ASX Announcement

Orthocell Finalises Formal Agreement with Marine Biomedical and Secures Strategic Rights to Groundbreaking Bone Regeneration Technology

- Orthocell has **finalised its Formal Agreement** with Marine Biomedical Pty Ltd, increasing its direct investment in **from 1.72% to 11.7% for a total consideration of AU$1.05 million**.
- As part of the investment, Orthocell has secured a **first right of refusal** in relation to the distribution rights for Marine Biomedical's bone regeneration technology, **PearlBone™,** as well as any subsequent products developed by Marine Biomedical in the **bone repair and regeneration space**.
- PearlBone is an innovative, next-generation bone substitute product developed using **sustainably sourced pearl shells from the West Australian Kimberley coast**. The product has highly promising applications in **bone repair and regeneration** across the orthopaedic, trauma and reconstructive surgery markets.
- Execution of the Formal Agreement converts the previously announced **Memorandum of Understanding** into a **binding commercial and strategic relationship**, further strengthening Orthocell's regenerative medicine platform.
- The agreement enhances Orthocell's position as a **multi-tissue regenerative medicine company**, complementing its existing **nerve and tendon repair portfolio with advanced bone repair solutions**, particularly in trauma and reconstructive procedures where multi-tissue regeneration is often required.
- Marine Biomedical is well advanced on its pathway to **U.S. regulatory approval** for PearlBone and commercialisation, with its pivotal study nearing completion to support a **U.S. FDA 510(k) submission by March 2026**. This positions PearlBone for potential entry into the **US$1.6 billion**[1] **global bone substitute market utilising Orthocell's growing distribution network**.
- Orthocell maintains **robust cash reserves of $49.4 million**[2] and is well positioned to support continued commercial expansion. The Company also expects to receive an **R&D tax incentive refund of approximately $3.0 million** in the **March quarter FY26**.

Perth, Australia; 16 January 2026: Regenerative medicine company Orthocell Limited (ASX: OCC, "Orthocell" or the "Company") is pleased to announce it has executed a binding Formal Agreement with Marine Biomedical Pty Ltd, increasing its equity interest to **11.7%** for a total investment of **AU$1.05 million**, and securing **global distribution rights** to PearlBone™ and future bone repair products developed by Marine Biomedical.

[1] USA bone substitute repair market size was estimated using referenced papers from both US and OUS databases and studies.

[2] As at 31 December 2025, the total cash reserves were $49.4 m, comprising $7.4 m in cash and cash equivalents and $42.0m in term deposits with maturities of 3 to 12 months.

This strategic agreement strengthens Orthocell's biologic product portfolio by adding a next generation bone substitute alongside its existing nerve and tendon repair technologies. It also enables Orthocell to leverage its established distribution networks, particularly in the United States, where the Company maintains deep relationships with specialist distributors and leading orthopaedic and plastic surgeons.

Orthocell Chair, John Van Der Wielen, said: *"This partnership adds further value to Orthocell's strategy by introducing a leading bone regeneration product that can be sold alongside Orthocell's market-leading collagen device. PearlBone strengthens our biologically driven portfolio and positions Orthocell as a multi-product company spanning bone, nerve and tendon repair.*

This investment is sensibly timed for shareholders, given the impending FDA application, and we believe Marine Biomedical has the potential to become a large and successful biotechnology company in its own right."

Strategic Rationale

PearlBone is a next-generation bone substitute derived from sustainably sourced pearl shells from the West Australian Kimberley coast. The product is designed to support bone repair and regeneration in orthopaedic, trauma and reconstructive surgery, where complex, multi-tissue injuries are common.

Securing distribution rights to PearlBone and future bone repair products aligns with Orthocell's strategy to provide surgeons with a comprehensive suite of biologically advanced regenerative solutions across nerve, tendon and bone.

The Marine Biomedical team operates autonomously and is not expected to require any significant internal resourcing commitment from Orthocell.

Regulatory and Commercial Outlook

Marine Biomedical continues to progress PearlBone toward U.S. regulatory approval and is nearing completion of its pivotal study to support a U.S. FDA 510(k) submission in the March quarter FY26, targeting entry into the US$1.6 billion global bone substitute market.

Governance Note

Orthocell's Managing Director, Paul Anderson, is also a Director of Marine Biomedical Pty Ltd. In accordance with best practice corporate governance, Mr Anderson abstained from Board deliberation and voting on Orthocell's decision to enter this Formal Agreement.

Release authorised by:

Paul Anderson, Orthocell Ltd CEO and MD

For more information, please contact:

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About Orthocell Limited

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Orthocell is a regenerative medicine company focused on regenerating mobility for patients by developing products for the repair of a variety of bone and soft tissue injuries. Orthocell's portfolio of products include a platform of collagen medical devices which facilitate tissue reconstruction and healing in a variety of dental and orthopaedic reconstructive applications. Striate+™ was the first product approved for dental GBR applications, is cleared for use in the US, Australia, New Zealand, Singapore, UK, Europe, Canada and Brazil and is distributed globally by BioHorizons Implant Systems Inc. Remplir™, for peripheral nerve reconstruction, recently gained clearance for use in the US. The Company has appointed a network of specialist US distributors and recorded initial sales. The Company's flagship nerve repair product is also approved in Australia, New Zealand and Singapore where it is distributed by Device Technologies Group. Other Remplir approvals include Thailand, Canada and Hong Kong. SmrtGraft™, for tendon repair, is available in Australia under Special Access Scheme or participation in a clinical trial. The Company's other major products are autologous cell therapies which aim to regenerate damaged tendon and cartilage tissue. Orthocell is accelerating the development of its tendon cell therapy in the US with technology transfer and FDA engagement to confirm the path to the US market and prepare for partnering discussions.

For more information on Orthocell, please visit www.orthocell.com or follow us on Twitter @Orthocellltd and LinkedIn www.linkedin.com/company/orthocell-ltd

Forward Looking Statement

Any statements in this press release about future expectations, plans and prospects for the Company, the Company's strategy, future operations, and other statements containing the words "anticipate," "believe," "estimate, "expect," "intend," "may," "plan," "predict," "project," "target, "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the Company's ability to successfully develop its product candidates and timely complete its planned clinical programs and the Company's ability to obtain marketing approvals for is product candidates. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.