

ASX RELEASE | OSTEOPORE LIMITED

## Osteopore Sponsors Australian Patient Trials To Further Develop Clinical Use Of Next Generation Bone Scaffolds

### Highlights:

- *Osteopore has signed an agreement with a renowned Queensland plastic and reconstructive surgeon to conduct two ground-breaking human clinical trials that will involve 10 patients in each study and run for up to five years.*
- *The clinical trials will involve detailed in-situ evaluation and validation of two of Osteopore's patented PCL-TCP 3D-printed bone scaffold systems and the world-leading surgical techniques used to treat patients with cranial or lower limb bone defects.*
- *The research is an important step in allowing Osteopore to further develop and refine its next generation scaffolds and expand their commercial use globally to improve the lives of more patients.*

**26 August 2021: Osteopore Limited** (ASX: OSX) (“Osteopore” or the “Company”), an Australian and Singapore based global leader in the manufacture of innovative regenerative implants at commercial scale, is pleased to announce it has signed an agreement to sponsor two clinical trials in Brisbane, Australia, to further evaluate and validate the clinical use of its next-generation cranial and long bone reconstruction scaffolds.

Brisbane-based Dr Michael Wagels, a world-recognised plastic and reconstructive surgeon will lead a team of specialist surgeons who will undertake a comprehensive study of Osteopore's next-generation 3D-printed medical grade polycaprolactone/tricalcium phosphate (PCL-TCP) scaffolds and the world-leading surgical technique used to implant them in patients. Further clinical investigation has been instigated after encouraging results in several first-in-human cases. These include reconstruction of two tibias, one midface, two mandibles and one skull.

Both studies are single-arm feasibility trials and each one will involve the recruitment of 10 patients who Dr Wagels and the team at the Australian Centre for Complex Integrated Surgical Solutions will follow closely for up to five years. Trial patients will be treated at the Princess Alexandra Hospital in Brisbane and supported by the Herston Biofabrication Institute, with future expansion to the Royal Brisbane and Women's Hospital.

One study will evaluate Osteopore's PCL-TCP scaffold system with corticoperiosteal tissue transfer for the reconstruction of acquired calvarial or upper cranial defects in adults. The other study will evaluate the Company's PCL-TCP scaffold system with corticoperiosteal tissue transfer for the reconstruction of critical sized lower limb bone defects. The trials will validate the clinical technique of using the corticoperiosteal flap in combination with these next-generation products and will provide Osteopore with important patient data to further support market adoption and penetration.

Dr Lim Jing, Osteopore Chief Technology Officer said: "This is an important milestone in the development of our second-generation regenerative implants. This study aims to clinically validate our regenerative solution for cranioplasty, and cements our standing in the field of in-situ tissue engineering. We look forward to keeping stakeholders abreast of our progress as we move through the recruitment period expected to be completed over the next 2-3 years, and as we follow our patients' progress at regular intervals for up to 24 months."

Khoon Seng Goh, Osteopore CEO added: "We are pleased to be working with Dr Wagels and his team to evaluate and further develop the applications of a new generation of implants. This is an important step in commercialising our latest innovations, which will increase our competitive edge in the regenerative industry and better improve the quality of patients' lives."

Dr Wagels, who has conducted three world-first operations using Osteopore patient specific implants, said: "These implants and the technique we have pioneered to implant them are the beginnings of a new and exciting era in regenerative medicine. We know from the operations we have performed that the technology can have a life-changing effect on patients' lives. We now have an opportunity to treat more patients in the same way and to study their outcomes in great detail, which will build on existing knowledge."

*This announcement has been approved for release by the Board of Osteopore.*

For more information, please contact:

**Carl Runde**

Chief Financial Officer

Osteopore Limited

+61 4 0011 8017

[carl\\_runde@osteopore.com](mailto:carl_runde@osteopore.com)

### **About Osteopore Limited**

Osteopore Ltd, an Australian ASX listed company (OSX) with R&D and manufacturing in Singapore, is the global leader in the manufacture of innovative regenerative implants at commercial scale. By combining biomimetic tissue science with proprietary 3D printing and materials technology, Osteopore produces medical implants to meet the needs of both tissue and bone reconstruction as well as restoration. These bioresorbable implants provide a scaffold for bone regeneration, dissolving predictably over time to leave only natural bone tissue. In collaboration with clinicians and researchers, Osteopore develops and manufactures implants that address unmet clinical needs which improve patient outcomes,

enhances lives, and potentially reduces healthcare costs. For more information, visit us at [www.osteopore.com](http://www.osteopore.com)

### **About the Herston Biofabrication Institute**

Herston Biofabrication Institute (HBI) is the first institute of its kind – advancing knowledge and patient outcomes in clinical applications of medical devices and ancillary technology. This includes new and emerging capabilities in 3D scanning, 3D modelling and 3D printing of medical devices and ultimately, human tissues with a bold plan for the biofabrication of organ systems. Opened in 2020, the Institute takes a multidisciplinary approach, bringing together clinicians, academics, industry, and consumers in its 1,500-sqm, state of the art facility.

The Herston Biofabrication Institute will transform how healthcare is provided by developing innovative and automated treatments as well as new interdisciplinary approaches to education and training for clinicians, scientists, engineers, and entrepreneurs.

Additionally, in line with the Advance Queensland agenda, HBI will continue growing Queensland's economy and scientific footprint, expanding advanced manufacturing and attracting industry engagement and research. Supported by its core academic partner the University of Queensland, the Institute has established translational clinical research programmes in the disciplines of orthopaedics, urology, vascular surgery, burns, skin and wounds, cancer care, craniofacial, and anaesthesia and intensive care.

For more information visit us at <https://metronorth.health.qld.gov.au/herston-biofabrication-institute>

### **About the Australian Centre for Complex Integrated Surgical Solutions**

The Australian Centre for Complex Integrated Surgical Solutions (ACCISS) facilitates access to clinically applied digital innovations. These may help patients with complex problems that challenge the full scope of established treatments. ACCISS can assist by assembling the necessary expertise to comprehensively evaluate the problem and then work towards a solution using existing and emerging clinically applied digital innovations. These may include clinically relevant aspects of 3D printing including reference biomodels and surgical guides, surface scanning, augmented and virtual reality, virtual surgical planning, navigated surgery, robotics, artificial intelligence and as yet, undeveloped modalities. At ACCISS, the patient and their clinical problem are the focus.

ACCISS was founded in 2019 with the support of Metro South Health, the Princess Alexandra Hospital Research Foundation and the Translational Research Institute (TRI). Since then, ACCISS has undertaken three first in human trials of new bioresorbable medical devices, which has spawned formal clinical trials sponsored by industry partners. With this foundation, ACCISS has developed a research portfolio that is clinically focussed.

For more information visit us at <https://www.tri.edu.au/acciss>

### **Forward Looking Statements**

Statements contained in this release, particularly those regarding possible or assumed future performance, revenue, costs, dividends, production levels or rates, prices or potential growth of Osteopore Limited, are, or may be, forward looking statements. Such statements relate to future events and expectations and, as such, involve known and unknown risks and uncertainties. Actual results may differ materially from those expressed or implied by these forward-looking statements depending on a variety of factors.