



Investor update

May 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 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
Board Member

- 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®
Soft tissue reconstruction platform medical device



- **Proven platform technology** – multiple indications
- **Approved for sale** in Europe (CE Mark)¹
- **Superior** clinical performance¹
- **Breakthrough nerve** regeneration clinical results
- **Global partnering** opportunities
- **Patent protected** in all major jurisdictions

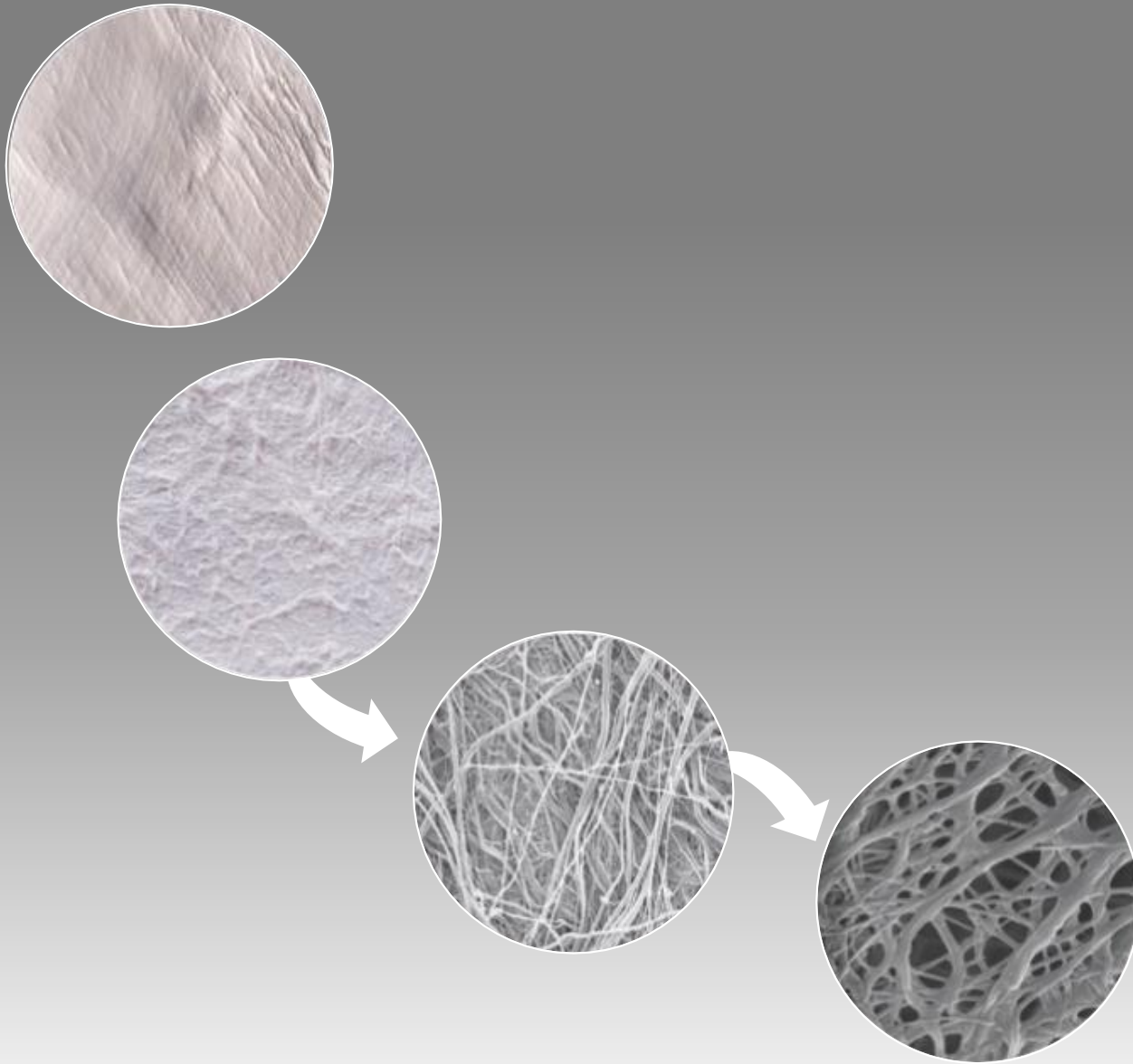
Ortho-ATI®
Cell therapy to regenerate damaged tendon tissue



