

# **ASX Announcement**

# Orthocell secures global distribution rights to innovative bone regeneration technology via its increased investment stake in Marine Biomedical

Enhances core regenerative medicine portfolio across nerve, tendon and bone

- Orthocell has executed a Memorandum of Understanding with Marine Biomedical Pty Ltd, a
  Western Australian biotech company, to increase its equity stake from 1.7% to 12.0% for a total
  consideration of AU\$1.0 million.
- The AU\$1 million dollar investment is contingent upon Orthocell securing exclusive first right of refusal in relation to the global distribution rights to Marine Biomedical's groundbreaking PearlBone™, a bone substitute product, developed using sustainably sourced pearl shells from the West Australian Kimberley coast.
- **PearlBone is an innovative, next-generation biomaterial** with promising applications in bone repair and regeneration in the orthopaedic, trauma and reconstructive surgery market.
- This strategic agreement enhances Orthocell's core regenerative medicine portfolio, providing surgeons with biologically advanced products across nerve, tendon and bone repair, particularly in trauma and reconstructive procedures where multi-tissue regeneration is often required.
- Marine Biomedical is well advanced in its path to US regulatory approval of PearlBone, nearing completion of its pivotal study designed to support a U.S. FDA 510(k) marketing submission in 1Q CY26 to commercially distribute PearlBone into the US\$1.6 billion¹ bone substitute market.
- Orthocell and Marine Biomedical will use reasonable endeavours to complete the Formal Agreements by the end of November 2025.
- Following its recent Placement, Orthocell is well funded with over \$50m in cash reserves

**Perth, Australia; 20 October 2025:** Regenerative medicine company Orthocell Limited (ASX: OCC, "Orthocell" or the "Company") is pleased to announce it has executed a Memorandum of Understanding (MoU) with Marine Biomedical Pty Ltd, a Western Australian biotechnology company, to increase its existing equity stake from 1.72% to 11.70% for a total investment of AU\$1.05 million.

The investment is contingent on Orthocell securing first right of refusal in relation to the global distribution rights to Marine Biomedical's products including PearlBone™ - a novel, next-generation bone substitute product developed using sustainably sourced pearl shells from Western Australia's Kimberley coast.

<sup>&</sup>lt;sup>1</sup> USA bone substitute repair market size was estimated using referenced papers from both US and OUS databases and studies.



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 delivers exactly what we look for — breakthrough science, a clear regulatory path, and immediate commercial synergy. With our strong surgeon relationships and global distribution channels, we are ideally positioned to bring this first-inclass product to market. Marine Biomedical has had significant grant support from the Western Australian Government and has been working for many years on the development of this product.

Orthocell is committed to its biologically driven portfolio for regenerative repair — bone, nerve, and tendon — and this partnership helps strengthen this strategic direction. It is a purposeful investment, with outstanding potential to enhance patient outcomes, grow revenue and shareholder value.

It is an ideal time to invest at this pivotal stage of the planned FDA submission for PearlBone, and Marine Bio Medical business is on a strong growth trajectory. We expect the value of the Marine Biomedical business to increase significantly as its unique bone products achieve regulatory approvals - a pathway well understood by Orthocell."

#### **About Marine Biomedical**

Marine Biomedical is a Western Australian biotech company developing marine-derived medical products, including PearlBone, a first-of-its-kind bone substitute made from pearl shell with promising applications in bone repair and regeneration in the orthopaedic, trauma and reconstructive surgery market. Marine Biomedical has a world-class team of scientific researchers and business leaders committed to developing innovative medical products derived from sustainable marine resources.

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

# **US Regulator progress**

Marine Biomedical is nearing completion of a pivotal study designed to support a U.S. FDA 510(k) marketing submission in Q1 CY2026. This will enable commercial distribution of the PearlBone in the US\$1.6 billion<sup>2</sup> bone graft and substitute market.

#### **Transaction timing**

The parties will use reasonable endeavours to negotiate and enter into a Formal Agreement within 30 business days of executing the MoU. Completion of the Subscription Agreement will occur within 5 business days of executing the Formal Agreement.

#### **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 Memorandum of Understanding.



# Release authorised by:

Paul Anderson, Orthocell Ltd CEO and MD

# For more information, please contact:

# **General enquiries**

Paul Anderson
Orthocell Limited
CEO and MD
P: +61 8 9360 2888
E: paul.anderson@orthocell.com

# **Media enquiries**

Haley Chartres
H^CK Director

P: +61 423 139 163 E: haley@hck.digital

# **Investor enquiries**

Shaun Duffy VECTOR Advisors

P: +61 404 094 384

E: sduffy@vectoradvisors.au

# About Orthocell Limited ACN 118 897 135

Registered Office – Building 191 Murdoch University, 90 South Street, Murdoch WA 6150 Australia. 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 14 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 and Canada. 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 <a href="www.orthocell.com">www.orthocell.com</a> or follow us on Twitter <a href="www.linkedin.com/company/orthocell-ltd">@Orthocell-ltd</a>

# **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.

