

## Orthocell Webinar Presentation -Accelerating Global Expansion-

**Perth, Australia; 26 February 2025:** Regenerative medicine company Orthocell Limited (ASX: OCC, “Orthocell” or the “Company”) is pleased to attach the Webinar Presentation to be delivered by the CEO and MD Paul Anderson at 11am EST today.

**When:** 11am EST, Wednesday 26<sup>th</sup> February

**Topic:** Remplir™ Global Expansion Update

**Register in advance for this webinar:** [Register Here](#)

After registering, you will receive a confirmation email containing information about joining the webinar.

Release authorised by Chief Executive Officer and Managing Director Orthocell Ltd, Paul Anderson.

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### About Orthocell Limited

**ACN 118 879 135**

**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 CelGro™ 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, and is distributed globally by BioHorizons Implant Systems Inc. Striate+™ is cleared for use in the US(510k), Canada (MDL), Australia (ARTG), New Zealand (WAND), the UK (UKCA Mark) and Europe (CE Mark). Remplir™, for peripheral nerve reconstruction, recently received approval in Australia, New Zealand and Singapore and is distributed exclusively by Device Technologies. 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](http://www.orthocell.com) or follow us on Twitter [@OrthocellLtd](https://twitter.com/OrthocellLtd) and LinkedIn [www.linkedin.com/company/orthocell-ltd](http://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.



# Remplir™

Global expansion update

February 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 clearance of breakthrough nerve repair device pending**



## **BEST IN CLASS PRODUCTS APPROVED IN NINE JURISDICTIONS**

Bone / Striate+: US, EU, UK, AUS, NZ and CAN  
Nerve / Remplir: AUS, NZ and SGP



## **MANUFACTURED IN AUSTRALIA**

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



## **GROWING RECORD REVENUE**

Third consecutive quarter of record revenue, reporting \$2.21m in the December 24 Quarter



## **>US\$4 Billion p.a. TAM<sup>1</sup>**

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



## **REMPHIR USA APPROVAL March / April CY25**

On track to achieve US FDA 510(K) clearance and commence sales in US\$1.6 billion market

<sup>1</sup> 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.



# Corporate snapshot

Well-funded beyond US market clearance of Remplir, supported by leading life science institutional investors

## ASX: OCC TRADING INFORMATION

|   |                 |
|---|-----------------|
| <b>Share Price</b> (as @ 25 <sup>th</sup> February)   | <b>\$1.24</b>   |
| 12 month low/high   | \$0.35/\$0.1.79 |
| Shares outstanding  | 241M            |
| <b>Market Capitalisation</b>  | <b>~\$300M</b>  |
| Cash (24 Feb)   | ~\$32.7M        |
| Debt (24 Feb)   | Nil             |
| <b>Substantial Shareholders</b>   | <b>%</b>        |
| Founders & Management   | ~11%            |
| Institutions & HNW's (Sankofa, Cerutti, Regal, Austral Capital, Thesis Asset Mgt, Frazis Capital, Private Portfolio Mgr's, FundBPO) | ~14%            |

## 12 Month Share Price and Volume



~AU\$32.7m

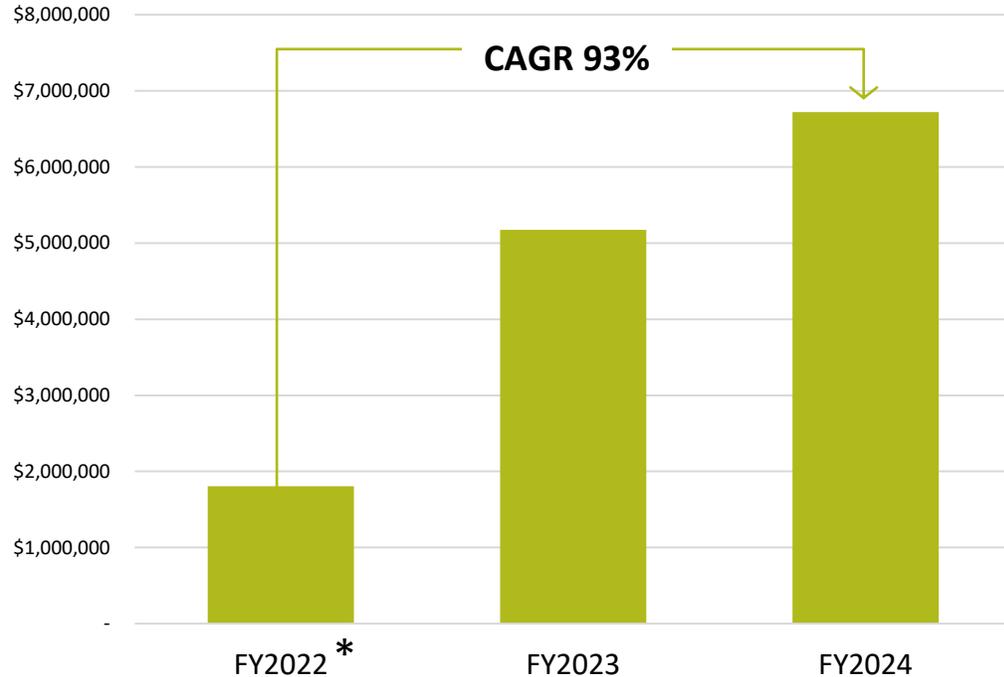
STRONG BALANCE SHEET, NO DEBT, NO ROYALTIES



# Growing Revenue

Orthocell's rapid market penetration continues with a third consecutive quarter of record revenue of \$2.21 million reported in the December 24 Quarter.

