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US market and operational update

2 February 2026

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Commercialisation of Remplir™ is on-track

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

Fully funded and investing in growth

It is Orthocell's view that it has the required funds for the investments necessary to reach profitability, with the cash balance estimated to stay above the high $20Ms

US Remplir strategy is on-track

Market access activities are clearly defined with execution progressing as planned and sales continuing to build

US market share[1] to reach cash breakeven[2] is less than 1%

Orthocell estimates that it requires approximately 10,000 Remplir unit sales per annum in the US to reach cash breakeven, which is less than 1% of the addressable market

1. Referenced papers used to estimate peripheral nerve procedures in the US per annum. Papers used included both the US and OUS databases and studies
2. Cash breakeven reflects the point at which net operating cash flow is zero, based on current pricing and cost assumptions

Company update

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Orthocell three-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

Continue growth in ANZ and Asia

Build global footprint with collagen medical devices

Advance the product pipeline

Organisational capability

Invest in people and capability

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

Systems and Data

- Enterprise Resource Planning (ERP) and Business Intelligence (BI) tools
- Commercial technology allowing integrated& targeted communication

Scaled manufacturing and facilities

- Automation of manual tasks to drive scale and reduce the cost of sales
- Upgrade current facility for additional manufacturing capacity and relocate front office staff

Product innovation and launch

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

Focus in FY26

Gaining market access and growing the customer base of Remplir™ in the US

Strategic Asia expansion focused on high-return Remplir markets

Complete UK and EU launch planning post-Q2 submission for FY27 entry

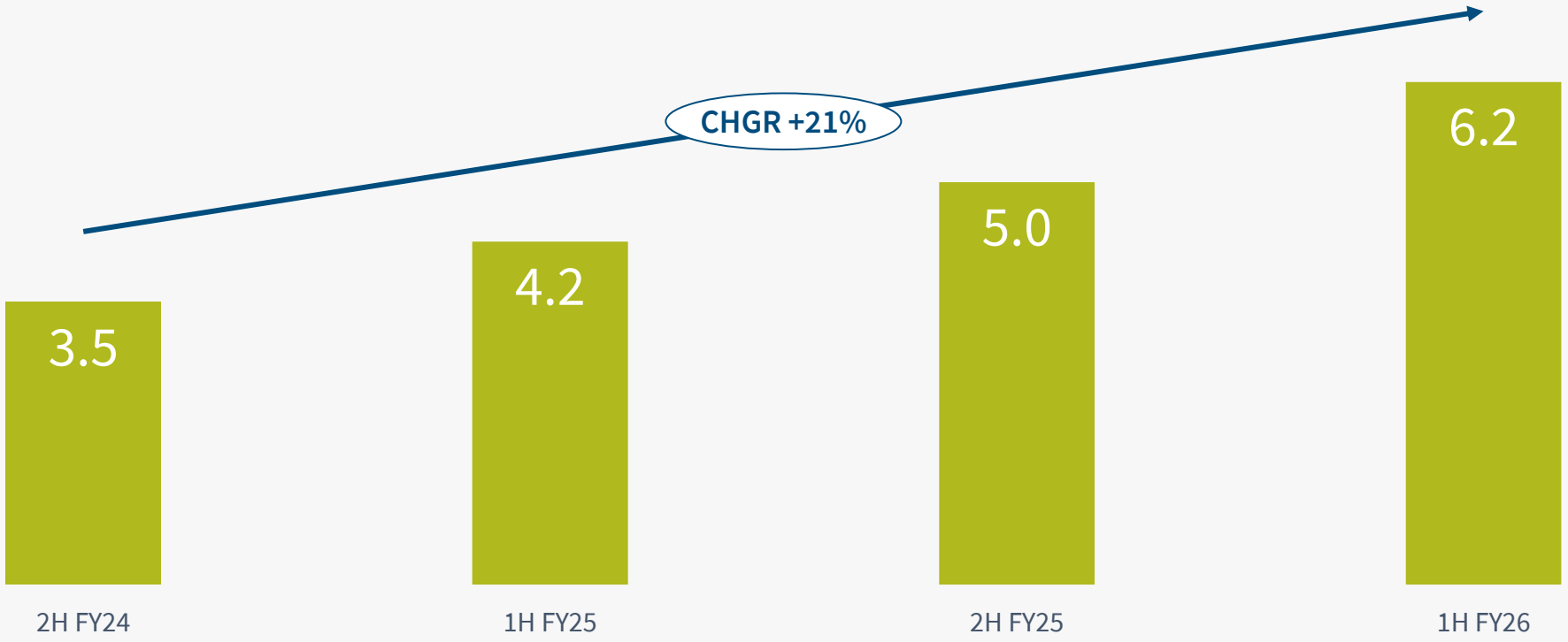
Recruit specialist talent to deepen expertise and enable scalable growth

Clarity + Execution

Continued revenue[1] growth

We have maintained constant growth over the last three halves, driven by device sales

Total Revenue by Half (A$M)



