

## Investor Presentation

**Perth, Australia; 15<sup>th</sup> September 2020:** Regenerative medicine company Orthocell Limited (ASX:OCC, “Orthocell” or the “Company”) is pleased to provide the attached investor presentation.

The presentation provides a comprehensive update of Orthocell’s regenerative medicine product portfolio, clinical and regulatory status and upcoming commercial milestones.

**Release authorised by:**

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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 soft tissue injuries. Orthocell’s portfolio of products include CelGro<sup>®</sup> platform technology, a collagen medical device which facilitates tissue repair and healing in a variety of orthopaedic, reconstructive and surgical applications. Orthocell has received European regulatory approval (CE Mark) for CelGro<sup>®</sup> and is marketed within the European Union for a range of dental bone and soft tissue regeneration procedures. CelGro<sup>®</sup> is being readied for first approval in the US and AUS. The Company’s other major focus is TGA-licensed cell therapies Autologous Tenocyte Implantation (Ortho-ATI<sup>®</sup>) and Autologous Chondrocyte Implantation (Ortho-ACI<sup>®</sup>), which aim to regenerate damaged tendon and cartilage tissue. Orthocell is moving forward with clinical studies designed to assist in the US (FDA) approval process and has completed its pre-IND meetings with the FDA.

For more information on Orthocell, please visit [www.orthocell.com.au](http://www.orthocell.com.au) 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.



A man and a woman are jogging on a paved path in a park. The man is on the left, wearing a light blue t-shirt and white shorts. The woman is on the right, wearing a grey long-sleeved shirt and purple leggings. They are both smiling and appear to be in good health. The background is a lush green park with many trees.

# Investor Presentation






September 2020

The logo for OrthoCell, featuring a stylized green and grey leaf-like shape above the text.

ortho·cell

# Orthocell overview

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

 <p><b>Advanced product portfolio with significant clinical evidence</b></p>	 <p><b>GMP-certified and TGA-licensed manufacturing capabilities</b></p>	 <p><b>Global patent portfolio</b></p>	 <p><b>Credentialed and highly aligned leadership</b></p>	 <p><b>Near-term milestones</b></p>
<p>Leading de-risked portfolio of regenerative medicine products that have shown in clinical studies and real world evidence to return patients to work, activities of daily living and elite sport pain-free.</p>	<p>Orthocell's Good Manufacturing Practice certified and Therapeutic Goods Administration licensed manufacturing facility underpin the Company's competitive advantage and can be readily scaled to meet market demand.</p>	<p>Regenerative medicine manufacturing technologies, products and treatment processes patent protected in all major jurisdictions including US, EU, China, Japan and AUS.</p>	<p>Credentialed and highly aligned leadership Orthocell is led by an experienced Board and management team with a successful track record of developing and commercialising novel healthcare and technology products.</p>	<p>Multiple near-term catalysts including US and AUS approvals of CelGro® in the near term and completion of Ortho-ATI™ study in collaboration with DePuy Synthes Products, Inc., part of the Johnson &amp; Johnson Medical Device Companies.</p>

**\$ Well-funded with \$20.4m cash as at June 30 2020**

# About Orthocell Ltd

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

## CelGro®

Collagen medical device



- Designed to augment surgical repair of soft tissue.
- Represents a breakthrough in soft tissue reconstruction.
- Multiple applications in nerve, tendon, and bone repair.
- Demonstrated superior clinical performance when compared to the current market leading product.
- Initial EU approval achieved.

## Ortho-ATI™

Cell therapy for tendon regeneration



- Injectable clinical stage cellular therapy for treatment of chronic tendon injuries.
- Multiple tendon sites including shoulder, elbow, hip, hamstring and achilles.
- Addressing a significant unmet clinical need for a safe, effective and non-surgical solution.
- First injectable cellular therapy in orthopaedics for tendon regeneration.

# Significant market opportunity

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

CelGro® - - - - - Ortho-ATI™ - - - - - Total addressable market



>US\$10bn



>US\$7.7bn

>US\$17 billion  
p.a.

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

1. Addressable markets include US, Japanese, European and Australian markets, Ortho-ATI™ 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



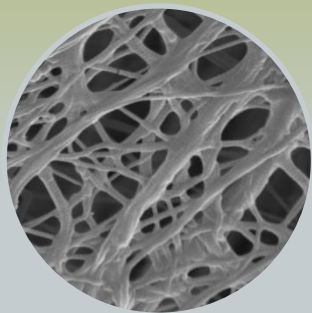
# CelGro®

A unique collagen medical device that augments tissue repair and regeneration

# CelGro<sup>®</sup>: unique characteristics

CelGro<sup>®</sup>'s unique characteristics deliver predictable outcomes in a shorter time empowering surgeons to improve the lives of patients with complex injuries.

Proven biocompatibility



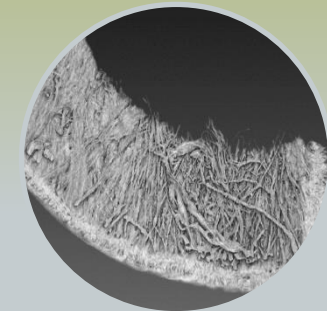
SMRT<sup>™</sup> manufacturing process removes all foreign tissue components and is completely absorbed by the body.

Ideal mechanical properties



Flexible and easy to handle even when wet. Does not collapse when placed over the defect and stays in place without pins or sutures

Superior tissue repair capability



Preservation of natural collagen structure promotes the rapid repair of soft tissue and regeneration



# CelGro<sup>®</sup>: strategic focus

Orthocell is focused on the development and commercialisation of the bone, nerve and tendon applications.

CelGro<sup>®</sup> has significant global commercial potential in its existing addressable markets as well as much wider applications in general surgical and soft tissue reconstructive applications.



1. US, Japanese, European and Australian markets.  
2. Analysis of addressable markets excludes the following CelGro<sup>®</sup> pipeline products including articular cartilage repair, ACL ligament replacement & general surgery.

# Strategic status

Advanced product portfolio with near term milestones and emerging pipeline

Application	Target Market	Clinical/Development Phase	Regulatory Phase			Upcoming Catalysts
			Design Trial	Implement Trial	Application	
NERVE	AUS	[Progress bar spanning Design, Implement, and Application phases]			<ul style="list-style-type: none"> <li>&gt; Q1 CY21: Multi centre mkg study kick off</li> <li>&gt; Q4 CY21: AU TGA approval (estimate)</li> </ul>	
	US	[Progress bar spanning Design and Implement phases]			<ul style="list-style-type: none"> <li>&gt; Q4 CY20: US 510k study commences</li> </ul>	
TENDON AND LIGAMENT	AUS	[Progress bar spanning Design and Implement phases]			<ul style="list-style-type: none"> <li>&gt; Q4 CY20: AU TGA submission (estimate)</li> </ul>	
	US	[Progress bar spanning Design phase]			<ul style="list-style-type: none"> <li>&gt; Q4 CY20: US FDA pre-submission meeting</li> <li>&gt; CY21 commence US 510k study commences</li> </ul>	
DENTAL BONE	AUS	[Progress bar spanning Design, Implement, and Application phases]			<ul style="list-style-type: none"> <li>&gt; Q4 CY20: AU TGA approval (estimate)</li> <li>&gt; Q1 CY21: AU complete reimbursement application</li> </ul>	
	US	[Progress bar spanning Design, Implement, and Application phases]			<ul style="list-style-type: none"> <li>&gt; 2Q CY21: US FDA approval (estimate)</li> </ul>	
	EU	[Progress bar spanning Design, Implement, and Application phases]			<ul style="list-style-type: none"> <li>&gt; Approved for use</li> <li>&gt; Ongoing: grow KOL product use</li> </ul>	

CelGro®

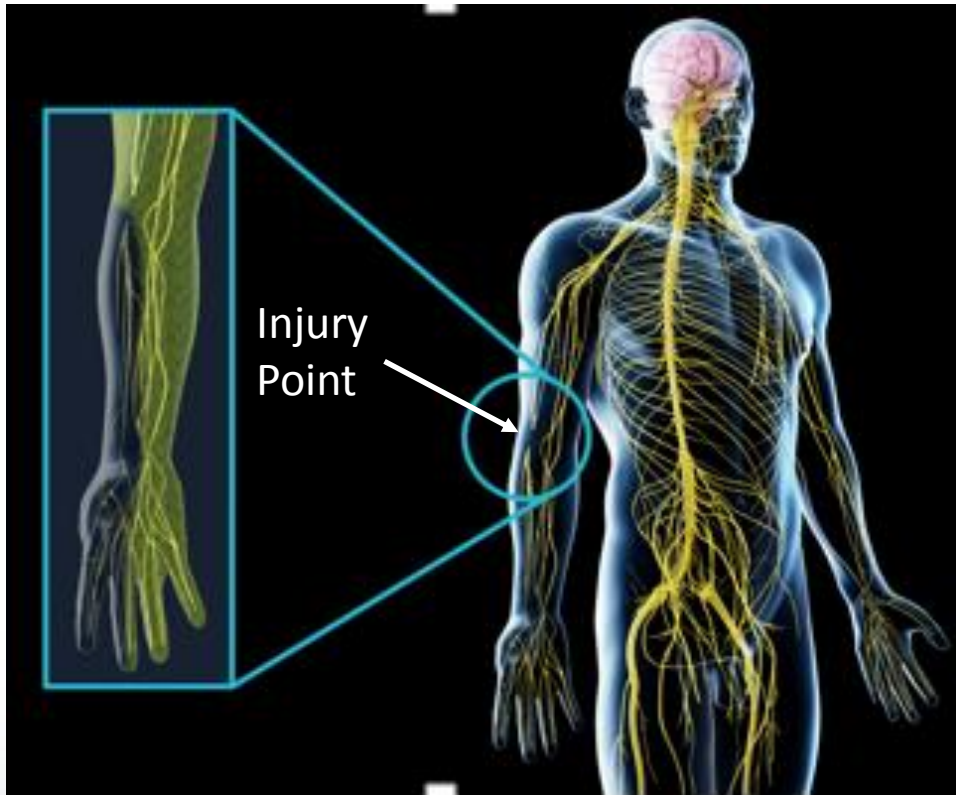


# CelGro<sup>®</sup> Nerve Regeneration

Revolutionising nerve repair

# The peripheral nervous system

The peripheral nervous system transmits signals from the brain to the rest of the body (including arms, hands, feet, legs and face) directing bodily function including muscle movement.