## Total Revenue



\* US Striate and AUS Remplir sales commenced in November 2022

## Key Highlights

- **US Striate+ and AUS Remplir product sales commenced in November 2022** and now ahead of expectations
- **Quarterly revenue has grown by 9%** compounded for the last nine quarters following the product launches in November 2022
- **Third consecutive quarter of record revenue**, reporting \$2.21m in the December 24 Quarter up 9% on the \$2.03 million achieved in the September 24 Quarter



# Highly Credentialed Board

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 Rravi 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**  
**Independent 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



**Hon Kim Beazley AC**  
**Independent Non-Executive Director**

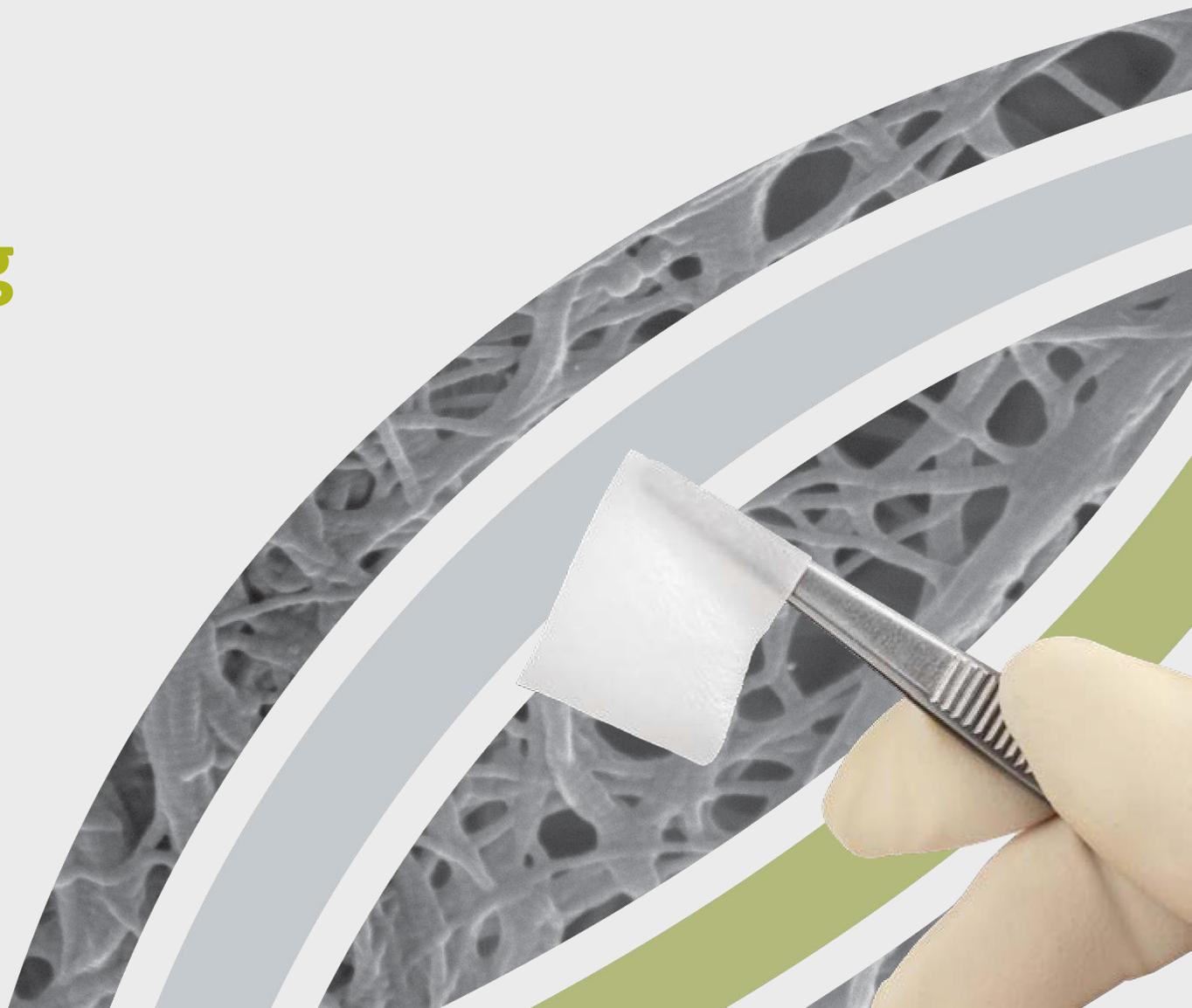
- Unrivalled experience engaging strategic partners in the US – highly regarded politician, executive and strategic adviser
- Former Australian US Ambassador and Governor of Western Australia, Deputy Prime Minister, and Minister for both Defence and Finance
- Extensive experience representing both public and private interests for Australia



