



# Investor Presentation - CelGro

## September 2016

### ASX: OCC

Paul Anderson  
Managing Director



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# Company Overview



## Delivering breakthrough products in regenerative medicine:

### *Cell therapies:*

- ▶ **Ortho-ATI®**. World's first stem cell therapy to regenerate tendons
- ▶ **Ortho-ACI®**. Next generation cartilage repair
- ▶ Actively engaging strategic partners in US and Japan

### *Soft tissue repair device CelGro®:*

- ▶ First EU approval imminent
- ▶ Platform technology
- ▶ Highest quality collagen scaffold to enhance soft tissue and bone regeneration
- ▶ Deal ready – positioned for commercialisation of products and rapid growth



# Corporate Overview



## Experienced team to execute

CEO	Paul Anderson	<ul style="list-style-type: none"><li>• Verigen</li><li>• Genzyme</li><li>• Biomet</li></ul>
CSO	Prof. Ming Hao Zheng	<ul style="list-style-type: none"><li>• Verigen</li><li>• Genzyme</li><li>• UWA</li></ul>
Executive Chairman	Dr Stewart Washer	<ul style="list-style-type: none"><li>• Cynata</li><li>• Minomic</li></ul>
Director	Matt Callahan	<ul style="list-style-type: none"><li>• iCeutica Inc</li><li>• Botanix Pharmaceuticals</li><li>• Dimerix</li></ul>
Director	Prof. Lars Lidgren	<ul style="list-style-type: none"><li>• UN Bone and Joint Chair</li><li>• Biomet</li><li>• Uni. Lund</li></ul>
Director	Qui Xiao Zhao	<ul style="list-style-type: none"><li>• Shenzhen Lightning Digital</li><li>• Technology Co Ltd</li></ul>

## Key Facts

ASX	OCC
Share Price	AU\$0.41 (@14th Sept 2016)
Ordinary Shares on Issue	91.2 million
Market Cap	AU\$37 million
Options & Warrants outstanding	21.2 million
Cash at bank	AU\$5 million (@ 30 June 2016)

## Shareholding Structure

Shareholders 3,050

Directors & Management 30%

60%

Top 20



# Investment Opportunity



## Soft Tissue Repair - Global Need & Opportunity

### Age quake

- ▶ Musculoskeletal disorders are twice as common as cardio-vascular conditions
- ▶ Increased demand for safe, efficient, cost effective treatments
- ▶ Global soft tissue repair market - US\$7B in 2013 expected US\$10B by 2020

### Compelling clinical evidence

- ▶ CelGro® - Highest quality pure collagen medical device
- ▶ Ortho-ATI® - 300 patients successfully treated - first to market

### Big Pharma currently investing/partnering

- ▶ Focus on cell therapies and scaffolds/devices
- ▶ Orthocell sits across all these areas

