

ASX ANNOUNCEMENT

20 November 2024

Chairperson's Address to Clarity's Annual General Meeting 2024

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, 20th of November 2024.

Good morning, everyone,

Welcome to our fourth 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. As usual, I would also like to add that at Clarity, we are "born and bred" in the Redfern precinct, where we are meeting today, which is the spiritual home of our Indigenous brothers and sisters, and we are a proud member of our community which has a long history and strong cultural ties to our Indigenous community.

Given our origin, we are so excited to now become the largest Australian Securities Exchange (ASX) listed pharmaceutical biotechnology company by capitalisation built purely from the bench top of great Australian science. When I state this, I often hear feedback regarding CSL Limited (CSL). And although CSL is a wonderful Australian biotech company, its origins of being a government entity focused on blood products for the first 70 years of its existence before being spun out, make it a very different prospect than translating university research from the bench top.

Our formula for achieving this goal has been relatively simple. Reinforced by the hard work and dedication of our still relatively small team is an unwavering focus on delivering great science, which has clearly differentiated us from our peers in the radiopharmaceutical field. The SAR Technology that underpins our Targeted Copper Theranostic (TCT) platform was invented and developed in Australia, firstly at the Australian National University, and then the pivotal work was completed at the University of Melbourne, as we continue to work closely with the University. This relationship continues to lead to the development of many exciting products, including our lead product, bisPSMA, which overcomes the shortfalls of the current generation of PSMA-targeting products. This incredible collaboration and our science-centric approach have led to some incredible outcomes for patients in recent times.

Our work is not done, but we are ready. The focus on science leaves us in a very unique position. Having developed our products from scratch, and with a deep understanding of the products of our competitors, we have an absolute insight into how our products perform, and nothing states this more than our announcement this week regarding an investigator-initiated trial (IIT) led by Clarity's long-term collaborator, Prof Louise Emmett at St Vincent's Hospital, Sydney. The Phase II trial led by Prof Emmett will be evaluating the performance of Clarity's ⁶⁴Cu-SAR-bis-PSMA in comparison to the standard-of-care ⁶⁸Ga-PSMA-11 product for the detection of prostate cancer recurrence. Prof Emmett has been a member of Clarity's Scientific Advisory Board since 2022 and is deeply embedded in Australia's multidisciplinary clinical development and cancer research efforts. We look forward to continuing to work with her on generating data to highlight the benefits of our bisPSMA molecule over the current-generation diagnostics. Importantly, through this IIT we also look to provide access to what we consider to be a best-in-class diagnostic to more men suffering from prostate cancer in Australia, and particularly in our city of Sydney. With the R&D Tax Incentive (RDTI) and significantly lower costs for clinical trials in Australia than in the U.S., it is a very low cost for true head-to-head data to clearly differentiate ourselves in the largest prostate imaging market where current PSMA agents are failing patients in detecting early disease. We receive requests for access to our bisPSMA products almost daily and we are deeply saddened when we cannot provide these products for patients in need of better diagnostics, especially when it is in our own city of Sydney. We hope that through the Co-PSMA trial we can meet some of this demand and help improve cancer outcomes for patients close to our home.

In the meantime, we are swiftly progressing our 2 registrational Phase III trials with ⁶⁴Cu-SAR-bisPSMA to change the paradigm of prostate cancer imaging, from first diagnosis to identifying recurrent disease. Our CLARIFY trial is progressing well in patients with confirmed prostate cancer pre-prostatectomy/pre-definitive treatment, and in October the U.S. FDA provided positive guidance on the second registrational Phase III trial, AMPLIFY, in patients with

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biochemical recurrence (BCR) of prostate cancer. We plan to commence patient recruitment into AMPLIFY early next year with excellent clinical data from the COBRA trial in this patient population demonstrating that we are able to pick up lesions far earlier and far smaller than other prostate-specific membrane antigen (PSMA) imaging agents. This data was most recently selected and presented as a Top-Rated Oral Presentation at the European Association of Nuclear Medicine (EANM) Congress 2024, one of the most prestigious conferences in the nuclear medicine space.

We also recently received the U.S. FDA Fast-Track Designation (FTD) for the use of ⁶⁴Cu-SAR-bisPSMA in the pre-prostatectomy setting. The FTD was designed to expedite the development and regulatory review of novel drugs and paves the way for a potentially faster process to bring ⁶⁴Cu-SAR-bisPSMA to the market. We hope this will allow us to bring our next-generation diagnostic to patients in need of novel imaging options sooner.

In our theranostic SECURE trial with SAR-bisPSMA, we have been seeing incredible data in the dose escalation stage of the trial and in the multi-dose cohort 4 that we are hoping to complete early next year before moving into the cohort expansion phase of the trial. The safety data generated in the trial so far is excellent, with no dose limiting toxicities (DLTs) reported to date. Our oldest patient in the trial was 93 years old and had a history of prostate cancer of over 26 years, failing multiple lines of therapy prior to entering the SECURE study. Even in this patient the only adverse event (AE) he experienced was moderate nausea after the first of his 2 doses of 12GBq of ⁶⁷Cu-SAR-bisPSMA, which resolved. While the dose escalation phase is focused on evaluating safety of the product, preliminary efficacy data has been impressive. We are seeing excellent responses in patients who have been heavily pre-treated prior to receiving ⁶⁷Cu-SAR-bisPSMA, sometimes having battled their cancer for over quarter of a century with little to no options left for treatment of their disease. Importantly, these responses appear to be durable, with some patients experiencing the maximum effect from the treatment months to years after being administered with ⁶⁷Cu-SAR-bisPSMA, based on the data from the previous cohorts of the SECURE trial and two case studies where patients were administered multiple doses of the product under the U.S. Food and Drug Administration (FDA) Expanded Access Program (EAP). We really look forward to completing cohort 4 and reporting additional data. All 3 remaining slots in this cohort have now been allocated with the 3 patients already dosed with their initial cycle of 12GBq of ⁶⁷Cu-SAR-bisPSMA. This data will inform the next stages of our clinical development program, including cohort expansion in the SECURE trial and a subsequent Phase III trial.

