

Advancing tissue repair and regeneration

Investor Presentation July 2018

Paul Anderson Managing Director



Regenerative medicine





What is regenerative medicine?



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

What is Orthocell's

position in this space?

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Relatively new field of medicine that seeks **to repair injured or diseased tissue** by harnessing the **body's own regenerative capabilities**

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

Innovative products



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



CelGro® Soft tissue reconstruction platform Medical device

- **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 Cell therapy*

- 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)
- **TGA:** licence to manufacture and treat patients in Australia, Singapore and Hong Kong
- US regulatory focus: process underway

Significant market opportunity



At the forefront of a large and growing market opportunity in regenerative medicine in the musculoskeletal space

Addressable markets^{1,2}





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

1. Addressable markets include US, Japanese, European and Australian markets

2. 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®: initial focus in bone regeneration



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

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

Dr Brent Allan (Chief Investigator): "CelGro[®] is an exciting new product with clear advantages over available alternatives."

1. Defect Site 2. Bone Graft 3. Apply CelGro® 4. Insert Crown

Dental bone procedure: approved for use in the EU

CelGro®: bone regeneration market opportunity



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

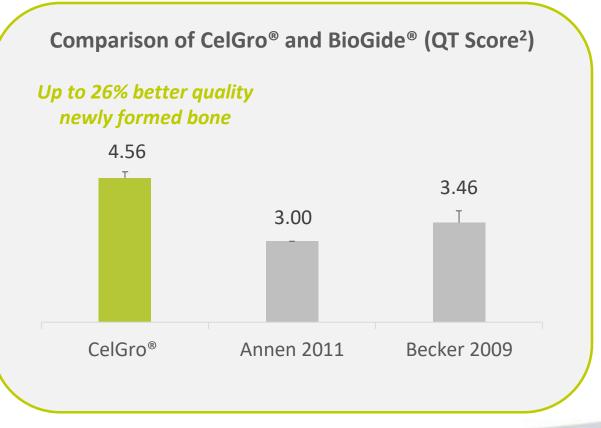
Very favourable market dynamics

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



~1.5m procedures per year

Superior clinical performance



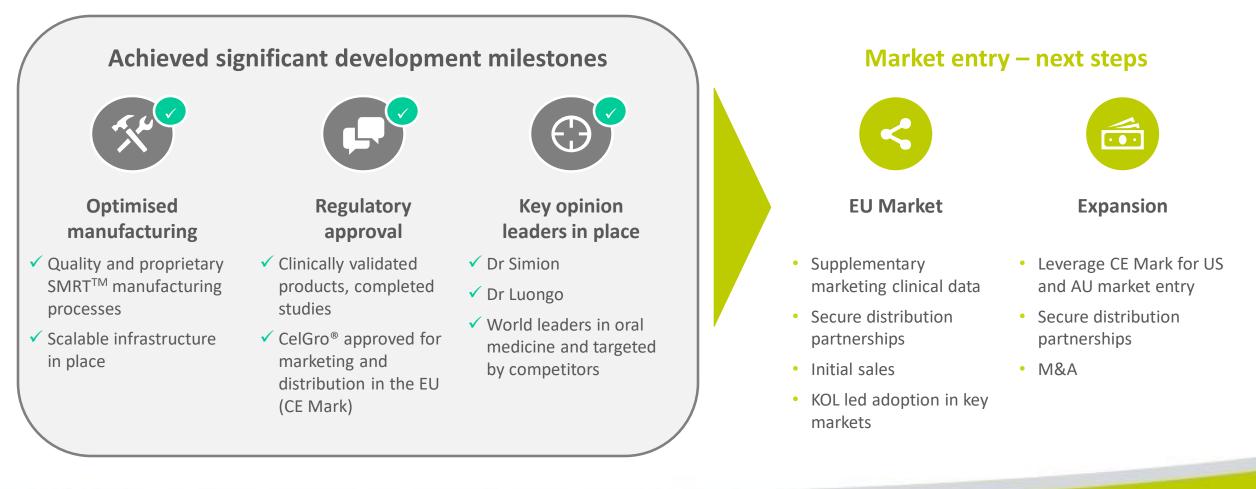
1. US, Japanese, European and Australian markets

