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Osteopore secures Hainan approval for custom orthopaedic devices

Highlights

- Osteopore has received approval from the Hainan Medical Products Administration (Hainan FDA) for the clinical use of its orthopaedic custom medical devices at the Hainan branch hospital of the prestigious Shanghai Ruijin Hospital, located within the Hainan Boao Lecheng International Medical Tourism Pilot Zone.
- The Hainan Boao Lecheng International Medical Tourism Pilot Zone is China's strategic and only special medical zone, benefitting from preferential national-level policies that allows innovative medical technologies and devices to be used clinically prior to receiving full mainland approval.
- The China orthopaedic devices market was valued at USD 2.5 billion (AUD 3.5 billion) in 2024, and is projected to reach USD 4.5 billion (AUD 6.4 billion) by 2035, at a CAGR of 5.6%.
- The Hainan FDA approval is a license which enables the Company to sell and market its devices in the Boao Lecheng International Medical Tourism Pilot Zone. This serves as an accelerated commercial launchpad and a regulatory springboard to full China-wide market access.
- The first patient has been identified and surgery has been scheduled in June 2026.

Australian-Singaporean regenerative medicine company **Osteopore Limited** (ASX: **OSX**; **Osteopore** or **Company**) – a global leader in 3D-printed biomimetic and bioresorbable implants – is delighted to announce that it has received approval from the Hainan Medical Products Administration (Hainan FDA) for the clinical use and sale of its orthopaedic custom



medical devices at the Hainan branch hospital¹ of Shanghai Ruijin Hospital, located within the Hainan Boao Lecheng International Medical Tourism Pilot Zone.

The Hainan FDA approval is a license which enables the Company to sell and market its devices in the Boao Lecheng International Medical Tourism Pilot Zone. Beyond early commercial and clinical engagement experience in Hainan, the Hainan FDA approval pathway allows companies to generate real-world data that can later support nationwide NMPA registration—significantly shortening the overall time to national approval. This makes Hainan FDA approval not only an accelerated commercial launchpad and also a powerful regulatory springboard toward full China-wide market access.

The Hainan Boao Lecheng International Medical Tourism Pilot Zone is China's strategic and only special medical zone, benefiting from preferential national-level policies that allow innovative medical technologies and devices to be used clinically prior to receiving full mainland approval². These include "first-in-trial" and "first-to-market" pathways, expedited import mechanisms, and real-world data pilot programs that accelerate patient access to advanced medical technologies

Shanghai Ruijin Hospital is a top-tier national institution under the Shanghai Jiao Tong University School of Medicine. It is a 3A-ranked hospital, which is the highest tier in China's national hospital classification system – not more than 5% of all hospitals in China are ranked 3A³.

¹ <https://www.boaolecheng.com/index/mechanism/article/id/6.html>

² <https://en.hainan.gov.cn/englishsite/ici/202506/d209a720422d4ba9985120cebebf0eaf.shtml?ddtab=true>

³ <https://www.chinamed.cc/blog/china-hospital-grading-system>



Additionally, Shanghai Ruijin Hospital is ranked #32 of all institutions for its share of global research output, outranking Cleveland Clinic and UCSF Health according to the latest index published by renowned publisher Nature⁴.

The hospital's strategic mandate is to be among the first in China to adopt and evaluate new drugs and devices, serving as a national-level platform for cutting-edge clinical innovation⁵.

China represents one of the largest and fastest-growing orthopaedic device markets globally, driven by demographic aging, rising musculoskeletal disorders, and rapid hospital modernisation.

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This aligns directly with Osteopore's strategy to expand its orthopaedic portfolio—particularly in customised bone regeneration solutions – and to target high-value markets where surgical innovation drives sustained demand.

Following this approval, Osteopore will commence clinical deployment and physician onboarding at Shanghai Ruijin Hospital and its Hainan branch hospital. The first patient has been identified and treatment has been scheduled in June 2026.

The Company will also evaluate strategic collaborations within China to strengthen its presence in China.

⁴ <https://www.nature.com/nature-index/institution-outputs/generate/all/global/healthcare>

⁵ <https://govt.chinadaily.com.cn/s/202305/08/WS64e468bf498ed2d7b7e98fb2/hainan-hospital-of-ruijin-hospital-affiliated-to-shanghai-jiao-tong-university-school-of-medicine.html>

⁶ <https://www.marketresearchfuture.com/reports/china-orthopedic-devices-market-44863>



Commenting on gaining access to Hainan for its orthopaedic devices, CEO Dr Yujing Lim, said:

"We are honoured to be associated with Shanghai Ruijin Hospital, a top tier 3A-ranked hospital in China particularly in orthopaedic reconstruction. The orthopaedic team whom I met recently, expressed a deep interest in regenerative bone healing, and our company is well-placed to support them in fulfilling this purpose.

"We are strongly encouraged that the first patient has been scheduled to receive surgery no later than June 2026, which gives us a quick commercial entry after obtaining regulatory approval", said Dr Lim.

ENDS

This announcement has been authorised for release to the ASX by the Board of Osteopore Limited.

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About Osteopore Limited

Osteopore Ltd. is a global medical technology company founded in Singapore and listed in Australia that commercialises products designed to enable 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 dissolves over time to only allow natural and healthy bone tissue, significantly reducing the post-surgery complications commonly associated with permanent bone implants. Our 3D printing technology is unique to Osteopore.

Forward-Looking Statements

Some of the statements appearing in this announcement may be similar to forward-looking statements. You should be aware that such statements are only predictions and are subject to inherent risks and uncertainties. Those risks and uncertainties include factors and risks specific to the industries in which the Company operates and proposes to operate as well as general economic conditions, prevailing exchange rates and interest rates and conditions in the financial markets, among other things.

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