

ASX Announcement



Remplir™ Nerve Sparing Prostate Cancer Surgery Commercial Opportunity Gathers Momentum with ~100 Surgeries Now Performed with Multiple Surgeons Nationwide

Company to invest in further research to strengthen clinical evidence ahead of medium-term U.S. launch with no further FDA approvals needed

- Adoption of Remplir™ among Australian urologists is accelerating, with ~100 surgeries conducted by surgeons nationwide.
- This promising new application for Remplir can potentially reduce post-surgical complications from peripheral nerve injury, representing a globally significant commercial opportunity for the Company.
- Despite advances such as nerve-sparing techniques and robotic-assisted radical prostatectomy (RARP), damage to the peripheral nerves in the neurovascular bundle (NVB) surrounding the prostate remains common — resulting in erectile dysfunction in up to 80% of men and urinary incontinence in up to 35% following surgery.
- Applying Remplir during prostate surgery aligns with its broader role in peripheral nerve protection and repair. In prostatectomy, surgeons are using Remplir to protect the NVB with the aim of supporting improved postoperative nerve function.
- The Company believes that the use of Remplir in nerve-sparing RARP presents a significant opportunity to expand its Total Addressable Market in the U.S. from U.S.\$1.6 billion to approximately U.S.\$2 billion¹.
- To support a targeted U.S. product launch in the medium term, the Company is setting up a commercialisation advisory board and investing in further research to strengthen the scientific evidence base for this new application of Remplir.
- Initial clinical performance data from nerve-sparing procedures using Remplir across Australia will be released once compiled. Data will support medical education initiatives and provide the scientific foundation for formal product launches in existing approved international markets, with a focus on the U.S.
- Remplir rollout in the U.S. market continues to track according to plan, with over 4,000 units now shipped into the U.S. Initial U.S. surgical cases continue to build with in-country representatives making significant progress working with distributors to gain hospital approvals, on-board surgeons and establish active accounts.

¹ Nerve repair market sizes estimated using referenced papers from both US and OUS databases and studies.

Perth, Australia; 20 November 2025: Orthocell Limited (ASX: OCC) is pleased to announce adoption of Remplir™ by Australian urologists is accelerating with the product increasingly being used during prostate cancer surgery in a promising new application aimed at reducing post-surgical complications from peripheral nerve injury. Remplir has now been used in ~100 surgical cases to assist in improving recovery of erectile function and urinary continence post-surgery.

The Company believes that using Remplir in nerve-sparing RARP presents a significant opportunity to expand its total addressable market in the U.S. from U.S.\$1.6 billion to approximately U.S.\$2 billion¹. This estimate is based on ~115,000 prostatectomies performed annually in the U.S., the majority of which are conducted robotically. To capitalise on this opportunity, the Company is establishing a commercialisation advisory board and investing in additional research to strengthen the scientific evidence base for this innovative peripheral nerve repair application, ahead of a targeted U.S. product launch in the medium term.

Orthocell is also collating clinical data on initial patients who underwent radical prostatectomies with Remplir in Australia. This data will be released once compiled and will support the scientific foundation for formal product launch in existing approved markets.

Orthocell CEO and MD, Paul Anderson, said: “We’re thrilled to see Remplir being adopted by urologists in Australia for nerve-sparing prostate surgery, reflecting its broader potential in peripheral nerve protection and repair. This demonstrates the utility of the product and represents the potential for a meaningful step forward in improving patient outcomes following these complex surgeries.

Prostate cancer and radical prostatectomies

Prostate cancer is the most commonly diagnosed cancer among men in Australia, with over 26,000 new cases in 2024 alone². For localised tumours, first-line treatment is radical prostatectomy (RP), the complete removal of the prostate gland and surrounding tissue to eliminate cancer cells. However, RP carries high rates of post-operative complications, including erectile dysfunction (ED) and urinary incontinence (UI), which significantly impact quality of life. Depending on patient risk factors and surgical technique, ED can affect up to 80% of men 12 months after surgery³, while UI affects up to 35% of patients three months post-surgery⁴. RARP offers greater surgical precision and improved preservation of prostate anatomy, reducing but not eliminating the risk of these complications.

Use of Remplir in robotic assisted radical prostatectomies

Erectile dysfunction and urinary incontinence after radical prostatectomy are caused by damage to the NVB, a network of nerves and blood vessels surrounding the prostate, making preservation of the NVB critical to maintaining sexual function and continence. Nerve-sparing procedures can reduce these risks, with up to 75% of patients eligible⁵, but NVB damage is difficult to avoid. Remplir, a nerve wrap used in peripheral nerve repair, is being adopted by Australian urologists in nerve-sparing RARP to protect and heal the NVB, potentially lowering rates of post-surgical complications. With over 12,000 RARP procedures performed annually in Australia using the da Vinci Surgical System, and strategic distribution support from Device Technologies across Australia, New Zealand, and Southeast Asia, Remplir’s introduction is well-positioned to expand into new surgical specialties.

With circa \$50 million in cash and no debt, Orthocell is well-positioned to drive rapid product adoption to deliver a step change in revenue in FY26. Remplir rollout in the U.S.\$2 Billion U.S. market continues to build momentum, with in-country representatives making significant progress working with distributors

² <https://www.canceraustralia.gov.au/cancer-types/prostate-cancer/prostate-cancer-australia-statistics>

³ Kesch C, Heidegger I, Kasivisvanathan V, et al Front Surg. 2021 May 28;8:684088.

⁴ Geraghty K, Keane K, Davis N. Ir J Med Sci. 2024 Jun;193(3):1603-1612

⁵ Moris, Lisa et al (2022) European Urology Focus, Volume 8, Issue 3, 690 - 70

to gain hospital approvals, on-board surgeons and establish active accounts. Initial U.S. surgical cases continue to build. The Company is also accelerating the launch of Remplir in Canada and remains on schedule to submit its EU/UK application in Q4 CY25.

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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 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 Thailand, Canada and Hong Kong. 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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