With our unique bisPSMA agent now progressing in both diagnostic and theranostic indications, as well as our preclinical program combining the benefits of this molecule with the alpha-emitting isotope of actinium-225, patients throughout the entirety of the prostate cancer journey may benefit from this extraordinary molecule. All of these individual indications, namely imaging in pre-prostatectomy and BCR patients, as well as therapy, are blockbuster markets individually for PSMA-targeted products, with an estimated combined market value of approximately US\$10-15 billion by 2030.

Although there is so much excitement around SAR-bisPSMA, Clarity has a pipeline of promising assets in development, both in the clinic, with SAR-Bombesin and SARTATE progressing in theranostic and diagnostic trials, as well as in pre-clinical development. Given our strong patent position on the proprietary SAR Technology and our dedicated focus on science and collaboration, we can generate an infinite number of TCTs addressing indications with high unmet need and will continue exploring the possibilities of this approach.

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 who continue to deliver outstanding results as we progress our pipeline of products from the benchtop to the clinic. We have grown from no employees 11 years ago to 62 highly educated and committed team members across Australia and the U.S. today, and we continue to attract the world's best talent. Some of our current team members have been working at the Company for many years, some even for over a decade, all driven by our important mission. Recognising the importance of our team, we are committed to promoting, training and developing all of our team members. Throughout the year we have promoted approximately 15 people. One important promotion was the appointment of Ms Michelle Parker to the position of Chief Executive Officer (CEO) after exceptional leadership over the last 6 years, leading the growth of the largest group within Clarity, our clinical group. Our colleague, Dr Colin Biggin, is now leading our operations, utilising his unique experience in the position of Chief Operating Officer. We have grown our Senior Executive Team (SET) to reiterate our focus on two important areas of our business, our clinical development and our people, with the addition of Eva Lengyelova, Executive Vice President, Clinical Development, and Mary Bennett, Head, People & Culture to the SET. Dr Othon Gervasio was further promoted to Chief Medical Officer and Dr Matt Harris is now Chief Scientific Officer.

At the Board level, there have been a number of changes as well. Clarity's Non-Executive Director, Mr Rob Thomas, retired from the Board following the completion of his tenure on 23 August 2024 and in line with the announcement dated 16 January 2024. Non-Executive Director, Dr Chris Roberts, has been appointed Chair of the Audit and Risk

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Committee and joined the Nomination and Remuneration Committee. Thomas Ramdahl joined the Audit and Risk Committee, and fellow Non-Executive Director, Ms Rosanne Robinson, took the role of Lead Independent Director.

With these changes Clarity remains on track towards its goal of maintaining a gender balance at Board and Senior Executive levels in accordance with the 40:40 Vision initiative led by HESTA and the Australian Council of Superannuation Investors (ACSI). The initiative is seeking to achieve gender balance in executive leadership across all ASX300 companies by 2030. Diversity at all levels of our company is highly important to us as we believe that the unique skills and talents of our directors, officers, employees, contractors and consultants are essential for an innovative company. It is important to note that all the progress and important milestones Clarity has achieved to date were accomplished by a team that is over 70% female. With the substantial majority of our team being incredibly bright and driven women who underpin our success in next-generation radiopharmaceuticals, we will continue ensuring this is reflected at all levels of our Company, including Board and Senior levels.

Clarity has continued and deepened its commitment to ESG practices over the year and we will be providing our ESG Report to shareholders before the year end.

From our very humble beginnings only a little more than a decade ago, from a very small office in this very building where we are today in Redfern, our team and our shareholders have built the sixth largest biotech or medtech company listed on the ASX, having recently broken into the ASX300 with a high likelihood of ASX200 inclusion shortly. Given these exciting developments and rapid growth, there is now a higher level of corporate governance expected from some shareholders and proxy advisers. And whilst we understand the importance of the governance guidelines, Clarity remains a pre-revenue, relatively small company by employee size, and we operate in a highly specialised field with unique requirements where retention of talent is paramount. While we will strive to comply with all governance recommendations in due course, at present the most appropriate way to achieve our common objective is through a pragmatic approach over time. The objective we are looking to reach is no small feat as we endeavor to build the most successful biotech ever that was derived purely from the benchtop of Australian science and become the most successful radiopharmaceutical company in the history of our field, supported by a united and experienced team of employees, directors and collaborators in order to together improve treatment outcomes of children and adults with cancer.

We remain highly confident about our technology, products, team and strategy as we enter FY25 with the powerful momentum of exceptional data and the radiopharmaceutical sector being centre stage of the massive oncology market, generating multi-billion-dollar mergers and acquisitions. With over \$130 million in cash and receivables, Clarity is well funded and on track to maximising the value of our Company while delivering on our ultimate goal of improving treatment outcomes for children and adults with cancer around the world.

We thank our shareholders for their support and look forward to reporting our progress to you as we continue along this exciting phase of our journey.

I will now hand over to our CEO Michelle Parker 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.