# SMRT™ Manufacturing

**DEVELOPING AND MANUFACTURING  
BIOLOGICAL MEDICAL DEVICES**

ortho·cell





# Collagen medical device platform

Our collagen medical device platform is comprised of a range of acellular, type 1 collagen devices for the surgical repair of bone, nerve, tendon and cartilage

## BONE

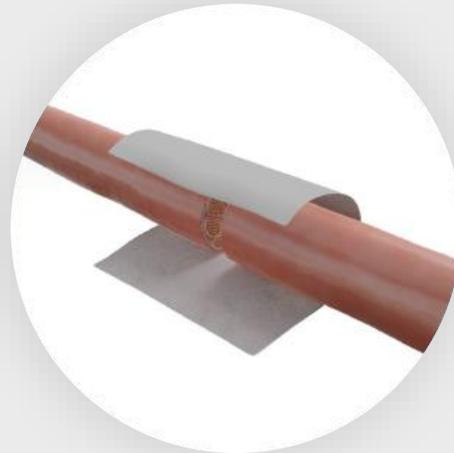
**Striate+™ membrane**  
Dental bone and tissue repair



Revenue generating in  
**US, EU/UK AU & CAN**

## NERVE

**Remplir™ nerve wrap**  
Peripheral nerve repair



Revenue generating in  
**AUS, NZ & SG**

## TENDON

**SmrtGraft™ scaffold**  
Tendon repair



AUS launch  
**CY 2025**

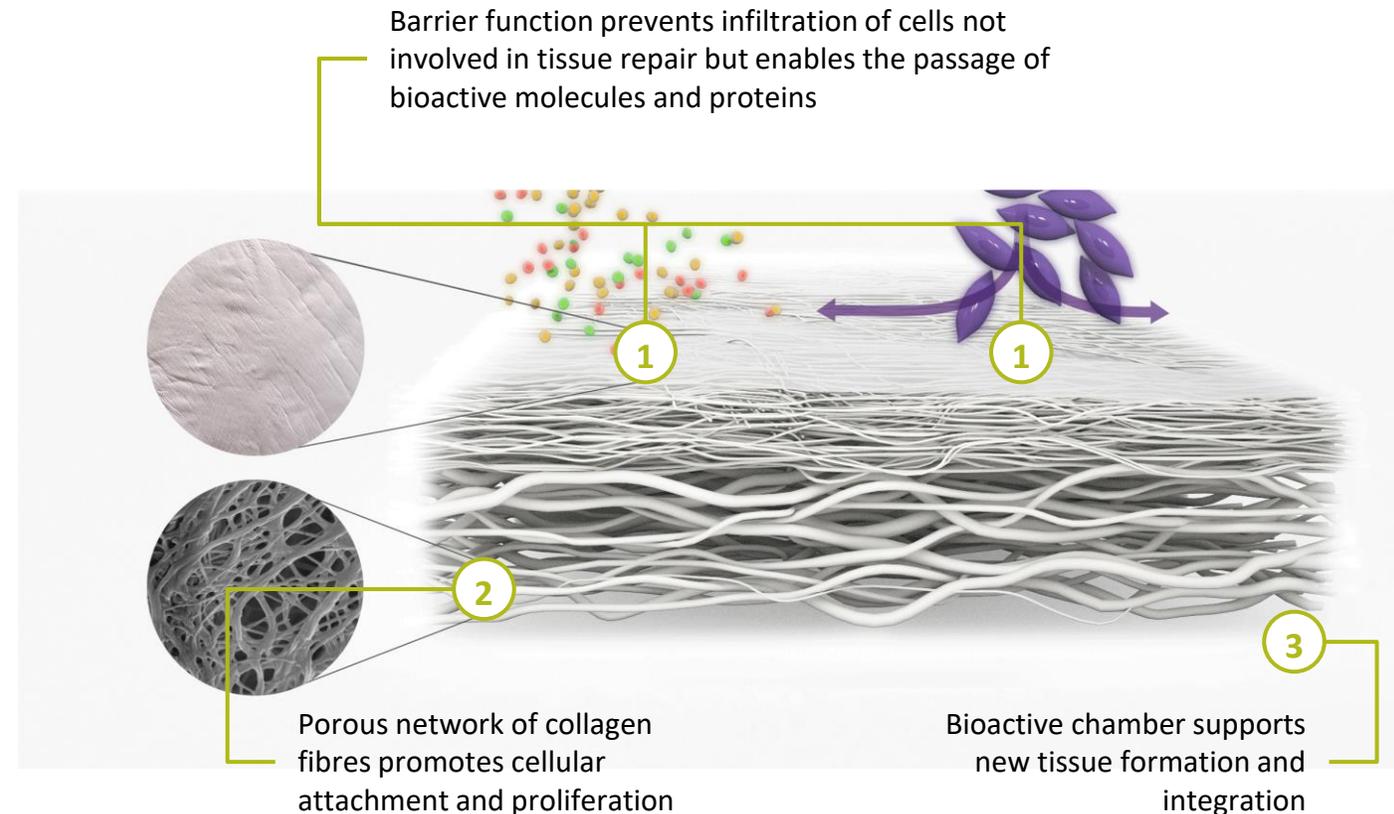


# SMRT™ manufacturing

Orthocell develops and manufactures innovative collagen medical devices that deliver the highest quality surgical repair of bone, nerve, tendon and cartilage

