



# Investor Presentation

October 2019





## What is regenerative medicine?

A **new field of medicine** seeking to repair injured or diseased tissue using **the body's own regenerative capabilities**

**Replacing**, engineering or regenerating **human cells**, tissues or organs to restore or establish normal function



## Why is regenerative medicine a promising field?

**Ageing population** and rising rate of musculoskeletal disorders

Demand for **safe, efficient** and **cost effective** treatments

International regulatory bodies (e.g. FDA), **accelerating development** and access to safe and effective regenerative medicine therapies



## What is Orthocell's position in this space?

Orthocell is a **world leading** regenerative medicine company with novel, **first in class**, most advanced portfolio of products

## Experienced Board with prior success commercialising regenerative medicine



**Dr Stewart James 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



**Professor 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

# Innovative products

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

## CelGro®

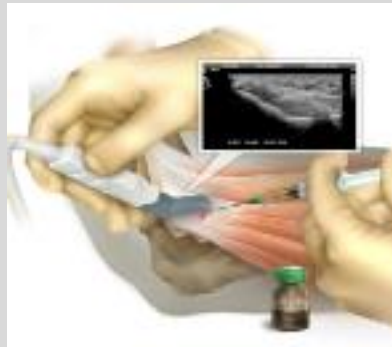
*Tissue reconstruction  
platform medical device*



- **Bone, tendon and nerve repair**
- **Approved for sale in Europe<sup>1</sup>**
- **US 510k submission Q4 2019**
- **Patent-protected** in all major jurisdictions

## Ortho-ATI®

*Cell therapy to regenerate  
damaged tendon tissue*

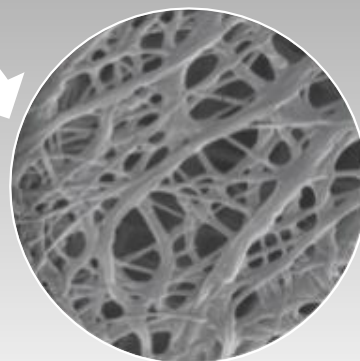


- **Proven technology** with +500 patients treated to date
- **Major US collaboration partner**
- **IND application Q4 2019 (RMAT Designation)**
- **Patent-protected** in all major jurisdictions

