Orthocell presents at 21st H.C. Wainwright Annual Global Investment Conference

Perth, Australia; 10th September 2019: Regenerative medicine company Orthocell Limited (ASX:OCC, "Orthocell" or the "Company") is pleased to announce it was **invited to present at the 21st H.C. Wainwright Annual Global Investment Conference** held at the Lotte New York Palace Hotel in New York City. Orthocell Managing Director, Paul Anderson presented the latest investor slide deck highlighting the upcoming catalysts. Mr Anderson will also meet with members of the investment community during scheduled one-on-one meetings at the conference.

A copy of the investor presentation is attached and can be found on the Company's website here: Orthocell HCW Conference Presentation

For more information, please contact:

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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 TGA-licensed cell therapies Autologous Tenocyte Implantation (Ortho-ATI®) and Autologous Chondrocyte Implantation (Ortho-ACI®), 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. The Company's other major product is the CelGro® platform technology, a collagen medical device which facilitates tissue repair and healing in a variety of orthopaedic, reconstructive and surgical applications. Orthocell recently received European regulatory approval (CE Mark) for CelGro®. The collagen medical device can now be marketed and sold within the European Union for a range of dental bone and soft tissue regeneration procedures and is being readied for first approval in the US and AUS.

For more information on Orthocell, please visit www.orthocell.com.au or follow us on Twitter **@Orthocellltd** and LinkedIn www.linkedin.com/company/orthocell-ltd

ortho·cell
advancing tissue repair & regeneration

Investor Presentation

H.C. Wainwright 21st Annual Global Investment Conference

September 2019

Regenerative medicine

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

Executive team

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

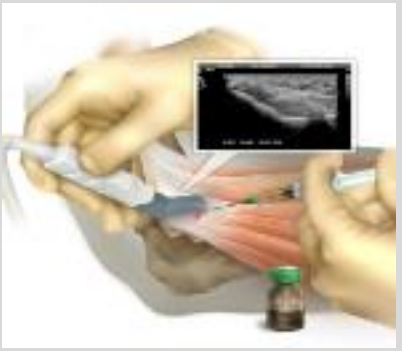
CelGro®

Tissue reconstruction platform medical device

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

Ortho-ATI®

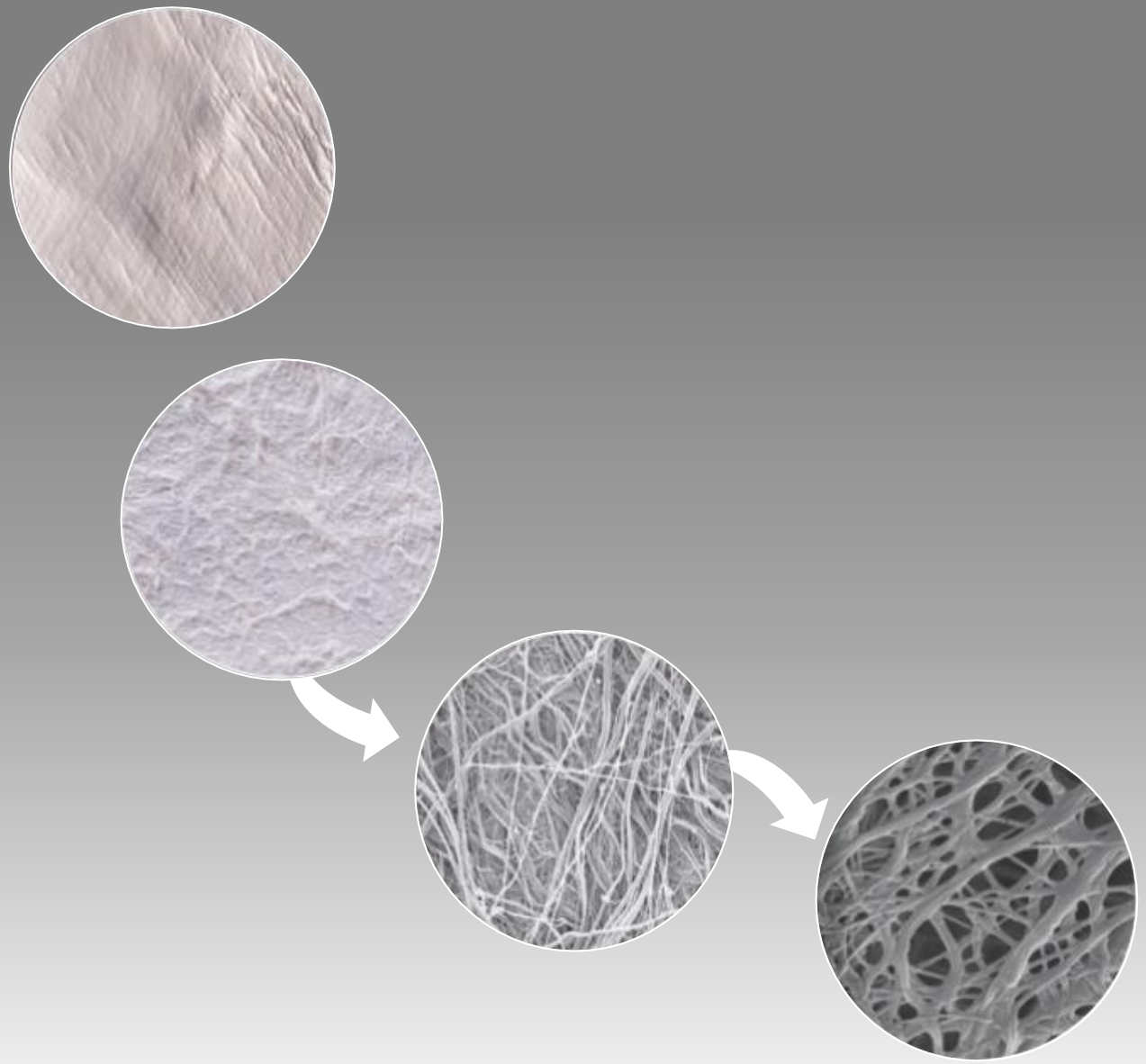
Cell therapy to regenerate damaged tendon tissue



