Orthocell Accelerates Global Market Expansion of Striate+™ and Remplir™ With Seven New Regulatory Applications Submitted and Planned on the Back of Record Revenues in FY24

- **Orthocell is accelerating global market expansion plans for its medical devices with seven regulatory applications in progress or planned in large and attractive new markets**
- **With Striate+™ gaining excellent traction in the US, Europe/UK and Australia, and being recently approved in Canada, the Company is accelerating market access into the large markets of Brazil and Singapore with regulatory approvals anticipated within 6-12 months**
- **Orthocell is also working with exclusive global distribution partner BioHorizons, to achieve further Striate+ regulatory approvals into multiple new large markets**
- **The key Remplir™ product is also gaining strong traction in Australia with regulatory approval in Singapore anticipated within 6 months and the material US FDA approval expected within 9 months**
- **The Company is accelerating market expansion of Remplir into other new markets with a further three regulatory applications in Canada, Thailand and EU/UK planned for submission in the coming months**
- **The global market opportunity for these products is estimated to be in excess of US$3 billion (circa A$4.5 billion)**
- **The Company has a strong balance sheet of $20.6 million, record revenue of $6.72m in FY24 (up 30% YoY) and is well-positioned to broaden its commercial footprint and grow product adoption and revenues in existing and new markets**

Perth, Australia; 24 July 2024: Regenerative medicine company Orthocell Limited (ASX: OCC, "Orthocell" or the "Company") is pleased to announce the accelerated market expansion of Striate+™ and Remplir™, with seven regulatory applications either in progress or planned for its medical device platform products.

Orthocell currently has two products gaining market traction – Striate+ for guided bone and tissue regeneration, and Remplir for peripheral nerve repair. The combined global market opportunity for these two products is estimated to be approximately US$3 billion[1] (circa A$4.5 billion) with Orthocell targeting a 20% market share for both products. Effective expansion into other markets would see an increase in these projections, demonstrating enormous growth potential for the Company in the near term.

Striate+™ for dental bone repair

Striate+ is a collagen barrier membrane used to support guided bone and tissue regeneration in dental implant procedures and is cleared for use in the USA, Australia, Europe/UK and Canada. Striate+ is exclusively distributed globally by BioHorizons Implant Systems Inc (BioHorizons), one of the largest global dental implant companies. BioHorizons successfully completed a US product launch of Striate+ in November 2022, with a focus on supplying existing Key Opinion Leader (KOL) accounts and other major customers.

[1] Company estimate of addressable market size for Striate+ (US, EU/UK, AU, CAN, BRZ & JAP) and Remplir (US, EU/UK & AU). Sources include iData Research Inc and other publicly available market research reports and published literature.

Strong sales traction for Striate+ in existing markets (AU, US, EU/UK) 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 markets where they have established accounts and/or distribution networks (Figure 1). Orthocell are 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 (Figure 1), with further applications under review.

Orthocell and BioHorizons are targeting large addressable markets with ~5.5M dental membranes estimated to be used in dental guided bone and tissue regeneration and implant procedures per annum in existing (US, EU/UK, Australia and Canada) and planned markets (Brazil and Singapore).

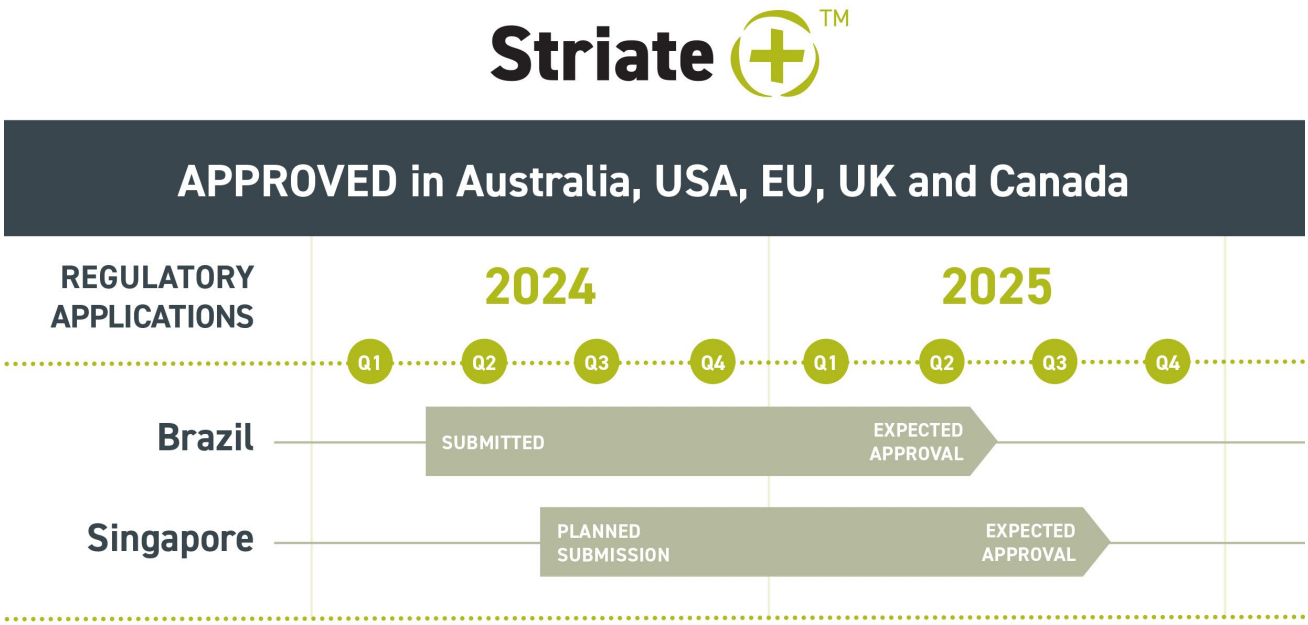

Figure 1: Global Regulatory Strategy for Striate+ 2024-2026

Remplir – Redefining Nerve Repair

Remplir is a collagen wrap used to augment nerve repair surgery. Remplir is approved for sale in Australia and New Zealand and is distributed by Device Technologies (DVT). DVT officially launched Remplir in Australia in November 2022, and the ramp up of product sold in the last ~18 months is gaining traction, with 120+ orthopaedic and plastic surgeons across Australia and New Zealand now using Remplir in peripheral nerve repair surgeries.