## SMRT manufacturing process

- **Pure collagen**  
Decellularization process removes all cellular and genetic material
- **Mimic human collagen**  
Natural collagen structure is preserved creating the ideal environment for cellular attachment and proliferation
- **70,000+ implants globally**  
Devices integrate and degrade commensurate with the tissue healing process





# Remplir™

**REDEFINING NERVE REPAIR**

ortho·cell

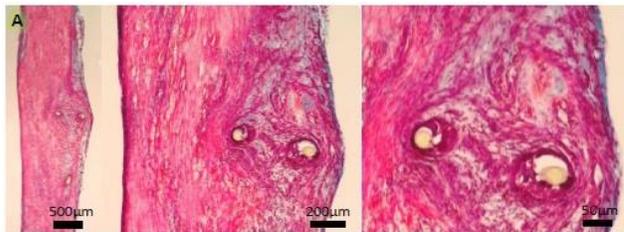
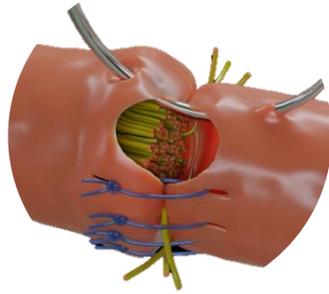




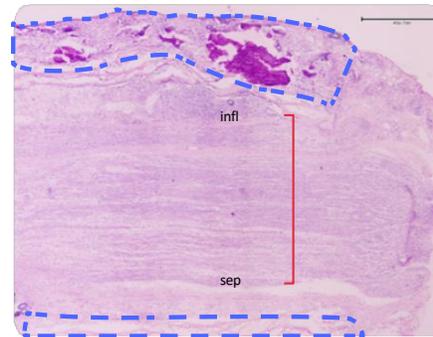
# Remplir™: Nerve repair breakthrough

Current repair methods can place delicate nerve tissue under tension, causing scarring, fibrosis and neuroma formation