- **First in class cell therapy** for tendon repair
- Global partnering - **major US collaboration partner**
- **De-risked** with +500 patients treated to date
- **Licence to manufacture and treat** patients in Australia, Singapore and Hong Kong (TGA)
- **US regulatory focus** - process underway
- **Patent protected** in all major jurisdictions

Total addressable market is estimated to be in excess of US\$10bn p.a.²

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® - 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

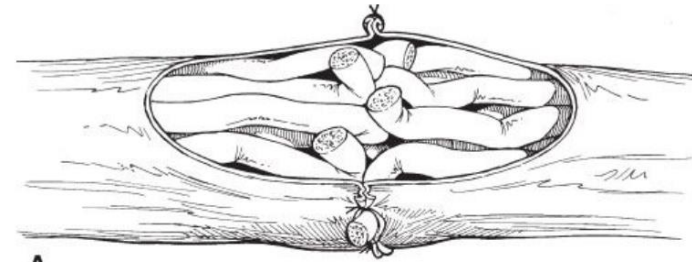


- Market leader generates \$US80m p.a. in US alone
- Significant addressable market US\$1.1bn

Traditional repair outcomes are suboptimal:

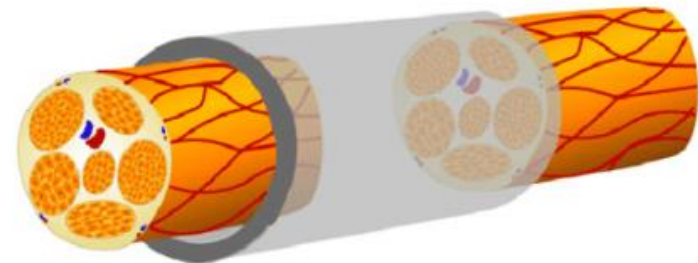
Direct suture

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



Rigid hollow tube

- ✗ Rigid tubes are limited in use and efficacy



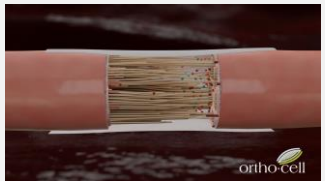
CelGro®: the solution for optimal tensionless repair



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® revolutionising nerve repair

(click to watch video)



“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

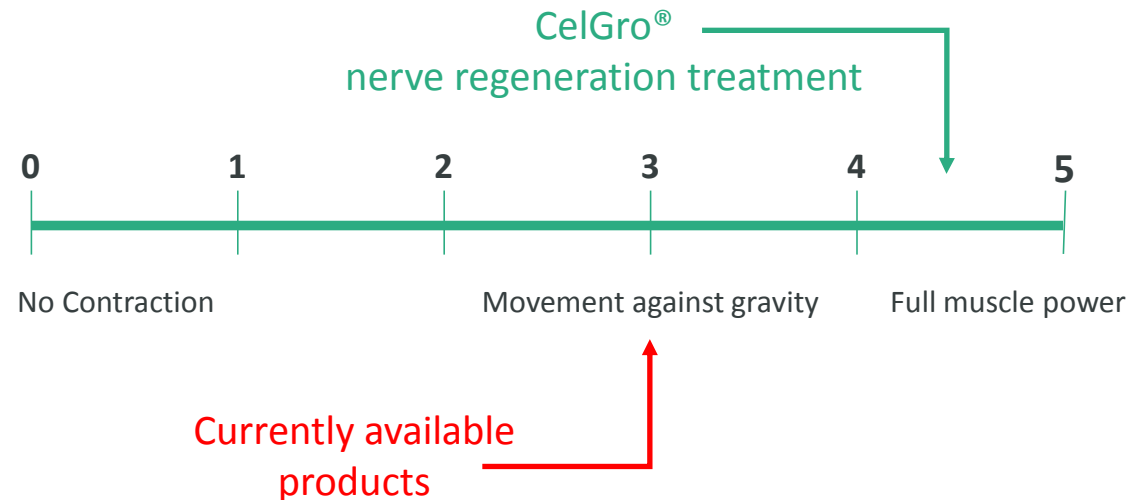
CelGro®: first patients complete nerve regeneration trial

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

First patients complete nerve regeneration trial:

- ✓ **Regain sensation** and function in affected limbs
- ✓ **83% improvement** in muscle power
- ✓ Commenced **return to work**, sport and activities of daily living