## Common and debilitating

- Nerve injury can occur from a variety of accidents such as motor vehicle use; sports; battlefield and gun shots; and power tools.

## Severe patient impact

- The impact on patients is significant, ranging from severe pain to impaired use of a limb to complete paralysis.
- Patients can lose the ability to independently eat, shower or take themselves to the toilet.
- Effects on self-esteem and mental health are profound.

## Repair requires delicate surgery

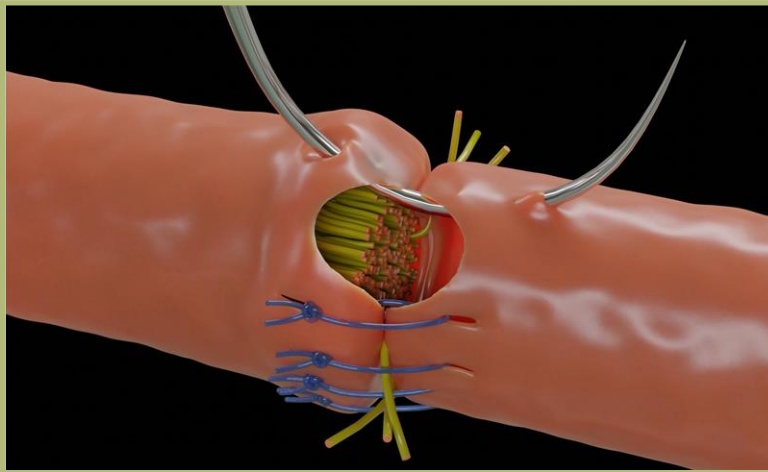
- Repairing severe nerve injury requires extremely complex and delicate surgery

# Traditional repair outcomes are suboptimal

Using traditional repair methods for crushed/severed nerves can be ineffective and unpredictable in restoring function to affected limbs.

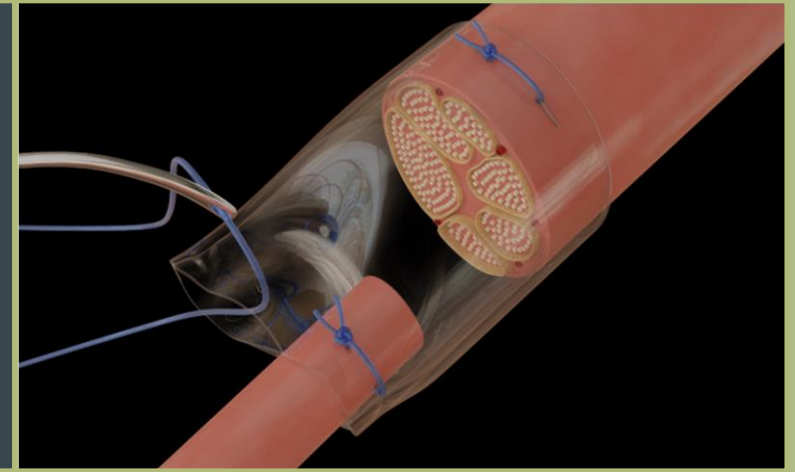
## Direct suture

Tension can result in buckling and misdirection of regeneration nerve fibres



## Rigid hollow tube

Rigid tubes are limited in use and efficacy and can result in a 34-57% failure rate<sup>1</sup>



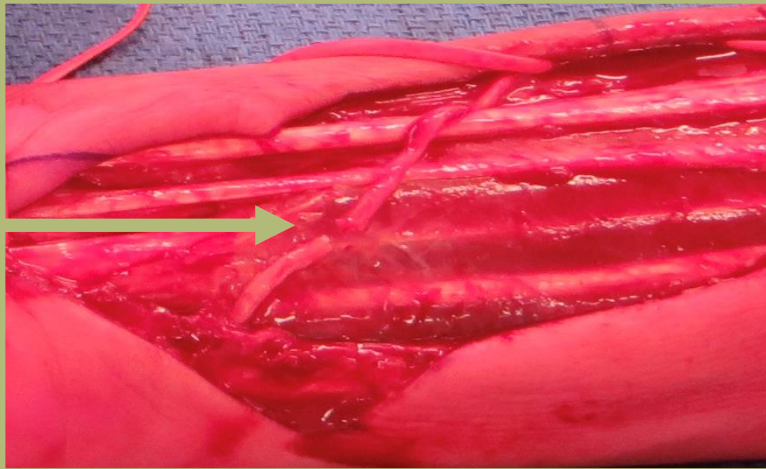
Strong demand for a medical device that enable surgeons to perform complex surgical repairs efficiently with better results

# CelGro<sup>®</sup>: nerve transfer surgery

CelGro<sup>®</sup> is a versatile medical device that can be used to repair, protect and cap nerve injuries to return function to impaired or paralysed muscles.

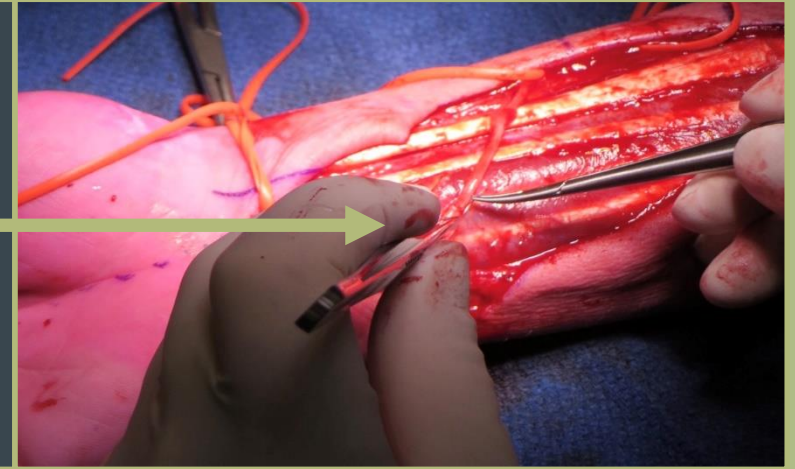
1

Transferring  
superficial radial  
to ulnar nerve



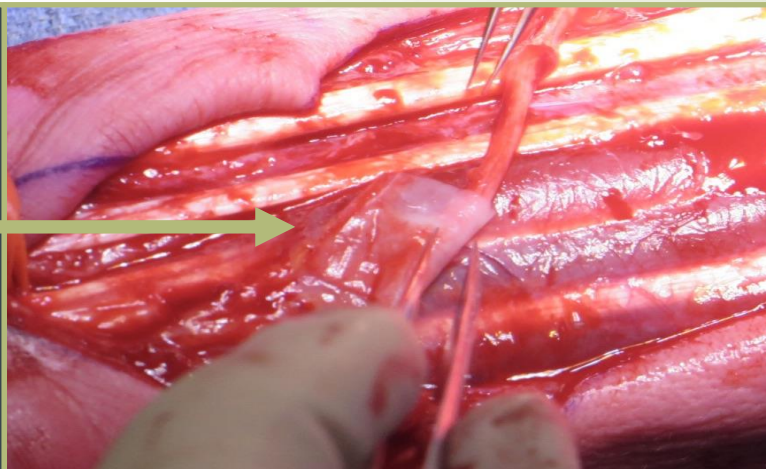
2

Placing a stay  
suture to oppose  
nerve ends



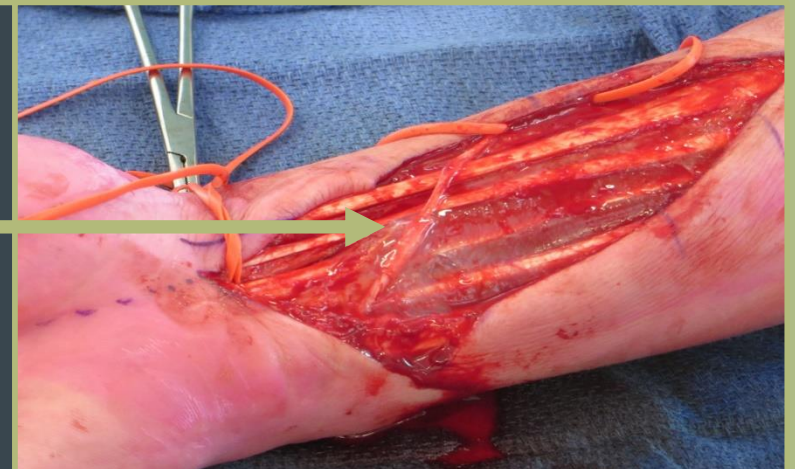
3

Wrapping  
CelGro<sup>®</sup> around  
nerve ends  
to create a  
customised  
conduit



4

CelGro<sup>®</sup> guides  
and supports  
nerve repair



A man with a beard and mustache, wearing a dark blue t-shirt and black pants, is seated in a wheelchair. He is wearing a black and red CelGro device around his waist. He is looking upwards and to the right. The background is a blurred indoor setting, possibly a gym or a rehabilitation center. The right side of the image features a decorative graphic with curved, overlapping bands in shades of green and yellow.

