

# Orthocell Ltd

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## Orthocell at forefront of growing market opportunity in regenerative musculoskeletal treatment

Orthocell Ltd (ASX:OCC) is confident that its unique regenerative medicine product portfolio can address growing market opportunities in the treatment of complex musculoskeletal disorders.

The company is pursuing a total addressable market for CelGro® and Ortho-ATI® of US\$10 billion and US\$7.7 billion respectively - representing a combined US\$17.7 billion per annum.

This market is driven by the rising rate of musculoskeletal disorders and demand for efficient and cost-effective treatments.

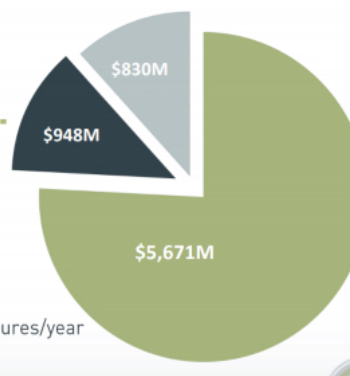
### CelGro® nerve repair

The company's CellGro collagen medical device is designed to augment surgical repair of soft tissue and represents a breakthrough in soft tissue reconstruction.

It has multiple applications in nerve, tendon and bone repair which have been demonstrated as having superior clinical performance when compared to current market leading product.

CelGro®'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

**Price:** 0.34

**Market Cap:** \$62.83 m

### 1 Year Share Price Graph



### Share Information

**Code:** OCC

**Listing:** ASX

52 week	High	Low
	0.68	0.18

**Sector:** Pharma & Biotech

**Website:** www.orthocell.com.au

### Company Synopsis:

Orthocell Ltd (ASX:OCC) is listed on the Australian Securities Exchange.

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CelGro nerve repair market opportunity.

### **Addressable market opportunities**

CelGro has significant global commercial potential in its existing addressable markets as well as much wider applications in general surgical and soft tissue reconstruction applications.

Nerve regeneration has a US\$7.5 billion addressable market, tendon and ligaments have a US\$1.4 billion addressable market and bone regeneration has a US\$1 billion addressable market.

The company is also executing a strategy to engage a global partner to manage the distribution and marketing of CelGro for dental bone and soft tissue repair procedures.

In addition, the company has identified that there has been very little innovation in the biologics membrane market resulting in a lack of product differentiation which represents an addressable market of more than US\$1 billion per annum.

### **Pathway to US market**

Orthocell has achieved initial EU approval for the product and with the safety and efficiency of the CelGro nerve repair product established, the company is now focused on executing its regulatory program to gain approval in the US.

The company is focused on the US 510(k) study which aims 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).

The US FDA pre-submission meeting has been completed, and ethics approval granted.

Surgical procedures will commence in quarter four 2020 with the target for the final data read out of quarter four 2021.

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 market<sup>2</sup>



The addressable market for Ortho-ATI is estimated at greater than US\$7.7 billion per annum.

### Ortho-ATI® therapy

The Ortho-ATI cell therapy for tendon regeneration is an injectable clinical stage cellular therapy for treatment of chronic tendon injuries. It can be utilised at multiple tendon sites including shoulder, elbow, hip, hamstring and achilles.

The therapy addressed an unmet clinical need for a safe, effective, and non-surgical option and is the first injectable cellular therapy in orthopaedics for tendon regeneration.

Ortho-ATI also has extensive clinical validation with more than 690 patients treated to date.

### Multiple addressable markets

Ortho-ATI is at the forefront of a large and growing market opportunity where the addressable market is estimated to be greater than US\$7.7 billion per annum.

This included tennis elbow (greater than US\$4.3 billion and 1,000,000 procedures per annum), Rotator cuff (greater than US\$4.4 billion and 530,000 procedures per annum) and Gluteal, patellar, hamstring, achilles (greater than US\$1 billion).

# Upcoming catalysts

## CelGro<sup>®</sup>: Dental

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

## 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

## 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

The company expects to reach these milestones in the near-term.

### Completing clinical studies

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

The objective of the current study underway is to assess the effectiveness of Autologous Tenocyte Injection (Ortho-ATI) compared to corticosteroid injection in the treatment of rotator cuff tendinopathy and tear.

This trial is being undertaken in collaboration with DePuy Synthes Products, Inc, part of the Johnson & Johnson Medical Device Companies.

### **Commercially viable products**

The company is confident that its Good Manufacturing Practice certificate and Therapeutic Goods Administration licensed manufacturing facility underpin its competitive advantage and can be readily scaled to meet market demand.

In addition, Orthocell's regenerative medicine manufacturing technologies, products and treatment processes patent

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