ASX Announcement

Annual General Meeting

Addresses by Chair and Managing Director

Perth, Australia; 6 November 2025: Orthocell Limited (ASX: OCC) is pleased to provide copies of the addresses to be delivered by the Chair and the Managing Director at today's Annual General Meeting.

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^CK 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 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.

From the Chairman

John Van Der Wielen

Good morning and welcome to the Orthocell Annual General Meeting for 2025. I am assisted here today by our founder and Managing Director Paul Anderson, and our Chief Operating Officer Alex McHenry. Unfortunately, our Chief Financial Officer Jim Piper is in NSW due to a family bereavement. The local board of directors, Professor Fiona Wood and Mr Michael McNulty, are also here in the audience.

We have an agenda today which will allow for questions after my address and a presentation from our Managing Director. We intend to spend some time answering questions here from the audience and from shareholders online. It is great to have so many people both in the room and tuning in remotely. It reflects the Company's growing maturity and our expanding shareholder base. I extend a warm welcome to our new shareholders.

Looking back on Financial Year 2025 (FY25) I am very pleased with the continued progress the Company is making. We have delivered for our patients, our clinicians and our valued investors.

As Chairman it has been a privilege to guide and celebrate several pivotal milestones, most notably the United States FDA approval for the Company's leading nerve regeneration device Remplir in April 2025 – a US$1.6 billion market opportunity. This prompted a re-rating of the stock, both in terms of market value and in our reputation within Australia's innovation and manufacturing sectors. Let's not forget this FDA approval was achieved at a time of macro-economic uncertainty due to changing international trade policies in the US. The approval arrived on the morning of Trump's "Liberation Day" tariff announcements, that caused considerable market volatility.

Over the past 12 months, we have secured regulatory approvals in Hong Kong, Thailand, the USA, and Canada. In the life sciences sector, investor patience is often essential given the sequential milestones required to build sustainable revenue and profitability. Orthocell stands apart from most biotech's by manufacturing its products entirely in-house — a model that delivers stronger margins while supporting ongoing research and development to drive future value.

We also finalised an agreement with the University of Western Australia to convert their future royalty interest into equity. This mutually beneficial arrangement enables the University to share in Orthocell's long-term success while freeing the Company from future royalty payments. Collectively, these achievements position Orthocell as a differentiated company with a clear and compelling pathway to cash generation.

Orthocell has progressed along a sequential pathway - from invention, to clinical data compilation, regulatory approvals, distributor appointments and clinician training. Which brings us to today, where revenue is building from the commercial use of our products. This has been a long pathway. but a rewarding one – only a small number of biotech companies actually reach this exciting stage.

Orthocell has executed each of these steps with rigorous discipline and the Company is now at the pivotal stage of revenue growth. The last quarter of $3 million revenue demonstrates the continued quarterly growth which has been delivered in a programmatic manner - we feel confident this will continue and potentially at a faster rate as each new international geography builds. Margins improve with scale and volume, and we now know our breakeven point will become a reality as the revenue grows.

Orthocell is now widely regarded as an Australian biotech and manufacturing success story, with all products in our portfolio developed, commercialised, manufactured and exported from our Perth headquarters. We are creating jobs, building a thriving local industry, and gaining attention and commercial traction in key healthcare markets all around the world.

The value we are building here at Orthocell is real, it is tangible, and it is underpinned by a sustainable and growing revenue base that will continue to serve us in the years ahead.

Please let me remind you that this company is now significantly de-risked. We are debt-free, have no royalty obligations, and hold over $50 million in cash. Our recent capital raise strengthened the shareholder base, bringing in leading institutions from the USA, UK, and Hong Kong, alongside high-net-worth Australian investors who have supported us throughout our growth. We viewed this raise as a strategic move to secure funding while market conditions were favourable. In an uncertain environment, it was prudent to ensure the Company remains well-capitalised to accelerate our successful commercialisation program. Importantly, the $30 million raise was oversubscribed by an additional $23 million, underscoring strong investor confidence.