# CelGro® Quadriplegic patient

*“When the accident happened, I knew straightway that I couldn’t feel my legs.*

*All I could think about at that moment, laying still on my back, was my wife and three kids.*

*Although I regained some movement in my arms over time, I still couldn’t use my wheelchair properly.”*

*“Since being in the trial I’ve managed our house renovation, I go to the gym a couple of times a week and play wheelchair rugby. My arm now feels 500 percent better than before the procedure.”*

**- CelGro® Nerve trial participant, Adrian Walsh**

**Meet Adrian Walsh, a 43-year-old father of three who was diagnosed with quadriplegia after he broke his neck in a mountain bike accident in June 2017.**



# CelGro<sup>®</sup>: compelling clinical results

Patients regain muscle function in affected limbs following CelGro<sup>®</sup> nerve regeneration treatment

## Prior to CelGro<sup>®</sup> nerve repair

- Patients suffered traumatic nerve injuries following motor vehicle, sporting and/or work-related incidents
- Site of injury varied - from peripheral nerve injury, to more complex injuries of the brachial plexus and spinal cord
- Patients experienced impaired use of the affected limbs and in the more severe cases, quadriplegia (partial or total loss of use of all four limbs and torso).

## Results 12 months after treatment with CelGro<sup>®</sup>

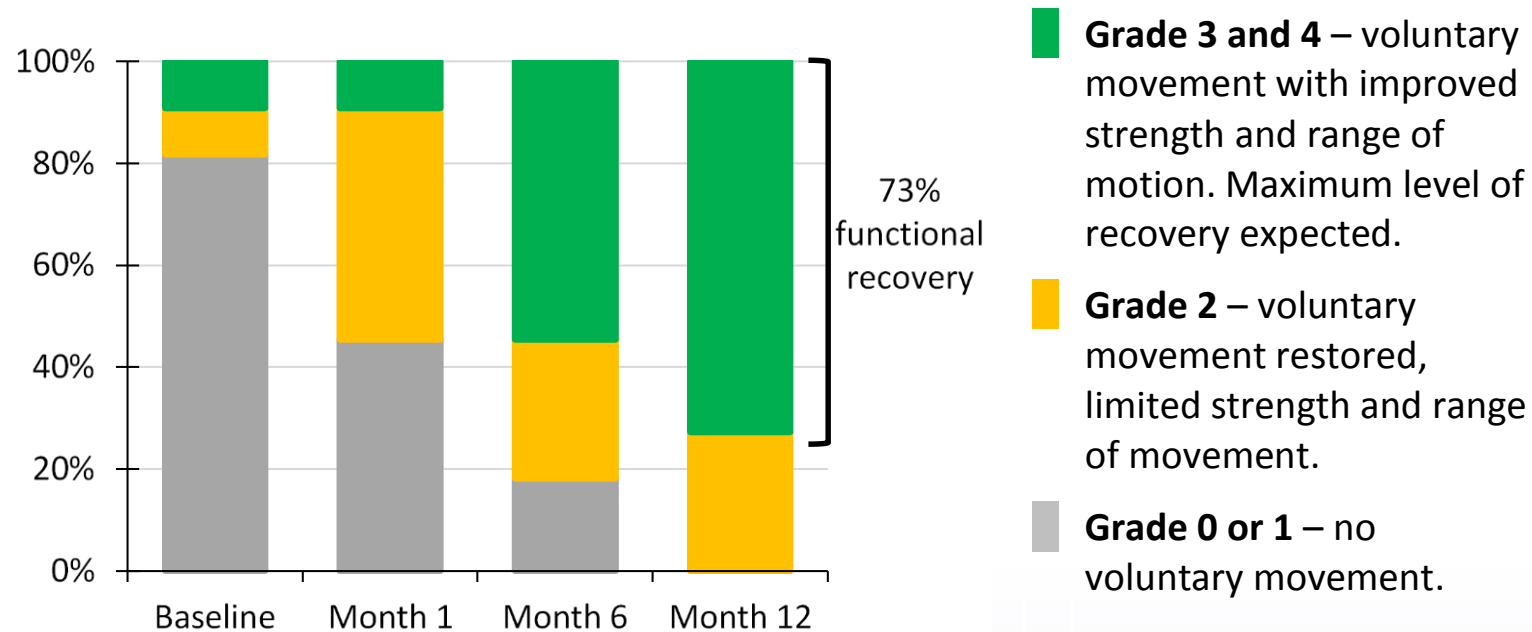
- ✓ 96% of nerve repairs restored voluntary movement to previously paralysed muscles
- ✓ 86% of patients reduced or stopped pain medication (including opioid-based medications)
- ✓ All quadriplegic patients increased movement and power of affected muscles following CelGro<sup>®</sup> nerve regeneration treatment.

**CelGro<sup>®</sup> is proven to be a faster and superior device for nerve repair.**  
Nerve repair using CelGro<sup>®</sup> resulted in improvements in muscle power at 12 months that were comparable to typical results expected at 24 months with other methods.

# CelGro<sup>®</sup>: compelling clinical results (continued)

## Recovery of muscle power in patients with quadriplegia

**Figure 1 – Recovery of Muscle Power in Patients with Quadriplegia (11 nerve repairs)**



- Almost half the nerve repairs (11 of 25) performed in quadriplegic patients.
- 73% of nerve repairs resulting in meaningful functional recovery (MRC grade 3 or 4) of affected muscles within 12 months.

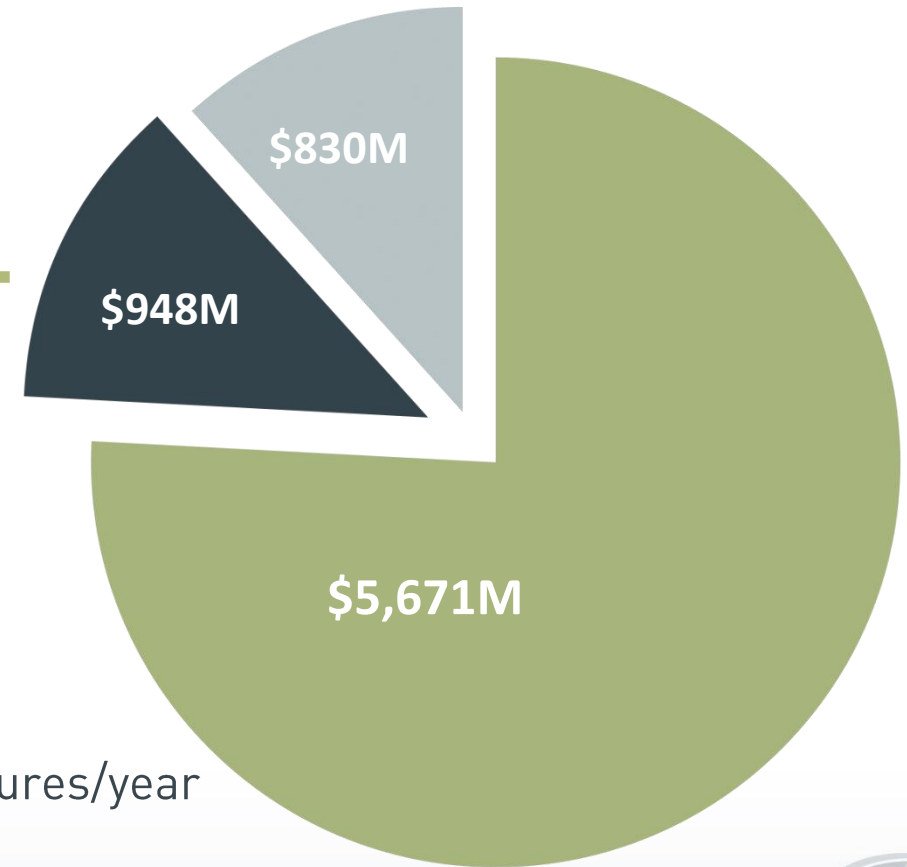
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# CelGro<sup>®</sup>: nerve repair market opportunity

CelGro<sup>®</sup>'s addressable market in peripheral nerve repair is estimated to be worth more than

>US\$7.5 billion per year.







Global potential annual procedural estimates<sup>1</sup>:

- > **CONNECT**: severed nerve repair, >2,000,000 procedures/year
- > **PROTECT**: carpal and cubital tunnel revisions, >350,000 procedures/year
- > **CAP**: amputations, >300,000 procedures/years

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.

# Pathway to US market

With the safety and efficacy of the CelGro<sup>®</sup> nerve repair product established, Orthocell is focused on executing its regulatory program to gain approval in the US.

	<b>US 510(k) Study Purpose</b>	To support an evaluation of substantial equivalence to an approved nerve repair device, meeting the requirements of the US 510(k) predicate product regulatory pathway.
	<b>Study Design</b>	<p>The study will involve the treatment of severed sciatic nerves in approximately seventy six (76) rats in three (3) study groups (control, CelGro<sup>®</sup> and comparator) with outcome measures recorded at four, eight and twenty weeks post treatment.</p> <p>The key outcome measures include the performance of CelGro<sup>®</sup> in facilitating high quality nerve regeneration and restoration of motor and sensory function.</p>
	<b>Collaboration</b>	Conducted in collaboration with University of Western Australia and Western Sydney.
	<b>Key Milestones</b>	<ul style="list-style-type: none"><li>✓ US FDA pre-submission meeting</li><li>✓ Ethics approval</li><li><input type="checkbox"/> Commence surgical procedures Q4 CY2020</li><li><input type="checkbox"/> Final data read out target Q4 CY2021</li></ul>