2. 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

CelGro®: bone regeneration commercial pathway



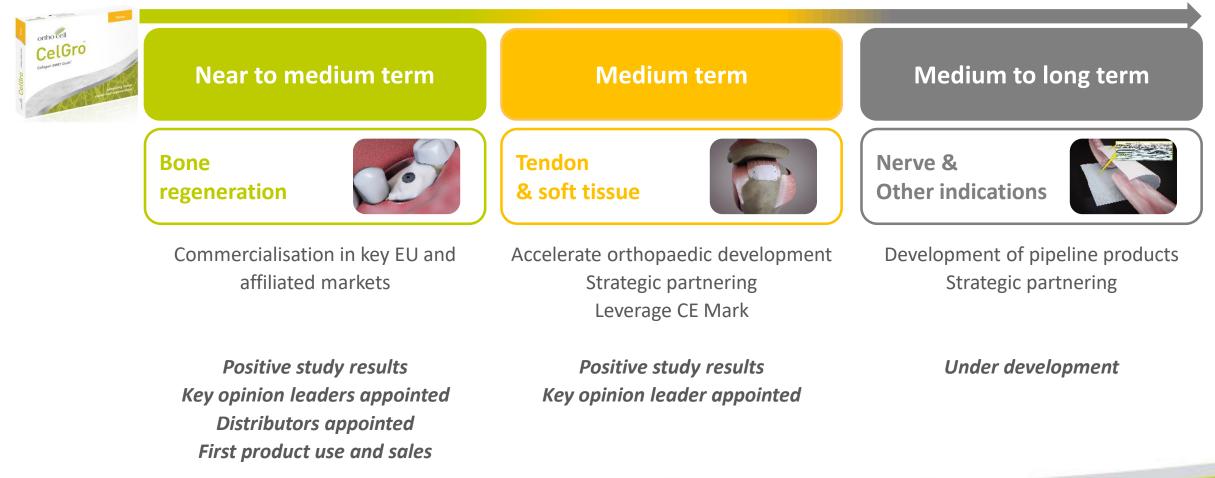
Key development and marketing approval milestones for CelGro[®] achieved, the focus is now on EU market entry in bone and soft tissue repair



CelGro®: strategic focus



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



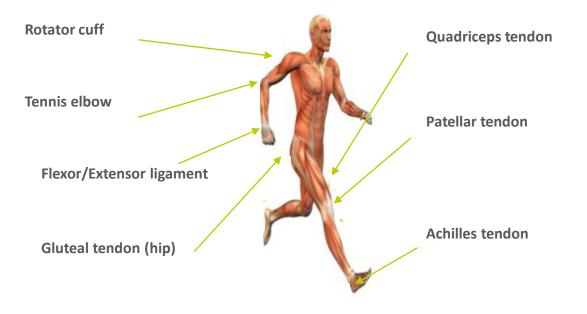
Chronic tendon injury: significant unmet clinical need

Chronic tendon injury is a common and painful disorder affecting millions of people every year with no effective, nonsurgical treatments currently available

Significant unmet clinical need...

- Millions of people suffer from chronic tendon injury every year
- **Chronic tendon injury significantly reduces** the ability of patients to work, exercise, and perform routine daily activities
- Increasing financial burden on the public health care system expected as the population ages
- **Demand for new treatments** that are safe, minimally invasive (non surgical), effective and cost efficient

Multiple tendon injury sites...



There are no 'non-surgical' treatments currently available to treat chronic tendon injury



Ortho-ATI®: preferred therapy for tendon repair



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

Ortho-ATI[®] overview

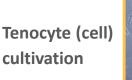
- **Breakthrough** in regenerative medicine
- Novel, cell therapy to treat chronic degenerative tendon injuries
- **Replenishes degenerative tissue** with healthy mature tendon cells, accelerating regeneration of tendon tissue
- Allows patients to return to the, workplace, recreational activities and competitive sport – evidenced by recent successful Ortho-ATI[®] study results
- Extensive clinical validation over 500 patient implants with Ortho-ATI[®] to date