Muscle power grading using MRC system¹

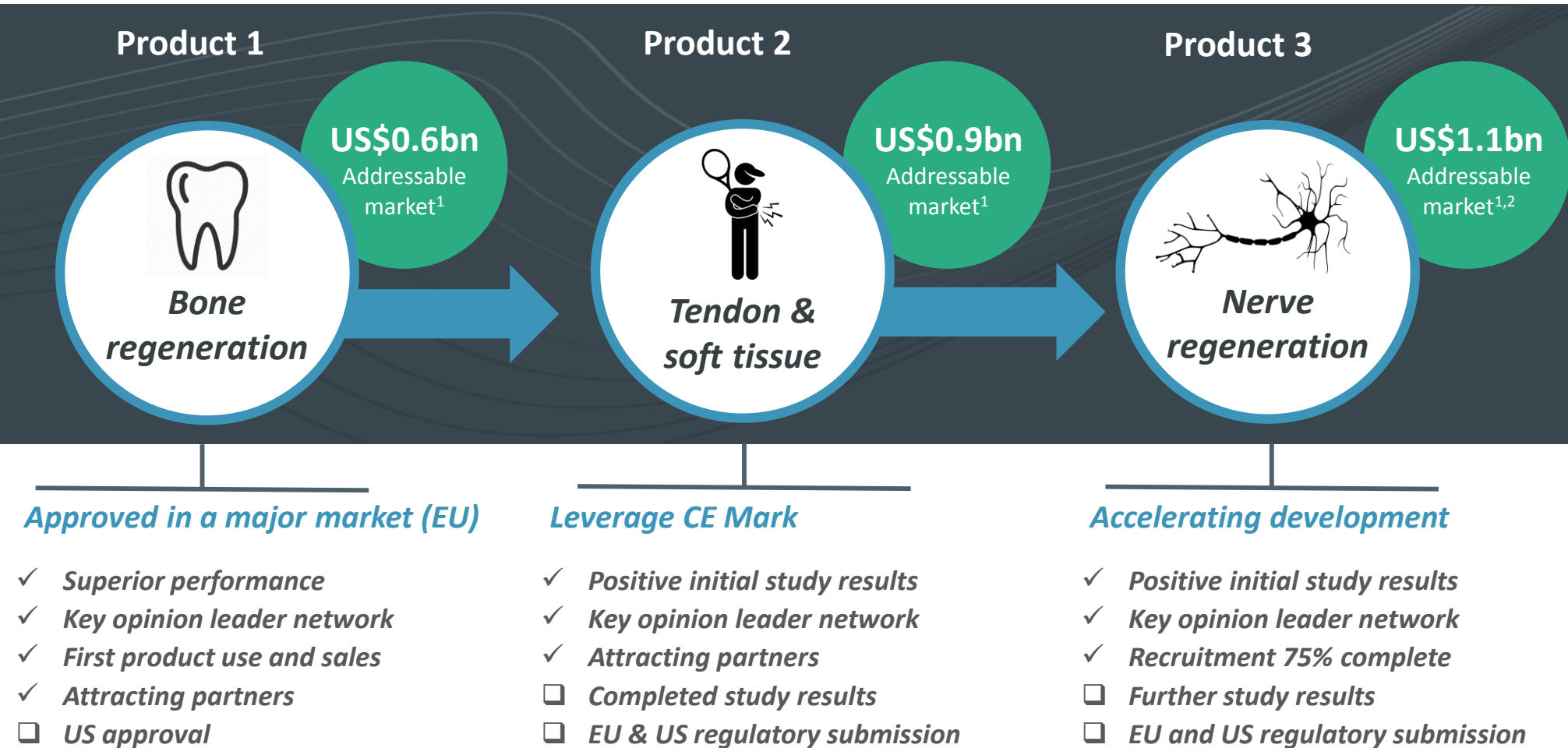


After my football injury, I had no feeling in my right shoulder. I couldn't pick up my kids, swim, or play football. ... I'm living a normal life now. I can pick up my kids and I even swam a duo to Rottneest! I might even be able to play footy again next year, something that I thought would never happen." - Daniel Hunt, trial participant.

