

ASX ANNOUNCEMENT

23 November 2023

Chairperson's Address to Clarity's Annual General Meeting 2023

Clarity Pharmaceuticals (ASX: CU6) ("Clarity"), a clinical-stage radiopharmaceutical company developing next-generation products to address the growing needs in oncology, is pleased to provide the Chairperson's Address to the Annual General Meeting of Shareholders being held at 10:00am, 23rd of November 2023.

Good morning everyone,

Welcome to our third Annual General Meeting as a listed company on the Australian Securities Exchange.

Before we begin with formalities, I would like to acknowledge the Gadigal people of the Eora Nation as the Traditional Custodians of the land we are meeting on today. I'd also like to add that at Clarity, we are also "born and bred" in the Redfern precinct, where we are meeting today, which is the spiritual home of our Indigenous people, and we are a proud member of our community which has a long history and strong cultural ties for our Indigenous community.

I have been fortunate to have close ties to this community ever since my grandparents immigrated from Europe to Redfern after the war. My earliest memories are of me on the balcony of the 14th floor of the Waterloo towers next door to the Clarity office, with a telescope and raw excitement of observing the world around us. And now, only 500 metres away and 45 years on, I have the opportunity to stand in front of all of you and share the exciting Australian science story of Clarity Pharmaceuticals and the incredible feats our team has accomplished over the last year to help cancer patients in need. But that experience as a child has not been forgotten, and is now reflected in our relationship with Story Factory, a local organisation we support to provide resources to local children and help them write and to find their own voice, telling their own stories so that one day they may also get the opportunity to follow their own dreams.

Last week, I was fortunate to pass through my 10-year anniversary at Clarity. Starting from very humble beginnings, as some of you may recall, of no employees, no money, and two obscure provisional patents for a copper chelator, I have been privileged to be able to tell all of you that the last year has been our best ever for the last 10 years, and this last year is no exception. We have come a long way, and our love of science has seen us accumulate 24 patent families, build new products and generate incredible data on 6 clinical stage products and a range of pre-clinical assets that have best-in-class potential and are producing some incredible clinical results as they enter late-stage clinical trials and head towards commercialisation. This rapid growth rests on a number of solid foundations at Clarity that have remained the same as they have supported and nurtured our progress over these years.

One of the key foundations is great Australian science and we pride ourselves to this day on always putting science first, which has clearly differentiated us from our peers. The SAR Technology that underpins our Targeted Copper Theranostic (TCT) platform was invented and developed in Australia, at the Australian National University, University of Melbourne and Australian Nuclear Science and Technology Organisation. We continue to work closely with Prof. Paul Donnelly of the University of Melbourne's Bio21 Institute, and this relationship has seen us relatively recently develop our own PSMA product with the intent of overcoming the shortfalls of the current generation of PSMA-targeting products. With some clever and groundbreaking chemistry, the team was able to develop the PSMA dimer molecule that is now known as SAR-bisPSMA, which has quickly become the jewel in the crown of our portfolio of assets with still 15 years of patent life related to its composition of matter as it enters late-stage clinical trials. Today, we are generating very exciting data in both our therapy and diagnostic trials with the SAR-bisPSMA product as we head towards the very large prostate cancer market.

In our theranostic SECuRE trial with SAR-bisPSMA, we successfully progressed to the highest dose cohort 3 and have now treated three patients with 12GBq ⁶⁷Cu-SAR-bisPSMA and we still see no dose limiting toxicities. The safety review committee will be meeting next week before we progress with an additional three patients in this cohort, which is expected to be enrolled before year end. The data from cohorts 1 and 2 is incredibly promising despite only a single dose being used, with a third of patients from the low dose cohort 1 and all patients in cohort 2 experiencing a PSA drop of greater than 80%.

Under the US Food and Drug Administration (FDA) Expanded Access Program (EAP), clinicians requested additional therapy cycles of ^{67}Cu -SAR-bisPSMA and even at the lowest dose of 4GBq we observed a drop of over 90% in PSA levels following the fourth cycle in one patient, without the need of any additional doses at this stage. The duration of response in PSA levels in this patient demonstrates the possibilities of sustained clinical benefits following multiple doses of ^{67}Cu -SAR-bisPSMA, which is currently being investigated in the SECuRE trial. We look forward to updating you all on other patients under EAP and progressing this trial to the multi-dose cohort where we anticipate an even stronger therapeutic response.

