ASX RELEASE | OSTEOPORE LIMITED

OSTEOPORE SUCCESSFULLY TRANSITIONS TO NEW EU MEDICAL DEVICE REGULATION

Highlights:

- *Osteopore achieves MDR transition; joins select group of companies to transit successfully (only 12.7% of certificates transitioned by the end of 2022)*
- *Osteopore now positioned to take advantage of its advanced compliance to further penetrate the European market worth USD 550 million annually*
- *Osteopore's two main products have a market opportunity of ~USD 410 million annually*

27 April 2023: Osteopore Limited (ASX: OSX) ("Osteopore" or the "Company"), a revenue-generating manufacturer of regenerative implants that empower natural tissue regeneration, is pleased to announce it has successfully transitioned to the Medical Devices Regulation 2017/745 (MDR), effective 24 April 2023. This represents a significant achievement in Osteopore's continued regulatory compliance and secures the Company's business continuity in the European Union.

The new European Union Medical Device Regulation 2017/745 (MDR) is replacing the Medical Device Directive (MDD) and the Active Implantable Medical Devices Directive (AIMDD). According to a report as of December 2022[1], only 12.7% of certificates are approved with the MDR. Osteopore is excited to join this select group of companies that have taken the initiative to transit to the MDR.

The new MDR aims to improve product quality, reliability, safety, and performance. Several of the new requirements involve an increased focus on traceability and transparency throughout the medical device supply chain, more clinical evidence and increased post-market surveillance activities.

There are three levels of classification for medical devices under the MDR, with Class I being the lowest risk devices, and Class III being the highest risk medical devices. Considerable time and effort were dedicated towards ensuring Osteopore products Osteomesh®, Osteoplug® and Osteoplug®-C all achieved the new MDR certification as Class III medical devices.

The European market presents an annual opportunity of around USD 550 million, of which Osteopore's two main products relating to craniotomy and burr hole[2] have an annual market opportunity of around USD 410 million. The MDR certification gives Osteopore the impetus to resume engagement with hospitals, surgeons and healthcare decision makers, through our distributors. This successful transition also secures continued supply of products for the Company going forward.

Osteopore's Executive Chairman, Mark Leong said:

"The European Union is an important market for the Company, and we made a conscious effort to act early in submitting all relevant applications and meeting the new requirements. This means it is

[1] https://www.team-nb.org/wp-content/uploads/members/M2023/Team-NB-MD-Sector-Survey-PressRelease-20230411.pdf

[2] Cetas Healthcare commissioned report, December 2020

business as usual for us, as we continue to actively engage with our European distribution partners to expand sales across the region."

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 products specifically engineered to facilitate natural 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 manufactured using a proprietary manufacturing technique with a polymer that naturally dissolve over time to leave only natural, healthy bone tissue, significantly reducing post-surgery complications commonly associated with permanent bone implants. Our 3D printer technology is not available in the market and unique to Osteopore.

Forward-Looking Statements

Statements contained in this press 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 various factors.