

ASX RELEASE | OSTEOPORE LIMITED

## DEVELOPMENT OF NEW 3D PRINTED BONE IMPLANT

**22 July 2020:** Osteopore Limited (ASX: OSX) (“Osteopore” or the “Company”), a revenue generating medical technology company that has commercialised a range of patented 3D printed bioresorbable products, is pleased to announce it has signed an Exclusive Option to Licence novel 3D printed modular bone implant technology being developed at the Queensland University of Technology (QUT).

The technology complements Osteopore’s current bone regenerating products and has shown encouraging early stage results for regrowth of long bone defects in patients who have lost more than six centimetres of bone to injury or disease. The modular implant technology is unique as it allows stacking and locking between implants while enabling the surgeon to reconstruct bone defects based on needs at the point of surgery. This latest technology has the potential to disrupt the supply chain model of customized implants, because customization may be achieved at the point of use.

QUT and Osteopore will initially collaborate to generate sufficient clinical data that will support and facilitate a regulatory submission to the TGA, FDA and European regulators, and de-risk the technology before evaluation of the potential opportunity for acquisition of the technology by Osteopore. If successful, Osteopore has the option to secure exclusive commercialisation rights via a further licensing agreement over the technology.

The agreement with QUT anticipates the relationship between Osteopore and QUT progressing through two stages:

### **Stage One: Gather Clinical Data**

Osteopore and QUT intend to initially collaborate on developing a clinical data set in compliance with ISO 13485, to support and de-risk a regulatory submission in relation to the Technology. This includes, conducting non-human pre-clinical trials in advance of future human trials, along with developing patent strategy and applications in relation to the technology. The first-in-human study (studies) are expected to be performed in collaboration with a well-regarded clinical institution in Australia.

After all necessary tests and clinical data are collected, if the data is favourable the exclusive licence to Osteopore will be activated, and Osteopore will lead further development, regulatory approval, and market launch.

### **Stage Two: Regulatory Approval & Commercialisation**

If Osteopore is satisfied on progress of the technology during Stage 1 and has executed an exclusive worldwide licence to commercialise the technology, further product development may be required and regulatory planning will commence with the design of clinical trials required to generate the data set needed for targeted submissions to the US FDA and other important authorities including CE and TGA.

Osteopore have a proven record of successfully commercialising research technology, evidenced by its global regulatory approvals for Osteoplug<sup>™</sup> and Osteomesh<sup>™</sup> products. Osteopore plans to develop a go-to-market strategy that takes advantage of the Company’s well-established sales network and relationships with clinical partners who can assist in driving product uptake.

## **Commercial Terms of the Collaboration**

Osteopore will provide cash of \$40,000, plus in-kind support towards this project, which has also secured a further \$100,000 of non-dilutive grant funding from QUT, providing Osteopore with a well leveraged and low-cost product development program with potential for future commercial outcomes. Under any future commercial agreement with QUT, Osteopore would be required to pay a market entry fee of \$100,000 and provide royalties on sales with a potential range of 2-6%.

Osteopore wishes to advise that this project has a long development pathway and it could take years to commercialise any products, or not at all.

## **Potential Market Opportunity**

The target market for this technology is orthopaedic surgery, in reconstruction of long bone defects in the upper and lower extremities. According to a market report by Boston Consulting Group in 2015, polymer-based biomaterials are entering the expansion phase of market adoption trend and maturity, indicating a significant growth potential. In a more recent report published in March 2018, the CAGR for reconstructive implants in orthopaedic and spine is at 5.1%, projecting a global market potential of approximately \$30 billion by 2022.

It is estimated that 2.2 million grafting procedures are carried out annually worldwide, with approximately 10% of the grafting being for long bones, giving an addressable market of 220,000 procedures. With the ability to regrow normal bone, the modular implant technology has a potential advantage over traditional grafting, where bone needs to be harvested from another site in the body. This could provide a commercial and clinical advantage, which would translate into a potential share of the bone grafting market.

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

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## **About Osteopore Limited**

Osteopore Ltd is an Australian and Singapore based medical technology company commercialising a range of bespoke products specifically engineered to facilitate bone healing across multiple therapeutic areas. Osteopore's patented technology fabricates specific micro-structured scaffolds for bone regeneration through 3D printing and bioresorbable material.

Osteopore's patent protected scaffolds are made from proprietary polymer formulations, that naturally dissolve overtime to leave only natural, healthy bone tissue, significantly reducing post-surgery complications that are commonly associated with permanent bone implants.