The diagnostic programs with SAR-bisPSMA are also generating a lot of excitement in the radiopharmaceutical field as Clarity is now progressing a registrational Phase III diagnostic trial for high-risk prostate cancer patients prior to radical prostatectomy. We engaged the US FDA and received positive feedback at our successful end of phase meeting. We now look forward to opening recruitment into the CLARIFY trial before the end of the calendar year.

Although there is so much excitement around SAR-bisPSMA, Clarity has a pipeline of promising assets in development. With our second product, SAR-Bombesin, we have also been exploring therapeutic and diagnostic benefits for prostate cancer patients, in particular those who have low or no PSMA uptake, a large patient group with a high unmet need and a very limited number of treatment options available to them at present. We successfully treated our first patient with ^{67}Cu -SAR-Bombesin in the theranostic Phase I/IIa trial, COMBAT, and look forward to progressing to the higher dose cohorts.

With the diagnostic product, we successfully closed recruitment in the Phase II SABRE trial with ^{64}Cu -SAR-Bombesin in patients with PSMA-negative prostate cancer. Subject to the data from the SABRE trial, we are planning to launch a pivotal Phase III trial with ^{64}Cu -SAR-Bombesin for first approvals in the US. In addition to the SABRE trial, SAR-Bombesin is also being investigated in patients with prostate cancer in an investigator-initiated trial (IIT) led by Prof Louise Emmett at St Vincent's Hospital, Sydney, and the exciting initial data was presented at one of the most prestigious nuclear medicine conferences in the world, European Association of Nuclear Medicine (EANM) 2023 Congress in Vienna, Austria.

Our third product, SARTATE, is in theranostic development for a very important indication, neuroblastoma, which is an aggressive childhood cancer, and we remain strongly committed to progressing its development. We have now successfully completed dosing in all cohorts of the dose-escalation stage where the last patients were safely dosed at the highest dose level of 375MBq of ^{67}Cu -SARTATE per kilogram body weight. We are yet to see any dose limiting toxicities in these patients and will report back to our shareholders once we have completed safety review. We are also progressing the SARTATE product in a diagnostic indication for neuroendocrine tumours and are planning to close recruitment into the ^{64}Cu -SARTATE DISCO trial shortly.

We are very excited and encouraged by the positive data so far generated by these theranostic and diagnostic trials with these three core products, SAR-bisPSMA, SAR-Bombesin and SARTATE, and look forward to providing further updates to the market in the future. What has excited us most, particularly in relation to bisPSMA therapy, is the preliminary efficacy seen to date and the so far positive safety profile, where quality of life is a priority for these patients. These safety and efficacy signals are paving the way for us to explore new, exciting products for cancer management, and we continue to seek opportunities to improve treatment outcomes in indications with high unmet needs. Most recently, Clarity acquired an exclusive worldwide license from Memorial Sloan Kettering Cancer Center (MSK) to intellectual property covering antibody pre-targeting technology. This cutting-edge technology harnesses the benefits of antibody targeting, amplifying uptake of radiopharmaceutical products in cancerous tissue, while reducing healthy tissue exposure to radiation that can arise due to the slow clearance of antibodies. There are many examples of poor toxicity profiles of antibody-based radiopharmaceuticals, and this gives us an opportunity to directly address this issue, a strategy which we have adopted in the past to help overcome some of the material barriers radiopharmaceuticals face in being accepted as mainstream therapies.

Our clinical development strategy involves developing our products through trials at high quality clinical sites and with experienced investigators for both rare and large indications where patients have significant unmet needs and demand for new treatments is high. We are strategically leading with the development of our diagnostic products, which have a shorter pathway to market, and will follow closely with the therapeutic versions, with the aim of first product approvals in the large US market and then expanding out to further territories.

In addition to the solid foundation of science, another important foundation supporting our platform of next-generation products is the supply and manufacturing advantage enabled by TCTs as it provides a reliable, scalable, environmentally friendly and cost-effective way to bolster radiopharmaceuticals into the large oncology market. With radiopharmaceuticals expanding into large oncology indications, such as prostate cancer, TCTs are

ideally positioned to provide a sustainable future for our field with minimal supply and logistical interruptions, unlike the current generation of products, such as gallium-68 based diagnostics and lutetium-177 based therapies.

