

## Updated Investor Presentation

**Perth, Australia; 27 July 2022:** Regenerative medicine company Orthocell Limited (ASX:OCC, “Orthocell” or the “Company”) is pleased to release an updated investor presentation being used for the Euroz Hartley’s Healthcare Conference and a number of non-deal investor meetings scheduled week commencing 01 August, 2022.

Managing Director, Paul Anderson will be sharing an update on the Company’s recent landmark global exclusive license and manufacturing agreement with BioHorizons for our Striate+™ dental membrane, together with the latest developments for our advanced pipeline of regenerative medicine products.

**Release authorised by Paul Anderson**

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Orthocell Ltd.

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**About Orthocell Limited**

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™, a collagen medical device which facilitates 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 cleared for use in US FDA (510k), Australia (ARTG) and Europe (CE Mark). Remplir™, for peripheral nerve reconstruction, recently received approval in Australia (ARTG). 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, manufacturing scale up and FDA engagement in advance of a randomised controlled study under FDA supervision.

For more information on Orthocell, please visit [www.orthocell.com.au](http://www.orthocell.com.au) or follow us on Twitter **@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.





# Investor Presentation

July 2022





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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.



# Key investment highlights

Orthocell is a regenerative medicine company delivering breakthrough products for the treatment of serious musculoskeletal disorders.



**Striate+ global exclusive license and manufacturing agreement with BioHorizons.**  
Strengthens the balance sheet, validates the CelGro™ portfolio and supports scale up of production requirements.



**GMP-certified and TGA-licensed manufacturing facility**  
ready to manufacture, scale up and distribute, globally.



**Comprehensive global patent portfolio**  
providing protection in all major jurisdictions including US, EU, AU, China, and Japan.



**Advanced portfolio with significant clinical evidence and near-term commercial milestones** returning patients to work, sport and recreation pain free.



# Corporate Snapshot

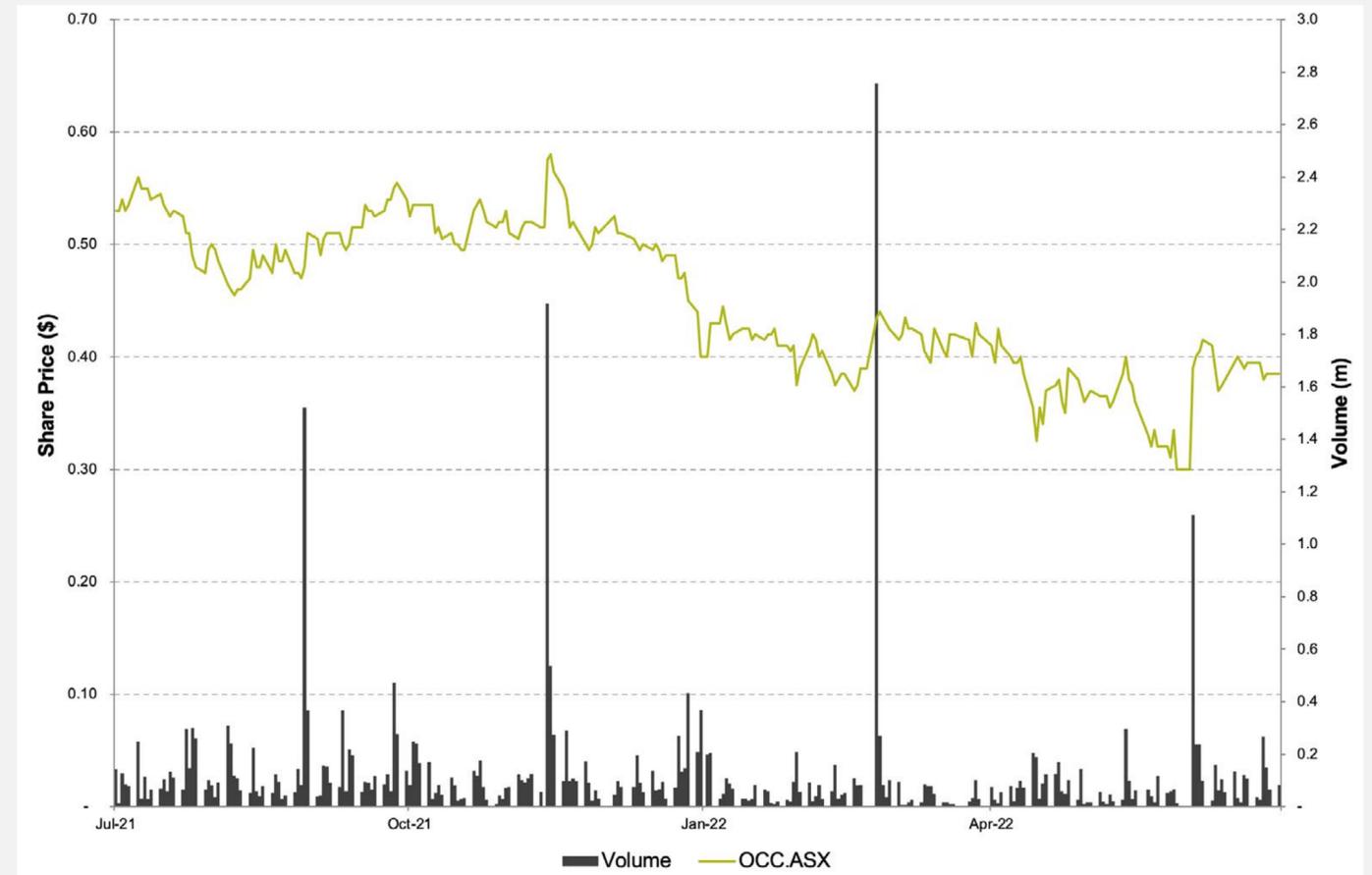
## ASX: OCC TRADING INFORMATION

<b>Share Price</b>	<b>0.385</b>
12 month low/high	\$0.300/\$0.580
Shares outstanding	197,127,913
<b>Market Capitalisation</b>	<b>75.9M</b>
Cash (25 July, 2022)	31M
Debt (25 July, 2022)	Nil
Enterprise Value	44.9M

## SUBSTANTIAL SHAREHOLDERS

Shareholder	%
Founders & Management	14.70%
Institutions	7.30%

## SHARE PRICE PERFORMANCE





# About Orthocell Ltd

Orthocell is a regenerative medicine company delivering breakthrough products that restore mobility and function.

## CelGro™

Medical device for bone and soft tissue reconstruction

- Designed to augment surgical repair of bone and soft tissue
- Striate+ for dental applications approved in US, EU and AUS
- Remplir for nerve repair now approved in AUS
- Demonstrated superior clinical performance when compared to the current market leading products
- Approaching pivotal near-term commercial milestones

## OrthoATI™

Cell therapy for tendon regeneration

- First injectable clinical stage cellular therapy for treatment of chronic tendon injuries
- Addressing a significant unmet clinical need for a safe, effective and non-surgical solution
- Successful OrthoATI v Corticosteroid (RCT) study
- US FDA engagement and commercial preparations in progress to support next RCT

# Significant market opportunity

At the forefront of a large and growing market opportunity in regenerative medicine in the musculoskeletal space.