1. Motor function of affected muscles assessed using the British Medical Research Council (MRC) grading system: 0 = No contraction, 1 = Flicker/trace contraction, 2 = Movement with gravity eliminated, 3 = Movement against gravity, 4 = Movement against resistance, 5 = Full muscle power

CelGro®: strategic focus

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

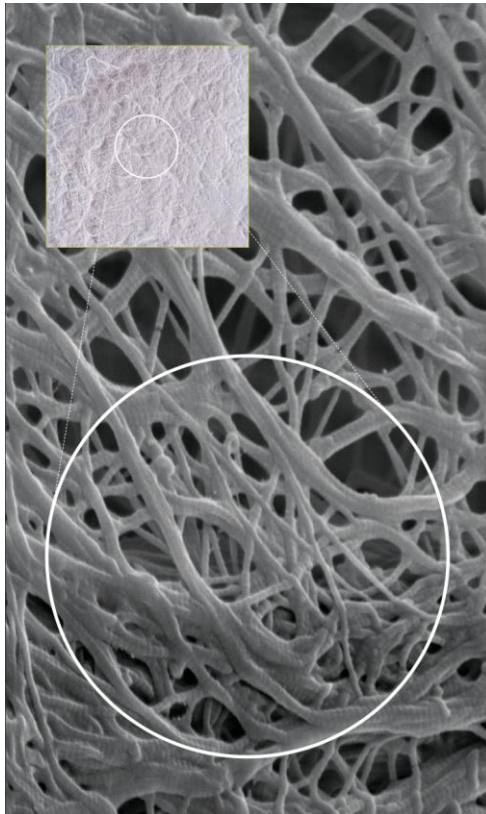


1. US, Japanese, European and Australian markets. 2. Analysis of addressable markets excludes the following CelGro® pipeline products including articular cartilage repair, ACL ligament replacement & general surgery.

CelGro[®]: Superior bone regeneration

Orthocell 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

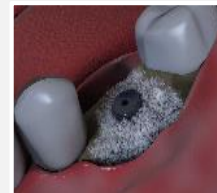


- ✓ **Superior tissue repair**
unique regenerative medicine qualities
- ✓ **Superior handling characteristics** over existing products
- ✓ Proprietary **SMRT™** manufacturing process
- ✓ **CE Mark** dental bone and soft tissue repair approved for use in the EU

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 product innovation to the dental market globally



Existing products have inferior functionality and handling characteristics



Strong demand from dentists / surgeons

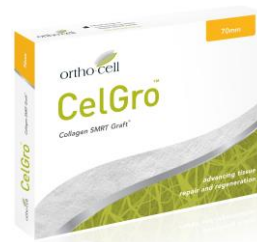
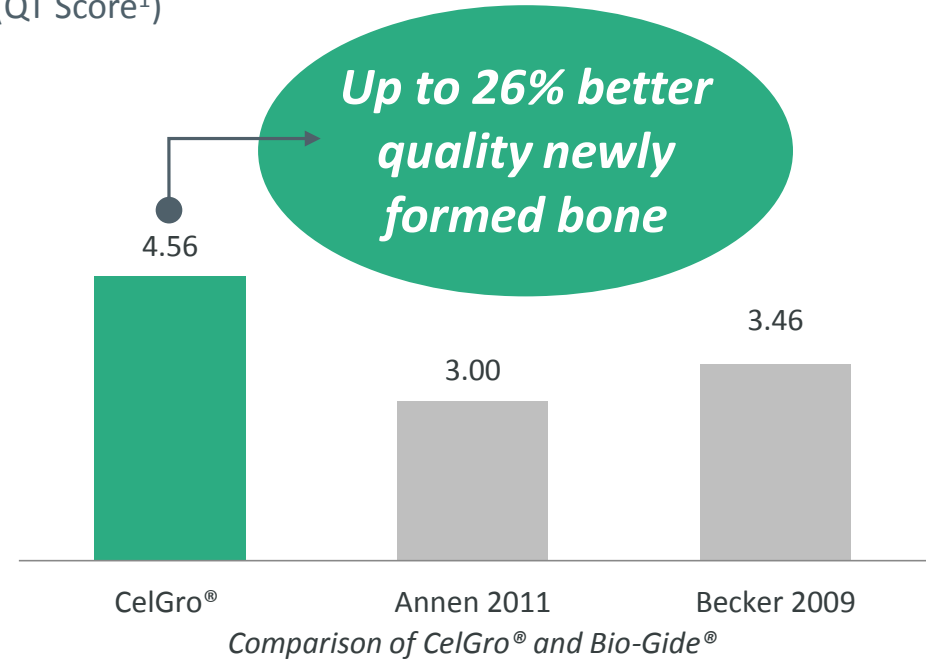


Market leader generates €50m p.a. in EU alone

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 Score¹)

