

Orthocell

Advancing tissue repair and regeneration

Investor update

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Product innovation

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



CelGro®

Soft tissue reconstruction platform

- **CE Mark** - Approved in Europe for bone and tissue
- **Superior** - Clinical performance
- **Commercialisation** - Key European markets
- **Multiple indications** - Superior collagen medical device
- **Optimised** - Manufacturing capabilities
- **Lack of innovation** – static market
- **Global partnering**



Ortho-ATI®

Regeneration of tendons

- **First in class** - Cell therapy for tendon repair
- **Significant unmet clinical need**
- **Global partnering** - Major US collaboration partner
- **De-risked** - Proven safe and effective (>500 patients treated)
- **Optimised** - Manufacturing capabilities
- **US regulatory focus** - Process underway

CelGro®- bone regeneration

CelGro®'s is approved in the EU (CE Mark) for dental bone and soft tissue repair

CelGro® is a unique collagen scaffold...

- ✓ **Integrates** with the soft tissue under repair
- ✓ **Completely absorbed** - degrades at the same rate as the body heals
- ✓ **Guides** a high quality of tissue repair
- ✓ **Superior handling** characteristics over existing dental products
- ✓ Manufactured inhouse at Orthocell's **quality controlled facility**, proprietary SMRT™ engineering process

Dr Brent Allan, Chief Investigator, dental bone regeneration trial:
"CelGro® is an exciting new product with clear advantages over available alternatives."



1. Defect Site



2. Bone Graft



3. Apply CelGro®



4. Insert Crown

Significant market opportunity

Ideally positioned to gain market traction in the rapidly growing and lucrative field of oral medicine

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 for
- Market leader generates E\$50m p.a. in EU alone



***CelGro® has superior clinical performance
and a significant market opportunity***



Significant addressable market¹

>US\$0.6bn p.a.

1.5m procedures per year

1. US, Japanese, European and Australian markets

CelGro[®] - bone regeneration commercial pathway

Key development and marketing approval milestones for CelGro[®] achieved, the focus is now on EU market entry in the bone and soft tissue

Achieved significant development milestones



Optimised manufacturing

- ✓ Quality and proprietary SMRT[™] manufacturing processes
- ✓ Scalable infrastructure in place



Regulatory approval

- ✓ Clinically validated products, completed studies
- ✓ CelGro[®] approved for marketing and distribution in the EU (CE Mark)



Key opinion leaders in place

- ✓ Dr Simion
- ✓ Dr Luongo
- ✓ World leaders in oral medicine and targeted by competitors

Market entry – next steps



EU Market

- Clinical data
- Secure distribution partnerships
- Initial sales
- KOL led adoption in key markets

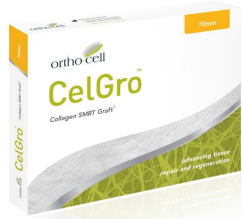


Expansion

- Leverage CE mark for US and AU market entry
- Secure distribution partnerships
- M&A

CelGro® - strategic focus

Orthocell is driving market entry for bone repair, leveraging position to accelerate introduction of the tendon and soft tissue indications



Ortho-ATI® - leading cell therapy for tendon repair

Ortho-ATI® has attracted the interest of the worlds largest health care company

Key factors in attracting research collaboration interest

- ✓ **Clinical validation**
Published clinical data in American Journal of Sports Medicine
Completed 500+ patient implants to date
- ✓ **Optimised manufacturing capability**
GMP-certified and TGA-licensed facility¹
PPI release criteria in place²
- ✓ **Treatment pathway**
Key opinion leader network established in Australia
- ✓ **Large unmet clinical need**
1.5m+ addressable procedures per year in the shoulder and elbow alone



Ortho-ATI® research collaboration

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

Vericel comparator case study

Significant value upside potential exists given Orthocell's valuable diversified product portfolio of cell therapies and regenerative medicine products, when compared to similar global peers