1. Revenue comprises sales revenue, interest income and grant income. The R&D tax incentive is excluded.

US update

Gaining market access and growing the customer base of Remplir™

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US peripheral nerve repair trends

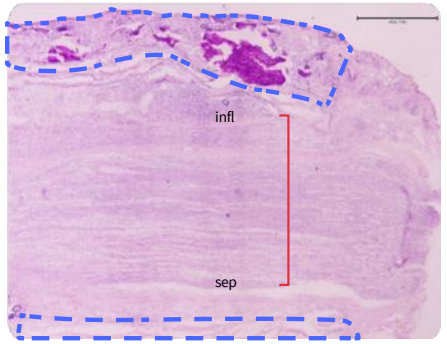
Suturing is still the most performed procedure and considered to be the “gold standard” technique for peripheral nerve repair

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

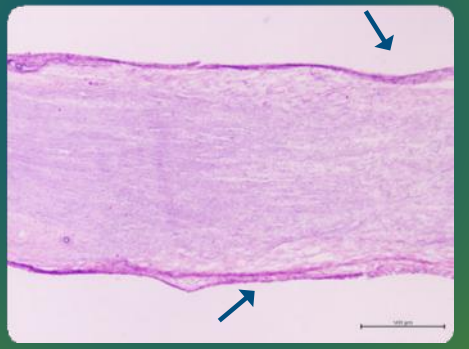
Current devices are not widely adopted

- 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

Significant US market opportunity

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

It is estimated that less than 1% of the market is required to reach cash breakeven[2]

- Orthocell estimates that it requires approximately 10,000 units in annual US sales to reach cash breakeven
- Peripheral nerve repair procedures using Remplir typically require more than one unit (average ~1.7 units per procedure)
  - This equates to ~5,000–6,000 procedures to achieve cash breakeven
- At 10,000 units, this represents less than 1% of total annual peripheral nerve repair procedures in the US

Estimated US market contribution required for cash breakeven[2] compared to the Australian market

	AUS (Current run rate 1H FY26)	US (cash breakeven target)
Total estimated number of peripheral nerve procedures conducted p.a.	25,000	700,000
Average units per procedure	~1.7[3]	
Units sold p.a.	4,500 - 5,000	~10,000
Orthocells estimated % of market	10-12%	<1%

1. Referenced papers used to estimate peripheral nerve procedures in the US per annum. Papers used included both US and OUS databases and studies.
2. Cash breakeven reflects the point at which net operating cash flow is zero, based on current pricing and cost assumptions.
3. Average units per procedure reflects observed utilisation from available data, supplemented by clinical assumptions regarding standard use per operation.

Market access funnel | US Remplir™

Requirements post FDA approval[1]

State licensing to allow clinical use of the product

Establish sales and support infrastructure including distributor network

Surgeon engagement through product training to gain clinician support for Value Analysis Committee (VAC) submission

VAC approval enables funding pathway within hospital for product usage

On-boarding new surgeon customers through product training and clinical support, delivered by sales team

Use referral networks to build hospital centres of excellence with multiple surgeon customers at one site

Build product loyalty through repeat use and leverage clinical experience for peer selling

1. Reference to ASX announcement 4/4/25

Market access funnel | US Remplir™

Requirements post FDA approval[1]

	Progress measures[2]
State licensing to allow clinical use of the product	Approved to sell in **45**[3] states
Establish sales and support infrastructure including distributor network	**7** direct team members hired **16** distributors, covering East and West of country
Surgeon engagement through product training to gain clinician support for Value Analysis Committee (VAC) submission	VACs submitted **71**
VAC approval enables funding pathway within hospital for product usage	**27** VAC approvals, some of which cover multi-site hospital groups
On-boarding new surgeon customers through product training and clinical support, delivered by sales team	Number of customers: **19**
Use referral networks to build hospital centres of excellence with multiple surgeon customers at one site	Number of hospitals with multiple customers: **4**
Build product loyalty through repeat use and leverage clinical experience for peer selling	Percentage of customers who are repeat users to date: **~70%**[4]