- **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.[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



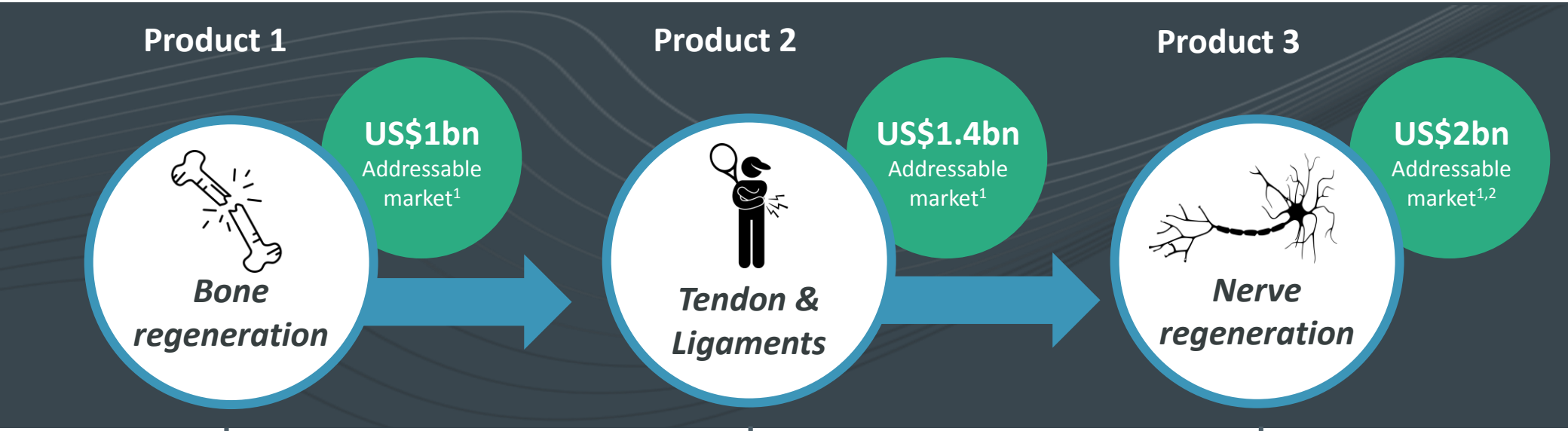
CelGro®

A unique collagen medical device that augments tissue repair and regeneration

ortho·cell
advancing tissue repair & regeneration

CelGro® : strategic focus

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



Approved in a major market (EU)

- ✓ *26% better quality bone repair than competitor*
- ✓ *Attracting partners*
- ❑ *US approval*

Leverage CE Mark

- ✓ *89% patients return to work and recreation pain-free*
- ✓ *Attracting partners*
- ❑ *EU & US regulatory focus*