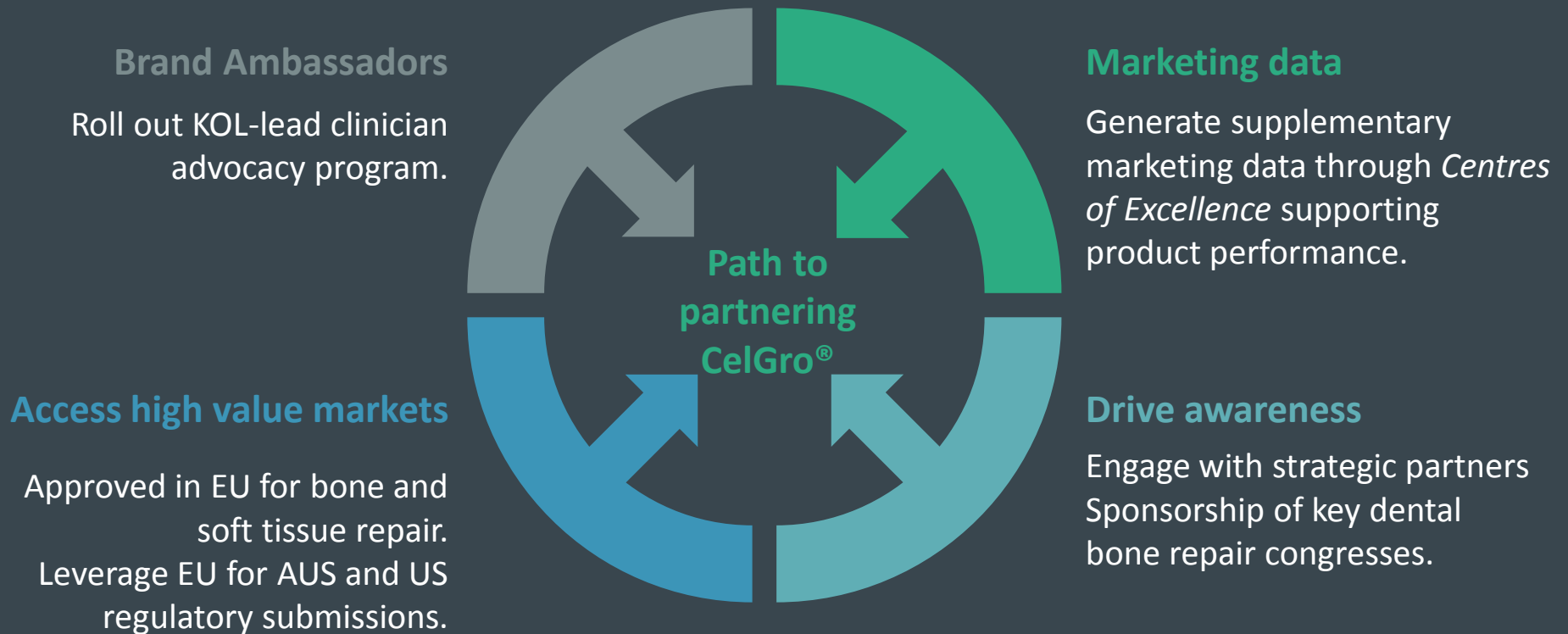


Significant addressable market²

>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.





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 the, workplace, recreational activities and competitive sport**
- **500 + patients treated**

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)

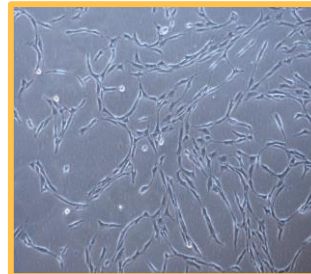
Two stage, minimally invasive procedure

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 facility¹ and PPI release criteria in place²*
- ✓ **Significant addressable market for Ortho-ATI®** - *>US\$7.7bn p.a.³*



Johnson & Johnson

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
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Next steps