This balance sheet allows us to further develop our manufacturing facility, expand in the USA and progress our exciting product pipeline, including collagen medical devices in tendon and ligament repair. The upcoming investment in Marine Biomedical adds a bone repair product to our portfolio and we believe the exclusive distribution deal will provide additional revenue and cost efficiencies as we scale our distribution network. Marine Biomedical will continue to operate autonomously, requiring minimal involvement from our management team.

Our USA progress has been remarkable since April 2025. In just 6 months we have appointed senior USA staff and specialist distributors covering 25 states, trained clinicians, distributed products and we have now had over 50 uses in the last 8 weeks. Momentum is building quickly, mimicking the strong adoption we saw in our home market of Australia.

I am proud to report that Orthocell has strengthened its governance by attracting an experienced board. The hallmark of our management approach is clarity of purpose and a commitment to deliver against our clearly defined goals. We are singularly focused on advancing your Company to profitability as soon as possible. We have exercised financial discipline, whilst executing on our international growth strategy, earning the trust of investors. I would like to take this opportunity to thank the Honourable Kim Beazley for his service to the board and sincerely wish him the best for a health recovery. He remains in touch and continues to offer support to the team.

In FY25, Orthocell has over-delivered on its milestones and become well-known for transparent reporting. Our investor base has become more institutional, with our top 20 shareholders now owning 27% of the stock. Investors now hail from the USA, Hong Kong, U.K, Singapore, China and Australia. While we value the addition of large investors to our register, we remain deeply grateful to our loyal retail shareholders, many of which are here today. We would not be where are now without their ongoing support.

The Company is now entering a solid growth phase, and we expect continued quarterly gains from key markets where Remplir is gaining traction. We will invest in expanded manufacturing facilities and grow our US workforce to capitalise on this Company -defining opportunity.

The Company has significant cash reserves, new international markets and a clear strategy - all I can say is it is an exciting time for this great Australian company.

I would like to sincerely thank the Orthocell team, my fellow Board members, our valued investors, collaborating clinicians and most notably, our patients, for entrusting us with innovating in healthcare.

We have more to do, but our proven track record gives us confidence that we will continue to deliver for investors in the years ahead

Thank you,

John Van Der Wielen
Orthocell Chairman

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AGM Presentation

Paul Anderson
Orthocell CEO and MD

November 2025

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It is acknowledged that the Company will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances or unanticipated events occurring after the date of this presentation except as required by law or by any appropriate regulatory authority.

Orthocell at a glance

Australian medical device company with growing international revenue and US market launch of its flagship nerve repair product, Remplir

Best In Class Products Approved In Nine Jurisdictions

Bone / Striate+: USA, EU, UK, AUS, NZ, CAN, SGP, HKG and BRZ
Nerve / Remplir: AUS, NZ, CAN, THA, SGP and USA

Manufactured In Australia

Scaled facility certified to manufacture in major jurisdictions under strict quality standards (i.e. MDSAP and MDR)

Growing Record Revenue

Sixth consecutive quarters of record revenue, reporting $3m in the Sep 25 Quarter

>US$4 Billion P.A. TAM[1]

Large, under penetrated markets in bone and nerve repair alone

Strong Balance Sheet, No Debt, No Royalties

Well-funded Company retaining all revenue benefits maximising cashflow

Remplir USA Approval Received Apr 25

Achieved US FDA 510(K) clearance for lead product and commenced sales in US$1.6 billion market

[1] Addressable markets include AUS, USA, EU/UK, SGP, CAN, BRZ, JAP & THA. Referenced papers were used to estimate procedures per annum. Papers used included both US and OUS databases and studies.

Orthocell 3-year vision

Business goal

Be at the forefront of regenerative medicine innovation, advancing toward ASX 300 inclusion through disciplined growth and a sustainable, well-funded product pipeline.

