

ASX Announcement



Orthocell Appoints Exclusive Remplir™ Distributor for UK

Key Component of \$750m UK/EU Market Commercialisation Strategy

- Highly credentialed medical device distribution company LEDA Orthopaedics appointed as the exclusive in-country distributor of Remplir™ in the United Kingdom (UK).
- Appointment follows Orthocell's application to the British Standards Institution (BSI) seeking approval to commercially distribute Remplir in the EU and UK market valued at US\$750 million¹, comprising an estimated 500,000 surgical repairs of peripheral nerves per year.
- UK regulatory submission was made in December 2025 and approval remains on track, with a decision anticipated in Q3 FY26.
- Early distributor appointments allow market access preparation ahead of approval, enabling rapid commercial launch.
- LEDA Orthopaedics has extensive experience in orthopaedic technologies across upper extremity, trauma and reconstructive procedures, including peripheral nerve repair, and maintains established relationships with orthopaedic surgeons across the UK, enabling comprehensive market coverage.
- Remplir's rollout in the UK will be supported by Orthocell's existing Australian-based Commercial teams, leveraging the proven medical education programs and scientific data that have underpinned the successful Australian and US launch.
- Remplir is already approved and selling in Australia, New Zealand, Singapore, the US and Hong Kong, with first sales expected in Canada in the near term.
- Orthocell remains well funded, with circa \$49 million cash reserves at 31 December 2025², providing a strong balance sheet to support its global distribution strategy, progress its EU and UK regulatory programs, and drive the ongoing commercial rollout of Remplir in existing and new markets.

Perth, Australia; 10 March 2026: Orthocell Limited (ASX: OCC) is pleased to announce the appointment of LEDA Orthopaedics as the exclusive distributor for Remplir™ in the United Kingdom. The appointment follows Orthocell's recent regulatory submission to the British Standards Institution (BSI) in December 2025 seeking approval to commercially distribute Remplir in the UK/EU. The submission process remains on track, with regulatory approval anticipated in Q3 2026.

Appointing an exclusive distributor ahead of regulatory clearance allows Orthocell and LEDA Orthopaedics to commence market development activities in preparation for launch. These activities include surgeon

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

² Cash reserves of \$49.4 million includes \$7.4 million in cash and cash equivalents and \$42 million in term deposits with maturities ranging from 3 to 12 months

engagement, medical education, hospital procurement pathways and distribution planning, enabling rapid commercial launch following approval.

LEDA Orthopaedics Co-Founder and Director, Jonathan Bloy said *“We are delighted to partner with Orthocell to introduce Remplir to the UK market. LEDA Orthopaedics has a strong track record in bringing innovative orthopaedic and surgical technologies to surgeons across the UK, and we believe Remplir represents an important advancement in peripheral nerve repair. We look forward to working closely with the Orthocell team to build awareness and adoption of this technology throughout the UK surgical community.”*

LEDA Orthopaedics Co-Founder and Director, David Plane said *“As a company, LEDA’s focus is on partnering with the world’s leading medical device manufacturers, to bring game-changing technology to UK surgeons and their patients. From the first minute we were introduced to Orthocell, we were blown away by their passion, professionalism and commitment to excellence. We can’t wait to launch Remplir to the UK’s orthoplastics and nerve repair specialists.”*

LEDA Orthopaedics is a UK-based specialist distributor of orthopaedic implants and surgical technologies. Founded in 2013 and headquartered in Huntingdon, the company focuses on innovative solutions for upper extremity, trauma and reconstructive procedures.

LEDA has more than 40 direct sales representatives across the UK and a dedicated Biologics Business Development Manager supporting the launch of Remplir™.

The company maintains established relationships with orthopaedic surgeons nationwide and distributes a portfolio of premium technologies from international partners including Skeletal Dynamics, Checkpoint Surgical, Groupe Lépine and Integrum, supporting complex upper limb and nerve-related procedures.

LEDA’s surgeon call pattern aligns closely with Orthocell’s nerve repair portfolio. The company also supports surgeon education through dedicated cadaveric training facilities and hands-on surgical training programs.

Orthocell CEO and MD, Paul Anderson said *“The UK represents an important growth market for Remplir, and we are pleased to partner with LEDA Orthopaedics to support our future commercial rollout.”*

LEDA brings deep expertise in orthopaedic distribution and established relationships with surgeons performing complex upper limb and nerve repair procedures. Their network and clinical focus align closely with Remplir’s target surgeon base.

Appointing LEDA ahead of regulatory approval allows us to prepare the market through surgeon education and engagement, positioning Orthocell for a rapid commercial launch following approval.”

The UK rollout of Remplir will be supported by Orthocell’s Australian-based marketing and medical education teams, leveraging established surgeon training programs and clinical evidence that have supported the successful launch of Remplir in Australia and the United States.

Remplir is already approved and selling in Australia, New Zealand, Singapore, the United States and Hong Kong. First sales in Canada are expected in 2H FY26 as the Company continues to expand its global commercial footprint.

Orthocell remains well funded with approximately \$49.4 million cash reserves at 31 December 2025, providing a strong balance sheet to support its global distribution strategy, advance regulatory programs in the UK and Europe, and drive the continued commercial rollout of Remplir across existing and new markets.

Release authorised by:

Paul Anderson

Orthocell Ltd CEO and MD

For more information, please contact:

General enquiries

Paul Anderson

Orthocell Limited

CEO and MD

P: +61 8 9360 2888

E: paul.anderson@orthocell.com

Media enquiries

Haley Chartres

H^ACK Director

P: +61 423 139 163

E: haley@hck.digital

Investor enquiries

Shaun Duffy

VECTOR Advisors

P: +61 404 094 384

E: sduffy@vectoradvisors.au

About Orthocell Limited

ACN 118 897 135

Registered Office – Building 191 Murdoch University, 90 South Street, Murdoch WA 6150 Australia

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.