***Total addressable market is estimated to be in excess of US\$12bn p.a.<sup>2</sup>***

1. CelGro® for dental bone and soft tissue repair
2. 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



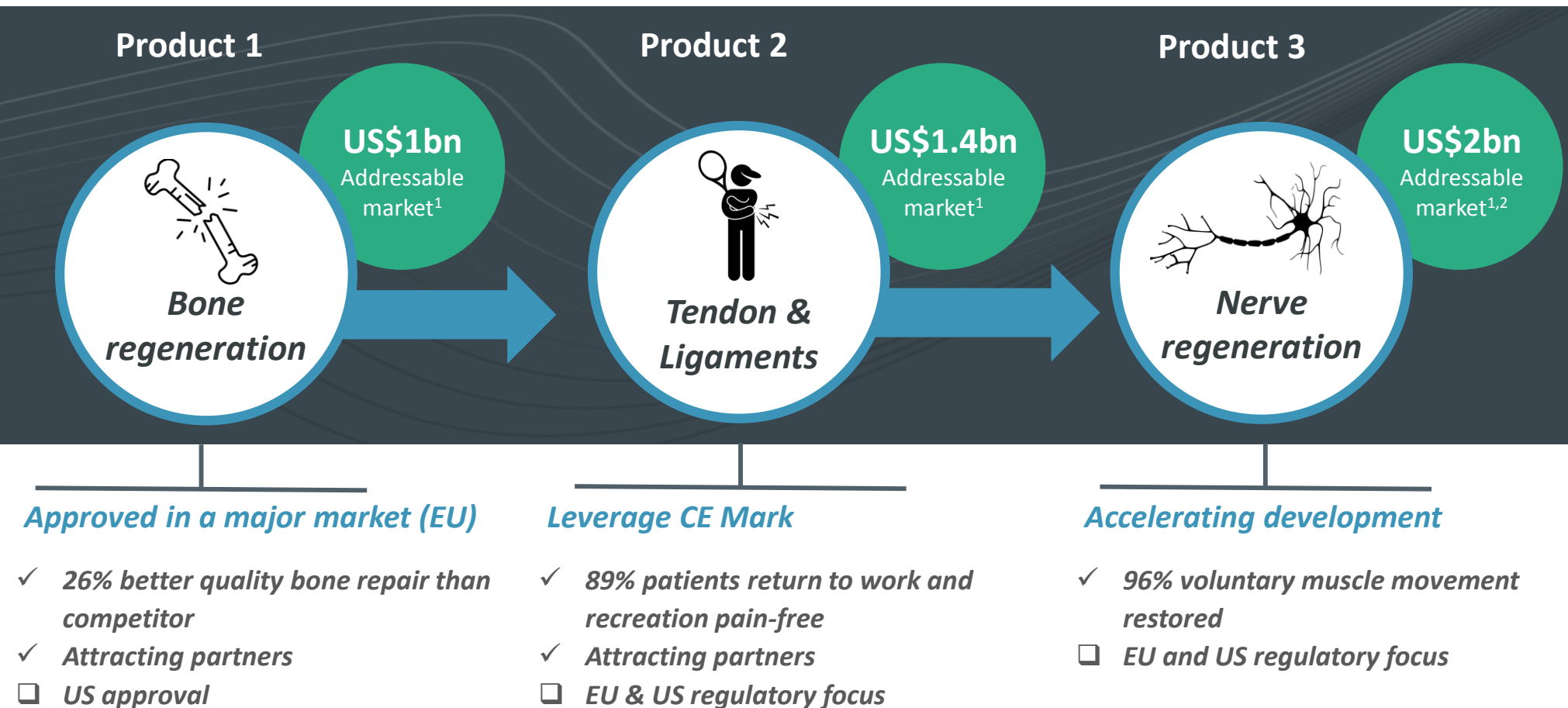


## CelGro®

A unique collagen medical device that  
augments tissue repair and  
regeneration

# CelGro® : strategic focus

Orthocell is driving market entry for bone repair, leveraging EU approval to accelerate introduction of the tendon and nerve indications

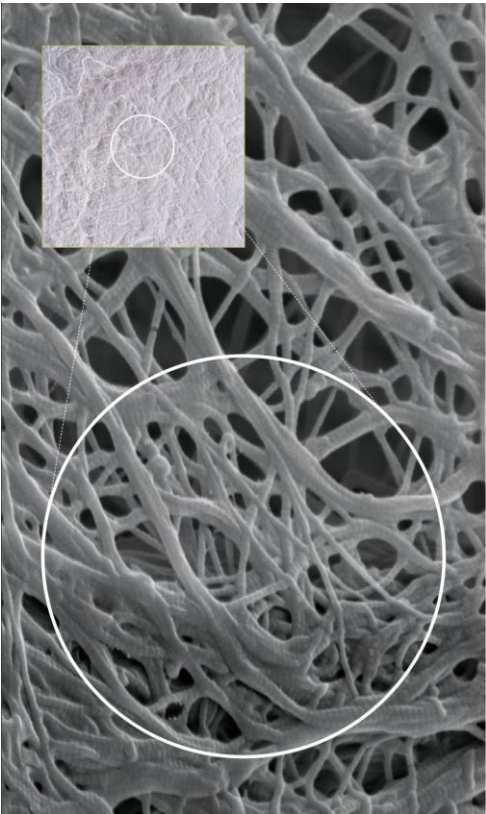


1. US, Japanese, European and Australian markets. 2. Analysis of addressable markets excludes the following CelGro® pipeline products including articular cartilage repair, ACL ligament replacement & general surgery.