Feedback and uptake by Surgeons has been very encouraging, with adoption driven by Remplir's unique qualities that enable the reduction of damaging sutures, the creation of the optimal healing microenvironment and facilitation of free gliding within the repair site during the critical healing period.

Orthocell's global expansion strategy for Remplir continues to build, with the Company on track to receive regulatory clearance from the US FDA in 1Q CY25. Regulatory approval for Remplir in Singapore is expected in

2H CY24, following an application to the Health Services Authority (HSA) in Singapore in January 2024 (Figure 2). Approval in Singapore is considered the gateway to other ASEAN markets (e.g. Thailand, Malaysia, Vietnam, Indonesia and Philippines). Orthocell has a further three applications planned in Canada, Thailand and EU/UK within the next 6-12 months.

Orthocell is targeting large addressable markets with ~1.6M peripheral nerve repairs estimated across existing (Australia) and planned markets (Singapore, USA, Canada, Thailan & EU/UK).

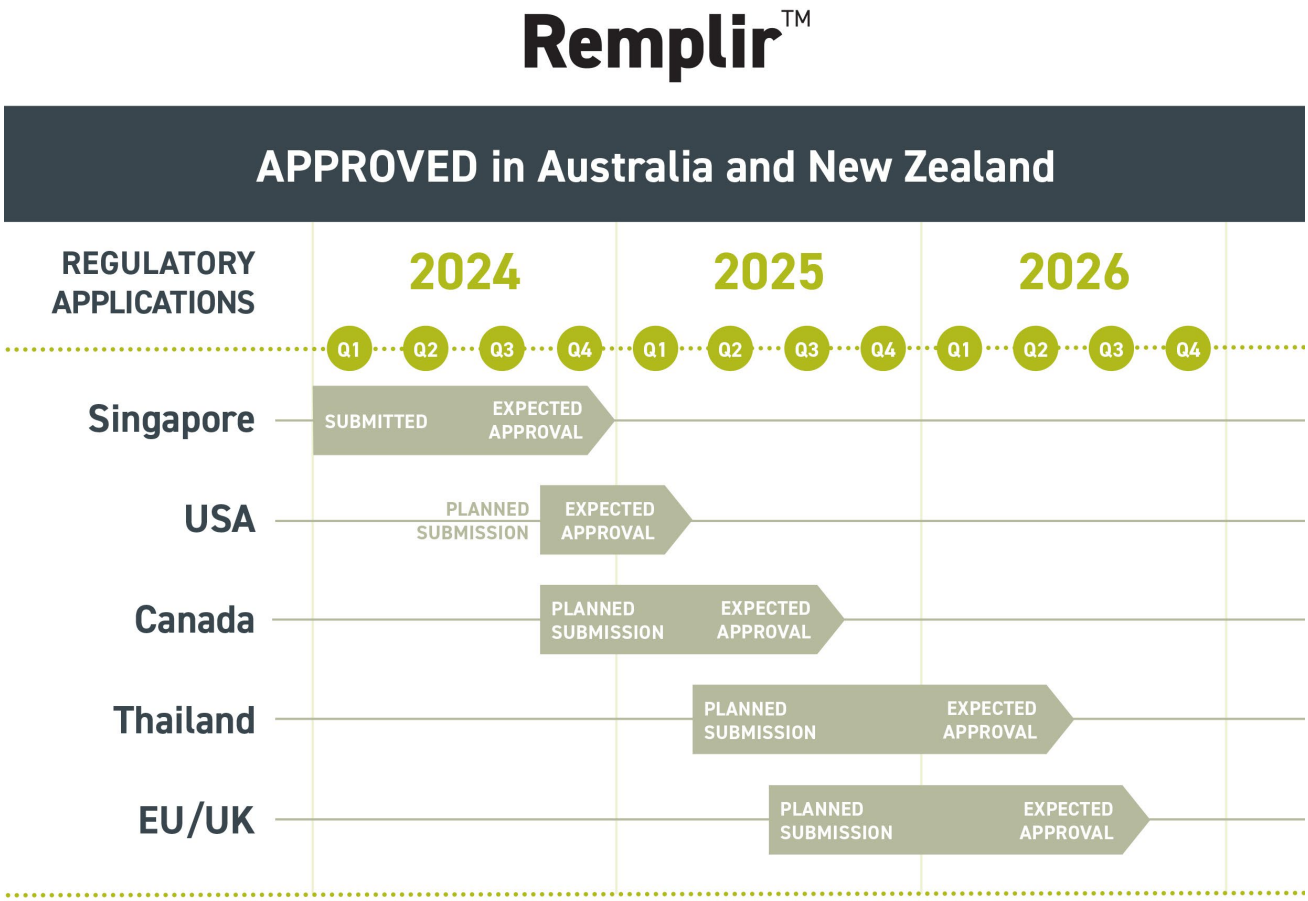

Figure 2: Global Regulatory Strategy for Remplir 2024-2026

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ortho·cell
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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 US FDA (510k), Australia (ARTG) 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 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.