

Orthocell Achieves a Third Consecutive Quarter of Record Revenue as Strong Growth Continues

- Orthocell's rapid market penetration continues with the achievement of a third consecutive quarter of record revenue, reporting \$2.21 million in the December '24 Quarter.
- Revenue is up 9% on the previous record of \$2.03 million achieved in the September '24 Quarter, an impressive result given the December Quarter traditionally is seasonally lower.
- Revenue is also up 46% on the previous corresponding December '23 Quarter of \$1.51 million showing significant and sustained growth.
- Striate+™ is currently sold in the US, Canada, Europe, UK, Australia and New Zealand. Remplir is currently sold in Australia, New Zealand and in the month of December recorded its first sales in Singapore.
- Multiple new international markets are nearing regulatory approvals as Orthocell pushes ahead with its global commercialisation plans targeting a market opportunity worth circa US\$4.5 billion¹ in key markets.
- Of particular focus is the near-term FDA approval of Remplir™ in the US which is expected by March/April 2025 and will open up the significant US\$1.6 billion² USA nerve repair market opportunity.
- The Company remains well funded to continue its aggressive growth plans with circa \$31 million in cash and an R&D rebate of approximately \$3 million expected in the March Quarter.

Perth, Australia; 8 January 2025: Regenerative medicine company Orthocell Limited (ASX: OCC, "Orthocell" or the "Company") is pleased to announce continued growth in sales of its market-leading medical devices, Striate+™ and Remplir™. The record revenue achieved for the December '24 Quarter marks the third consecutive quarter of record revenue for the Company.

Orthocell CEO and MD, Paul Anderson, said: "We are delighted with the continued growth in demand and record quarterly revenue for our market-leading products Striate+ and Remplir. The majority of revenue growth is in existing markets, demonstrating increasing market traction, driven by the consistent and predictable outcomes surgeons can achieve using our products. We are excited by the potential for exponential growth and believe we are on track to become a key player in the US\$4.5 billion global market we are targeting. The near-term US FDA approval which we expect in March / April 2025 will be a very significant catalyst of value for the Company, opening up the substantial US\$1.6 billion US nerve repair market."

Orthocell currently has two products in market – Striate+ for dental bone regeneration and Remplir for peripheral nerve repair. The global market opportunity for these two products in nine key jurisdictions (USA, EU, UK, AUS/NZ, SGP, CAN, BRZ, JAP, THA) is estimated to be approximately US\$4.5 billion. Expansion into other markets would see an increase in these projections, demonstrating significant growth potential for the Company in the immediate future.

¹ Addressable markets include AUS, USA, EU/UK, SGP, CAN, BRZ, JAP & THA. Referenced papers were used to estimate procedures per annum. Papers used included both US and OUS databases and studies.

² USA nerve repair market size was estimated using referenced papers from both US and OUS databases and studies.



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Striate+ is distributed globally by BioHorizons Implant Systems Inc (BioHorizons), one of the largest global dental implant companies. Remplir is distributed by Device Technologies (DVT), a respected name in the provision of medical devices and healthcare solutions across Australia, New Zealand and Singapore. Orthocell has been working with its distributor partners to drive uptake of Striate+ and Remplir in key regulatory markets.

These strategic partnerships have resulted in significant revenue growth, with increasing quarterly revenue of \$2.21 million in the December '24 Quarter, up 46% from \$1.51 million in the same quarter last year. This revenue growth is evidence that Orthocell's products are achieving traction with new and existing surgeons in their respective markets, which is underpinned by excellent performance of these novel devices in clinical practice.

Striate+ is currently available for sale in the US, Europe, UK, Australia, New Zealand and Canada, while Remplir is available for sale in Australia, New Zealand and Singapore. The significant revenue growth Orthocell has achieved is set to increase with additional approvals in other markets. Orthocell has a regulatory and clinician engagement strategy in place for both products to expand access into other geographical regions.

Orthocell has a strong balance sheet with ~\$31 million in cash as at 31 December 2024 (and a R+D Grant of over \$3 million expected in the March '25 Quarter) to support its focused growth strategy. Orthocell is well funded for its global market expansion strategy and beyond the pivotal US product registration for Remplir expected by March/April 2025.

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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 US FDA (510k), Australia (ARTG), New Zealand (WAND), UK (UKCA Mark) and Europe (CE Mark) and is distributed globally by BioHorizons Implant Systems Inc. Remplir™, for peripheral nerve reconstruction, recently received approval and reimbursement in Australia and is distributed exclusively by Device Technologies in the Australian market. 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 its 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.



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