Maximum Tolerated Dose (MTD) is reached.

Cohort 4 participants are being treated with a single dose of 375MBq of  $^{67}\text{Cu}$ -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  $^{67}\text{Cu}$ -SARTATE
- Cohort 2 – 3 participants received an initial single dose of 175MBq/kg body weight  $^{67}\text{Cu}$ -SARTATE
- Cohort 3 – 3 participants received an initial single dose of 275MBq/kg body weight  $^{67}\text{Cu}$ -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  $^{67}\text{Cu}$ -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  $^{67}\text{Cu}$ -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 to the dose-expansion phase of the trial.





## DISCO: Diagnostic $^{64}\text{Cu}$ -SARTATE NETs trial

Clarity successfully closed recruitment for the Phase II diagnostic  $^{64}\text{Cu}$ -SARTATE trial, DISCO ([NCT04438304](#))<sup>8</sup> with the final patients soon to complete the follow-up period. A total of 45 patients have been enrolled and imaged in the trial.

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 across 4 sites in Australia comparing the diagnostic performance of  $^{64}\text{Cu}$ -SARTATE at 4 and 20 hrs post-administration to the current standard of care,  $^{68}\text{Ga}$ -DOTATATE, at 1 hr. The study looks to build on earlier studies with SARTATE (Hicks, R. et al)<sup>27</sup> which demonstrated that delayed imaging may lead to better identification of disease.

The trial was originally planned for up to 63 patients based on an expected discordance level between imaging with Clarity's  $^{64}\text{Cu}$ -SARTATE and the current SOC,  $^{68}\text{Ga}$ -DOTATATE. The sample size was adjusted to 45 patients based on the pre-planned assessment of the images to generate sufficient evidence to plan for a Phase III trial in this indication.

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# 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.

## Targeted Alpha-particle Therapy

As part of the Discovery Platform, Clarity has been conducting research and preclinical studies for some months, combining the bisPSMA targeting agent with actinium-225 (Ac-225 or  $^{225}\text{Ac}$ ). To date, the program with  $^{225}\text{Ac}$ -bisPSMA has focused on identifying a lead compound from a number of different analogues. This is achieved by assessing the biodistribution, tumour uptake, radiolabelling efficiency and product stability of the different analogues in order to select the best one to progress to clinical development.

Clarity's SAR-bisPSMA product has shown impressive results in a number of preclinical and clinical trials to date, and the dual targeting of the product enables

increased uptake and retention in prostate cancer tumours compared to the mono-targeted form of the product. By combining the optimised bisPSMA with Ac-225, Clarity has the opportunity to complement its beta-particle therapy product,  $^{67}\text{Cu}$ -SAR-bisPSMA with an alpha-particle therapy product,  $^{225}\text{Ac}$ -bisPSMA.

Developing both alpha- and beta-emitting therapy products for prostate cancer puts Clarity in a unique position to offer powerful treatment approaches to improve outcomes for these patients as using each product at different stages of the disease would provide more options for patient care.

## Pre-targeting

In August 2023, Clarity added a worldwide exclusive license from Memorial Sloan Kettering Cancer Center NYC, U.S. (MSK) to its intellectual property (IP). The license is to intellectual property that covers cutting-edge technology that enables antibody "pre-targeting" for the diagnosis and treatment of cancer, U.S. 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 (**Figure 17**).

A clinical trial using the MSK licensed technology is open for recruitment in patients with pancreatic, colorectal, bladder cancer or cancers with elevated CA19.9 at MSK headed by Dr Pandit-Taskar (NCT05737615)<sup>28</sup>.

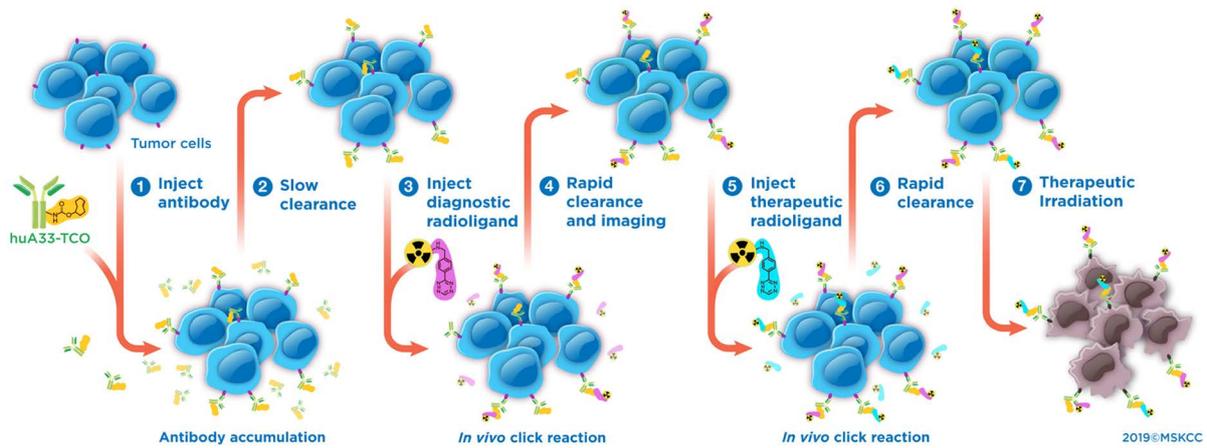


Figure 17. This pre-targeting therapy starts with an antibody 'tagged' with trans-cyclooctene (TCO). The antibody tagged-TCO is injected in the body and binds to cancer cells (1). The unbound antibody slowly clears the body (2) so that there is primarily binding to the cancer cells with limited background. 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 radiolabelled, irradiate the cancer cells with a therapeutic dose (5).

## New Targets

Clarity is also progressing research and development of novel Targeted Copper Theranostics (TCTs) to various cancer targets. This involves a process of identifying high value targets, development of compounds to those targets, selection of lead drug candidates and progression of a lead candidate through formal preclinical studies required for clinical trials. The process develops new patents that broaden and strengthen Clarity's IP position. This process should produce new TCTs for clinical development through the next 12-18 months.

## Combination Therapy

In addition to the development of Clarity's products as 'stand-alone' therapies, most cancer treatments are provided as part of a treatment regime and often in combination with a second or third drug. One promising combination is with immuno-oncology (IO) drugs already on the market for the treatment of a range of cancers. Clarity presented such combination studies at the American Association of Cancer Research (AACR) conference in the U.S. in April 2024 entitled "Copper-67 based targeted radiotherapy primes immunologically cold Pancreatic Ductal Adenocarcinomas (PDAC) for immunotherapy". This preclinical work highlighted that copper-67 based products have the potential to work in combination with immunotherapy drugs to improve efficacy of the products when used in combination. This work is currently being extended to preclinical studies with <sup>67</sup>Cu-SARTATE, which may advance to clinical studies should the data be favourable and if a clinical and commercial opportunity is viable.



# MANUFACTURING & SUPPLY: THE GAME CHANGER IN RADIOPHARMACEUTICALS

**Targeted Copper Theranostics (TCTs) hold a number of competitive advantages, including clinical benefits, which Clarity is actively exploring through its clinical program.**

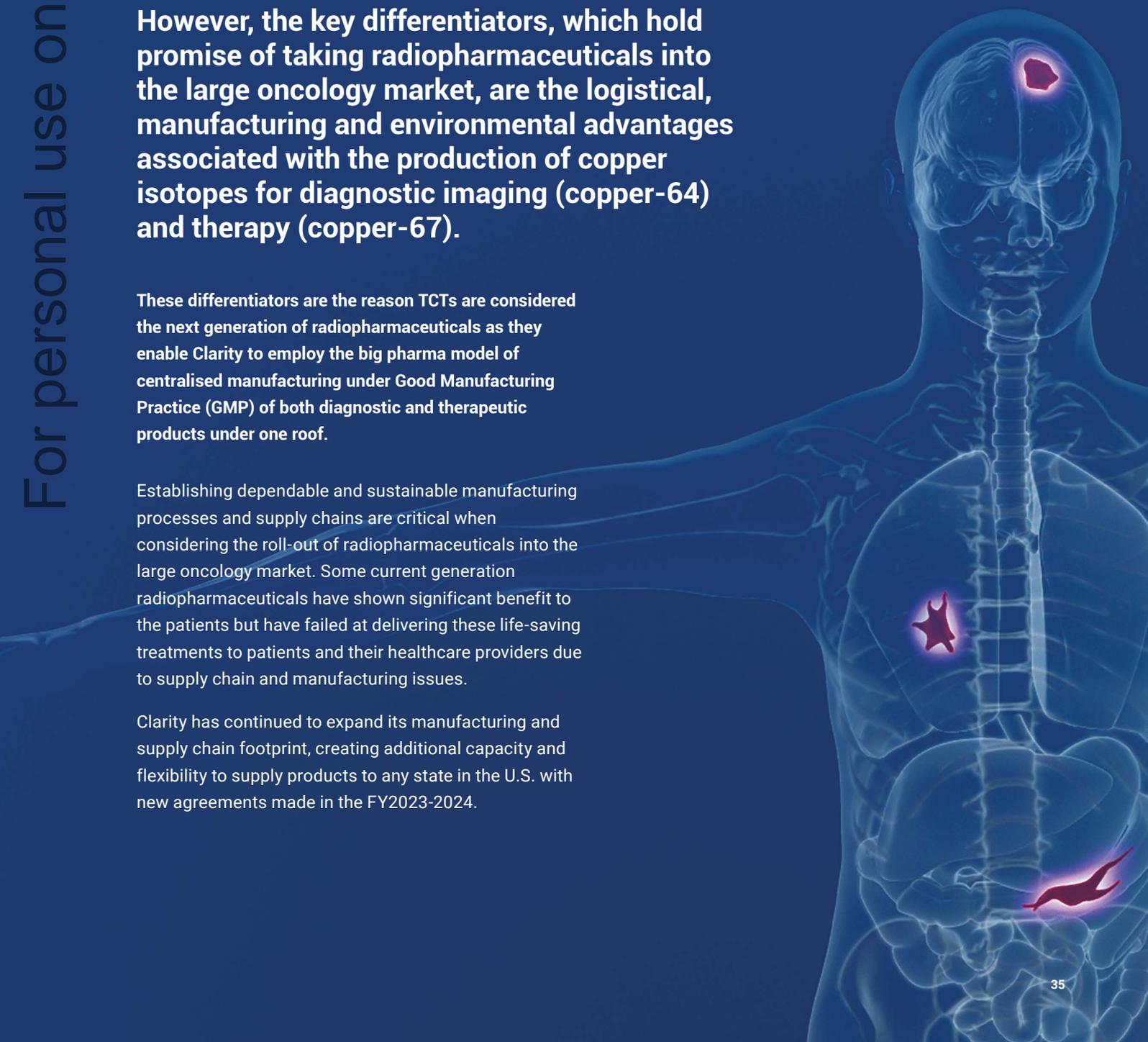
**However, the key differentiators, which hold promise of taking radiopharmaceuticals into the large oncology market, are the logistical, manufacturing and environmental advantages associated with the production of copper isotopes for diagnostic imaging (copper-64) and therapy (copper-67).**

**These differentiators are the reason TCTs are considered the next generation of radiopharmaceuticals as they enable Clarity to employ the big pharma model of centralised manufacturing under Good Manufacturing Practice (GMP) of both diagnostic and therapeutic products under one roof.**

Establishing dependable and sustainable manufacturing processes and supply chains are critical when considering the roll-out of radiopharmaceuticals into the large oncology market. Some current generation radiopharmaceuticals have shown significant benefit to the patients but have failed at delivering these life-saving treatments to patients and their healthcare providers due to supply chain and manufacturing issues.

Clarity has continued to expand its manufacturing and supply chain footprint, creating additional capacity and flexibility to supply products to any state in the U.S. with new agreements made in the FY2023-2024.

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# Copper-67

**Copper-67 (Cu-67 or  $^{67}\text{Cu}$ ) is a therapeutic isotope produced on electron accelerators, which are relatively inexpensive and readily scalable in all geographies of the world, including the U.S., Europe and Asia.**

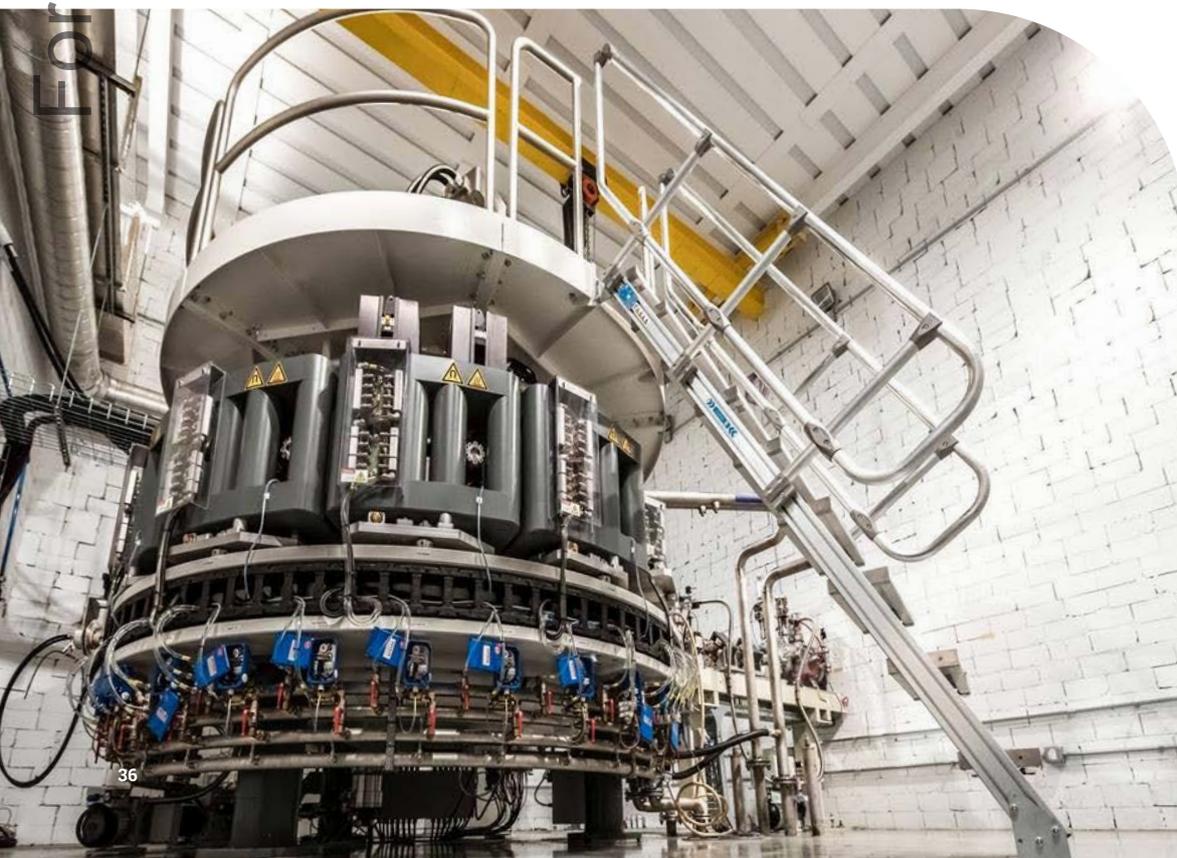
Other commonly used therapeutic isotopes, such as lutetium-177 (Lu-177 or  $^{177}\text{Lu}$ ), are produced on a small number of aging nuclear reactors worldwide, many of which are approaching the end of their “useful life”. This results in planned and unplanned shutdowns, causing shortages of therapeutic isotopes worldwide<sup>29</sup>.