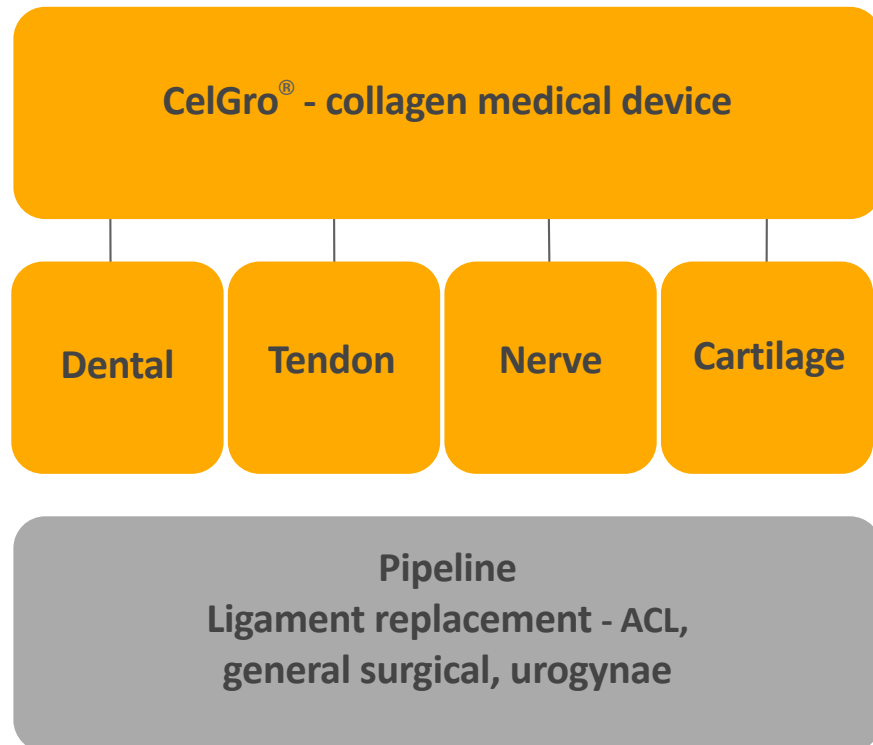


### Recent M&A Deals

- ▶ 2014 – Organogenesis acquired Dermagraft (Human Dermis Scaffold - Orthopaedic applications) for US \$300MM
- ▶ 2013 – DSM acquires Kensey Nash (Orthopaedic applications) for US \$360MM

## A Paradigm Shift in Soft Tissue Reconstruction

*Celgro® is a pure collagen medical device manufactured by Orthocell to augment soft tissue and bone regeneration.*



### *Ideal collagen scaffold qualities:*

- Compatibility
- Guided tissue repair/ optimal tissue integration remodeling
- Tensile strength
- Versatility

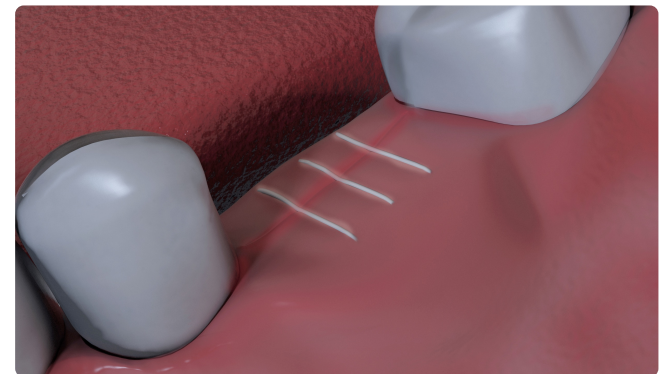
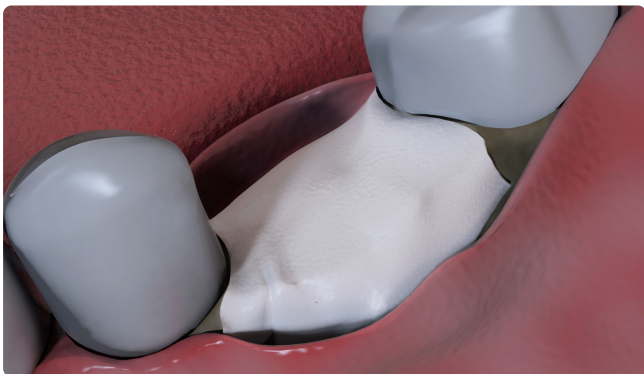
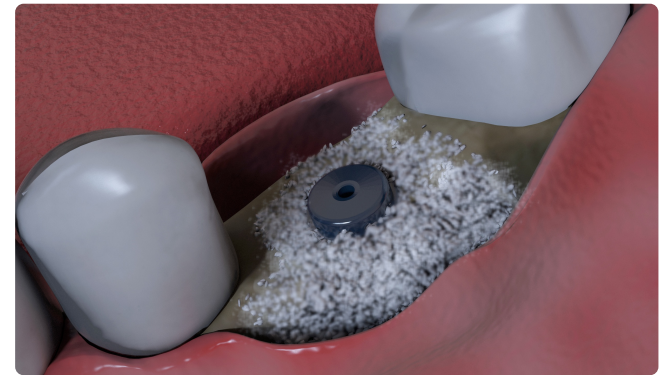
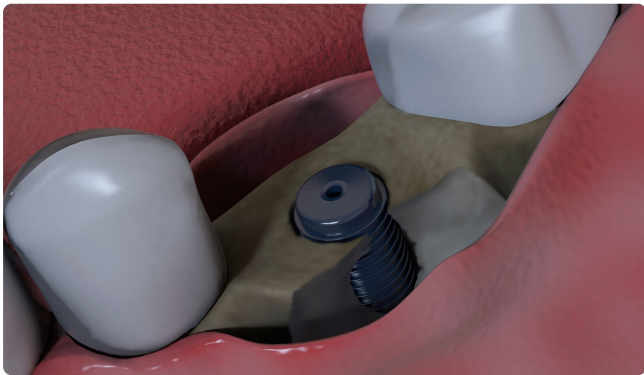
### *Competitor limitations:*