# CelGro®: Superior bone regeneration

Establishing CelGro® as the best in class membrane for bone and soft tissue repair in the significant and growing global market

## CelGro®: a true regenerative medicine scaffold



- ✓ **Superior tissue repair**  
unique regenerative medicine qualities
- ✓ **Superior handling characteristics** over existing products
- ✓ Proprietary **SMRT™** manufacturing process
- ✓ **Dental bone and soft tissue** repair approved for use in the EU

## Illustrative example



**Defect Site** - insufficient bone volume available



**Bone Graft** - defect site filled



**Apply CelGro®** - placed over defect site



**Implant Crown** - tissue stitched over CelGro® and crown secured

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

# CelGro®: bone regeneration market opportunity

## Very favourable market dynamics



**No recent product innovation** to the dental market globally



Existing products have **inferior functionality** and **handling characteristics**



**Strong demand** from dentists / surgeons

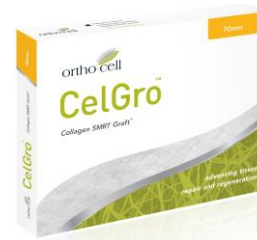
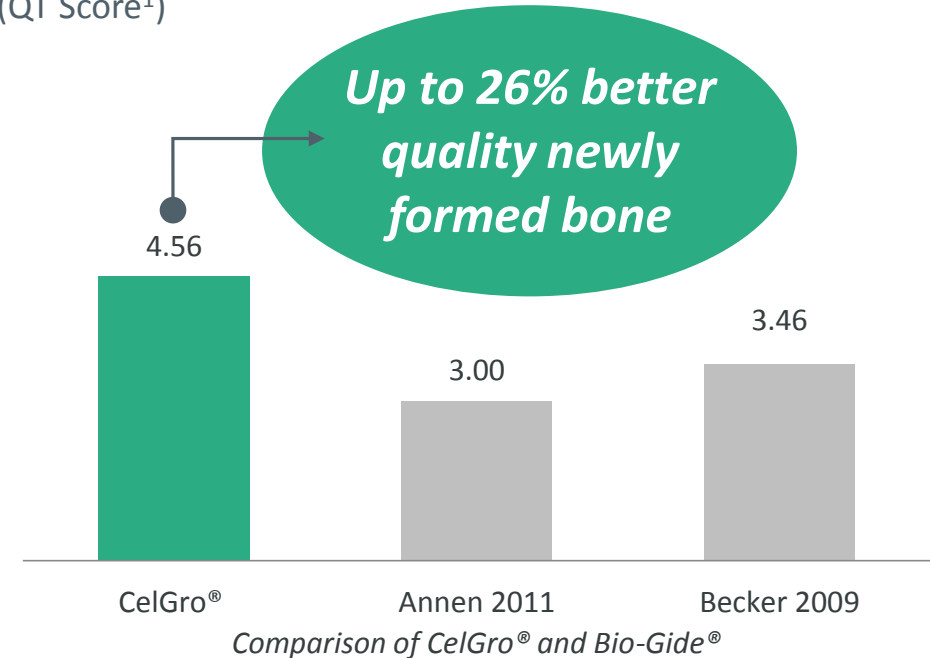


Market leader generates **€50m p.a. in EU alone**

1. The QT Score is based on a six (6) point (0 to 5) Likert scale. Therefore, an improvement of one (1) point on the QT Scale equates to a 16.67% percentage improvement
2. US, Japanese, European and Australian markets based on ~1.5m procedures per year

## Superior clinical performance

(QT Score<sup>1</sup>)