Two stage, minimally invasive procedure

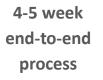




Healthy tendon cells removed via minimally invasive procedure



Healthy cells grown at Orthocell's laboratory







Ultrasound guided implementation of healthy cells

Ortho-ATI®: multiple, large addressable markets



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:









Other indications >US\$1.0bn Gluteal, Patellar, Hamstring & Achilles



Illustrative analysis: tennis elbow addressable market²

~864m	~11.3m p.a.	~1.2m p.a.	~1.0m p.a.	>US\$4.3bn	
Total population In key markets ¹	Estimated incidence Based on ~1.3% incidence rate p.a.	Resistant patients Assumed ~10.5% resistant to conservative treatment	Total procedures Assumed ~81.3% treatable with Ortho-ATI®	Estimated market size Assumed US\$4,500 price	

1. Includes US, EU, Japan, Australia and New Zealand markets

2. Illustrative analysis subject to rounding estimates

Ortho-ATI®: research collaboration



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

Key factors in attracting research collaboration interest

Large unmet clinical need

1.5m+ addressable procedures per year in the shoulder and elbow alone

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



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

Significant upside value potential



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

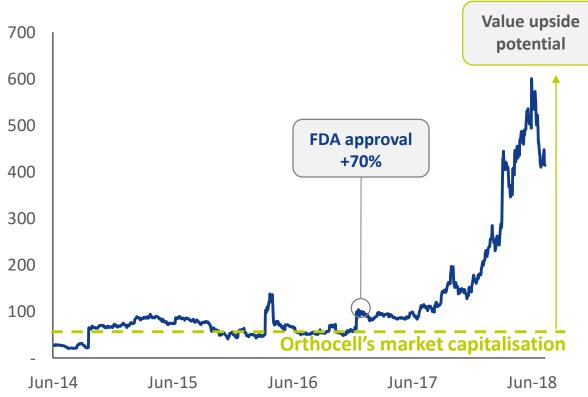


Develops, manufactures, and markets two regenerative medicine products for epidermal autografts and cartilage regeneration

Product comparison (Orthocell vs. Vericel)

	Orthocell	Vericel	Z
ACI stem-cell product (cartilage focus)	\checkmark	\checkmark	-
ATI stem-cell product (tendon focus)	\checkmark	×	- 2
Platform technology (multi-use scaffold)	\checkmark	×	

Vericel's market capitalisation (US\$m)



Significant M&A activity 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

Regulatory approval

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 and initial sales

Key comparisonsOrthocellRotation MedicalTendon regeneration✓✓Platform technology✓×Multiple regenerative
medicine products✓×

 \checkmark

Product comparison (Orthocell vs. Rotation Medical)

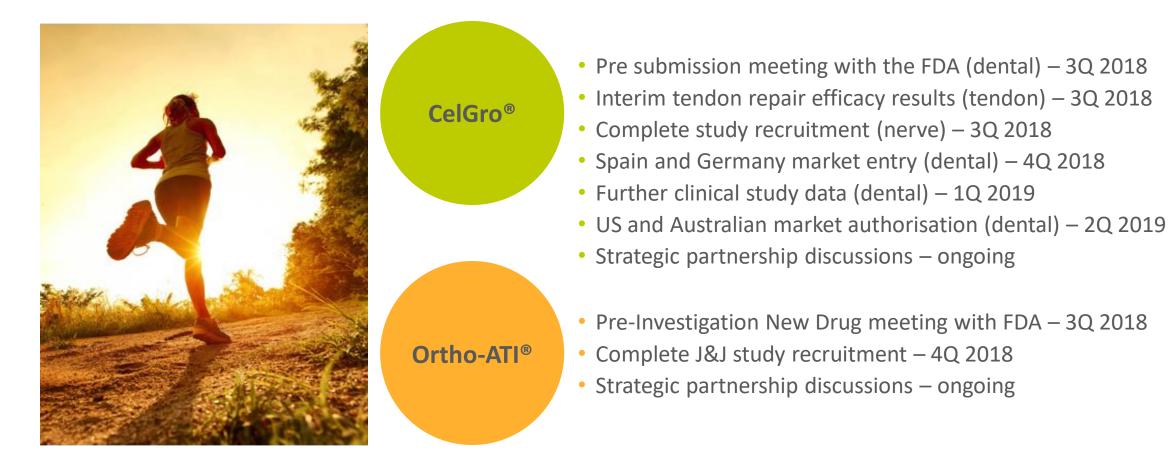


 \checkmark

Upcoming catalysts



Summary of the upcoming operational milestones



Significant upside

Significant market interest

Addressable markets worth

>US\$10bn p.a.