Accelerating development

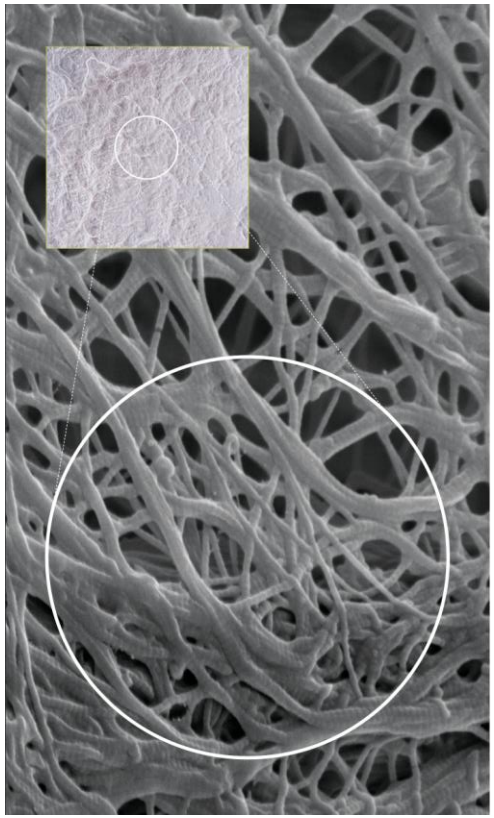
- ✓ *83% improvement in muscle power*
- ❑ *Further study results 3Q CY19*
- ❑ *EU and US regulatory focus*

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

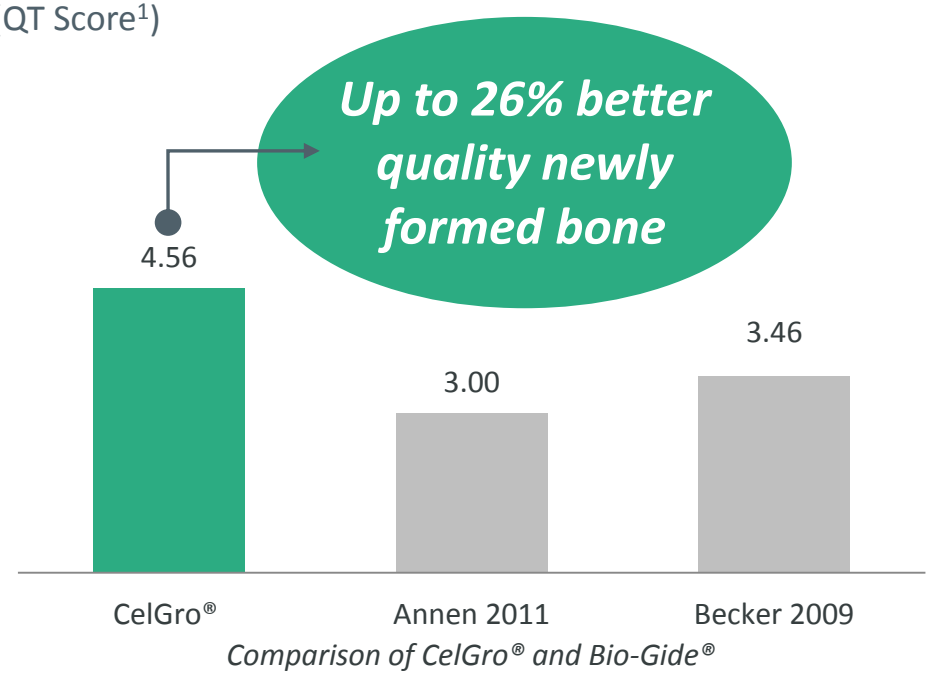
CelGro®: bone regeneration market opportunity

Very favourable market dynamics

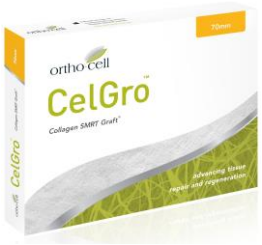
- **No recent product innovation** to the dental market globally
- Existing products have **inferior functionality** and **handling characteristics**
- **Strong demand** from dentists / surgeons
- Market leader generates **€50m p.a. in EU alone**

Superior clinical performance

(QT Score[1])



Comparison of CelGro® and Bio-Gide®



Significant addressable market[2]

>US$0.6bn p.a.

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

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.

Brand Ambassadors

Roll out KOL-lead clinician advocacy program.

Marketing data

Generate supplementary marketing data through *Centres of Excellence* supporting product performance.

Access high value markets

Approved in EU for bone and soft tissue repair.
Leverage EU for US and AUS regulatory submissions.

Engagement

Engage with strategic partners
Sponsorship of key dental bone repair congresses.