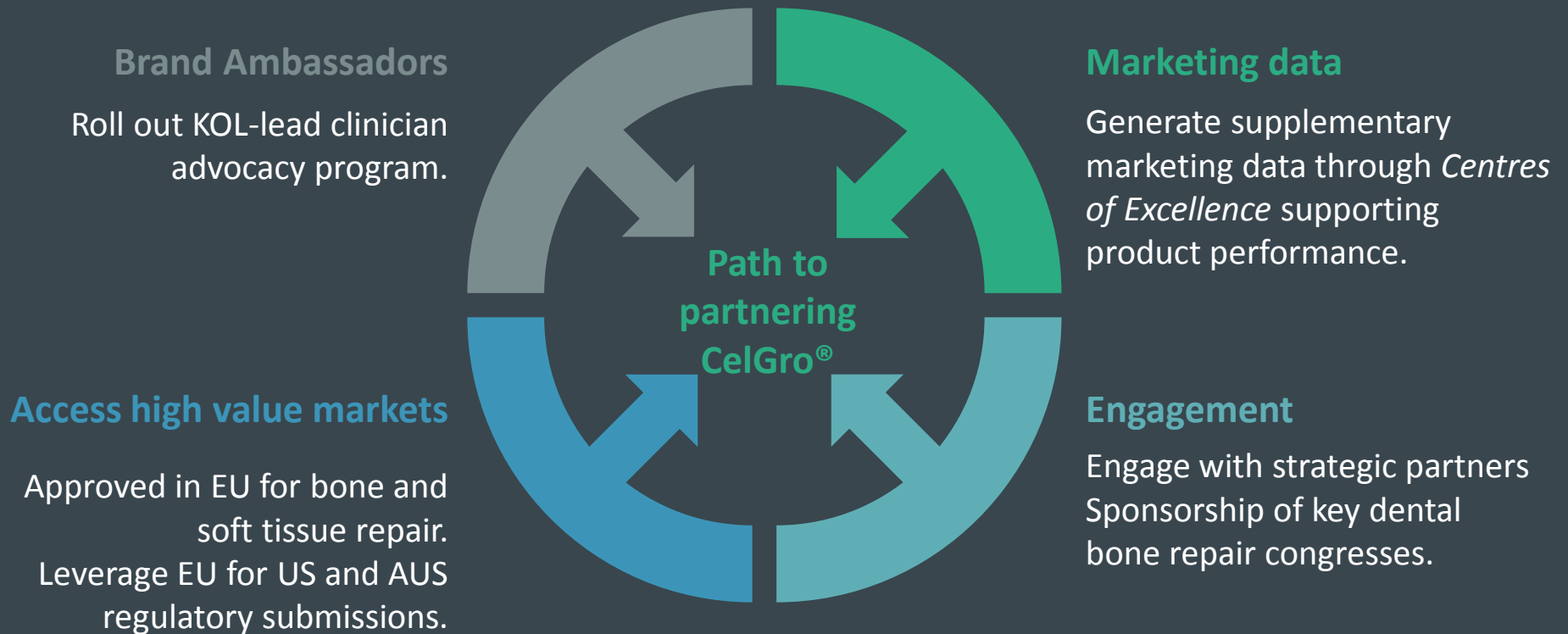
**Significant addressable market<sup>2</sup>**

**>US\$0.6bn p.a.**



# CelGro®: path to partnering

Optimised and scalable manufacturing in place, regulatory approval achieved and brand ambassadors appointed. Orthocell is well placed to execute on its partnering strategy.



# CelGro®: nerve repair market opportunity

## Very favourable market dynamics:



- Millions of people suffer from peripheral nerve injury as a result of motor vehicle, sporting or work-related incidents



- Existing products have inferior functionality and handling characteristics



- Strong demand from orthopaedic surgeons

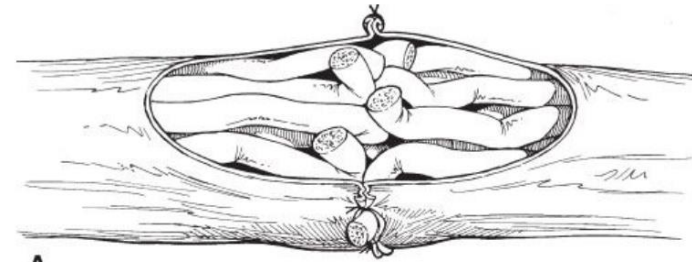


- Market leader generates \$US80m p.a. in US alone
- Significant addressable market US\$1.1bn