Strategic focus

Win in the Americas

- Effective launch of Remplir in US & Canada
- Build product portfolio with SmrtGraft

Continue growth in ANZ & Asia

- Lead the ANZ nerve repair market
- Clinical validation of Remplir in new therapeutic areas
- Onboard strategic countries in Asia

Build global footprint with collagen medical devices

- Regional go-to-market plan for EU/UK market
- Identify strategic global markets for entry with Remplir

Advance our product pipeline

- Collagen scaffold applications in musculoskeletal repair
- Build nerve repair portfolio
- Validate advancements in cell therapy technology

Organisational capability

Invest in people & capability

- Commercial Leadership in key geographies
- Financial Analysis and Performance
- Clinical & Medical Affairs
- People & Culture

Systems & data

- Enterprise Resource Planning (ERP) and Business Intelligence (BI) tools
- Commercial technology allowing integrated communications and personalisation

Scaled manufacturing & facilities

- Automation of manual tasks to drive scale
- Reconfigure current facility for additional manufacturing capacity and relocate front office staff

Product innovation & launch

- Dedicated upstream product development and evidence generation teams
- Establish and foster partnerships for licensing and/or development

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FY26 Commercial Focus

- Effective launch of Remplir in the US, delivering on our commitments
- Strategic Asia expansion focused on high-return Remplir markets
- Complete UK & EU launch planning post FY26 Q2 submission for FY27 entry
- Recruit specialist talent to deepen expertise and enable scalable growth

Clarity

+ Execution

Remplir US Roll Out

Early adoption commenced - Momentum to build in Dec Quarter and grow in 2H FY26

Surgical use into US$1.6 billion total addressable market[1] has commenced. >60 surgeries completed over the last 4 months. Low volumes initially to build surgical familiarity with a view to momentum and sales ramp up building in Dec Qtr and into 2H FY26.

US Remplir commercialisation drivers

Key workstreams required for US sales ramp up ahead of schedule :

1. **Network of nerve repair specialist distributor's**

   Initial focus on east coast market for coverage from distributor network with established relationships with surgeons and hospitals.

2. **Key Opinion Leader and surgeon engagement**

   Internal Sales , Marketing & Med Ed team closely engaged with distributors developing business plans and targeting specific surgeons/hospitals.

3. **State licenses and Value Analysis Committee approvals**

   Comprehensive program to secure state licenses and Value Analysis Committee approvals. Critical to Hospitals stocking Remplir for use in nerve repair surgeries.

4. **Active accounts**

   Targeting key surgical centres and high value Hospital accounts - view to momentum building in December Quarter and into 2H FY26.

Manufacturing and logistics in place, first 4,000 units shipped to US from Australia

Ready to fill sales orders with inventory warehoused at Uniphar's GMP certified 65,000 square feet facility in the US with central coordination of warehousing, order processing, shipping, and customer service validated.

Highly Credentialed Board

Recent appointments of John Van Der Wielen and Professor Fiona Wood AM places Orthocell in a strong position to drive its products into global markets and accelerate revenue growth

Mr John Van der Wielen

Independent Non-Executive Chairman

- 35+ years experience in international financial services including large funds management, insurance and private banking
- Former CEO of HBF with annual revenues over $2B
- Extensive corporate strategy, institutional and strategic investor engagement and M&A transaction experience

Mr Paul Anderson

Founder and Managing Director

- 25+ years in regenerative medicine industry
- Former MD at Verigen, successfully commercialised cartilage repair cell therapy (MACI)
- Extensive experience in product development, navigating regulatory pathways, international market launches, medical education and sales force leadership

Dr Ravi I. Thadhani

Independent Non-Executive Director

- 30 years of specialist experience working in US healthcare sector – highly regarded executive, medical administrator and researcher
- Former professor of medicine at Harvard Medical School and chief academic officer at Mass General Brigham hospital, where he oversaw a $2.3 billion research enterprise
- Extensive US regulatory experience and commercialisation of devices and therapeutics

Professor Fiona Wood AM

Non-Executive Director

- 30+ years experience as a plastic and reconstructive surgeon
- Inventor of RECELL “spray on skin” treatment, now supplied by Avita Medical Inc, a AU$450M dual-listed company with operations in 30+ countries including the US
- Unrivalled track record in development and commercialisation of innovative regenerative medicine products.