Geopolitical considerations are also vital as Russia remains the predominant supplier of stable isotopes used in the production of a variety of isotopes. Clarity remains unaffected by supply disruptions due to its strategy of developing reliable, scalable and environmentally preferred solutions to radionuclide sourcing with all radioisotope supply coming from the U.S.

In April 2024, Clarity entered into a Clinical Supply Agreement with NorthStar Medical Isotopes, LLC (NorthStar) for the production of the  $^{67}\text{Cu}$ -SAR-bisPSMA final drug product for Phase I/II and Phase III trials. NorthStar is a global innovator in the development, production and commercialisation of therapeutic radiopharmaceuticals.

This agreement builds on the existing copper-67 Master Supply Agreement with NorthStar signed in 2021 and uniquely provides large-scale manufacturing of both the therapeutic isotope and current GMP (cGMP) radiopharmaceutical product in the U.S. under one roof and ready for shipment to clinical sites. Under the Master Supply Agreement signed in 2021, NorthStar supplies copper-67 exclusively to Clarity to support TCT programs, with three active theranostic trials underway in the U.S. NorthStar is the first operational commercial-scale supplier of copper-67. Their large-scale production of this important therapeutic isotope uses a highly efficient, environmentally preferable electron accelerator technology.

Integrated manufacturing offers significant logistical, manufacturing and environmental advantages, including simplified logistics with minimal shipping requirements, efficient utilisation of the radioisotope, and reduced carbon footprint.



## Copper-64

**Copper-64 (Cu-64 or <sup>64</sup>Cu) is a diagnostic imaging isotope with an ideal half-life of 12.7 hrs, which facilitates a significantly longer product shelf-life (up to 48 hrs) compared to most commonly used radio-diagnostics on the market. This helps to overcome the acute supply restraints of current-generation radiodiagnostics based on gallium-68 (Ga-68 or <sup>68</sup>Ga) with a half-life of ~1 hour and fluorine-18 (F-18 or <sup>18</sup>F) with a half-life of ~2 hrs.**

The longer shelf-life of copper-64 based diagnostics enables centralised manufacture, as opposed to the current-generation prostate-specific membrane antigen (PSMA) PET diagnostics that require an expensive and extensive network of cyclotrons, radioisotope generators and radiopharmacies next to imaging sites due to the shorter half-life and shelf-life of Ga-68 and F-18. Cu-64 is produced on cyclotrons, with a single cyclotron able to supply the entire Phase III diagnostic clinical program.

Those characteristics of Cu-64 also allow for wider geographic distribution, which can improve patient access to this important diagnostic tool. This has the potential to reduce disparities in prostate cancer care and ensure that all patients, regardless of geographic

location, can benefit from the latest advances in diagnostic imaging.

In May 2024, Clarity has entered into a Supply Agreement with SpectronRx, a robust and established private supplier of Cu-64. The agreement is for the production of Cu-64, strengthening the Company's supply network and ensuring seamless supply of the diagnostic isotope for Clarity's products which continue to progress through clinical trials, including the ongoing pivotal Phase III clinical trial, CLARIFY, and the second registrational Phase III trial with <sup>64</sup>Cu-SAR-bisPSMA in prostate cancer patients with biochemical recurrence, the planning of which is ongoing following positive data from the COBRA study in this patient population.

## Targeted Alpha-particle Therapy program

**Due to the unique properties of the dual-targeted bisPSMA molecule and with the recent signing of the supply agreement for actinium-225 (Ac-225 or <sup>225</sup>Ac) with TerraPower Isotopes, Clarity is now well positioned to develop a best-in-class Targeted Alpha-particle Therapy (TAT) program with <sup>225</sup>Ac-bisPSMA to complement its treatment paradigm in prostate cancer, particularly in later-stage prostate cancer patients.**

In July 2024 Clarity signed an agreement with TerraPower Isotopes (TerraPower) for the supply of the therapeutic alpha-emitting isotope, Ac-225, for Clarity's first Targeted Alpha-particle Therapy (TAT) program with bisPSMA. TerraPower has a unique Ac-225 manufacturing process in the U.S. that has the potential to provide the scale and dependability required for commercial manufacturing at a purity level appropriate for clinical use. This avoids having to supply Ac-225 from Russia and use sources

containing significant Ac-227 contamination, a radionuclide more radiotoxic than plutonium, and fits into Clarity's strategy of developing sustainable, scalable and environmentally preferred solutions of next-generation radiopharmaceutical products.

Clarity will continue adding Ac-225 suppliers to its network as the manufacturing process continues to develop and progress to meet standards for clinical and commercial use.

# 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 rare-earth elements, and the creation of radioactive waste are all associated with the production of isotopes used for the current-generation radiopharmaceuticals and present significant environmental issues for the sector.**

The production of  $^{64}\text{Cu}$  and  $^{67}\text{Cu}$  has favourable environmental characteristics in comparison to the current generation of theranostics. Some of the potential environmental benefits of TCTs in comparison to the current generation of radiopharmaceuticals are:<sup>30</sup>

## Copper-64

The 48-hour shelf-life of  $^{64}\text{Cu}$ -based products creates multiple advantages:

- The products can be centrally manufactured and shipped from a single cGMP facility, alleviating the need for an extensive and expensive network of 50+ cyclotron, generator and/or nuclear pharmacy facilities 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.

## Copper-67

- $^{67}\text{Cu}$  production uses a widely available transition metal, zinc, as its source material, in comparison to  $^{177}\text{Lu}$ , which primarily uses the rare earth element, ytterbium.
- $^{67}\text{Cu}$  production is driven by electricity-powered electron accelerators with minimal production of long-lived radioactive waste products. In contrast, uranium-powered nuclear reactors, such as those used to produce  $^{177}\text{Lu}$ , create long-lived radioactive waste products that take millions of years to decay.
- $^{67}\text{Cu}$  eliminates the reliance on an ageing fleet of nuclear reactors, which are primarily located outside of the U.S. and dependent upon foreign government subsidies to operate.
- Domestic production of  $^{67}\text{Cu}$  using electron accelerators helps to avoid the significant carbon footprint associated with international supply chains, and allows for the start-to-finish production of  $^{67}\text{Cu}$ -based therapeutics to occur entirely in the U.S., the largest oncology market globally.
- $^{67}\text{Cu}$ -based products are manufactured at room temperature, significantly lowering the risk of batch failures, in contrast to current-generation radiopharmaceuticals, including  $^{177}\text{Lu}$ -based products, some of which require heating of the biological targeting agents to  $90^\circ\text{C}$  during manufacture. Batch failures create additional waste that must be disposed of, leading to an unnecessary environmental footprint.

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# TEAM & 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 and diverse team, including the Board of Directors and Advisory Board, and continues to attract some of the best talent in the industry with a wide range of skills and expertise together with extensive experience in the global radiopharmaceutical market.**

During and since the FY2023-2024, Clarity has continued its efforts to build a team with world-class expertise and knowledge in radiopharmaceutical development and commercialisation, supporting the rapid growth of the Company and its pipeline of products in development. Clarity has grown from 41 team members in July 2023 to 61 people today, with historically low turnover.

Approximately 60% of the team are based in Australia and 40% in the U.S. today, reflecting Clarity's accelerating clinical trial expansion in the U.S. With almost a quarter of the current team promoted based on their performance during financial year ending 30 June 2024, the career growth and progression reflect Clarity's strong emphasis on learning and development, nurturing talent within the organisation.

To align with the pace of Clarity's growth, the Company has made a number of changes at the executive level. Ms Michelle Parker, a long-time member of Clarity's senior executive team, was invited to the Board as an Executive Director and promoted to Chief Clinical Officer. Other changes to the senior executive team include the promotion of Dr Othon Gervasio to Chief Medical Officer, the internal appointment of Dr Matt Harris to Chief Scientific Officer and Ms Eva Lengyelova, VP of Clinical Development, joining the senior executive team.

In line with the announcement dated 16 January 2024, Clarity's Non-Executive Director, Mr Rob Thomas, retired from the Board following the completion of his tenure on 23 August 2024. Non-Executive Director, Dr Chris Roberts, has been appointed Chair of the Audit and Risk Committee and will join the Nomination and Remuneration Committee. Thomas Ramdahl will join the Audit and Risk Committee, and fellow Non-Executive Director, Ms Rosanne Robinson, will take the role of Lead Independent Director. With these changes Clarity remains on track towards its goal of maintaining a minimum 30% gender balance at a Board level, in accordance with the 30% Club Australia goal. The Club launched in May 2015 with the primary objective of campaigning for 30% women on boards of Australian Securities Exchange (ASX) 300 companies. One third of Clarity's Board and one third of Clarity's Senior Executive Team are now female, demonstrating Clarity's belief in the importance of gender diversity. Clarity will continue to build its Board and team as the Company pursues its ultimate goal of better treating children and adults with cancer.

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# 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, Clarity's team is currently involved in progressing 7 clinical trials with its Targeted Copper Theranostics (TCT) products, including 2 registrational Phase III trials, whilst continuing to expand the Research and Development (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 is committed to its Core Values shared by its directors, officers, employees, contractors and consultants:**



**INNOVATION**



**THOUGHT LEADERSHIP**



**COLLABORATION**



**RELIABILITY AND TRUST**



**HONESTY AND INTEGRITY**



**ENVIRONMENT**

Clarity recognises the importance and value of a diverse workforce and utilises the skills and talent of the team to achieve the Company's objectives. Clarity celebrates its diversity and hires staff based on capability, agility and commitment to the team effort. To support staff the Company offers flexible work conditions and also 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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# REFERENCE LIST

1. ClinicalTrials.gov Identifier: NCT04868604 [clinicaltrials.gov/ct2/show/NCT04868604](https://clinicaltrials.gov/ct2/show/NCT04868604)
2. ClinicalTrials.gov Identifier: NCT05633160 [clinicaltrials.gov/ct2/show/NCT05633160](https://clinicaltrials.gov/ct2/show/NCT05633160)
3. ClinicalTrials.gov Identifier: NCT04023331 [clinicaltrials.gov/ct2/show/NCT04023331](https://clinicaltrials.gov/ct2/show/NCT04023331)
4. ClinicalTrials.gov Identifier: NCT06056830 [clinicaltrials.gov/ct2/show/NCT06056830](https://clinicaltrials.gov/ct2/show/NCT06056830)
5. ClinicalTrials.gov Identifier: NCT05249127 [clinicaltrials.gov/ct2/show/NCT05249127](https://clinicaltrials.gov/ct2/show/NCT05249127)
6. ClinicalTrials.gov Identifier: NCT05407311 [clinicaltrials.gov/ct2/show/NCT05407311](https://clinicaltrials.gov/ct2/show/NCT05407311)
7. ClinicalTrials.gov Identifier: NCT05613842 [clinicaltrials.gov/ct2/show/NCT05613842](https://clinicaltrials.gov/ct2/show/NCT05613842)
8. ClinicalTrials.gov Identifier: NCT04438304 [clinicaltrials.gov/ct2/show/NCT04438304](https://clinicaltrials.gov/ct2/show/NCT04438304)
9. Mandel P et al. Influence of Tumor Burden on Serum Prostate-Specific Antigen in Prostate Cancer Patients Undergoing Radical Prostatectomy. *Front Oncol.* 2021.
10. Scher HI et al. Trial Design and Objectives for Castration-Resistant Prostate Cancer: Updated Recommendations From the Prostate Cancer Clinical Trials Working Group 3. *JCO*, 2016.
11. Falagario UG. Biochemical Recurrence and Risk of Mortality Following Radiotherapy or Radical Prostatectomy. *JAMA Netw Open.* 2023.
12. Rahbar K et al. PSMA targeted radioligand therapy in metastatic castration resistant prostate cancer after chemotherapy, abiraterone and/or enzalutamide. A retrospective analysis of overall survival. *Eur J Nucl Med Mol Imaging*, 2018.
13. Ahmadzadehfar H et al. Overall survival and response pattern of castration-resistant metastatic prostate cancer to multiple cycles of radioligand therapy using [177Lu]Lu-PSMA-617. *Eur J Nucl Med Mol Imaging*, 2017.
14. Pienta et al. A Phase 2/3 Prospective Multicenter Study of the Diagnostic Accuracy of Prostate Specific Membrane Antigen PET/CT with <sup>18</sup>F-DCFPyL in Prostate Cancer Patients (OSPNEY). *Journal of Urology*, 2021.
15. Hope et al. Diagnostic Accuracy of <sup>68</sup>Ga-PSMA-11 PET for Pelvic Nodal Metastasis Detection Prior to Radical Prostatectomy and Pelvic Lymph Node Dissection. *JAMA Oncol*, 2021.
16. Petersen et al. <sup>68</sup>Ga-PSMA PET/CT compared with MRI/CT and diffusion-weighted MRI for primary lymph node staging prior to definitive radiotherapy in prostate cancer: a prospective diagnostic test accuracy study. *World Journal of Urology*, 2019.
17. Surasi et al. Diagnostic Performance and Safety of Positron Emission Tomography with <sup>18</sup>F-rhPSMA-7.3 in Patients with Newly Diagnosed Unfavourable Intermediate- to Very-high-risk Prostate Cancer: Results from a Phase 3, Prospective, Multicentre Study (LIGHTHOUSE). *European Urology*, 2023.
18. Zia, N. et al. A Bivalent Inhibitor of Prostate Specific Membrane Antigen Radiolabeled with Copper-64 with High Tumor Uptake and Retention. *Angew Chem Int Ed Engl.* 2019.
19. Lengyelova, E et al. <sup>64</sup>Cu-SAR-bisPSMA (PROPELLER) positron emission tomography (PET) imaging in patients with confirmed prostate cancer. *ASCO*, 2023.
20. Afshar-Oromieh A, Holland-Letz T, Giesel FL, et al. Diagnostic performance of <sup>68</sup>Ga-PSMA-11 (HBED-CC) PET/CT in patients with recurrent prostate cancer: evaluation in 1007 patients. *Eur J Nucl Med Mol Imaging.* 2017 Aug;44(8):1258-1268.
21. Ferraro DA, Rüschoff JH, Muehlematter UJ, et al. Immunohistochemical PSMA expression patterns of primary prostate cancer tissue are associated with the detection rate of biochemical recurrence with <sup>68</sup>Ga-PSMA-11PET. *Theranostics.* 2020;10(14):6082-6094.
22. Baratto L, Song H, Duan H, et al. PSMA- and GRPR-Targeted PET: Results from 50 Patients with Biochemically Recurrent Prostate Cancer. *J Nucl Med.* 2021;62(11):1545-1549.
23. Mapelli P, Ghezzi S, Samanes Gajate AM, et al. <sup>68</sup>Ga-PSMA and <sup>68</sup>Ga-DOTA-RM2 PET/MRI in Recurrent Prostate Cancer: Diagnostic Performance and Association with Clinical and Histopathological Data. *Cancers (Basel).* 2022;14(2):334.