Key investment highlights

De-risked product portfolio

Substantial clinical data CE Mark (EU) achieved for CelGro¹ Validated manufacturing process GMP-certified and TGAlicensed manufacturing capabilities

Credentialed and highly aligned leadership team

Proven track record in commercialising cell therapy products







Appendix

Executive management, key product portfolio, intellectual property, additional product information, clinical data and R&D pipeline



Corporate overview



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

Share Price (A\$) Volume (k) 0.50 2,000 1,600 0.40 1,200 0.20 800 0.10 400 Jul-17 Sep-17 Nov-17 Jan-18 Mar-18 May-18 Jul-18 Volume traded (RHS) -OCC (LHS)

Share price performance

Trading information

Share price (12-Jul-18)	A\$0.300		
Shares on issue ¹	110.0m		
Market capitalisation	A\$33.1m		
Cash (as at 31-Mar-18)	A\$4.7m		
Debt (as at 31-Mar-18)	-		
Enterprise value	A\$28.4m		

Top shareholders (as at Jul-18)

Stone Ridge Ventures – Associated with non-executive director	9.3%
Ming Hao Zheng – CSO and founder	6.7%
Paul Anderson – Managing director	6.4%
Qi Xiao Zhou – Non-executive director	5.4%
Mr Jia Xun Xu – Former director	5.0%

1. Excludes 12.1m unquoted warrants with exercise price \$0.58, expiry 19-Nov-2020 and 3.3m unquoted options with exercise prices ranging from \$0.51-\$0.65 and expiry dates between Feb-2019 and Jun-2020

Founders story



Orthocell's founders have extensive commercial and scientific experience in regenerative medicine, having previously demonstrated success in developing, commercialising and monetising cell therapy products



Paul Anderson

Managing Director

- **20+ years' experience** within the medical device and cellular therapy fields, with intimate knowledge of the regenerative medicine space
- Former Managing Director and Executive Director of Verigen Australia (prior to its sale to Genzyme in 2005)
- Extensive and proven experience in commercialising medical technology, corporate transactions, establishing certified manufacturing facilities, and navigating regulatory pathways for cell therapies

Professor Ming Hao Zheng¹

Chief Scientific Officer Significant educational, scientific and professional experience within China¹

- Work (current): Chung Kong Lecturing Professor, First Affiliated Hospital, Zhejiang University
- **Previous experience:** Histopathologist, Lecturer & Tutor at Sun Yat-Sen University of Medical Sciences²; Consultant Histopathologist at The Huizhou People's Hospital²
- Education: Masters of Medicine in Pathology, Sun Yat-Sen University of Medical Sciences; Bachelor of Medicine, Shantou University
- Advisor, Assessor, Reviewer: Cheung-Kon Scholar Foundation, Ministry of Education; Chinese National Science Foundation
- Honours/Awards: Chang Jiang Scholar at Zhejiang University, Honorary Professor at Sun Yat-Sen University of Medical Sciences² and Shantou University

^{1.} Experience only reflects selected China-related experience

^{2.} Department of Pathology

Board of directors





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
- Extensive experience in commercialising emerging technologies

Commercialisation Corporate Capital markets

Regenerative medicine Commercialisation Regulatory, clinical manufacturing



Matthew Callahan Non-Executive Director

- Developed 3 FDA approved products
- Previous investment director of 2 VC firms (life science focus)
- Extensive corporate and IP experience

Corporate Regulatory and clinical IP and legal



Professor Lars Lidgren

Board Member

World leading innovator in

• Entrepreneur and founder

companies (Scandimed,

Bone Support, AMeC and

the orthopaedic space

of multiple biotech

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

Corporate Commercial

Executive Management Team



Professor M.H. Zheng Chief Scientific Officer

- Inventor of the Orthocell technology with a strong track record of innovation
- Director of Research in the Department of Orthopaedic Surgery at the University of WA
- Research focus on new treatment methods for osteoporosis, osteoarthritis and tendon injuries using cellular and molecular biology techniques
- Ph.D., Doctor of Medicine and Fellow of the Royal College of Pathologists