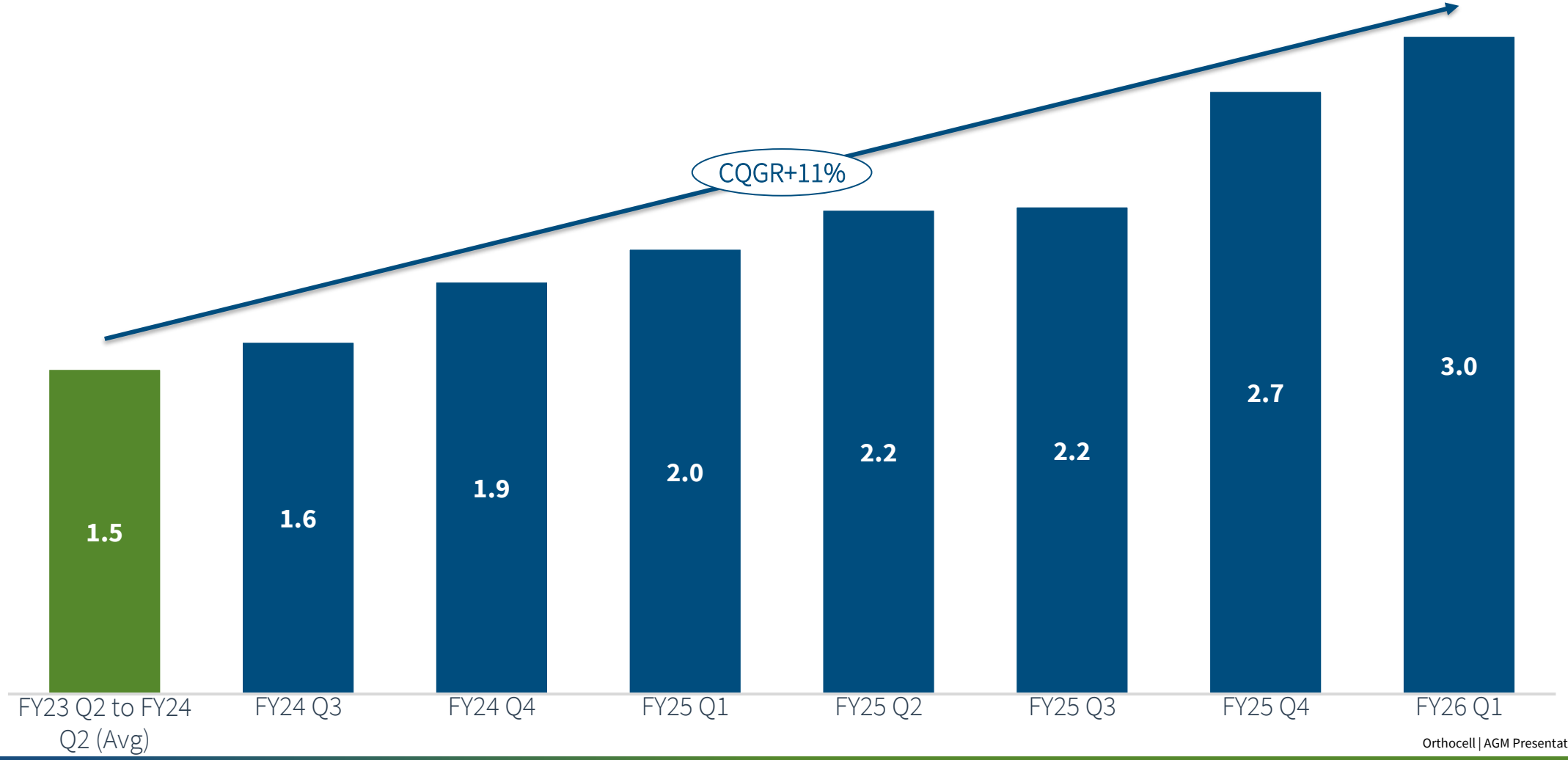
Mr Michael McNulty

Independent Non-Executive Director

- Commencing 1 September 2025
- Chartered Accountant with 30+ years of accounting and finance experience.
- Former Managing Partner, Deloitte Perth and member of the Deloitte Australia Board.
- Will Chair Audit Committee.

