

Orthocell Continues Global Market Expansion with First Sales of Striate+™ in New and Significant Market of Canada

- Orthocell's exclusive global distribution partner BioHorizons has recorded first sales of Striate+™ in the key market of Canada
- First sales for Striate+, for use in dental guided bone and tissue regeneration, have quickly followed the recent regulatory approval from Health Canada in early July, demonstrating the rapid conversion from approval into sales and revenue generation in new markets
- The Canadian market alone is estimated to be worth AU\$60 million, with the global market opportunity for Striate estimated to be in excess of AU\$1 billion¹.
- Striate+ is gaining excellent traction and growing revenue in US, EU, UK and AU, supported by an outstanding 98.6% success rate from the Striate+ dental implant post-market clinical study.
- Given traction in existing markets, the Company is accelerating market access into multiple new large markets, with Brazil and Singapore regulatory approvals anticipated within 6-12 months.
- Clear revenue traction is being demonstrated by the Company with record revenue of \$6.76m in FY24 (up 30.76% YoY), including record revenue of \$1.84m in the June 23 Qtr.

Perth, Australia; 06 September 2024: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") today announced global distribution partner BioHorizons has recorded a fast transition to first sales of Striate+™ in the key market of Canada, following recent regulatory approval in early July. Striate+ can now be used in Canada in dental guided bone and tissue regeneration procedures. For more information [click here](#).

Orthocell Managing Director, Paul Anderson, said: "Commencement of sales in Canada is further validation of Orthocell's expanding global footprint. Our valued partner BioHorizons has executed a rapid transition from approval to first sales. This reaffirms the high-quality nature of our product and partnership. Once Singapore and Brazil applications are approved, Striate+ will be available for use in guided bone and tissue repair in seven large and attractive markets. And we will continue to accelerate approvals in what is a significant AU\$1 billion annual global market."

Striate+ is a collagen membrane used to support dental guided bone and tissue regeneration procedures. Striate+ is approved for use in the USA, Australia, New Zealand, Europe, United Kingdom and Canada and is exclusively distributed by BioHorizons Implant Systems Inc (BioHorizons), one of the largest global dental implant companies. The global market opportunity for Striate+ is estimated to be approximately >US\$730 million¹ (circa AUD\$1.1 billion), with the Canadian market contributing approximately US\$40 million (circa AU\$60 million).

Strong sales traction for Striate+ in existing markets has resulted from BioHorizon's comprehensive marketing and medical education program, and the outstanding 98.6% success rate observed in the Striate+ post-market clinical study. Striate+'s high quality performance is driving BioHorizons' pursuit of other large, attractive

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

markets where they have established accounts and/or distribution networks. Orthocell is currently working with BioHorizons to expand regulatory approvals of Striate+ in multiple new markets. In particular, regulatory approval for Striate+ in Brazil and Singapore is anticipated within 6-12 months, with further applications under review.

The strategic partnership has resulted in significant revenue growth for Orthocell, with increasing quarterly revenue and record annual total revenue in FY24 of \$6.76 million, up 30.76% from the previous year (FY23) of \$5.17 million. This revenue growth is evidence that Orthocell's products are achieving strong uptake in their respective markets.

Orthocell is well positioned to drive Striate+ into global markets, with a strong cash position of \$20.6m¹, focused regulatory program targeting multiple strategic markets and a global distribution partner driving product marketing and sales.

Release authorised by Managing Director Orthocell Ltd, Paul Anderson.

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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 Collagen Medical Device platform 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, Canada, Australia, New Zealand, UK and Europe 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 and New Zealand markets. 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](https://twitter.com/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.

ⁱ Cash position as at 30 June, 2024

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