## Traditional repair outcomes are suboptimal:

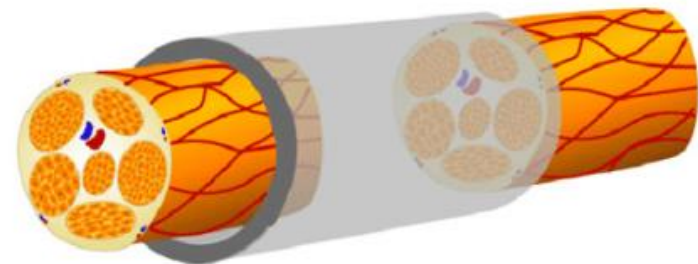
### Direct suture

- ✗ Tension can result in buckling and misdirection of regeneration nerve fibres



### Rigid hollow tube

- ✗ Rigid tubes are limited in use and efficacy



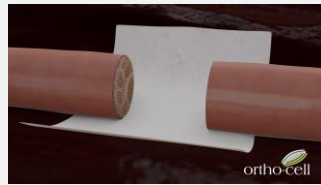
# CelGro®: revolutionising nerve repair

## CelGro®: the solution for optimal tensionless repair



### **1. Peripheral Nerve Injury**

*Crushed peripheral nerve after traumatic injury to limb*



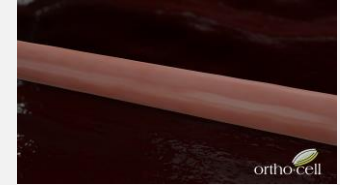
### **2. Preparation of Repair Site**

*CelGro® is secured around nerve ends, forming a sealed conduit*



### **3. CelGro® guides and supports nerve repair**

*New nerve fibres reconnect*



### **4. Nerve Healing**

*Healed nerve restores function and sensation to affected limb*

*“CelGro® is easier to use and performs better for its intended purpose. It is not rigid – it facilitates tensionless repair, increases the strength of the repair, and creates a bioactive chamber for healing.” - Dr Alex O’Beirne, Orthopaedic nerve specialist and CelGro® trial Principal Investigator*

# CelGro®: Positive CelGro® nerve regeneration interim results

Patients regain muscle function in affected limbs following CelGro® nerve regeneration treatment

## First patients complete nerve regeneration trial:

- ✓ **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® nerve regeneration treatment



### ***Trial participant Adrian Walsh, said***

*"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. When I heard about the CelGro® trial, I thought it was worth a try. My arm now feels 500 percent better than before the procedure. 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."*





## Ortho-ATI®

Advanced cellular therapy that  
directly addresses the root cause of  
degenerate tendon injury



# Ortho-ATI®: non-surgical solution for chronic tendon repair

Advanced cellular therapy that directly addresses the root cause of degenerate tendon injury

## Ortho-ATI® overview

- **Breakthrough** in regenerative medicine
- **Novel, cell therapy** to treat chronic degenerative tendon injuries
- Replenishes degenerative tissue with healthy mature tendon cells, **accelerating regeneration of tendon tissue**
- Allows patients to **return to work, recreational activities and competitive sport**
- **500 + patients treated**

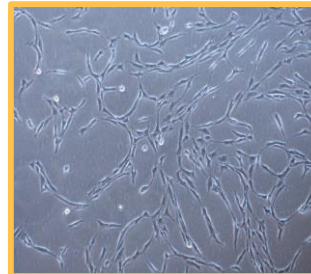
## Two stage, minimally invasive procedure

### 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-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 Johnson & Johnson logo is displayed in a red, cursive script font. It is positioned to the right of a vertical dashed line, which separates it from the key factors list. The background of the slide features a blurred image of a medical syringe.

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)