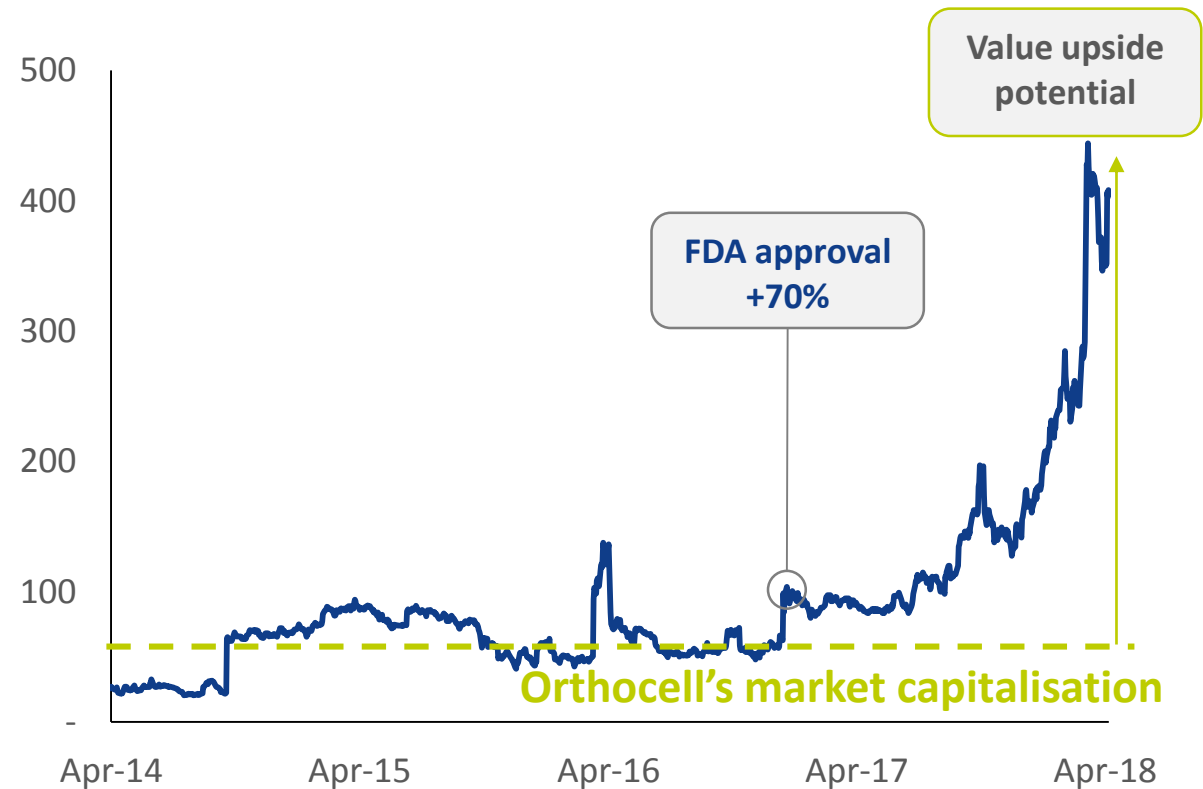


Develops, manufactures, and markets two regenerative medicine products for epidermal autografts and cartilage regeneration

Product comparison (Orthocell vs. Vericel)

	Orthocell	Vericel
ACI stem-cell product (cartilage focus)	✓	✓
ATI stem-cell product (tendon focus)	✓	✗
Platform technology (multi-use scaffold)	✓	✗

Vericel's market capitalisation (US\$m)



Significant interest in regenerative medicine

Smith & Nephew's recent US\$210m acquisition of Rotation Medical, a comparable peer to Orthocell, demonstrates the strong interest by major players within the regenerative medicine sector

US\$210m acquisition of Rotation Medical



- **M&A activity** - Major players are actively securing emerging regenerative medicine technologies
- **US\$210m acquisition** of Rotation Medical in October 2017
- **Rotation Medical** - medical scaffold company focused on rotator cuff repair with FDA 510(k) clearance & initial sales

Product comparison (Orthocell vs. Rotation Medical)

Key comparisons	Orthocell	Rotation Medical
Tendon regeneration	✓	✓
Platform technology	✓	✗
Multiple regenerative medicine products	✓	✗
Regulatory approval	✓	✓

Upcoming catalysts

Summary of the upcoming operational milestones



CelGro®

- Clinical data release – April 2018
- Secure distribution networks - 2Q 2018
- First sales in the EU – 2Q 2018
- US and Australian market authorisation – 1Q 2019
- Strategic partnership discussions - ongoing

Ortho-ATI®

- Accelerate completion of rotator cuff study – 2Q 2018
- Pre-Investigation New Drug meeting with FDA – 3Q 2018
- Strategic partnership discussions - ongoing

Key investment highlights

Regenerative medicine in the musculoskeletal space is one of the most compelling unmet market opportunities, and Orthocell is focused on developing innovative products for a variety of soft tissue injuries



Significant upside

Significant market interest in the sector underpinned by recent transactions and increased attention by the FDA. Orthocell's products address markets worth >US\$10bn p.a.



De-risked product portfolio

Developing novel and innovative products with substantial clinical data. In addition, CelGro® has CE Mark (EU) for dental bone and soft tissue reconstructive applications



Validated manufacturing process

GMP-certified and TGA-licensed manufacturing capabilities represents a significant competitive advantage in the sector which attracts interest from potential major partners



Credentialed and highly aligned leadership team

Experienced founders and management team with successful and proven track record in developing, commercialising and monetising cell therapy products

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