- Not fit for purpose
- Poor integration
- Limited applications

### *CelGro® has a unique design history:*

- Regenerative medicine focus
- Meets needs of soft tissue reconstruction
- Fit for purpose

## Dental Application



## Dental Opportunity



2 million

# annual dental membranes  
used in conjunction with  
bone graft substitutes <sup>1.</sup>

\$800  
million

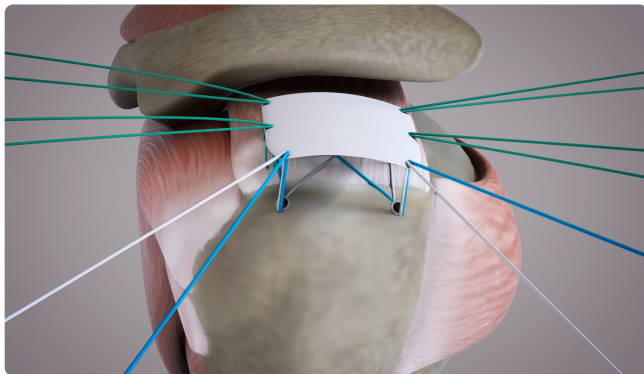
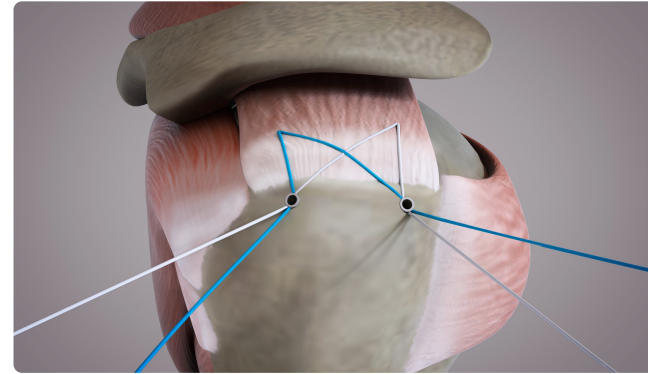
Value of addressable market  
in dental <sup>1.</sup>

CelGro<sup>®</sup>  
opportunity

- Guided tissue repair
- Optimal tissue remodeling
- Better bone quality

1. US, JP, EU & AUS - 2015

# Tendon Application



## Tendon Opportunity



650,000

**# annual rotator cuff  
procedures suitable for Celgro <sup>1.</sup>**

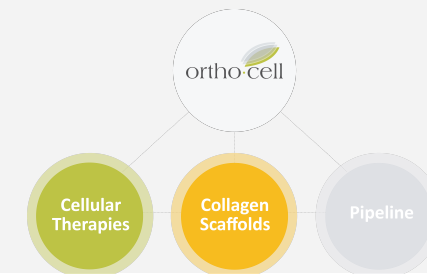
\$1.6  
billion

**Value of addressable market  
in rotator cuff surgeries <sup>1.</sup>**

**CelGro<sup>®</sup>**  
opportunity

- **Guided tissue repair**
- **Optimal tissue remodeling**
- **Reduced surgical failure rates**