Growing Revenue

Record revenue of $3.0 million achieved for the quarter ended 30 September 2025 representing the sixth consecutive quarter of record revenue. **Outstanding result does not yet include material revenue from Remplir sales in the US, which are expected to build during the December 2025 Quarter and grow into 2H FY26.**



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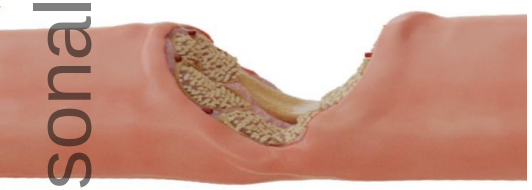
Nerve repair made SMRT™

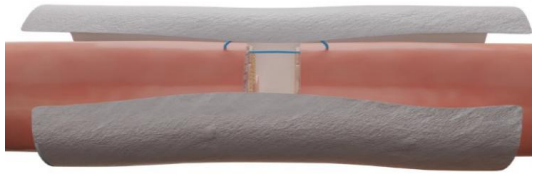
Remplir is engineered with Orthocell's proprietary SMRT™ technology to help patients reclaim touch, movement, and their lives.

Remplir™

Remplir™ Nerve repair, made SMRT

Collagen nerve wrap used in the repair of peripheral nerve injuries. It provides compression-free protection to the nerve, generating an ideal microenvironment to aid nerve healing





- Mimics the natural epineurium with an absolute collagen wrap
- Creates an optimal healing environment for nerve regeneration
- Easy to handle and suture sparing, simplifying the surgical process
- Protects the repair site from scarring, adhesions, and inflammation

Guiding predictable outcomes in peripheral nerve repair

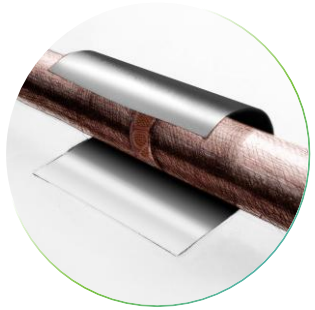
Remplir™ Indications

Remplir is a highly versatile product that delivers a single solution for either connecting severed nerves, protecting damaged nerves or capping amputated nerves

~ 300 surgeons
now using the device in existing markets

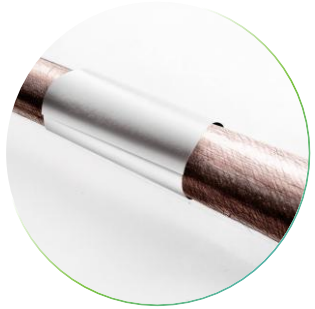
> 200 hospitals
now supply the device to plastic reconstructive and orthopedic surgeons

Repair with Remplir™



CONNECT

Enables tensionless repair of transected nerve injuries, supporting direct repairs with or without grafts, as well as nerve transfers and free functioning muscle transfers



PROTECT

Helps manage non-transected nerve injuries by reducing the risk of adhesion formation and supporting smooth nerve gliding in conditions such as carpal and cubital tunnel syndrome

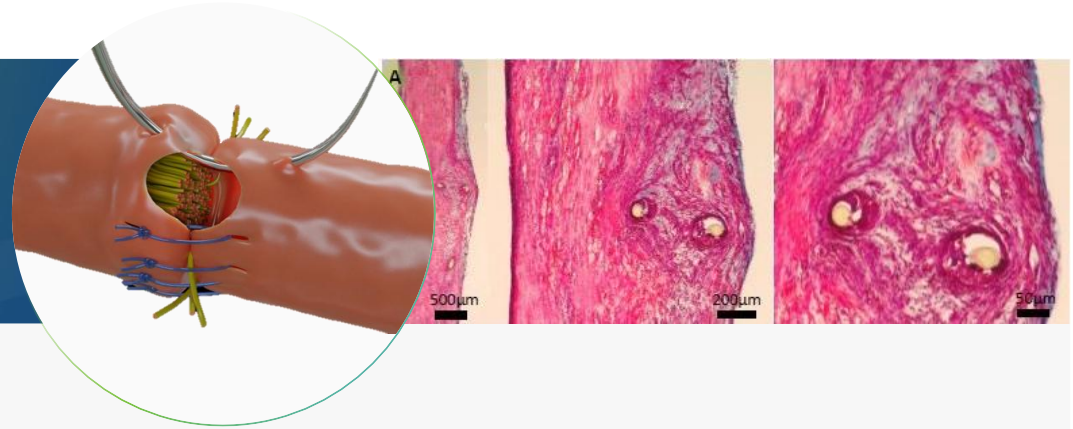
CAP

Prevents neuroma regrowth after resection of a terminal neuroma, or formation of neuromas post amputation

Remplir™ US Peripheral Nerve Repair Trends

Suturing is still the most commonly performed procedure and considered to be the “gold standard” technique for peripheral nerve repair

Over 700,000[1] peripheral nerve repair procedures in the US per year, 90% undertaken using suture only method.



