

24 October 2024

Osteopore steps up global expansion in Brazilian craniofacial market

Highlights

- Osteopore signs exclusive 5-year Distribution Agreement with Medsite Equipamentos e Produtos Para Saude Ltda (Medsite) to distribute Osteopore's craniofacial products in Brazil.
- Osteopore seeks to leverage its global regulatory capabilities and success in North America with the US Food and Drug Administration (FDA).
- Osteopore has 24 months to complete product registration requirements with the Brazilian Health Regulatory Agency (Anvisa).
- The Agreement provides Osteopore with exposure to the \$6b p.a. Brazilian medical device market, while boosting its presence in the Latin American (LATAM) market.

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 the signing of an exclusive 5-year Distribution Agreement with Medsite Equipamentos e Produtos Para Saude Ltda (Medsite).

Under the agreement, Medsite will manage the regulatory filings in Brazil, a process expected to take approximately two years to complete. To enhance commercial adoption, Medsite will work with Zeiki Medical Produtos Medicos Ltda (Zeiki).

Established in 2006 under CEO and Founder Cristina Seixas, the Rio de Janeiro-based Zeiki supports circa 2,000 surgeries per annum. Zeiki sources innovative, high-quality and reliable products for the Brazilian market via leading global manufacturers. Zeiki's team collaborates with health operators, public entities, hospitals and clinicians across Brazil.

Zeiki is a member Abraidi (Associação Brasileira de Importadores e Distribuidores de Produtos para Saúde), of whose 300 members and associates supported circa 1.5 million surgeries (2022). In 2022, Brazil consumed USD \$3 billion in medical devices of which 39% was imported according to Abraidi.

The Agreement spans an initial 5-year term, coinciding with a projected 24-month regulatory period to complete Anvisa product registration requirements.

Commenting on Osteopore's global expansion into Brazil and LATAM, CEO Dr Yujing Lim, said:

"The decision to enter the Brazilian craniofacial market is a strategic one as it leverages the strength of US FDA and European Union CE Mark regulatory approvals. We are looking forward to introducing our craniofacial solutions to more patients in need.

"With the right partner, the Brazilian market represents a significant market opportunity. With our initial Brazilian engagement, we were strongly encouraged by the enthusiastic response of the Brazilian craniofacial surgical community," said Dr Lim.

The Brazilian medical device market is valued at more than \$6 billion annually, signifying LATAM's biggest healthcare market.

Brazilian regulatory clearance will enable Zeiki to leverage its extensive sales network and market knowledge to drive the adoption of Osteopore's products.

The Agreement will boost Osteopore's presence in LATAM and pave the way for market entry in countries including Colombia and Panama.

ENDS

This announcement dated 24 October 2024 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.

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