**Driven by rising rate of musculoskeletal disorders and demand for efficient and cost-effective treatments.**

**CelGro™  
>US\$10bn**

**OrthoATI™  
>US\$7.7bn**

**Total Addressable Market  
>US\$17bn p.a.**

1. Addressable markets include US, Japanese, European and Australian markets, OrthoATI™ addressable market includes the following indications: tennis elbow, rotator cuff, gluteal, patellar, hamstring and Achilles. CelGro™ addressable market includes the following indications: dental, rotator cuff and nerve



# US Strategic Focus

Advanced product portfolio with near term milestones and emerging pipeline

Product	Application	Clinical Development Phase	US Regulatory Phase			Upcoming Catalysts
			Design Trial	Implement Trial	Approved	
<b>CelGro™</b> Medical Device	Striate+ <sup>1</sup>					<b>Engaged BioHorizons</b> - exclusive license and manufacturing partner
	Remplir <sup>2</sup>					<b>US commercialisation strategy</b> - finalise US regulatory/reimbursement study
	SmrtRope (Ligament replacement)					<b>Commence pre-clinical study</b> - ACL repair
<b>OrthoATI™</b> Cell Therapy	Rotator Cuff					<b>Release RCT results</b> - OrthoATI v corticosteroids
	Lateral epicondyle					<b>Recruitment complete</b> - OrthoATI vs surgery

<sup>1</sup> Approved in the US, AUS & EU

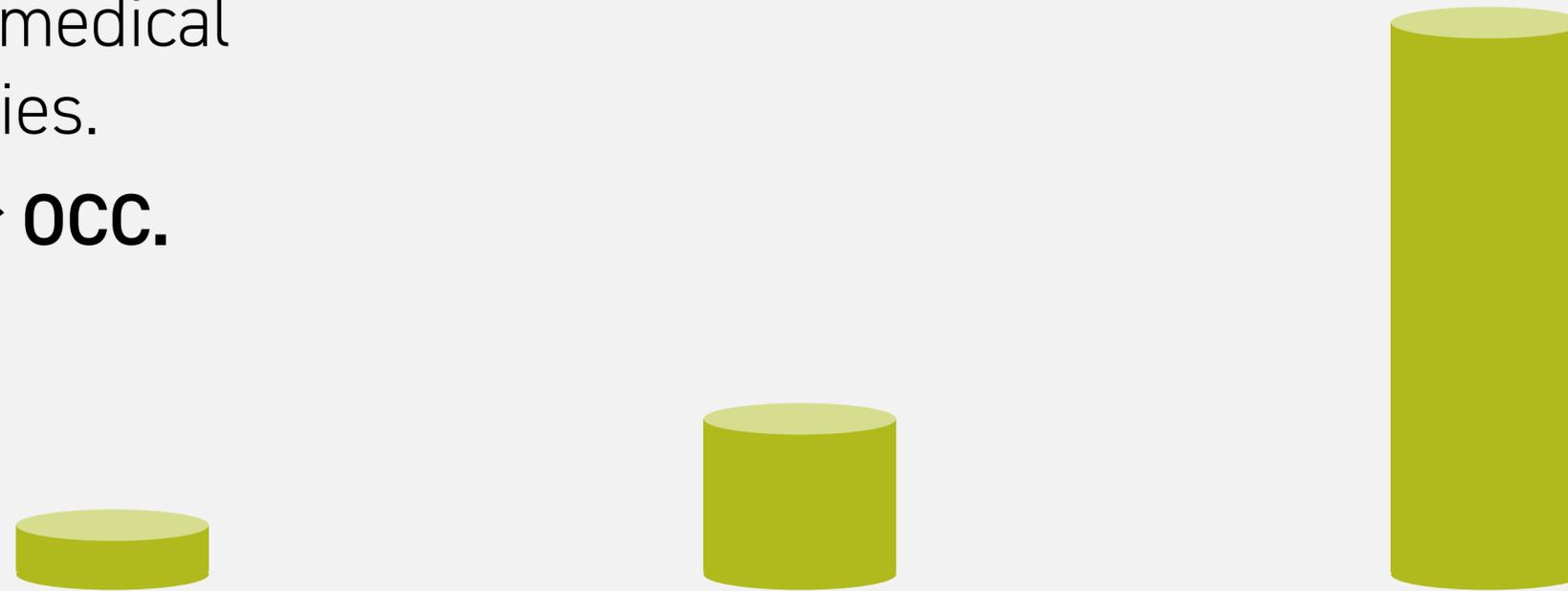
<sup>2</sup> Approved in AUS



# Valuation upside

Valuation comparison to other medical device and life science companies.

**Significant upside potential for OCC.**



Market Capitalisation	\$80m	\$200m	\$1B
Company			
Device	Autologous injectable therapy and medical device	Autologous cell harvesting device	Synthetic scaffold device
Indication	Bone, tendon and nerve	Acute thermal burn wounds	Dermal wound repair
Stage	US Approved 2021	US Approved 2018	US Approved 2015

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**Striate**  <sup>TM</sup>

**MORE THAN A  
BARRIER MEMBRANE**



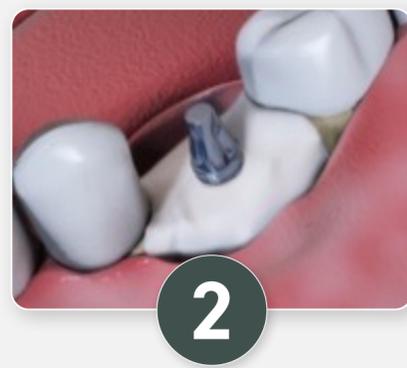


# Striate+™ premium dental membrane

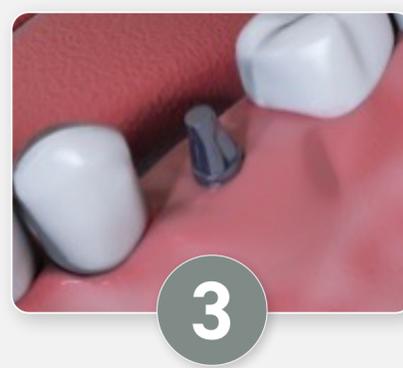
- Striate+ is a sterile, resorbable collagen membrane for use in dental bone and tissue regeneration procedures.
- Striate+ is designed to protect the bone defect from ingrowth of gingival tissue, to provide a favourable environment for osteogenesis and to assure reliable formation of high-quality bone.



**1**  
Preparation of repair site. Defect site is filled with bone graft



**2**  
Striate+ placed over defect and implant abutment installed



**3**  
Wound closure



**4**  
Crown placement 3-6 months later



# Striate+™ global exclusive license and manufacturing agreement with BioHorizons



We are very pleased to partner with Orthocell to offer our valued customers a dental membrane with excellent handling properties and regenerative potential. Striate+™ will be a highly complementary addition to our global biomaterials product portfolio for dental tissue regeneration.