CelGro®: nerve repair market opportunity

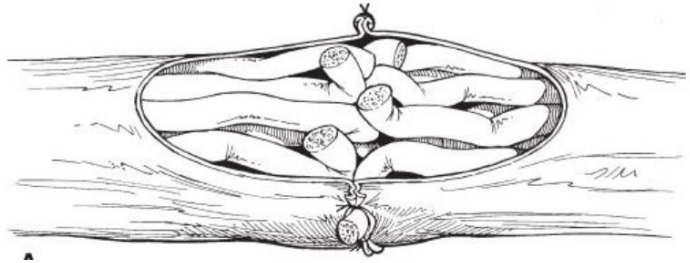
Very favourable market dynamics:

- 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:

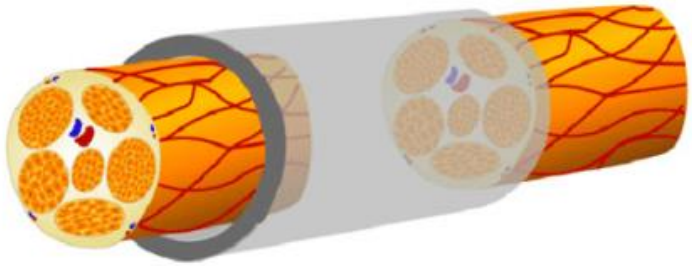
Direct suture

✕ Tension can result in buckling and misdirection of regeneration nerve fibres



Rigid hollow tube

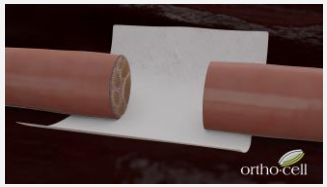
✕ Rigid tubes are limited in use and efficacy



CelGro®: revolutionising nerve repair

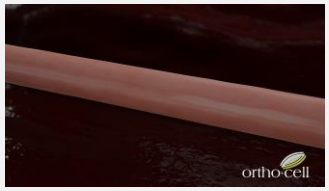
CelGro®: the solution for optimal tensionless repair

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® 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***

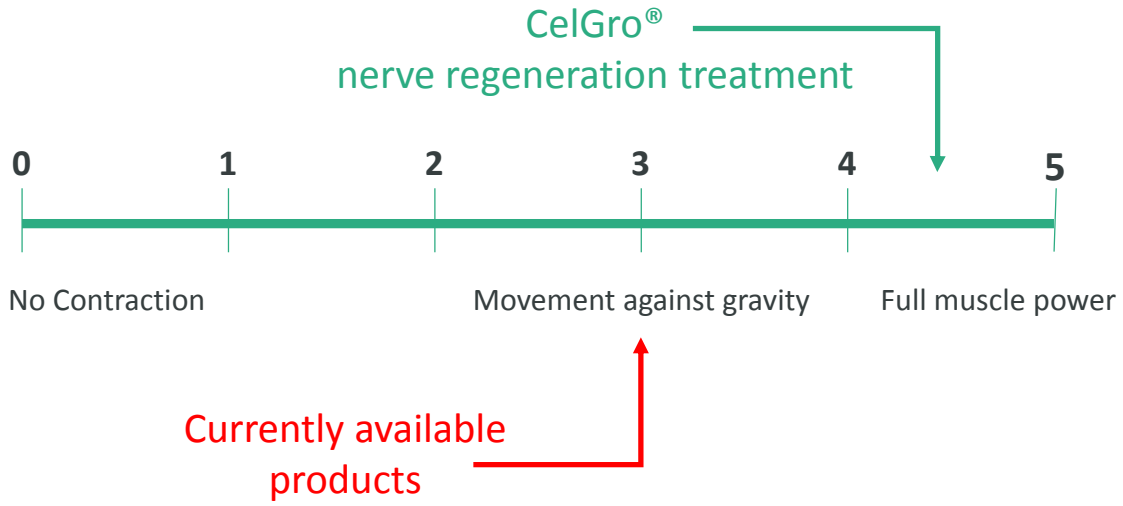
CelGro®: first patients complete nerve regeneration trial

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 system[1]



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 Rottnest! 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

Ortho-ATI®

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

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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

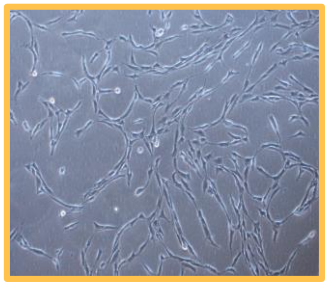
- **Breakthrough** in regenerative medicine
- **Novel, cell therapy** to treat chronic degenerative tendon injuries
- Replenishes degenerative tissue with healthy mature tendon cells, **accelerating regeneration of tendon tissue**
- Allows patients to **return to work, recreational activities and competitive 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[1] and PPI[2] release criteria in place*
- ✓ **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
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