24. Vlachostergios PJ, Niaz MJ, Sun M, et al. Prostate-Specific Membrane Antigen Uptake and Survival in Metastatic Castration-Resistant Prostate Cancer. *Frontiers in oncology*. 2021;11.
25. Sherrington Li et al. Utility of <sup>64</sup>Cu-Sarcophagine-Bombesin PET/CT in Men with Biochemically Recurrent Prostate Cancer and Negative or Equivocal Findings on <sup>68</sup>Ga-PSMA-11 PET/CT. *The Journal of Nuclear Medicine*, 2024.
26. Brennan, Z. (2024, 30 August). Ipsen sells priority review voucher for highest price since 2016. [endpts.com/ipsen-sells-priority-review-voucher-for-highest-price-since-2016/](https://endpts.com/ipsen-sells-priority-review-voucher-for-highest-price-since-2016/)
27. Hicks R et al. First-in-human trial of <sup>64</sup>Cu-SARTATE PET imaging of patients with neuroendocrine tumours demonstrates high tumor uptake and retention, potentially allowing prospective dosimetry for peptide receptor radionuclide therapy. *The Journal of Nuclear Medicine*. 2018.
28. ClinicalTrials.gov Identifier: NCT05737615 <https://clinicaltrials.gov/ct2/show/NCT05737615>
29. Brown, A. (2024, June 14). Radiopharma execs warn that lutetium could be at risk of shortage. *Endpoints News*. [endpts.com/radiopharma-execs-warn-that-lutetium-could-be-at-risk-of-shortage/](https://endpts.com/radiopharma-execs-warn-that-lutetium-could-be-at-risk-of-shortage/)
30. Norenberg J et al. Environmental Considerations Resulting from the Increased Use of Theranostics: Advantages of Targeted Copper Theranostics. *Journal of Nuclear Medicine* June 2022, 63 (supplement 2) 2655.19. [https://jnm.snmjournals.org/content/63/supplement\\_2/2655](https://jnm.snmjournals.org/content/63/supplement_2/2655)

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# DIRECTORS' REPORT

FOR THE YEAR ENDED 30 JUNE 2024

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 2024.

## 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 (retired effective 23 August 2024)
Ms Rosanne Robinson	Non-Executive Director
Dr Christopher Roberts	Non-Executive Director
Dr Thomas Ramdahl	Non-Executive Director
Ms Cheryl Maley	Non-Executive Director (resigned 16 January 2024)

## 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 \$42.3 million (2023: \$24.6 million loss). In the year ended 30 June 2024, there was a significant increase in research and development expenditure, up \$10.5 million to \$42.0 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 \$136.5 million (2023: \$65.0 million) comprising cash on hand of \$47.9 million (2023: \$31.2 million) and term deposits of \$88.6 million (2023: \$33.8 million).
- Net assets increased to \$146.3 million from \$69.1 million at 30 June 2023.

The Board believes the Group is well placed to support its programs throughout financial year 2025.

## REVIEW OF OPERATIONS

### Corporate Overview

The financial year ended 30 June 2024 has been a momentous time for Clarity Pharmaceuticals. The Group made significant progress in its clinical development program, with a number of trials releasing exciting data and reaching crucial milestones. The Group also grew its supply and manufacturing advantage by locking in a number of significant supply agreements. Clarity Pharmaceuticals successfully completed a capital raising of \$121 million in April 2024 and received ~\$10 million in non-dilutive cash funding through R&D Tax Incentive in June 2024, ensuring the Group is well positioned to continue progressing its best-in-class products to achieve its goal of improving treatment outcomes for children and adults with cancer.

The achievements made in the last financial year position Clarity Pharmaceuticals as a leader in the radiopharmaceuticals space, with a strong competitive advantage. The Group's strategy is to first launch its Targeted Copper Theranostic (TCT) products for approval in the United States, the largest oncology market in the world, with five open Investigational New Drug (IND) applications with the US Food and Drug Administration (FDA), for a total of six products with both therapeutic and diagnostic applications. Due to the strong IP position around its SAR chelator technology, the Group has also continued to progress its Discovery Platform, investigating new targets and products that hold the promise of addressing unmet needs for patients with cancer and other serious diseases.

### Clinical

Clarity Pharmaceuticals is actively progressing trials in its three key product areas, SAR-bisPSMA, SAR-Bombesin and SARTATE. Progress made and key milestones achieved since 1 July 2023 are set out below.

#### SAR-bisPSMA - Prostate Cancer

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

The SECuRE trial is a Phase I/IIa theranostic trial in the US and Australia for identification and treatment of an advanced form of prostate cancer, metastatic castrate-resistant prostate cancer (mCRPC). It is a multi-centre, single arm, dose escalation study with a cohort expansion planned for up to 44 participants that aims to determine the safety and tolerability of both <sup>64</sup>Cu-SAR-bisPSMA and <sup>67</sup>Cu-SAR-bisPSMA, as well as determine the efficacy of <sup>67</sup>Cu-SAR-bisPSMA as a therapy.

During the reporting period, Clarity Pharmaceuticals successfully completed cohort 2 at the 8GBq dose level and cohort 3 at the 12GBq dose level, the highest dose level in the dose escalation phase of the SECuRE trial. No dose-limiting toxicities (DLTs) have been reported in any of the cohorts to date and an overall safety review of cohorts 1, 2 and 3 (4, 8 and 12GBq single dose, respectively) showed a favourable safety profile, with no adverse events related to <sup>64</sup>Cu-SAR-bisPSMA reported, and most adverse events related to <sup>67</sup>Cu-SAR-bisPSMA being mild-to-moderate.

In cohorts 2 and 3, at what could be considered therapeutic doses of 8GBq and 12GBq respectively, Prostate Specific Antigen (PSA) reductions of greater than 35% were observed in 78% of participants and PSA was reduced by over 80% in approximately 1 in every 2 patients, all from a single dose. Only two patients did not respond with a PSA drop below baseline in cohort 2 and 3, with both patients having previously failed five lines of therapy and high PSA levels. These preliminary results are encouraging, given the considerable reductions in PSA observed following the administration of only one dose of <sup>67</sup>Cu-SAR-bisPSMA.

In March 2024, Clarity Pharmaceuticals successfully dosed the first participant in the fourth and final cohort of the dose escalation phase of the SECURE trial. Cohort 4 is the first multi-dose cohort in the trial and explores the anti-cancer effects of multiple therapy cycles of <sup>67</sup>Cu-SAR-bisPSMA at the dose level of 12GBq.

Based on the favourable safety profile observed in the first 3 cohorts of the SECURE trial, a change to the dosing schedule of cohort 4 from “2 doses” to “up to 4 doses” has been approved by the Safety Review Committee and implemented at the clinical sites. This will allow patients who are benefiting from <sup>67</sup>Cu-SAR-bisPSMA to receive 2 additional doses under the SECURE trial in cohort 4 (up to 4 doses in total).

Recruitment into cohort 4 is ongoing and the study is continuing as planned, with trial design data presented at the American Society of Clinical Oncology Genitourinary Cancers (ASCO GU) in January and the American Society of Clinical Oncology (ASCO) and Society of Nuclear Medicine and Molecular Imaging (SNMMI) annual meetings in June 2024.

*Patient Case Study: Complete Response with Two Cycles of 8GBq of <sup>67</sup>Cu-SAR-bisPSMA*

The first patient ever to be dosed with two cycles of <sup>67</sup>Cu-SAR-bisPSMA at 8GBq achieved a complete response to treatment based on Response Evaluation Criteria In Solid Tumours (RECIST v1.1) assessment. The patient received the first cycle of <sup>67</sup>Cu-SAR-bisPSMA as part of cohort 2 of the SECURE trial, and a second cycle under the US FDA Expanded Access Program (EAP), as requested by the patient’s clinician. Prior to <sup>67</sup>Cu-SAR-bisPSMA, the patient had failed multiple lines of treatment, including hormone therapy, an investigational agent and chemotherapy.

Following the administration of the first cycle of <sup>67</sup>Cu-SAR-bisPSMA, the patient showed a reduction of PSA level of >99%. The patient then received a second cycle of <sup>67</sup>Cu-SAR-bisPSMA, which resulted in further reduction of his PSA to undetectable levels (confirmed by two consecutive tests). The patient’s PSA remains undetectable for almost 8 months following the administration of the second cycle of <sup>67</sup>Cu-SAR-bisPSMA.

A complete response (absence of detectable cancer after treatment) was also observed in all lesions that had been previously identified using computed tomography (CT). No PSMA uptake was observed in any of the lesions using <sup>64</sup>Cu-SAR-bisPSMA following the second cycle of <sup>67</sup>Cu-SAR-bisPSMA. This constitutes complete response using multiple tests to detect cancer: anatomical (CT), molecular (positron emission tomography (PET)) and biochemical (PSA) assessments.

Data from this case study was presented at the SNMMI 2024 Annual Meeting.

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

The CLARIFY diagnostic trial is a 383-patient registrational Phase III trial of participants with high-risk prostate cancer prior to radical prostatectomy. It opened enrolment and recruited its first participant in December 2023. The trial will examine the diagnostic potential of <sup>64</sup>Cu-SAR-bisPSMA to detect regional nodal metastasis. In addition to investigating the benefits of Clarity Pharmaceuticals’ optimised bisPSMA product in this patient population, CLARIFY will look at the potential benefits of both same-day and next-day imaging, a benefit currently unique to the SAR technology platform. Recruitment into the CLARIFY trial remains ongoing as planned.

Other milestones in relation to the CLARIFY trial in the reporting period include a successful End of Phase (EOP) meeting with the US FDA with positive feedback received from the agency in July 2023, partnering with PSI CRO

AG, a global clinical research organisation (CRO) committed to on-time enrolment in radiopharmaceutical clinical trials, in October 2023, and initiating the first clinical site at XCancer Omaha, NE, in November 2023.

In May, CLARIFY was presented by one of the study's lead clinicians, Dr. Michael Gorin, at the American Urological Association (AUA) Annual Meeting 2024 in San Antonio. The presentation outlined the trial design, generating a lot of interest around next-day imaging, a feature unique to  $^{64}\text{Cu}$ -SAR-bisPSMA and not feasible with approved PSMA PET agents. Clarity Pharmaceuticals also had the opportunity to present the CLARIFY trial design at the ASCO Annual Meeting in June, which was met with enthusiasm.

#### COBRA – a diagnostic $^{64}\text{Cu}$ -SAR-bisPSMA trial

The COBRA diagnostic trial was a first-in-human trial of  $^{64}\text{Cu}$ -SAR-bisPSMA in patients with biochemical recurrence (BCR) of prostate cancer with negative or equivocal standard of care (SOC) imaging at study entry. In February, initial results of the trial showed that  $^{64}\text{Cu}$ -SAR-bisPSMA is safe and highly effective in detecting prostate cancer lesions. In this patient group in whom SOC imaging was unable to identify the location of the cancer,  $^{64}\text{Cu}$ -SAR-bisPSMA identified prostate cancer in up to 80% of patients. The number of lesions detected by  $^{64}\text{Cu}$ -SAR-bisPSMA almost doubled from same-day (up to 80) to next-day imaging (up to 153), demonstrating the benefits of delayed scans. Next-day imaging is a feature with important clinical relevance, not offered by currently approved PSMA imaging agents. Clinicians involved in the trial reported they would change their treatment plan in approximately 50% of patients due to  $^{64}\text{Cu}$ -SAR-bisPSMA scans, signalling a potential material improvement in patient care.

$^{64}\text{Cu}$ -SAR-bisPSMA was also found to be able to detect much smaller lesions than anticipated, including a lesion of less than 2mm in size. This compares favourably to the current SOC PSMA PET imaging agents, including PYLARIFY® and the generic product  $^{68}\text{Ga}$ -PSMA-11, with which the detection of lesions smaller than 5mm is challenging.

These data were presented at both ASCO and SNMMI Annual Meetings 2024, highlighting the advantages of  $^{64}\text{Cu}$ -SAR-bisPSMA and value of next-day imaging.

Clarity Pharmaceuticals has been using the data collected from the COBRA trial to inform the trial design for a pivotal Phase III study in this patient population with BCR of prostate cancer and is currently preparing for an EOP meeting with the US FDA. The purpose of an EOP meeting is to determine the safety of proceeding to Phase III, to evaluate the Phase III plan and protocols and the adequacy of current studies.

### SAR-Bombesin – Prostate Cancer

#### COMBAT – a theranostic $^{64}\text{Cu}/^{67}\text{Cu}$ -SAR-Bombesin prostate cancer trial

The COMBAT theranostic trial is a US-based Phase I/IIa trial for identification and treatment of mCRPC expressing the Gastrin-Releasing Peptide receptor (GRPr) protein, using  $^{64}\text{Cu}/^{67}\text{Cu}$ -SAR-Bombesin in participants who are ineligible for therapy with  $^{177}\text{Lu}$ -PSMA-617. Clarity Pharmaceuticals treated the first participant in the COMBAT trial in October 2023. The aim for the trial is to determine the safety and efficacy of  $^{67}\text{Cu}$ -SAR-Bombesin in this patient group. Recruitment is ongoing.

The COMBAT trial design was presented at the ASCO GU and SNMMI 2024 Annual Meetings.

#### SABRE – a diagnostic $^{64}\text{Cu}$ -SAR-Bombesin prostate cancer trial

The SABRE diagnostic trial was a US-based Phase II trial in participants with suspected recurrence of their prostate cancer and who have negative or equivocal findings of prostate cancer on SOC imaging, including approved PSMA agents. During the period, Clarity Pharmaceuticals achieved its recruitment target for the SABRE trial, where 53 patients were imaged with  $^{64}\text{Cu}$ -SAR-Bombesin on the day of product administration (same-day imaging) and 24 hours later (next-day imaging). The primary objectives of the SABRE trial are to investigate the safety and tolerability of the product as well as its ability to correctly detect recurrence of prostate cancer. Results from the SABRE trial will guide the design of the registrational Phase III study in this patient population. The SABRE trial is currently in its follow-up phase.

The SABRE trial design was presented at the ASCO GU and SNMMI 2024 Annual Meetings.

#### BOP – a diagnostic $^{64}\text{Cu}$ -SAR-Bombesin investigator-initiated prostate cancer trial

The BOP diagnostic trial, which was completed in June 2023, was an Australia-based investigator-initiated Phase II PET imaging trial of participants with negative PSMA PET or low PSMA expression disease in patients with mCRPC with suspected BCR of their prostate cancer using  $^{64}\text{Cu}$ -SAR-Bombesin. The trial was led by Prof Louise Emmett at St Vincent's Hospital, Sydney. Initial data from the BOP trial was presented at the European Association of Nuclear Medicine (EANM) 2023 Congress in September 2023.  $^{64}\text{Cu}$ -SAR-Bombesin was found to be safe and able to detect prostate cancer lesions in over a third of participants with negative or equivocal SOC PSMA PET.