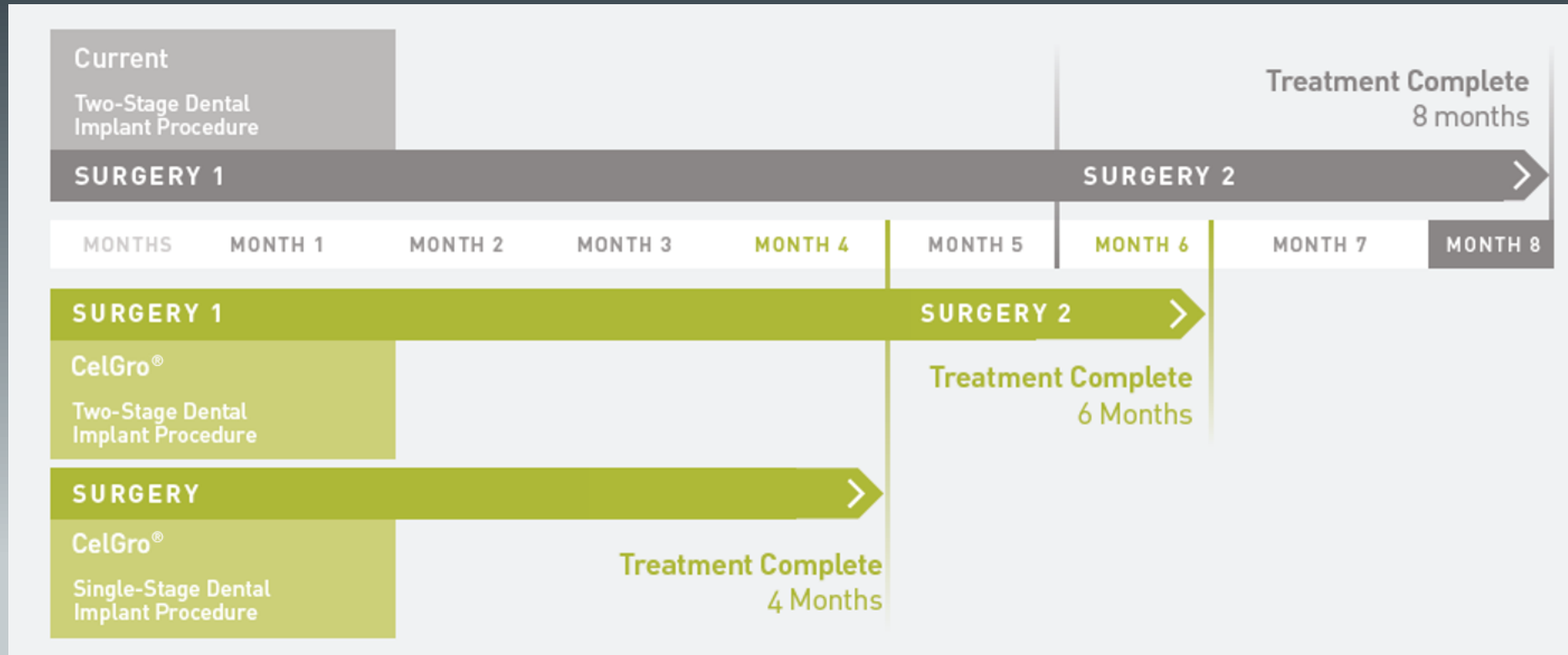


CelGro®

Guiding superior bone regeneration

# CelGro<sup>®</sup>: better results sooner

Patients treated using CelGro<sup>®</sup> successfully generated enough new bone to stabilise their implants and complete their treatment in approximately 4 months, compared to the 8 months required for standard dental implant treatment<sup>1</sup>.



# CelGro<sup>®</sup>: orthognathic surgery

*“My experience in using CelGro<sup>®</sup> in dental implant procedures has given me the confidence to use it in Orthognathic procedures. Corrective jaw surgeries are life changing and technically demanding. Predictable and high-quality bone regeneration is of utmost importance to deliver functional as well as aesthetically pleasing outcomes for patients.”*

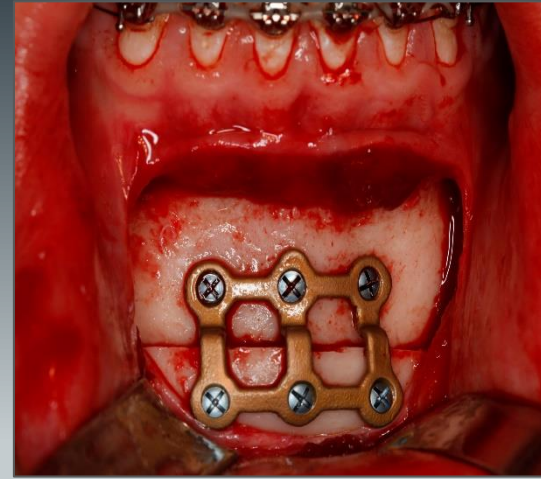
- Dr Brent Allan, Chief Investigator, Dental Bone Regeneration Trial



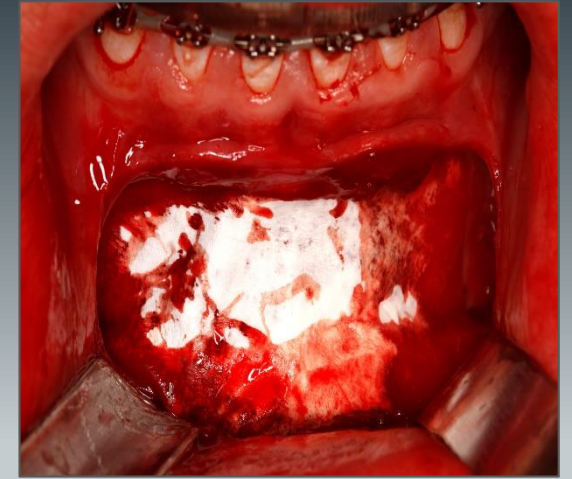
CT Scan showing significant underbite



3D model planning jaw reconstruction



Jaw reconstruction surgery



CelGro<sup>®</sup> positioned over augment area to protect site and guide bone regeneration

# CelGro<sup>®</sup>: building a world class KOL group

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**Nick Fahey**  
UK



**Massimo Simion**  
Italy



**Brent Allan**  
Australia



**David Little**  
USA



**Pamela Ray**  
USA



**Sinead McEnhill**  
UK



**Lance Knight**  
UK



**Amanda Seay**  
USA



**Guiseppe Luongo**  
Italy



**Elaine Halley**  
UK



**Kathy Fraser**  
USA







**Maria Lopez Howell**  
USA



# CelGro<sup>®</sup>: dental path to partnering

Executing a strategy to engage a global partner to manage the distribution and marketing of CelGro<sup>®</sup> for dental bone and soft tissue repair procedures.

Path to partnering	Market development activities
 <p><b>Grow body of clinical evidence and product use</b></p>	<ul style="list-style-type: none"> <li>• Publication in high impact journals</li> <li>• Increase SAS use in key accounts (AUS)</li> <li>• Increase product use in key accounts (UK)</li> </ul>
 <p><b>Build market awareness amongst surgeons and potential partners</b></p>	<ul style="list-style-type: none"> <li>• Increase digital marketing engagement with surgeons</li> <li>• Continue virtual and in person clinical conference participation</li> <li>• Active social media program led by OCC KOL group</li> </ul>
 <p><b>Clinician advocacy program</b></p>	<ul style="list-style-type: none"> <li>• Emphasis on distance education led by OCC KOL's with significant digital following (eg. interactive webinars and podcasts)</li> <li>• Increase key dental editorial coverage</li> <li>• Support key dental associations education programs</li> </ul>
 <p><b>Access high value markets</b></p>	<ul style="list-style-type: none"> <li>• Q4 CY20: AUS TGA approval (estimate)</li> <li>• Q1 CY21: AU complete reimbursement application</li> <li>• 2Q CY21: US FDA approval (estimate)</li> </ul>

# CelGro<sup>®</sup>: GBR market opportunity

There has been very little innovation in the biologics membrane market resulting in a lack of product differentiation.

Existing products have inferior functionality and handling characteristics:

- ✗ Don't hydrate immediately
- ✗ Stick to instruments
- ✗ Deforms and collapses over defect site
- ✗ Lack strength to hold a suture or pin
- ✗ Lack predictability in GBR and GTR outcomes

The CelGro<sup>®</sup> advantage:

- ✓ Regenerative medicine collagen membrane manufactured to deliver predictable, higher quality outcomes
- ✓ Provides optimal handling characteristics
- ✓ Reduces the timeframe and costs for patients to achieve their goals

**Significant addressable market<sup>1</sup> >US\$1bn p.a.**

1. US, Japanese, European and Australian markets based on ~1.5m procedures per year



# CelGro<sup>®</sup> Tendon Regeneration

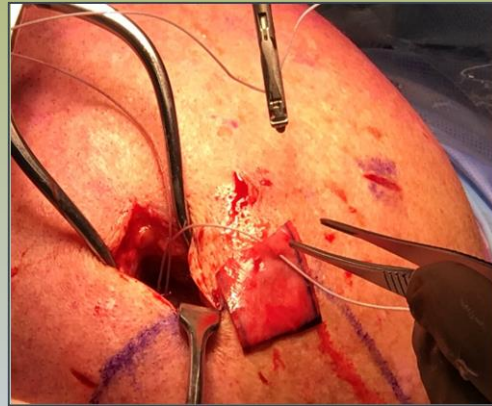
Revolutionising mobility

# CelGro<sup>®</sup>: reducing surgical revisions

CelGro<sup>®</sup>'s handling characteristics assist surgeons perform reconstructive procedures, while creating a unique healing environment to improve the quality of the regenerated tendon tissue. Better quality tissue strengthens the repair and reduces the risk of re-tear.