# Pathway to Market



## Near Term Regulatory Approvals - First CelGro<sup>®</sup> EU

Product	Current Applications/Study	Stage of Development			Regulatory Targets <sup>2</sup>	
		Discovery	Pre-clinical	Clinical	0-6 months	Thereafter
<b>CelGro<sup>®</sup></b>	Dental, guided bone, soft tissue regeneration				<b>CE Mark (EU)</b>	<b>FDA (US)</b> <b>ARTG (AUS)</b>
	Rotator-cuff tendon repair					<b>CE Mark (EU)</b> <b>FDA (US)</b> <b>ARTG (AUS)</b>
	Peripheral nerve repair					<b>CE Mark (EU)</b> <b>FDA (US)</b>
	Cartilage repair					<b>CE Mark (EU)</b>
<sup>1.</sup> <b>Ortho-ATI<sup>®</sup></b>	Tennis elbow, gluteal, patella, achilles & rotator-cuff					<b>PMDA (JP)</b> <b>PreIND (US)</b> <b>ARTG (AUS)</b>
<sup>1.</sup> <b>Ortho-ACI<sup>®</sup></b>	Knee & ankle cartilage repair					<b>Asia Pacific</b> <b>ARTG (AUS)</b>
<b>Pipeline</b>	Ligament replacement - ACL, growth factors, lab grown tendon					<b>In development</b>

1. Marketed in Australia, Singapore, Hong Kong and New Zealand

2. Orthocell's estimates for regulatory applications



# CelGro® - CE Mark

Collagen  
Scaffolds

**CelGro® First EU approval -  
guided bone regeneration and  
soft tissue reconstruction**

## What does it mean?

- ✓ Authorised to market and distribute in the EU
- ✓ EU approved manufacturing facility