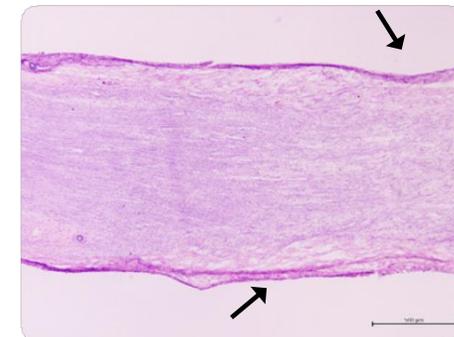
1860s  
Suturing



2000s  
Conduits



2020s  
Next generation



Success  
Rates

50-70%

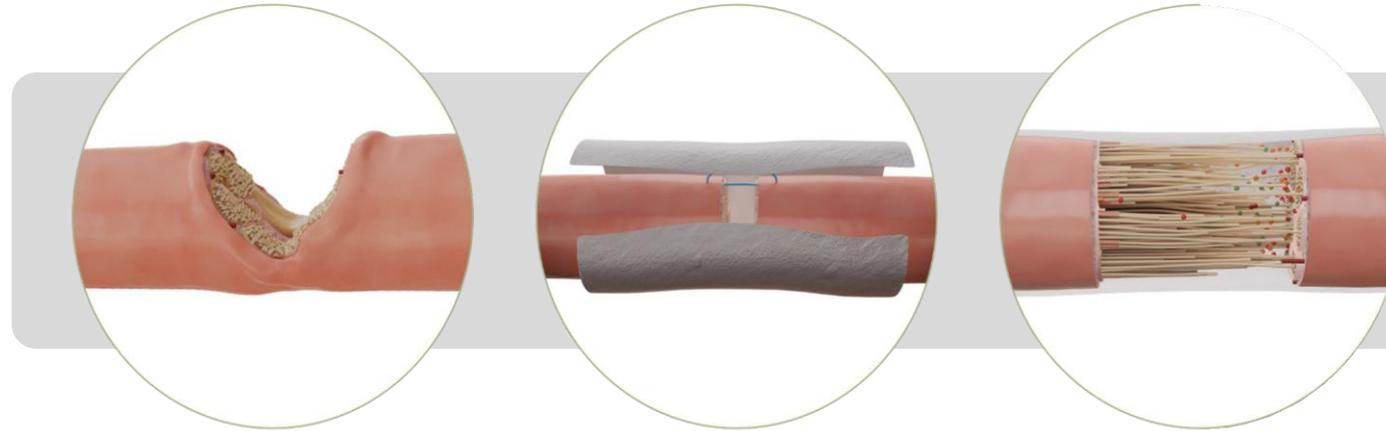
55%

85%



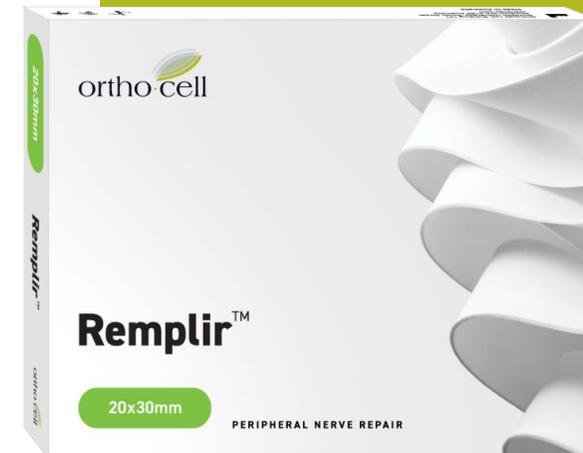
# Remplir™: Redefining nerve repair

Collagen nerve wrap approved and reimbursed in Australia.  
Intended for use in peripheral nerve repair



- ✓ Exceptional handling characteristics
- ✓ Reducing sutures
- ✓ Mimics epineurium (nerve outer layer)
- ✓ Returns nerve to pre-injured state

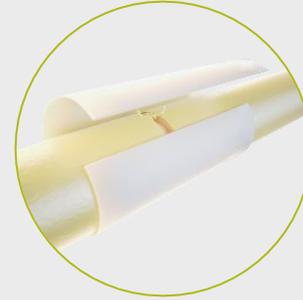
GUIDING PREDICTABLE  
OUTCOMES IN  
PERIPHERAL  
NERVE REPAIR





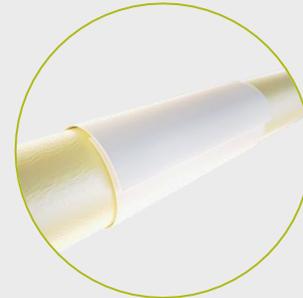
# Remplir™: indications

Remplir is the only device that can be used for either connecting severed nerves, protecting damaged nerves or capping amputated nerves



## CONNECT

Trauma: motor vehicle, power tool, surgical injuries, sports and military related accidents



## PROTECT

Compression: blunt trauma, revisions surgeries (e.g. carpal/cubital tunnel)