Alexander McHenry Chief Operating Officer

- Over 14 years of experience in corporate advisory and management consulting
- Background in the implementation of corporate transaction and business transformation initiatives
- Master of Business Administration from The University of Western Australia
- Former senior manager of the strategy and operations division of Deloitte, Perth WA

Nicole Telford Chief Financial Officer

- Chartered accountant with over 14 years' commercial experience in financial controller and group accountant roles
- Background of broad commercial experience in financial and management reporting, office administration and staff management
- Achieved professional qualifications whilst employed with Arthur Andersen in the audit division

Gregor Maier Sales & Marketing Director

- Over 14 years' commercial experience in the pharmaceutical and surgical industries having previously worked in the UK, EU, Malaysia and South Africa
- Oversaw successful launch of Ortho-ATI[®] and Ortho-AC[®] launch into Hong Kong, NZ and Singapore markets
- Wealth of senior management experience following key management roles in Malaysia and South Africa

Dr Clair Lee Clinical Research Manager

- Clinical research professional with over 17 years of experience in pharmaceutical and medical device clinical trials
- Specialist in translation of basic scientific research into clinical trial and regulatory application strategies
- Ph.D. in Cell Biology from the University of WA
- Former Program Manager and Faculty Member at Telethon Kids Institute, Perth WA

Monique Cannon Quality Director

- Background includes research in cellular development and differentiation, with significant experience in cell culture
- Previous role in the GMP-compliant manufacture of an autologous cell-based therapeutic product
- Over 14 years experience in coordination of qualification systems, quality system management, and significant regulatory experience (ISO, TGA, FDA)

Key product portfolio



Diversified product portfolio with exciting R&D development pipeline

Diversified				Stages of development		
health care	Products	Key focus	Applications	Discovery	Pre-clinical	Clinical
Pure		Biological medical device for soft tissue reconstruction & repair	Bone		EU (CE Mark)	
collagen medical	CelGro®		Orthopaedic			
device			ACL ligament			
Cell based therapies	Ortho- ATI®	Tendon regeneration	Tennis elbow, gluteal etc.			
	Ortho- ACI®	Cartilage regeneration	Knee & ankle cartilage repair		AUS (ARTG)	
	R&D	"Off-the shelf" tissue repair therapies	Growth factors			
	pipeline	Allogenic tendon repair	Lab grown tendon			

CelGro®

Tissue and bone repair

Off the shelf collagen scaffold to support soft tissue and bone repair



Ortho-ATI® Regeneration of tendons

Two stage, minimally invasive, walkin & walk-out procedure



Proven and logical clinical development strategy, grounded on an evidence-based translational programme to deliver cost effective treatments that transform patients lives

Key products are well protected and clinically validated Ortho cell

Orthocell has significant levels of clinical validation and has protected its suite of development products through various patents granted across major jurisdictions, with further applications awaiting grant