CelGro<sup>®</sup> shaped and cut to size required



Sutures from bone anchors passed through CelGro<sup>®</sup> outside of the joint



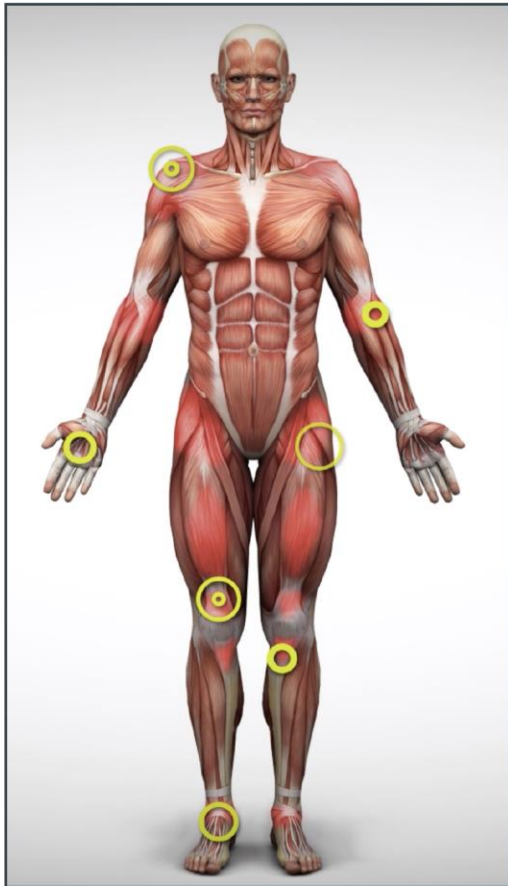
CelGro<sup>®</sup> passed in to the joint and positioned on top of rotator cuff



Rotator Cuff augmented repair with CelGro<sup>®</sup>

# CelGro<sup>®</sup>: tendon indications

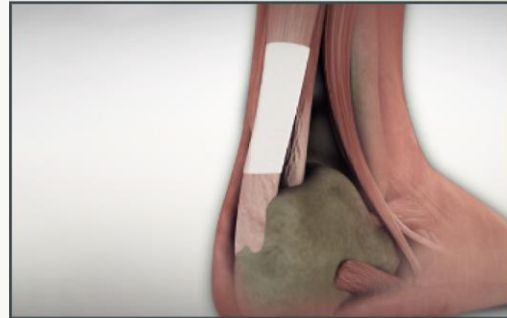
CelGro<sup>®</sup> is currently being used via SAS by KOL's to augment tendon repair at multiple sites throughout the body.



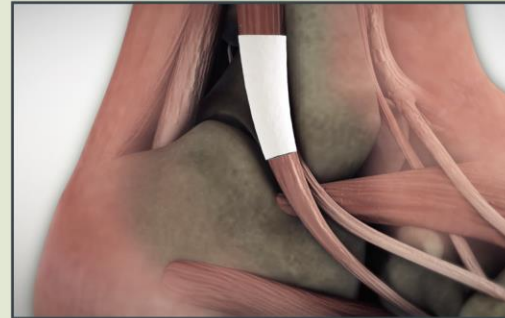
Tennis elbow surgical repair



Hand tendon repair



Achilles tendon surgical repair



Ankle tendon repair



Ligament repair within the knee

# CelGro<sup>®</sup>: key benefits and upcoming milestones

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*“Rotator cuff repair can be a challenging area. An effective biological augment to surgical repair is increasingly desired by the orthopaedic community. CelGro<sup>®</sup> has been shown to improve tissue healing and assists in reducing the surgical revision rate of rotator cuff tendon.”*

– Professor Alan Wang, Orthopaedic surgeon and CelGro<sup>®</sup> trial Principal Investigator

## CelGro<sup>®</sup> enhances tendon regeneration in three different ways

- Creates a bio-active healing environment to improve the quality of tissue repair
- Facilitates and promotes higher quality tissue repair, reducing the risk of re-tear
- Can be used in tendons at multiple sites throughout the body

## Regulatory milestones

- Q4 CY20: AU TGA submission (estimate)
- Q4 CY20: US FDA pre-submission meeting to define study requirements



# Ortho-AT1™

Advanced cellular therapy to directly address the root cause of degenerate tendon injury

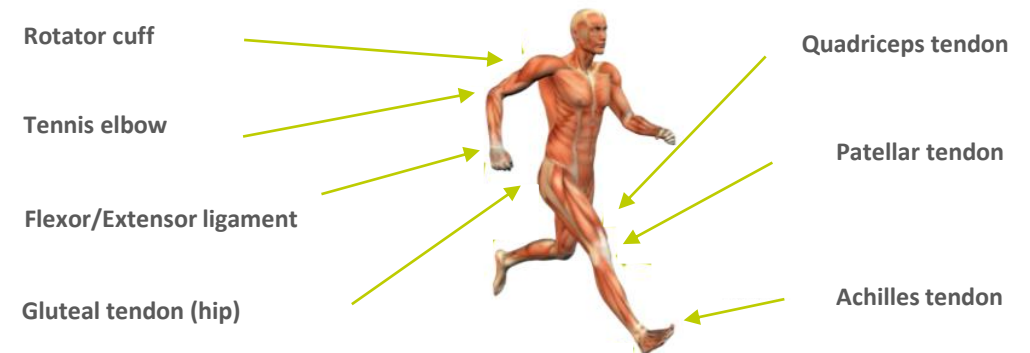
# Chronic tendon injury: significant unmet clinical need

Chronic tendon injury is a common and painful disorder affecting millions of people every year with no effective, non-surgical treatments currently available

## Significant unmet clinical need

- Millions of people suffer from chronic tendon injury every year
- Traditional repair outcomes suboptimal i.e. PRP, corticosteroids and surgery
- Chronic tendon injury significantly reduces the ability of patients to work, exercise, and perform routine daily activities

## Multiple tendon injury sites



There are no 'non-surgical' treatments currently available to treat chronic tendon injury



# Ortho-ATI<sup>®</sup>: a clinical first

Injectable cell therapy that returns patients to the workplace, recreational activities and elite sport pain-free.

## Ortho-ATI<sup>™</sup> is a novel treatment

- ✓ Breakthrough in regenerative medicine directly addressing the root cause of injury
- ✓ Replenishes degenerative tissue with healthy mature tendon cells, accelerating regeneration of tendon tissue
- ✓ Extensive clinical validation - over 690 patients treated with Ortho-ATI<sup>™</sup> to date
- ✓ There are no 'non-surgical' treatments currently available to treat chronic tendon injury

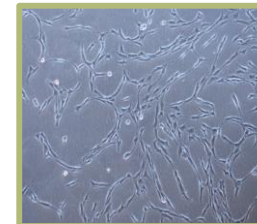
## Two stage, minimally invasive procedure

1. Biopsy procedure



Healthy tendon cells removed via minimally invasive procedure

Tenocyte (cell) cultivation



Healthy cells grown at Orthocell's laboratory

2. Tenocyte (cell) implantation



Ultrasound guided implementation of healthy cells

4-5 week  
end-to-end  
process

ortho·cell

# Ortho-ATI™: compelling clinical evidence



Orthocell has treated 690 patients during clinical development of Ortho-ATI™



Patients are aged 18 to 77 years of age, and average 53 years



Patients have experienced an average of two years chronic pain and three failed treatments. At this point, the only remaining treatment option is generally elective surgery.



Living with a chronic pain has a significant impact on quality of life and their capacity to participate in the workforce.

# Ortho-ATI™: reducing pain

Ortho-ATI™ treatment provides a meaningful and lasting reduction in pain

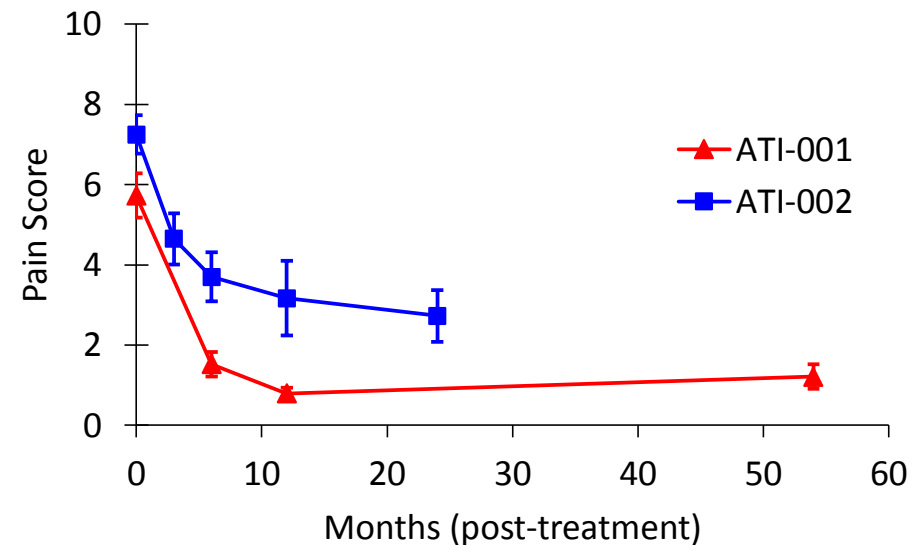
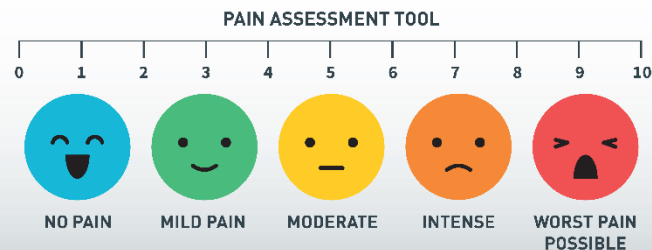
## Clinical studies of Ortho-ATI™

### Clinical Study Results

- Patients in clinical studies of Ortho-ATI™ for lateral epicondylitis (ATI-001) and gluteal tendinopathy (ATI-002) experienced a significant reduction in pain within 6 months of Ortho-ATI™ treatment
- The improvements in pain were maintained in all studies, for up to 4.5 years post-treatment in the case of ATI-001 and two years post-treatment in ATI-002.

### Pain Assessment

- Pain was assessed using a 0-10 Visual Analogue Pain Scale (VAS), where 0 = no pain, and 10 = worst pain ever
- A 1.4 point improvement indicates a clinically significant improvement in pain levels
- A score of 3 or less is considered acceptable by most patients.



Pre-and post-treatment VAS pain score in clinical studies of Ortho-ATI™ for lateral epicondylitis (ATI-001), gluteal tendinopathy (ATI-002).