We continue to further build and expand our supply and manufacturing footprint. Our commercial-scale copper-67 supplier, NorthStar Medical Radioisotopes (NorthStar), is now routinely producing the radioisotope using their large-scale, highly efficient, environmentally preferable electron accelerator technology. NorthStar complements our ongoing supply from the Idaho State University's (ISU) Idaho Accelerator Center (IAC), which has been supplying us copper-67 for all our pre-clinical and clinical development over the last 8 years. This year, we further enhanced our ongoing collaboration with ISU and IAC by establishing a Center of Excellence, which we hope will help to advance the commercial readiness of TCTs close to a source of copper production while offering ISU students innovative career opportunities in the field of theranostic radiopharmaceuticals, our way of giving back to the science community.

This year has been monumental for Clarity as we are now progressing seven trials and getting closer to registrational studies with the clinical development as well as supply and manufacturing developing rapidly. None of that would be possible without our most important foundation, our team. As such, I would like to extend my utmost thanks to our small but extremely driven and dedicated team who are all united by our important mission of improving treatment outcomes for children and adults with cancer and continue to deliver outstanding results as we progress our pipeline of products from the benchtop to the clinic. It has grown from no employees 10 years ago to 43 highly educated and committed employees across Australia and the US today with very little turnover of staff while we continue to attract the world's best talent. Some of our team members today have been working at the Company for many years, driven by our important mission from day one. Our team is highly educated with over 26% having a PhD and over 96% having a bachelor's degree or higher in FY2023. We are committed to further training and development of our staff and this year over 73% of the team participated in external training, development and/or education programs. As a result of exceptional performance and learning, 12% of our employees were internally promoted to senior positions in FY2023. All of them were women. We are fully committed to better treating children and adults with cancer and driving significant shareholder value, and it is important to note that this is being achieved by a team that is over 75% female, and we are very proud of our team that includes a substantial majority of incredibly bright and driven women underpinning our success in next-generation radiopharmaceuticals.

I would also like to thank our Board of Directors, Advisory Board, the investigators and collaborators who are assisting us in skilfully implementing our strategic approach to advancing our diagnostic and therapy platform.

Clarity has continued and deepened its commitment to ESG practices over the year and we have just provided our ESG Report to shareholders. It outlines how we are integrating ESG policies and practices into our overall strategic objectives and sets clear goals to ensure Clarity remains at the forefront of the radiopharmaceutical industry within an ESG framework.

When it comes to the environment, radiopharmaceuticals provide superior options for diagnosis and treatment of disease and Clarity's technology has a number of advantages that clearly differentiate it when considering a sustainable future for our sector. These include our proposition of non-reactor sourced isotopes with no reliance on rare earth elements for their production, the absence of any long-lived radioactive waste products from the manufacturing process, and the avoidance of the inefficiencies of diagnostic products that utilise shorter half-life isotopes.

Our social mission of improving cancer treatment outcomes or positively affecting the lives of children extends beyond our own products. We continue working with the Australian charity Neuroblastoma Australia as their platinum sponsor of their marquee event, Run2Cure, and as mentioned earlier, with the local community organisation Story Factory, who endeavours to give a voice to local kids from under-resourced backgrounds through developing the skills of writing. We also supported the Kids' Cancer Project's Christmas for a Cure initiative, the pinnacle annual event for the charity that aims to support childhood cancer research. In the US, we started working with the EVAN Foundation, funding their Treats and Treasures Carts program. The EVAN Foundation is a charity that is making a difference every day in the fight against neuroblastoma and other childhood cancers and the Treats & Treasures Carts Program is a simple but impactful initiative that brings smiles to over 1,300 childhood cancer patients a week across 18 participating hospitals in the US and Canada. These initiatives have recently been detailed and provided to the market in our ESG report.

We remain highly confident about our technology, products, team and strategy as we enter FY24. We look

forward to reporting our progress to you as we continue along this exciting phase of our journey driven by our ultimate goal of developing next-generation radiopharmaceuticals.

I will now hand over to our CEO Colin Biggin to provide a more detailed update on Clarity's clinical and operational progress throughout the year.

Yours sincerely,

Dr Alan Taylor
Executive Chairperson, Clarity Pharmaceuticals

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This announcement has been authorised for release by the Executive Chairperson.