Patents granted

IP portfolio and strategy

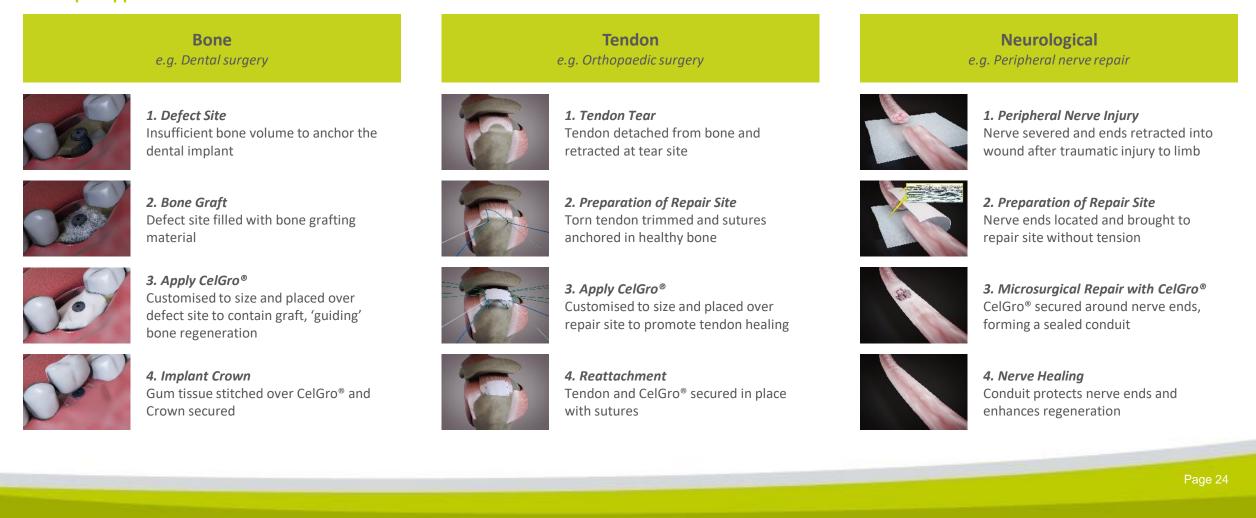
- Focused on maintaining patent protection for its leading manufacturing technologies and treatment processes
- Maintains an active program of patenting, with ownership of 31 granted patents across the Ortho-ATI[®], Ortho-ACI[®] and CelGro[®] technologies, and related methods of treatment and manufacturing
- Currently has 31 patent applications across 7 different patent families
- Patent protection is targeted at major jurisdictions across Australia, Asia, Europe and North America, which represent key regions where Orthocell is targeting regulatory approval



CelGro[®] - platform technology



CelGro[®] is a platform technology that supports tissue growth and enables rapid repair, it has demonstrated clinical efficacy and has a clear path to market across multiple applications Multiple applications



CelGro[®] - key advantages



CelGro[®] boasts superior tissue repair qualities and can be customised to accommodate the specific needs of tissue repair in multiple applications, making it the best in class bioderived scaffold on the market



Orthocell's proprietary SMRTTM manufacturing process method produces collagen scaffolds with numerous competitive advantages over existing tissue repair scaffolds, particularly in the areas of compatibility, tensile strength, promotion of quality tissue repair and versatility

	Dental		Tendon		Nerve		ortio Cell		
Key advantages	Biogide®	BioMed Extend [®]	GraftJacket [®]	Tissuemend®	AxoGuard®	Neuroflex®	CelGro	Comments	
Proven compatibility	\checkmark	+/-	+/-	+/-	+/-	+/-	V	SMRT [™] process removes all DNA and other tissue components, collagen scaffold is biocompatible and naturally degrades after implantation at the same rate as the body heals	
Strong mechanical properties	+/-	 ✓	~	~	~	✓	✓	No cross-linking or artificial additives required to boost strength of intact collagen fibres. CelGro® is easy to use, ductile and very strong	
Quality of tissue repair (Native bilayer structure)	✓	x	x	x	x	x	✓	Preservation of the natural collagen structure from the source material promotes healing and regeneration. CelGro® integrates with the soft tissue under repair leaving no remnant material to scar or cause inflammation	
Versatile/customisable to multiple applications	х	x	x	x	x	x	√	Easily customisable, with multiple applications and the ability to be used on its own in surgical repair, or in combination with stem cells and other drugs	

Biogide® currently generates €50m p.a. in dental bone graft sales in the EU alone – CelGro® has been proven, through clinical studies, to produce superior bone regeneration +/- No clinical data available to support characteristic required for optimal tissue repair