Next steps

# Regenerative medicine case study: PolyNovo

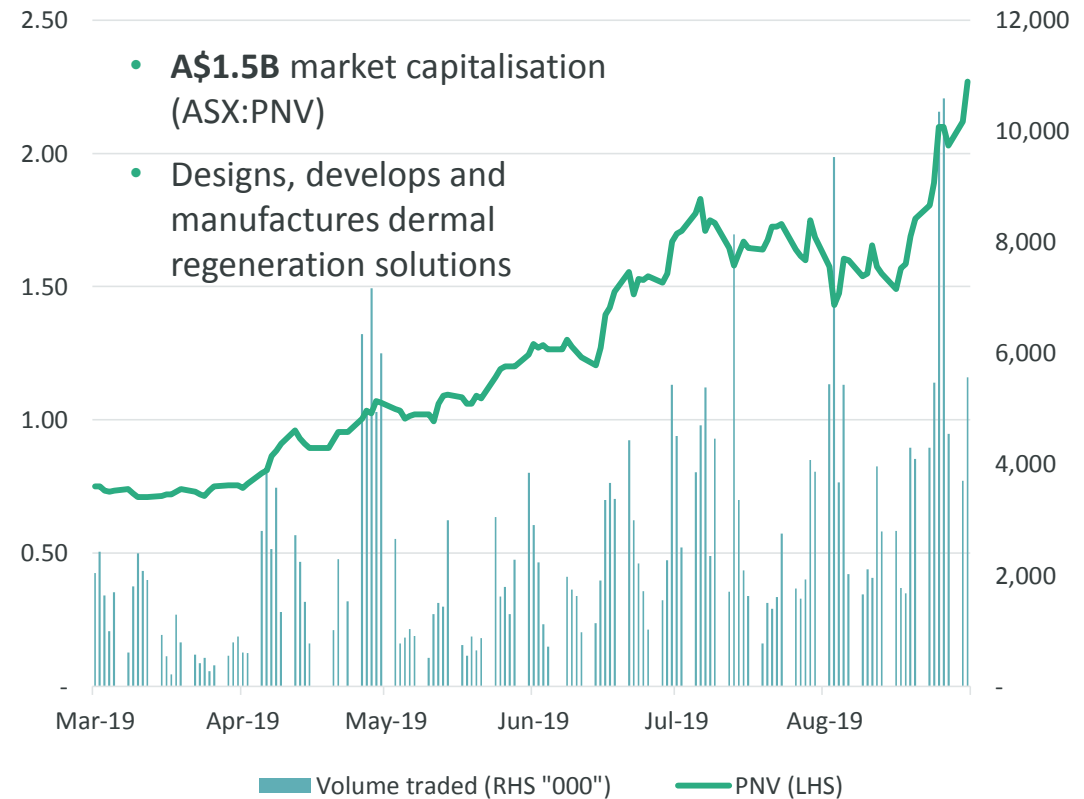
## ortho·cell Growth drivers:

- CelGro® gaining traction in key markets
- Achieving **US approval for CelGro®**
- Potential to address **multiple indications**, in significant markets with multiple products
- **Ortho-ATI® commercialisation** (research collaboration with a major US partner)
- **Global partnering opportunities**

*Strong share price movement in the months following first sales in a large, attractive international market*



Price (A\$)





# Upcoming catalysts

## CelGro® - Dental

Roll out European advocacy program	Ongoing
Australian market authorisation	1Q CY2020
US market authorisation	3Q CY2020

## CelGro® - Tendon and Nerve

Approval to commence FDA study	4Q CY2019
CE Mark (EU) submission	4Q CY2019
TGA (AUS) submission	1Q CY2020

## Ortho-ATI®

Investigation New Drug submission FDA	4Q CY2019
Complete J&J study recruitment	4Q CY2019

***Strategic partnership discussions ongoing for all products***



# Corporate overview

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

## Share price performance



## Trading information

Share price (25-Oct-19)	A\$0.54
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Shares on issue <sup>1</sup>	154.7m
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<b>Market capitalisation</b>	<b>~A\$84m</b>
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Cash (as at 30-Jun-19)	A\$11.2m
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Debt (as at 30-Jun-19)	-
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<b>Enterprise value</b>	<b>~A\$73</b>
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## Top shareholders (as at Sep-19)

Ming Hao Zheng – CSO and founder	4.9%
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Paul Anderson – Managing director and founder	4.6%
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Board and Management	8.5%
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1. Excludes 12.1m unquoted warrants with exercise price \$0.58, expiry 19-Nov-2020 and 27m unquoted options with exercise prices ranging from \$0.25-\$0.65 and expiry dates between Dec-2019 and Jun-2022

# Key investment highlights



## Significant upside

*Significant market interest*

*Addressable markets worth >US\$12bn p.a.*

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## De-risked product portfolio

*Substantial clinical data*

*CE Mark achieved for CelGro® in EU*

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## Validated manufacturing process

*GMP-certified and TGA-licensed  
manufacturing capabilities*

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## Credentialed and highly aligned leadership

*Proven track record in commercialising cell  
therapy products*

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## Contact us

**Paul Anderson**

Orthocell Limited

Founder and Managing Director

P: +61 8 9360 2888

E: paulanderson@orthocell.com.au

Visit us

[www.orthocell.com.au](http://www.orthocell.com.au)

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