## Benefits of a CE Mark:

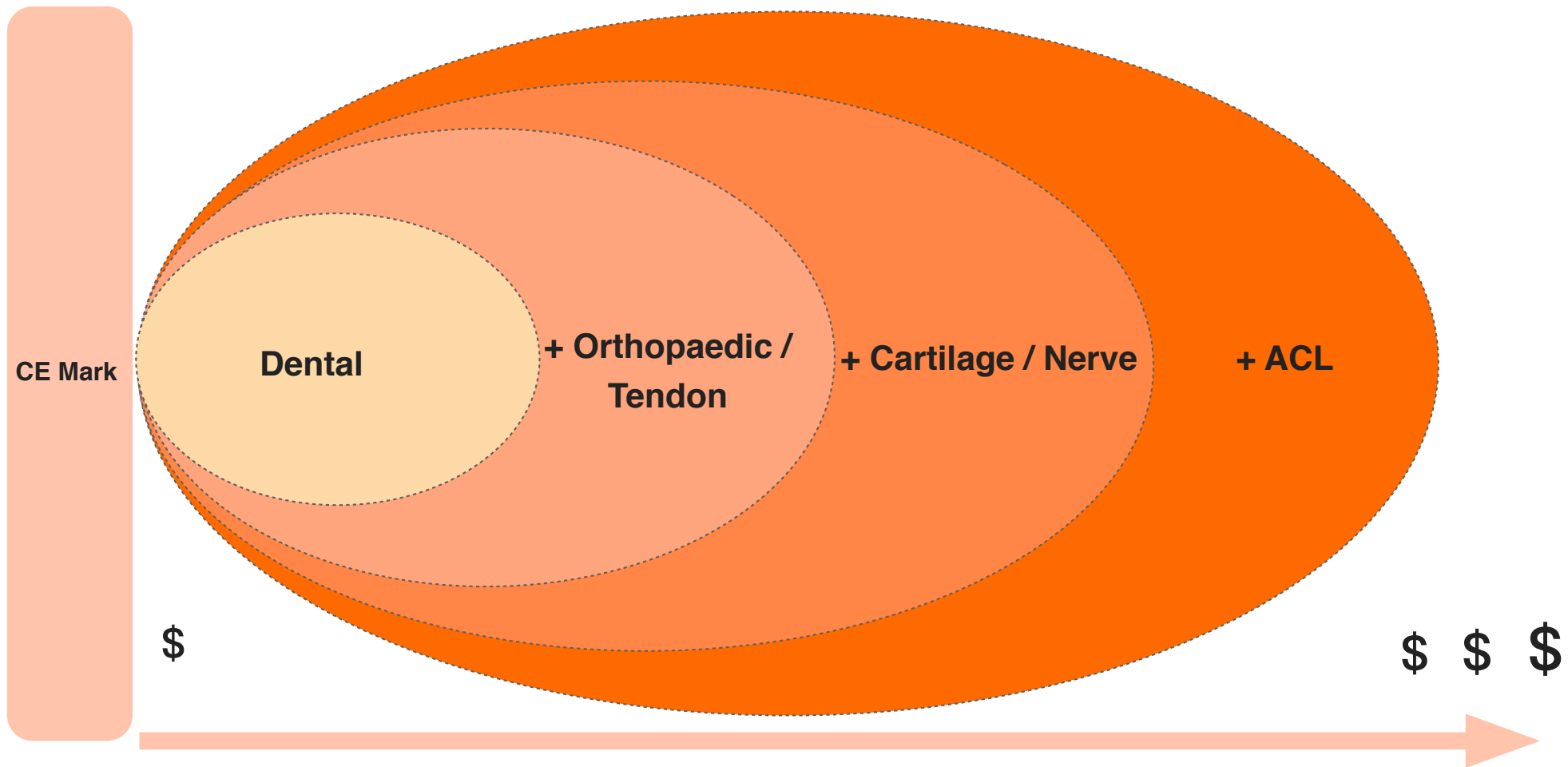
- Allows market entry in EU
- Foundation for regulatory application in other jurisdictions - US(FDA) and AU(ARTG)
- Platform technology validation



# CelGro® - Platform

Collagen  
Scaffolds

Value Increases With Every Additional Application



## 12 Month Milestones - Lead Applications

### ***Regulatory Targets***

- EU approval for Dental application -  
with regulatory applications in other jurisdictions to follow (US, AUS, JP)
- EU Tendon application -  
with regulatory applications in other jurisdictions to follow (US, AUS, JP)

### ***Clinical Studies***

- Dental study completion and publication
- Patient recruitment completion, for tendon, cartilage and nerve studies