CelGro[®] - clinical trials completed and in progress

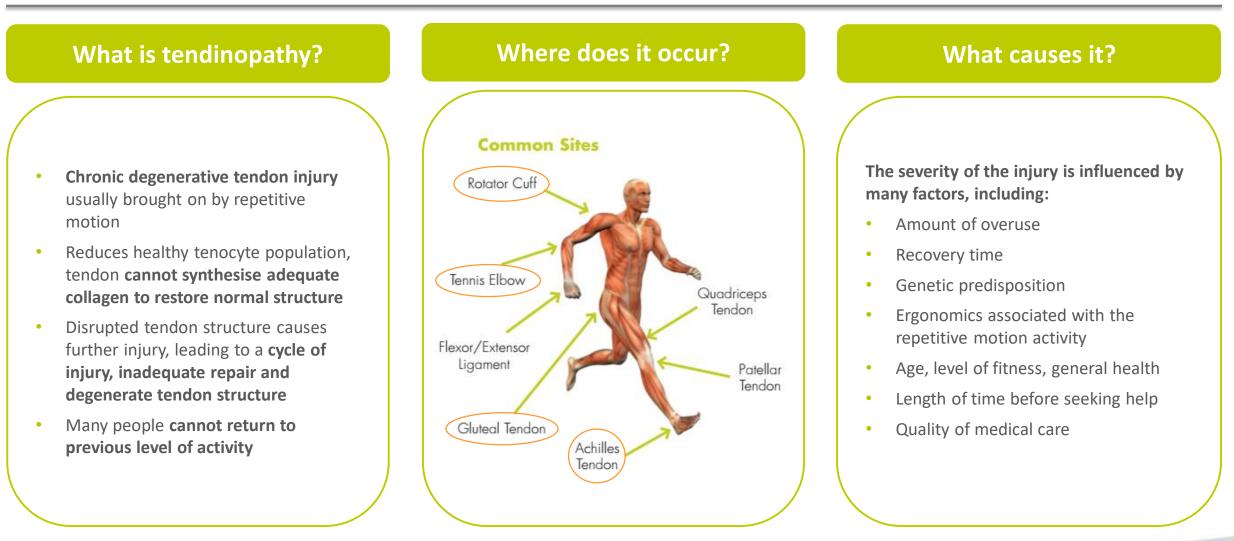


Orthocell's clinical development strategy is designed to increase the probability of achieving regulatory approvals, with significant levels of clinical validation achieved, and optimised manufacturing capabilities in place

Study ID	Description	No. of subjects	Treatment site	Duration (months)	Outcome Measures	Study status
CG-002	Study of CelGro for dental guided bone regeneration around dental implants	10	Dental	6	Bone regeneration	Unpublished 2 stage procedure completed 1 stage procedure recruiting patients
CG-004	Study of CelGro to augment surgical repair of rotator cuff tendinopathy and tear	30	Shoulder	12	 Improvement in pain and function of shoulder Quality of life Measurement of tendon healing by MRI 	Recruiting patients Interim results presented at APKASS Conference, June 18
CG-005	Treatment of hip cartilage defects with microfracture and CelGro	25	Hip	12	 Improvement in pain and function of hip Return to sporting activities Quality of life 	Recruiting patients
CG-006	Surgical repair of peripheral nerve injury with CelGro	20	Upper limb	24	 Improvement in pain and function of arm/hand Recovery of nerve function (sensory and motor) Quality of life 	Recruiting patients
CG-007	Study of CelGro to augment arthroscopic repair of rotator cuff tendinopathy and tear	30	Shoulder	12	 Improvement in pain and function of shoulder Quality of life Measurement of tendon healing by MRI 	Recruiting patients

Ortho-ATI® - tendinopathy





Ortho-ATI® - key advantages



Ortho-ATI[®] is the preferred therapy for degenerative tendon repair because it addresses the underlying pathology, is minimally invasive, cost effective with long term clinical data

Tenocytes PRP¹ **Corticosteroids** Surgery (Ortho-ATI[®]) Minimally invasive X +/-Long term clinical data Х +/- \checkmark Cost effective \checkmark +/-+/-X Addresses underlying \checkmark X X X pathology

Comparative advantages to traditional therapies

Traditional therapies only address the symptoms of tendinopathy (pain, immobility and stiffness), thus have limited long-term efficacy

- **Rest, physiotherapy and injections:** ineffective in the degenerative injury phase (more suited to acute injury)
- PRP¹: associated with symptomatic relief, but has inconsistent outcomes and duration of effect is not long-lasting
- **Corticosteroids:** reduces pain but weakens tendon structure long term (especially if repeated)
- Surgery: invasive, expensive, requires lengthy rehabilitation and increases economic burden on the healthcare system; patients cannot return to work / sport for months after treatment