- President and CEO of BioHorizons,  
Steve Boggan

- In consideration of the license granted, Orthocell has received in cash **AU \$21,461,686 million**, net of fees.
- BioHorizons is part of Henry Schein, Inc (NASDAQ: HSIC) and a leading global provider of dental implants and tissue regenerative products for dentists.
- Orthocell will supply BioHorizons with Striate+™ products, and BioHorizons will exclusively market and distribute Striate+ globally.



# Significant re-rating event



## Unrestricted and non diluting capital

- Non diluting payment is free of encumbrances - cash can be used without restrictions .

## Strong capital position

- \$31m cash at bank<sup>1</sup>
- Well positioned to advance the commercialisation of the US nerve and tendon repair programs.

## Validation of the portfolio

- Proves the platform potential and positions company to commercialise US nerve repair product – BioHorizons deal is restricted to the dental field only and does not prohibit a nerve or tendon deal.

## Established local manufacturer

- This supports the scaling of production to meet both BioHorizons supply requirements and the Company's nerve production requirements.

## Global market launch

- Actively preparing for US market launch with recurring revenue growth driving towards sustainability

1. Cash at bank as at 25th July 2022



# Striate+™: path to partnering



Executed a strategy to engage a global partner to manage the distribution and marketing of Striate+



## Clinical data and regulatory approval

Successful regenerative medicine-driven product development strategy produced a market leading product approved in US, EU and AUS.



## Clinician advocacy and awareness

Established a world-class KOL network to validate the product and support ongoing discussion with potential distribution partners.



## Manufacturing and logistics

Scaling up to >100,000 units per annum. High-quality US and EU warehouse and logistics solution established.



## Extensive partner engagement

Engaged early with multi-national dental companies for US marketing and distribution rights

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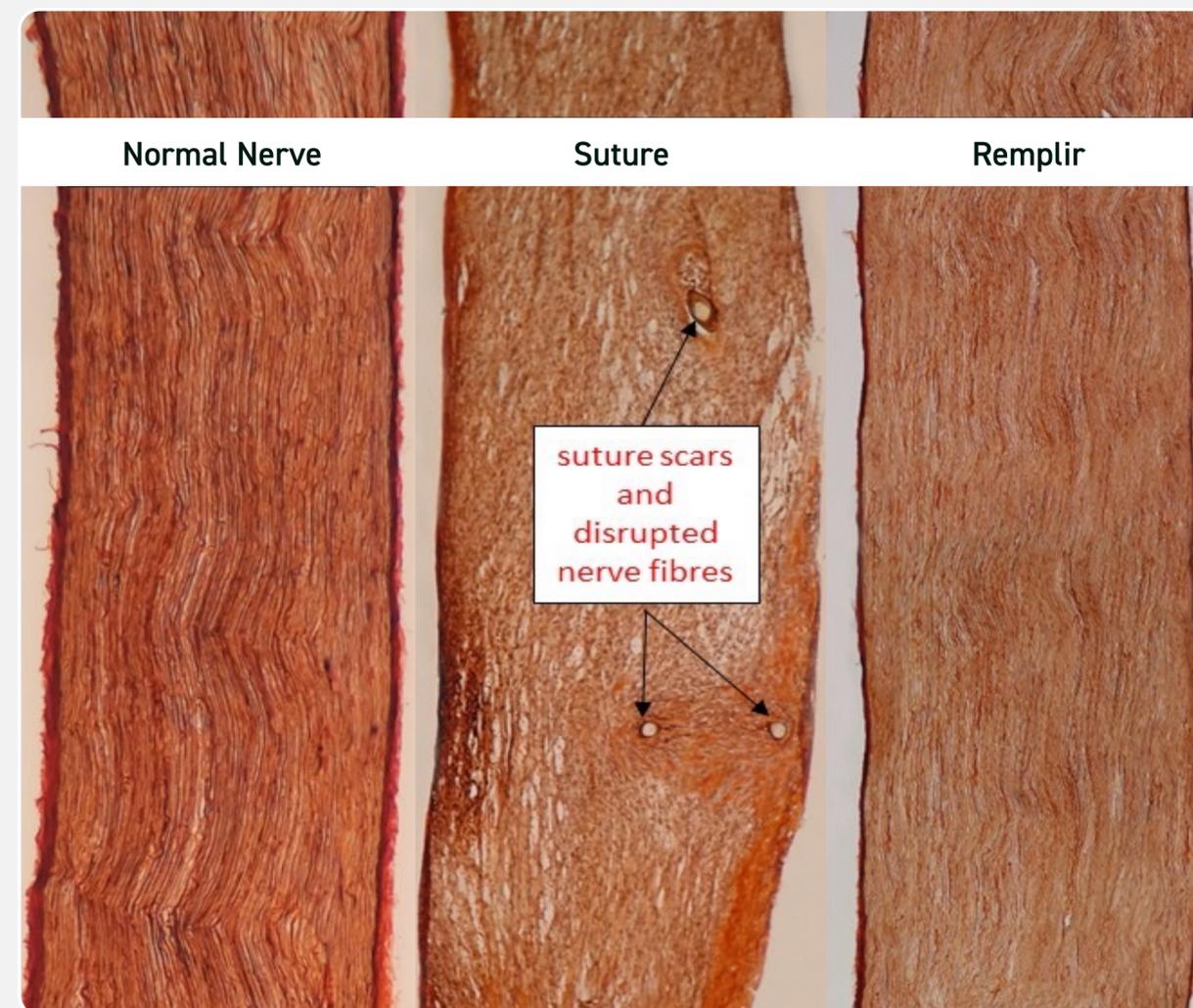
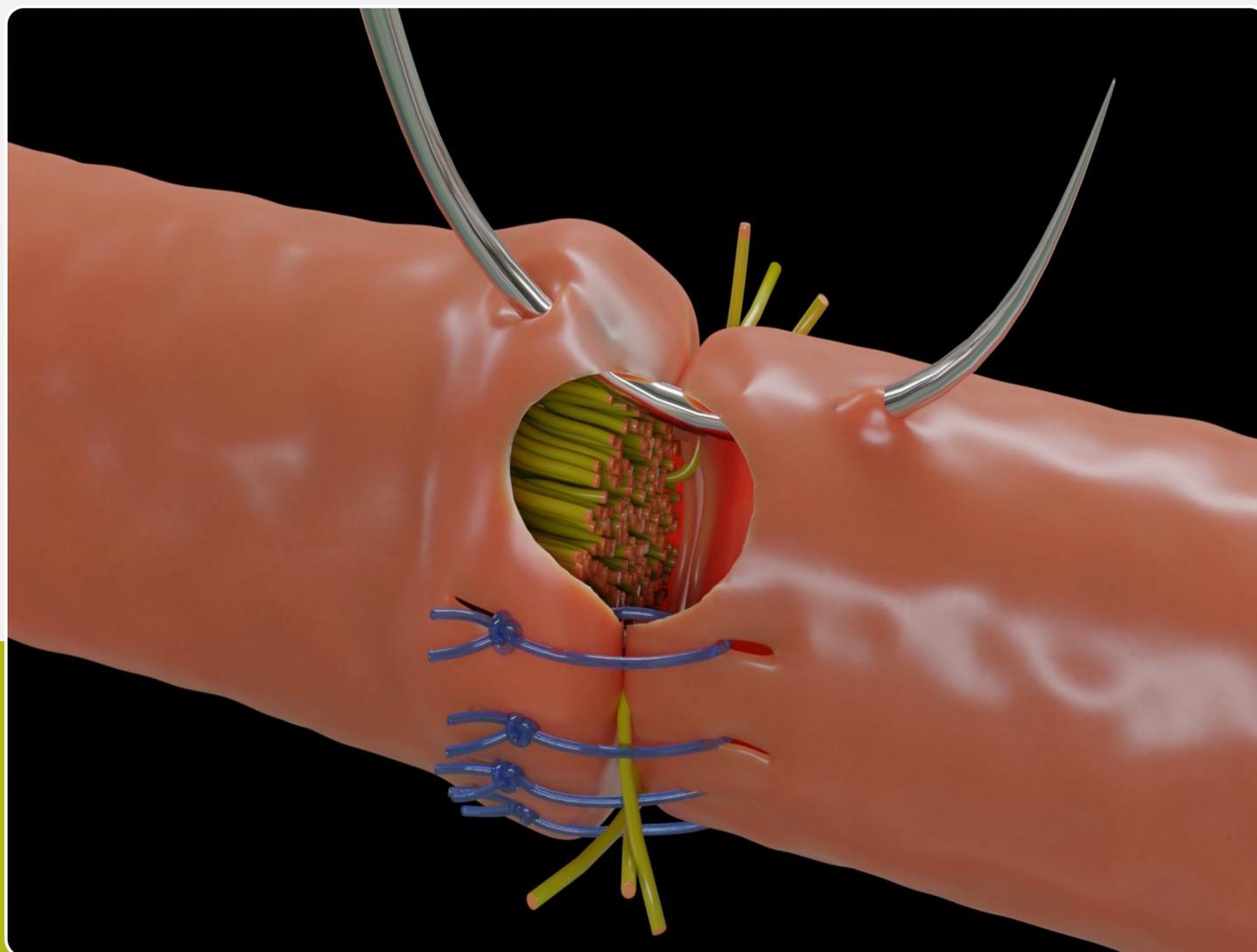
# Remplir™