### SARTATE – Neuroblastoma and NETs

#### CL04 – a theranostic $^{64}\text{Cu}/^{67}\text{Cu}$ -SARTATE neuroblastoma trial

The CL04 theranostic trial is a US-based Phase I/IIa trial in paediatric participants with high-risk neuroblastoma using  $^{64}\text{Cu}/^{67}\text{Cu}$ -SARTATE. In the reporting period, Clarity Pharmaceuticals successfully completed cohort 3 of the trial at the dose level of 275MBq/kg body weight and treated the first participant in cohort 4 at 375MBq/kg body weight, the highest dose level in the dose escalation phase of the trial. Recruitment is ongoing for cohort 4.

#### DISCO – a diagnostic $^{64}\text{Cu}$ -SARTATE NET trial

The DISCO diagnostic trial was an Australia-based Phase II trial of participants with known or suspected Neuroendocrine Tumours (NETs) using  $^{64}\text{Cu}$ -SARTATE. Recruitment was successfully completed in December 2023, with a total of 45 patients enrolled and imaged. DISCO aims to build on earlier work with SARTATE, which demonstrated that imaging at later time points, enabled by the longer half-life of Cu-64 in comparison to Ga-68, may lead to better identification of disease. The results will guide the study design for a Phase III diagnostic trial in NETs.

## Discovery Platform

Clarity Pharmaceuticals is expanding its product pipeline with a new generation of radiopharmaceuticals through its Discovery Program. In August 2023, Clarity Pharmaceuticals added a worldwide exclusive license from Memorial Sloan Kettering Cancer Centre (MSK) to intellectual property that enables antibody “pre-targeting” for the diagnosis and treatment of cancer.

In the reporting period, the Group has been conducting research and preclinical studies, combining the bisPSMA targeting agent with actinium-225 (Ac-225 or  $^{225}\text{Ac}$ ) isotopes. The program with  $^{225}\text{Ac}$ -bisPSMA to date focused on identifying a lead compound from a number of different analogues through measuring biodistribution, tumour uptake, radiolabelling efficiency and product stability in order to progress the product to clinical development.

Clarity Pharmaceuticals' bisPSMA agent has shown impressive results in preclinical and clinical trials to date and the dual targeting of the product enables increased uptake and retention in prostate cancer tumours. By combining the optimised bisPSMA with an alpha-particle emitting isotope of Ac-225, the Group has the opportunity to complement its beta-particle therapy product,  $^{67}\text{Cu}$ -SAR-bisPSMA.

Developing both alpha- and beta-emitting therapy products for prostate cancer puts Clarity Pharmaceuticals in a unique position to offer powerful treatment approaches to improve outcomes for patients. This strategy allows the opportunity to use the same product with different isotopes and different energies at different stages of the disease to provide more treatment options for patients across the continuum of disease progression.

## Manufacturing and Supply Chain

Clarity Pharmaceutical's Targeted Copper Theranostics' (TCTs) key differentiators are the logistical, manufacturing and environmental advantages associated with the production of copper isotopes for diagnostic imaging (copper-64) and therapy (copper-67). Clarity Pharmaceuticals continued to expand its manufacturing and supply chain footprint in the period, creating additional capacity and flexibility to supply products to any ZIP-code in the US.

NorthStar Medical Radioisotopes, LLC (NorthStar), a global innovator in the development, production and commercialisation of therapeutic radiopharmaceuticals, successfully validated large scale Rhodotron production of the therapeutic radionuclide copper-67 and since August 2023 NorthStar-produced copper-67 is in routine use across Clarity Pharmaceuticals' therapeutic clinical programs. In April 2024, Clarity Pharmaceuticals entered into a clinical supply agreement with NorthStar to produce  $^{67}\text{Cu}$ -SAR-bisPSMA drug product for its Phase I/II and Phase III trials. This agreement builds on the existing copper-67 supply agreement with NorthStar, signed in 2021, and uniquely provides large-scale manufacturing of both the therapeutic isotope, copper-67, and cGMP radiopharmaceutical product in the US under one roof and ready for shipment to clinical sites.

In May 2024, Clarity Pharmaceuticals entered into a Supply Agreement with SpectronRx for the production of copper-64, strengthening the Company's supply network and ensuring seamless supply of the diagnostic isotope for Clarity Pharmaceuticals' products. SpectronRx is a robust and established private supplier of copper-64 that will support Clarity Pharmaceuticals as it progresses towards a commercial launch of its TCT products. The agreement complements and expands Clarity Pharmaceuticals' existing network of copper-64 suppliers across the US and Australia.

In July 2024, Clarity Pharmaceuticals signed a supply agreement for therapeutic alpha-emitting isotope, actinium-225, with TerraPower Isotopes.

### Team and collaborators

Clarity Pharmaceuticals has built a diverse and high-performing team, including its Board of Directors, Advisory Board and collaborators, that delivers a unique range of skills, expertise, extensive experience in the global radiopharmaceutical market and outstanding performance. In the reporting period, Clarity Pharmaceuticals' Senior Executive Team welcomed Kathryn Williams Day as Vice President, Regulatory Affairs and Quality. Mary Bennett joined as Head of Human Resources.

Ms Cheryl Maley resigned from the Board of Directors, effective 16 January 2024, to take up her new role as Chief Executive Officer of Starpharma Limited. On that same date Mr Rob Thomas announced his retirement from the Board on the date of expiry of his tenure, effective 23 August 2024. The Board extended its gratitude to Ms Maley and Mr Thomas for their contribution to the company

These changes give Clarity Pharmaceuticals an opportunity to complement its Board and open the doors to fresh perspectives, skills and knowledge in line with the Corporate Governance Principles and Recommendations from the ASX Corporate Governance Council. Clarity Pharmaceuticals will continue to build its Board and team as the Company pursues its ultimate goal of better treating children and adults with cancer.

## 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

Mr Rob Thomas retired from the Board, effective 23 August 2024.

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

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

## 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>
1 December 2019	1 December 2024	\$0.605	200,000
1 March 2020	1 March 2025	\$0.938	200,000
1 July 2020	1 July 2025	\$0.938	3,420,000
26 August 2020	26 August 2025	\$0.938	50,000
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	5,300,000
26 May 2022	26 May 2027	\$1.400	400,000
1 July 2022	1 July 2027	\$0.508	2,566,437
12 October 2022	12 September 2027	\$0.725	162,500
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	72,235
1 July 2023	1 July 2028	\$0.790	2,654,913
10 July 2023	10 July 2028	\$0.840	45,207
5 September 2023	5 September 2028	\$1.110	83,131
23 November 2023	23 November 2028	\$0.793	1,692,023
23 November 2023	23 November 2028	\$0.721	1,001,946
1 July 2024	1 July 2029	\$5.505	1,361,848
8 July 2024	8 July 2029	\$5.643	8,000
1 August 2024	1 August 2029	\$6.952	10,000
			22,571,092

<sup>1</sup> For options issued prior to 13 July 2021, the number under option and exercise price have been re-stated for the effect of a 1:20 share split completed on 13 July 2021 (623,000 in pre-split terms re-stated as 12,460,000).

Options were issued under various conditions to both employees and non-employees of the Group. Vesting conditions are described in Note 19 to the Financial Statements. These options do not entitle the holder to participate in any share issue of the Company.

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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 2023	0.220	1,196,563
13 November 2023	0.605	92,587
20 November 2023	1.125	87,969
29 November 2023	0.605	200,000
19 January 2024	0.825	181,873
8 February 2024	0.605	225,685
21 March 2024	0.605	477,671
12 April 2024	0.825	100,000
12 April 2024	0.605	100,000
12 April 2024	0.508	10,227
2 May 2024	0.605	100,000
16 May 2024	0.938	100,000
16 May 2024	0.508	34,450
3 June 2024	0.938	122,756
3 June 2024	0.825	317,443
19 June 2024	0.605	191,898
1 August 2024	0.6050	1,225,076
1 August 2024	0.7900	16,881
1 August 2024	0.8400	12,755
1 August 2024	0.8450	24,078
1 August 2024	0.9375	41,431
2 August 2024	0.6050	445,262
9 August 2024	0.6050	905,625
9 August 2024	0.7900	10,636
9 August 2024	0.8250	700,000
14 August 2024	0.8250	214,962
14 August 2024	0.9375	117,702
		<b>7,253,530</b>

## 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, seven meetings of Directors were held. Attendances by each Director during the year were as follows:

	Meetings eligible to attend	Meetings attended
Dr Alan Taylor	7	7
Dr Colin Biggin	7	7
Mr Rob Thomas	7	7
Ms Rosanne Robinson	7	7
Dr Christopher Roberts	7	7
Dr Thomas Ramdahl	7	7
Ms Cheryl Maley	3	3

## 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.

During the year ended 30 June 2024 and up to the 23 Aug 2024, the Audit and Risk Committee comprised Mr Rob Thomas (Chair), Ms Rosanne Robinson and Dr Christopher Roberts. From 26 August 2024, the Committee will comprise Dr Christopher Roberts (Chair), Ms Rosanne Robinson and Dr Thomas Ramdahl.

## NOMINATION AND REMUNERATION COMMITTEE MEETINGS

During the period, four 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)	4	4
Dr Thomas Ramdahl	4	4
Mr Rob Thomas	4	4
Ms Cheryl Maley (resigned 16 January 2024)	3	3

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 comprised Ms Rosanne Robinson (Chair), Dr Thomas Ramdahl, Mr Rob Thomas and Ms Cheryl Maley from 1 July 2023 to 16 January 2024. From 17 January 2024 to 25 August 2024, the Committee comprised Ms Rosanne Robinson (Chair), Dr Thomas Ramdahl and Mr Rob Thomas. From 26 August 2024, the Committee will comprise Ms Rosanne Robinson (Chair), Dr Thomas Ramdahl and Dr Christopher Roberts.

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## 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 over 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.

<b>Interest in Issued Shares</b>	14,609,662
<b>Interest in Issued Options</b>	5,048,207
<b>Other Current Listed Directorships</b>	Nil
<b>Previous Listed Directorships (last 3 years)</b>	Nil

### 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.

<b>Interest in Issued Shares</b>	3,249,764
<b>Interest in Issued Options</b>	3,966,843
<b>Other Current Listed Directorships</b>	Nil
<b>Previous Listed Directorships (last 3 years)</b>	Nil

**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 Investments 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 Chair of the State Library of New South Wales Foundation.

<b>Interest in Issued Shares</b>	1,175,000
<b>Interest in Issued Options</b>	Nil
<b>Other Current Listed Directorship</b>	Starpharma Holdings Ltd Biotron Ltd
<b>Previous Listed Directorships (last 3 years):</b>	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.

<b>Interest in Issued Shares:</b>	Nil
<b>Interest in Issued Options:</b>	200,000
<b>Other Current Listed Directorships:</b>	Nil
<b>Previous Listed Directorships (last 3 years):</b>	Nil

**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 Health 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.

<b>Interest in Issued Shares</b>	17,911,280
<b>Interest in Issued Options</b>	200,000
<b>Other Current Listed Directorships</b>	HealthCo Healthcare and Wellness REIT Sigma Healthcare Ltd
<b>Previous Listed Directorships (last 3 years)</b>	OncoSil Medical Ltd (ceased October 2021)

**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.

<b>Interest in Issued Shares</b>	520,000
<b>Interest in Issued Options</b>	200,000
<b>Other Current Listed Directorships</b>	Nil
<b>Previous Listed Directorships (last 3 years)</b>	Nordic Nanovector ASA, Norway (Ceased September 2022)

**Ms Cheryl Maley - Non-Executive Director**

Ms Maley served on the Board from February 2023 to January 2024 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).

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

## REMUNERATION REPORT – AUDITED

This Remuneration Report for the year ended 30 June 2024 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, 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 (retired effective 23 Aug 2024)
Ms Rosanne Robinson	Non-Executive Director
Dr Christopher Roberts	Non-Executive Director
Dr Thomas Ramdahl	Non-Executive Director
Ms Cheryl Maley	Non-Executive Director (resigned 16 Jan 2024)

### Executive directors

Dr Alan Taylor	Executive Chairperson
Dr Colin Biggin	Managing Director

### Other key management personnel

Mr David Green	Chief Financial Officer
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## 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 50 employees (at 30 June 2024), the Group is currently progressing five clinical trials with its products while continuing to expand its R&D pipeline and discovery program through the development of further novel products.

These factors have influenced the Board to keep its remuneration structure simple and 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 variable remuneration (STVR) as cash or participation in equity incentives; and
3. long-term variable remuneration (LTVR) as participation in equity incentives, to ensure employee retention and align employee interests to shareholder outcomes.

The remuneration structure is based on Key Performance Indicators (KPIs) which are designed to align with the interests of shareholders and to reward reaching 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.

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 highly skilled workforce, 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, potential 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 uses 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.

	2024		2023	
	No.	%	No.	%
Total Women employed	35	70%	24	75%
Women in non-board senior executive roles	2	33%	2	29%
Women in other management roles	7	58%	4	44%
Women in board positions	1	17%	2	29%

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 talent and diversity in the team. 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 attendance at charity fundraising events where possible. The Group strives to partner with select organisations that share the Group's values and goals, to ensure the development of a strong team culture.

The Group's Senior Executive Team promotes these principles and works to foster a positive and constructive culture in the workplace. This is achieved through tailored onboarding, team meetings and regular interaction with all employees across the organisation. They are also supported by the Company's written policies and further enabled by the company's performance management system.

#### Remuneration Governance

The Nomination and Remuneration Committee, consisting of three non-executive directors, advises the Board on remuneration policies and practices. The Committee 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 Variable Remuneration (STVR) and Long-Term Variable Remuneration (LTVR) 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 STVR and LTVR 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 at a minimum biennial 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 (short- and long-term 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.

Ensuring Total Remuneration remains competitive is crucial to the Group's overall strategy and to this end in May 2024 the NRC engaged Godfrey Remuneration Group Ltd (GRG) to complete a benchmarking assessment for the Group. This assessment compared the current remuneration quantum and structure of Key Management Personnel (KMP) and other members of the senior executive team against similar organisations of similar market capitalisation. In addition, GRG was also engaged to provide Non-Executive Director market data for additional analysis and review.

Benchmarking exercises will continue to be conducted by the NRC and Head of Human Resources to monitor for external market shifts given the dynamic nature of the radiopharmaceutical industry.

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 biannually. 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.

### Salary reviews

The Group reviews salary annually. 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 2023 Annual General Meeting (AGM)

Of the votes cast on the Company's remuneration report for the 2023 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 advisors 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** by setting both short- and long-term performance targets 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 criteria 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 style="list-style-type: none"> <li>• Base Salary</li> <li>• Retirement plan contributions</li> </ul>
Short-Term Variable Remuneration (STVR)	<ul style="list-style-type: none"> <li>• Performance based cash bonuses</li> <li>• Equity Incentive Plan</li> </ul>
Long-Term Variable Remuneration (LTVR)	<ul style="list-style-type: none"> <li>• Equity Incentive Plan</li> </ul>

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 at least biennially 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 \$700,000 (including superannuation payments), approved at the Company's AGM in November 2023.

### 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. Non-Executive Director Fees are benchmarked at least biennially.

The aggregate directors' fees paid to non-executive directors for the year ended 30 June 2024 was \$368,425 excluding share-based payments expense of \$17,241 (2023: \$390,623 excluding share-based payments expense of \$52,839).