Ortho-ATI® - clinically validated product



Ortho-ATI® gluteal tendon study

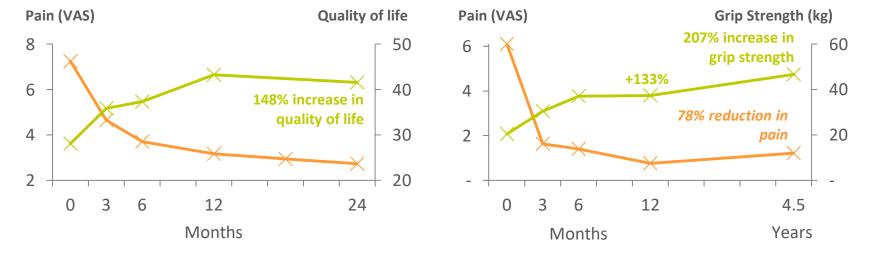
- 12 patients with gluteal tendinopathy no remaining treatment options
- The patients had been experiencing symptoms for an average of 33 months
- Significant clinical improvement in pain and function scores at 24 months

Ortho-ATI® tennis elbow study 1

- 17 patients that had failed all other treatments
- The patients had been experiencing symptoms for an average of 31 month
- Data to 4.5 years published in American Journal Sports Medicine

Ortho-ATI® tennis elbow study 2

- 24 patients experiencing work related tennis elbow symptoms for an average of 23 months
- 47% of patients required absence from work due to symptoms (average 142 days absent)
- 78% of patients experienced, on average, three failed treatments, including oral nonsteroidal antiinflammatory drugs (18%), steroid injections (68%), physical therapy (55%), PRP (45%), surgery (18%)



B8% Of patients in the study returned to work

Ortho-ATI[®] significantly improved clinical outcome of patients with long term tennis elbow degeneration, showing reduced pain and increased functionality enabling patients to return to work



"I'm 100% happy with the Ortho-ATI® treatment, the only thing that enabled me to get back to doing normal daily activities without pain and return to swimming at an international level."

> Christian Sprenger Swimming Olympic medallist





"I couldn't write, drive, play my violin, or even walk without pain. Ortho-ATI® gave me my life back."

> Jasmine Trebse Professional Violinist

Ortho-ACI[®] and R&D pipeline



Orthocell is undertaking a "capital light" approach to commercialising Ortho-ACI[®] and developing other pipeline products which represent exciting potential value upside within the regenerative medicine space

Orthocell's foundation product

Ortho-ACI®

Marketable cartilage repair and regeneration therapy

- 3rd generation product
- >500 patient implants to date
- Included on the Australian Register of Therapeutic Goods, enabling the commencement of the process for reimbursement
- Cost effective treatment with potential for multiple applications

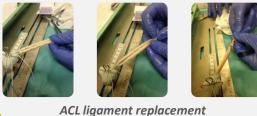


Ortho-ACI® procedure

Significant market opportunity CelGro[®] pipeline

Potential for innovative platform technology solutions

- ACL ligament replacement: commence clinical study; positive results from initial animal study (recently completed)
- Other potential applications: General surgery, Urogynaelogical, Collagen powder (for bone void fillers)



Actingument replacement

Leverage existing knowledge towards human clinical trials

- Cell factory-derived tissue specific growth factors to augment bone, cartilage and tendon repair
- Part of successful international collaboration² – multiple animal studies completed and published
- "Cell Factory" patents granted in key jurisdictions (USA and Europe)

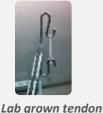


Growth factor samples

Significant commercial appeal expected in "off the shelf" products Growth factors Lab grown tendons

Next generation product to complement Ortho-ATI®

- Successfully manufactured human tendon in a laboratory
- Ongoing collaboration with academic researchers¹ (received ARC linkage grant)
- Significant unmet patient needs and multiple applications (i.e. hand, shoulder and hamstring)



1. Successful collaboration with Griffith University; University of Western Australia; La Trobe University; and University of Auckland

2. Successful collaboration with Lund University (Sweden); University of Western Australia; Indian Institute of Technology Kanpur (India)



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