## CAP

Amputation: amputations, stump neuroma, mastectomies, schwannoma



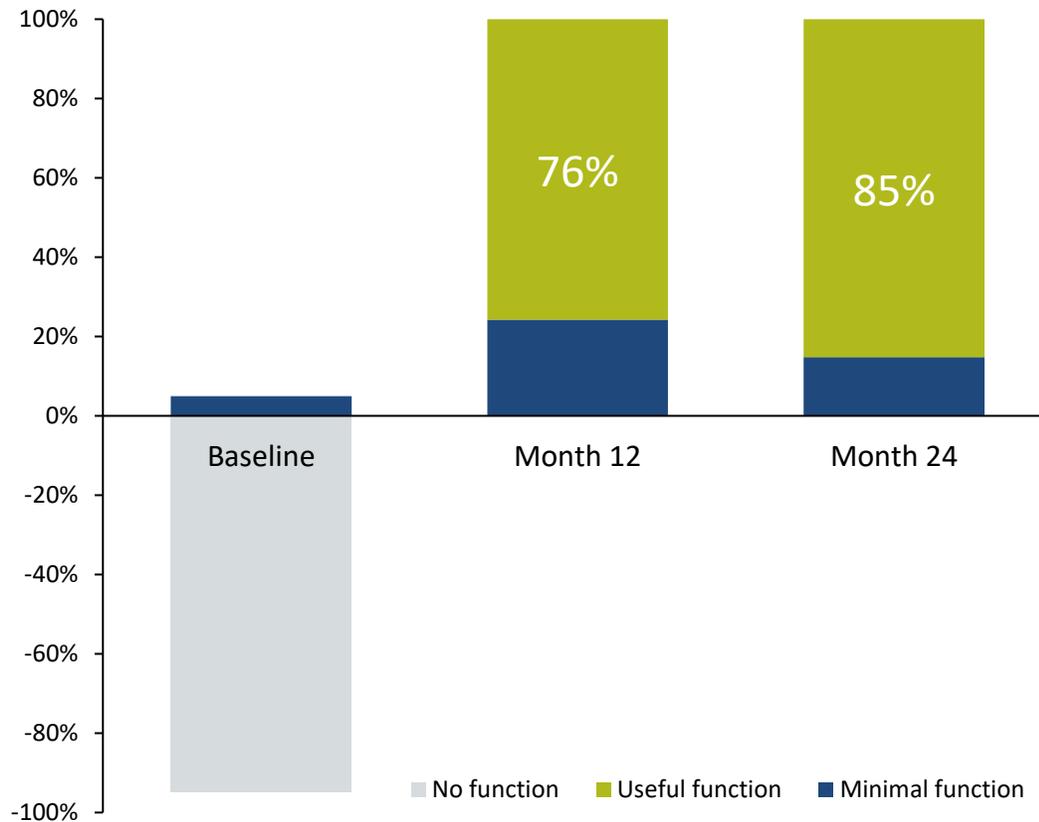
# Remplir™: compelling clinical results

Patients regained voluntary muscle movement within 12 months, increasing strength and range of motion at 24 months



We are now seeing a consistent return of arm and hand function following nerve transfer surgery with Remplir. Remplir is increasing the success rate and efficiency of nerve transfer surgery.

- Leading Australian orthopaedic nerve specialist and clinical trial lead, Dr Alex O'Beirne



## Useful Function

Voluntary movement with improved strength and range of motion

## Minimal Function

Voluntary movement restored, limited strength and range of movement

## No Function

No voluntary movement

## FINAL RESULTS

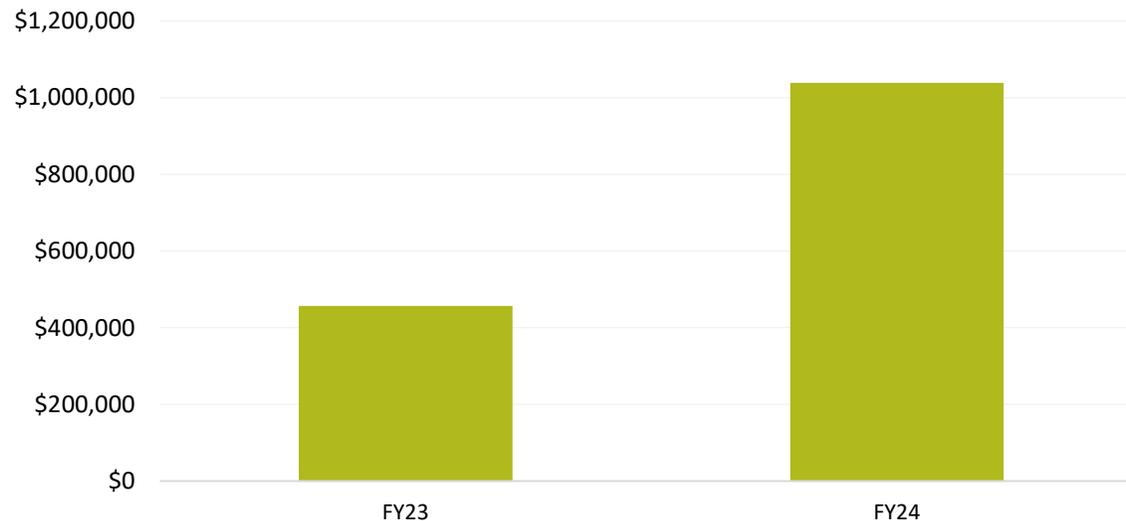
**85% (23 of 27)** of nerve repairs resulted in functional recovery of muscles controlled by the repaired nerve



# Successful launch with growing revenue

**AUS commercial launch<sup>1</sup> of Remplir with Device Technologies, reimbursed in the private healthcare system in November 2022, with sales unit volumes exceeding expectations**

## Remplir product revenue since AUS market launch



- **127% growth in Remplir revenue from \$457K in FY23 to \$1.04M in FY24**
- **Product sales to Device Technology significantly exceeding guidance** – over 180 orthopaedic and plastic reconstructive surgeons
- **First major international regulatory approval** - appointment of an exclusive distributor and achievement of first sales in the key market of Singapore
- **Adoption drivers** - enables less suturing, creation of the optimal healing microenvironment and facilitation of free gliding within the repair site during the critical healing period

1. Orthocell supplies Device Technologies (DVT) with Remplir products, and DVT exclusively market and distribute Remplir in Australia.