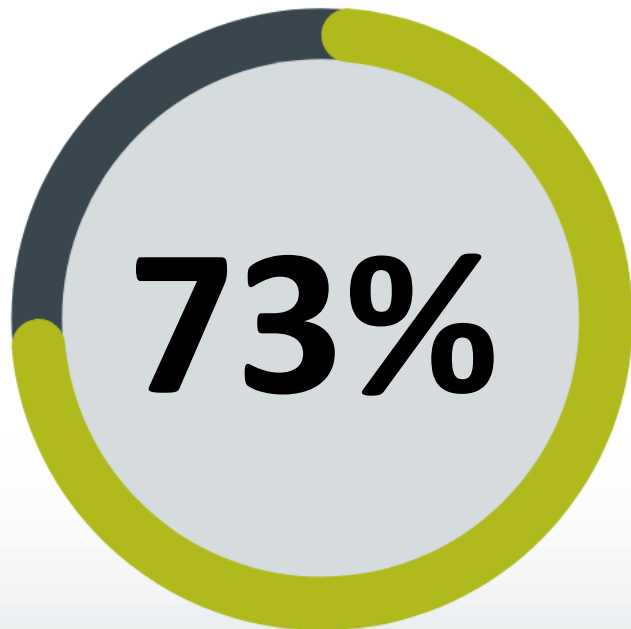
# Ortho-ATI™: reducing pain

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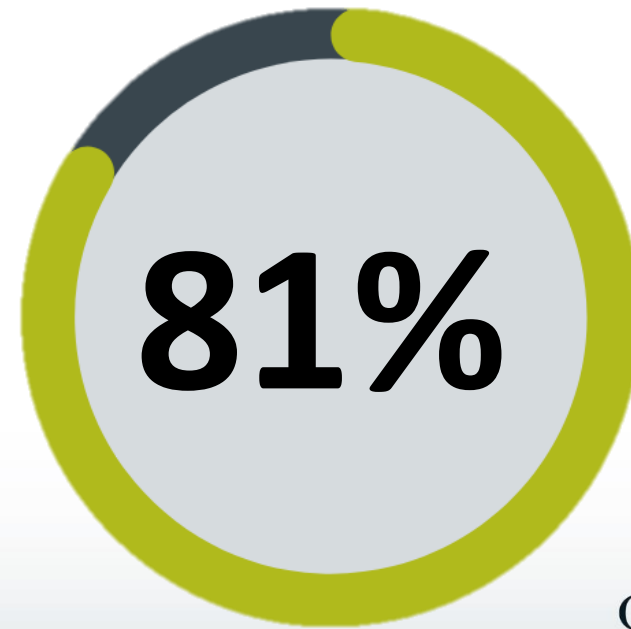
Ortho-ATI™ treatment provides a meaningful and lasting reduction in pain

## Annual Quality Study

73% of patients were satisfied with symptom relief after Ortho-ATI™ treatment<sup>1</sup>



81% of patients did not receive any other treatments for their tendon injury<sup>1</sup>



# Returning to function

## Ortho-ATI™ treatment improves strength and function

### Clinical studies

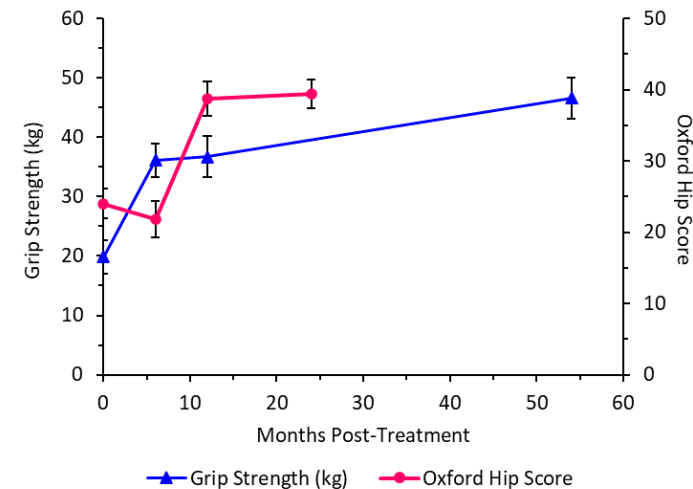
#### Clinical study results

- **Long term increases in strength** - Patients in clinical study of Ortho-ATI™ for lateral epicondylitis (ATI-001) mean grip strength at baseline was 19.85kg, improving to 37.38kg at one year and 46.60kg at final follow-up.
- **Sustainable increases in function** - Patients in clinical study of Ortho-ATI™ for gluteal tendinopathy (ATI-002) mean OHS improved from 24.0 at baseline to 38.8 points at 12 months, and 39.4 at 24 months post-treatment.

#### Oxford Hip Score (OHS)

- OHS is a joint-specific, patient-reported outcome measure tool designed to assess disability in patients. It produces an overall score running from 0 to 48 with 48 being the best outcome.
- If the post-treatment OHS is higher than 8 or more points compared to the pre-treatment score, this indicates that a patient has experienced a clinically meaningful improvement in function.

#### Long term improvements in strength and function following Ortho-ATI® treatment



Pre-and post-treatment disability and function scores in clinical studies of Ortho-ATI™ for lateral epicondylitis (ATI-001), gluteal tendinopathy (ATI-002).

# Returning to function: real world evidence

Ortho-ATI™  
improves  
strength  
and  
function

## RETURN TO WORK<sup>1</sup>

All patients in workers compensation study returned to work - 70.1% with no restrictions

## RETURN TO SPORT

Elite athletes:

- > AFL players, Australian soccer players, Olympic downhill skiers returned to competition pain-free
- > Olympic swimmer and elite gymnast with rotator cuff tendinopathy returned to competition<sup>2,3</sup>

Weekend warriors:

Elderly male with (77 years old) with rotator cuff tendinopathy able to resume gardening and golf<sup>4</sup>

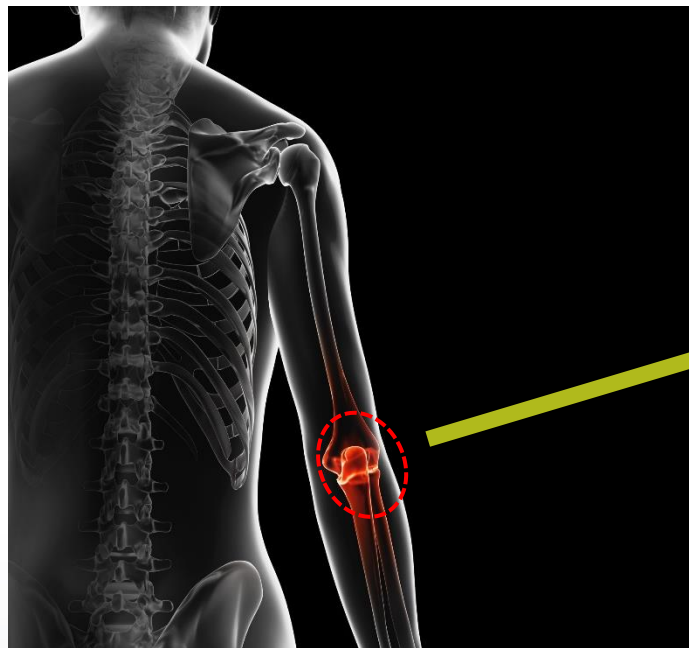
## RETURN TO DAILY ACTIVITIES

Overall 87.5% satisfaction in patients who received Ortho-ATI® tendon repair treatment in the shoulder<sup>5</sup>

1. Orthocell's retrospective workers compensation study involving 17 patients with severe lateral epicondylitis  
2. Schwab LM, Blanch P, Young M. Phys Ther Sport. 2018;29:19-25.  
3. Wang AW, Bauer S, Goonatilake M, Bredahl W, Zheng MH. BMJ Case Rep. 2013;2013.  
4. McRae B, Fitzpatrick J, Khan H. International Journal of Case Reports. 2020;4:124.  
5. Results from the four Annual Quality Surveys conducted between 2015 and 2019

# Tendon Structure

MRI assessments in clinical studies of LE and RC tendinopathy demonstrated improvements in tendon structure, including in-fill of tendon tears and resolution of tendinopathy. Improvements in tendon structure were sustained at 4.5 years post-treatment (ATI-001).



Before treatment



1 Year after Ortho-ATI™



5 years after Ortho-ATI™



MRI scans from patient in ATI-001 study (tennis elbow) before and after treatment (3 slices).

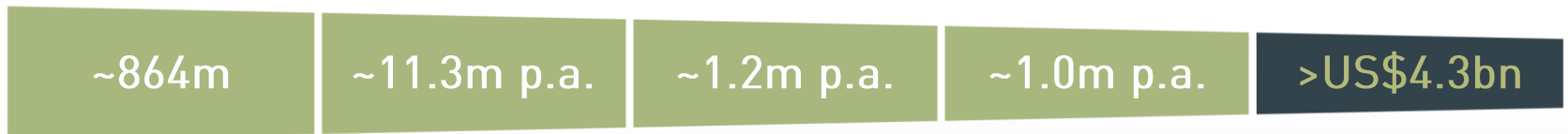
# Ortho-ATI™: multiple, large addressable markets

Ortho-ATI™ is at the forefront of a large and growing market opportunity where the addressable market is estimated to be >US\$7.7bn p.a.

Estimated addressable market in excess of US\$7.7bn incorporates:



## Illustrative analysis: tennis elbow addressable market²



Total population  
In key markets¹

Estimated  
incidence  
Based on ~1.3%  
incidence rate p.a.

Resistant patients  
Assumed ~10.5%  
resistant to  
conservative treatment

Total procedures  
Assumed ~81.3%  
treatable  
with Ortho-ATI®

Estimated market size  
Assumed US\$4,500 price



1. Includes US, EU, Japan, Australia and New Zealand markets  
2. Illustrative analysis subject to rounding estimates



# Ortho-ATI™: research collaboration

Orthocell is focused on completing current clinical studies and preparing for US market entry

## Key factors in attracting Ortho-ATI™ research collaboration

- **Significant clinical validation:** published clinical data in American Journal of Sports Medicine and 500+ patient implants to date
- **Large unmet clinical need:** 1.5m+ addressable procedures per year in the shoulder and elbow alone
- **Optimised manufacturing capabilities:** GMP-certified and TGA-licensed facility<sup>1</sup> and PPI<sup>2</sup> release criteria in place
- **Significant addressable market for Ortho-ATI™:** >US\$7.7bn p.a.<sup>3</sup>

The logo for Johnson & Johnson, featuring the company name in a red, cursive script font.