From 1 October 2023, the base fee for non-executive directors was \$73,000 plus superannuation. Non-executive directors received a fee of \$10,000 plus superannuation for chairing a committee and committee members received a fee of \$5,000 plus superannuation. Directors based outside Australia received additional fees in lieu of superannuation. The Lead Independent Director received a further \$10,000.

In addition to Board fees, non-executive directors may receive equity-based incentives as part of their overall remuneration, subject to 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 a remuneration review, which considers industry benchmarks, the market performance of the Group and individual performance. 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 short-term variable remuneration is based on a prescribed scorecard of agreed Company and individual KPIs which is assessed by the Nomination and Remuneration Committee. Performance-based long-term variable remuneration comprises an equity-based incentive based on a 3-year performance test of Total Shareholder Return (TSR) growth compared to the TSR of the S&P/ASX300 Accumulation Index over the measurement period. 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 equity-based incentives and, in some cases, a cash bonus based on Company and individual KPIs and performance 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 their 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, manufacturing and corporate programs. These are the key areas which will deliver value to stakeholders in the short-to-medium 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. In addition, the board may award discretionary bonuses based on exceptional performance.

### Equity Incentive Plan – Service period-related

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 to complement salary and as a retention tool. In certain limited cases it 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.

Equity Incentive Plan – market performance-related

Clarity Pharmaceuticals' long-term variable remuneration may include a component of market performance-related equity incentive. The Board believes in the importance of maintaining a link between executive remuneration outcomes and returns to shareholders. Total Shareholder Return (TSR) relative to a market index measured over a 3-year performance period is used as a performance metric.

Equity incentive plan structure

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 STVR.

Service period-related option grants for each employee are determined based on a percentage of the employee's fixed remuneration and 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.

Extra service period-related options may be awarded for exceptional performance as determined by the Nomination and Remuneration Committee based on the Executive Directors' recommendation.

Market performance-related options are awarded at the Nomination and Remuneration Committee's discretion at a pre-determined percentage of fixed remuneration.

The Group grants options to its employees annually and 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 last updated 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:

<b>Eligibility</b>	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.
<b>Types of securities</b>	<p>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:</p> <p>Options – Options are an entitlement to receive a share upon the satisfaction of specified conditions and payment of a specified exercise price;</p> <p>Performance Rights – Performance Rights are an entitlement to receive a share for nil consideration upon the satisfaction of specified conditions; and</p>

	<p>Restricted shares – Restricted Shares are shares subject to specified disposal restrictions.</p> <p>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.</p>
<b>Invitations to participate</b>	<p>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.</p> <p>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.</p>
<b>Consideration payable for grant of Options, Performance Rights and/or Restricted Shares</b>	<p>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.</p>
<b>Performance conditions</b>	<p>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.</p> <p>Generally, the performance conditions must be satisfied for the securities to vest or otherwise cease to be subject to restrictions.</p> <p>Time-based service conditions are designed to retain employees whose expertise and experience are deemed vital to Clarity Pharmaceuticals' operational success.</p> <p>Market Performance-based performance hurdles set are designed to maintain a link between executive remuneration outcomes and Total Shareholder Return (TSR).</p>
<b>Rights associated with Options and Performance Rights</b>	<p>Options and Performance Rights will not carry any voting rights or right to dividends.</p> <p>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.</p>
<b>Rights associated with Restricted Shares</b>	<p>Restricted Shares will have the same rights and entitlements as other issued Shares, including voting and dividend rights.</p>
<b>Vesting</b>	<p>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.</p>
<b>Restrictions on dealing</b>	<p>Participants must not sell, transfer, encumber, hedge, or otherwise deal with securities granted under the Equity Incentive Plan.</p> <p>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.</p>
<b>Bonus issues, pro-rata issues and capital</b>	<p>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</p>

<b>reorganisations and reconstructions</b>	<p>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.</p> <p>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.</p>
<b>Cessation of employment</b>	<p>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”.</p> <p>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.</p> <p>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.</p>
<b>Clawback of equity</b>	<p>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.</p>
<b>Change of control</b>	<p>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.</p>
<b>Source of Restricted Shares and Shares</b>	<p>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).</p>
<b>Trustee</b>	<p>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.</p>
<b>Amendments to Equity Incentive Plan</b>	<p>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.</p>
<b>Exercise Price</b>	<p>The Exercise Price of service-based options is set at a 10% premium to the 5-day Volume Weighted Average Price (VWAP) at the time of grant. The Exercise Price of market performance-based options is set at the 5-day VWAP.</p>
<b>Term</b>	<p>Generally, options have a term of 5 years from the grant date.</p>

The Group measures cost of equity-settled share-based payments at Fair Value (FV) of the Share Options at grant date.

Service-based options are valued 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.

For performance-based options based on TSR growth compared to the S&P300/ASX300, the company employs the Monte Carlo simulation method. The terms & conditions upon which the instruments were granted are considered. Inputs into the Monte Carlo valuation model require a level of estimation and judgement.

Consequences of performance on Shareholder Wealth:

	2024	2023	2022	2021	2020
<b>EPS (cents)</b>	(0.1549)	(0.0948)	(0.0959)	(0.0538)	(0.0446)
<b>Dividends</b>	Nil	Nil	Nil	Nil	Nil
<b>Net loss (\$,000)</b>	(42,324)	(24,602)	(23,754)	(10,221)	(6,953)
<b>Share price (\$) <sup>1</sup></b>	5.0050	0.7213	0.5176	-	-

1. In 2020 and 2021 the Company was not listed, and no active market existed for the shares.

Performance-based remuneration is apportioned as follow:

**Performance-based remuneration for the year ended 30 June 2024**

	Position Held	Related to performance conditions		Not related to performance conditions			Total
		Non-salary Cash-based Incentives %	Options / Rights %	Options/ Rights <sup>2</sup> %	Fixed Salary/ Fees %	Consulting Fees %	%
Dr A Taylor	Executive Chairperson	18	6	42	34	-	100
Dr C Biggin	Managing Director	16	6	39	39	-	100
Mr R Thomas	Lead Independent Director	-	-	-	100	-	100
Ms R Robinson	Non-Executive Director	-	-	6	94	-	100
Dr C Roberts	Non-Executive Director	-	-	7	93	-	100
Dr T Ramdahl	Non-Executive Director	-	-	7	93	-	100
Ms Cheryl Maley <sup>1</sup>	Non-Executive Director	-	-	-	100	-	100
Mr D Green	Chief Financial Officer	12	-	16	72	-	100

1. Ms Maley resigned from the Board on 16 January 2024
2. Options not related to performance were granted based on time-based service conditions rather than milestone-based

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

	Position Held	<u>Related to performance conditions</u>		<u>Not related to performance conditions</u>			<u>Total</u>
		Non-salary Cash-based Incentives %	Options / Rights %	Options/ Rights <sup>3,4</sup> %	Fixed Salary/ Fees %	Consulting Fees %	%
Dr A Taylor	Executive Chairperson	22	-	31	47	-	100
Dr C Biggin	Managing Director	21	-	33	46	-	100
Mr R Thomas	Lead Independent Director	-	-	-	100	-	100
Ms R Robinson	Non-Executive Director	-	-	17	83	-	100
Dr C Roberts	Non-Executive Director	-	-	19	81	-	100
Dr T Ramdahl	Non-Executive Director	-	-	19	81	-	100
Dr C G O'Bryan-Tear <sup>1</sup>	Non-Executive Director	-	-	7	93	-	100
Ms Cheryl Maley <sup>2</sup>	Non-Executive Director	-	-	-	100	-	100
Mr D Green	Chief Financial Officer	-	-	13	87	-	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 were granted based on time-based service conditions rather than milestone-based
4. Options from the year ended 30 June 2023 have been restated to reflect a correction based on an incorrect calculation.

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**Director Remuneration for the year ended 30 June 2024**

	<u>Short-term benefits</u>			<u>Post Employment</u>	<u>Termination Benefits</u>	<u>Share-based Payment</u>	<u>Total</u>
	<u>Directors fees &amp; Salary</u>	<u>Bonus</u>	<u>Other<sup>1</sup></u>	<u>Superannuation</u>	<u>Termination Benefits</u>	<u>Options</u>	
	\$	\$	\$	\$	\$	\$	\$
<u>Non-Executive Directors</u>							
Mr R Thomas	80,757	-	-	8,883	-	-	89,640
Ms R Robinson	77,378	-	-	8,512	-	5,747	91,637
Dr C Roberts	76,180	-	-	-	-	5,747	81,927
Dr T Ramdahl	76,180	-	-	-	-	5,747	81,927
Ms C Maley <sup>1</sup>	40,535	-	-	-	-	-	40,535
<u>Executive Directors</u>							
Dr A Taylor <sup>2</sup>	639,591	350,000	-	27,399	-	941,022	1,958,012
Dr C Biggin <sup>2</sup>	482,233	214,875	-	27,399	-	578,415	1,302,922
<b>Total</b>	<b>1,472,854</b>	<b>564,875</b>	<b>-</b>	<b>72,193</b>	<b>-</b>	<b>1,536,678</b>	<b>3,646,599</b>

1. Ms Maley resigned from the Board on 16 January 2024
2. The salary of Executive directors includes the movement in annual leave and long service leave obligations

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## Director Remuneration for the year ended 30 June 2023

	<u>Short-term benefits</u>			<u>Post Employment</u>	<u>Termination Benefits</u>	<u>Share-based Payment</u>	<u>Total</u>
	Directors fees & Salary \$	Bonus \$	Other <sup>1</sup> \$	Superannuation \$	Termination Benefits \$	Options <sup>4</sup> \$	\$
<u>Non-Executive Directors</u>							
Ms R Robinson	72,000	-	-	7,560	-	16,162	95,722
Dr C Roberts	70,720	-	-	-	-	16,162	86,882
Dr T Ramdahl	70,720	-	-	-	-	16,162	86,882
Dr C G O'Bryan-Tear <sup>1</sup>	60,596	-	-	-	-	4,353	64,949
Ms C Maley <sup>2</sup>	29,467	-	-	-	-	-	29,467
Mr R Thomas <sup>2</sup>	72,000	-	-	7,560	-	-	79,560
<u>Executive Directors</u>							
Dr A Taylor <sup>3</sup>	550,564	271,500	-	25,292	-	377,390	1,224,746
Dr C Biggin <sup>3</sup>	444,091	210,000	-	25,292	-	341,291	1,020,674
<b>Total</b>	<b>1,370,158</b>	<b>481,500</b>	<b>-</b>	<b>65,704</b>	<b>-</b>	<b>771,520</b>	<b>2,688,882</b>

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
4. Options from the year ended 30 June 2023 have been restated to reflect a correction based on an incorrect calculation.

## Group Key Management Personnel

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

Details of KMP Remuneration for the year ended 30 June 2024 (not including KMP who are also Directors)

	Short-term Benefits		Post Employment	Termination Benefits	Share-based Payment	Total
	Salary <sup>1</sup>	Bonus	Superannuation		Options	
	\$	\$	\$	\$	\$	\$
<u>Key Management Personnel</u>						
Mr D Green	305,178	55,000	27,399	-	69,654	457,231
Total	305,178	55,000	27,399	-	69,654	457,231

1. 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 2024

	Grant Date	Nature of compensation	Service and performance criteria	% Paid	% Forfeited	Minimum/Maximum possible grant for 2023/2024
Dr A Taylor	July 2023	Cash	Clinical & corporate milestones <sup>1</sup>	90	10	\$0/\$324,000
	June 2024	Cash	Ex-gratia, related to capital management <sup>2</sup>	100	-	\$0/\$58,400
Dr C Biggin	July 2023	Cash	Clinical & corporate milestones <sup>1</sup>	90	10	\$0/\$238,750
Mr D Green	June 2024	Cash	Ex-gratia, related to capital management <sup>2</sup>	100	-	\$0/\$55,000

- Clinical & corporate milestone bonuses were approved in June 2024 and paid in July 2024 and were for KPIs set for the period July 2023 to June 2024. The KPIs consisted of strategic clinical and corporate milestones, each with a specific weighting. Clinical and corporate 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 including critical advancement of its clinical trial programs.
- The ex-gratia bonuses were approved in June 2024 and paid in July 2024 and were awarded as a one-time payment on successful completion of a capital raise.

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

	Short-term Benefits		Post Employment	Termination Benefits	Share-based Payment	Total
	Salary <sup>2</sup>	Bonus	Superannuation		Options	
	\$	\$	\$	\$	\$	\$
<u>Key Management Personnel</u>						
Mr D Green <sup>1</sup>	215,729	-	22,073	-	35,810	273,612
Total	215,729	-	22,073	-	35,810	273,612

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
3. Options from the year ended 30 June 2023 have been restated to reflect a correction based on an incorrect calculation.

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

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

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 2024 are set out below:

Name	Base salary <sup>1</sup>	Term of agreement	Notice period
	\$		
Dr A Taylor	972,000	Unspecified	6 months
Dr C Biggin	525,250	Unspecified	6 months
Mr D Green	390,250	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 2024 (2023: nil).

**Performance rights****2024**

No performance rights were issued to Directors or KMP.

**2023**

No performance rights were issued to Directors or KMP.

**Terms and conditions of options on issue to Directors and KMP in 2024**

	Grant date	Vesting and exercisable date	Expiry date	Exercise price \$	Value per option \$	Vesting condition achieved <sup>1</sup>	% Vested
A Taylor <sup>1</sup>	17 Jun 21	13 Apr 24	18 Dec 24	0.825	0.4114	100%	100%
C Biggin <sup>1</sup>	17 Jun 21	13 Apr 24	18 Dec 24	0.825	0.4114	100%	100%
C Roberts <sup>1</sup>	17 Jun 21	13 Apr 24	18 Dec 24	0.825	0.4114	100%	100%
T Ramdahl <sup>1</sup>	17 Jun 21	13 Apr 24	18 Dec 24	0.825	0.4114	100%	100%
R Robinson <sup>1</sup>	17 Jun 21	13 Apr 24	18 Dec 24	0.825	0.4114	100%	100%
D Green <sup>1</sup>	1 Jul 22	1 Jul 24	1 Jul 27	0.508	0.3306	0%	0%
D Green <sup>1</sup>	1 Jul 22	1 Jul 25	1 Jul 27	0.508	0.3306	0%	0%
A Taylor <sup>1</sup>	25 Nov 22	25 Nov 23	24 Nov 27	0.508	0.8044	100%	100%
A Taylor <sup>1</sup>	25 Nov 22	25 Nov 24	24 Nov 27	0.508	0.8044	0%	0%
A Taylor <sup>1</sup>	25 Nov 22	25 Nov 25	24 Nov 27	0.508	0.8044	0%	0%
C Biggin <sup>1</sup>	25 Nov 22	25 Nov 23	24 Nov 27	0.508	0.8044	100%	100%
C Biggin <sup>1</sup>	25 Nov 22	25 Nov 24	24 Nov 27	0.508	0.8044	0%	0%
C Biggin <sup>1</sup>	25 Nov 22	25 Nov 25	24 Nov 27	0.508	0.8044	0%	0%
D Green <sup>1</sup>	1 Jul 23	1 Jul 24	1 Jul 28	0.790	0.4379	0%	0%
D Green <sup>1</sup>	1 Jul 23	1 Jul 25	1 Jul 28	0.790	0.4379	0%	0%
D Green <sup>1</sup>	1 Jul 23	1 Jul 26	1 Jul 28	0.790	0.4379	0%	0%
A Taylor <sup>1</sup>	23 Nov 23	1 Jul 24	23 Nov 28	0.793	0.9136	0%	0%
A Taylor <sup>1</sup>	23 Nov 23	1 Jul 25	23 Nov 28	0.793	0.9136	0%	0%
A Taylor <sup>1</sup>	23 Nov 23	1 Jul 26	23 Nov 28	0.793	0.9136	0%	0%
C Biggin <sup>1</sup>	23 Nov 23	1 Jul 24	23 Nov 28	0.793	0.9136	0%	0%
C Biggin <sup>1</sup>	23 Nov 23	1 Jul 25	23 Nov 28	0.793	0.9136	0%	0%
C Biggin <sup>1</sup>	23 Nov 23	1 Jul 26	23 Nov 28	0.793	0.9136	0%	0%
A Taylor <sup>2</sup>	23 Nov 23	30 Jun 26	23 Nov 28	0.721	0.8498	0%	0%
C Biggin <sup>2</sup>	23 Nov 23	30 Jun 26	23 Nov 28	0.721	0.8498	0%	0%

1. Vesting conditions are met when the grantee remains in service to the Company up to the vesting date.
2. Options vest on meeting performance criteria, measuring Total Shareholder Revenue (TSR) growth compared to the S&P300/ASX 300 indices over the performance period.

