Orthocell Announces First US Remplir™ Sales Revenue

- **Orthocell has recorded its first US sales revenue from its flagship Remplir™ nerve repair product.**
- **Revenue follows first surgical use of Remplir™ on 26 June in Ohio and subsequent early surgical cases in Florida sourced from the Company's network of specialist distributors.**
- **Orthocell has transitioned from receipt of US FDA 510(k) clearance for Remplir™ to first revenue generation in just over 3 months.**
- **Early-stage surgeries conducted in out-patient day surgeries, known as Ambulatory Surgery Centers in the US, play a crucial strategic role in building experience and knowledge amongst the US surgical community in the significant US$1.6 Billion[1] US market.**
- **Order fulfillment and associated customer invoicing workflow validated.**
- **Remplir™ US inventory held and shipped to customers by on-the-ground logistics partner Uniphar.**

Perth, Australia; 10 July 2025: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce it has recorded its first sales revenue from its flagship Remplir™ nerve repair product in the US. The critical milestone in the commercialisation of Remplir™ in the US$1.6 Billion[1] US market follows the first surgical use of Remplir™ on 26 June 2025 and subsequent early surgical cases.

The achievement marks a transition from US FDA 510(k) clearance for Remplir™ to first sales revenue in just over three months. Surgical cases conducted to date have been sourced from Orthocell's network of nerve repair specialist distributors.

In addition to building crucial surgical knowledge and experience with Remplir™, the early surgical cases have been an important real-world validation of the order fulfillment process coordinated by on-the-ground logistics partner Uniphar and the associated customer invoicing requirements.

Orthocell CEO and MD, Paul Anderson, said: "Translating Remplir's regulatory clearance in the US to first sales revenue in a little over three months is a testament to the hard work we've done with our US roll out plan. This covers everything from our key internal hires in sales, marketing and medical affairs, appointing specialist distributors, Australian manufacturing ramp up and working with our on-the-ground US logistics partner.

I must stress these early-stage day surgery cases are an ideal starting point and represent the perfect strategic platform to build from. This approach is similar to the market access model we have successfully undertaken in Australia where early surgery cases build familiarity and knowledge, leading to widespread adoption and therefore revenue growth. We expect to follow a similar path in the US, albeit on a far larger scale.

We are confident our efforts in the US are on track to drive growth in sales of Remplir during the second half of calendar 2025."

Remplir™ is a collagen wrap used in nerve repair surgery to improve regeneration of damaged nerves and patient outcomes. It is supported by robust clinical evidence, including recent studies confirming its superiority over standard suture techniques in nerve regeneration, earlier return to function, and higher quality nerve tissue restoration.

Orthocell is targeting a large global addressable nerve repair market estimated to be worth in excess of US$3.5 billion[2] with an estimated ~2.0M peripheral nerve repairs performed across Australia/New Zealand, Singapore, USA, EU/UK, Canada, Brazil, Japan, Hong Kong and Thailand.

[1] USA 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, EU/UK, CAN, BRZ, JAP & THA). Sources include iData Research Inc and other publicly available market research reports and published literature.

The Company has a strong balance sheet with approximately $28.6 million cash at bank (as at 30 June 2025) and no debt and is very well funded to continue to broaden its commercial footprint and grow revenues in existing and new markets.

Release authorised by:
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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 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'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 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.