REVOLUTIONISING  
NERVE REPAIR



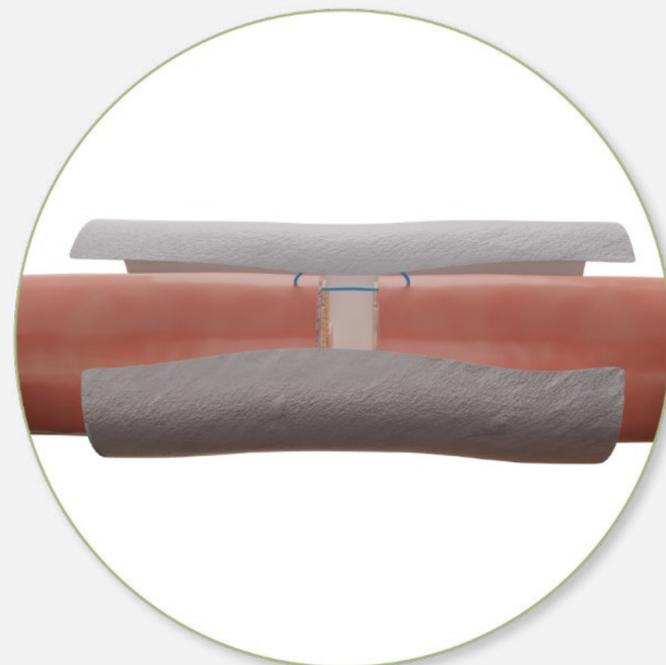
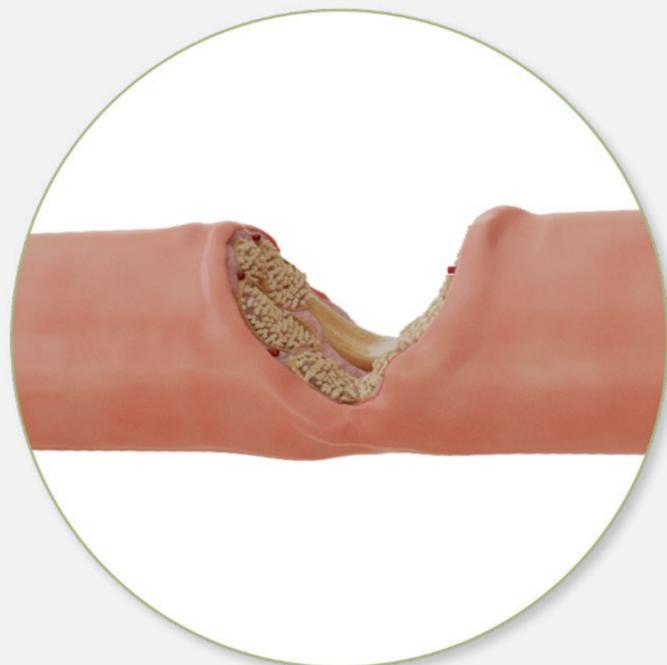
# Traditional repair outcomes are suboptimal

Direct suture = tension, buckling and can be ineffective and unpredictable in restoring function.