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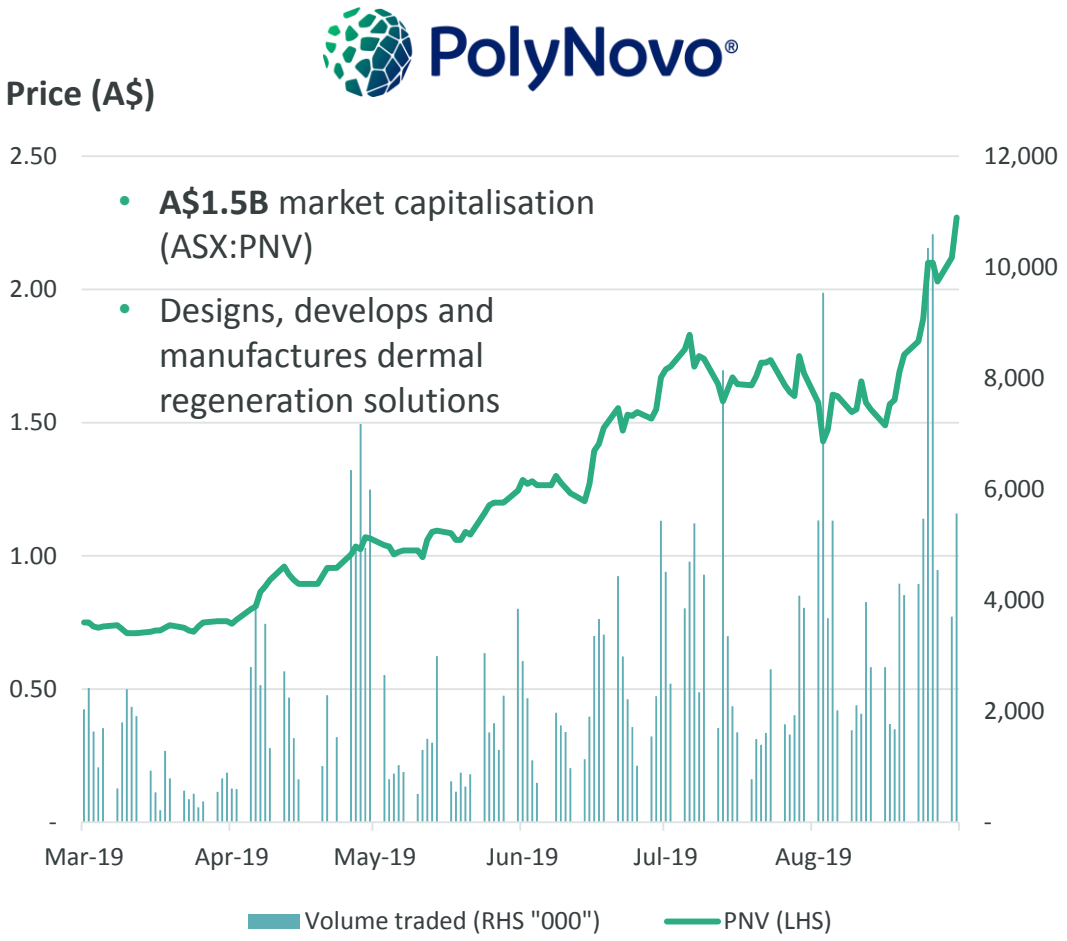
Regenerative medicine case study: PolyNovo

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

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



Corporate overview

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

Share price performance

Trading information

Share price (04-Sep-19)	A$0.40
Shares on issue[1]	154.3m
Market capitalisation	**~A$62m**
Cash (as at 30-Jun-19)	A$11.2m
Debt (as at 30-Jun-19)	-
Enterprise value	**~A$50.1**

Top shareholders (as at Sep-19)

AustralianSuper	4.8%
Ming Hao Zheng – *CSO and founder*	4.8%
Paul Anderson – *Managing director and founder*	4.2%
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
Australian market authorisation	1Q CY2020
US market authorisation	3Q CY2020

CelGro® - Tendon and Nerve

Nerve repair clinical data	3Q CY2020
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

Key investment highlights

Significant upside

Significant market interest

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

De-risked product portfolio

Substantial clinical data

CE Mark achieved for CelGro® in EU

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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