

## **Chairman's Address to 2023 Annual General Meeting**

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Dear Shareholders,

I am honoured to welcome you all to the Annual General Meeting of Paradigm Biopharmaceuticals Ltd for the year 2023. Paradigm Biopharmaceuticals is a global, Australian-based late-stage drug development company driven by a purpose to improve patients' health and quality of life by discovering, developing, and delivering pharmaceutical therapies.

The past year has been one of both challenges and triumphs, reflecting the dynamic nature of the biotech sector. Despite global uncertainties, Paradigm Biopharmaceuticals has remained steadfast in its commitment to developing iPPS for the treatment of diseases where inflammation plays a major pathogenic role, indicating a need for the anti-inflammatory and tissue regenerative properties of pentosan polysulfate sodium.

2023 has seen Paradigm deliver positive clinical data, achieving several key milestones and significant progress in both of Paradigm's clinical assets of osteoarthritis (OA) and mucopolysaccharidosis (MPS).

The significant progress and milestones achieved in the phase 3 osteoarthritis clinical program during fiscal year 2023 culminated in the identification of the lowest effective dose for our phase 3 OA program and the enrolment of all the participants needed for stage 1 of the PARA\_OA\_002 clinical trial.

The Paradigm team worked tirelessly throughout the 12-month period to achieve our goal of activating 120 clinical trial sites to ensure rapid recruitment of the PARA\_OA\_002 study. The global phase 3 clinical trial is now operating in seven countries following regulatory and ethics approvals from the key regulatory agencies in Europe, the United Kingdom, and Canada, adding to the regulatory approvals already achieved in the US and Australia. This has been a key strategic focus for Paradigm to achieve a phase 3

clinical trial protocol that is harmonised across the major markets to achieve a clinical data package suitable for simultaneous registration across key global markets.

The successful completion of the PARA\_OA\_008 phase 2 clinical trial was another major milestone and achievement for Paradigm during 2023. Paradigm's iPPS has now demonstrated that it not only has a durable and beneficial effect on pain, function, and the patient's impression of improvement out to 12 months but is also showing improvements in the underlying disease as early as 6 months following a single 6-week treatment course. The data produced in this study will be critical in the pursuit of achieving provisional approval to market iPPS in Australia through the TGA Provisional Approval pathway.

In completing stage 1 of the PARA\_OA\_002 study, and combined with previous phase 2 results, Australian managed access program (SAS) experience, and the recently reported significant clinical and structural improvements from PARA\_OA\_008, Paradigm believes we have the necessary data to demonstrate to the FDA that the lowest effective dose for continuation in our phase 3 studies is the 2 mg/kg twice weekly dose.

Paradigm's rare disease clinical asset MPS has also delivered key program milestones during the year with the positive read-out of the MPS 1 open-label study conducted in Australia, and 100% recruitment of the MPS VI multicentre, placebo-controlled, phase 2 study in Brazil, for which we expect to provide top-line data in the very near future. We are continuing discussions to progress the development of iPPS for patients with MPS and believe that the data produced from both clinical studies will contribute to planning and design for the registration of injectable PPS as an adjunctive therapeutic option for patients with MPS I and MPS VI.

Against the backdrop of a tough share market for biotech companies, it is critical that the Company remains in a well-funded position. The recently completed \$30.1 million AUD capital raise conducted through an institutional placement and rights entitlement offer strengthens the company's balance sheet and provides the potential for additional funding through short-term option exercise. The Company and the Board remain prudent in deploying the resources available to the phase 3 OA program to continue its mission to bring iPPS to commercialisation via the most efficient path possible. I would like to thank our existing shareholders for their continued support and welcome new shareholders on our journey.

At a Board level we have also undergone changes. After 9 years, John Gaffney informed the Paradigm Board that he would be stepping down from his role as a non-executive director. I would like to take this opportunity to personally thank John for his hard work, dedication, and stewardship to Paradigm over the last 9 years. Helen Fisher has also agreed to hand over duties on the PAR board once a suitable NED is identified.

The Board of Directors has also engaged a global recruitment firm to commence a search for an appropriate Independent Chairperson capable of guiding the Company through to the completion of PAR's late-stage clinical trials, regulatory approvals, and commercialisation. I will remain in the current role as Executive Chairman until a suitable appointment is ready to be announced. The Board of Directors looks forward to updating shareholders on this process.

As we continue to discuss the achievements and challenges of the past year, I encourage each shareholder to actively participate in the discussions today. Your insights and perspectives are invaluable, and together, we can navigate the path forward with clarity and purpose.

In closing, I express my sincere appreciation to our shareholders, employees, partners, and stakeholders. Your continued support is the cornerstone of our success. Paradigm Biopharmaceuticals remains committed to its mission, and I am confident that our collective efforts will lead to a future defined by ground-breaking advancements for iPPS and sustained growth for shareholders.

Yours Sincerely,

Paul Rennie

### **About Paradigm Biopharmaceuticals**

Paradigm Biopharmaceuticals Ltd (ASX:PAR) is a late-stage drug development company driven by a purpose to improve patients' health and quality of life by discovering, developing and delivering pharmaceutical therapies. Paradigm is currently developing pentosan polysulfate sodium for the treatment of pain associated with musculoskeletal disorders driven by injury, inflammation, ageing, degenerative disease, or genetic predisposition, such as osteoarthritis (phase 3) and mucopolysaccharidosis (phase 2).

## Forward Looking Statements

This Company announcement contains forward-looking statements, including statements regarding anticipated commencement dates or completions dates of preclinical or clinical trials, regulatory developments and regulatory approval. These forward-looking statements are not guarantees or predictions of future performance, and involve known and unknown risks, uncertainties and other factors, many of which are beyond our control, and which may cause actual results to differ materially from those expressed in the statements contained in this presentation. Readers are cautioned not to put undue reliance on forward-looking statements.

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Authorised for release by the Paradigm Board of Directors.

To learn more please visit: [www.paradigmbiopharma.com](http://www.paradigmbiopharma.com)

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