

## **Orthocel Achieves First Remplir™ Sales in US\$75 million Canadian market**

- First commercial sales of Remplir™ completed in Canada, marking a key milestone in Orthocell's global rollout of its flagship nerve repair device.
- Follows Canadian regulatory approval and market launch activities in CY25, including a KOL-led product roadshow across Canada, with revenue generation now underway in this ~US\$75 million<sup>1</sup> market.
- Highlights the effectiveness of Orthocell's distributor-led model, enabling efficient and capital-light market entry through established relationships with surgeons and hospitals.
- Remplir is now approved for sale and generating revenue in Australia, New Zealand, USA, Singapore, Hong Kong and Canada, with expansion planned into the US\$750 million<sup>2</sup> EU/UK market following expected approval in 2H CY26.
- Orthocell will continue to execute its distributor-led program across key non-U.S. markets, while focusing internal resources on the Company-led U.S. market, where recent approvals provide access to a growing network of ~336 hospitals, including 221 U.S. military medical centres.
- The Company remains well funded, with over A\$48 million<sup>3</sup> in cash as at 31 March 2026 and no debt, supporting continued commercial expansion and positioning Orthocell to capitalise on expanded U.S. hospital access and drive increased utilisation of Remplir across key healthcare segments, including military.

**Perth, Australia; 30 April 2026:** Regenerative medicine company Orthocell Limited (ASX: OCC, "Orthocell" or the "Company") is pleased to announce the first commercial sales of Remplir™ in Canada, marking a key milestone in the Company's global commercialisation strategy for its flagship nerve repair medical device.

The first sales follow regulatory approval from Health Canada for Remplir and distributor appointments in 2H CY25, which currently provide majority national coverage across the Canadian market and position the Company to support surgeon and hospital adoption nationwide.

Orthocell has worked alongside its distributors on initial launch activities, including a KOL-led product roadshow across Canada (Vancouver to Toronto). The program featured Australian orthopaedic surgeon Dr Stuart Kirkham, who presented his clinical experience and use of Orthocell's Remplir collagen nerve

<sup>1</sup> Nerve repair market sizes estimated using reference papers from both US and OUS databases and studies.

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<sup>3</sup> AU\$48.0M as of 31 March 2026, this includes \$7.8 million in cash and cash equivalents and \$40.2 million in term deposits with maturities ranging from 3 to 12 months.

repair device to plastic and orthopaedic peripheral nerve surgeons. This activity supported product education and early engagement, contributing to the first commercial sales.

The commencement of commercial revenue generation in Canada reflects the effectiveness of Orthocell's distributor-led model, enabling efficient and capital-light market entry across non-U.S. markets.

Orthocell continues to execute its distributor-led commercialisation program across key non-U.S. markets, including Canada, Hong Kong, Singapore and Australia. This approach allows the Company to prioritise internal resources on the U.S. market, valued at approximately US\$1.6 billion<sup>4</sup>. Recent approvals provide access to U.S. Department of Defense hospital networks, including approximately 221 military medical centres, alongside broader access to approximately general 115 U.S. hospitals, with the total network continuing to expand.

Following the Canadian launch, Orthocell will continue to work closely with its distributor network to onboard surgeons and establish active accounts, supported by the Company's existing US-based marketing and medical education teams. This coordinated approach provides clinical engagement, training and operational efficiencies across the U.S. and Canada.

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**Orthocell Managing Director Paul Anderson said:** "We are delighted to announce the first commercial sales of Remplir in Canada, a key milestone following Health Canada approval and the roll out of our distributor-led model, which provides coverage across the majority of this ~US\$75 million market.

This milestone represents an important early step in our Canadian commercialisation strategy and reinforces the strength of our execution. We expect increasing surgeon engagement to support continued adoption and further revenue growth."

#### **Release authorised by:**

**Paul Anderson**

**Orthocell Ltd CEO and MD**

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<sup>4</sup> US nerve repair market sizes estimated using referenced papers from both US and OUS databases and studies

## About Orthocell Limited

### ACN 118 897 135

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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 Canada, Hong Kong and Thailand. 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](http://www.orthocell.com) or follow us on Twitter @OrthocellLtd and LinkedIn [www.linkedin.com/company/orthocell-ltd](http://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.