# Remplir™ – Approved in Australia (TGA)

Collagen nerve wrap intended for use in peripheral nerve repair



GUIDING PREDICTABLE  
OUTCOMES IN  
PERIPHERAL  
NERVE REPAIR

Proven biocompatibility

Exceptional handling characteristics

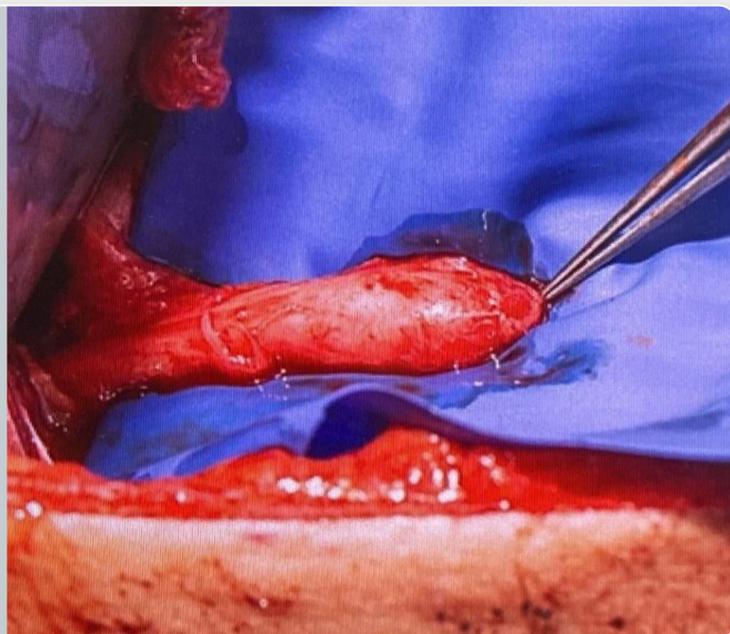
Provides a bioactive chamber



# Surgical technique – Remplir™ assisted coaptation

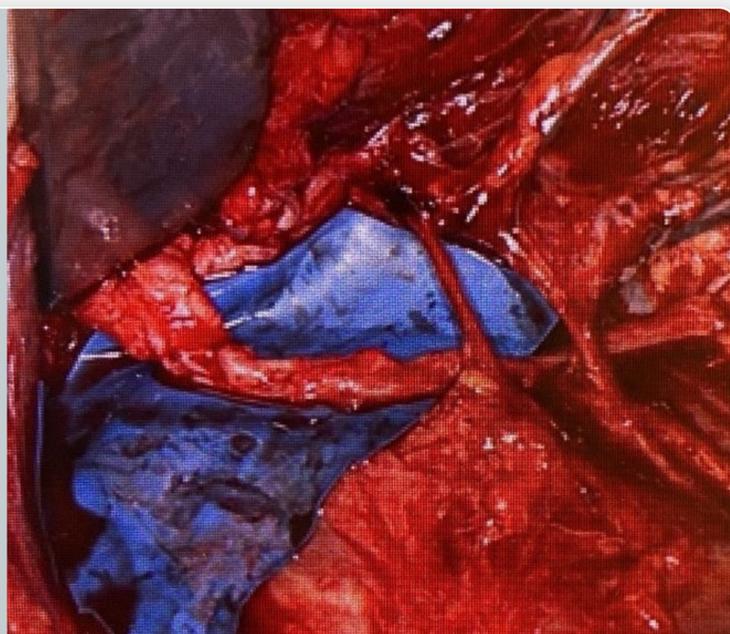
1

Isolating donor nerve



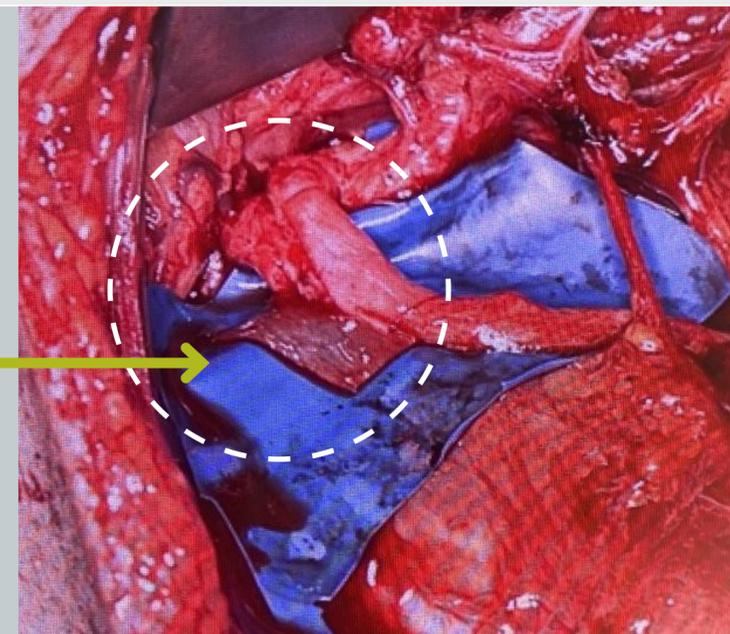
2

Co-adapting donor and recipient nerve



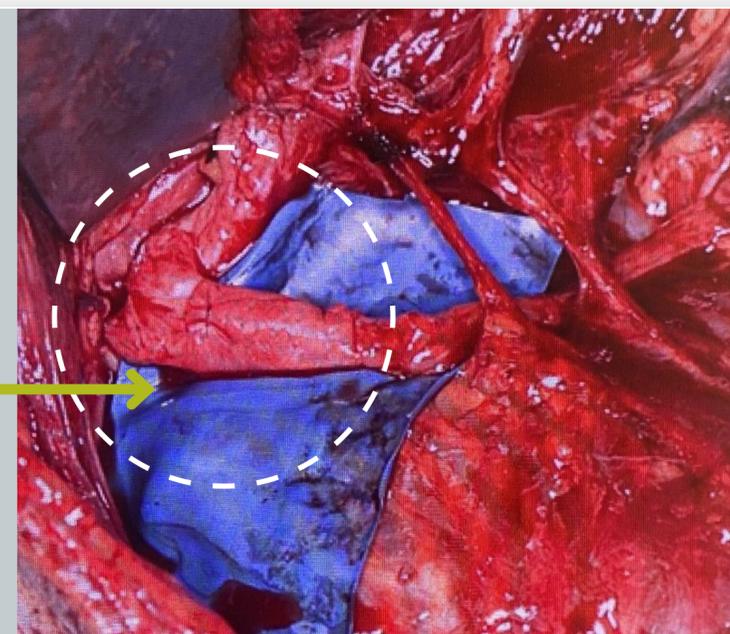
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Wrapping Remplir around nerve ends to create a customised conduit



4

Remplir guides and supports nerve repair





# Remplir™: compelling long term clinical results

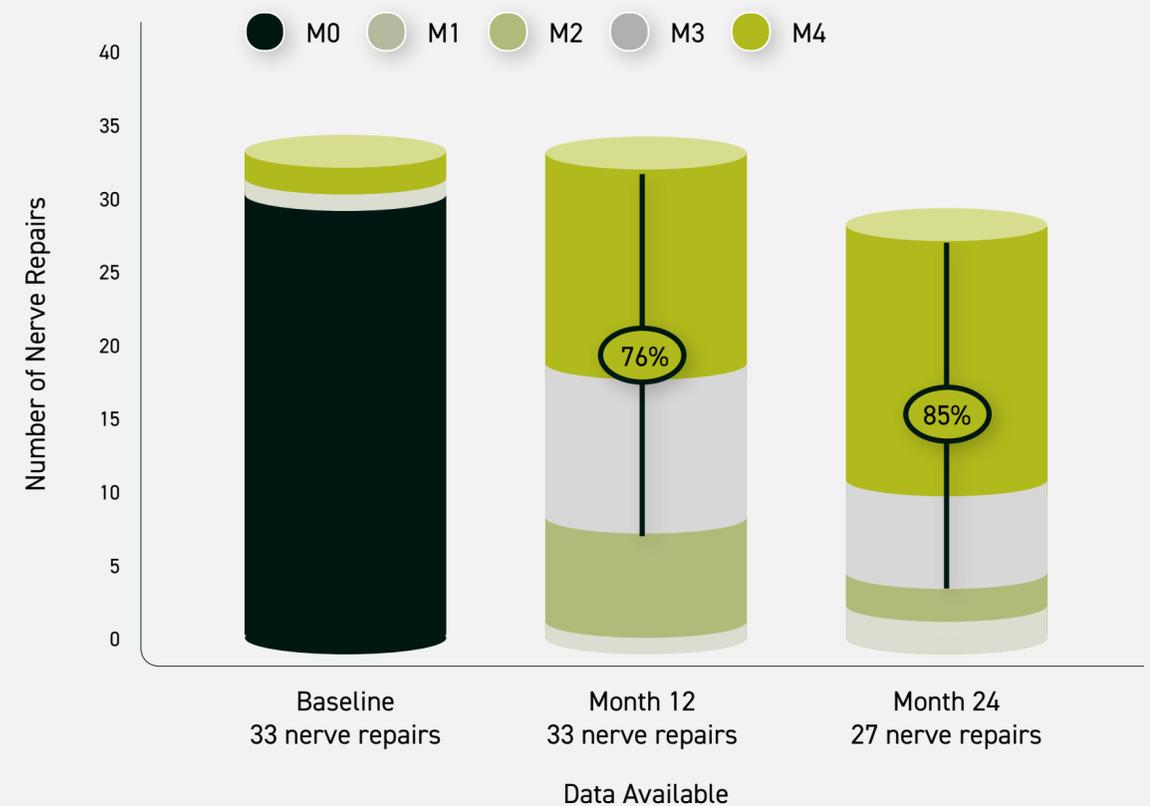
Patients regained voluntary muscle movement within 12 months, increasing strength and range of motion at 24 months