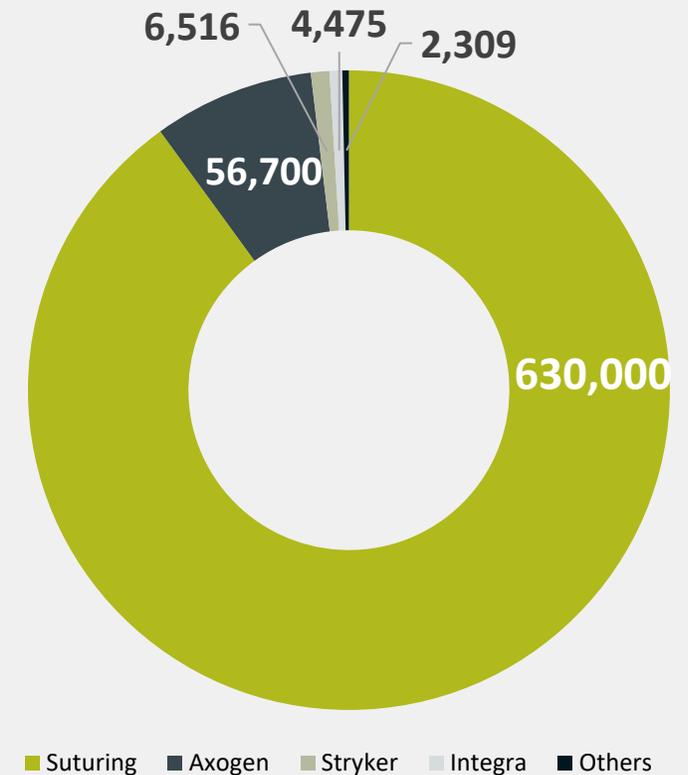
# US FDA APPROVAL EXPECTED MARCH / APRIL CY25 TO US\$1.6 BILLION MARKET



Over 700,000<sup>1</sup> peripheral nerve repair procedures in the US per year, 90% undertaken using suture only method.

- **Successfully completed the 510(k) Regulatory study**, meeting all endpoints and providing key data required to support December 24 marketing submission
- **US market clearance anticipated in late March or early April 2025** immediately followed by sales
- **Current devices are not widely adopted** due to suboptimal outcomes – Axogen, Integra and Stryker collectively sell ~70k units per year (10% of procedures)

Annual US nerve reconstructions



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



# US Sales and Medical Affairs Executives

Orthocell has appointed two experienced US-based executives, John Walker and Phillip Edmondson, to drive the market launch and sales of Remplir following the expected US FDA market clearance in March / April 2025



**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.



# Remplir™: Path to partnering

Orthocell is underpinned by a proven business model for innovating, developing, launching and successfully partnering medical device products

## Scale Organisation

- ✓ Executive team
- ✓ Manufacturing facility
- ✓ Quality system
- ✓ Third party logistics
- ✓ Organisational team
- ERP implementation
- Hire in-country team

## US Approval

- ✓ Pilot study
- ✓ Pre-submission meeting
- ✓ Animal surgeries
- ✓ In-life assessments
- ✓ Data analysis
- ✓ 510k submission

## Brand Ambassadors

- ✓ Scientific narrative
- ✓ KOL panel design
- ✓ KOL engagement strategy
- ✓ In-country collaboration
- ✓ Centres of excellence
- ✓ Clinician advocacy program

## Data Package

- ✓ Published preclinical
- ✓ Published clinical
- ✓ TGA approval
- PMCF
- In country study

## Sales and Marketing

- ✓ Positioning strategy
- ✓ Pricing strategy
- ✓ Customer segmentation
- ✓ Promotion plan
- ✓ Launch collateral
- ✓ Medical education program
- US team training material
- Engage distributors
- Establish key accounts



# Remplir™: Market Expansion

Regulatory approval for Remplir in Singapore achieved in 2H CY24 with a further four applications planned in EU, UK & Brazil in the next 6-12 months

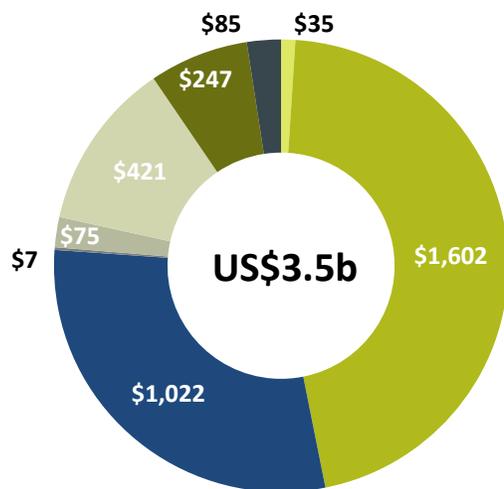
| APPROVED in Australia, New Zealand and Singapore |           |                   |    |                    |                    |                   |    |                   |                   |
|--|-----------|-------------------|----|--------------------|--------------------|-------------------|----|-------------------|-------------------|
| REGULATORY APPLICATIONS                          | 2024      | 2025              |    |                    |                    | 2026              |    |                   |                   |
|  | Q4        | Q1                | Q2 | Q3                 | Q4                 | Q1                | Q2 | Q3                | Q4                |
| <b>USA</b>                                       | Submitted | Expected Approval |    |                    |                    |                   |    |                   |                   |
| <b>Canada</b>                                    |           | Submitted         |    |                    |                    | Expected Approval |    |                   |                   |
| <b>Thailand</b>                                  |           | Submitted         |    | Expected Approval  |                    |                   |    |                   |                   |
| <b>EU + UK</b>                                   |           |                   |    | Planned Submission |                    |                   |    | Expected Approval |                   |
| <b>Brazil</b>                                    |           |                   |    |                    | Planned Submission |                   |    |                   | Expected Approval |