**Options and rights converted to shares**

During the year ended 30 June 2024 the following current and former directors and KMP exercised options:

	Number	Number used in cashless exercise	Exercise price
Dr C Biggin	1,000,000	305,004	\$0.220
Dr T Ramdahl	400,000	-	\$0.605

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

	Number	Number used in cashless exercise	Exercise price
Dr C Biggin	600,000	112,792	\$0.220

During the year ended 30 June 2024, no current or former directors and KMP received shares following conversion of performance rights.

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

**Options lapsed during the year****2024**

No 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

**Directors and KMP relevant interests in securities**

Relevant interest in securities during the year ended 30 June 2024 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	1,106,308	694,996	-	1,801,304
Rob Thomas	550,000	25,000	-	575,000
Stornaway Nominees Pty Ltd ATF R. Thomas Pension Fund <sup>4</sup>	300,000	10,000	-	310,000
Murtoa Flour Mills Pty Ltd <sup>5</sup>	250,000	10,000	-	260,000
The Tony McCullough Foundation <sup>6</sup>	25,000	5,000	-	30,000
Dr T Ramdahl	120,000	400,000	-	520,000
	34,329,248	1,144,996	-	35,474,244

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

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**(b) Unlisted Options**

	Opening balance	Granted 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	200,000	-
Dr C Roberts	200,000	-	-	-	-	200,000	200,000	-
Dr T Ramdahl	600,000	-	(400,000)	-	-	200,000	200,000	-
Dr A Taylor	3,883,226	1,764,981	-	-	-	5,648,207	3,070,807	-
Dr C Biggin	5,637,855	928,988	(1,000,000)	-	-	5,566,843	4,009,464	-
D Green	200,000	212,354	-	-	-	412,354	50,000	-
	<b>10,721,081</b>	<b>2,906,323</b>	<b>(1,400,000)</b>	-	-	<b>12,227,404</b>	<b>7,730,271</b>	-

Options vest on the fulfilment of a service period or on achievement of performance criteria.

**END OF AUDITED REMUNERATION REPORT****INDEMNIFYING OFFICERS AND AUDITORS**

During the financial year the Group paid a premium of \$457,440 (2023: \$594,851) 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 compliance and advisory services. 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:

	2024 \$	2023 \$
Tax compliance & advisory services	152,257	88,843
	<b>152,257</b>	<b>88,843</b>

## 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.



Dr Alan Taylor  
Chairperson  
Date: 23 August 2024

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## Auditor's Independence Declaration

### To the Directors of Clarity Pharmaceuticals Ltd

In accordance with the requirements of section 307C of the *Corporations Act 2001*, as lead auditor for the audit of Clarity Pharmaceuticals Ltd for the year ended 30 June 2024, 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.



Grant Thornton Audit Pty Ltd  
Chartered Accountants



L M Worsley  
Partner – Audit & Assurance

Sydney, 23 August 2024

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ACN-130 913 594

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# FINANCIAL STATEMENTS

# CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

FOR THE YEAR ENDED 30 JUNE 2024

	Note	2024 \$	2023 \$
Finance income	6	2,771,380	1,864,260
Research and development tax incentive	6	11,506,665	9,800,556
<b>Income</b>		<b>14,278,045</b>	<b>11,664,816</b>
Corporate and administration expenses	7	(10,524,619)	(4,705,417)
Research and development expenses	8	(45,782,703)	(31,458,645)
<b>Loss before income tax</b>		<b>(42,029,277)</b>	<b>(24,499,246)</b>
Income tax expense	20	(295,151)	(103,200)
<b>Loss for the year from continuing operations</b>		<b>(42,324,428)</b>	<b>(24,602,446)</b>
<b>Loss for the year</b>		<b>(42,324,428)</b>	<b>(24,602,446)</b>
<b>Other comprehensive loss</b>			
Exchange differences on translating foreign entity		19,555	(12,072)
<b>Total comprehensive loss for the period</b>		<b>(42,304,873)</b>	<b>(24,614,518)</b>

Earnings per Share	Note	2024 cents	2023 cents
Basic, loss for the year attributable to ordinary equity holders	10	(15.5)	(9.5)
Diluted, loss for the year attributable to ordinary equity holders	10	(15.5)	(9.5)

The accompanying notes form part of these financial statements

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# CONSOLIDATED STATEMENT OF FINANCIAL POSITION

AS AT 30 JUNE 2024

	Notes	2024 \$	2023 \$
<b>Assets</b>			
<b>Current</b>			
Cash and cash equivalents	11	47,900,692	31,213,092
Financial assets	12	88,604,970	33,801,828
Research & development tax incentive receivable	13	11,024,578	9,469,604
Other receivables	13	1,610,115	532,608
Prepayments	14	4,921,024	1,660,789
<b>Total current assets</b>		<b>154,061,379</b>	<b>76,677,921</b>
<b>Non-current</b>			
Plant & equipment	15	554,802	206,142
Other financial assets	12	13,026	12,343
<b>Total non-current assets</b>		<b>567,828</b>	<b>218,485</b>
<b>Total assets</b>		<b>154,629,207</b>	<b>76,896,406</b>
<b>Liabilities</b>			
<b>Current</b>			
Trade and other payables	16	6,958,425	6,739,431
Employee entitlements	17	1,130,466	802,609
<b>Total current liabilities</b>		<b>8,088,891</b>	<b>7,542,040</b>
<b>Non-current</b>			
Employee entitlements	17	242,866	178,698
<b>Total non-current liabilities</b>		<b>242,866</b>	<b>178,698</b>
<b>Total liabilities</b>		<b>8,331,757</b>	<b>7,720,738</b>
<b>Net assets</b>		<b>146,297,450</b>	<b>69,175,668</b>
<b>Equity</b>			
Share capital	18	249,447,200	132,820,320
Share option reserve	19	9,523,415	6,723,640
Accumulated losses		(112,698,697)	(70,374,269)
Foreign currency translation reserve		25,532	5,977
<b>Total equity</b>		<b>146,297,450</b>	<b>69,175,668</b>

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## CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

FOR THE YEAR ENDED 30 JUNE 2024

	Share Option Reserve \$	Foreign Currency Reserve \$	Share Capital \$	Accumulated Losses \$	Total \$
<b>Year ended 30 June 2023</b>					
Balance at 30 June 2022	5,898,745	18,049	132,115,430	(45,795,690)	92,236,534
Loss for the year	-	-	-	(24,602,446)	(24,602,446)
Foreign currency translation	-	(12,072)	-	-	(12,072)
<b>Total Comprehensive Loss</b>	-	<b>(12,072)</b>	-	<b>(24,602,446)</b>	<b>(24,614,518)</b>
Transactions with owners in their capacity as owners:					
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
<b>Balance at 30 June 2023</b>	<b>6,723,640</b>	<b>5,977</b>	<b>132,820,320</b>	<b>(70,374,269)</b>	<b>69,175,668</b>
<b>Year ended 30 June 2024</b>					
Loss for the year	-	-	-	(42,324,428)	(42,324,428)
Foreign currency translation	-	19,555	-	-	19,555
<b>Total Comprehensive Loss</b>	-	<b>19,555</b>	-	<b>(42,324,428)</b>	<b>(42,304,873)</b>
Transactions with owners in their capacity as owners:					
Transfer to share capital for options exercised	(1,372,902)	-	1,372,902	-	-
Ordinary shares issued on exercise of options	-	-	919,151	-	919,151
Issue of share capital	-	-	120,982,468	-	120,982,468
Capital raising costs	-	-	(6,647,641)	-	(6,647,641)
Share-based options	4,172,678	-	-	-	4,172,678
<b>Balance at 30 June 2024</b>	<b>9,523,415</b>	<b>25,532</b>	<b>249,447,200</b>	<b>(112,698,697)</b>	<b>146,297,450</b>

The accompanying notes form part of these financial statements

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## CONSOLIDATED STATEMENT OF CASHFLOWS

FOR THE YEAR ENDED 30 JUNE 2024

	Notes	2024 \$	2023 \$
<b>Cash Flows from Operating Activities</b>			
Interest received		2,095,537	1,580,082
Research and development incentive received		9,951,691	6,726,900
Payments to suppliers and employees		(55,203,344)	(35,703,739)
Income taxes paid		(80,987)	(103,200)
<b>Net operating cash flows</b>	22	<b>(43,237,103)</b>	<b>(27,499,957)</b>
<b>Cash Flows from Investing Activities</b>			
Investment in Term Deposits		(54,803,825)	3,197,574
Purchase of plant & equipment		(504,005)	(46,562)
<b>Net investing cash flows</b>		<b>(55,307,830)</b>	<b>3,151,012</b>
<b>Cash Flows from Financing Activities</b>			
Proceeds from issue of share capital		120,982,468	-
Proceeds from unissued share capital		20,000	61,000
Exercise of options		858,151	183,335
Cost of capital raising	18	(6,647,641)	(12,750)
<b>Net financing cash flows</b>		<b>115,212,978</b>	<b>231,584</b>
<b>Net increase/(decrease) in cash held</b>		<b>16,668,045</b>	<b>(24,117,361)</b>
Cash at the beginning of the financial year		31,213,092	55,336,328
Effect of exchange rate changes on cash and cash equivalents		19,555	(5,875)
<b>Cash at the end of the financial year</b>	11	<b>47,900,692</b>	<b>31,213,092</b>

The accompanying notes form part of these financial statements

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# NOTES TO THE FINANCIAL STATEMENTS

FOR THE YEAR ENDED 30 JUNE 2024

## 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 for-profit entity for the purpose of preparing the financial statements.

The consolidated financial statements for the year ended 30 June 2024 were approved and authorised for issue by the Board of Directors on 23 August 2024. 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 \$129.2 million at 22 August 2024.

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 2023.

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 2023. The AASB has amended *AASB 101 Presentation of Financial Statements*, requiring entities to disclose material accounting policy information rather than their 'significant accounting policies'. This has had the effect of removing disclosures which are not material to the Group's consolidated financial statements.

The Group has not adopted any accounting standards that are issued but not yet effective. The Group has assessed the upcoming standards, interpretations or amendments and concluded there is no material impact expected from the adoption of these new standards, interpretations or amendments.

## 3. Summary of material accounting policies

### (b) Overall considerations

The consolidated financial statements have been prepared using the material accounting policy information 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.

### 3. Summary of material accounting policies continued

#### (c) Basis of consolidation

The Group financial statements consolidate those of the Parent Company and its subsidiaries as of 30 June 2024. 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 2024. The other subsidiary, Clarity Pharmaceuticals Europe SA (CPEU), has a reporting date of 31 December 2023.

All transactions and balances between Group companies are eliminated on consolidation as at 30 June 2024, 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.

#### (d) 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.

#### (e) Other income

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

*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 2024 has been recognised as income for the said year.

### 3. Summary of material accounting policies continued

#### (f) Income tax

The charge for current income tax expense is based on the profit for the period adjusted for any non-assessable 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.

#### (g) 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.

#### (h) 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.

#### (i) 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.

#### (j) 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.

### 3. Summary of material accounting policies continued

#### (k) 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	20 - 40%

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

#### (l) 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.

#### (m) 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.

### 3. Summary of material accounting policies continued

#### (n) 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.

#### (o) 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.

### 3. Summary of material accounting policies continued

#### (p) 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.

#### (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.

*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 – 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 either the Black-Scholes valuation methodology (for options with service-based vesting conditions) or the Monte Carlo simulation valuation methodology (for performance-based vesting conditions) considering the terms and conditions upon which the instruments were granted. Inputs into both valuation models requires 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. As the Group was not trading publicly prior to 25 August 2021, judgement was also required to determine the share price input for the valuation for options granted before that date.

### 4. 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. 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.

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**5. Interests in subsidiaries**

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

Name of the Subsidiary	Country of Incorporation and principal place of business	Principal Activity	Proportion of ownership interests held by the group	
			30 Jun 2024	30 Jun 2023
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:

	2024 \$	2023 \$
Finance income	2,771,380	1,864,260
Research and Development Tax Incentive	11,506,665	9,800,556

**7. Corporate and administration expenses**

	2024 \$	2023 \$
Corporate and administration employment costs	(5,476,803)	(2,025,226)
Depreciation	(153,068)	(100,513)
Insurance, professional fees, rent and other	(4,894,748)	(2,579,678)
	<b>(10,524,619)</b>	<b>(4,705,417)</b>

**8. Research and development expenses**

	2024 \$	2023 \$
Clinical trials and supporting activities	(32,415,630)	(21,965,377)
Research and development employment costs	(12,081,559)	(8,297,119)
Patents and related costs	(1,285,514)	(1,196,149)
	<b>(45,782,703)</b>	<b>(31,458,645)</b>

**9. Leases**

	2024 \$	2023 \$
Short-term leases	(170,836)	(151,384)

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**

	2024 Cents	2023 Cents
Basic earnings (loss) per share	(15.5)	(9.5)
Diluted earnings (loss) per share	(15.5)	(9.5)

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

	\$	\$
Net (Loss)	(42,324,428)	(24,602,446)

	Number	Number
Weighted average number of Ordinary shares on issue in the calculation of basic earnings per share	273,158,189	259,604,114
Effect of dilutive securities <sup>1</sup>	-	-
Adjusted weighted average number of Ordinary shares used in the calculation of diluted earnings per share	273,158,189	259,604,114

- At 30 June 2024 there were 25,200,861 (2023: 25,192,250) 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:

	2024 \$	2023 \$
Cash at bank – Australian Dollars	31,386,656	5,189,905
Cash at bank – US Dollars	1,154,856	617,810
Cash at bank – Euro	159,180	167,106
Term deposits – cash equivalents – Australian Dollars	15,200,000	2,105,774
Term deposits – cash equivalents – US Dollars	-	23,132,497
	<b>47,900,692</b>	<b>31,213,092</b>

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

**12. Other financial assets**

	2024 \$	2023 \$
<b>Current</b>		
Term deposits	88,604,970	33,801,828
	<b>88,604,970</b>	<b>33,801,828</b>

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 to 365 days with interest rates between 4.07% and 5.31% (2023: 91 days with interest rates between 4.16% and 4.26%).