Suturing

- Technically difficult to achieve alignment and tensionless repair
- Induces foreign body reaction leading to chronic inflammation, fibrosis and scarring
- Can lead to suboptimal axonal regeneration and return of function and sensation

Success Rates **50-70%**

1. Referenced papers used to estimate peripheral nerve procedures in the US per annum. Papers used included both US and OUS databases and studies

Remplir™ Significant US Market Opportunity

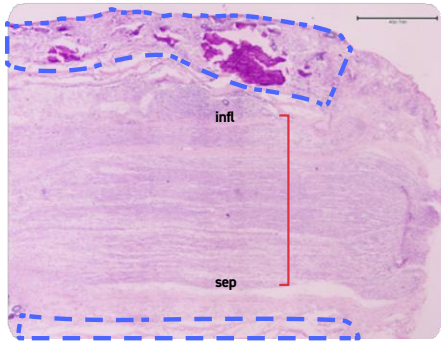
Orthocell has commenced commercial distribution into an estimated US$1.6 billion total addressable nerve repair market[1] in the US alone

Remplir is not seeking to replace a current dominant market incumbent. **Devices are only used in ~10% of procedures.**

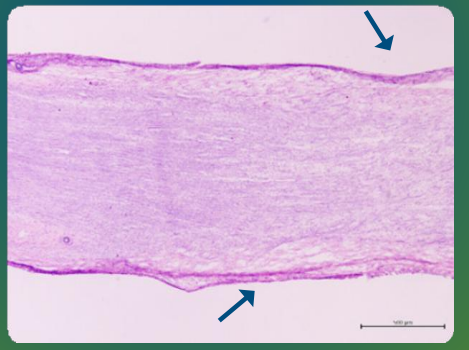
Current devices are not widely adopted

- Materials are too rigid, challenging to deploy and make it difficult to manage size differences between nerve ends, leading to compression injuries or neuroma formation
- Fail to fully integrate into native tissue, leaving residual material that impairs the healing process
- Have not significantly improved the consistency of outcomes

Current devices



Remplir™



1. Referenced papers used to estimate peripheral nerve procedures in the US per annum. Papers used included both US and OUS databases and studies

Remplir™ US Commercialisation Platform

Well positioned to drive rapid product adoption to deliver a step change in revenue in FY26.

Manufacturing

Existing GMP facility in place in Western Australia

Logistics / Shipping

US based central warehousing, order fulfillment, customer service

4,000 units of inventory in place shipped from Australia

US Market Roll Out

Internal Sales and Med Ed team combined with external Distributor Network

Manufacturing

Remplir™
Manufacturing / Product Supply

Capacity in place to deliver the volumes through to company profitability

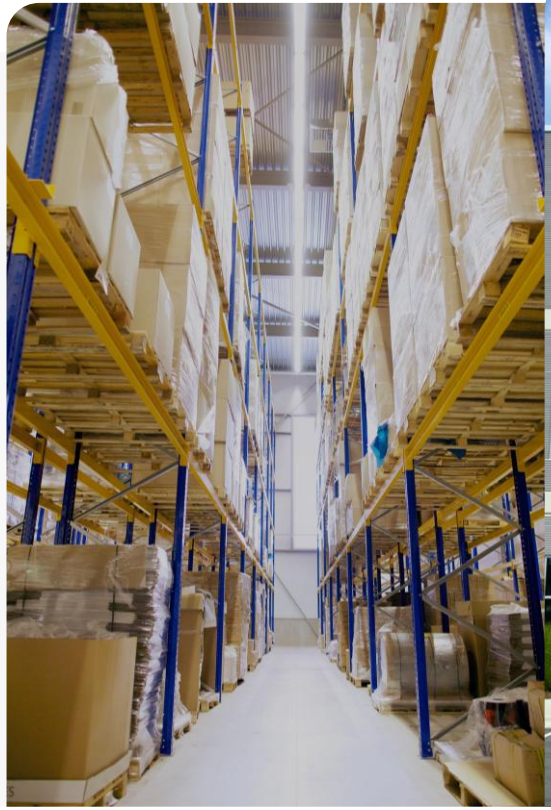
- Annual medical device production capacity of **100,000 units** in place at certified GMP facility in Western Australia
- Already in production for Australia, New Zealand, Singapore, USA, Canada and Hong Kong
- MDSAP, MDR quality standards
- Production ramp up underway in anticipation of US FDA approval with **significant inventory in place** (3-year shelf life)
- Plentiful raw material source, with **back up suppliers**