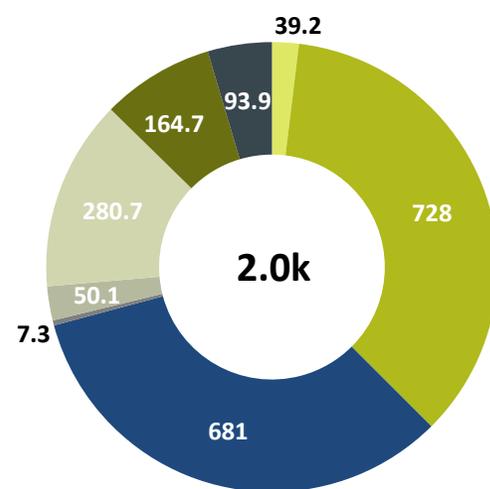
# Remplir™: Large addressable market in nerve reconstruction

Remplir is a breakthrough product on track to be the global market leader in peripheral nerve repair – a retail market estimated to exceed US\$3.5 billion<sup>1</sup> per annum

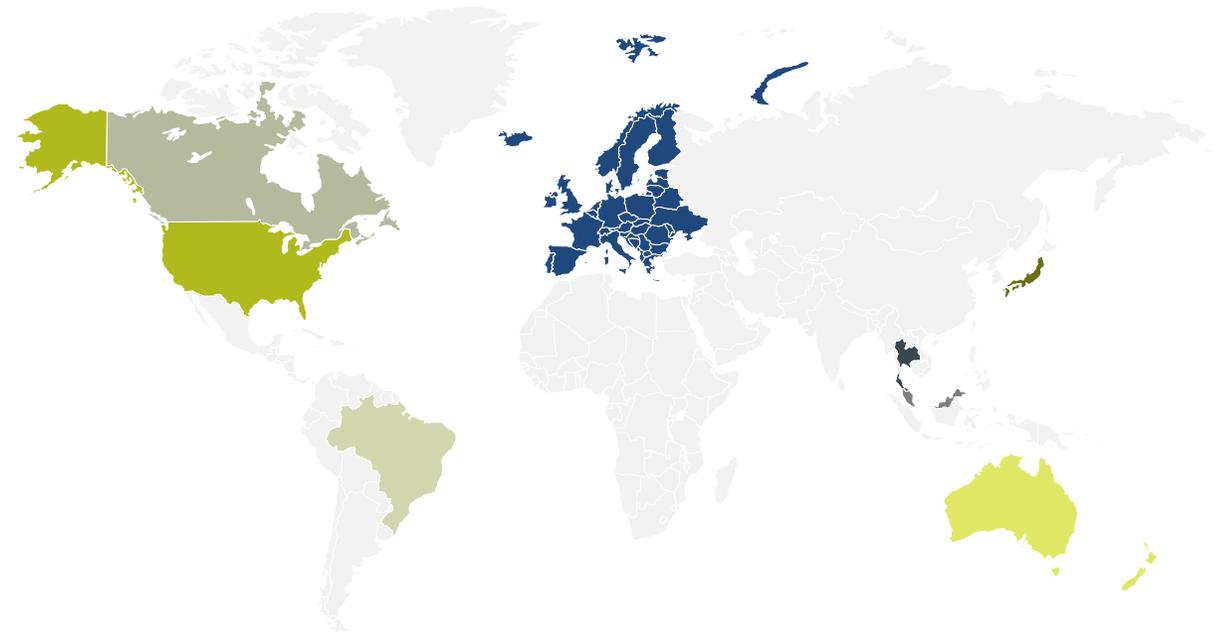
Total Addressable Retail Market (US\$m)



Est. procedures p.a. at peak ('000)



■ AU/NZ ■ USA ■ EU/UK ■ SGP ■ CAN ■ BRZ ■ JAP ■ THA



Targeting a 20% share of the US\$3.5 billion total addressable retail 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



# Upcoming catalysts<sup>1</sup>

## Remplir – redefining nerve repair

US FDA market clearance

1Q / 2Q CY25

Appoint US sales team

1Q CY25

Appoint US distributors

2Q CY25

US first sales

2Q CY25

EU+UK & Brazil submissions lodged

3Q / 4Q CY25

## Striate+ – growing better bone

Columbia submission lodged

1Q CY25

Germany, Austria, Switzerland market launch

1Q CY25

Singapore product registration

1Q CY25

Brazil product registration

2Q CY25

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



# Key Investment Highlights



**Commercial-stage** medical device company at revenue inflection point



**Best in class** products for Bone, Nerve and Tendon repair



**Strengthened board** with the appointments of highly experienced executives John Van Der Wielen, Professor Fiona Wood and Kim Beazley



**~\$32.7M cash at bank, strengthened register, no royalty liabilities and funded to US approval** of breakthrough nerve repair device



**Near term value drivers** including Remplir US 510(k) market clearance on track for March / April CY25



**Authorised for release by:**

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