The objective of this study is to assess the effectiveness of **Autologous Tenocyte Injection (Ortho-ATI™)** compared to corticosteroid injection in the treatment of **rotator cuff tendinopathy** and tear. The trial is being undertaken in collaboration with DePuy Synthes Products, Inc., part of the **Johnson & Johnson Medical Device Companies**.

1. GMP: good manufacturing practices; TGA: Therapeutic Goods Administration  
2. PPI: purity, potency and identity  
3. Market made up of: Tennis elbow (>US\$4.3bn), Rotator cuff (>US\$2.4bn), other indications (>US\$1.0bn)

# Upcoming milestones

Orthocell is focused on completing current clinical studies and preparing for AUS and US market entry

Randomised Clinical Study	Indication	Status	Market	Upcoming Milestones
Ortho-ATI™ v Surgery	Treatment of chronic lateral epicondylitis	33 of 50 patients enrolled	AUS	<ul style="list-style-type: none"> <li>CY21: Finish recruitment</li> <li>TGA application to follow</li> </ul>
Ortho-ATI™ v Corticosteroids <sup>1</sup>	Treatment of chronic rotator cuff tendinopathy	Patient treatment complete (30 patients)	US	<ul style="list-style-type: none"> <li>Last patient 12 month follow up 3Q CY2021</li> <li>IND protocol and submission in late stages of development</li> </ul>

In collaboration with DePuy Synthes Products, Inc.,  
part of the Johnson & Johnson Medical Device Companies





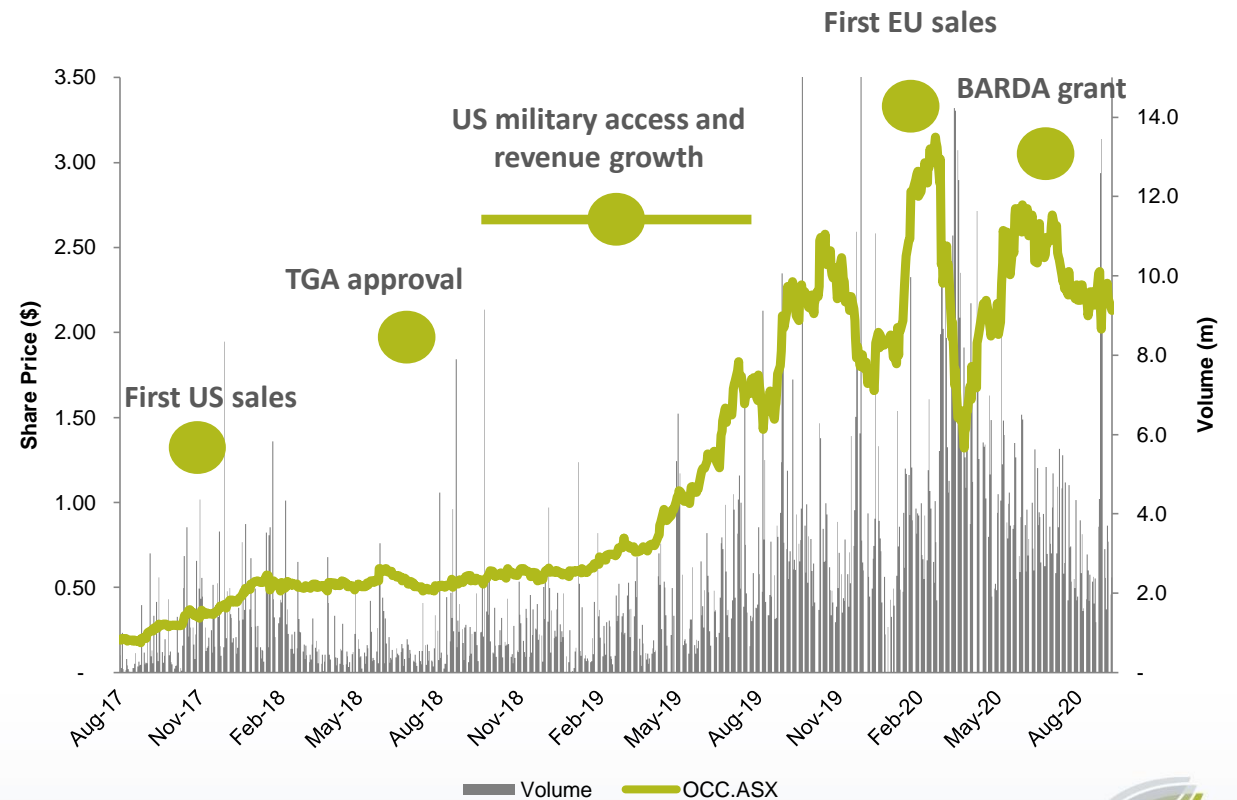
Near-term milestones

# Regenerative medicine case study: PolyNovo®

Orthocell is well positioned to deliver significant shareholder upside in the near term

## Value Drivers:

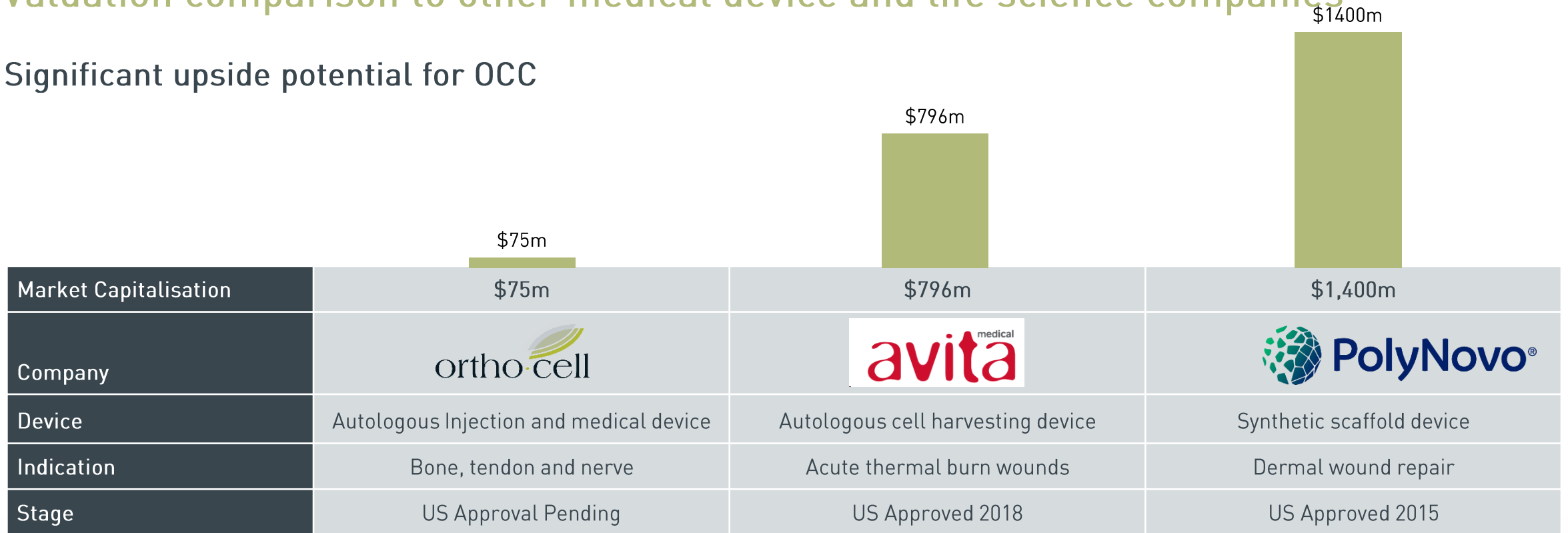
- US and AUS market authorisation
- Brand ambassadors and additional marketing data
- Gaining traction in key markets with distribution partners
- BARDA grants and military access



# Valuation upside

## Valuation comparison to other medical device and life science companies

Significant upside potential for OCC



# Upcoming catalysts

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## CelGro<sup>®</sup>: Dental

Australian market authorisation estimate	4Q CY2020
US market authorisation estimate	2Q CY2021

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## CelGro<sup>®</sup>: Nerve and Tendon

Clinical study data update (nerve)	4Q CY2020
Australian market authorisation estimate (nerve)	CY2021
Commence FDA (US) regulatory study (nerve)	3Q CY2020
TGA (AUS) submission (tendon)	4Q CY2020

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## Ortho-ATI<sup>™</sup>

Investigation New Drug submission FDA	1Q CY2021
Ortho-ATI v Corticosteroid (RCT) study complete	3Q CY2021
Ortho-ATI v Surgery (RCT) recruitment complete	CY2021