### ***Strategic Partnering***

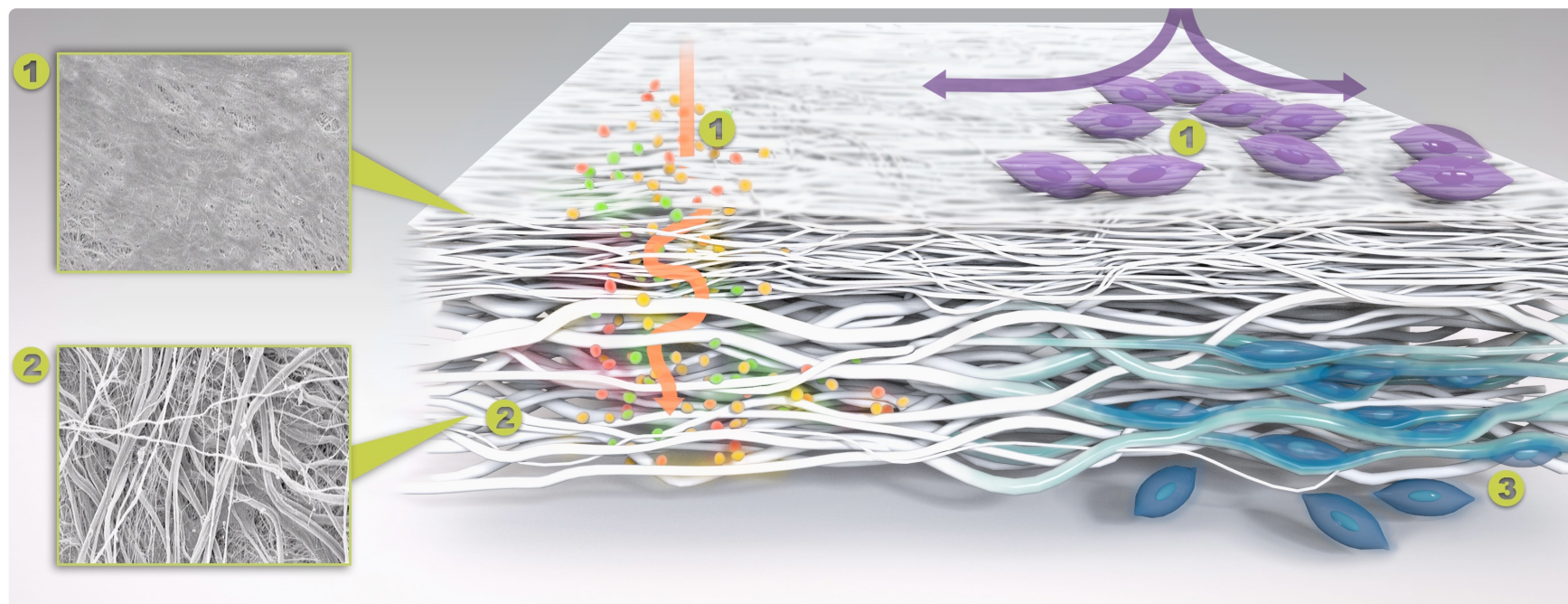
- Partnering deals in EU, US and JP



- Superior products
- Significant de-risked opportunity
- Clear pathway to large markets
- Expertise to partner and execute

# *Appendices*

## How CelGro<sup>®</sup> Works



## Positioning CelGro<sup>®</sup>

	CelGro <sup>®</sup>	Biogide <sup>®</sup>	Tissuemend <sup>®</sup>	Osseoguard <sup>®</sup>	BioMend Extend <sup>®</sup>	GraftJacket <sup>®</sup>
Highest Quality Raw Material	✓	✗	✗	✗	✗	✗
Proven Compatibility	✓	+/-	+/-	+/-	+/-	+/-
Native Bilayer Structure	✓	✓	✗	✗	✗	✗
Strong Mechanical Properties	✓	+/-	✓	+/-	✓	✓
Versatile Platform	✓	✗	✗	✗	✗	✗



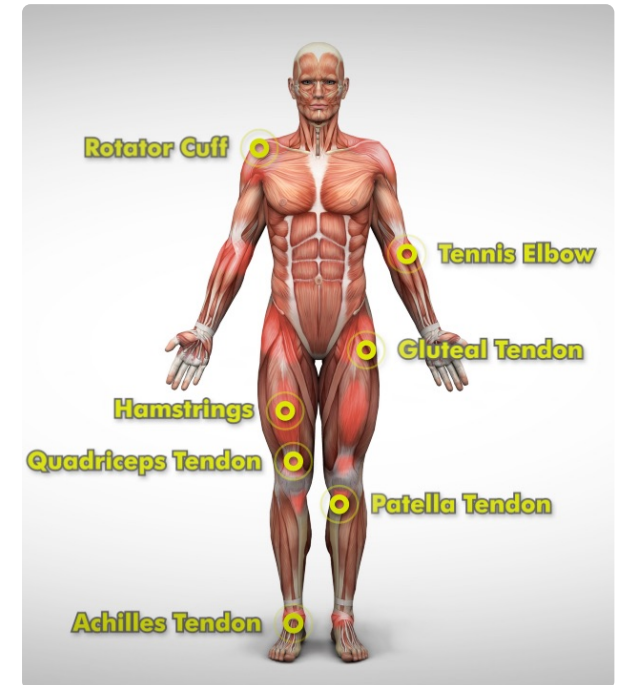
## Orthocell's Autologous Tenocyte Implantation