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

Figure 1. 76% functional recovery at 12 mths increasing to 85% at 24 mths



**Grade 3 and 4**  
voluntary movement with improved strength and range of motion

**Grade 2**  
voluntary movement restored, limited strength and range of movement

**Grade 0 and 1**  
no voluntary movement

**FINAL RESULTS**

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

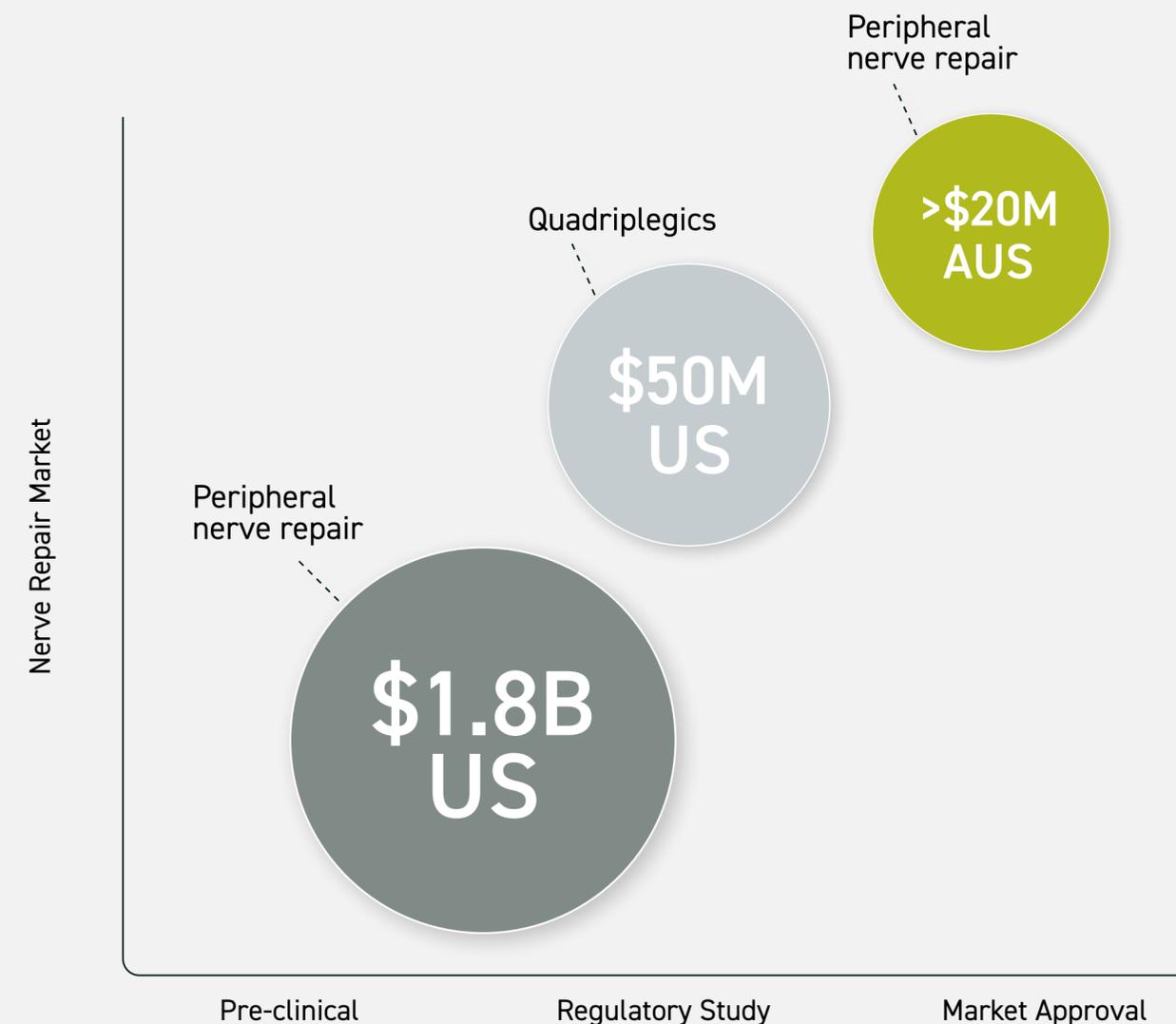


# Remplir™: peripheral nerve repair market

Remplir's addressable market in peripheral nerve repair is estimated to be worth more than **US\$7.5 billion<sup>1</sup> per year.**

**Orthocell is executing AUS market entry and focusing on gaining US market approval.**

Strong demand for a medical device that enables surgeons to perform complex surgical repairs efficiently with better results.



1. Addressable markets include US, Japanese, European and Australian markets. Referenced papers were used to derive specific assumptions in the procedure potential estimates. Papers used include both U.S. and OUS databases and studies.



# OrthoATI™

ADVANCED CELLULAR  
THERAPY FOR CHRONIC  
TENDON INJURY



# OrthoATI™: a global clinical first

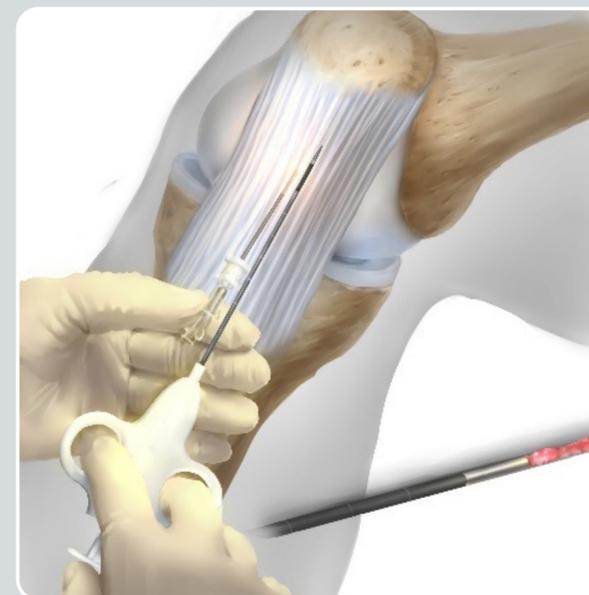
Injectable cell therapy returns patients to work, recreation and elite sport, pain-free.