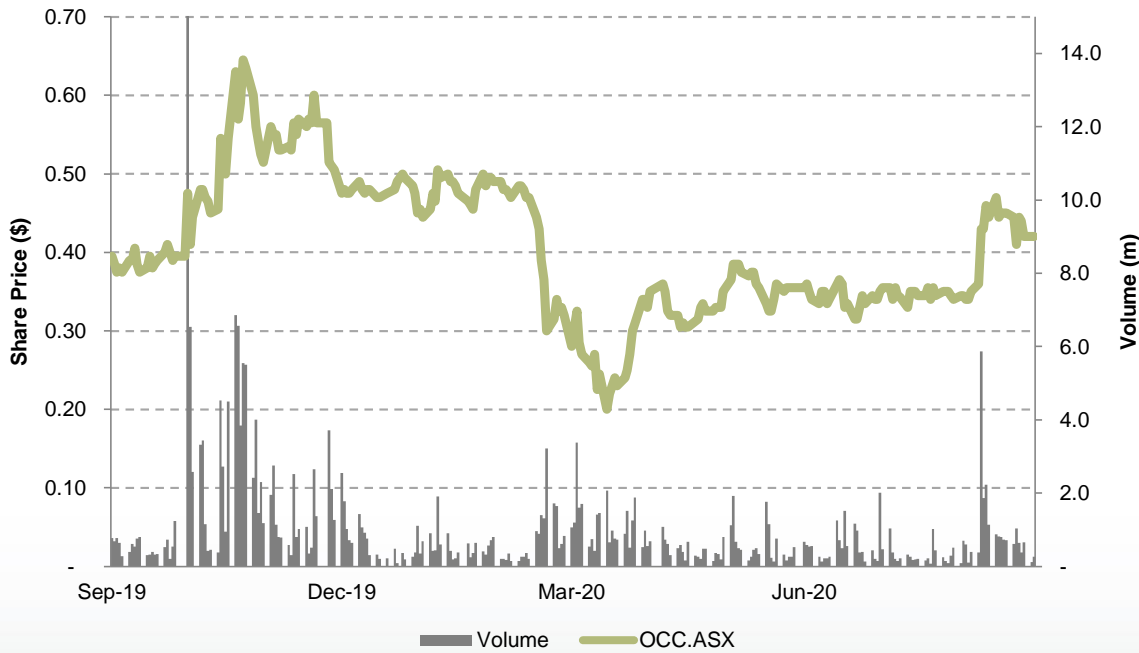
# Appendix

Corporate overview | Executive team | Global patent portfolio | Patient testimonials | Ortho-ACI™ and R&D Pipeline

# Corporate overview

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

## Share price performance



## Trading information

Share price (29-June-20)	A\$0.41
Shares on issue <sup>1</sup>	184.7m
<b>Market capitalisation</b>	<b>~A\$75m</b>
Cash (as at 3-June-20)	A\$20.4m
Debt (as at 31-March-20)	-
<b>Enterprise value</b>	<b>~A\$55</b>

## Top shareholders (as at January-20)

Ming Hao Zheng – <i>CSO and founder</i>	4.1%
Paul Anderson – <i>Managing director and founder</i>	3.8%
Board and Management	7.0%





# Executive team

Experienced Board with prior success commercialising regenerative medicine



**Dr Stewart Washer**  
*Chairman*

- 20+ years' CEO and board experience
- Commercialisation, capital markets and corporate advisory



**Paul Anderson**  
*Managing Director*

- 20+ years' regenerative medicine experience
- Former MD of Verigen Australia
- Extensive experience in commercialising emerging technologies



**Matthew Callahan**  
*Strategic Adviser*

- Developed 3 FDA approved products
- Previous investment director of 2 VC firms (life science focus)
- Extensive corporate and IP experience



**Prof. Lars Lidgren**  
*Board Member*

- World leading innovator in the orthopaedic space
- Entrepreneur and founder of multiple biotech companies (Scandimed, Bone Support, AMeC and GWS)



**Mr Qi Xiao Zhou**  
*Board Member*

- 15+ years in China as a senior business manager and executive
- Experience within public markets of Hong Kong, China and Taiwan

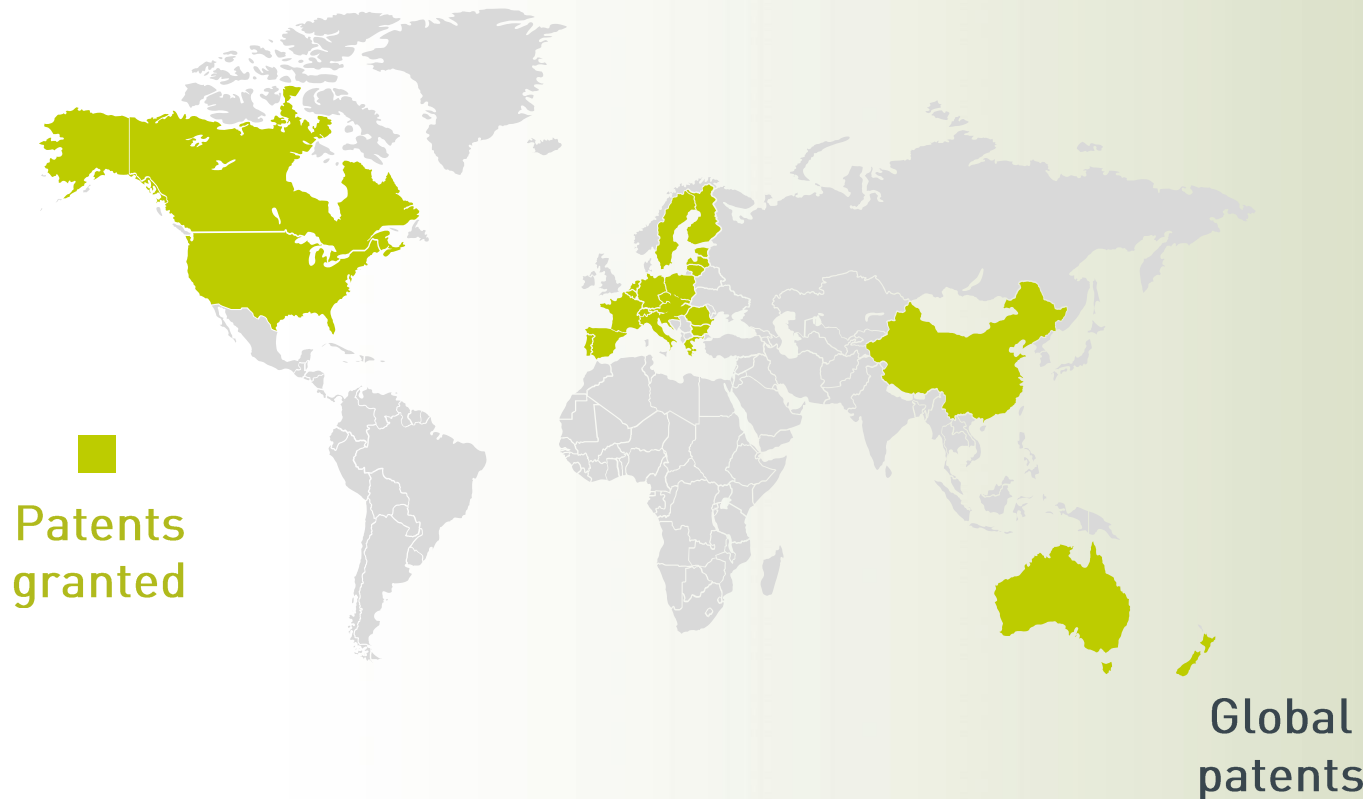


**Ms Leslie Wise**  
*Board Member*

- 20+ years medtech and pharma experience - Bristol Myers-Squib, Sanofi, Biomet Orthopedics and AngioDynamics
- Specialist in US regulatory and reimbursement

# IP: well protected and clinically validated

Orthocell has significant levels of clinical validation and has protected its suite of regenerative medicine products in 11 patent families comprising 108 separate patents/applications (78 Granted) across major jurisdictions, with further applications awaiting grant.



## IP portfolio and strategy

- > Focused on maintaining patent protection for leading manufacturing technologies and treatment processes
- > Patent protection is targeted at major jurisdictions across Australia, Asia, Europe and North America, which represent key regions where Orthocell is targeting regulatory approval

11

Patent Families

108

Separate patents  
/application

78

Granted

# Ortho-ATI™: patient testimonials



*"I'm 100% happy with the Ortho-ATI™ treatment, the only thing that enabled me to get back to doing normal daily activities without pain and return to swimming at an international level."*

**- Christian Sprenger**  
Swimming Olympic medallist



*"I couldn't write, drive, play my violin, or even walk without pain. Ortho-ATI™ gave me my life back."*

**- Jasmine Trebse**  
Professional Violinist

# CelGro<sup>®</sup>: patient testimonials



*“The tendon in my right shoulder was frayed at the ends and difficult to repair because I’d left it so long. I’m an active person and wanted long-lasting mobility, without going under the knife again and again. That’s why CelGro<sup>®</sup> made sense for me. So much so, I have gone back to get my other shoulder done.”*

**- Kevin Winfield**

**CelGro<sup>®</sup> tendon repair trial participant**

*“Since being in the trial I’ve managed our house renovation, I go to the gym a couple of times a week, and play wheelchair rugby. My arm now feels 500 percent better than before the procedure.”*

**- Adrian Walsh**

**CelGro<sup>®</sup> for nerve trial participant**



# Ortho-ACI™ and R&D pipeline

Orthocell is undertaking a “capital light” approach to commercialising Ortho-ACI® and developing other pipeline products which represent exciting potential value upside within the regenerative medicine space

Orthocell’s foundation product

## Ortho-ACI™

**Marketable cartilage repair and regeneration therapy**

- 3rd generation product
- >600 patient implants to date
- Included on the Australian Register of Therapeutic Goods, enabling the commencement of the process for reimbursement
- Cost effective treatment with potential for multiple applications

Significant market opportunity

## CelGro® pipeline

**Potential for innovative platform technology solutions**

- ACL ligament replacement: positive results from initial animal study. Planning next study
- Other potential applications: General surgery, Urogynaecological, Collagen powder (for bone void fillers)

Significant commercial appeal expected in ‘off-the-shelf’ products

## Growth factors    Lab grown tendons

**Leverage existing knowledge towards human clinical trials**

- Cell factory-derived tissue specific growth factors to augment bone, cartilage and tendon repair
- Part of successful international collaboration<sup>2</sup> – multiple animal studies completed and published
- “Cell Factory” patents granted in key jurisdictions (USA and Europe)

**Next generation product to complement Ortho-ATI®**

- Successfully manufactured human tendon in a laboratory
- Ongoing collaboration with academic researchers<sup>1</sup> (received ARC linkage grant)
- Significant unmet patient needs and multiple applications (i.e. hand, shoulder and hamstring)

1. Successful collaboration with Griffith University; University of Western Australia; La Trobe University; and University of Auckland  
2. Successful collaboration with Lund University (Sweden); University of Western Australia; Indian Institute of Technology Kanpur (India)

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