

Orthocell Receives Regulatory Approval from Health Canada to Commence Sales of Remplir™ in US\$75 million¹ market

- Orthocell has been granted a Medical Device Licence (MDL) by Health Canada to allow sales of Remplir™ to commence into the US\$75 million¹ Canadian nerve repair market.
- The application was lodged by Orthocell in February 2025 and approval received earlier than expected - a testament to the quality of the product and clinical data.
- The global addressable market for Remplir is rapidly expanding, following approvals from the US and Thai Food and Drug Administrations received this month and pre-existing approvals in Australia, New Zealand and Singapore.
- With the Canadian approval, regulatory-approved markets for Remplir now equate to a significant total addressable market of \$1.8 billion² with further jurisdictions planned.
- Orthocell has achieved strong revenue growth over the last 12 months and, with the continued growth in existing markets and recent approvals for Remplir in the US, Thailand and Canada, the Company expects a step change in revenue once sales traction is achieved in these new markets.
- Negotiations are underway to appoint distribution partners in Canada to drive market penetration, with first sales expected in the second half of 2025.
- Existing cash reserves of \$31.7 million (as at 31 March 2025) see the Company fully funded for the growing global roll-out of product portfolio.

Perth, Australia; 30 April 2025: Regenerative medicine company Orthocell Limited (ASX:OCC, “Orthocell” or the “Company”) is pleased to announce it has received a Medical Device Licence (MDL) from Health Canada for its flagship nerve repair product Remplir™. The MDL adds the US\$75 million¹ Canadian nerve repair market to the existing list of jurisdictions in which Remplir is approved for sale, taking the total addressable market (TAM) for approved jurisdictions to US\$1.8 billion.

Orthocell has received the approval well ahead of initial timing expectations with the regulatory submission having been lodged in February 2025. A testament to the quality of the product, clinical data and track record of regulatory approvals.

Orthocell intends to appoint non-exclusive, local specialist distributors to drive sales in Canada. Negotiations are underway to appoint the appropriate partners. Orthocell believes the use of external distributors continues to be the most efficient process to drive sales in each new market, allowing internal resources and sales and marketing spend to remain focussed on the larger, more strategically important US market.

Orthocell CEO and MD, Paul Anderson, said: “We are building a significant portfolio of jurisdictions in which Remplir is approved for sale, and we’re delighted to add Canada to this growing list. Each new regulatory approval is an important addition to the overall value of our product portfolio and our Company.

¹ Canada nerve repair market size was estimated using referenced papers from both US and OUS databases and studies

² Company estimate of addressable market size for Remplir (AUS, NZ, SGP, USA, THA, CAN). Sources include iData Research Inc and other publicly available market research reports and published literature



“We have a focused and effective strategy to grow sales in the key markets around the world, with the bulk of our internal sales, marketing and medical education resources focused on the US, by far the largest addressable market for us. The most efficient way for us to engage with markets outside the US is to use local distributors with existing customer relationships and sales channels. We’re in discussions with parties that we believe will be the right partners for us in Canada.

“Using this strategy, we’re expecting the recently approved jurisdictions for Remplir to start contributing revenue during the second half of calendar year 2025.”

Remplir is a collagen wrap used in nerve repair surgery to assist surgeons to improve outcomes in the repair and regeneration of damaged nerves. In addition to the approved markets identified above, regulatory applications for the EU and UK are on track to be submitted in the next 6-12 months.

Orthocell is targeting a large global addressable nerve repair market estimated to be worth in excess of US\$3.5 billion with an estimated ~2.0M peripheral nerve repairs performed across Australia/New Zealand, Singapore, USA, EU/UK, Canada, Brazil, Japan and Thailand³.

The Company has a strong balance sheet with A\$31.7 million cash at bank as at 31 March 2025 and no debt, and is very well funded to continue to broaden its commercial footprint and grow revenues in existing and new markets.

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³ Company estimate of addressable market size for Remplir (AUS, SGP, USA, CAN, THA, EU/UK & BRZ). Sources include iData Research Inc and other publicly available market research reports and published literature.



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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 its first four US distributors, with first sales expected to follow shortly. The Company's flagship nerve repair product is also approved in Australia, New Zealand and Singapore and is distributed exclusively by Device Technologies Group. 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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