## OrthoATI is a novel treatment

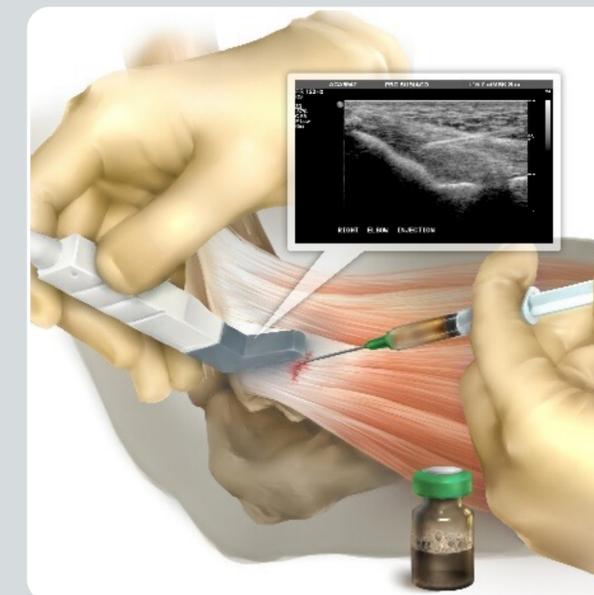
- Breakthrough in regenerative medicine directly addressing the root cause of injury
- Replenishes degenerative tissue with healthy mature tendon cells, reducing pain and returning function
- Extensive clinical validation - over 1,000 patients treated with OrthoATI to date
- No 'non-surgical' treatments currently available to treat chronic tendon injury
- Optimised manufacturing capabilities: GMP-certified and TGA-licensed facility<sup>1</sup> and PPI<sup>2</sup> release criteria in place

1. GMP: good manufacturing practices; TGA: Therapeutic Goods Administration  
 2. PPI: purity, potency and identity  
 3. Internal Orthocell modelling based on published epidemiology data and assuming target pricing for a subset of the rotator cuff injury segment.

## Two stage, minimally invasive procedure



1. Biopsy procedure and tenocyte cultivation



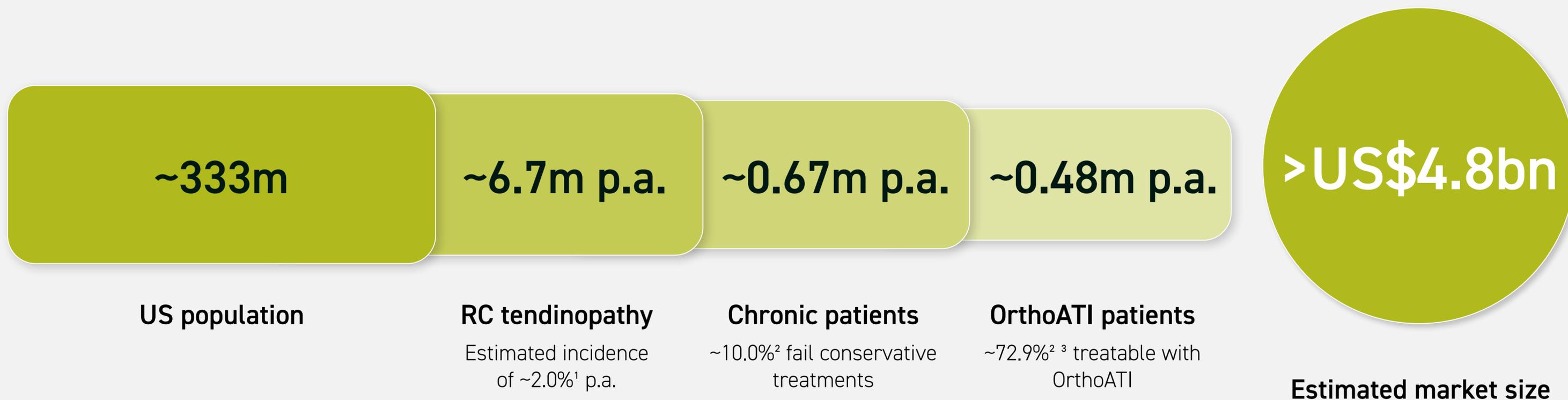
2. Tenocyte implantation via ultrasound

**Applicable to >480,000 rotator cuff patients per year in the US alone – US\$4-5 billion<sup>3</sup> market opportunity.**



# OrthoATI™ – US Rotator Cuff addressable market

OrthoATI is at the forefront of a large and growing market opportunity where the addressable market is estimated to be >US\$4.8bn p.a.