Remplir™
Logistics / Shipping

Logistics / Shipping

On the ground logistics in the US to deliver into early sales orders

- Stable product for shipping, **no temperature control required**
- **Initial inventory of 4,000 units in place,** shipped from Australia
- Stock warehoused at Uniphar's GMP certified **65,000 square feet facility in the US** with central coordination of warehousing, order processing, shipping, and customer service
- The facility is equipped with redundant power supply, environmental monitoring systems, and advanced inventory management, **ensuring compliance with FDA, ISO, and DSCSA regulations.**
- Orders received before 2:00 PM local time will be **shipped the same day** for a next day delivery – order fulfillment process has been validated



US Sales, Marketing and Medical Affairs Executives

Orthocell has appointed experienced US-based executives to drive the market launch and sales of Remplir

John Walker

Vice President – Sales

Mr Walker is a highly experienced sales executive, who has successfully led global product launches and sales strategies, most notably helping to lead the growth of nerve repair device sales at Axogen.

Phillip Edmondson

Vice President – Medical Affairs

Mr Edmondson is an award-winning medical affairs professional, who excels in creating product awareness, building advocacy and implementing successful medical education programs that contribute to sales growth.

Kevin Leach

Head of Marketing

Mr. Leach is a highly regarded senior marketing executive with extensive knowledge and experience in the development and commercialization of technologies for peripheral nerve regeneration and repair in the USA.

Remplir™ Path to sales ramp up

Distributor network and surgeon engagement ahead of schedule. Surgical use growing. On track for sales ramp up in 2H FY26

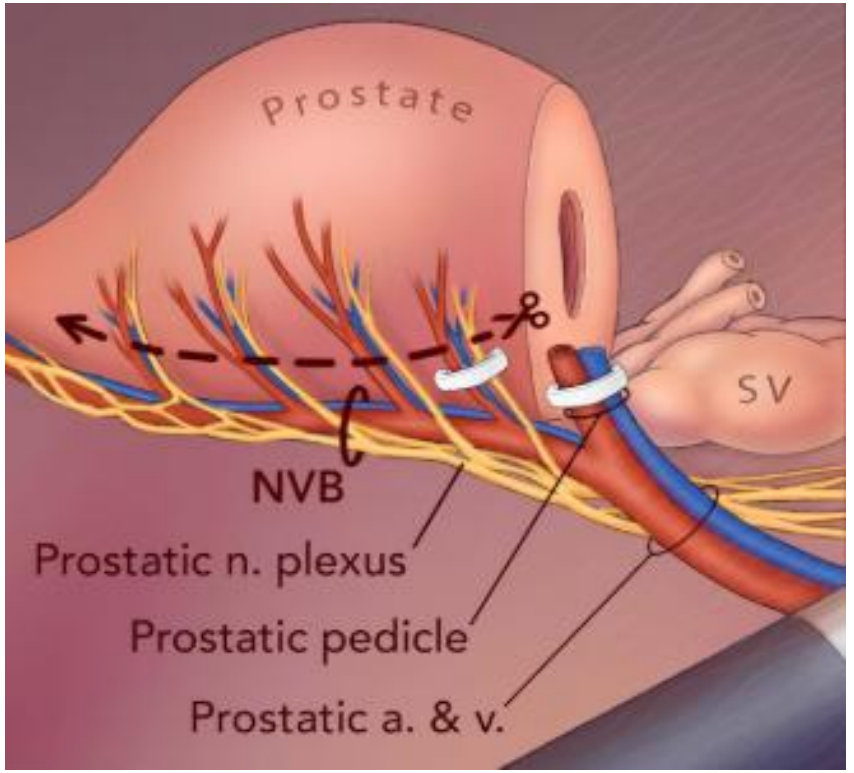
FY26 Targets	Status
1. Distributor network: >40% of US population coverage	Ahead of schedule - 25 States covering 40% of population
2. Surgeon Engagement: Advisory Board in place and >100 surgeons trained	Ahead of schedule – 14 X Advisory Board under contract. >100 surgeons engaged
3. State licenses and Value Analysis Committee: all state licenses achieved and >100 VAC* approvals	On schedule - 51 VAC's submitted, 16 approved. State licenses in progress
4. Active accounts: >25 hospital groups with stock on shelf	On Schedule - >60 early cases completed from initial active accounts. 53 in last 2 months.