<b>Non-current</b>		
Security deposit	13,026	12,343
	<b>13,026</b>	<b>12,343</b>

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**

	2024 \$	2023 \$
Research & development incentive receivable	11,024,578	9,469,604
Consumption taxes receivable	622,381	221,061
Interest receivable	987,734	311,547
	<b>1,610,115</b>	<b>532,608</b>

All amounts are short-term.

**14. Prepayments**

	2024 \$	2023 \$
Clinical trials and supporting activities	4,530,578	1,102,336
Corporate activities	302,298	265,624
Patents and related costs	88,148	99,831
Equipment	-	192,998
	<b>4,921,024</b>	<b>1,660,789</b>

All amounts are short term. Prepayments for clinical trials includes upfront payments to clinical research organisations which will be recouped on completion of the clinical trial contract.

**15. Plant & equipment**

	2024 \$	2023 \$
Equipment	929,433	435,885
Less accumulated depreciation	(374,631)	(229,743)
	<b>554,802</b>	<b>206,142</b>
Balance as at 1 July	206,142	260,092
Additions	504,005	46,562
Disposals	(2,277)	-
Depreciation	(153,068)	(100,513)
<b>Balance as at 30 June</b>	<b>554,802</b>	<b>206,142</b>

**16. Trade & other payables**

Trade and other payables recognised consist of the following:

	2024 \$	2023 \$
<b>Current:</b>		
Trade creditors	2,084,373	2,846,510
Sundry creditors	3,092,025	2,769,069
Taxes Payable	214,164	-
Payroll liabilities	1,432,698	910,749
Superannuation payable	135,165	129,775
Other liabilities	-	83,329
	<b>6,958,425</b>	<b>6,739,431</b>

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 \$1,624,949 (2023: \$1,355,035) and operations of \$827,234 (2023: \$1,021,851).

**17. Employee entitlements**

	2024 \$	2023 \$
<b>Current</b>		
Annual leave liability	1,104,647	782,764
Long service leave liability	25,819	19,845
	<b>1,130,466</b>	<b>802,609</b>
<b>Non-Current</b>		
Long service leave liability	<b>242,866</b>	<b>178,698</b>

Movement in total employee entitlement provisions:

Balance as at 1 July	981,307	793,155
Arisen during year	654,831	454,179
Utilised and reversed	(262,806)	(181,942)
Probability revaluation <sup>1</sup>	-	(84,085)
<b>Balance as at 30 June</b>	<b>1,373,332</b>	<b>981,307</b>

1. In the previous year, the Group 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.

**18. Equity**

	2024 \$	2023 \$
Ordinary shares issued and fully paid	262,400,287	139,125,766
Cost of capital raising	(12,953,087)	(6,305,446)
<b>Total contributed equity at 30 June</b>	<b>249,447,200</b>	<b>132,820,320</b>

	\$	Number
Movement in ordinary shares on issue:		
Balance as at 1 July 2023	132,820,320	260,662,670
Issue of share capital	120,982,468	47,444,105
Issue on exercise of share options	2,292,053	3,539,122
Transaction costs	(6,647,641)	-
<b>Balance as at 30 June 2024</b>	<b>249,447,200</b>	<b>311,645,897</b>

**18. 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.

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 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 (2023: nil).

**19. Share option reserve**

	2024 \$	2023 \$
Balance as at 1 July	6,723,640	5,898,745
Share options expensed – employees & consultants	4,172,677	1,251,067
Options exercised	(1,372,902)	(402,306)
Options lapsed	-	(23,867)
<b>Balance as at 30 June</b>	<b>9,523,415</b>	<b>6,723,640</b>

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 of service-based options is determined using a Black-Scholes valuation of the options. Service-based share options held by employees and consultants issued under Clarity Pharmaceuticals' Equity Incentive Plan vest based on conditions regarding service provided to the Company. These options vest at the end of the stated service period. These options expire 5 years after their grant date.

For service-based options granted during the year, the valuation model inputs for the Black-Scholes valuation method used to determine the fair value at the grant date are as follows:

Grant date	1 Jul 2023	10 Jul 2023	5 Sep 2023	23 Nov 2023
Share price	\$0.721	\$0.764	\$1.008	\$1.274
Exercise price	\$0.790	\$0.840	\$1.110	\$0.793
Volatility rate	72.9%	72.9%	74.0%	73.0%
Options life	5 years	5 years	5 years	5 years
Risk-free interest rate	3.98%	4.21%	3.84%	4.19%

**19. Share option reserve continued**

The expense related to performance-based options is determined using a Monte Carlo simulation.

Performance-based options only vest based upon achievement of pre-determined levels of growth of the Company's total shareholder return (TSR) compared to the S&P300/ASX300 indices over the performance period. The fair value of performance-based options granted was determined using a Monte Carlo simulation which estimates Clarity Pharmaceuticals' TSR relative to the Index's TSR over the performance period and prices the options accordingly. The number of options that ultimately vest is determined by Clarity Pharmaceuticals' actual TSR against the Index TSR as follows:

Clarity Pharmaceuticals TSR Growth compared to Index	Percentage of Options that will vest
Below Index growth	0%
Equal to Index	50%
Greater than Index but by less than 30%	Pro rata basis 51% to 99%
Index growth greater than 30%	100%

These options expire 5 years after their grant date.

For performance-based options granted during the year, the valuation model inputs for the Monte Carlo simulation used to determine the fair value at the grant date are as follows:

Grant date	23 Nov 2023
Share price	\$1.274
Exercise price	\$0.721
Performance period	3 years
Share Price volatility	70.0%
Index volatility	17.5%
Correlation	0.25
Risk-free interest rate	4.19%
Options life	5 years

Options on issue at 30 June 2024 comprise:

Expiry Date	Balance 1 Jul 2023	Weighted Average Exercise Price	Granted during year	Lapsed during year	Exercised during year	Balance 30 June 2024	Vested and exercisable	Weighted Average Exercise Price	Weighted Average Remaining Life (years)
1 Jul 23	1,600,000	\$0.220	-	-	(1,600,000)	-	-	-	-
3 Dec 23	200,000	\$0.605	-	-	(200,000)	-	-	-	-
10 Dec 23	200,000	\$0.605	-	-	(200,000)	-	-	-	-
21 Mar 24	700,000	\$0.605	-	-	(700,000)	-	-	-	-
5 Aug 24	2,100,000	\$0.605	-	-	(300,000)	1,800,000	1,800,000	\$0.605	0.10
5 Aug 24	100,000	\$0.605	-	-	(100,000)	-	-	-	-
1 Oct 24	1,000,000	\$0.605	-	-	-	1,000,000	1,000,000	\$0.605	0.30
21 Oct 24	100,000	\$0.605	-	-	(100,000)	-	-	-	-
1 Dec 24	200,000	\$0.605	-	-	-	200,000	200,000	\$0.605	0.40
1 Mar 25	200,000	\$0.938	-	-	-	200,000	200,000	\$0.938	0.70
2 Mar 25	400,000	\$0.938	-	-	(400,000)	-	-	-	-
1 Jun 25	100,000	\$0.938	-	-	-	100,000	100,000	\$0.938	0.90
1 Jul 25	3,560,000	\$0.938	-	-	(100,000)	3,460,000	3,460,000	\$0.938	1.00
21 Mar 24	100,000	\$0.605	-	-	(100,000)	-	-	-	-
26 Aug 25	100,000	\$0.938	-	-	-	100,000	100,000	\$0.938	1.20
15 Dec 23	918,220	\$1.125	-	-	(918,220)	-	-	-	-
4 May 26	200,000	\$0.938	-	-	-	200,000	200,000	\$0.938	1.80
10 May 26	1,000,000	\$0.938	-	-	-	1,000,000	1,000,000	\$0.938	1.90
18 Dec 24	6,650,000	\$0.825	-	(50,000)	(350,000)	6,250,000	6,450,000	\$0.825	0.50
26 May 27	400,000	\$1.400	-	-	-	400,000	100,000	\$1.400	2.90
1 Jul 27	2,774,865	\$0.508	-	(161,478)	(46,950)	2,566,437	646,768	\$0.508	3.00
12 Sep 27	350,000	\$0.725	-	(187,500)	-	162,500	87,500	\$0.725	3.20
14 Nov 27	161,771	\$1.060	-	-	-	161,771	40,442	\$1.060	3.40
25 Nov 27	1,921,081	\$0.508	-	-	-	1,921,081	480,271	\$0.508	3.40
6 Mar 28	60,000	\$0.970	-	-	-	60,000	15,000	\$0.970	3.70
1 May 28	96,313	\$0.845	-	-	-	96,313	24,078	\$0.845	3.80
1 Jul 28	-	-	2,685,383	-	-	2,685,383	-	\$0.790	4.00
10 Jul 28	-	-	60,276	-	-	60,276	-	\$0.840	4.00
5 Sep 28	-	-	83,131	-	-	83,131	-	\$1.110	4.20
23 Nov 28	-	-	1,692,023	-	-	1,692,023	-	\$0.793	4.40
23 Nov 28	-	-	1,001,946	-	-	1,001,946	-	\$0.721	4.40
	<b>25,192,250</b>	<b>\$0.732</b>	<b>5,522,759</b>	<b>(398,978)</b>	<b>(5,115,170)</b>	<b>25,200,861</b>	<b>15,904,059</b>	<b>\$0.766</b>	<b>1.984</b>

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**20. 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:

	2024 \$	2023 \$
Result before income tax	(42,029,277)	(24,499,246)
Prima facie tax payable on (loss) before income tax at 30% (2023: 30%)	(12,608,783)	(7,349,774)
Add: Tax effect of:		
Non-deductible research and development expense subject to R&D tax incentive	6,819,326	5,857,487
Non-deductible share-based payment	1,251,803	375,320
Less: Tax effect of:		
Research & development incentive recognised	(3,307,373)	(2,840,881)
Adjustment to prior year research & development incentive	(144,626)	(99,286)
Other differences	(23,135)	(379,575)
Tax effect of losses not brought to account	8,307,940	4,539,909
<b>Income tax expense attributable to loss before income tax</b>	<b>295,151</b>	<b>103,200</b>
Unused tax losses for which no tax loss has been recognised as a deferred tax asset:		
Tax effect:		
Australia (30%)	16,641,279	9,261,656
Europe (20%)	33,775	27,201
U. S. A. (25.55%)	-	-

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.

**20. Income tax continued**

	2024 \$	2023 \$
<u>Deferred tax asset not recognised</u>		
Blackhole deduction	827,045	1,299,783
Provisions	452,549	333,325
Unused tax losses	16,675,054	9,261,656
	<b>17,954,648</b>	<b>10,894,763</b>

No deferred tax asset was recognised in the year ended June 2024 due to the uncertainty of its recoverability.

**21. Employee remuneration****(a) Employee benefits expense**

Expenses recognised for employee benefits are analysed below:

	2024 \$	2023 \$
Wages, salaries	10,822,379	7,281,434
Superannuation costs	541,487	457,213
Share-based payments	4,086,611	1,240,369
Other employee expenses	1,722,068	952,706
<b>Employee benefits expense</b>	<b>17,172,545</b>	<b>9,931,722</b>

**(b) Share-based employee remuneration**

As at 30 June 2024, the Group maintained a share-based payment scheme for employee remuneration. This program is settled in equity.

In total \$4,086,611 (2023: \$1,240,369) 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 the share option reserve.

**22. Cash flow statement reconciliation**

	2024 \$	2023 \$
<b>Reconciliation of net loss after tax to net cash flows from operations</b>		
Loss from ordinary activities after Income Tax	(42,324,428)	(24,602,446)
Loss on sale of fixed assets	2,277	-
<u>Non-Cash items in Total Comprehensive Income:</u>		
Depreciation expense	153,067	100,513
Share option expense	4,172,678	1,251,067
<u>Changes in Assets and Liabilities:</u>		
Unrealised currency (gain)/loss	(19,555)	5,875
(Increase) in Trade and Other Receivables	(2,632,481)	(3,344,639)
Decrease/(Increase) in Prepayments	(3,260,235)	(1,104,584)
(Decrease)/Increase in Trade and Other Payables <sup>1</sup>	259,994	18,177
Increase in Provisions	392,025	188,152
Currency differences on translating a foreign entity	19,555	(12,072)
<b>Cash Flow from Operations</b>	<b>(43,237,103)</b>	<b>(27,499,957)</b>

1. Excluding \$41,000 in equity related items which are non-operating (2023: \$70,000).

**23. Financial instruments****(a) Assets**

	2024 \$	2023 \$
<b>Current assets</b>		
Financial assets:		
Cash at bank	47,900,692	31,213,092
Term deposits	88,604,970	33,801,828
<b>Total financial assets</b>	<b>136,505,662</b>	<b>65,014,920</b>
<b>Non-current assets</b>		
Financial assets:		
Other financial assets	13,026	12,343
<b>Total financial assets</b>	<b>13,026</b>	<b>12,343</b>

**23. Financial instruments continued**

	2024 \$	2023 \$
<b>Financial assets maturity analysis</b>		
Less than 30 days	32,700,692	8,080,595
31 – 60 days	-	10,824,714
61 – 90 days	15,200,000	12,307,783
More than 90 days	88,617,996	33,814,171
More than 1 year	-	-
<b>Balance at 30 June</b>	<b>136,518,688</b>	<b>65,027,263</b>

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**

	2024 \$	2023 \$
<b>Financial liabilities:</b>		
Trade & other payables	5,176,398	5,615,578
<b>Total financial liabilities</b>	<b>5,176,398</b>	<b>5,615,578</b>

**Financial liabilities maturity analysis**

Less than 1 year	5,176,398	5,615,578
<b>Balance at 30 June</b>	<b>5,176,398</b>	<b>5,615,578</b>

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 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 in radiopharmaceuticals.