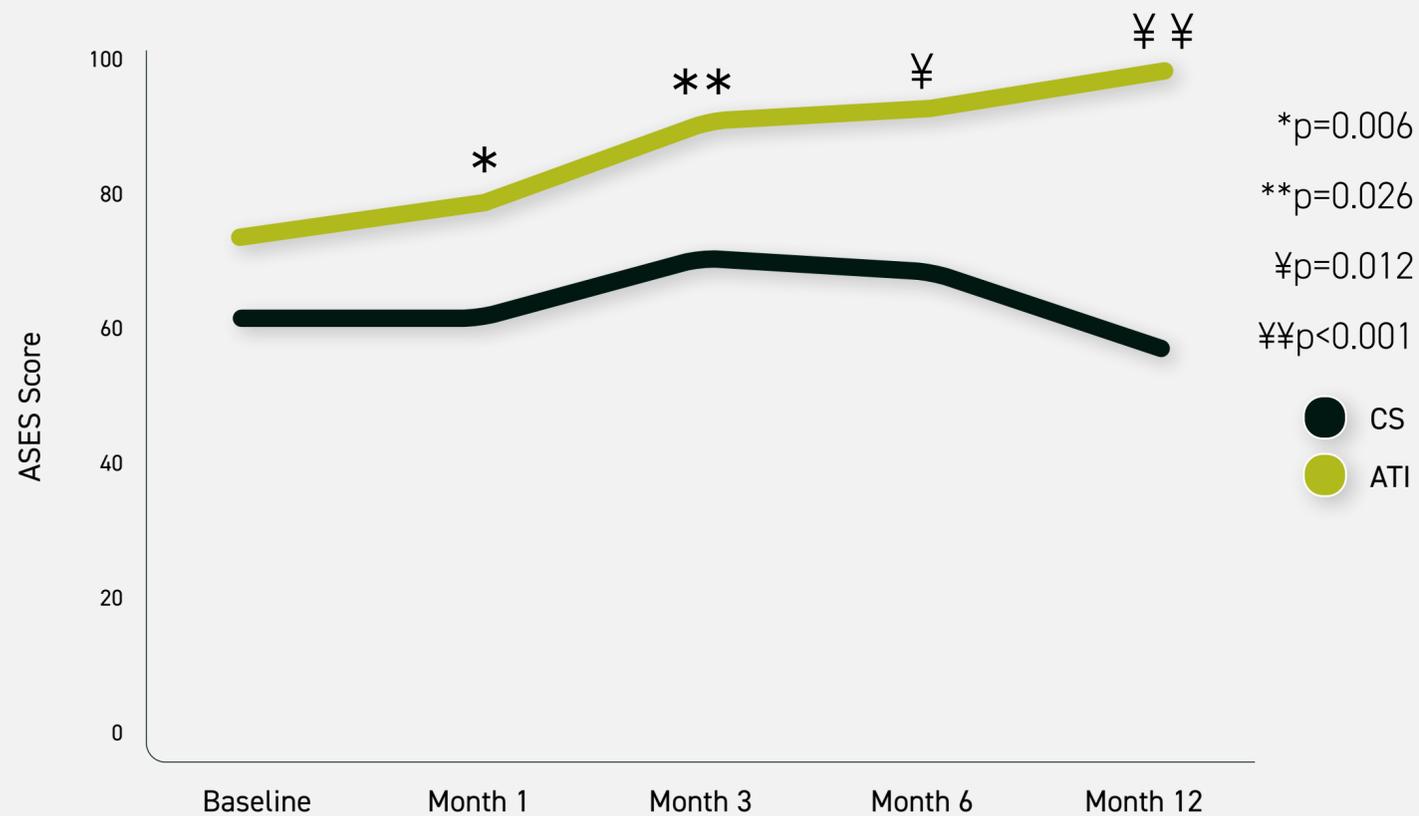


1. Littlewood et al, 2013. Shoulder and Elbow 5, pp 256-265  
2. Kane et al, 2019. Am Fam Physician 100(3):pp 147-157  
3. Parikh et al, 2021. Current Medical Research and Opinion, 37(7):pp 1199-1211



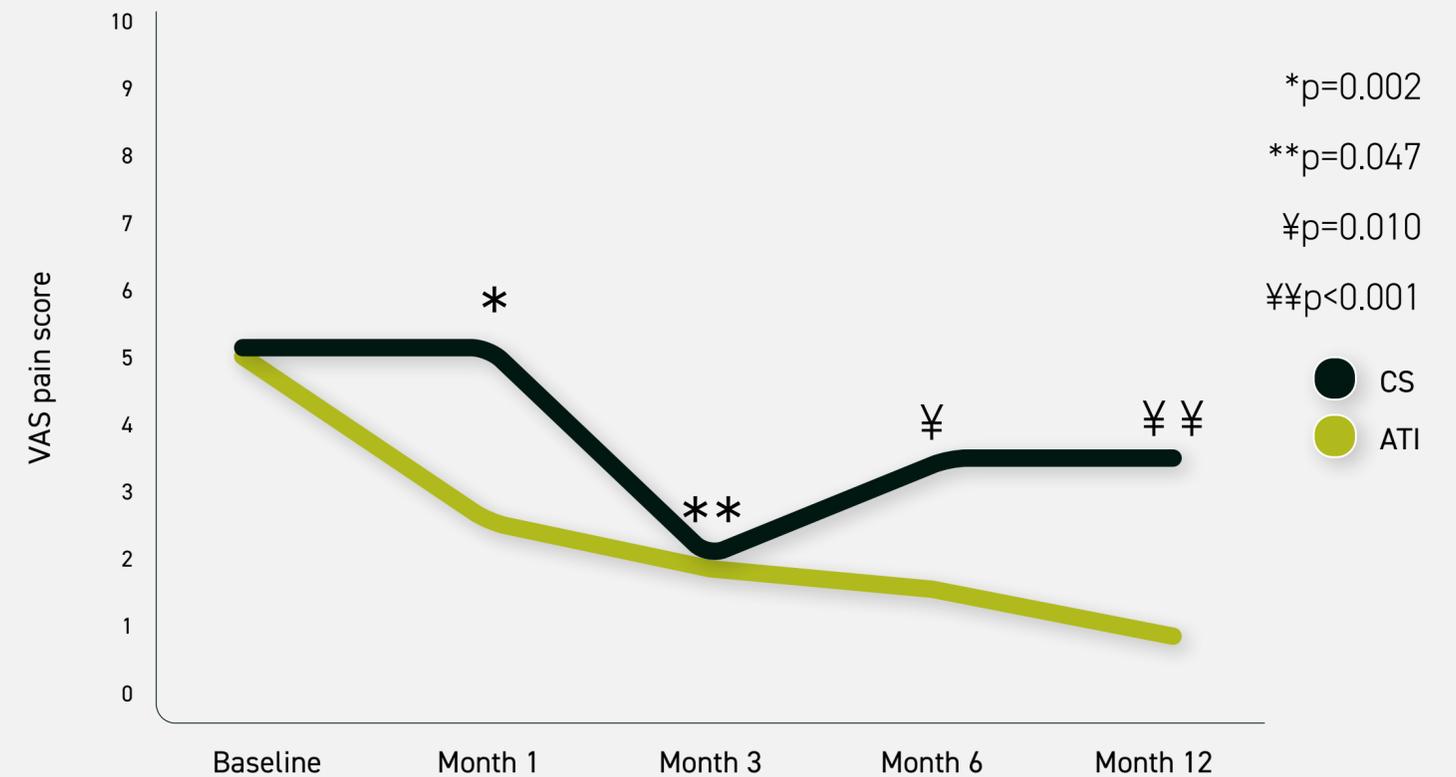
# OrthoATI™ RCT study results

OrthoATI is significantly more effective than steroid injection for treatment of rotator cuff tendinopathy with intrasubstance tendon tear



## OrthoATI returns function

- Significant and sustained return of shoulder function
- Average ASES score improved from 74.2 pre-treatment to 93.3 at 12 months post-treatment (MCID = 12.0)



## OrthoATI reduces pain

- Significant and sustained reduction in pain after treatment
- At 6 months post-treatment, 67% of participants reported a VAS pain score of 3 or less ("successful outcome"), improving to 84% of participants at 12 months post-treatment.

# OrthoATI™ – next steps

Clinical program can now be initiated in the US with manufacturing scale up and commercial support

- Advancing next interaction with FDA to approve clinical development plan and secure Regenerative Medicine Advanced Therapy (RMAT) Designation to accelerate regulatory processes, to lead to a successful Biologic License Application (BLA)
- Planning randomised clinical study under FDA supervision
- Commercial preparations, key opinion leader engagement, reimbursement and market entry activities being advanced with new team members
- Team has unrivaled experience with FDA regulated cell therapy product development and commercialisation





# Upcoming Catalysts<sup>1</sup>

## Striate+™ premium periodontal membrane

Global product launch

2022

## Remplir™ premium nerve wrap

Engage AUS marketing and distribution partner/s

FDA pre-submission

Australian market reimbursement

3Q 2022

4Q 2022

## OrthoATI™

OrthoATI v Corticosteroid (RCT) cross over patient data (shoulder)

OrthoATI v Surgery (RCT) last patient 12mth follow-up (elbow)

3Q 2022

2Q 2023

1. Timelines are an estimate only and may be subject to change due to matters not under the Company's control such as COVID-19 mitigation measures.



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