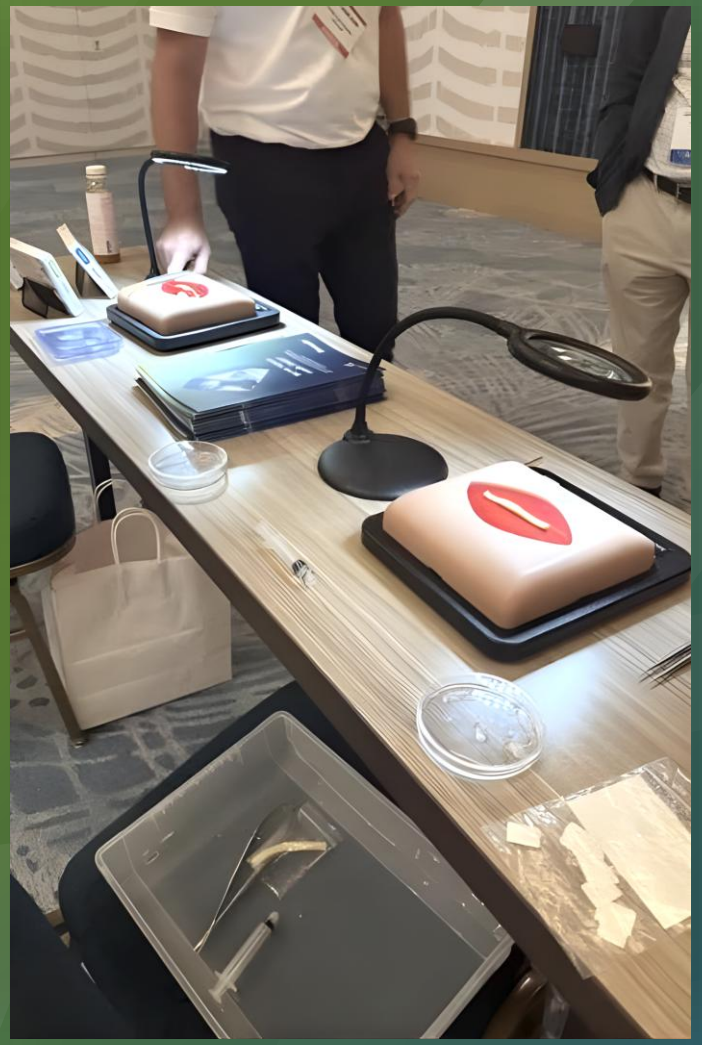
Activities up until 31st Jan 26

Sales data up until 31st Dec 25

1. Reference to ASX announcement 4/4/25
2. Measures calculated as of 31/01/26 for items 1-4 and as of the 31/12/25 for items 5-7
3. The remaining five state licenses expected in 1Q CY26, submitted in CY25, are awaiting approval.
4. Percentage of customers who are repeat users to date represents the proportion of clinicians with more than one recorded procedure, excluding those whose first use occurred within the past 4 weeks to allow sufficient time for a follow-up case.

Combined AAHS, ASPN & ASRM conference

Chula Vista, California - January 2026



Investing in growth

Deployment of capital raising funds growing capability in the US and manufacturing capacity

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People

Dedicated US team to support scaled growth

Speed to market enabled by team with prior execution experience

Sales

- VP Sales
- Regional Sales Director East
- Regional Sales Director West

Drives distributor training and performance. Facilitates new customer on-boarding

Medical Education

- VP Medical Education
- Medical Education Co-Ordinator

Manages Key Opinion Leader Surgeon program and co-ordinates education events to promote product awareness

Clinical Affairs

- Senior Manager, Clinical & Medical Affairs

Drives the evidence generation program to support adoption of Remplir™ in US. Responds to clinical queries on product science

Marketing

- VP Marketing

Creates clear product messaging and training materials to ensure effective communication of scientific narrative and targeting of new surgeon accounts

Manufacturing expansion – stage 1

Planned capacity upgrades are in place to deliver the volumes estimated and reduce the cost of sale

Stage 1 expansion capital approved

- $5–5.5M investment to expand the office footprint, increasing manufacturing and warehousing capacity
- Construction beginning June CY26

Automation project in the validation phase

- Automated processing and fume-hood upgrades
- No increase to headcount in the medium term
- Enabling 24-hour operations

Secure and reliable supply chain

- Manufacturing upgrades will provide inventory to support expected growth demands
- Inventory availability unaffected during construction with stock held in the US and AU

Designed for scalable production

- Manufacturing cycle times reduced
- Improved device unit operating costs
- 4x times the current device manufacturing capacity

1. Includes acquisition of new machines post-automation project completion

Achievements and upcoming catalysts[1]

Remplir™ | Nerve repair, made SMRT

US first surgical use	Achieved
US first sales	Achieved
Appoint further US sales team members	Achieved
Appoint first and second distributors in CAN	Achieved
Appoint first distributor in HKG	Achieved
EU+UK submissions lodged	Achieved
Marine BioMedical global rights and $1m investment	Achieved

R&D refund ($3M)	***1Q CY26***
Initial prostate patient data	***1Q CY26***
Appoint UK distributor	***1H CY26***
First sale in Canada	***1H CY26***
EU+UK market clearance	***2Q CY26***

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

Investment highlights

Commercial stage medical technology company progressing through **Market Access** activities following US FDA approval[1] of its flagship Remplir™ product, with sales underway

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

Strengthened board with highly experienced directors John Van Der Wielen, Professor Fiona Wood and Michael McNulty

Best-in-class platform for Bone, Nerve and Tendon repair approved in nine[2] jurisdictions. Compelling supportive clinical data

With ~$50M[3] total cash reserves and a strengthened share register, it is Orthocell's view that we are well-funded for US rollout, with the cash balance estimated to stay above the high $20Ms

1. Reference to ASX announcement 4/4/25
2. Orthocell's collagen platform of products, including Striate+™ and Remplir™.
3. AU$49.4M as of 31 December 2025, This includes $7.4 million in cash and cash equivalents and $42.0 million in term deposits with maturities ranging from 3 to 12 months

Questions

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Thank you for attending

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Authorised for release by
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