* VAC – Value Assessment Committee

Promising New Application for Remplir™ in Prostate Cancer Surgery

Surgeons are using Remplir in prostate surgery to preserve nerve function and improve functional recovery. Potential significant expansion of the Total Addressable Market. **Initial patient data expected Q4 CY25.**

- Australian urologists are using Remplir during prostate cancer surgery to reduce post-surgical complications due to peripheral nerve damage.
- Despite best practice techniques, up to 80% of men experience erectile dysfunction and up to 35% suffer from urinary incontinence due to damage of the peripheral nerves in the neurovascular bundle (NVB) surrounding the prostate.
- Remplir has been used in approximately **>75 surgeries in Australia** to assist in improving recovery of erectile function and urinary continence post-surgery.
- **Data from the nerve-sparing procedures and will be released once available.** The Company is investing in further research to build evidence and assist medical education initiatives.
- Prostate cancer remains the most diagnosed cancer among men globally. This promising new application has the potential to significantly expand the global Total Addressable Market for Remplir.



Pipeline

Advanced product portfolio with near term milestones and emerging pipeline. Orthocell is working with a US adviser to secure a partner to accelerate the commercialisation of the tendon cell therapy.

Product	Status	Next Steps	Multi-Billion US Markets
Medical Devices			
Tendon repair	Successful clinical study completed	US registration study	>500,000 RC procedures per year
Ligament augment	Successful pilot study completed	Pre-clinical and clinical study in development	>200,000 procedures per year
Tendon Cell Therapy			
Rotator cuff	RCT shows significantly more effective than steroid injection	US partnering strategy in development	>1,000,000 procedures per year
Lateral epicondyle	RCT shows as effective, and potentially better than surgery		

Upcoming Catalysts[1]

Remplir™ Redefining nerve repair

US FDA market clearance and Pre-Launch	Achieved
Appoint initial US distributors	Achieved
HKG product registration	Achieved
US first surgical use	Achieved
US first sales	Achieved
Appoint further US sales team members	Achieved
Appoint first & second distributors in CAN	Achieved
Appoint first distributor in HKG	Achieved
EU+UK submissions lodged	***4Q CY25***
Initial Prostate Patient Data	***4Q CY25***
Canada first surgical use	***4Q CY25***
Marine BioMedical global rights and $1m investment	***4Q CY25***
EU+UK market clearance	***2Q CY26***

1. Timelines may be subject to change due to circumstances not under the Company's control

Remplir™ Investment Highlights

Commercial-stage medical device company at **revenue inflection** point following US FDA approval for its flagship Remplir product with sales commenced

Product margins retained in-house Manufacturing facility and all IP owned by the company

Strengthened board with the appointments of highly experienced executives John Van Der Wielen, Professor Fiona Wood and Michael McNulty

Best in class products for Bone, Nerve and Tendon repair approved in eight jurisdictions. Compelling supportive clinical data.

~$50M cash at bank, strengthened share register, share market momentum, well-funded for US roll out

Authorised for release by
Co-Founder and Managing Director, Paul Anderson

Orthocell Limited
P: +61 8 9360 2888
E: paul.anderson@orthocell.com.au

orthocell.com