**23. 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 2024 \$	Fixed Less than 1 Year 2024 \$	Non-interest bearing 2024 \$
<b>Financial assets:</b>			
Cash and cash equivalents	30,299,975	15,200,000	2,400,717
Financial assets	-	88,604,970	-
Security deposits	-	-	13,026
<b>Total financial assets</b>	<b>30,299,975</b>	<b>103,804,970</b>	<b>2,413,743</b>
<b>Financial liabilities:</b>			
Trade and other payables	-	-	5,176,398
<b>Total financial liabilities</b>	<b>-</b>	<b>-</b>	<b>5,176,398</b>

**23. 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.

		2024 \$	2023 \$
Increase or decrease in interest rate by 1% - change in profit and equity	+/-	1,365,057	650,149
Increase or decrease in USD/AUD foreign exchange rate by 5 cents - change in profit and equity	+/-	1,165,150	(700,292)

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

**24. Related party transactions****(a) Parent Entity**

The Group is controlled by the following entity:

<u>Name:</u>	<u>Type:</u>	<u>Place of business/incorporation:</u>
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 2024

	Salary <sup>1</sup> \$	Bonus \$	Superan- nuation \$	Options \$	Total \$	Unpaid at 30 Jun 2024 \$
<u>Key Management Personnel</u>						
Dr A Taylor	639,591	350,000	27,399	941,022	1,958,012	356,850
Dr C Biggin	482,233	214,875	27,399	578,415	1,302,922	221,725
Mr D Green	305,178	55,000	27,399	76,128	463,705	61,850
<b>Total</b>	<b>1,427,002</b>	<b>619,875</b>	<b>82,197</b>	<b>1,595,565</b>	<b>3,724,639</b>	<b>640,424</b>

1. Salary includes movements in annual and long service leave

**24. Related party transactions continued**

Year ending 30 June 2023

	Salary <sup>1</sup> \$	Bonus \$	Superan- nuation \$	Options \$	Total \$	Unpaid at 30 Jun 2023 \$
<u>Key Management Personnel</u>						
Dr A Taylor	550,564	271,500	25,292	377,390	1,224,746	277,823
Dr C Biggin	444,091	210,000	25,292	341,291	1,020,674	216,323
Mr D Green	215,729	-	22,073	35,810	273,612	6,323
<b>Total</b>	<b>1,210,384</b>	<b>481,500</b>	<b>72,657</b>	<b>754,491</b>	<b>2,519,032</b>	<b>500,469</b>

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 2024, Clarity Personnel Inc. invoiced Clarity Pharmaceuticals Ltd \$7,971,970, of which \$1,574,853 was unpaid at 30 June 2024 (2023: \$3,889,863 invoiced, of which \$535,316 was unpaid at balance date).

Share transactions of Directors

In the year ended 30 June 2024, Dr Biggin exercised 1,000,000 using a cashless exercise mechanism at a price of \$0.22 per option, resulting in the issue of 694,996 shares and Dr Ramdahl exercised 400,000 in cash at a price of \$0.605 per option, resulting in the issue of 400,000 shares

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.

Other transactions with Directors

Directors receive a fixed Director's fee and, from time-to-time, options. Transactions with Directors in the year ended 30 June 2024 were as follows:

	Directors' fees \$	Options \$	Total \$	Unpaid at 30 Jun 2024 \$
<u>Non-executive directors</u>				
Ms R Robinson <sup>1</sup>	85,890	5,747	91,637	2,180
Dr C Roberts	76,180	5,747	81,927	-
Dr T Ramdahl	76,180	5,747	81,927	-
Ms C Maley	40,535	-	40,535	-
Mr R Thomas <sup>1</sup>	89,640	-	89,640	2,304
<b>Total</b>	<b>368,425</b>	<b>17,241</b>	<b>385,666</b>	<b>4,484</b>

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

**24. Related party transactions continued**

Transactions with Directors in the year ended 30 June 2023 were as follows:

	Directors' fees \$	Options <sup>2</sup> \$	Total \$	Unpaid at 30 Jun 2023 \$
<u>Non-executive directors</u>				
Ms R Robinson <sup>1</sup>	79,560	16,162	95,722	1,890
Dr C Roberts	70,720	16,162	86,882	-
Dr T Ramdahl	70,720	16,162	86,882	-
Dr C G O'Bryan-Tear	60,596	4,353	64,949	-
Ms C Maley	29,467	-	29,467	19,448
Mr R Thomas <sup>1</sup>	79,560	-	79,560	1,890
<b>Total</b>	<b>390,623</b>	<b>52,839</b>	<b>443,462</b>	<b>23,228</b>

1. Directors' fees for Ms Robinson and Mr Thomas includes superannuation payable.
2. Options from the year ended 30 June 2023 have been restated to reflect a correction based on an incorrect calculation.

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 \$103,906 (2023: \$106,206). All fees were charged on normal commercial terms. Mr Pratt did not receive any payment for his services as Director of Clarity Personnel Inc.

**25. Auditors' remuneration**

	2024 \$	2023 \$
Audit of financial report	166,450	113,820

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

Tax compliance and advisory services	152,257	88,843
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**26. Commitments & 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, Memorial Sloane Kettering Cancer Center and University of Antwerp, representing contingent liabilities totalling \$10,263,711 (Jun 2023 \$7,256,880). 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 conducting clinical trials to entering Phase III trials, along with commencement of sales of radiopharmaceutical agents. It is anticipated that some milestones may be reached in the year ending 30 June 2025 which will result in payments to licensors totalling \$80,697 (2023 nil).

**27. 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, included in Note 26. The Parent Entity uses the same accounting policies as the Group.

	2024 \$	2023 \$
<b>Statement of financial position</b>		
Current assets	141,701,796	75,322,836
Total assets	153,741,671	77,037,965
Current liabilities	(8,873,092)	(3,840,005)
Total liabilities	(8,630,226)	(8,130,275)
<b>Net assets</b>	<b>145,111,445</b>	<b>68,907,690</b>
Issued capital	249,447,200	132,820,320
Share option reserve	9,523,415	6,723,641
Retained losses	(113,859,170)	(70,636,271)
<b>Total equity</b>	<b>145,111,445</b>	<b>68,907,690</b>
<b>Statement of profit or loss and other comprehensive income</b>		
Loss for the year	43,222,899	24,806,660
<b>Total comprehensive loss</b>	<b>(43,222,899)</b>	<b>(24,806,660)</b>

**28. Post-reporting date events**

Mr Rob Thomas retired from the Board, effective 23 August 2024.

There are no other 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.

## CONSOLIDATED ENTITY DISCLOSURE STATEMENT

AS AT 30 JUNE 2024

Set out below is a list of entities that are consolidated in this set of consolidated financial statements at the end of the financial year.

Entity Name	Entity Type	Country of incorporation	% of share capital held	Australian or foreign resident	Country of residence for tax purpose
Clarity Pharmaceuticals Ltd	Body corporate	Australia	100%	Australian	Australia
Clarity Pharmaceuticals Europe SA	Body corporate	Belgium	100%	Foreign	Australia
Clarity Personnel Inc.	Body corporate	U. S. A.	100%	Foreign	Australia & U.S.A.

### Basis of Preparation

This Consolidated Entity Disclosure Statement has been prepared in accordance with the *Corporations Act 2001*. It includes certain information for each entity that was part of the consolidated entity at the end of the financial year.

### Consolidated entity

This Consolidated Entity Disclosure Statement includes only those entities consolidated as at the end of the financial year in accordance with AASB 10 Consolidated Financial Statements (AASB 10).

### Determination of Tax Residency

Section 295 (3A) of the *Corporations Act 2001* defines tax residency as having the meaning in the *Income Tax Assessment Act 1997*. The determination of tax residency involves judgment as there are currently several different interpretations that could be adopted, and which could give rise to a different conclusion on residency.

In determining tax residency, the consolidated entity has applied the following interpretations:

- *Australian tax residency* - The consolidated entity has applied current legislation and judicial precedent, including having regard to the Tax Commissioner's public guidance in *Tax Ruling TR 2018/5*.
- *Foreign tax residency* - The consolidated entity has used independent tax advisers in foreign jurisdictions to assist in its determination of tax residency to ensure applicable foreign tax legislation has been complied with.

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# DIRECTORS' DECLARATION

## FOR THE YEAR ENDED 30 JUNE 2024

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 2024 and of its performance for the financial year ended on that date;
- the attached consolidated entity disclosure statement is true and correct; 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



Dr Alan Taylor  
Chairperson

Dated this 23<sup>rd</sup> day of August 2024

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## Independent Auditor's Report

To the Members of Clarity Pharmaceuticals Ltd

### 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 2024, 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 material accounting policy information, the consolidated entity disclosure statement 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 2024 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.

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## 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.

Key audit matter	How our audit addressed the key audit matter
<p><b>Research and Development Tax Incentive (Note 6 &amp; Note 13)</b></p> <p>The Group receives a research and development (R&amp;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&amp;D expenditure if its turnover is less than \$20 million per annum. Registration of R&amp;D Activities Application is filed with AusIndustry in the following financial year and, based on this filing, the Group receives the incentive in cash.</p> <p>Management reviewed the Group's total R&amp;D expenditure to estimate the refundable tax offset receivable under the R&amp;D tax incentive legislation.</p> <p>This area is a key audit matter due to the degree of judgment and interpretation of the R&amp;D tax legislation required by management to assess the eligibility of the R&amp;D expenditure under the scheme.</p>	<p>Our procedures included, amongst others:</p> <ul style="list-style-type: none"> <li>• Performing procedures to understand the design and implementation of controls in place over the R&amp;D expenditure;</li> <li>• Utilising an internal R&amp;D tax specialist to: <ul style="list-style-type: none"> <li>– review the expenditure methodology employed by management for consistency with the R&amp;D tax offset rules; and</li> <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> </li> <li>• selecting a sample of R&amp;D expenditure and agreeing to supporting documentation to determine the validity of the claimed amount and eligibility against the R&amp;D tax incentive scheme criteria; and</li> <li>• assessing the appropriateness of the financial statement disclosures.</li> </ul>

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

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 2024, but does not include the financial report and our auditor's report thereon.

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:

- a) the financial report that gives a true and fair view in accordance with Australian Accounting Standards and the Corporations Act 2001 (other than the consolidated entity disclosure statement); and
- b) the consolidated entity disclosure statement that is true and correct in accordance with the Corporations Act 2001, and

for such internal control as the directors determine is necessary to enable the preparation of:

- i) the financial report that gives a true and fair view and is free from material misstatement, whether due to fraud or error; and
- ii) the consolidated entity disclosure statement that is true and correct and is free of 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.

#### 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: [http://www.auasb.gov.au/auditors\\_responsibilities/ar1\\_2020.pdf](http://www.auasb.gov.au/auditors_responsibilities/ar1_2020.pdf). 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 59 to 79 of the Directors' report for the year ended 30 June 2024.

In our opinion, the Remuneration Report of Clarity Pharmaceutical Ltd, for the year ended 30 June 2024 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.

*Grant Thornton*

Grant Thornton Audit Pty Ltd  
Chartered Accountants

*L M Worsley*

L M Worsley  
Partner – Audit & Assurance

Sydney, 23 August 2024



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# ASX ADDITIONAL INFORMATION

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 6 September 2024.

#### SUBSTANTIAL SHAREHOLDERS OF ORDINARY SHARES (AS REPORTED TO THE ASX)

Name	Number of Shares Held	%
CABBIT PTY LTD ATF ROBWill TRUST	17,911,280	5.67
TM VENTURES PTY LTD	16,699,842	5.29

#### DISTRIBUTION OF SHAREHOLDERS AND SHAREHOLDINGS – ORDINARY SHARES

There are 315,759,910 ordinary shares on issue held by 6,540 shareholders.

Range	Ordinary Shares	%	No. of holders	%
1 to 1,000	1,124,512	0.36	2,475	37.84
1,001 to 5,000	5,466,299	1.73	2,062	31.53
5,001 to 10,000	5,528,885	1.75	731	11.18
10,001 to 100,000	31,107,533	9.85	1,050	16.06
100,001 and Over	272,532,681	86.31	222	3.39
<b>Total</b>	<b>315,759,910</b>	<b>100.00</b>	<b>6,540</b>	<b>100.00</b>

#### DISTRIBUTION OF OPTION HOLDERS AND HOLDINGS – OPTIONS (UNLISTED)

There are 22,164,945 unlisted options on issue held by 71 option holders. Of these 21,764,945 were issued under an employee share plan to 70 option holders.

Range	Options	%	No. of holders	%
1 to 1,000	-	-	-	-
1,001 to 5,000	7,619	0.03	2	2.82
5,001 to 10,000	81,251	0.37	10	14.08
10,001 to 100,000	1,255,789	5.67	26	36.62
100,001 and Over	20,820,286	93.93	33	46.48
<b>Total</b>	<b>22,164,945</b>	<b>100.00</b>	<b>71</b>	<b>100.00</b>

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**UNMARKETABLE PARCELS**

The number of shareholders holding less than a marketable parcel of ordinary shares is 61, based on the Company's closing share price of \$7.20 on 6 September 2024.

**TWENTY LARGEST SHAREHOLDERS**

Rank	Name	No. Shares	%
1	CITICORP NOMINEES PTY LIMITED	22,818,280	7.23
2	UBS NOMINEES PTY LTD	19,336,534	6.12
3	CABBIT PTY LTD ATF ROBWILL TRUST	17,911,280	5.67
4	J P MORGAN NOMINEES AUSTRALIA PTY LIMITED	16,935,337	5.36
5	TM VENTURES PTY LTD	16,699,842	5.29
6	HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	14,248,257	4.51
7	A.C.N. 136 437 913 PTY LTD ATF THE TAYLOR FAMILY A/C	13,266,660	4.2
8	ARGO INVESTMENTS LIMITED	9,802,322	3.1
9	YARRAWAH PTY LTD ATF PETER HENDERSON P/L S/F A/C	8,040,000	2.55
10	VANTRES PTY LTD ATF ASTEN SUPER FUND A/C	6,812,340	2.16
11	BOORRIS PTY LTD ATF BOORRIS TRUST	6,065,800	1.92
12	BNP PARIBAS NOMS PTY LTD	5,356,049	1.7
13	PACIFIC CUSTODIANS PTY LIMITED	5,280,485	1.67
14	SMARTER CAPITAL PTY LTD	5,004,543	1.58
15	NATIONAL NOMINEES LIMITED	4,438,511	1.41
16	KYLACO PTY LTD	3,896,280	1.23
17	BNP PARIBAS NOMINEES PTY LTD	3,713,550	1.18
18	AUSTRALIAN NUCLEAR SCIENCE & TECHNOLOGY ORGANISATION	3,599,920	1.14
19	COLIN BIGGIN	3,249,764	1.03
20	WYARGINE HOLDINGS PTY LTD ATF SHELLCOVE SUPER FUND	3,210,425	1.02
	<b>Total</b>	<b>189,686,179</b>	<b>60.07</b>
	<b>Balance of register</b>	<b>126,073,731</b>	<b>39.93</b>
	<b>Grand total</b>	<b>315,759,910</b>	<b>100.00</b>

**ON-MARKET BUY BACK**

There is no current on-market buy back.

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## 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.

## 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 <https://www.claritypharmaceuticals.com/investor-center/>.

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 30 September 2024. It has been approved by the board and is available on the Company's website under Investors at <https://www.claritypharmaceuticals.com/investor-center/>.

# CORPORATE DIRECTORY

## Directors

Dr Alan Taylor  
Executive Chairman

Dr Colin Biggin  
Managing Director and  
Chief Executive Officer

Ms Michelle Parker  
Executive Director  
Chief Clinical Officer

Ms Rosanne Robinson  
Non-Executive Director  
Chair of the Nomination of  
Remuneration Committee

Dr Chris Roberts  
Non-Executive Director  
Chair of the Audit and Risk  
Committee

Dr Thomas Ramdahl  
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](http://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](mailto:registrars@linkmarketservices.com.au)

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