Ortho-ATI® is a stem cell therapy to regenerate tendons and ligaments which:

- uses each patient's own stem cells to regenerate tendon tissue
- enables healing of tendons, reduces pain and increases strength
- greatly improves the patient's mobility and quality of life
- multiple tendon applications

Ortho-ATI® is a two stage minimally invasive, walk-in, walk-out process:

- Biopsy procedure and tenocyte cultivation
  - Cell implantation
- 
- 4-5 week end to end process
  - early symptomatic relief, followed by structural and functional improvements



Common sites for Ortho-ATI®

## Breakthrough Regenerative Medical Therapy

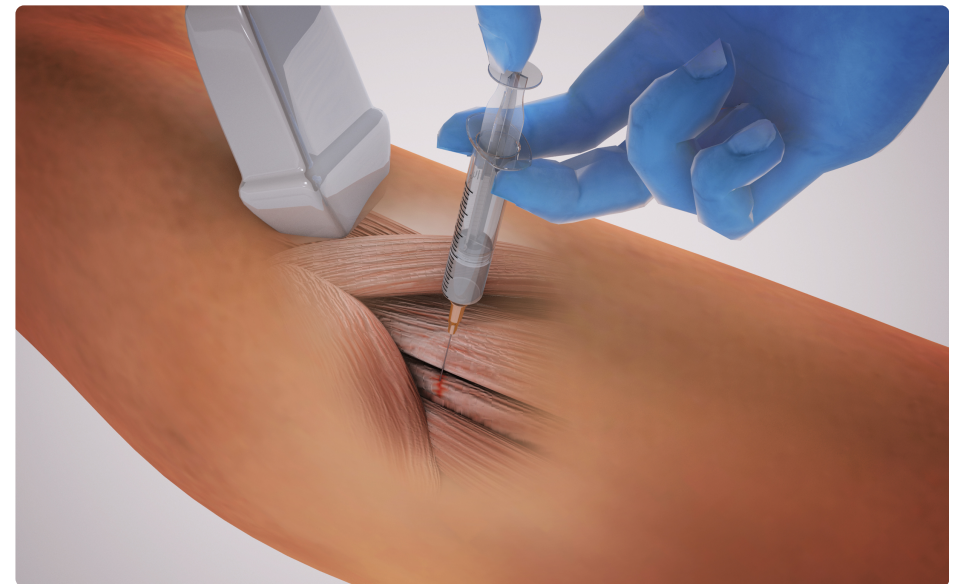
**Market leading** world first tendon regeneration treatment manufactured in Orthocell's TGA licensed facility

**Over 300 patients** treated to date. Demonstrated pathway to market

**Non operative** procedure with high cost-benefit outcomes

**Directly addresses** the underlying pathology of tendinopathy (disease modifying)

**Patent protected** in all major jurisdictions including USA, Australia, China, Singapore, Hong Kong and New Zealand



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## Expansion Plans

### Validated pathway to market

- Referral pathway
- Treatment pathway
- Manufacturing optimisation
- Tech transfer ready

### Bringing Ortho-ATI<sup>™</sup> to the world's largest markets:

- IND being prepared for US Phase 2 tennis elbow study
- partnering discussions ongoing with US and EU potential partners
- discussions in Japan underway to leverage abridged approval process