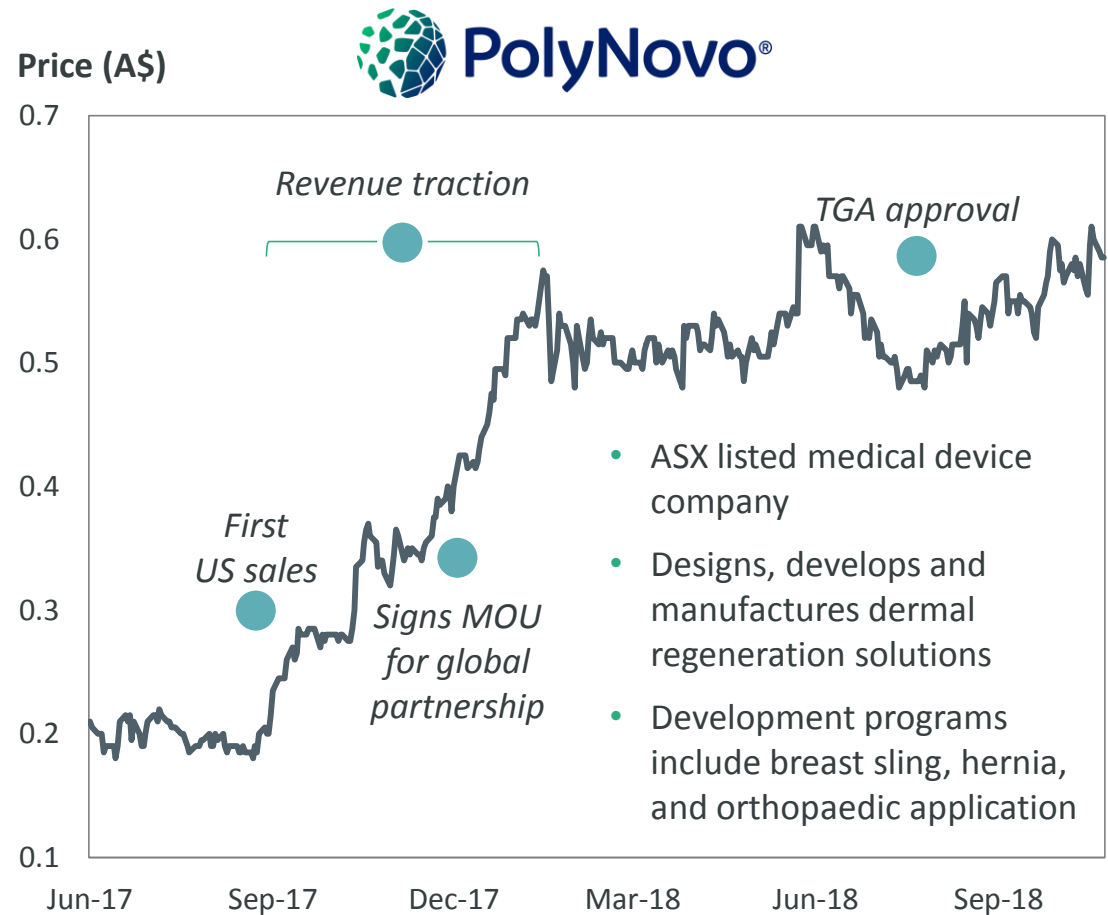
Regenerative medicine case study: PolyNovo

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

ortho·cell **Rating based on:**

- 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



Corporate overview

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

Share price performance



Trading information

Share price (17-May-19)	A\$0.49
Shares on issue ¹	123.1m
Market capitalisation	~A\$60m
Cash (as at 31-Mch-19)	A\$3.2m
Debt (as at 31-Mch-19)	-
Enterprise value	A\$57.1

Top shareholders (as at May-19)

SRV Custodians pty ltd	6.1%
Ming Hao Zheng – CSO and founder	5.8%
Paul Anderson – Managing director and founder	5.2%
Board and Management	10.2%

1. Excludes 12.1m unquoted warrants with exercise price \$0.58, expiry 19-Nov-2020 and 26.42m unquoted options with exercise prices ranging from \$0.25-\$0.65 and expiry dates between Oct-2019 and Dec-2021

Upcoming catalysts

CelGro® - Dental

Roll out European advocacy program	Ongoing
Single stage dental implant data	2Q CY2019
Spain and Germany market entry	3Q CY2019
Australian market authorisation	1Q CY2020
US market authorisation	2Q CY2020

CelGro® - Tendon and Nerve

Tendon repair clinical data	2Q CY2019
CE Mark (EU) submission	3Q CY2019
TGA (AUS) submission	3Q CY2019
Nerve repair clinical data	1Q CY2020

Ortho-ATI®

Investigation New Drug submission FDA	3Q CY2019
Complete J&J study recruitment	3Q CY2019

Strategic partnership discussions ongoing for all products

Key investment highlights



Significant upside

Significant market interest

Addressable markets worth >US\$10bn p.a.



De-risked product portfolio

Substantial clinical data

CE Mark (EU) achieved for CelGro[®]



Validated manufacturing process

*GMP-certified and TGA-licensed
manufacturing capabilities*



Credentialed and highly aligned leadership

*Proven track record in commercialising cell
therapy products*

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